Psychosocial Factors Associated with an MRI Diagnosis of Chronic Non-specific Low Back Pain in Saudi Arabia

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Abstract

Introduction

In patients with chronic low back pain, psychosocial factors have a considerable influence on pain perceptions. These factors also affect treatment and rehabilitation responses, as well as increasing the probability of disability associated to back pain. It is postulated in various studies that in low back pain (LBP) patients, there could be a relationship between psychosocial factors, including catastrophising and fear avoidance, and treatment responses. However, at this time, the research exploring this relationship of psychosocial factors as predictors of pain and disability outcomes in chronic low back pain (CLBP) is insufficient.

Although there is consensus in clinical guidelines that MRI is impractical for diagnosing CLBP, healthcare professionals continue to request further investigations to explain the symptoms radiologically. Despite evidence that MRI for CLBP does not change how the condition is managed, it is nevertheless associated with an increase in pain medication and doctors' visits. However, the psychological impact of being given the results of an MRI on people with CLBP has not been reported in the literature.

Several publications recommend that to avoid unnecessary medical procedures and keep medical costs down, alternative options be made available to patients. Physiotherapy is one such alternative to MRI that increases beneficial outcomes for LBP patients, as well as reducing medical expenditure.

This project aims I) to identify the psychosocial factors associated with change in pain and disability in CLBP patients treated by a physiotherapist. II) to explores the psychosocial factors associated with MRI diagnosis, and finally, III) determine the feasibility of conducting a definitive randomised control trial to answer the question, does MRI diagnosis negatively influence psychosocial and disability outcomes in patients with CLBP treated by physiotherapy in Saudi Arabia.

Methods

This project has adopted the Medical Research Council framework for complex intervention. Firstly, the association between psychosocial factors and changes in pain and disability outcomes was determined by conducting a systematic review.

Secondly, the psychosocial factors associated with receiving an MRI diagnosis were explored using in-depth qualitative interviews with three different groups (doctors, patients and physiotherapists).

Finally, a feasibility trial with process evaluation was conducted to test the feasibility of a definitive trial to determine the impact of MRI diagnosis on psychosocial, pain and disability outcomes in people with CLBP treated with physiotherapy. People presenting to spine clinics were randomised to receive an MRI diagnosis (intervention) plus physiotherapy rehabilitation or physiotherapy alone (Non-MRI/control group). The acceptability of randomisation to the non-MRI or MRI group was tested during recruitment and by qualitatively interviewing study participants and referring physicians.

Results

Regardless of the form of physiotherapy, the psychosocial factors of catastrophising, depression, fear of movement and self-efficacy can predict disability outcomes following physiotherapy intervention. However, the influence of these factors on predicting pain severity after physiotherapy intervention is less likely.

The qualitative data from 11 patients, six physiotherapists and six doctors highlighted that fear of movement and anxiety were the main psychosocial consequences following MRI diagnosis. Furthermore, the study identified a need for national clinical guidelines for CLBP management in Saudi Arabia.

The feasibility study failed to reach the recruitment target: 16/24 participants were recruited in 4 months (12.4% of those screened); 33% declined. The process evaluation identified a number of factors that may affect the success of a definitive RCT in Saudi Arabia. These were research resources, including limited availability of physicians' time for research, lack of research infrastructure e.g. to support recruitment to trials and limited research capacity in terms of the knowledge and skills of the healthcare team and limited funding. Interviews with five participants from both groups and physicians raised concerns about the acceptability and feasibility of randomly allocating patients to non-MRI group.

Conclusion

The results of studies revealed that disability outcomes could be predicted reliably by measures of psychosocial factors including catastrophising,

depression, fear of movement and self-efficacy regardless of the physiotherapy intervention. This indicates that future physiotherapy screening of CLBP patients ought to include an evaluation of these factors.

The interview study indicated a lack of local clinical guidelines of CLBP management in Saudi Arabia and a mismatch in priorities between primary care and secondary care levels that might explain the long waiting time in secondary care doctors' appointments. The study also highlighted a possible association between fear and anxiety in patients with CLBP following diagnostic MRI and an over-reliance on biomedical education from the healthcare practitioners.

Various barriers limit the feasibility of conducting a definitive RCT to test the influence of MRI diagnosis on psychosocial and disability outcomes in people with CLBP treated with physiotherapy in Saudi Arabia. A large trial would require multiple recruitment centres, a lengthy recruitment period and research staff trained in good clinical practice. Moreover, physician and participant concerns surrounding the acceptability of randomising patients not to receive an-MRI may limit success and suggest that progressing to large scale RCT would be impractical at the present time.

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Chapter One: Introduction

1.1. Definition of chronic low back pain

Low back pain (LBP) refers to discomfort experienced in the anatomical area between the lower costal margin and the gluteal fold and may persist for variable periods of time (Dionne et al., 2008). The variability in the duration of LBP may be associated with several different scenarios, such as exceeding the normal recovery period for an injury. However, the specification of a recovery period for a structure is impractical as many factors, such as age, gender and occupation, can play a role in limiting the recovery time (Hildebrand et al., 2005). Chronic low back pain (CLBP), according to Hoy et al. (2012), is defined as a type of pain that involves symptoms that last longer than three months. Similarly, recent literature suggests that back pain with a duration equal to or greater than 12 weeks, and in the absence of underlying pathology, is considered chronic (Koes, 2006; Deyo, 2014). Therefore, the term 'chronic' should be used to refer to pain duration, and not the recurrence and the time needed for the tissue to heal.

In contrast, non-specific chronic lower back pain (NS-CLBP) refers to CLBP without a recognised, known, and specific pathology such as infection, tumour, inflammatory process, osteoporosis. (Chou et al., 2007). It is a descriptive term used to diagnose people with CLBP in the absence of clear aetiology (Koes et al., 2006).

1.2. Epidemiology of chronic low back pain

Although the prevalence of LBP is high, with up to 80% of the world's population reporting at least one episode during their lifetime (Deyo and Weinstein, 2001; Hoy, 2012), most people with LBP naturally recover within one month (Croft et al., 1998). However, between 10% and 40% of all people with LBP fail to recover and develop chronic symptoms and disability (Van Tulder, 2002; Meucci , 2015). Within this group, 85% are reported to have NS-CLBP, where a specific diagnosis cannot be found on radiological imaging (Leboeuf-Yde, 1997; van Tulder , 2002).

A number of socio-demographic characteristics have been associated with the global prevalence of LBP (Meucci et al., 2015): age (the highest incidence of CLBP is observed in 40–80-year-olds) (Hoy, 2012; Meucci, 2015), socioeconomic status (i.e. CLBP is prevalent among people of low economic status) (Hoy, 2012; Meucci, 2015), education level (i.e. incidence of CLBP is higher in individuals with lower levels of education) (Hoy, 2012, Meucci, 2015), and gender (i.e. females are more likely to develop CLBP than males) (Hoy, 2012; Meucci, 2015).

1.2.1. Epidemiology of chronic low back pain in Saudi Arabia

As Saudi Arabia is considered a developing country, there are no national statistics on the prevalence of LBP among the general population. However, several small-scale studies have been conducted on the phenomenon of LBP in industrial settings. In a systematic review of cross-sectional prevalence studies conducted in Saudi Arabia, Awaji (2016) reported a LBP lifetime

prevalence of 53–80%. These studies were typically conducted in clinical settings involving a range of professions including nurses, dental practitioners, and industrial workers, thereby making it difficult to generalise the findings to the wider population.

1.3. Socio-economic impact of chronic low back pain

Burden of back pain disability

The economic burden of LBP and the fact that a significant proportion of LBP cases will develop into NS-CLBP are well documented in the literature (van Tulder, 2002; Global Burden of Disease, 2016; Hartvigsen, 2018). LBP accounts for a major portion of the total cost of health care globally. A 2015 Global Burden of Disease (GBD) review evaluated the disease burden in 195 regions worldwide and its relation to 315 causes between 1990 and 2015. The findings from that study provide an exhaustive and extensive evaluation on disease patterns, prevalence, burden, and disability associated with these acute and chronic conditions (Global Burden of Disease, 2015). The global years lived with disability (YLD) for LBP as of 2015 stood at an estimated 60.1 million years, 54% higher than that recorded in 1990 (Vos et al., 2015). The GBD study also revealed that of the 21 regions, LBP was the highest cause of disability in 14. LBP was also the highest cause of disability in the world (Vos et al., 2015). The number of severe and very severe cases of LBP was low (below 28% of the reported n =151 million cases) but contributed to a significantly high rate of disability (77%) with 46.5 million YLD (Global Burden of Disease, 2015).

Cost of care

Costs of LBP care are categorised into direct and indirect medical costs. The direct costs refer to those incurred in the healthcare system whereas the indirect costs are incurred in other sectors of the economy such as reduced productivity and absenteeism from work. The effects of LBP on the UK economy are as significant as those associated with other chronic and high-risk disorders such as cancer, autoimmune conditions, cardiovascular diseases, and mental illnesses (Maniadakis & Gray, 2000). Moreover, LBP is considered one of the most expensive conditions with a direct cost of 1.6 billion pounds per year (Maniadakis & Gray, 2000). An observational study conducted in the United Kingdom in 2006 aiming to estimate the annual musculoskeletal consultations in primary care practice revealed that the complaints of one out seven patients were associated with musculoskeletal conditions, with back pain disorders being the most common, with an estimated annual rate of 417 medical consultations for every 10,000 registered patients (Jordan et al., 2010). In a 12-month retrospective study of costs associated with the treatment of CLBP, Hong et al. (2013) used the UK's General Practice Research Database (GPRD) to identify patients with CLBP using the records of diagnostic imaging requests and pain relief prescriptions (n = 52,986). A person-to-person comparison was made. This comparison matched the age and gender of people without CLBP visiting the same general practitioners (GPs). Hong et al. reported that the cost of care for CLBP was significantly higher than that for the control group (£1074 vs. £516 per person costs). However, the study only included the costs of medication and diagnostic examinations. In Saudi Arabia,

there are no data on the health and social care costs for LBP or musculoskeletal conditions or the number of working days missed because of LBP.

Impact on work

Disability as a result of LBP is prevalent in the global workforce (Vos, 2015; Global Burden of Disease, 2016; Hartvigsen, 2018). The prevalence of disability due to LBP in high-income countries is attributed to variations in the schemes of social compensation than to individual and occupational vulnerability (Anema et al., 2009). This is the result of rigorous regulatory standards in the workplace. LBP was also found to be the highest cause of early retirement and approved absenteeism from work in Europe (Coggon et al., 2013). The incidence of work disability is however highly varied across European countries. For instance, in a study conducted in 2000 in Norway and Sweden it was reported that certified sick leaves related to back pain were similar in both countries: 5.1% in Norway and 6.4% in Sweden. The frequency of long-term absenteeism was however statistically different: 22% in Norway compared with 15% in Sweden (Ihlebæk et al., 2006). In the UK, approximately 35% of sickness-related absence from work was due to musculoskeletal problems with back and/or neck pain the most frequently cited reason for absence (Office for National Statistics, 2017). Moreover, in a study on the working population of Jersey (a principality of the United Kingdom) (Watson et al., 1998), only 3% of the population was absent from work for longer than six months for LBP, and this group accounted for 33% of the total care costs associated with injured workers. In the United States, LBP is the

musculoskeletal disorder associated with the highest number of missed workdays (US Bone & Joint Initiative, 2014). Importantly, it should be noted that there are no studies which have considered the impact of LBP on the Saudi Arabian working population.

1.3.1. The psychosocial challenge of non-specific chronic low back pain

Living with non-specific chronic back pain is associated with a range of psychosocial challenges. These are illustrated by the findings of a systematic review and meta-synthesis by Froud et al., (2014) which considered 49 studies exploring the impact of LBP on patients' lives (total sample size across these studies = 982 patients). This review identified 5 main themes: i) Activity, within which people with LBP described the difficulties they experienced in basic life activities, such as inability to engage in housework, sleep disturbance, and inability to engage in leisure activities. One important barrier experienced by these people was their inability to predict LBP, which led to difficulties when planning an activity; ii) Relationships, individuals living with LBP reported negatively impacted relationships with their close friends and family. Whilst they stated a need for support, they tended to avoid their loved ones when suffering from pain; iii) Work, individuals living with LBP expressed worries concerning their ability to fulfil their work duties and reported being fearful about their ability to find future employment; iv) Stigma, individuals living with LBP reported difficulties when convincing their families, co-workers, and friends of the pain they were suffering from, so they would start identifying the sources of their pain themselves, since they did not have a specific pathoanatomical diagnosis to refer to; v) Change in outlook, as a result of the reduced likelihood of

receiving an accurate diagnosis, people with LBP reported a change in their outlook. This change manifested in different forms of psychological and emotional states such as depression, fear, embarrassment, and mood swings.

Furthermore, Froud et al. (2014) also noted that LBP is a problem that is often interpreted within a biopsychosocial model, where the individual is indexed to a combination of biological, psychological, and social variables. Engaging in meaningful activities is one of the concerns of patients with LBP as they attempt to come to terms with their diagnosis and symptoms. As they seek treatment, patients want to be reassured of the absence of pathology. Others struggle with the fear of disapproval or are disinclined towards accommodating social demands (Froud et al., 2014).

Similarly, MacNeela et al. (2015), in a meta-ethnography of 38 qualitative articles published between 1994 and 2011 (total sample size across the studies = 1068 patients), proposed 4 themes which captured the lived experiences of patients living with CLBP: i) the undermining influence of pain; ii) its disempowering impact; iii) unsatisfying relationships with healthcare practitioners, and iv) learning to live with the pain. MacNeela et al. (2015) noted that the impacts of LBP on the patients' lives are poor quality of life, depression, and functional disability, which all resonate with the themes identified by Froud et al., 2014. Together, the findings from both reviews illustrate that patients with LBP are not able to function normally compared with people without LBP (Smeets, 2011;Hildebrandt, 2017).

In addition, there have been several published studies which have described the impact of living with LBP on social life. For example, Bailly et al. (2015) studied CLBP impact on social relationships and quality of life by conducting a semi-structured interview with 26 CLBP participants in Paris, France. According to their findings, participants with CLBP reported negative perceptions of themselves at work and home owing to their reduced physical abilities and other people's perceived reaction. However, they reported that they had been receiving support from their co-workers and family members to cope with and manage their condition. In a case-controlled research design, Esteves et al. (2013) studies the emotional processing and its link to CLBP involving 55 people with CLBP and 55 asymptomatic people in the UK. They were controlling for emotional processing and its association with CLBP. The intervention was measured by the Emotional Processing Scale (EPS), which involved emotional processing factors, such as avoidance, unregulated emotion, and indications of unprocessed emotions, amongst others, against which the participants were scored. The patients' emotional processing was measured. This analysis investigated whether CLBP patients processed their emotions differently. The findings of this study clearly demonstrated an association between CLBP and dysfunctional emotional processes since the 55 patients with CLBP scored higher on EPS than the 55 who had no history of CLBP. These findings, similar to the systematic review conducted by Froud et al. (2014), showed that LBP has significant psychosocial and biological effects on the lives of individuals.

1.4. Diagnosis of Chronic Low Back Pain

1.4.1. Low back pain and flags' screening

The observation and recording of specific signs and symptoms of LBP can help guide primary care clinicians towards an appropriate diagnosis (e.g. Balague et al., 2012). These signs and symptoms are grouped into categories of 'flags', depending on their characteristics: red, orange, yellow, blue, and black (see Table 1). The flags tool is particularly helpful during the clinical decision-making process when a serious pathology is suspected, as the early detection of spinal tumours can help prevent metastases (e.g. Atlas and Deyo, 2001).

Table 1: Flag screening tool explanation (Buck et al., 2009)

Flag colour	Explanation	Example
Red	Signs of serious pathology	Tumour; Cauda equina
Yellow	Cognitive, behavioural and emotional signs	Beliefs concerning pain; Avoidance behaviour; Worry
Orange	Psychiatric illness	Clinical depression
Blue	Relationship between work and health	Beliefs that work supervisors or colleagues are unsupportive
Black	System obstacles	Conflict with an insurance provider concerning an injury claim

Red flags

Red flags are signs or symptoms indicating serious pathology; for example, cauda equina syndrome (loss of lumbar plexus function due to damage to the cauda equina), fractures, infections, inflammatory disorders, or malignancy. Clinical presentations of these symptoms call for early detection for successful treatment (Verhagen et al., 2016). Therefore, a series of questions asked to patients can aid in the identification of these red flags. Loss of body weight, previous diagnosis of cancer, and night pains can draw the attention of the physician towards investigations for metastasis (Downie et al., 2013). However, the reliability of these questions when detecting serious pathology is questionable (Ross and Boissonnault, 2010). For instance, a typical question used to identify a red flag is: ‘Does the pain wake you up at night?’ An answer of ‘yes’ increases the suspicion of serious pathology. However, almost all people with acute back pain and arthritis complain of night pains, yet these individuals do not require further medical screening. By simply rolling around in the bed, an individual may experience acute pain and awaken. Ross and Boissonnault (2010) suggested that the likelihood of detecting serious pathologies is higher when a combined cluster of signs and symptoms is identified.

The number of patients who may have serious pathology is small, yet early identification of the pathology could save lives. Henschke et al. (2009) studied a cohort of 1,172 acute LBP patients from primary care clinics, following them over a one-year period. It was found that only 11 of the 1,172 patients could be classified as having a serious pathology. In fact, throughout the entire cohort,

there was no case of malignancy, and spinal fractures were found in only eight cases. However, of the entire cohort, 80% had at least one red flag.

Care should be taken when the red flag tool is used to screen for severe pathology. In a systematic review of 14 studies concerned with how precise the red flag tool was in the diagnosis of fractures and malignant conditions in the context of primary care and emergency cases, Downie et al. (2013) found that multiple red flags increased probability of fracture presence. For instance, back pain in older individuals is not as suspicious as back pain and corticosteroid use in older individuals. Furthermore, the authors reported 7% (95% confidence interval 3–16%) and 33% (CI 22-46%) post-test probability of past malignancy history in primary care and emergency cases, respectively. Meanwhile, in a different study, eight cohort studies with a total of 6,622 patients were systematically reviewed regarding use of the red flag tool to screen for malignancy in primary care, and less than 0.66% of patients were found to have malignancy (Henschke et al., 2013).

Yellow flags

Psychological prognostic factors (e.g. beliefs concerning pain, pain behaviour, emotional disturbance, appraisal, and judgment) are referred to as yellow flags. These psychological factors have been implicated in the transition from acute to chronic lower back pain. For example, Jensen et al. (2010) followed 196 patients with LBP for one year after their first back pain episode. They identified LBP patients' baseline clinical and psychosocial risk factors influencing pain and disability and determined the differences between non-specific LBP and

radiculopathy, with a one-year follow up. The study found a strong positive correlation (r = 0.84) between pain severity and fear avoidance. Furthermore, the relationship between pain severity and fear avoidance was significantly correlated with high levels of anxiety, i.e. 0.19% (95% CI: 0.06–0.33; p = 0.005).

Several instruments have been developed to detect the presence of yellow flags in musculoskeletal conditions. For instance, the Örebro Musculoskeletal Pain Questionnaire (OMPQ) is widely used as a screening tool to predict psychological factors (Hill et al., 2010). Another newly developed means to measure the psychological risk associated with LBP is the STarT Back screening questionnaire, specifically designed to screen LBP in a primary care setting (Hill et al., 2010). These studies, therefore, show the extent to which these instruments can detect the presence of yellow flags and are thus relevant.

1.4.2. Low back pain diagnosis by MRI

Magnetic resonance imaging (MRI) is a method of medical imaging that is effective in enabling visualisation of anatomical structures, thus helping detection of disease processes. For instance, MRI provides good specificity and sensitivity in the diagnosis of metastasis, bone morrow inflammation, and fractures. These cases account for less than 4% of LBP patients who visit primary care (Henschke et al., 2009). However, the effectiveness of MRI in diagnosing herniated disc problems is questionable. It has a sensitivity level of 0.89 to 1.0 and specificity of 0.43 to 0.53, which is poor (Jarvik and Deyo,

2002), resulting in false positive misclassifications, showing major problems in individuals with healthy spines. CLBP with a false-positive MRI result is disregarded by most CLBP clinical guidelines, as most CLBP cases are non-specific with symptoms unrelated to the radiological findings (Koes et al., 2010). However, Jabali et al. (2015), whose study focused on key factors influencing MRI use in Saudi Arabia, identified an overall increase in MRI scanning in a Saudi Arabian university hospital in a five-year-long audit study. The study used descriptive statistics and did not report on which conditions gave rise to the increase in MRI scans.

1.4.3. Diagnostic accuracy of MRI in low back pain

Despite no systematic review of the accuracy of diagnostic tests to establish the source of LBP Hancock et al. (2007), a number of authors have noted a range of limitations around their use. For example, Airaksinen et al. (2006) pointed out that the patient's pain symptoms must be relieved in order for any tests to diagnose the source of CLBP. One problem with the accuracy of radiological diagnosis is that it can invite subjective bias from the radiologists' perspective. Brinjikji et al. (2015) found that many of the changes observed with MRIs were coincidental or unrelated to an individual's symptoms because the likelihood of detecting degeneration in asymptomatic individuals is proportionate to age. Therefore, despite the accuracy of lumbar spine MRIs in detecting pathoanatomical destructions and despite it being the preferred method for identifying specific pathologies, false-positive findings were reported in the lumbar spines of asymptomatic individuals(Jarvik and Deyo, 2002). Jarvik and Deyo reviewed original articles and systematic reviews on clinical

information accuracy and imaging for patients with LBP in primary health care settings. Their study used data from 1966 to 2011. The results suggest that treatment can commence without imaging, except where there is suspicion of a serious pathology, when laboratory testing and plain X-ray are sufficient to confirm the diagnosis. additionally, MRI may incorrectly classify a number of patients for herniated nucleus pulposus (HNP) and spinal stenosis Wassenaar et al. (2012). The sensitivity and specificity of MRI diagnosis compared to surgical confirmation of HNP was 75% (95% CI 65–83%) and 77% (95% CI 61–88%), respectively. Moreover, there was no conclusive evidence for MRI's diagnostic accuracy since the results could be distorted by the large degree of heterogeneity Wassenaar et al. (2012).

In a further illustration of the unreliability of the MRI as a diagnostic tool Herzog et al. (2017) describes how one patient received 10 separate MRI scans, which yielded 49 individual findings and none of the 10 reports contained identical findings. This study questions the reliability of interpretive findings. This is in line with the claim of Jarvik et al. (2005) about the inaccuracy of MRI in LBP. This study highlights the issues with MRI as an objective tool of diagnosis in a clinical setting; there is subjectivity involved when interpreting the image, and a finding can be explained differently by different observers.

1.4.4. Imaging guidelines for low back pain

Clinical guidelines have been developed to assure consistent best practice, to decrease the use of low-value interventions in patient care and help clinicians to make evidence-based decisions (Koes ,2010; O'Connell, 2016; Bernstein

,2017). The clinical importance of MRI in LBP was compared in clinical guidelines for the management of NS-CLBP in 15 countries across Europe, North America, and Australia (Koes et al. 2010). They found a consensus on the impracticality of using MRI for NS-CLBP, hence discouraging the use of any radiological imaging for people with chronic back pain, unless there was a suspicion of serious pathology. The result of in-depth interviews with 53 healthcare professionals regarding the primary care clinical guidelines for CLBP in England showed that clinicians were well oriented to the published guidelines (Bishop et al., 2015). However, some clinicians relied on their clinical experiences as part of evidence-based management.

Several published materials have addressed various strategies to encourage adherence to the clinical guidelines concerning the imaging of patients experiencing NS-CLBP. For example, Jenkins et al. (2015) proposed that the most successful strategy is a modified referral from primary care doctors, which allowed only the guidelines appropriate indication for MRI alongside a targeted reminder to the referring physicians. This approach showed a 34% reduction in referral rates and is highly recommended for clinical guideline adherence.

In a retrospective study of 3022 LBP claims in the USA over 1 year, Webster et al. (2013) found that increasing the use of imaging only resulted in unnecessary surgical and medical costs, as suggested in Jarvik et al. (2003). The reason is that false-positive findings - such as degeneration and disc prolapse - may lead to increased referrals for more specialised services, resulting in unnecessary surgery and costs (Webster et al., 2013). In a randomised control trial (RCT) comparing rapid MRI for patients with LBP (n=190) to plain x-ray (n =190) over

one year in USA, Jarvik et al. (2003) reported that the rapid group showed no clinical difference in pain level and quality of life after one-year follow up. They suggested that MRI findings might promote further unnecessary medical and surgical treatment as 10 patients from the MRI group underwent surgery compared to 4 patients in the control group.

There are four reasons why imaging at this stage is discouraged. Firstly, it is unlikely that imaging will lead to findings of any primary pathology (Chou, 2009; Berg, 2013). Secondly, patients' awareness of the imaging result might elevate their fear of movement (Chou et al., 2009). Thirdly, imaging exposes the individuals to radiation, which is discouraged unless pathology is expected (Kochen et al., 2009). Lastly, false-positive findings, as mentioned earlier, may result in increased referrals to more specialised services (Webster et al., 2013).

1.4.5. The experience of people with chronic low back pain and MRI diagnosis

A growing body of literature has investigated the experience of NS-CLBP patients who receive an imaging diagnosis (Serbic and Pincus, 2014; Bunzli, 2015). Many studies find that patients may experience feelings of relief when receiving a diagnosis, even if the diagnosis does not in fact explain their pain. For example, Serbic & Pincus explored the impact of diagnostic labelling on self-management and pain-related guilt experiences. Using a grounded theory approach, 20 patients with CLBP seeking treatment from a pain clinic or an osteopathy clinic in UK were interviewed. The study revealed that while patients with CLBP experienced greater relief after an MRI they also

experienced increased feelings of guilt regarding their lack of improvement (Serbic and Pincus, 2014).

As far as the impact of diagnosis is concerned, informing acute LBP patients of their MRI results may lead to a diminished sense of well-being (Childs et al., 2015). For example, in a prospective cohort study of 150 LBP patients and 96 radiculopathy patients, Ash et al. (2008) found that patients who were blinded to the imaging results for 6 weeks had an improved sense of wellbeing compared to those who were given the results within 2 days. Furthermore, recommending an MRI for patients with NS-LBP was not associated with an improvement in management but merely served to increase the workload for primary care physicians (Kendrick et al., 2001).

The above-mentioned study draws attention to the issue regarding the exact conditions under which radiological methods, in general, and MRI, in particular, should be applied. The possibility of misinterpretation of the radiological diagnosis by the patients might increase to the complexity of the NS-CLBP. Bunzli et al. (2015) qualitatively studied the underlying pain-related fear and how it evolves in 36 NS-CLBP patients in a physiotherapy clinic in Australia with high scores on the Tampa Scale for Kinesiophobia. The study indicated that whilst people were eager to learn about their medical diagnosis, they misinterpreted the meaning, making it seem more serious. A need to remedy this propensity is therefore needed in healthcare settings for people with CLBP. Similarly, Jenkins et al. (2015) surveyed 300 people with CLBP in primary care practices in the USA concerning their beliefs on the importance of having a radiological examination for their condition. In all, 48% of the survey

respondents reported that all sufferers of back pain should be examined radiologically. The study also showed a correlation between people who believe that imaging is important and low levels of education, older age, and high scores on the Back-Belief Questionnaire. Therefore, this study specifies the characteristics of CLBP patients with whom doctors might fail to comply with regard to clinical imaging guidelines.

The importance of properly informing patients about their condition and investigative methods employed has been highlighted by McCullough et al. (2012) in a US retrospective study of information about lumbar spine epidemiology provided in 237 MRI reports regarding minor degenerative alterations, with comparative analysis of the rates of replicated cross-sectional imaging and treatments over the course of 12 months. Results indicated that the number of narcotic prescriptions was reduced when epidemiological information was included in MRI reports. Addressing a similar topic related to the necessity to ensure that patients can comprehend medical reports, Bossen et al. (2013) argued that patients were less emotionally affected and reports were better understood when simpler terminology was used.

In summary, MRI diagnosis is encouraged when there is a suspicion of serious pathology in order to facilitate early detection and better treatment options. However, most CLBP cases are non-specific and the signs and symptoms cannot be explained with the use of MRI as a diagnostic tool. Indeed, the utilisation of MRI to explain NS-CLBP symptoms did not improve the outcomes. Furthermore, the psychological consequences of undergoing MRI in this context remain largely unexplored.

1.5. Biopsychosocial approaches to the management of CLBP

The biopsychosocial model of CLBP management aims to target biological, psychological and social contributors to pain and disability (Main 2012). Therefore, it employs a multidisciplinary approach (van Middelkoop, 2011; Kamperet, 2014).In order for physicians to identify the most appropriate treatment, it is important to understand the biopsychosocial impact of LBP on individuals. Indeed, biomedical model-based treatment options for CLBP such as 'back school programmes' and generalised exercise (Pincus et al., 2013b) have been found to be less effective than treatment options based on the biopsychosocial model (van Middelkoop et al., 2011). Additionally, Monotherapies (i.e. the use of single treatments) have also proved ineffective, and this has attracted further research into the multidisciplinary approach (Artus 2010). Favourable outcomes from clinical practice have also helped to promote the application of multidisciplinary rehabilitation. The multidisciplinary rehabilitation approach concurs with the theory that back pain is caused by complications in the anatomy or psychology of a human being. Some psychological aspects of an individual can intensify or extend the duration of pain (Main 2012). Examples of these psychological elements include anxiety, propensity to catastrophize, fear, and mood disturbance. disability on the long term can also be influenced by environmental and social factors such as conditions of the workplace, anticipation to resume work and physical requirements of the workplace (Shaw 2009). In response to these concepts, structures of different rehabilitation programs have been adjusted to incorporate physical, psychological, social, and workplace environments in their

policies. A combination of these constituents is offered by teams of skilled clinicians (Kamper et al., 2014). In the recent past, the biopsychosocial model has been widely accepted and as a result, more research has been conducted into the multidisciplinary method of rehabilitation (Foster ,2011). The biopsychosocial approach to multidisciplinary rehabilitation can be made available through outpatient services, rehabilitation institutions and multidisciplinary pain management clinics.

1.5.1. Fear-avoidance model of pain

The fear-avoidance model (FAM) conceptualises painful CLBP to the broader biopsychosocial approach rather than merely relating it to biological injury (Vlaeyen & Linton, 2000; Wertli, 2014). FAM aims to elucidate the transformation of acute musculoskeletal pain into chronic pain (Vlaeyen and Linton, 2000; Zale and Ditre, 2015). The model is used to assess the anxiety and fear avoidance components of disabling chronic pain. Whenever the incidence of major trauma causes acute pain, the FAM focuses on two activities: It first identifies normal function, re-engagement, and recovery. The other activity it focuses on is in contrast with the first, i.e. an individual's technique of coping with negative influence. The model identifies any anxiety brought about by fear, pain, avoidance, possibility of disability, inactivity, depression, and persistent pain. It also identifies the likelihood of being caught in the avoidance cycle (Leeuw et al., 2007). The ordinary response to pain is withdrawal, and CLBP patients are particularly vulnerable to withdrawal. This type of response enables body organs to gain back their health. LBP patients who discontinue active behaviour promote a maladaptive process, which

ultimately leads to advanced muscle weakness and disability (Vlaeyen and Linton, 2000; Leeuw, 2007).

Individuals with the catastrophizing characteristic present their pain as being considerably worse than it already is in order to receive sympathy; it is also evidence of poor self-management of pain (Sullivan et al., 2006). A cross-sectional review was carried out in Netherlands in 2006 by Swinkels-Meewisse et al. (2006) on 96 cases of acute LBP. The study's main objective was to evaluate the correlation between pain-associated fear and disability in LBP patients. The review's findings showed fear of movement has a high potential for causing disability. Sullivan et al. (2004) also suggested that a chronic pain patient is more susceptible to pain catastrophizing in the presence of an observer, and that catastrophizing patients have a higher likelihood of developing pain-associated fear and even disability (Leeuw at al., 2007). These events lead to a continuous cyclic process whose negative implications for the patient continue to intensify (Vlaeyen & Linton, 2000). It has, however, been observed that a faster and more efficient recovery can be facilitated by involvement in active processes, confronting pain, and refraining from catastrophization. Norton & Asmundson (2003), for instance, provide an interpretation on the effect of physiological activities on fear-avoidance responses in chronic pain patients.

Catastrophic and avoidance behaviour, depression, hyper-vigilance, and the fear of movement constitute the major components of the FAM (Vlaeyen & Linton, 2000). The aforementioned behaviours are known to greatly contribute to the outcomes of pain and disability. Evidence-based analysis has further

revealed a positive correlation between the model constituents and the likelihood of developing disability (Turk & Okifuji, 2002; Leeuw, 2007) and that diminished ability to physical activity can be attributed to fear-avoidance practices (Vlaeyen & Linton, 2000; Wertli, 2014).

The amount of pain felt by chronic pain patients does not necessarily influence the level of pain-induced fear (Gheldof et al., 2010). This observation is based on interventional analysis that was not primarily focused on the fear avoidance model and its capacity to cause change. The authors of this study are particularly reserved on concluding whether an effective treatment outcome can be directly caused by minimising catastrophic and fear-avoidance behaviour (Vlaeyen & Linton, 2000; Wertli, 2014). However, there is evidence that catastrophizing behaviour affects fear-avoidance, pain, and disability outcomes (George and Stryker, 2011).

Pincus et al. (2010) pointed out that intervention reviews on FAM fail to provide improved results on which to base conclusive recommendations. Pincus et al. (2010) further associated this limitation to poor selection of the samples, resulting in inclusion of many patients who were not at a high risk of being fear-avoidant. Many studies have focussed on identifying the impact of behavioural and cultural beliefs on a patient becoming fear-avoidant. However, to date there is no clear definition of the specific forms and types of behaviours and beliefs that contribute to fear-avoidance (Pincus et al., 2010). The results of the analytical review were inconclusive as it was not clear if the research was focused on beliefs or behaviours. Reviews conducted in the past on analytical studies have also expressed their concern on the lack of distinction between

various psychological states of individuals, which has resulted in the incorrect and inaccurate use of terms such as depression and distress (Pincus, 2002; Turk & Wilson, 2010).

The current literature on the FAM model also has some weaknesses. Leeuw et al. (2007), for instance, revealed that the FAM model overlooks the variations in the course of back pain that different patients experience. These variations occur in the duration and intensity of pain, number of incidences, and the overall effect on the patient. The model also draws conclusions after analysing a small portion of LBP patients. On the other hand, Wideman et al. (2013) proposed a re-evaluation of the FAM model since it fails to validate the assumptions of causality in the component variables. The model also fails to include potentially deterministic variables such as resilience, which could be used to demonstrate that the pathways proposed by FAM are not always an accurate representation of the real-life course the pain takes. Leeuw at al. (2007) also criticised the causality assumptions in the FAM model and suggested additional evidence-based analysis. In general, components included in the FAM model have distinct effects on the outcome of LBP, but the model fails to provide an exhaustive description on the transition stages an individual goes through in the advancement of LBP.

1.5.2. How psychosocial factor influence low back pain

Evidence advances the idea of the interrelation of social and behavioural factors that exert influence on the results derived from the use of physical therapy in treatment. It also attempts to discover the degree to which their

influence considerably differs among patients. The focus of substantial research efforts, as a consequence, is on the development of newly designed clinical tools used in the identification and highlighting of psychosocial factors that are present, to a significant degree, in decision making. The description and structure of the conceptual differences (by which the psychosocial factors influence results) are encompassed by three common research terms. These research terms are present in the form of prognostic factors, treatment effect modifiers (or moderators), and treatment mediators. (Hill & Fritz, 2011).

Prognostic factors

The characteristics that assist in estimating the likely outcomes of the patient, regardless of the selected management, are the Prognostic factors. Identification of predictive factors should be made from longitudinal and single-group, as well as from unit studies. There are multiple systematic reviews identified numerous factors that could predict outcomes of LBP patients (Wessels, 2006; Hilfiker, 2007; Kent, 2008; Verkerk, 2012).

Several physical and psychosocial factors have been found to be a prognostic factor of disability in patients with LBP (Hilfiker, 2007; Balague, 2012). These prognostic factors included, catastrophising, scoring high in baseline disability measures, unemployment, widespread pain and having a high score Chronic Pain Grade (Grotle et al., 2010).

Treatment effect modifiers or moderators

Moderator factors or treatment effect modifiers are factors which are recognised at the baseline treatment level, which are considered to potentially

be able to influence treatment outcomes in patients. As a result, people with LBP and sciatica might show poor improvement from a certain group of therapies compared to LBP alone. The identification of treatment modifiers is made with the use of interactions tests in demonstrating that in patients possessing certain baseline characteristics, the efficacy of an intervention is remarkably more compared to a different one.

There is, therefore, a need for a study that has not less than two treatment arms, with preference of participants allocated to treatment groups in random order, in the identification of a precise treatment effect modifier (Hancock, 2009; Hill & Fritz, 2011).

The focus of several clinical decision-making for LBP in physical therapy is traditionally on issues from the early physical examination with regards to making a determination on the strategy for most effective treatment. A significant and specific intervention determinant to be utilised is based on whether this baseline discovery is exhibited by a patient (Werneke, 2009; Hill & Fritz, 2011).

There is a likelihood of psychosocial factors playing essential role in the form of modifiers affecting treatment. For example, in a systematic review of four RCTs (n=7208 LBP patients) Gurung et al., (2015) found that age, the use of pain killers, education level and employment status were moderate moderator ($p < 0.05$) to response for treatment.

Treatment Mediators

Mediators are factors which are able to change during or as a result of the treatment, meaning that they have a level of influence on the treatment outcome (Kraemer et al,.2002). It is possible for this result, for example, to be fulfilled through the reduction of fear of movement on the part of patient or avoidance of fear behaviour (mediator), on the assumption that an underlying association among treatment and possible mediator (Hill & Fritz, 2011). Statistical technique performed in confirming whether a result such as the degree of disability accompanying treatment like therapy for cognitive behavioural therapy is mediated through changes in a third variable like fear of movement is the mediation analysis (Mackinnon et al., 2007)

It is possible for clinicians to be assisted in trying to understand the treatment component strength for improved results and how the impacts of such treatment are possibly taking place by comprehending the influence of various treatment mediators.

Conducting mediation analysis calls for patients who have undergone specific treatment to make data sets available. It also requires the inclusion of possible mediators at baseline and for follow-ups to be made for possible analysis of mediator factor with regards to how they relate to the results. Therefore, secondary analysis of RCT data provides the best chance in examining specific treatment mediators (Hill & Fritz, 2011)

Studies that have come up with reports on the LBP treatment mediators' results are considerably fewer compared to reports on prognostic factors. (Lee et

,2015; Mansell,2016). In a systematic review of mediation studies (n=12) for back and neck pain, Lee et al., (2015) found that self-efficacy, psychological distress, and fear mediated the relationship between pain and disability. However, the author suggested that since half of the included studies were cross-sectional, conclusive finding cannot be drawn from this systematic review.

1.6. Treatment of chronic non-specific low back pain

The approaches to treating CLBP vary, and chronic pain affects individuals differently (Waddell & Burton, 2001; Van Tulder, 2006; Koes , 2010; Hartvigsen, 2018). The implications range from minimal disruption to severe disability, overdependence on prescription drugs, and psychological distress. An increase in the severity of pain indicates progression of the disease and, ultimately, an increased socioeconomic burden. Most clinical guidelines emphasise conservative non-pharmacological treatment rather than surgical intervention (e.g. Waddell & Burton, 2001; Van Tulder, 2006; Koes , 2010; Hartvigsen, 2018). The international clinical guidelines for managing acute LBP are not significantly different from those applied for persistent LBP; they are more focused on non-pharmacological therapy and the control of comorbidities such as depression (NICE. 2016; Hartvigsen, 2018).

The main focus in the guidelines' recommendation is early identification of patients that may need further services (e.g. imaging, referral to surgery) through the introduction of a triaging service in the primary care. Afterwards, one valuable step that could be taken is applying a model of patient

stratification to enable primary care practitioners to appropriately refer LBP patients, thereby enabling the efficient allocation of medical resources to patients based on urgency (Foster et al., 2014). The STarT Back is a tool used in primary care settings in the UK to classify CLBP patients (Hill et al., 2010). The tool consists of two parts. The first phase includes a short questionnaire completed by the patient used to assess the risk of unrelenting pain that is rated high, medium, or low risk. In the second phase, the most effective diagnosis and management tools are matched to the identified risk of pain for each patient. Clinical guidelines in the UK now emphasise the stratification of risk in LBP patients using the STarT back tool (Foster et al., 2014).

The recommendations for the management of CLBP are awareness of the disease (patient education), self-management techniques, and continued physical activity while avoiding work absenteeism (Hartvigsen et al., 2018). However, it should be noted that the evidence for these recommendations is limited (Sieper and Van Der Heijde, 2013; Goubert, 2016; Sions, 2017).

There appears to be variability in the non-pharmacological management strategies advocated to address CLBP. In 2016, for instance, NICE proposed manual and psychological therapy, exercise, self-management, joint psychological and physical initiatives, and return-to-work initiatives. However, the guidelines outlined by the American Pain Society and the American College of Physicians recommend interdisciplinary treatment, manual therapy, acupuncture, exercise therapy, yoga, massage, and cognitive behavioural therapy (Sieper and Van Der Heijde, 2013). Surgical interventions like spine

fusion and decompression are only advised in the presence of red flag signs and symptoms as well as unequivocal radiological evidence (Foster et al.,2018)

1.6.1. Conservative treatment

Conservative treatment is the preferred choice for both chronic and acute LBP in the absence of red flag signs and symptoms (Delitto, 2012; Airaksinen, 2006). Physiotherapy is an example of conservative treatment that does not involve invasive procedures (Airaksinen, 2006: Moffett and McLean, 2006).

There are various physiotherapy interventions practiced to reduce pain and disabilities associated with CLBP. However, the supporting evidence for these interventions is not adequate largely because of poor methodology (Moffett and McLean, 2006). The evidence related to the effectiveness of physiotherapy interventions has been systematically reviewed (83 RCTs) by Van Middelkooop et al. (2011). The review examined 8,816 patients in total who received physiotherapy intervention and could return to work. Despite the fact that most studies were of low methodological quality, interventions such as exercise, 'Back School' treatment programmes, and laser therapy were commonplace (Huang, 2015; Poquet, 2016). Other interventions included transcutaneous electrical stimulation, behavioural treatment, education, and massage. Indeed, many treatments employed a multidisciplinary approach. The review authors found evidence of the effectiveness of multidisciplinary treatment in reducing pain in the short term compared to no treatment and other interventions (Van Middelkooop et al., 2011). However, the heterogeneity of the population, variation in the types of intervention, and in the comparison, groups made it

difficult to draw any clear conclusions on the individual effectiveness of the physiotherapy interventions.

A summary of three different countries clinical guidelines for managing CLBP conservatively (NICE, 2017; Qaseem, 2017; Stochkendahl, 2018), reported by Foster et al. (2018). In short, the recommendations divide the conservative treatment options into core (first-line) treatment and adjunctive (second-line) treatment.

The core treatment options include education and advice on staying active. Essentially, this is the first treatment to be given to any patient presenting with LBP. The patient should receive information about the nature of back pain, and if serious pathology is not indicated, advice should be given on staying active and returning to work as soon as possible. The second recommendation is exercise. No specific form or duration of exercise should be recommended; rather, any exercise programme should be tailored to the patient's capability and preference.

Recommended treatment options encompass spinal manipulation, acupuncture and yoga, to be used for a short period only. Additionally, when there is a high level of disability and poor response from core treatments, the patient should be advised to engage in either mindfulness-based stress reduction or multidisciplinary rehabilitation.

Furthermore, the effectiveness of a broader biopsychosocial intervention was examined by Kamper et al. (2014) in a systematic review and meta-analysis of 41 RCTs. This study compared multiple biopsychosocial treatments with

various non-multidisciplinary biopsychosocial treatment for 6,858 CLBP patients. The findings suggest that multidisciplinary biopsychosocial rehabilitation for CLBP was slightly superior to physiotherapy treatment or medication alone. Multidisciplinary biopsychosocial treatment found to decrease pain by standardised mean difference of 0.21 (95% CI 0.04 to 0.37) and disability 0.23 (95% CI 0.06 to 0.4) when compared to non-multidisciplinary biopsychosocial treatment. However, multidisciplinary biopsychosocial treatment does not imply a specific treatment approach; hence, the results of each study varied greatly. However, it is important to note that not all patients with CLBP require multidisciplinary biopsychosocial treatment, and further research is necessary to determine what psychosocial factors influence response to treatment. Therefore, it is necessary to selectively target people who may benefit from this treatment approach.

1.6.1.1. Evidence for psychosocial treatments

The difficulty in managing NS-CLBP arises from the lack of clear pathological origin. Therefore, different psychosocial and pathoanatomical aspects should be considered when managing NS-CLBP. In the next two sub-sections, an example of CLBP rehabilitation based on a range of psychosocial theories will be reviewed.

Cognitive behavioural therapy

Cognitive behavioural therapy (CBT) is a form of psychotherapy that has been found to be effective in managing chronic pain conditions (Richmond et al. 2015). Initially, CBT aims to educate an individual of how pain interacts with

various psychological, emotional, and environmental factors. It then seeks to provide an appropriate training programme to help patients cope with pain (Nielsen et al., 2014). Based on these aims, a counsellor (physiotherapist or therapist) designs a programme tailored to meet an individual's functional goals. Therefore, the compassion and professionalism of the physiotherapist play a major role in the outcome of the programme (Nielsen et al., 2014).

In a systematic review of 23 RTCs (n = 3329 patients) on the effectiveness of CBT as treatment for NS-CLBP, Richmond et al. (2015) reported that the application of CBT showed long-term improvement in disability (SMD = -0.19, 95%CI -0.38 to 0.01) and pain (SMD = 0.23, 95%CI -0.43 to -0.04) when compared to a control group or other guideline-based active treatments (e.g. strengthening exercise). The CBT intervention was delivered by a variety of medical professionals, including psychotherapists, physiotherapists, and GPs. However, the authors of this study reported a high risk of bias due to the poor quality of reporting in the studies under review.

Graded exposure approach

The graded exposure approach places an emphasis on gradually exposing CLBP patients to a specific fear of movement situation that they typically fear most. In a recent systematic review of the evidence, Lopez-de-Uralde-Villanueva et al. (2016) investigated the effectiveness of graded exposure approaches in the management of NS-CLBP (13 studies with N=1486 patients). The found that graded exposure was more effective than control group (active physiotherapy, exercise or waiting list) in reducing disability (2 studies, n = 105,

SMD = 0.39, 95% CI 0.003 to 0.78, P = 0.048) and catastrophizing (2 studies, n = 105, SMD = 0.48, 95% CI 0.09 to 0.87, P = 0.02).

1.6.2. Surgical treatment

Surgical intervention is only recommended if red flag signs and symptoms are detected. There is a consensus within the CLBP clinical guidelines (Koes, 2010; NICE, 2016; Foster,2018) on deferring the surgical management option. Multiple trials have shown that fusion surgery is no better than intensive rehabilitation and the prolonged effect of treatment is the same (Brox, 2010; Saltychev, 2014). This explains why surgical intervention is not recommended for CLBP in most cases.

1.6.3. Back pain management in Saudi Arabian healthcare system

The Ministry of Health (MOH) is the primary healthcare provider in Saudi Arabia. There are three levels of hierarchy of care within the MOH: primary and secondary, and tertiary (Almalki et al., 2011), providing preventive, curative, and rehabilitative healthcare for Saudi citizens (Walston et al., 2008). There are 2,325 primary healthcare centres (PHCs) in Saudi Arabia, providing curative and preventative services as well as referrals to secondary healthcare centres (Al-Ahmadi and Roland, 2005). In addition, the number of private healthcare hospitals is increasing; recent MOH statistics show that there are 152 hospitals across the country (Ministry of Health, 2017).

There is no established pathway of care or clinical guidelines for patients with LBP in Saudi Arabia. Patients may visit the general practitioner (GP) at the primary care centre or pay to see a spine consultant at a private hospital

without GP referral. As previously described, GPs in primary care centres can refer patients to a consultant in a higher centre for services that are not available at the primary care level, such as physiotherapy, advanced imaging and laboratory tests. This process extends the time for patients to see physiotherapist up to four months which, therefore, might heighten the chances of progressing to CLBP (see Figure 1).

Current international guidelines emphasise that LBP should be managed at the primary care level since very few cases will be medical emergencies (Foster et al., 2018). That said, it should be noted that there are no clinical guidelines or pathways of care for LBP in Saudi Arabia. The Saudi Spine Society, however, is working towards developing national guidelines of management of LBP (Saudi Spine Society, 2017).

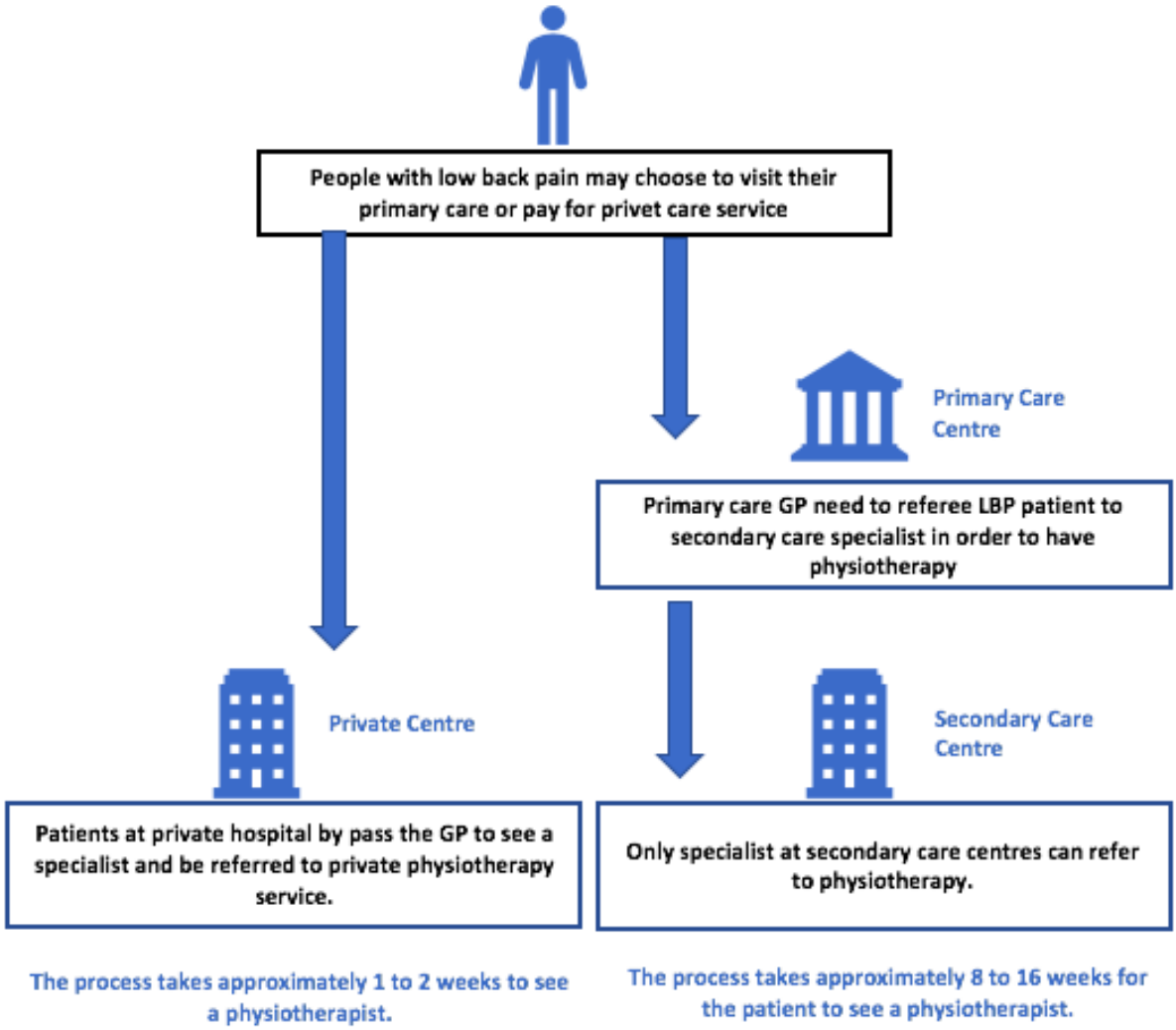


Figure 1 Illustrated process for attending physiotherapy service in Saudi Arabia

PHC accessibility was the focus of the studies by Al-Ahmadi and Roland (2005) and Alzaied and Alshammari (2016), with findings revealing that accessibility was more adequate in urban areas than in rural areas. However, LBP management in PHC or the pathway of care has never been investigated due to the fact that provision of rehabilitation services is restricted to secondary and tertiary healthcare centres.

The cross-sectional study conducted by Alsaleh et al. (2016) among 80 GPs from Riyadh, Saudi Arabia, sought to determine how aware those GPs were regarding the use of the red flag tool to screen for LBP. The proportion of GPs who possessed such awareness was 68%. In a separate study, Alsaleh et al. (2015) reported that, in cases where disc prolapse was diagnosed based on MRI, 61% of 80 primary care doctors referred patients to higher levels of care. This was possibly due to the absence of consistent guidelines and care pathways for the management of LBP. These studies suggest that primary care management of LBP patients is suboptimal and the referral of these patients to higher care levels may put pressure on secondary and tertiary level services.

1.7. Justification for this research study

CLBP is a major socioeconomic burden despite increasing understanding of pain and advancement in technology and laboratory testing (van Tulder, 2002; Global Burden of Disease, 2016; Hartvigsen, 2018). The most prevalent type of CLBP is classified as NS-CLBP. The attempts to diagnose NS-CLBP using MRI have been studied prospectively and findings indicate that MRI diagnosis may result in a higher consumption of pain medication and increased visits to healthcare professionals (Jarvik and Deyo, 2002; Henschke, 2009; McCullough , 2012).

With that said, the recommended treatment based on the clinical guidelines of 15 countries, is that CLBP should be managed conservatively and even plain radiography should be avoided if no serious pathology is suspected (Koes et al., 2010).

The presence of psychosocial factors, such as fear or depression are strong mediators in the transition from acute back pain to complex NS-CLBP (Jensen et al., 2010). The association between diagnosing people with NS-CLBP with an MRI and the impact of the diagnosis on different psychosocial factors has not yet been investigated.

The current project attempts to explore the psychosocial impact of diagnosing people with NS-CLBP by MRI and the influence of an MRI diagnosis on physiotherapy outcomes in Saudi Arabia. To provide a plausible explanation for this research, the project was divided into three stages. Firstly; to identify the psychosocial factors associated with changes in pain and/or disability levels after physiotherapy a systematic review was conducted. Secondly; The project explored the psychosocial experiences of people with NS-CLBP following MRI diagnosis, and sought to obtain healthcare professionals' opinions on guidelines for the use of imaging to diagnose NS-CLBP in Saudi Arabia by interviewing people with NS-CLBP, physiotherapists and doctors. The identified psychosocial factors from the stage one and two informed the design a booklet of outcome measures for stage three. The third stage aimed to test the feasibility of conducting a randomised controlled trial in Saudi Arabia to i) determine the impact of MRI diagnosis on psychosocial, pain and disability outcomes in people with CLBP treated with physiotherapy and ii) explore the acceptability of randomisation to diagnosis using MRI (intervention) plus physiotherapy rehabilitation or physiotherapy alone (Non-MRI/control group).

1.8. Aims and objectives of the study

This doctoral research utilised the Medical Research Council (MRC) framework for the development and evaluation of complex interventions. While MRI diagnosis cannot be regarded as an intervention per se, the adaptation of the MRC framework will assist the conceptual development of a clinical trial by identifying and examining the outcome measures to be used in a definitive RCT and consequently, testing the feasibility of recruiting and randomising patients in Saudi Arabia. The justification for adopting this framework is the nature of the study and the fact that multiple psychosocial components must be addressed from different perspectives. The MRC framework highlights the requirement that a complex intervention that must pass through five phases before being tested in a definitive clinical trial. The first phase is the pre-clinical phase, or the theoretical phase, the second phase is the modelling phase, followed by the exploratory study (phase three). The fourth phase is the definitive RCT and, finally, the fifth phase is the long-term implementation (Craig et al., 2008). The MRC framework was introduced in 2000 (Campbell et al.,2000). The most recent update has introduced an evaluation process that can be used to assess the quality and consistency of implementation (Moore et al., 2015).

Aims of the study

This three stage PhD study used different approaches to address the following aims (Table 2)

- To identify the psychosocial factors associated with changes in pain and disability outcomes in CLBP patients treated by a physiotherapist.

- To explore the psychosocial factors associated with MRI diagnosis in people with NS-CLBP.
- To assess the feasibility of randomising patients to two groups in terms of patients' and physicians' acceptability.
- To explore the acceptability of randomisation and the study design among both healthcare practitioners involved in trial delivery and patient participants.

Stage one was the systematic review (Chapter two). This review critically appraised longitudinal and cross-sectional studies on LBP and determined the applicability of the findings to healthcare practice. Its purpose was to assist in identifying the psychosocial factors associated with changes in pain and/or disability outcomes in CLBP patients treated with physiotherapy. This pre-clinical phase will address the following question:

What are the psychosocial factors associated with changes in pain and disability outcomes in CLBP patients treated by a physiotherapist?

The second stage of the project is qualitative (Chapter Three). This study explored the opinions of people living with CLBP and of healthcare professionals on the influence of an MRI diagnosis of NS-CLBP on psychosocial factors. This study involves interviews with three groups: people with CLBP, physiotherapists, and doctors with expertise in CLBP management. This modelling phase answered the following question:

What are the psychosocial consequences of associating NS-CLBP with radiological diagnoses?

The last stage of this project was a sequential mixed-method study. It consisted of a feasibility RCT, followed by a process evaluation (Chapter Four). The aim was to evaluate the feasibility of a conducting a definitive RCT investigating whether MRI adversely impact psychosocial and disability outcomes in patients with CLBP undergoing physiotherapy.

The process evaluation of the feasibility RCT was implemented alongside and following the feasibility RCT to explore the acceptability of randomisation and the study design among both healthcare practitioners involved in trial delivery and patient participants. The interviews also explored the broader social, political, economic, and environmental (context) aspects that may have influenced trial delivery. This exploratory study addressed the following question:

Does MRI diagnosis negatively influence psychosocial and disability outcomes in patients with CLBP undergoing physiotherapy?

Table 2 Research aims and questions

Aim	Research Question	Method	Chapter
To identify the psychosocial factors associated with the changes in pain and disability outcomes in CLBP patients treated by a physiotherapist.	What are the psychosocial factors associated with changes in pain and disability outcomes in CLBP patients treated by a physiotherapist?	Systematic review	Chapter two
To explore the psychosocial factors associated with MRI diagnosis in people with NS-CLBP.	What are the psychosocial consequences of associating NS-CLBP with radiological diagnoses?	Qualitative interview	Chapter three
1-To assess the feasibility of randomising patients to two groups in term of patients' and physicians' acceptance. 2-To explore the acceptability of randomisation and the study design among both healthcare practitioners involved in trial delivery and patient participants.	Does MRI diagnosis negatively influence psychosocial and disability outcomes in patients with CLBP undergoing physiotherapy?	Feasibility study with process evaluation	Chapter four

Chapter Two

Psychosocial Factors Associated with Changes in Pain and Disability Outcomes in Chronic Low Back Pain Patients Treated by a Physiotherapy: A Systematic Review

Summary

Clinical guidelines emphasise conservative physiotherapy and an active lifestyle. Whilst the presence of psychological factors predicts poor recovery after surgical intervention, the psychosocial factors that predict outcomes following physiotherapy have yet to be identified. Electronic searches of PubMed, Medline, CINAHL and PsycINFO were conducted using detailed search strategy. Prospective papers examining the relationship between psychosocial factors and pain and disability outcomes after physiotherapy were included. Two reviewers selected, appraised, and extracted the studies independently. In total, 21 studies were included in this systematic review. The result suggests that factors like fear of movement, depression, self-efficacy, and catastrophizing were frequently reported to predict change disability outcomes after physiotherapy. However, these factors were less likely to be predictive of change in pain outcomes following physiotherapy intervention.

2.1. **Background**

It has been shown in previous studies that low back pain (LBP) is one of the most prevalent musculoskeletal disorders presenting in modern, industrialized societies (Hoy, 2012;Kamper, 2016; Hartvigsen, 2018). Even though the incidence of low back pain is high, affecting up to 80% of people at least once at some point in their lifetime (Hoy, 2012; Kamper, 2016; Hartvigsen, 2018), the majority of these recover within just a single month, with no long term problems thereafter (Jarvik and Deyo, 2002). On the other hand, it is also seen that between 10–40% of all individuals suffering from low back pain go on to develop chronic symptoms and suffer some form of disability, to a certain degree.

When examining the connection that exists psychological, behavioural, and social elements in relation to later incidence of chronic pain and any disability associated thereafter, the biopsychosocial model can be used in this regard, as recommended by a range of different clinical guidelines (Airaksinen,2006; Koes,2010; NICE, 2016; Stochkendahl ,2018). In recent times, substantial changes have been made to the general suggestions offered throughout various national guidelines, when it comes to clinical practice (Foster et al,.2018). In turn, these changes have brought about an increase in the prevalence of physical self-management and psychological therapies in these cases, instead of surgical and pharmacological interventions which were more common practice in the past. These new recommendations are an attempt to

encourage the implementation of more active treatments which take into account the differing psychosocial characteristics of the patient as an individual, which can mean that the patient experiences improved results (Airaksinen, 2006; Koes, 2010; NICE, 2016; Stochkendahlet ,2018).

It is important to note that psychosocial factors contribute significantly to pain persistence, response to treatment and rehabilitation, and the likelihood of developing disability. There have been a number of studies which focus on analysing the potential link that exists between psychosocial factors such as catastrophising and fear avoidance and response to treatment in CLBP patients, and this topic has been a popular area of research over the past few decades(Gheldof , 2010; Pincus , 2002) . According to Kamper et al. (2014), the psychosocial factors most considered relate to cognition, behaviour, the psychology of individuals, social and socio-occupational characteristics.

For the most part, studies looking into this topic are based on a prognostic study model, which attempts to examine the predictive value of these psychosocial factors when it comes to changes in patient outcome, without taking into account the specific type of treatment administered (Hill & Fritz 2011). The relationship between level of disability and psychosocial factors has been presented in a number of previous systematic reviews. Examples include catastrophising thoughts and disability in CLBP patients (Geisser,2003; Wertli , 2014), depression association with disability in CLBP (Linton ,2000; Geisser, 2003; Mallen ,2007; Ramond ,2011), the predictive value of self-efficacy of change in disability in CLBP (Geisser , 2003; Jackson , 2014), functional coping mechanisms (Wessels et al. 2006) and finally, fear avoidance beliefs as

examined extensively in a number of different publications (Linton, 2000; Pincus , 2002; Geisser , 2003; Pincus , 2006; Lakke , 2009; Ramondet , 2011; Verkerk , 2012; Zale , 2013; Wertli , 2014).

Most of the aforementioned studies and reviews highlight the importance of psychosocial as predictors of change in disability level and the subsequent recovery from pain in mixed groups of LBP patients both in prospective cohort and cross-sectional study designs (Kendall et al., 2017). It is important to keep in mind many reviews underline the fact that most studies involved were not high quality, the patient population were heterogenic, and the study design sometimes inappropriate. As a result, it is often not possible to draw any strong, reliable conclusions from this type of review.

Although predictive psychosocial factors of outcome in LBP are reported to be similar in acute and chronic conditions (Balague, 2012; Kendall, 2017), its noteworthy that the natural course of acute versus chronic back pain is different (Hayden, 2010, Grotle, 2010, Costa, 2012; Kendall, 2017). This suggests that some psychosocial factors might be more prognostic in LBP when considering the duration of illness (chronicity).

Apart from Wessels et al. (2006), none of the reviews mentioned above have explored the psychosocial factors associated with change in pain and disability in chronic low back patients after conservative therapy. However, the authors only included 6 studies pertaining to this association and suggested that no conclusion could be drawn from the review due to this limited number of studies.

As discussed in chapter one of this thesis, physiotherapy is considered as the formal conservative treatment for LBP patients in Saudi Arabia, but it is not readily accessible in primary healthcare. Instead, physiotherapy services are only accessible through GP referrals, which means that there is a significant delay before the patient is actually provided with these services, which in turn increases the chances of an acute case of lower back pain transitioning into a more chronic condition (Macfarlane, 1999; Crook, 2002). Moreover, low back pain severity and associated disability are the main patients' complaints and are therefore advised as the core outcome measures instrument for NS-LBP trails (Chiarotto et al., 2018) and change in these outcomes is frequently used to indicate recovery from LBP (Burton,2004; Grotle,2007; Costa, 2015).

This chapter seeks to identify the prognostic value of psychosocial factors in the change in pain and/or disability in CLBP patients following physiotherapy interventions as recommended by clinical guidelines (NICE, 2016). The presented systematic review will summarize these psychosocial factors in order to allow for a topic guide interview to be established and applied in the next chapter of this thesis.

2.2. Methods/Design

2.2.1. Eligibility criteria

Research studies published in the English language and which met the following inclusion criteria (see 2.2.3) were included in the review.

2.2.2. Inclusion criteria

Participants;

- Adult aged over 18 years.
- Chronic low back pain; Pain between bottom of ribs and buttock creases that lasts for at least three months (Amundsen et al,.2018).
- No pathoanatomical diagnosis; e.g. stenosis, fracture, malignancy, vertebral fracture, infections, cardiovascular, respiratory, neurological, gastrointestinal, urogenital, or related conditions (Amundsen et al,.2018).
- Patients received a guideline-recommended physiotherapy intervention; either alone or as part of multidisciplinary team.

Study design:

- Prospective design.
- Reporting of psychosocial outcomes (fear, anxiety, etc.) and their correlation with pain and disability.
- Studies with mixed patient groups (acute and chronic) were included if separate analysis of chronic patients was reported.

2.2.3. Primary outcome measures of included studies:

- Pain outcome measures (e.g. Visual Analog Scale, McGill Pain Questionnaire).
- Disability outcome measures (e.g. Roland Morris, Oswestry Disability index)
- Psychosocial outcome measures (e.g. Fear Avoidance Belief Questionnaire).

2.2.4. Information source

Two independent reviewers (AH, MA) conducted an electronic search of four academic databases PubMed, Medline, CINAHL and PsycINFO from inception to 9/11/2018 to extract relevant studies. In addition, the reference sections of the extracted articles were manually searched to include any articles missed by the electronic search. Searching the electronic database involved the following three steps, then all of these steps were combined with an *"AND"* statement*:*

- Studies related to CLBP population identified using the following keywords: Low Back Pain, Recurrent Low Back Pain, Lower Back Aches, Low Back; Back Pains, Lower Back Pain; Back Ache, Chronic Low Pains, Chronic Lower Back Pain; Low Back Ache, Back Aches, Low Back Aches, Low Backache; Backache, Low Backaches; Backaches. Combined with "OR" statement.
- Patients undergoing clinical guideline recommended physiotherapy were identified using the following words: Exercise; Psychosocial Therapy, Self-management, Psychological Therapy, Manipulation; Mobilisation, Soft Tissue Techniques, Cognitive Behavioural Therapy, Psychosocial Approach; Education; Multi-Disciplinary, Biopsychosocial Rehabilitation, Physiotherapy; Physical Therapy, Rehabilitation. Active Therapy. Combined with "OR" statement.
- Study include psychosocial outcomes were identified using the following words: sensitivity, Anxiety, Vigilance, Hypervigilance, Attention, Kinesiophobia, Fear, Fear Avoidance Beliefs, Beliefs, Cognitive, Depression. Coping Pain Coping, Fear; Avoidance; Anxiety, Return to Work; Absentees;

Self-Efficacy. Sick Leaves, Mediation, Predictors, Prognostic. Combined with "OR" statement.

2.2.5. Selection of sources

Two reviewers (AA & MA) independently screened the titles and abstracts of all the studies retrieved from the database search. Studies which did not include keywords related to psychosocial factors, physiotherapy or rehabilitation of back pain in their titles were not included. Similarly, if the abstract did not clearly state that physiotherapy was occurring, or the sample was made up of participants with acute cases of back pain only, the study was not included. In cases of uncertainty as to whether the paper should be excluded purely on the basis of the abstract, a full-text copy of the article was retrieved and reviewed. Any disagreements were resolved by discussing the study's outcomes and other measures with a third independent reviewer (either KR or NC). The studies excluded from the review were listed and reasons for exclusion were noted.

2.2.6. Data collection process

The included studies were subjected to a data extraction process in which two reviewers (AA, MA) independently extracted the following information: title and authors; objectives and study design; start and end dates; duration of study participation; description of the population from which the participants were drawn; study setting; inclusion and exclusion criteria; methods of recruiting study participants; the number and demographic characteristics of participants;

severity of their CLBP; and the study outcomes, conclusions, and limitations reported by authors.

2.2.7. Risk of bias of the included studies

Considering that the aim is to find the prognostic psychosocial factors, the risk of bias in studies included in the review was assessed by two reviewers (AA, MA) independently using the Quality in Prognostic Studies (QUIPS) tool (Hayden et al,.2013). The tool has six domains covering study participation, attrition, prognostic factor measurement, outcome measurement, confounding, and statistical analysis & reporting.

2.2.8. Quality assessment

Since the search strategy was not limited to any study design and all of the studies included were either cross-sectional or prospective cohort studies, the quality of evidence and strength of recommendation was assessed using the Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies developed by the National Institute of Health (National Institute of Health, 2014). This tool is made up of a total of 14 criteria, which were established by the reviewer as being fulfilled, or otherwise. The assessment was carried out by two independent reviewers (AA, MA).

2.3. Results

2.3.1. Selection of the studies

The PRISMA chart (Figure 1) shows the process of study selection. A total of 21 studies met the inclusion criteria after full-text screening. The most common reasons for exclusion by abstract screening were absence of a physiotherapy

intervention or psychosocial outcome measure. The main reason for excluding full-text studies was the lack of separate data for CLBP in studies involving mixed chronic and acute back pain patients.

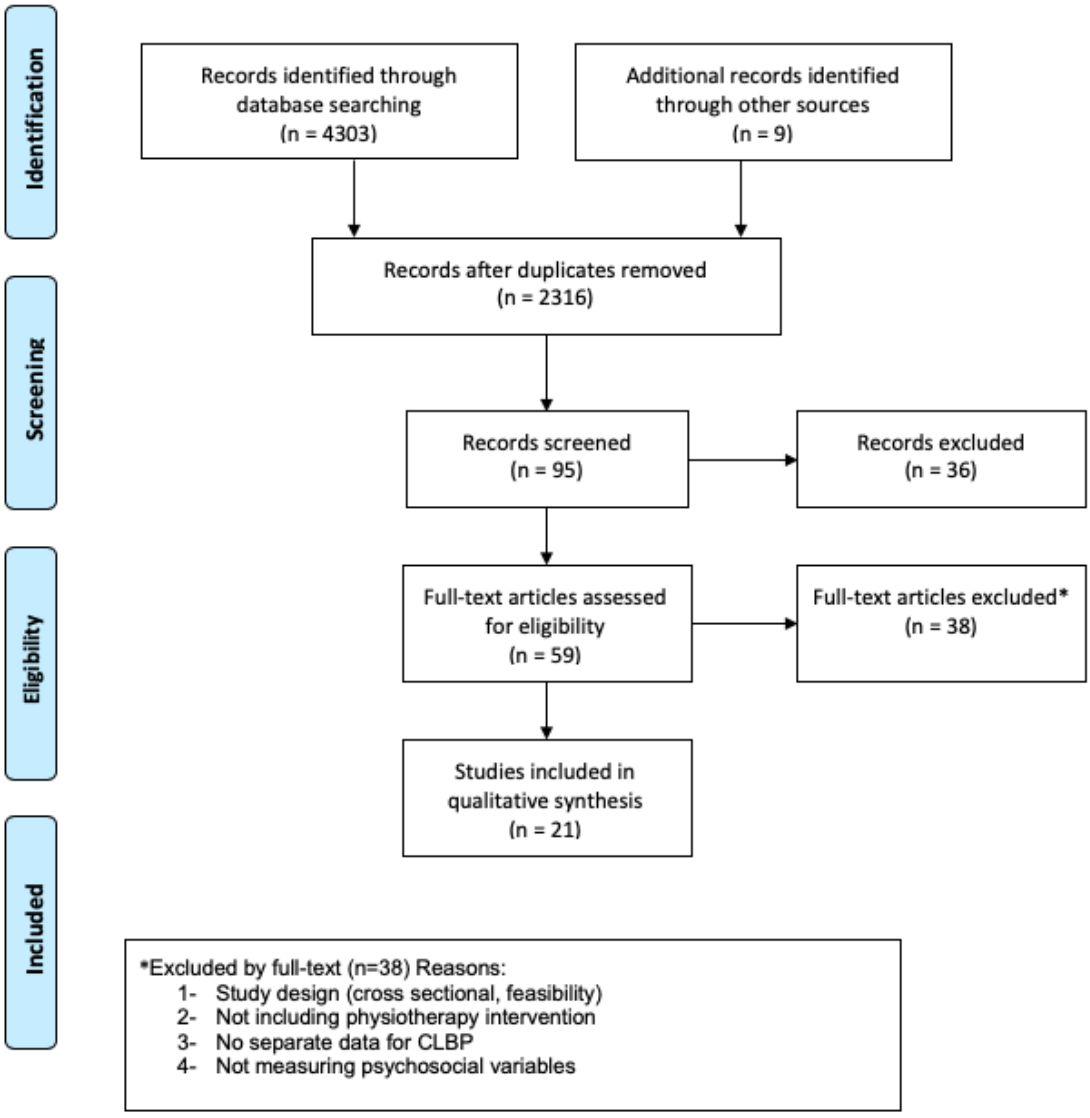


Figure 2 PRISMA Chart

2.3.2. Study characteristics

The total number of participants was 5,249. The mean age across the studies was 44.9 years (SD ± 4.2) with a higher proportion of women (62%). The average pain intensity measured at baseline before physiotherapy commenced in the reported studies was 5.3 (S.D. ±0.86) on the Visual Analogue Scale (VAS). The mean dropout rate was 3%. All prospective cohort studies reported measurements before and after physiotherapy intervention (Table 3).

Table 3 Characteristics of the included studies

		Study Origin	Sample Size (n)	Age mean (SD)	Baseline Pain Severity VAS	Follow Up (Months)
1	**Anderson et al,.2013**	Norway	96	37.5	5.9	1
2	**Evans et al,.2010**	USA	26	52	7.5	1.5
3	**Farin et al,.2013**	Germany	688	51	5.3	6
4	**Farin et al,.2015**	Germany	262	52	5.4	1
5	**Glattacker et al,.2018**	Germany	214	50.7	N/A	6
6	**Grotle et al,.2010**	UK	668	45	3	12
7	**Grotle et al,.2006**	Norway	50	40.5	6.1	12
8	**Kendell et al et al,.2018**	Australia	290	51	5.8	12
9	**Macedo et al,.2014**	Australia	172	50	6.1	10
10	**Niemistö et al,.2004**	Finland	204	37		12
11	**Rasmussen et al,.2012**	Sweden	71	38	5.4	36
12	**Scholich et al,.2012**	Germany	52	49	7.5	6
13	**Sherman et al,.2013**	USA	74	49	4.4	3
14	**Skidmore et al,.2015**	UK	109	42	N/A	1
15	**Van Der Hulst et al,.2008**	Netherland	162	39	5	6
16	**Verkerk et al,.2015**	Netherland	1760	40	5.5	12

17	**Woby l et al,.2004**	UK	83	41	4	2
18	**Woby et al,.2007**	UK	102	43.9	4.4	2
19	**Woby et al,.2008**	UK	166	44.4	4	2
20	**Page et al.,2015**	Canada	53	44	2.7	12
21	**Costa et al., 2015**	Australia	406	44	N/A	12

2.3.3. Methodological quality and risk of bias

The QUIPS bias assessment tool for prognostic studies showed a low risk of bias. The overall quality of the included studies was good to fair as per the Quality Assessment Tool for Observational and Cohort Studies, with 100% agreement between the two assessors.

2.3.4. Synthesis of the results

The included studies have reported different type of physiotherapy intervention and utilised different outcome measures when reporting the association between the intervention and outcomes. Only two studies included have reported mediation relationship between disability and pain with psychosocial outcome measures, the remaining 19 studies were concerned with prognostic association. Table 4

Several psychosocial factors were found to correlate with pain and disability outcomes following physiotherapy interventions in patients with CLBP. Different outcome measures were used in the selected studies (Table 4).

Fear Avoidance:

Fear avoidance factors were reported to either correlate with or predict disability outcomes in seven studies (Anderson, 2013; Frain, 2015; Glattacker, 2018; Grotle, 2010; Grotle , 2006; Scholich, 2012; Woby , 2004). The outcome measures used were the TAMPA scale of kinesiophobia (TSK) in three studies, the fear-avoidance belief questionnaire (FABQ) in three studies and Avoidance of Social Activities (ASAS) in one study. Furthermore, two studies reported depression, as assessed through the Hopkins Symptoms Checklist (HSCL) (Grotle et al., 2006), and self-efficacy, as measured by (CPSS-PF) (Woby et al., 2007), as a mediator of this relationship. The significance of the link between fear avoidance and disability is limited when the above two factors are used in the regression analysis.

Only one study reported a correlation between baseline fear avoidance and pain intensity at discharge (Farin et al., 2013).

Self-efficacy:

Level of self-efficacy forecasted the level of pain-related disability, as shown in five studies (Evans, 2010; Glattacker, 2018; Rasmussen, 2012; Sherman, 2013; Woby, 2008). Outcome measures used were pain self-efficacy questionnaire (PSEQ), self-efficacy scale (SES), and chronic pain self-efficacy scale (CPSS).

With regard to pain intensity correlation, only two studies reported a predictive role of self-efficacy to pain intensity in CLBP (Woby et al., 2008).

Catastrophising:

The measure of pain catastrophising was correlated with disability level in three studies (Farin, 2013; Glattacker, 2018; Grotle, 2010). The outcome measure used was the pain catastrophising scale (PCS).

Depression;

An association between disability levels and depression was reported in three studies (Van Der Hulst, 2008; Scholich, 2012; Skidmore, 2015). Three different outcome measures were used in each study, namely major depression inventory (MDI), depression symptoms checklist (SCL-90) and hospital anxiety and depression scale (HADS).

Only one study highlighted a correlation between depression and pain intensity (Scholich et al., 2012).

Anxiety;

Anxiety scores measured using the pain anxiety symptoms scale (PASS-20), HADS and state trait anxiety inventory (STAI) were reported in three studies to correlate with levels of disability (Glattacker, 2018; Macedo, 2014; Scholich, 2012).

Pain coping;

Two studies reported the predictive value of pain coping in the change of disability measures (Macedo, 2014; Grotle, 2010). The outcome measures used in both studies were the coping strategy questionnaire (CSQ).

Quality of life;

Quality of life was correlated with change in disability level in two studies (Scholich, 2012; Anderson, 2013), where the outcome measures used were health related quality of life questionnaire (HRQOL) and patient global impression of change (PGIC).

Only one study reported a correlation of quality of life and pain intensity after intervention (Scholich et al,.2012).

Days missed because of LBP:

The number of days missed because of CLBP was reported to be correlated with disability levels and work outcomes, i.e. return to work, in two studies (Niemistö, 2004; Costa, 2015)

STarT Back Tool:

High and medium modifiable psychological risk factors brought about a greater risk of poor recovery compared to the lower risk group, according to the STarT Back tool (Kendell, 2018; Page , 2015).

Table 4 : Summary of reported pain (*highlighted*) and disability outcomes, type of association and type of intervention in the included studies.

Type of study	Outcome measure	Results	Type of intervention	type of association
Anderson et al,.2013	Disability score in (RMDQ) is weakly correlated with Fear Avoidance Belief score (FABQ-PA). Patient's Global Impression of Change (PGIC) was moderately correlated with disability score (RDMQ).	(r= 0.23, p<0.05) (r= -0.51, p<0.05)	Multidisciplinary rehabilitation for 4 weeks	Predictive
	Patient's Global Impression of Change (PGIC) was moderately correlated with pain intensity score (VAS)	(r= -0.46, p<0.05)		
Evans et al,.2010	Baseline Self-efficacy scale (SES) predicts disability (RMDQ) after 6 months	β= -0.21; P<0.05	Physiotherapy and Yoga for 6 weeks	Predictive
	Baseline Self-efficacy scale (SES) predicts pain (VAS) after 6 months	β= -0.56; P<0.01		
Farin et al,.2015	Pain catastrophising (PCS) at the end of the treatment is associated with baseline disability (ODI)	r= .38, p<0.05	Multidisciplinary rehabilitation for 3 weeks	Predictive

Farin et al,.2013	Higher level of Fear Avoidance work beliefs (FABQ-W) is a predictor of disability outcomes (ODI)	r=1.42; P<.001	Multidisciplinary rehabilitation for 3 weeks	Predictive
	Higher level of Fear Avoidance work beliefs (FABQ-W) is a predictor of pain outcomes (VAS)	2.15; P<.001		
Glattacker et al,.2018	Disability measured by (RMDQ) is correlated with Fear Avoidance Belief Questionnaire, (FABQ), Pain Self-efficacy Questionnaire, Anxiety (HADS) and Catastrophing (PCS)	r= .504 (<.001) r= _.560 (<.001) r= .347 (<.001) r= .353 (<.001)	Inpatient multidisciplinary rehabilitation for 3 weeks	Predictive
Grotle et al,.2010	Being unemployed, as well as scoring high level of fear of pain (TSK), catastrophising and coping (CSQ24) and chronic pain grade scale are prognostic indicators of higher disability (RMDS)	(Standardized β= 0.22; P<0.01); (Standardized β= 0.08; P<0.01) ; (Standardized β= 0.11; P<0.01); (Standardized β= 0.02; P<0.01)	Not reported	Predictive
Grotle et al,.2006	Fear Avoidance beliefs work (FABQ-W) was associated with a disability score after 12 months. When distress outcomes (HSCL-25) were introduced into the regression analysis, FABQ-W was no longer significant. (β = 0.06, P=0.74).	β = 0.300, P=0.048	Not reported	
	Fear Avoidance beliefs work (FABQ-W) was correlated with pain intensity. When distress (HSCL-25) outcomes were introduced into the regression analysis, FABQ-W was no longer significant. (β = 0.13, P=0.54)	β = 0.32, P=0.038		

Kendell et al et al,.2018	Both high and medium risk groups in Start Back screening tool had more than 100% risk of poor recovery in disability scale compared to low risk group	RR=2.30 CI 95% (1.28-4.10) RR=2.86 CI 95% (1.60-5.11)	Exercise and psychological therapy	Predictive
	Both high and medium risk groups in Start Back screening tool had 25% risk of poor recovery in pain scale compared to low risk group	RR=1.25 CI 95% (1.04-1.51) RR=1.26 CI 95% (1.03-1.52)		
Macedo et al,.2014	Lumbar Spine Instability Questionnaire (LSIQ), Coping strategies Questionnaire (CSQ) and low fear on (PASS-20) were predictive of change in disability (RMDQ)	OR= 2.72 (1.39, 4.06), P<.001 OR= 1.81 (0.47, 3.16), P=.008 OR= 1.5 (0.13, 2.85), P=.032	Motor control exercise and graded activity	Predictive
Niemistö et al,.2004	More than 25 days missed due to back pain was a predictor for change in pain and disability score	OR 4.19,95%CI 1.5-11.3	Manipulation or stabilization exercise	Predictive

Rasmussen et al,.2012	Pre-intervention level of Self-Efficacy Scale (SES) and higher pre-intervention pain intensity are predictive of disability measured by Oswestry LBP disability scale (ODI).	Self-efficacy: (OR 9.8, CI 95% 2.1-45.5) Pain intensity (VAS> 5.3, OR 11.8, CI 95% 1.5-91.9)	Exercise	Predictive
	Higher level of pain intensity in VAS is predictive of poor outcome or pain	(VAS> 5.3, OR 3.9, CI 95% 1.7-21.2)		
Scholich et al,.2012	Strong correlation between disability score of Chronic Pain Grade level (CPG) and Health Related Quality (HRQOL) of life and depression (DBI). Moderate correlation with Trait Anxiety (STAI) and Fear Avoidance (KPI-ASAS)	(r= -.60) (r=51); P<0.05 (r= .39) (r=37); P<0.05	Not reported	Predictive
	Strong correlation between pain intensity (VAS) and Health Related Quality (H)RQOL of life and depression (DBI). Moderate correlation with Trait Anxiety (STAI) and Fear Avoidance (KPI-ASAS)	(r= -.58) (r=53); P<0.05 (r= .36) (r=30); P<0.05		
Sherman et al,.2013	Reduced Disability (RMDQ) in 12 weeks stretching exercise (-2.00,95% CI= -3.37 to -0.72) is 28.3% mediated with self-efficacy score.	(-0.47, 95% CI=-1.13 to -0.02)	Yoga or Stretching or Self-care for 12 weeks	Mediation
Skidmore et al,.2015	Higher level of self-efficacy and depression predict a higher score on the pain intensity level at discharge.	β = -0.368 CI 95% -5.04-1.45; P=0.001 β = 0.24 CI 95% -0.02-4.07; P=0.005		Predictive

Van Der Hulst et al,.2008	Higher depression score (SCL-90) on baseline was a predictor of poor improvement in disability scale and mental health sub scale of SF36.	(β = 0.17, P=0.07) (β = -0.42, P=0.18)	Multidisciplinary rehabilitation for 3 weeks	Predictive
Verkerk et al,.2015	Work participation is a prognostic factor of reduction of disability in 5 months	OR 1.34, 95% CI 0.93-1.92	Multidisciplinary rehabilitation for 8 weeks	Predictive
	Work participation is a prognostic factor of reduction of pain intensity in 5 months	OR 1.27, 95% CI 0.93-1.73		
Woby et al et al,.2004	Reduction in Fear Avoidance behaviour (FABQ-PT and W) is associated with reduction in disability level (RMDQ)	(β= 0.31; P<0.01) (β= 0.021, P<0.05)	Cognitive behavioural therapy delivered by PT	Predictive
Woby et al,.2007	Self-efficacy (CPSS-PF) mediates the relation between pain related fear (TSK) and disability (RMDQ)	(standardized β= -0.42; P<0.05)	Cognitive behavioural therapy delivered by PT	Mediation
	Self-efficacy (CPSS-PF) mediates the relation between pain related fear (TSK) and pain intensity (VAS)	(standardized β= -0.46; P<0.05)		
Woby et al,.2008	Decreases in fear of pain (TKS) and increases in Self-efficacy (CPSS-PF) are related with reduction in disability scale (RMDS)	(β= -0.20; P<0.05) ;(β= -0.27; P<0.05)	Cognitive behavioural therapy delivered by PT	Predictive
	Increase in Self-efficacy (CPSS-PF) is related to reduction in pain (VAS)	(β= -0.23; P<0.05)		

Page et al, 2015	SRarT Back score correlate with disability score (ODI) at 12 months follow up	(r= 0.22); P<0.05	Not reported	Predictive
	SRarT Back score correlate with numerical rating scale of pain (NRS) at 12 months follow up	(r= 0.34); P<0.01		
Costa et al, 2015	previous sick leave due to low back pain high disability levels at chronic presentation and greater perceived risk of persistent pain were significantly associated with delayed recovery.	likelihood ratio χ^{21}=4.9, (P=0.03), χ^{21}=20.1, (P<0.001), χ^{21}=10.0, (P=0.002)	Not reported	Predictive

2.3.1. Results of individual studies

In a prospective study of 96 CLBP patients, Anderson et al. (2012) studied the correlation of Patients' Global Impression of Change (PGIC) with pain and disability. Patients receiving physiotherapy were tested before and four weeks after the intervention. The study found a weak correlation between fear avoidance beliefs questionnaire (FABQ) scores and disability measures (RMDQ) ($r= 0.23$, $p<0.05$), and moderate correlation between PGIC and disability and pain intensity ($r= -0.51$, $p<0.05$), ($r= -0.46$, $p<0.05$) respectively.

In a longitudinal prospective study, Evans et al. (2010) studied predictors of short-term outcomes in CLBP after physiotherapy and yoga (n=53). They found that self-efficacy measured by Self-Efficacy Scale (SES) was a predictor of change in pain and disability after six months ($\beta= -0.56$; $P<0.01$), ($\beta= -0.21$; $P<0.05$) respectively.

Farin (2015) examined the association between catastrophising and pain and disability in 262 CLBP patients, with measurement taken at baseline and two weeks after discharge from in-patient multidisciplinary rehabilitation. It was considered that a high score in the pain catastrophing scale (PCS) had a clear link with high disability in the Oswestry Disability Index (ODI) at baseline ($r= 0.38$, $p<0.05$).

In another study by Farin et al. (2013) about the predictors of outcomes after in-patient multidisciplinary rehabilitation in (n=688) CLBP, the main psychosocial predictor of disability and pain after discharge was found to be a high score in the FABQ work scale ($r=1.42$; $P<.001$) ($r=2.15$; $P<.001$).

A recent paper conducted by Glattacker et al, (2018) examined the different psychosocial predictors of recovery from CLBP, using a sample of 214 patients who were going through in-patient multidisciplinary rehabilitation. Disability measured by RMDQ is correlated with the Fear Avoidance Belief Questionnaire, (FABQ) r= .504 (<.001), Pain Self-efficacy Questionnaire (PSEQ) r= .504 (<.001), Anxiety measured by Hospital Anxiety and Depression Scale (HADS) r= .347 (<.001) and catastrophising (PCS) r= .353 (<.001).

In another study by Grotle et al. (2006), the clinical course of fear avoidance beliefs in acute (n=123) and chronic (n=50) LBP patients was examined, as well as their relation to disability after a one year follow up. The findings suggest that, although the fear avoidance beliefs were associated with disability and pain after a one year follow up (β = 0.300, P=0.048), (β = 0.32, P=0.038), this association does not remain significant once the distress outcome measure (HSCL-25) is used in the analysis (β = 0.13, P=0.54), (β = 0.06, P=0.74). The study suggests that the (HSCL-25) outcome is a mediator in the relation between fear of pain, and disability and pain.

Grotle et al. (2010) investigated the prognostic factors for poor recovery in acute and chronic LBP using data from two large prospective studies conducted in the UK. They reported that being unemployed is a predictor of a high disability scale (RMDQ)in CLBP (Standardized β= 0.22; P<0.01). Furthermore, a high level of fear of pain (TSK), catastrophising and coping (CSQ24) and chronic pain grade scale (CPG) are prognostic indicators of higher disability (RMDS) (Standardized β= 0.08; P<0.01); (Standardized β= 0.11; P<0.01); (Standardized β= 0.02; P<0.01) respectively.

The predictive ability of the STarT Back tool in the CLBP cohort (n=290) was examined recently by Kendell et al (2018), The treatment delivered was multidisciplinary, including exercises and psychological therapy, with follow-ups occurring up until one year. The findings of this study suggest that high and medium psychological groups according to Start Back tool were at a 25% higher risk of not achieving a full recovery from pain, compared with the lower risk group, at RR=1.25 CI 95% (1.04-1.51) RR=1.26 CI 95% (1.03-1.52) respectively. With respect to the disability prediction, medium and high-risk groups are at more than a 100% risk of not being able to recover in the disability scale compared with the low risk group, at RR=2.30 CI 95% (1.28-4.10), RR=2.86 CI 95% (1.60-5.11) respectively.

In an attempt to identify the predictive factors for one-year outcomes following exercise and manipulation in 204 patients with CLBP in Finland, Niemistö et al. (2004) highlighted the importance of working days missed due to back pain as a predictor of recovery. The study suggested that the odd ratio of scoring low in RMDS when missing more than 25 working days per year is OR 4.19,95%CI 1.5-11.3.

In a secondary analysis of RCT, Rasmussen et al. (2012) investigated the predictors of clinical improvement in pain and disability outcome of (n=71) CLBP after a graded exercise intervention. It was found that the pre-intervention level of Self-Efficacy Scale (SES) (OR 9.8, CI 95% 2.1-45.5) and higher pre-intervention pain intensity (VAS> 5.3, OR 11.8, CI 95% 1.5-91.9) are predictive of disability measured by the Oswestry LBP disability scale (ODI) pain intensity.

Macedo et al. (2014) conducted a secondary analysis with a large Australian study investigating the effect of two different forms of exercise in CLBP patients and studied the predictors of recovery after treatment. They reported that the Lumbar Spine Instability Questionnaire (LSIQ) was the strongest predictor of improvement in the disability scale (RMDQ) OR= 2.72 (1.39, 4.06), P<.001. The Coping Strategies Questionnaire (CSQ) and low fear on (PASS-20) were also found to be predictive of change in disability (RMDQ) at (OR= 1.81 (0.47, 3.16), P=.008 OR= 1.5 (0.13, 2.85), P=.032) respectively.

In a longitudinal cohort study, Scholich et al. (2012) studied the relationship between multiple psychosocial factors and pain and disability in CLBP who received in-patient rehabilitation for 10 days (n=53). Disability results were measured with the Chronic Pain Grade (CPG). The outcomes showed a strong correlation with the measured health-related quality of life (HRQOL) and depression measured by back depression inventory (BDI) after 6 months (r= -.60) (r=51); P<0.05. The study also reported a moderate correlation with anxiety and fear of movement (r= .39) (r=37); P<0.05.

When contrasting the outcome measures above with pain intensity (VAS), the correlation patterns seen were analogous.

The mediator of improvement in pain and disability of CLBP patients undergoing stretching or yoga exercises (n=228) was examined by Sherman et al. (2013). The study emphasised the importance of self-efficacy as mediator of improvement in disability level and calculated Reduced Disability (RMDQ) over

12 weeks of stretching exercise (-2.00,95% CI= -3.37 to -0.72) is 28.3% mediated by the self-efficacy score (-0.47, 95% CI=-1.13 to -0.02).

Van Der Hulst et al. (2008) sought to identify the predictors of multidisciplinary treatment outcomes in CLBP after a 6 month follow up (n=163). The study suggested that a higher depression score (SCL-90) on the baseline was a predictor of poor improvement in the disability scale and mental health sub scale of SF36 (β = 0.17, P=0.07), (β = -0.42, P=0.18) respectively.

Verkerk et al. (2015) undertook a large cohort study of CLBP undergoing multidisciplinary treatment in the Netherlands (n=1,760), aiming to address the prognostic course of CLBP. This study underlined the value of work participation as a predictor of improvement in pain as well as disability, following 5 months of intervention (OR 1.27, 95% CI 0.93-1.73), (OR 1.34, 95% CI 0.93-1.92) respectively.

Woby et al. (2004) studied the role of patient adjustment to CLBP in relation to fear avoidance, catastrophising, and pain control. The 54-patient study showed that reductions in pain-related fear measured by the Fear Avoidance Belief Questionnaire (FABQ-PA) were significantly associated with reduced disability (β = 0.31; p<.05) but not to pain intensity. However, 31% of the participants dropped out before completing the physiotherapy intervention. The physiotherapy programme was a cognitive behavioural therapy (CBT) led by a physiotherapist and consisted of exercise, education, and goal setting. The programme involved weekly, 3.5-hour-long sessions over eight weeks. The exercise aspect focused on stretching and strengthening exercises for

increased range of motion and endurance. The education involved medical terms used to describe the back pain and physical and the psychological aims of the rehabilitation programme. During the goal setting part of the programme, behavioural goals in the short term were set as well as the long term, in line with the specific needs of each patient.

In a prospective cohort of 96 CLBP patients receiving CBT led by a physiotherapist, a study (Woby et al., 2007) showed the mediating role of self-efficacy between pain intensity and pain-related fear, which suggested that when functional self-efficacy is high, pain-related fear is not a predictor of high pain intensity ($\beta = 0.08$; $p < 0.01$). The reported dropout rate was 7%.

Woby et al. (2008) studied cognitive changes after a specific six-week physiotherapy programme called ‘Work back to life’. The programme aimed to reduce fear of movement and catastrophizing and to enhance self-efficacy by gradually exposing patients to activities that they perceived as harmful. The programme was similar to that described by Woby et al. (2004) with an additional focus on gradual exposure. In all, 137 CLBP patients completed the programme with a dropout rate of 17%. The study reported a correlation between functional ability measured by the RMDQ and fear of movement (TSK) ($\beta = -0.27$; $P<0.05$) and self-efficacy (CPSS-PF) ($\beta = -0.20$; $P<0.05$).

The association between clinical outcomes and STarT back tool was studies by Page et al. (2015) in a cohort study with 12 months follow-up (n=53). The study did not report the type of intervention the patients have received during the follow up period. Results from this study suggest a correlation between STarT

back scoring with disability score measured by ODI ($r=0.22$; $p<0.05$) and pain intensity ($r=0.33$; $p<0.01$).

The association between psychosocial factors and overall recovery from back pain was examined by Costa et al. (2015). The recovery confirmed if patient reported no pain or no disability related to back pain or return to work in their previous capacity. The type of intervention was not reported. Three factors identified to have a significant association with recovery from back pain were previous sick leave due to low back pain high disability levels at chronic presentation and greater perceived risk of persistent pain likelihood ratio $\chi21=4.9$, ($P=0.03$), $\chi21=20.1$, ($P<0.001$); $\chi21=10.0$, ($P=0.002$) respectively.

2.4. **Discussion**

The aim of this systematic review was to evaluate the evidence pertaining to the prognostic value of psychosocial factors in changes in pain and disability in cases of CBLP specifically for adult populations, who are currently undergoing treatment by physiotherapists.

There are a range of physiotherapy interventions which can be used to help alleviate back pain. However, the current study focused on NICE guideline recommended interventions exclusively. These interventions include exercise, self-management, education, manual therapy, psychological therapy, and a combination of psychological and physical therapy.

In this paper, the knowledge established by the earlier published systematic review of Wessels et al. (2006), which put forward the notion that functional coping and pain intensity are correlated with post treatment disability level, as

reported in six studies is built upon. On the one hand, Wessels et al. (2006) suggested that conclusions cannot be drawn from such a limited and heterogenic number of studies. On the other hand, in this systematic review, a number of psychosocial factors have been identified as being consistent predictors of change to the disability level after physiotherapy (non-surgical) interventions have been conducted.

This systematic review established that self-efficacy and fear avoidance belief had significant weight as predictors of change in disability, following physiotherapy interventions occurring in CLBP patient populations. These findings are in line with the results published in the work of Werlti et al. (2014) which relate to the moderating role of fear avoidance in treatment efficacy of sub-acute LBP patients and previously reported reviews (Geisser, 2003; Jackson, 2014; Linton,2000; Pincus, 2002; Pincus, 2006; Lakke, 2009; Ramond, 2011; Verkerk, 2012; Zale, 2013). In addition, these findings are supported by the FAM (Vlaeyen and Linton, 2000), which suggests that the presence of psychological factors such as fear of pain, catastrophising, and depression after experiencing pain may lead to fear of movement, inactivity, and further disability as a result. Furthermore, the correlation between fear avoidance and disability level was found to be mediated by two factors in two different studies, which were self-efficacy and depression. Once these factors were implemented in the analysis model, it was seen that the previously significant weight attached to fear avoidance belief was no longer present. However, it should be noted that formal mediation analysis and preferred study

design (Hill and Fritz, 2011) was not applied to one of the studies (Woby et al,.2004).

The results of this systematic review also highlight the influence of catastrophising, anxiety, depression and pain control when it comes to any change to the disability score after physiotherapy intervention was applied for CLBP.

Psychosocial factors can predict poor outcomes of treatment, and this is indeed a challenge for physiotherapists (Hill and Fritz, 2011). Psychosocial factors may play a key role in persisting symptoms, disability, and the development of chronic pain (Hill and Fritz, 2011). These types of factors are able to have an effect on the patient's reaction to the treatment they are given. This aspect of chronic back pain presents itself clinically in the form of psychological co-morbidities such as different forms of anxiety, depressive symptoms, and elevated somatic awareness.

The application of psychosocial treatment based on physiotherapy showed disappointing results when studied in RCTs (Smeets et al., 2006). Smeets et al. followed a total of 223 CLBP patients, who were randomly assigned into active physical therapy or cognitive-behavioural therapy groups, or a combination of both, or instead placed on a waiting list. It was seen that the treatments were universally more effective than the waiting list group, who received no treatment, with the active physical therapy group showing improvements not only in their level of pain catastrophising, but also in underlying depressive symptoms; a change that was only seen in this group.

Therefore, a screening tool was developed (STarT Back tool) to stratify patients according to the risk of psychosocial factors, in order to be assigned the most appropriate treatment for their LBP (Pincus et al., 2010). The RCT results for LBP showed an improvement in disability scores and a remarkable reduction in the cost of care (n =1,573) (Hill et al., 2011).

The STarT Back tool was found to be predictive for the disability level of CLBP after a one year follow up, however, its ability to predict pain after a 12-month period was not nearly as effective (Kendell et al,.2018). It should be noted that most of the included studies found that there was a poor correlation between psychosocial factors and pain outcomes in CLBP patients, with a varying follow up rate.

Although there are a number of psychosocial factors which have been identified as prognostic factors for patients with back pain in the literature, the current systematic review was only concerned with those factors pertaining to CLBP after physiotherapy intervention had been completed. It should be noted that identifying a correlation does not necessarily mean there is any causation (Maxwell & Cole 2007; Palinkas, 2014). Therefore, there is a need for mediation studies which are able to better explain the extent to which these psychosocial factors explain the changes noticed when it comes to pain and disability. In a systematic review involving 12 studies examining what mediates disability in back and neck pain patients by Lee et al (2015), it was identified that fear, self-efficacy and psychological distress were mediating towards the relationship between pain and disability. However, one limitation noted by the author is that more than the half of the included studies are cross-sectional

designs, which means that a definitive conclusion with regard to causality might not be drawn.

The physiotherapy intervention in the included studies was not always specified and sometimes formed part of a holistic multidisciplinary biopsychosocial rehabilitation. Therefore, it remains unclear which, if any, type of physiotherapy intervention or mode of delivery might have influenced the outcomes of interest positively or negatively. Improved reporting of physiotherapy interventions in research, for example, by using the TiDieR Checklist (Hoffmann et al., 2014) would assist in the selection of studies for review and interpretation. Developed by an international group of experts and stakeholders. the checklist aims to enhance the quality of description of the studies in order to be used by clinician and research. The TIDieR (Template for Intervention Description and Replication) checklist and guide were developed to improve the reporting of interventions in any evaluative study, including randomized trials. The checklist contains 12 items include: intervention name; theory behind the intervention; materials related to the intervention and the way to be accessed; detailed procedure description; who will provide the intervention; how it's going to be delivered; where it's going to be delivered; the exact time of delivery (number, duration, dose) if the sessions; tailoring; modifications; and finally, the fidelity and monitoring of the session. This would also help identify the physiotherapy interventions that might positively influence pain and disability outcomes after treatment (Yamato et al., 2016) and expedite the translation of research into better outcomes for people with CLBP.

From this systematic review, the identification of these factors will help this author's future research in determining which of these factors are effective treatment modifiers for people with CLBP undergoing physiotherapy in Saudi Arabia, which will therefore help clinicians in choosing treatment strategies to improve clinical outcomes. As discussed in (chapter one) multidisciplinary treatment cannot be offered to patients who are at the primary care level, and therefore an effective solution to this involves the psychologically-informed practice in which clinicians are addressing the pain related activity limitations noticed, such as fear and anxiety (Chehade, 2016; Cedraschi, 2018).

The finding of this systematic review endorses fear avoidance model elements to be predictive of change in pain and disability outcomes in physiotherapy treated CLBP will advocate FAM to be a theoretical model for the topic guide of the qualitative interview in the next chapter (chapter three).

Finally, it should be noted that several quality assessment tools have been used to evaluate observational studies. However, these tools lack validity and reliability (Shamliyan et al., 2010). Therefore, further research is needed to develop a standardised and validated quality assessment tool for observational studies.

2.5. **Limitations**

The exclusion of studies which were not reported in English might mean that this review overlooks certain important contributions to the literature. For example, previous reviews by Wessels et al. (2006) have included both English and German language reported studies.

2.6. **Conclusion**

This systematic review has extended the knowledge available regarding the psychosocial factors that associated with pain and disability in CLBP following non-surgical treatment. The fact that the studies consistently found measures of psychosocial factors including fear of movement, self-efficacy, catastrophising and depression to predict disability outcomes irrespective of the type of physiotherapy suggests that these factors should be addressed in future physiotherapy screening of CLBP. Further research is needed to understand the extent to which these factors explain the changes seen in pain and disability in CLBP patients.

Chapter Three

Psychosocial Consequences of Diagnosing Non-Specific Low Back Pain Patients Radiologically in Saudi Arabia

Summary

This chapter explores the experiences of people with LBP after receiving an MRI diagnosis. Furthermore, it explores the experiences of healthcare professionals (physiotherapists and spinal surgeons) in relation to the management of NS-CLBP patients in Saudi Arabia. One-to-one interviews were conducted with 11 patients, 6 physiotherapists, and 6 spinal surgeons. The interviews were digitally recorded and transcribed verbatim. The transcribed data were analysed using framework analysis.

Synthesis of the data obtained from the three different groups revealed four key themes: management of NS-CLBP in Saudi Arabia, patient education, the impact of pain on people with NS-CLBP, and MRI use in people with NS-CLBP. This study provides an insight into the experience of living with NS-CLBP from the perspective of three different groups. It highlights the difference in expectations between healthcare providers and patients on how NS-CLBP should be managed and the lack of coordination between primary and secondary healthcare services. Although patients seek imaging to confirm NS-CLBP, they react to the results negatively. In accordance with the fear avoidance model, participants reported fear avoidance behaviours and anxiety after MRI. This affected their participation in activities of daily life. In conclusion, this study showed that the psychosocial consequences of diagnosing by MRI are fear avoidance and anxiety. The current biomedical education given to these patients may promote these consequences.

3.1. Background

CLBP is a complex biopsychosocial problem. It has affected society in a variety of ways, mainly through healthcare usage and associated costs (Gore, 2012; Depont, 2010; Stewart, 2015). Despite the increasing awareness of clinicians and understanding of researchers, the cost of care is still increasing, and the inefficiency of the oft-used MRI has led to complications with treating CLBP.

MRI is a commonly used diagnostic tool, but it is arguably over used (Espeland and Baerheim, 2003). One problem arising from the use of MRI as a diagnostic tool is that of high false-positives (Jarvik and Deyo, 2002; Jarvik, 2005; Berg, 2013). In one study, 52% of an asymptomatic population were found to have disc bulges and 27%, disc protrusions (McCullough et al., 2012). These abnormalities did not predict LBP after a follow-up period of seven years (Modic et al., 2005). In another trial, MRI revealed no abnormalities in 50% of the people with LBP (Boden et al., 1990). As a consequence, imaging for CLBP is discouraged by international clinical guidelines (Koes et al., 2010).

Despite the fact that MRI diagnosis is associated with high false-positive findings, MRI scans could negatively affect people with CLBP. McCullough et al. (2012), in a retrospective study of 231 CLBP patients who had undergone MRI scanning, reported higher consumption of narcotics in the MRI group than in the control group. In another study, Kendrick et al. (2001) reported an increased number of doctor visits in the MRI group as compared to the control group. Webster et al. (2013) found that high work absenteeism was associated with expedited MRI imaging for CLBP patients.

A growing body of literature has investigated the experience of NS-CLBP patients who receive an imaging diagnosis (Espeland and Baerheim,2011;Serbic and Pincus, 2014; Bunzli, 2015; Franz, 2015 Tousignant-Laflamme ,2017). Many studies find that patients may experience feelings of relief when receiving a diagnosis, even if the diagnosis does not in fact explain their pain. For example, Serbic & Pincus explored the impact of diagnostic labelling on self-management and pain-related guilt experiences. Using a grounded theory approach, 20 patients with CLBP seeking treatment from a pain clinic or an osteopathy clinic in UK were interviewed. The study revealed that while patients with CLBP experienced greater relief after an MRI they also experienced increased feelings of guilt regarding their lack of improvement (Serbic and Pincus, 2014). Looking at the highly disabled CLBP prospective about diagnostic certainty Bunzil et al.,2015 reported that although patients seek for justifiable reason for their constant pain, they tend to misinterpret the meaning of the diagnosis, one patient stated that being diagnosed with degeneration in spine is “petrifying”. Recently Traeger et al.,2018 published a study protocol for systematic review synthesis the qualitative studies that explored patient, healthcare and public beliefs about back pain.

As discussed in chapter two, psychosocial factors have been implicated in patients’ recovery from back pain, e.g. fear, depression, catastrophizing, and anxiety (Linton, 2000; Beneciuk , 2013; George and Beneciuk, 2015). Furthermore, the views of healthcare providers’ can also influence patients’

beliefs and ultimately the decisions they make (Linton et al., 2002). Therefore, such beliefs may contribute to an increase in patients' avoidance behaviour.

To date, little attention has been given to understanding the psychosocial consequences of MRI imaging for CLBP. Therefore, the aim of this qualitative study was to explore the associated psychosocial consequences of imaging in NSCLBP patients in Saudi Arabia and to explore the pathways of care for NS-CLBP in Saudi Arabian healthcare.

3.2. Method

This study sought to explore the experiences and opinions of three important groups – patients, physiotherapists and doctors – about the psychosocial consequences of diagnosing CLBP patients by magnetic resonance imaging (MRI) scan. Therefore, a qualitative approach utilising a framework analysis was employed (Braun and Clarke, 2006). The qualitative research approach puts an emphasis on the systematic collection of information from textual materials as well as organisation and analysis of the information obtained from data collection techniques, such as observation, in order to explain or offer insights into social phenomena within a natural context as experienced and perceived by people (Malterud, 2001). According to Tobin and Begley (2004), qualitative research is usually viewed as a naturalistic standard, which is explained by Charmaz (2004) as a description of experiences as lived by people. One of the primary characteristics of this technique is a reliance on contextualisation as a premise upon which understanding can be hinged. Such an approach also explains where the data came from in order to explicate the experiences of the participants and the associated theoretical frameworks

justifying them, while also understanding that pluralism offers limited generalisability because of the likelihood that the research settings are unique. Finally, there are constraints related to the researcher's knowledge, especially on what can be understood as well as discoveries that can be communicated more convincingly and precisely (Sutton, 1993). By way of contrast, qualitative research answers questions of what, how and why, while quantitative research answers questions related to how many (Ritchie et al., 2013).

Marrow (2007) suggested that a qualitative research approach utilises inductive procedures since it proceeds by way of research questions instead of assumptions or hypothesis. The inductive process follows a bottom-up method to gain knowledge by drawing on observation of the world in order to build theories and hypotheses. Conversely, a deductive approach is a top-down method that is premised on the testing of hypotheses or theories against observations with a view of either confirming or refuting those (Ritchie et al., 2013). However, there is a likelihood that induction and deduction techniques do not help in answering the qualitative research questions as well as do analysis and interpretations, which may be affected by known facts or literature examples in the particular area of study (Ritchie et al., 2013). Moreover, Ritchie et al. (2013) further asserted that the hypotheses or theories forming the initial quantitative inquiry were generated by way of induction. This is a view supported by Gale et al. (2013) in their argument that research standards can be achieved by utilising both inductive and deductive procedures.

A study conducted by using a qualitative research approach achieves validity through such elements as clinical significance, triangulation of methods and

findings, attention to destructive cases, validation of responses, detailed analysis of data obtained from various data collection methods and reflexivity as well as transferability within specific sampling limits (Malterud, 2001).

3.2.1. Sampling and data collection

A non-probability convenience sampling method, which is advisable for qualitative exploration of complex phenomena (Small, 2009), was adopted in this study. This method of sampling was considered practical, given the limited time available for the research and the willingness of the eligible participants to be recruited for this research. This approach provides the researcher a chance to include individuals of specific interest to the study (Creswell, 2013). In a qualitative research, besides clearly outlining the sampling process, it is necessary to provide comprehensive information about the sample. Contextual information that relates to demographics and research setting helps enhance transferability. Transferability describes whether the research findings could be applied in other settings, which the readers can understand, using the included background information (Malterud, 2001). Considering the tendency of recruiting a small sample in qualitative research and the objective not to generalise the findings, the contextual factors remain critical to the reader, based on their relevance to the setting (Bryman, 2014).

3.2.2. Inclusion criteria

Patient participants: Males and females aged 18–65 years who experienced CLBP with no clear medical diagnosis (e.g. malignancy, fracture, infection,

spinal stenosis, spondylolisthesis, or inflammatory disease), had undergone an MRI scan, and had received a report for LBP in the previous month were included. LBP was considered chronic if the pain had persisted for more than 3 months.

Doctor participants: Doctors in direct contact with NS-LBP patients and with the authority to refer patients for MRI were recruited as clinician participants.

Physiotherapist participants: Outpatient physiotherapists with a primary interest in LBP management were included.

3.2.3. Exclusion criteria

Patients who had undergone pain-relieving procedures (i.e. injection or denervation) in the previous 3 months, who had documented evidence of neurological impairment, and women who were pregnant or less than six months postpartum were excluded from the study.

3.2.4. Recruitment

Recruitment of patient participants: The physiotherapy team leader identified patients meeting the inclusion criteria from their physiotherapy referral and invited them to participate in the first physiotherapy session. An information sheet (Appendix 1) detailing the objective and methods of the study, how their information would be utilised, and guarantee of participant confidentiality was given to each patient. The author (A.A.) was available in person at all times to answer any questions and concerns the candidates might have had about the study. Signed consent (Appendix 2) was required from each patient to be enrolled in the study. Then, sociodemographic data such as age, gender,

nationality, marital status, education, and medical history were taken from each participant and the time and date of the interview were agreed upon. The interview took place in the physiotherapy department's conference room.

Recruitment of clinician participants: Physiotherapists and doctors meeting the inclusion criteria were identified by their team leads and invited by e-mail to participate in the study. Attached to the email was an information sheet (Appendix 3) detailing the objective and methods of the study, how their information would be utilised, and guarantee of participant confidentiality. After agreeing to participate, an interview was scheduled by the author (A.A.) at the clinician's preferred location at an agreed time.

3.2.5. Interviews

The researcher preferred using a semi-structured methodology in this study. The use of semi-structured interviews is suitable for the data collection, since the study focuses on exploring the individual perspectives, as well as the experience of LBP, which the semi-structured interview tool can effectively manage (Offredy and Vickers, 2010). The use of semi-structured interviews allows an individual to schedule the interview, according to the area that the study intends to cover. However, the tool provides flexibility for pursuing any new topic of interest that might emerge (Bryman, 2014). Using a semi-structured interview provides the researcher with great control on the area to focus on, ensuring that the study aligns with the objective of the qualitative research, which is gaining comprehensive information from the participants. A semi-structured interview presents a chance to consider new information, which

may not have been identified at the beginning of the study (Offredy and Vickers, 2010). As documented by Barbour (2014), there is a need to find a balance within the researcher's topic guide and the opportunity for respondents to share their views. In this sense, a semi-structured interview is well-suited for fulfilling this aspect of the study. Indeed, a semi-structured interview presents a chance for a deeper understanding of the social phenomena, which only could be realised where the quantitative approach such as questionnaires is applied (Silverman, 2010). Gill et al. (2008) agree that a semi-structured interview is significant where the researcher wants detailed information from the respondents.

A semi-structured interview schedule was formulated for all groups utilising two theoretical models (Appendix 6) and the results of the systematic review study (Chapter two). Given its association with LBP, Vlaeyen and Linton's (2000) fear avoidance belief model was adopted. In addition, Loisel's (2002) disability prevention model, as a more comprehensive paradigm, was also used as the former model overlooks the circumstances and dynamics of pain experience. The work environment, healthcare infrastructure, and individual experience were the three aspects addressed by the semi-structured interview questions. This two-model approach allowed the semi-structured interview strategy to be widened to consider consequences at a personal (patient), healthcare and societal (workplace and economic) level.

All interviews were undertaken in person by a single interviewer (A.A.) to maximise the interviewer's familiarity with the data. The interviews lasted

approximately (15–40) minutes for patient participants and (20-30) minutes for healthcare participants.

3.2.6. Ethical considerations

Ethical approval was obtained from the Research Ethics Committee of the Faculty of Medicine and Health Science at the University of Nottingham (Ethics Reference Number OVS 18082016) (Appendix 7) and from King Fahad Medical City to conduct the study in November 2016 (IRB: H-01-R-R-012) (Appendix 8). All participants signed a consent form (Appendix 5) prior to the interview.

3.2.7. Data analysis

Each interview was digitally recorded and transcribed verbatim by the author (A.A.). Data analysis was guided by the framework approach. Ritchie and Spencer (1994) introduced the framework approach, which works effectively with qualitative data analysis. According to Gale et al. (2013), framework analysis initially was applied to social policy research. However, in the recent past, the tool has been increasingly used in healthcare research. The framework is largely used where predefined topics exist or when informing the research themes. For this reason, the analysis is done deductively. Nonetheless, the approach provides flexibility in allowing the themes to be derived from the data (Srivastava and Thomson, 2009; Mays and Pope, 2000). Ideally, the pre-determined areas will not of necessity restrict the analysis, and it is important that the research provides the flexibility for new ideas to emerge from the analysed data (Srivastava and Thomson, 2009). Indeed, the analysis is important for the research, as it states the pre-defined objective and decides

the issues to explore. Nonetheless, it provides recognition to new topics that may emerge from the available data, which is essential to the research project, as phases inform one another. The method gives the chance to adopt a combined approach, when it comes to exploring the pre-defined aims or themes while, at the same time, allowing aspects that were not considered initially to be considered (Gale et al., 2013).

Ritche, Spenser and O'Connor (2003) argue that the framework analysis encompasses a matrix-based method that provides assistance in the organising, as well as synthesising of qualitative data. The framework typically has five important steps (Mays and Pope, 2000; Ritchie and Spencer, 2002). The five stages are comprehensively described in the findings of Ritchie and Spencer (2002). The first stage is described as familiarisation, where the researcher is immersed in the data and becomes aware of the transcripts, including notes of ideas and themes. The second stage entails identification of the thematic framework, which consists of constructing a thematic framework using the researcher's pre-determined themes or issues, as well as topics that emerge from the data. This is important in facilitating data sorting, which forms important research themes. Subsequently, thematic data are applied to the collected data, using the indexing approach. Here, the data found are annotated in line with corresponding references to the thematic framework. The process facilitates the presentation of summarised data into a whole chart. Lastly, mapping and interpretation entails the use of charts that are created to help in data interpretation, where data are viewed as a whole, and there is a

need to look for patterns and explanation in the data, for developing a final representation (Ritchie and Spencer, 2002).

Despite the fact that the framework is described as a distinct stage, it will require the researcher to move between stages, as he or she analyses the research data (Ritchie and Spencer, 2002). In this research, the framework offers guidance to the qualitative analysis, and it will not necessarily be stringent (Spencer et al., 2014). This gives room for critical thinking and creativity (Ritchie and Spencer, 2002). Nonetheless, it is important to follow the systematic process, ensuring that all the identified stages are accessible to researchers, as is well documented. This gives analysts a chance to make connections and go back to previous ideas, as well as develop final themes (Ritchie and Spencer, 2002). This framework is considered credible since it is based on research data (May, 2001; Ritchie and Spencer, 2002). Notably, the framework is designed to ensure that a systematic process is followed in the analysis and gives a chance for easy access to original data (Ritchie and Spencer, 2002). The fact that the framework has a number of stages confers credibility upon it, since it clearly provides an audit of the data analysis steps and the processing of final data in the presentation (Gale et al., 2013). The framework enables the management of substantial amounts of data (Bowling and Ebrahim, 2005). The study uses phases that are interdependent, making this approach suitable. As mentioned earlier, the framework method presents an audit trail of data analysis, from the transcript to the final themes. Ideally, the use of the framework method will harness conformability of the findings, as it gives the reader a chance to know the data analysis process followed

(Shenton, 2004). The framework method has previously been used in qualitative studies, outlining the experience of chronic LBP (Cooper et al., 2009; May, 2007). Therefore, in the current research, the framework is important, as it encouraged the exploration of topics that might not have been considered initially (Ritchie and Spencer, 2002). The approach is robust since it provides a clear audit trail from the collected raw data to the final theme, providing a comprehensive understanding of the data and presenting a pre-defined aim to be explored, and, at the same time, providing the flexibility to discuss emerging topics from the data (Gale, 2013; Ritchie and Spencer, 2002).

3.2.8. Quality and rigor

The use of triangulation method (Guba and Lincoln.,1994; Hussain,2009; Torrance, 2012) was employed in this present study, to ensure validity is guaranteed while eliminating researcher bias and addressing matters like the absence of reproducibility and generalisability. Different possibilities of considering the same events as a way of adding credibility and in concluding on what came out from the interviews were explored by this method. The researchers made a comparison between several patients' and clinicians' perspectives concerning psychosocial consequences of diagnosing CLBP by MRI and in exploring the similarities and differences existing between opinions and experiences while offering reasonable explanations for the emergent phenomena and adding credibility to the findings. It should be noted that

respondent validation (Torrance, 2012) was not possible due to the limited time frame and poor postal service in Saudi Arabia.

The rigour of the study was assessed based on three criteria (Guba and Lincoln.,1994; Yardley,2000; Anney,2014)

Credibility (i.e. internal validity)

This study made provision for the promotion of confidence accurately recorded, and information researchers attempted to explore. Developing affinity between the interviewer and participants was accomplished through preliminary informal talks that makes it possible for extended engagement between the researcher and the participants to take place while guaranteeing that all parties had enough comprehension of the activities taking place and putting in place the relationships of trust.

The use of maximum variation sampling in recruiting participants was one other implemented provision in guaranteeing credibility. In spite of random sampling implementation by this study, the physiotherapy and orthopaedic department made this list available for the negation of possible researcher bias in the selection of participants. Furthermore, there was legislation of strategies guaranteeing honesty among participants. People with CLBP and clinicians, for example, were provided with the option of refusing participation in the study as a way of guaranteeing the data collection sessions involving people genuinely willing to participate and make offer for data freely. The participants were given encouragement to be frank right from the start of every interview or discourse

and making it clear in every instance that no right or wrong ‘answers’ were in play.

Transferability (i.e. external validity)

Since of the precise nature of this qualitative study on a small number of participants, it is possible for this to be challenging in linking the findings and conclusions with other conditions or populations. In addressing this challenge, the collection and recording of this information were made in detail regarding the process in the entire study, in which data collection methods used and the participants’ characteristics, as well as the number and length of data gathering session and the time period for the data gathering.

Dependability (i.e. reliability)

It should be noted that the use of clear research design may further guarantee reliability in order to have the study repeated within a similar context and the same participants in order to attain similar results. The creation of a detailed research design was made, and, of which, the data gathering operational details that extensively described work performed in the field.

3.3. Results

3.3.1. Study participants

A total of 23 study participants agreed to participate in this study, and all of them attended the scheduled one-to-one interviews. The study participants comprised 11 patients with LBP who had undergone an MRI scan, six physiotherapists, and six doctors (i.e. spinal surgeons).

The patient participants were six men and five women, whose ages ranged from 27 years to 61 years, with an average age of 37.6 years (SD = 12 years); all of them had experienced CLBP. Heterogeneity was observed in the duration of the CLBP experienced by the participants, ranging from 6 years to 25 years. Five patients reported having CLBP for 6 years, 2 for 10 years, and 1 for 8 years. The longest duration of CLBP experienced by a patient was 25 years at the time that the interview was conducted (See Table 5 for characteristics of patient participants). Three patient participants were housewives, while the rest were in full-time employment.

The average intensity of reported CLBP ranged from 3 to 8 as measured on the visual analogue scale (where zero = no pain and 10 = extreme pain). However, two patients reported pain intensities of 9 and 10, and, interestingly, these were the patients who had experienced CLBP for a duration of 20 and 25 years, respectively. The level of disability associated with CLBP is measured with a non-standardised measure of numerical scoring ranging from zero to ten. The average disability score ranged from 1 through 9, with one patient, who had experienced CLBP for 10 years, reporting a disability score of 0 (0 being no disability).

Table 5 Characteristics of patient participants

Participant code	Age (years)	Gender	Level of Education	Occupation	Duration of LBP (years)	Avg. pain intensity	Avg. Disability
PT.1	36	Female	High	Housewife	10	5	3
PT.2	34	Female	University	Employed full-time	6	3	1

PT.3	32	Male	University	Employed full-time	6	4	4
PT.4	57	Female	Primary	Housewife	20	9	9
PT.5	61	Female	Secondary	Housewife	25	10	2
PT.6	30	Male	College	Employed full-time	8	5	7
PT.7	48	Male	High	Employed full-time	14	8	7
PT.8	28	Female	University	Employed full-time	6	6	6
PT.9	27	Male	University	Employed full-time	6	5	6
PT.10	31	Male	University	Employed full-time	10	5	0
PT.11	30	Male	University	Employed full-time	6	8	7

Table 6 presents the characteristics of the physiotherapist participants in this study. The group (n = 6) included two male and four female physiotherapists, with an age range of 28–38 years. Two participants held a postgraduate diploma and the rest had a master's degree in physiotherapy. Participants were grouped into physiotherapist Band 1 (bachelor's or master's degree with less than 2 years' experience, n = 1) and physiotherapist Band 2 (more than 2 years' experience with post qualification master's degree, n = 2), while the remainder were senior physiotherapists (post-graduate degree with at least 5 years' experience, n = 3), with 5–11 years' experience.

Table 6 Characteristics of physiotherapist participants

Participant code	Age (year)s	Gender	Education	Occupation	Post qualification experience (years)
Phys.1	32	Female	Postgraduate Diploma	Senior Physiotherapist	7
Phys.2	38	Female	Master's Degree	Senior Physiotherapist	10
Phys.3	35	Male	Master's Degree	Senior Physiotherapist	11
Phys.4	28	Female	Master's Degree	Physiotherapist 1	6
Phys.5	28	Female	Postgraduate Diploma	Physiotherapist 2	5
Phys.6	34	Male	Master's Degree	Physiotherapist 1	9

Six doctors participated in this study (See Table 7 for characteristics of doctor participants). All were men and aged from 30 to 50 years, with the average length of post qualification experience ranging from 4 to 12 years in practice. Doctor participants were resident doctors, consultants, or assistant consultants.

Table 7 Characteristics of doctor participants

Participant code	Age (years)	Gender	Education	Occupation	Experience (years)
Doc.1	30	Male	University Degree	Resident	4

Doc.2	50	Male	Doctorate Degree	Consultant	12
Doc.3	40	Male	Master's Degree	Assistant Consultant	10
Doc.4	38	Male	University Degree	Consultant	12
Doc.5	30	Male	University Degree	Assistant Consultant	6
Doc.6	31	Male	University Degree	Assistant Consultant	6

3.3.2. Themes and key findings

The findings from the qualitative analysis revealed four key themes, which appeared to be related to the psychosocial consequences of MRI. These included management of CLBP in Saudi Arabia, patient education, MRI utilisation by people with CLBP, and effects of pain on people with CLBP. Table 8 shows the sub-themes which were identified from these key themes.

Table 8 Themes and sub-themes identified from interviews

1. Management of CLBP in Saudi Arabia
1.1 Availability of clinical guidelines
1.2 Physiotherapy service as first contact
1.3 The healthcare system
1.3.1 Lack of trust in primary healthcare
2. MRI utilisation for people with CLBP

	2.1 Psychosocial effects of MRI diagnosis
	2.1.1 Fear of diagnosis
	2.1.2 Anxiety after MRI diagnosis
	2.2 Conflict in diagnosis
	2.3 MRI uses in NS-CPBP
	2.3.1 patients' urgency for MRI
	2.3.2 Need for repeated MRI
	2.4.1 Over-utilisation of MRI
	2.4.2 MRI's effect on patient management
3. Patient Education	
	3.1 Biomedical education
	3.2 Biopsychosocial education
	3.3 Reassurance
4. Effects of pain on people with CLBP	
	4.1 Psychological effects of pain
	4.1.1 Social Impact
	4.1.2 Psychological impact
	4.2 Effects on work

After interviewing all participants from the three groups, one prominent theme that emerged from the data was related to the healthcare system in Saudi Arabia, specifically the management of CLBP.

3.3.2.1. Management of CLBP in Saudi Arabia

The availability of local evidence-based clinical guidelines and protocols, considered vital to the provision of good quality of service, was identified as lacking by both doctors and physiotherapists. Furthermore, all three groups of

participants voiced concerns around the management of LBP in the Saudi Arabian healthcare system. In particular, the concerns were related to the lack of resources and doctors and a low level of trust in the primary healthcare service.

Availability of clinical guidelines

The majority of physiotherapists and doctors were in agreement regarding the convenience of international clinical guidelines for managing LBP.

'Although it is good to follow the guidelines to assure a good quality outcome, but I honestly don't'. Phys.4.

'Unfortunately, we don't have one (clinical guidelines). I think it could ensure the quality of the services'. Doctor.3.

Clinical guidelines do not currently exist in Saudi Arabia nor is there an internationally adapted version available.

'We do not have clinical guidelines for chronic low back pain, and we are thinking of adapting international clinical guidelines'. Doct.5.

Instead, some of the physiotherapist participants acknowledged that in times of uncertainty, guidelines would sometimes be referred to.

'I use it (international clinical guidelines) as a reference when I am not sure about something'. Phys.1.

Physiotherapy as first treatment

Interestingly, the interviews also identified the strong emphasis placed by many patients on the importance of early physiotherapy treatment in the care

pathway. Many of the patients believed that they would experience improvement through physiotherapy alone without the need for medication and/or MRI scans.

'We want to have physiotherapy from the beginning. Some patients could improve with physiotherapy alone'. PT.8.

'Physiotherapy should be our first contact to decrease the need for medication'. PT.2.

Early physiotherapy intervention through primary care services was also highlighted by both physiotherapists and doctors as critical for patients.

'Physical therapy and primary healthcare providers are very important cornerstones in the treatment of the chronic back pain'. Doct.4.

Moreover, most of the doctor participants claimed that the majority of the people they saw could be treated by the GP (family doctor) and physiotherapist.

'70% of the cases that we see here could be treated by family doctors and physiotherapy'. Doct.4.

Several physiotherapist participants added that early physiotherapy intervention could be beneficial in reducing the need for further investigation.

'If physiotherapy was used as a first contact in these cases, we would not need MRI diagnosis for most of the cases'. Phys.1.

The healthcare system in Saudi Arabia

Both physiotherapists and doctors raised concerns surrounding the management of CLBP in the Saudi Arabian healthcare system. In particular, doctors voiced concerns surrounding the cases referred to secondary-level services and questioned the validity of their referral.

'The way patients get referred, the type of patients to be referred, and the validity of their medical reports are obstacles in improving care to the patients in secondary hospitals'. Doct.4.

These referrals might be the result of the lack of services at primary care levels.

'They (the patients) have an excuse because primary level hospitals usually lack spinal surgeons'. Doct.4.

In their view, this problem is a mismatch of priorities, with too much emphasis on secondary hospital care and too little on primary care.

'Coordination between the services is not satisfactory. We need a lot of work to have this functioning. If we could reach a good level of coordination between healthcare providers, we would decrease costs and time'. Doct.4.

The consequence of this imbalance is an unnecessarily increased burden on secondary care staff and services and longer patient waiting times. Several patient participants highlighted that high patient loads and long waiting times were the two primary problems within secondary care.

'After I went back to my GP with no improvement, they sent me to the spine clinic and that took 6 months. The first time I saw them they requested an MRI. I could have had this scan from the beginning'. PT.1.

Lack of trust in primary care services

Unfortunately, it appeared that the lack of coordination within the healthcare service may relate to a lower level of trust of primary care service by patients. However, doctor and physiotherapist participants related that mistrust to a general deficiency in healthcare resources, including doctors, and available services (rehabilitation and diagnostic), which was identified as a primary obstacle to delivering adequate primary healthcare.

'People have more trust in secondary level hospitals. For a period, the primary care had a lack of resources; therefore, people have this idea of distrust'. Doct.3.

'We have a lack of primary care centres and staff. We need time to build the community trust in these centres and the peripheral hospitals. People outside Riyadh also don't trust their centres'. Physio.4.

3.3.2.2. MRI for people with CLBP

MRI is an essential diagnostic procedure to identify potential pathology. The use of such a diagnostic tool in relation to CLBP repeatedly emerged in the interviews.

Psychosocial effects of MRI diagnosis

Physiotherapists recognised that patients adhere to their MRI diagnosis and often relate their symptoms to their medical imaging report.

'When you ask the patient, "what happened to your back?", they will tell you the result of the MRI - they don't describe the symptoms'. Phys.2.

Fear of diagnosis

Following a diagnosis from MRI scanning, patients voiced the impact of the MRI diagnosis on their movement and work.

'Before I got diagnosed with disc prolapse it was OK, but now I take care with movement and work. What I used to do for 3 hours I now tend to do only for 30 minutes and then leave the rest'. PT.5.

Additionally, some patients appear to have been surprised with the diagnostic term 'disc prolapse'.

'I was not expecting my diagnosis to be a disc prolapse! I thought I pulled a muscle or something, but not in my spine'. PT.9.

Many physiotherapists are aware of patients' misconceptions with respect to their MRI diagnosis and the consequences of such misconceptions. One therapist suggest that this issue can be solved with proper education.

'Patients have wrong beliefs about their diagnosis. A lot of them exhibit fear avoidance, which can only be broken by education'. Phys.3.

'CLBP Patients always expressing fear from their MRI diagnosis. All what they think of is the result. They don't express their symptoms'. Phys.1.

Anxiety after MRI diagnosis

The use of MRI scanning was also shown to trigger anxiety in many of the patient participants.

'This diagnosis made me nervous. Yes, nervous. When I lie on my bed I think a lot about it and it starts to hurt again'. PT.8.

As a result of increased fear after the diagnosis, self-education about back pain was highlighted by one patient respondent.

'After hearing about my diagnosis, I started to be anxious. I read a lot about my symptoms and suggested exercises. Now I anticipate pain before any movement. I can't sit comfortably. I need a comfortable chair'. PT.10.

Conflict of diagnosis

Some patients described how they received conflicting messages and diagnoses from doctors. One patient explained his experience of having three different diagnoses and three different treatment plans.

'A private hospital told me, "You have a slipped disc; your disc is out of place. If it continues like this, we'll have to perform surgery". Another hospital said, "You have nothing wrong and everything is normal". The third hospital told me, "It is a disc prolapse that's caused some deformity in your spine". I did not understand my diagnoses'. PT.7.

In the example above, the conflicting information might be the result of dissatisfaction with the original diagnosis. This conflicting information appeared to lead to a heightened level of confusion and pain, as one patient highlighted below.

'From the beginning, the diagnosis should be clear. If you receive different diagnoses from every doctor, you lose motivation to improve and rely more on pain killers'. PT.8.

MRI use in NS-CLBP

A high demand for MRI scanning by patients with NS-CLBP was reported by healthcare practitioners, as these patients are keen to identify any changes to their condition over time, compared with their original scan. However, the healthcare practitioners claimed rarely to alter their original clinical exam decision, despite further scans.

Patients' demand for MRI scanning

A high demand for MRI scanning by patients with CLBP was reported by several of the doctor participants and was largely related to the credibility of the diagnosis in absence of MRI.

'We face pressure from patients for more advanced imaging. If they have not had an MRI, they will doubt your clinical diagnosis'. Doct.2.

Furthermore, one patient participant highlighted that the identification of an objective explanation of the source of pain by MRI can be a relief to the patient.

'I feel relieved after knowing what the problem and the source of pain is. I didn't know all that before the MRI'. PT.1.

Need for repeated MRI scanning

However, patients did not only initially request MRI scans to confirm their diagnosis but also requested subsequent scans at a later date, to monitor changes in their condition. The doctors believed that the perspective of patients regarding the use of MRI scans could be changed through relevant education.

'When I send patients for MRI, they come for follow-up after a year or so and they ask for another one. When you explain to them that nothing will change and it's a degenerative process, they are usually convinced'. Doct.4.

Doctors found that patients were attached to their MRI diagnosis and, as identified earlier in relation to conflict, patients were not advised to seek a second (or third) opinion from a different hospital or doctor if they were not content with the first diagnosis.

'The issue with the patients sometimes is they insist we do an MRI or they come and request it, or they ask us to do an MRI for them to see how quickly the condition is progressing or what the extent of the problem is'. Doct.6.

Effect of MRI on patient management

With relation to NS-CLBP, healthcare practitioners claimed rarely to amend their clinical decision after MRI scan results, therefore further reducing the value of this assessment tool.

'Very rarely the MRI will affect the treatment decision. Usually we don't depend on the MRI'. Doct.5.

'I mostly depend on the patient's clinical symptoms. I don't use the MRI report to guide my physiotherapy'. Physio5.

Over-utilisation of MRI

The findings suggest that many patients are referred for MRI scanning by their doctor, without first undergoing a simple clinical examination or having their prior history taken. One physiotherapist highlighted the fact that all patients undergo MRI scanning prior to the clinical exam, purely to identify whether or not a problem is indicated.

'Generally, most patients are sent for MRI without clinical examination and history taking, which could filter out patients who don't need an MRI'. Phys.3.

Similarly, several doctors agreed that MRI scanning was requested with no plausible indication. However, some doctors reported requesting MRI scanning only when there was a clear indication for it and relying otherwise on their clinical experience.

'Some doctors really over-utilise MRIs. They do an MRI for any chronic back pain, for any symptoms. They frequently do an MRI without real indications. Other surgeons and doctors are more specific. They don't do MRIs unless indicated'. Doct.3.

3.3.2.3. Patient education

Although patient education is emphasised within most international CLBP management guidelines, the content of education provided differs among healthcare practitioners. While the majority of the doctor respondents followed a biomedical approach in the form of explaining the MRI findings and stages of prolapse, some of the physiotherapist respondents adopted a biopsychosocial approach when trying to educate their patients.

Biomedical education

Most doctors described how they would try to explain the medical basis of the condition to their patients as well as the surgical options.

'I try to explain to the patients the different stages of the disc prolapse. They think this word is scary because they don't know what stage they are at. Some stages require surgery, but most do not'. Doct.3.

In order to further support the education of their patients, several doctor participants explained that they showed the MRI scan to their patients. As the one doctor described below, it may suggest a practice of reassurance. However, it also leaves the patients with no explanation of their chronic pain.

'I show the patients the MRI and explain to them all the parts of the image, so nothing is hidden from them and they are more comfortable with the findings'. Doct.6.

Biopsychosocial education

In contrast, some of the physiotherapist participants described how the type of information they provided to patients was more holistic and acknowledged both internal and external factors contributing to their pain experience.

'We teach patients that pain is an experience that differs from person to person depending on intrinsic and extrinsic factors; that is what we are trying to educate patients about'. Phys.5.

Reassurance

Furthermore, across the different healthcare practitioner participants, there was a consensus that patient reassurance was practiced.

'At the beginning, we assure the patient that his condition is not a disease caused by a pathoanatomical source and that the pain is real, but it is not always linked to the finding on his MRI'. Phys.5

'We assure the patient that his problem is simple and manageable with medication and physiotherapy, and nothing is hidden in his diagnosis'. Doct.2.

It is clear that different healthcare practitioners will understand and therefore apply reassurance in different ways. In the situation below, the doctor seemingly tried to give the patient some assurance. They also suggested that the patients might ultimately need surgery should the more conservative treatment not be successful.

'Last time I saw my doctor. he showed me the result and told me there was nothing to worry about. He told me to try exercise now and that I might need surgery later'. PT.7.

3.3.2.4. Impact of pain on individuals with CLBP

Pain resulting from CLBP is frequently cited by patients as affecting their social life, with the potential to affect their work and whole family.

Psychosocial effect of pain

Pain has been shown to impact patients' social lives, making them less likely to participate in social activities for fear of worsening their pain. The following subsections further explore the psychosocial impact of CLBP on patients' lives.

Impact on participation and social life

Many patient participants in this study explained how their back pain had a negative impact on their social and family life, through withdrawal from valued activities and a lack of social participation, as two patients explain below.

'My back pain impacted my family mainly. I used to play and run with them. Now I am cautious and afraid to carry my kids or even let them touch my back'. PT. 9.

'My kids always want to go to public places. I refuse to go with them because of my back pain. When my sister invites me, I apologise due to my back pain'. PT.5.

Psychological impact

A number of patients reported that pain elicits fear of movement due to the pain or discomfort that they may feel if they attempt it or even when seated thus causing anxiety and impacting on their physical function as the patient below explains.

'The pain in my back causes anxiety. I am anxious and thinking a lot about it. I can't sit comfortably with my friends and I must change position all the time'. PT.1.

The pain interfered with physical activities, for instance, walking, which is cited by a number of patients as hindering their free participation for fear of the excruciating back pain ensuing from such movement. The patient below captures it very well.

'Frankly, back pain has affected my life. I am so cautious when it comes to movement. The doctor instructed me to walk but when I walk I feel pain the next day'. PT.5.

Effect on work

An adverse impact on work performance was also reported by a number of patient participants. Specifically, patients described the challenge of living with LBP and meeting the standards expected by their employers and potential impact on job performance.

'My annual evaluation was poor, which affected my annual allowance. I got a warning from my manager, but I can't (stop working); my job requires a lot of standing'. PT.1.

In some situations, patients were left to consider changing their occupation to something that would be more manageable. As one woman explains.

'I have a problem: frankly I worry about any movement and I am considering changing my profession as a teacher to a less active job'. PT.9.

3.4. Discussion

The aim of this study was to explore the associated consequences of MRI scanning in NS-CLBP in Saudi Arabia and the management of NS-CLBP in Saudi Arabian healthcare. This study explored the experience of CLBP management from the perspectives of three different groups. It provides a unique insight into the experiences of CLBP patients after MRI diagnosis and the healthcare management of CLBP in Saudi Arabia. The findings of these interviews show that although patients are eager for more advanced imaging to explain their NSCLBP, they tend to react negatively to the results. This negative reaction might be explained by the reliance on biomedical education, i.e. using scanning or models that rely more on the pathoanatomical explanation of the problem and draw the patient's attention solely to anatomical changes without holistic exploration of the factors that might affect the pain and ability to return to function.

The first theme highlights the current pattern of healthcare delivery in Saudi Arabia with regard to CLBP. Specifically, data from this study showed the lack of availability of local, specific clinical guidelines for CLBP management and that healthcare providers consequently consult international guidelines or do not refer to any clinical guidelines at all when managing CLBP. Compared with other health problems observed in primary care, the lack of clinical guidelines for CLBP management also posed a special challenge for these healthcare practitioners. For instance, international guidelines recommend that healthcare providers should not resort to laboratory and imaging tests immediately but instead focus on functional recovery (Rossignol et al., 2000). However, patients in Saudi Arabia believe that MRI scanning should be performed in the first instance and request their healthcare practitioners refer them for this procedure. The lack of local clinical standards for CLBP management is a challenge for healthcare professionals and may put them at a disadvantage with respect to having the necessary tools and evidence-based guidance for primary care.

In addition, the lack of coordination in healthcare delivery showed that services have been over-utilised in secondary healthcare for cases that could be managed at the primary care level. The healthcare practitioners recommended early treatment at the primary healthcare level to reduce the load on medical practitioners and the cost of care. Ideally, patients with CLBP should seek care for their condition through their primary care doctor. However, these doctors might not have the resources available to properly diagnose and treat such chronic conditions. Secondary care is readily available in Saudi Arabia but

identifying the proper specialist and coordinating this care may be challenging. As a result, the care of patients with CLBP often ends up being fragmented among several providers. Again, this relates to the lack of clinical guidelines of LBP management specifically tailored to Saudi Arabian healthcare. Care coordination measures should focus primarily on ensuring good communication, smooth transition, and timeliness of care given to patients by healthcare teams (Kim et al.,2015).

The lack of local guidelines and pathways of care suggest poor coordination between healthcare services, over-utilisation of secondary healthcare services, and underutilisation of primary healthcare. The current over-utilisation of secondary services was associated with increased waiting time for patients to receive treatment according to the doctor participants. Increased waiting time has been associated with increased chronicity of LBP (Macfarlane, 1999; Crook, 2002). Consequently, time off work may increase, with a negative impact on the productivity of patients with LBP (Crook et al., 2002). The impact of poor utilisation of the healthcare system might therefore have larger negative socioeconomic consequences that might be reflected in both individuals and society.

These suggested limitations of the current healthcare system in managing CLBP could be addressed by the implementation of local or national pathways of care. The implementation of the Inter-Professional Spine Assessment and Education Clinics (ISAEC) clinical pathways of LBP in Toronto, Canada (Rampersaud, 2014; Zarrabian, 2017) showed promising results in a system with similar limitations to those encountered in the healthcare system in Saudi

Arabia. The pathway emphasises the provision of early education to patients and appropriately screening patients for biomedical, psychological, and social risk factors for pain and disability at the primary care level. With the implementation of ISAEC, a high rate of patient satisfaction (98%) was reported. More importantly, MRI utilisation decreased (30%) as did the waiting time for specialist care, resulting in appropriate referrals to specialists (Zarrabian et al., 2017). Additionally, employment status improved by 41% at 1-year follow-up (Harris and Rampersaud, 2016). Therefore, the overall annual cost for LBP-related imaging was reduced by 27%, and estimated savings in the first year after implementing the pathway were approximately 517K Canadian dollars. (Rampersaud, 2014; Zarrabian, 2017).

Physiotherapy is the standard conservative treatment recommended by clinical guidelines for people with CLBP (van Middelkoop, 2011, Koes, 2010). However, this service is not available in primary healthcare in Saudi Arabia and is considered a referral-based service at the secondary level. In this study, most of the participants agreed on the importance of initiating physiotherapy treatment at an early stage. Empirical evidence has shown that physiotherapists are proficient in efficient management of complaints pertaining to musculoskeletal care within the general practice/primary care environment in various countries (Holdsworth and Webster, 2004; Ludvigsson and Enthoven, 2012; Goodwin and Hendrick, 2016). In addition, the physiotherapy approach has been shown to result in a high level of patient satisfaction (Webster, 2008; Goodwin and Hendrick, 2016). These findings correspond with the global

strategy of integrating physiotherapy within primary care services (Snow, 2001; Nordeman, 2006; Cott, 2011).

The study findings suggest that early initiation of physiotherapy services could lead to early recovery and subsequent decrease in medication, consultation, and imaging costs. This is consistent with previous research that suggested reduced cost of care with integrated physiotherapy services at the primary care level (Fritz, 2013; Cott, 2011; Nordeman, 2006).

The second theme of the findings showed the relationship between MRI utilisation and its effect on the psychosocial wellbeing of patients, patient urgency, and patient needs. In this study, multiple psychosocial effects of MRI were reported by participants after a diagnosis. Fear was frequently reported by patient participants. This fear of diagnosis and prognosis might lead to movement restriction. Anxiety is another psychosocial effect reported by participants from different groups. These factors are consistent with the FAM (Vlaeyen and Linton, 2000), which suggests that the presence of elevated fear of movement and anxiety could explain chronic musculoskeletal pain owing to the adoption of avoidance behaviour. In addition, MRI scanning may reveal a condition such as a disc prolapse in the lower back that does not actually require any treatment because it is not the source or cause of the pain (Nakashima et al., 2015). This results in fear and anxiety among patients, especially when the healthcare practitioner starts using medical terms (such as disc prolapse) when talking to patients about the findings of the MRI.

The value of MRI scanning for people with NS-CLBP was elaborated on by healthcare practitioners. They claim that MRI findings rarely change their clinical diagnosis, and this is supported by studies (Kendrick,2001; Chou, 2009) reporting on the over-utilisation of MRI, which can inflate the cost of care for these conditions. Furthermore, Deyo et al. (2009) reported that even with clinical guidelines recommending prudent imaging, MRI of the lumbar spine has increased by 307% across geographical regions, and surgery rates have increased in areas where MRI scanning rates are high. When assessed in light of the guidelines, one- to two-thirds of MRI scanning referrals were found to be inappropriate according to the guidelines (Rao et al., 2002). This study has highlighted several factors in the over-utilisation of MRI scanning in Saudi Arabia, including patient demand and the compelling need for visual evidence among patients and healthcare practitioners alike. McPhillips-Tangum et al. (1998) reported how patients often insist on repeated clinic visits and repeated MRI scanning when diagnosed with LBP. This is exactly what is happening in the healthcare setting in Saudi Arabia, as demonstrated in this study. Saudi patients often visit clinics as frequently as monthly and demand MRI scanning for monitoring and surveillance. In addition, the insistence of patients on further medical explanations for their pain could be linked to the over-utilisation of MRI scanning for NS-CLBP. It has been reported that patients with CLBP believe that imaging is necessary for diagnosis (Jenkins et al., 2016). This finding is also consistent with that of Espeland and Baerheim (2003), who suggested that one of the factors affecting the referral for imaging for CLBP is the patient's degree of insistence. This pressure is expected from patients who are

categorised as “non-specific” CLBP. Patients seek an explanation for their pain, and when the only explanation provided is biomedical, they tend to accept it (Serbic and Pincus, 2014; Bunzli, 2015).

Unfortunately, one limitation of excessive MRI scanning is that it may result in findings that are irrelevant but considered alarming by patients. For instance, a positive MRI finding for a herniated disc is common in asymptomatic individuals but may be interpreted as a serious finding by the patients. This study highlights how patients tend to be attached to their medical diagnosis and to try to link improvements with changes in their MRI scans.

The third theme of the findings showed the diversity of patient education in Saudi Arabia. Education by itself is an important component of CLBP management (Traeger, 2015; Moseley, 2004; Moseley, 2002). The elements of education provided to patients vary. Although biopsychosocial education is effective in reducing fear, anxiety, and disability in CLBP (Moseley, 2002 and 2004; Louw, 2011, Brox, 2008), few healthcare practitioners reported practising any form of biopsychosocial education. Most healthcare practitioners rely on biomedical education alongside MRI scanning and spinal models to deliver education. The relationship between this form of education and patient attachment to the MRI diagnosis is worth investigating. Patients with CLBP tend to experience exacerbation that can recur over time. Unfortunately, patients with CLBP may not obtain complete resolution of their pain. For these individuals, the goal is continuous pain management and prevention of future pain flare-ups. This is an essential aspect of patient education. Doctors in this study tended to take a biomedical approach. For patients with CLBP, the

ultimate functional outcomes often depend more on psychosocial factors than on medical treatment, which, interestingly, was being practised by few physiotherapists in this study.

Reassurance, pain physiology, and fear avoidance training are examples of evidenced-based education (Brox et al., 2008). The study highlighted that the content of education received by patients is diverse and sometimes ambiguous. A reassuring message followed by “You might need surgery later” might not be encouraging and could affect patients negatively.

The fourth theme of the findings explored the effects of pain on activities of daily living. The results of this study endorse previous qualitative research finding regarding the difficulties patients face in dealing with their family and social obligations (Strunin and Boden, 2004; Corbett, 2007). Patient participants emphasised difficulties mainly with interacting with their children and socialising with others in public places.

The impact of the pain itself is immense: the patients reported an impact on their work and productivity. The burden of back pain on work and productivity is well documented (McDonald, 2011; Hartvigsen, 2018). Furthermore, it is considered a significant socioeconomic burden (Linton, 1998; Loisel, 2002). The findings from patients highlight the cognitive assumption that active jobs will result in chronic pain. Patients reported that a more active job means they will experience constant pain. The assumption is justified by fear avoidance behaviours or the lack of return-to-work rehabilitation.

The study findings support the FAM (Vlaeyen and Linton, 2000, Leeuw, 2007), which highlights the role of pain belief on patient behaviour, and specifically, how patients tend to avoid movement because of perceived beliefs that movement is associated with pain exacerbation.

Since there is no formal questionnaire to measure LBP patients' beliefs about diagnosis, a serious of 12 questions were chosen from sub-themes of mainly the second theme to format a non-standardised questionnaire to be used alongside the standardised questionnaires in the next phase of the project (chapter Four). This step will help in gaining more responses from CLBP patients which therefore, benefit the generalisability of the data.

3.5. Limitations

There are a number of limitations of this research that must be acknowledged. Despite it representing the first study on the psychosocial effects of MRI diagnosis on patients with CLBP and exploring the means through which CLBP is treated in the Saudi Arabian healthcare system. Firstly, the researcher's position as a physiotherapist was known to the research participants who were also healthcare professionals, thus introducing a degree of interviewer bias to the study. However, this limitation was mitigated by using a list of practitioners provided by the team leads and by adopting a semi-structured interview approach.

Further, subjectivity may have arisen during analysis because a single individual undertook the interviews, transcription, and preliminary coding. Nevertheless, it performing these steps individually have facilitated the familiarity of the gathered data. An additional potential weakness of the study

was that the geographical transferability of findings may be undermined by the inclusion of a single, prominent governmental location. However, patients from across Saudi Arabia travel to the dedicated secondary level care facility that was studied.

3.6. Conclusion

This study explored the views of patients and healthcare practitioners (doctors and physiotherapists) on the psychosocial effects of NS-CLBP diagnosis through radiological means in Saudi Arabia. This interview-based study emphasised the importance of having local clinical guidelines specifically tailored to Saudi patient and healthcare practitioners. The study also found a perceived need for better coordination between healthcare services and for early management of CLBP patients at primary care level in Saudi Arabia. Fear of movement and anxiety were reported by patients as the main psychosocial consequences of diagnosing LBP using MRI scanning. The education currently provided to these patients is mainly biomedical, which further promotes psychosocial consequences.

Chapter Four

Does MRI diagnosis negatively influence psychosocial and disability outcomes in patients with CLBP undergoing physiotherapy? A Feasibility Randomised Controlled Trial and Process Evaluation

Summary

In this study, we applied a mixed-methods approach; a single-centre feasibility RCT with embedded qualitative interviews. The findings from Chapters two and three were utilised to identify psychosocial and disability outcomes impacted by MRI for the outcome measures booklet. Patients who met the inclusion criteria were randomised to receive an MRI diagnosis or not prior to physiotherapy. Psychosocial and disability outcomes were measured before and after physiotherapy intervention. All patients and doctors were invited to participate in qualitative semi-structured interviews to explore the acceptability of randomisation and broader social, political, economic, and environmental factors that might have influenced the trial delivery. From 129 patients screened (mean age 39 (SD 10.7, 22–55 years) over 4 months, 24 were eligible, and out of these, 16 (67% of eligible and 12% of those screened) patients with CLBP consented. This was 67 percent of target. The response rate was 75%. The sample was too small for formal statistical analysis. Interviews involving 5 patients (3 men, mean 39.8 (SD 11.2, 24–55 years) and two doctors highlighted several obstacles to the feasibility trial. These could be summarised as follows: Limited recruitment window, lack of a research assistant, and no patient database from which potential participants could be screened. Although the consent rates were good, recruitment was below the target due to the time limitation and the fact that this study was limited to one centre. Trial participants and doctors questioned the acceptability of randomly allocating patients to the non-MRI group. Conducting a definitive trial in the Saudi Arabian context may not be feasible at the present time, as it would require an extensive recruitment period, multiple centres, consultant buy-in and considerable resources

(funding and infrastructure) allocated to screening and recruitment, which do not currently exist.

4.1. **background**

Although consensus in international guidelines is against the use of imaging to routinely diagnose low back pain (Waddell and Burton, 2001; Koes, 2010; Van Tulder, 2006; NICE, 2016; Stochkendahl, 2018; Hartvigsen, 2018), a number of studies have identified an increase in the practice of imaging referral for diagnosis (Williams, 2010; Dagenais, 2014; Jenkins, 2015). Similarly, the qualitative interviews conducted with healthcare practitioners in Saudi Arabia (Chapter three) suggested a similar pattern. This issue clearly indicates a degree of poor adherence amongst clinical practitioners to the established guidelines. Apart from the direct cost of imaging, diagnosing people with LBP using MRI has received a considerable amount of criticism. Berg et al. (2013) and Chou et al. (2009), for example, asserted that the method lacks the ability to identify the primary pathology. Additionally, Kotchen et al. (2009) observed that MRI unnecessarily exposes the patient to radiation. Furthermore, Webster et al. (2013) stated that MRI was prone to give false-positive findings resulting in a larger number of patient referrals to specialist facilities. The results of the qualitative research interview (Chapter 3) further support the claim that using MRI to diagnose CLBP patients is problematic. The patient participants in the study described experiencing high levels of anxiety and fear regarding their diagnosis and prognosis after undergoing an MRI. This resulted in constrained movements to avoid pain exacerbation.

A number of publications have investigated strategies intended to reduce the use of diagnostic imaging in the LBP population. In a systematic review examining the most effective ways to reduce the use of imaging (n=7 RCTs)

Jenkins et al (2015) reported that modifying the referral form for MRI resulted in a 36.8% decrease in the rate of referrals. This suggests that referral for imaging is permitted for only three particular conditions as indicated by LBP management guidelines i.e. presence of neurologic abnormalities (hypesthesia, hyperesthesia or anaesthesia of lumbar or sacral dermatomes), lower extremities weakness or hyporeflexia, and bladder or bowel incontinence. The other strategy, which achieved a 22.5% reduction in MRI use, is a targeted reminder to primary care general practitioners.

A promising programme for the reduction in the imaging rate in spine clinics was suggested by Kindrachuk et al., (2014) in which a trained physiotherapist performed triaging for new patients and only referred those with clear indications (e.g. chronic steroid use, presence of neurological deficits) of the need for surgery to the spine surgeon. For those patients who exhibited no indication of the need for spinal surgery, adequate education and self-management advice was provided. In addition, patients were triaged based on the STarT Back tool as the most appropriate guideline for recommended treatment. The preliminary data suggested a reduction in referrals to imaging and waiting time to see a surgeon (Kindrachuk et al., 2014).

Patient expectations regarding the treatment might also inform treatment options. Not providing an objective proof of diagnosis “MRI” can be unacceptable to patients (Zusman, 2013). Moreover, many studies have found that patients may experience feelings of relief when receiving a diagnosis, even if the diagnosis does not in fact explain their pain. For example, Serbic & Pincus explored the impact of diagnostic labelling on self-management and

pain-related guilt experiences. Using a grounded theory approach, twenty patients with CLBP seeking treatment from a pain clinic or an osteopathy clinic in the UK were interviewed. The study indicated that while patients with CLBP experienced a greater sense of relief following an MRI, they also experienced heightened feelings of guilt regarding their lack of apparent improvement (Serbic and Pincus, 2014).

The provision of an alternative treatment option for patients is a suggestion for overcoming the idea of acceptability (Santa, 2013). Physiotherapy services are known to be a credible and acceptable option for many patients (Fritz, 2015; Blackmore, 2011; Srinivas, 2012).

When comparing LBP patients who underwent MRI at first visit to a primary care clinic in USA with those who received a physiotherapy intervention, fritz et al., (2015) showed that the cost of care was on average $4,793 higher over one year for the rapid MRI group.

Numerous publications suggest that rapid physiotherapy intervention for LBP is linked to better patient outcomes and greater satisfaction (Nordeman, 2006; Lau, 2008; Fritz, 2012; Maeng, 2017; Bianca, 2018). Moreover, the direct costs associated with LBP—including the number of MRI scans, visits to the GP and prescription medications—were lower for people with CLBP who received early physiotherapy intervention (Fritz, 2012; Maeng, 2017; Bianca, 2018; Samsson, 2015; Frogner, 2018). For example, in a retrospective study of 32 people with LBP visiting primary care, Fritz et al. (2012) examined the difference in costs associated with early physiotherapy (within two weeks) or delayed treatment

(beyond 14 days) in an 18-month follow-up study in USA. The study suggests that early access to physiotherapy is associated with a decrease in the number of doctor visits, MRI scans, medications and surgical interventions. The reported decrease in the use of healthcare resources results in a savings of $2,736.23 over the study period for those who had rapid access to physiotherapy services.

This evidence suggests that early access to physiotherapy treatments may prevent unnecessary medical expenditure whilst also improving the degree of patient satisfaction. On the other hand, delayed access to physiotherapy for CLBP patients is linked to poor outcomes (i.e. Physical, return to work and satisfaction) and chronicity (Macfarlane, 1999; Crook, 2002; Rihn, 2011).

Considering the results outlined in the previous chapter (Chapter Three), a number of healthcare providers have suggested that MRI is an overused practice. Furthermore, it is significant that patients have described feeling an elevated sense of fear and anxiety following their MRI diagnosis. When linked to the aforementioned literature and guideline recommendations, it is not known if altering the practice of the routine use of MRI in Saudi Arabia would be acceptable to healthcare practitioners and patients or lead to improved psychosocial and disability outcomes. Moreover, the identification of psychosocial factors associated with MRI from previous qualitative studies cannot be generalised. Therefore, this study will seek to examine the feasibility and acceptability of conducting a randomised control trial to answer the question: does MRI diagnosis negatively influence psychosocial and disability

outcomes in patients with CLBP who are undergoing physiotherapy? At the same time, the feasibility study set out to;

- Estimate the recruitment rate
- Determine the reasons for non-recruitment
- Estimate sample size parameters required for definitive RCT

The process evaluation aims were:

- To explore the acceptability of randomisation and the study design to healthcare practitioners involved in trial delivery and patient participants.
- To explore the broader social, political, economic, and environmental (context) aspects that may influence trial delivery and intervention implementation.

4.2. **Method**

In the literature, RCTs are widely regarded as the most suitable method to study the effectiveness of a clinical intervention (Bowling et al., 2014), as studies of this type limit the potential for bias. Nevertheless, the framework published by the Medical Research Council (2008) emphasised that complex interventions must be tested to reduce uncertainty when implementing definitive RCTs, and the most effective way of intervention delivery must be determined.

As outlined by Eldridge et al. (2016), one of the defining features of a feasibility study is the way in which it attempts to answer the question of whether a certain objective can be achieved, which method could facilitate the

achievement of the objective, and – if an appropriate method exists – how it could be implemented in the most effective, reliable, and generalizable way. Ultimately, it is important to note that feasibility studies, although related to pilot studies (Thabane et al., 2010), are distinct from the latter in a variety of ways, most notably with respect to the way a feasibility study is utilised to test pre-defined parameters to inform a large-scale study.

Furthermore, the MRC advocates supplementing the feasibility studies with a process evaluation to identify the contextual elements associated with the outcome (Moore et al., 2015). Therefore, a mixed methods feasibility trial with embedded qualitative interviews was used to examine the parameters addressed in the study objectives and to analyse the following five domains of feasibility (Table 9).

Table 9 Process evaluation domains

Domain	Explanation	Methods of Data Collection
Recruitment	Procedures used to approach and attract participants	Documentation of recruitment process by research team Interviews with healthcare providers and patient participants
Reach	The proportion of the intended target audience that participates in an intervention	Documentation of recruitment process by research team Interviews with healthcare providers
Acceptability	Participants' and healthcare providers' acceptability of randomisation	Qualitative interviews with healthcare providers and patient participants

Unintended consequences	Are there unintended changes in processes and outcomes?	Documentation of recruitment process by research team and qualitative interview
Context	Aspects of the larger social, political, and economic environment that may influence intervention implementation	Qualitative interviews and end of site meetings

4.2.1. Sampling Frame

Feasibility study

Given this was a feasibility study, a sample size calculation was not required. However, to ensure the precision and efficiency of the feasibility study, a sample target of between 24-50 participants was recommended (Sim and Lewis, 2012; Julious, 2005).

The original intention was to use two centres (government and private) for the recruitment of participants for the study over a period of 12 weeks. An ideal target of 30 participants was estimated based on audit data received by telephone from the private centre, which suggested that 80 people with general problems with their spine are seen in each clinic per month. This target of 30 participants was based on the assumption that two thirds of the patients may not be eligible and 50% of the eligible patients may refuse consent.

Unfortunately, the private hospital declined to participate in the study for policy-related reasons. Consequently, a revised target of 24 participants was set based on the timeframe and the quantity of new patients attending the spinal

clinics of the King Fahad Medical City each month. An estimated number of patients per month obtained from the recruitment centre suggested that 6 patients who satisfy the inclusion criteria visited the clinics each month.

Process evaluation

Semi-structured telephone interviews were proposed to be conducted by the author (AA) with a purposive sample of 4–6 patients and 2–4 healthcare practitioners in recruiting centres participating in the feasibility study.

4.2.2. Recruitment

Feasibility RCT

For the purpose of identifying potential participants and constructing an appropriate sample from the clinics at King Fahad Medical City (Riyadh, Saudi Arabia), patients who met the inclusion criteria (See 4.2.2.3) were approached and recruited by one of the usual care team during their initial appointment at the spine clinic.

Process evaluation interviews

Additional ethics for the embedded process evaluation aspects was obtained later. Therefore, patients who had consented to participate in the feasibility study were invited again by email to participate in the telephone interviews. Additional consent forms (Appendix 9) and information sheets (Appendix 8) related to this part of the study were attached to the email. Mr Ahmed Alhowimel (author) was responsible for answering any questions concerning participation and for obtaining their consent either by email or telephone.

Furthermore, doctors from the recruitment clinics were invited by email to participate in the interview study to share their experiences of the feasibility RCT. The author was responsible for contacting the doctors and explaining the study aims.

4.2.3. Inclusion criteria

Participants were eligible for inclusion in the feasibility RCT if they satisfied all of the following criteria:

- Individuals (male or female)
- Age range 18 to 65 years
- CLBP patients with no clear medical diagnosis (malignancy, fracture, infection, spinal stenosis, spondylolisthesis, or inflammatory disease)
- If the patient's pain has persisted for more than three months

4.2.4. Exclusion criteria

Participants were excluded if any of the following were applicable:

- Pregnant
- A new mother less than six months postpartum
- Individuals (male or female) who have undergone pain-relieving procedures (i.e. injection or denervation) in the previous three months
- Individuals (male or female) who display evidence of neurological impairment specific to LBP
- Have received physiotherapy treatment for their LBP in the last six months prior to recruitment
- Have received an MRI scan and a report for LBP in the last six months

4.2.5. Voluntary and informed consent

An existing member of staff in the clinic carried out the process of screening new patients for inclusion in the study. All the patients who satisfied one or more of the exclusion criteria were excluded and the reason for their exclusion recorded.

Potential participants who fulfilled the inclusion criteria were recruited only after informed consent had been obtained by the author (A.A) during their initial visit to the spine clinic. In order to do this, several measures were implemented: firstly, contact was established with prospective patients' healthcare providers (members of the usual care team) to provide information about the study and to request that they I) provide potential participants with an explanation of the study's aims and purpose, a description of what would be involved and II) hand out participant information sheets (Appendix 7) to those fitting the inclusion criteria. Those fitting the inclusion criteria and expressing an interest in taking part were approached by the thesis author (AA) and given the opportunity to ask any questions. Once any questions had been answered satisfactorily, written informed consent was obtained by AA and baseline measurement took place.

4.2.6. Baseline measurement

The baseline measures were collected immediately after consent was obtained. Baseline data were collected by either the thesis author or the nurse in charge, and all endpoint data were collected by the thesis author.

The content of the booklet of outcome measures (Appendix 10) was informed by previous studies, as presented in Chapters 2 and 3. Demographic data

included the following: age, gender, marital status, number of children, employment status, monthly income, highest educational level, duration of back pain, number of sick days in the last three months, severity of back pain in the last three months, and any history of surgery.

Previous qualitative study findings (Chapter 3) were used to prepare 12 non-standardised questions which are not covered in the standardised outcome measures. Additionally, four standardised outcome measures were included in each questionnaire booklet:

Roland Morris Disability Questionnaire (RMDQ): This is a self-administered tool for assessing the level of physical disability caused by LBP (Roland and Morris, 1983). It contains 24 closed-ended questions about the physical abilities the patient has possessed in the past 24 hours. The scoring ranges from 0 (no disability) to 24 (maximum disability) (Smeets et al., 2011), The reliability and validity of the RMDQ has been reported to be effective (Macedo, 2011; Davies and Nitz, 2009). Cross-cultural adaptation and translation of the RMDQ to the Arabic language is also reported to have good reliability and validity (Maki et al., 2014).

Fear-Avoidance Beliefs Questionnaire (FABQ): This questionnaire is based on the Fear avoidance model (Vlaeyen and Linton, 2000). Its purpose is to measure the degree to which patients are fearful of physical activities and, thereby, avoid them, along with the impact of this avoidance on their work. The tool consists of 16 items scored from 0 (low fear) to 6 (high fear).

Orebro Musculoskeletal Pain Questionnaire (OMPQ): This questionnaire was developed to guide the primary care clinician in identifying patients with a high risk of persistent back pain (Linton et al., 2011). The short form of the OMPQ contains 10 questions that address issues such as: days off work, anxiety and tension, depression, pain, activities associated with daily living that are related to pain, coping, fear-avoidance beliefs, and patient's expectations to recover. It is widely used and adapted in back pain management clinical guidelines (Hockings, 2008; Sattelmayer, 2012). The questionnaire has been translated to Arabic in a previous study on the Saudi Arabian population (Darwish and Al-Zuhair, 2013), but the validity of the translated version is not reported in the literature.

Back Beliefs Questionnaire (BBQ): This questionnaire was developed to assess patients' beliefs relating to back pain and recovery. It contains 14 statements scored on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). The validity of the questionnaire has been reported to be strong for the general population (Bostick et al., 2013). In addition, it is notable that the questionnaire has been translated and cross-culturally adapted to the Arabic population (Alamrani, 2016; Maki, 2017).

4.2.7. Randomisation

Simple randomisation took place using opaque envelopes containing details of the group allocation prepared by an independent non-healthcare practitioner. After giving consent to take part in the study and filling in the baseline measures, participants were randomly allocated to one of two groups, MRI in addition to usual physiotherapy treatment (usual care) i.e. the Intervention

Group or non-MRI (physiotherapy treatment only) i.e. the Control Group. The participants were informed of the allocation outcome by the author, during the same initial clinic visit. The result was communicated to the treating doctor to plan and track their next visit. If the patient refused to proceed, then they were permitted to continue with their usual treatment programme.

4.2.8. MRI group

Participants allocated to the MRI group were sent for an MRI scan of the lumbar spine, and a follow-up visit was planned to discuss the results. The time interval to undergo MRI ranged from 3 to 6 weeks. After discussing the results with their doctor, the patients were referred to physiotherapy. Next, another copy of the questionnaire booklet was completed by the participants after finishing the physiotherapy treatment, which lasted for a period of 2 weeks to 4 weeks.

4.2.9. Non-MRI group

Following allocation participants in the control arm (namely, the non-MRI group) were immediately asked to complete the booklet of questions and standard questionnaires. Participants were then referred to a physiotherapist for treatment, and the time required to initiate physiotherapy ranged from 1 week to 2 weeks. After completing the physiotherapy treatment programme, which lasted for 2 weeks to 4 weeks, the second assessment was taken.

4.2.10. Blinding

Despite the benefits associated with the implementation of blinding methods in RCTs, primarily owing to the way in which they limit the potential for bias (Boutron, 2006, Karanicolas, 2010), concealing the approach to group

allocation adopted in this research from either the participants or the health professionals was not possible. A successful approach to blinding would have required an overly creative and resource-intensive strategy (Karanicolas et al., 2010); however, achieving this was not practical for this study. In view of these considerations, blinding was not applied in the present study.

4.2.11. Data analysis

Feasibility RCT study

Given that the present study is a feasibility study, the reader should note that the data analysis is primarily concerned with reporting descriptive statistics. This includes the sociodemographic information pertaining to the participants, the number of dropouts, the number of participants who refused to give consent, and the rate of loss associated with follow-up investigations. In order to report on the difference between groups, median scores and interquartile ranges were used along with means and standard deviations (SD).

Process evaluation

The process evaluation utilised both quantitative data from the recruitment process collected by the research team and qualitative data from participants' interviews.

Quantitative data:

The participating centre was described in terms of number of doctors, supporting staff, and caseload. The number of participants was recorded to highlight the rate of participation, attrition, and drop out.

Qualitative data:

Semi-structured interviews were used to explore the acceptability of the study design to both patient participants and healthcare practitioners involved in the trial delivery (Appendix 11). All interviews were audio-recorded, transcribed verbatim and analysed thematically (Braun & Clarke, 2006) using NVivo software. Validity of the obtained data was assured by data triangulating through which a summary of the finding was communicated with 20% of the qualitative interview participants.

4.2.12. Criteria for the success of the feasibility study

Declaring the criteria for a successful feasibility study is critical when proceeding to a large-scale RCT (Thabane et al., 2010). Therefore, the following criteria was set to inform progression to large scale RCT:

- Recruitment: Recruit 24 participants
- Follow-up: If there is no more than 20% of loss to follow-up
- Acceptability: If most participants interviewed stated that randomisation is acceptable, and if at least 65% of eligible patients consent to participate in the trial.

4.2.13. Ethical considerations

Ethical approval for the present feasibility study was obtained from the Research Ethics Committee of the Faculty of Medicine and Health Science at the University of Nottingham (Ethics Reference Number OVS 18082016) and from King Fahad Medical City in Riyadh, Saudi Arabia (IRB: H-01-R-R-012).

4.3. Results

4.3.1. Recruitment of participants

Data collection took place at King Fahad Medical City (Riyadh, Saudi Arabia) between April 2017 and August 2017. The total number of screened patients was 129, and after the inclusion and exclusion criteria were applied, 24 participants were found to be eligible. Eight patients refused to consent to participation for reasons given in Figure 3, The remaining 16 patients were randomised into one of two groups (as outlined in the flow diagram in Figure 2). One patient from the MRI group withdrew from the study soon afterwards to undergo elective spine surgery, while a further 3 participants failed to complete the outcome measures booklet. Consequently, a total of 6 participants in each arm of the trial completed the study.

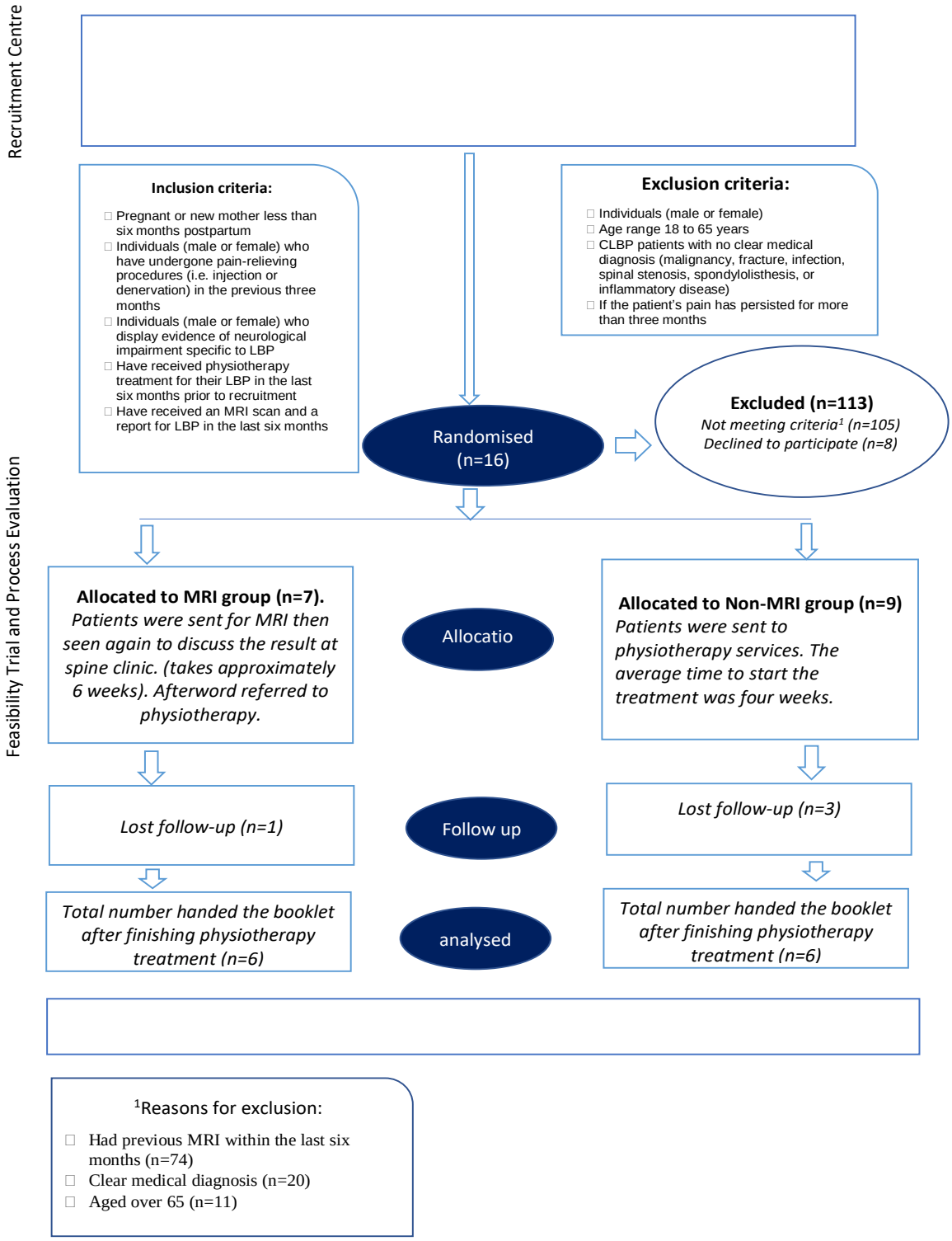


Figure 3 Participant Flow Diagram

4.3.2. Sample characteristics

Demographic characteristics

The demographic characteristic of the participants are illustrated in Table 10 below. The groups were equivalent in terms of mean age and baseline pain levels, with the results for the control group (Non-MRI) being 40 years and 6/10, and the results for the MRI group being 38 years and 5.9/10, respectively. In the control group, there were more women (ratio of 6:1), which contrasted with a more balanced representation in the MRI group (5:4). There were no differences between the groups in terms of their level of education or use of pain medication. However, there is a discernible difference with respect to the number of sick days taken for back pain, three participants in the MRI group had taken between 1 and 5 days off sick in the past three months, while none of the PT only group had had any days off sick. Furthermore, there were fewer full-time employees (0 vs 6) and more unemployed participants (2 vs 0) in the control group. There were also disparities in monthly income between the two groups with 5/9 participants in the MRI group earning more than 9,000 SR. However, more people in the Control group earned over 11,000 SR per month (3 vs 2) than in the MRI group.

Table 10: Participants' Demographic Characteristics

	Control group n = 7 (43.75%)			MRI group n = 9 (56.25%)		
Age	Mean	S.D.	Range	Mean	S.D.	Range
	40.57	10.77	22-52	37.78	11.25	24-55
History of back pain (months)	54.86	27.59	24-96	32.67	17.78	6-72
Initial Pain level (out of 10)	6.00	1.15	1-7	5.88	1.83	3-9
Gender	N	%		N	%	
Male	1	14.3		4	44.4	
Female	6	85.7		5	55.6	
Level of Education						
primary school	1	14.3		2	22.2	
Secondary school	1	14.3		1	11.1	
College/Diploma	2	28.6		1	11.1	
University Degree	2	28.6		4	44.4	
Postgraduate	1	14.3		1	11.1	
Occupational status						
Employed full-time	1	14.3		6	66.7	
Employed part-time	1	14.3		1	11.1	
Retired	1	14.3		0	0.00	
Unemployed	2	28.6		0	0.00	
Housewife	2	28.6		2	22.2	

Use of pain medication				
Yes	4	57.1	4	44.4
No	3	42.9	5	55.6
Number of sick leave days due to Back Pain				
0	7	100	6	66.7
1	0	0.00	1	11.1
3	0	0.00	1	11.1
5	0	0.00	1	11.1
Average monthly income in Saudi Riyals				
less than 3,000 SR	3	42.9	2	22.2
3,000–5,000	0	0.00	1	11.1
7,000–9,000	1	14.3	1	11.1
9,000–11,000	0	0.00	3	33.3
more than 11,000 SR	3	42.9	2	22.2

4.3.3. Results of non-standardised questions

The results derived from the qualitative interview study (see Chapter Three) were used to identify items and generate questions that were not included in the standardised outcome questionnaires (Table 11). There was a consensus among the participants' in their response to questions about the importance of MRI or radiography for back pain, which even after physiotherapy treatment, appeared not to change. One person in the control group changed their opinion about its importance.

Table 11 Results of non-standardised questions

	MRI Group				Control Group			
	Baseline n=9		After physiotherapy n=6		Baseline n=7		After physiotherapy n=6	
	Agree N (%)	Disagree N (%)	Agree N (%)	Disagree N (%)	Agree N (%)	Disagree N (%)	Agree N (%)	Disagree N (%)
Magnetic resonance imaging (MRI) and computerised tomography (CT scan) are always needed.	9 (100%)	0	6 (66.7%)	0	7 (100%)	0	5 (71.4%)	1 (14.3)
An X-ray is NOT always needed	2 (22.2%)	7 (77.2)	2 (22.2%)	4 (44.3%)	0	7 (100%)	1 (14.3%)	5 (71.4%)
Diagnosis can be made by taking medical history and physically examining the patient without the need for additional tests	4 (44.4%)	5 (55.6%)	3 (33.3%)	3 (33.3%)	2 (28.6%)	5 (72.4%)	1 (14.1%)	5 (71.4%)
Laboratory tests such as glycaemia, cholesterol, and urine are always needed	4 (44.4%)	5 (55.6%)	3 (33.3%)	3 (33.3%)	2 (28.6%)	5 (72.4%)	4 (57.1)	2 (28.6%)

Pain in the lumbar region that usually improves in three weeks (with or without treatment)	5 (55.6%)	4 (44.4%)	5 (55.6%)	1 (11.1%)	4 (57.1)	3 (42.9%)	4 (57.1)	2 (28.6%)
Back pain is untreatable pain in the lumbar region	3 (33.3%)	6 (66.7%)	5 (55.6%)	1 (11.1%)	3 (42.9%)	4 (57.1)	3 (42.9%)	3 (42.9%)
Back pain is pain in the lumbar region requiring surgery	3 (33.3%)	6 (66.7%)	1 (11.1%)	5 (55.6%)	0	7 (100%)	0	6 (85.7%)
Back pain is pain in the lumbar region lasting more than 3 months	6 (66.7%)	3 (33.3%)	4 (44.4%)	2 (22.2%)	4 (57.1)	3 (42.9%)	5 (72.4%)	1 (14.1%)
The explanation that I received about chronic pain was helpful	5 (55.6%)	4 (44.4%)	5 (55.6%)	1 (11.1%)	4 (57.1)	3 (42.9%)	5 (72.4%)	1 (14.1%)
The information that I have received about back care has been helpful	7 (77.2)	2 (22.2%)	4 (44.4%)	2 (22.2%)	5 (72.4%)	2 (28.6%)	6 (85.7%)	0
Back pain impacted my family life and interaction with my kids	8 (88.9%)	1 (11.1%)	5 (55.6%)	1 (11.1%)	4 (57.1)	3 (42.9%)	5 (72.4%)	1 (14.1%)

	Agree N (%)	Not sure N (%)	Agree N (%)	Not sure N (%)	Agree N (%)	Not sure N (%)	Agree N (%)	Not sure N (%)
I feel relieved after knowing my diagnosis	8 (88.9%)	1 (11.1%)	6 (66.7%)	0	4 (57.1)	3 (42.9%)	6 (85.7%)	0

Responses to the definition of back pain showed varied responses from both groups, with 56% agreeing with the statement. Notably, after the treatment intervention, this rate of response did not change.

In response to the statement asking the participants whether back pain is a curable condition, the percentage of respondents from the MRI group increased after physiotherapy (from 33.3% to 55.6%). Contrastingly, after physiotherapy, the rate of agreement with the statement in the control group remained unchanged.

Participants in the control group disagreed with the statement that pain in the lumbar region requires surgery (at the level of 100%), while 3 participants in the MRI group agreed with the statement (33.3%). However, after participants in the MRI group received treatment from the physiotherapist, this number decreased to 1 (11.1%).

The information received during the visits revealed a higher level of agreement on its helpfulness from the MRI and Non-MRI groups (78% and 72%, respectively) prior to physiotherapy. However, the percentage of agreement dropped to 44% in the MRI group, while it rose to 86% in the Non-MRI group.

Both the control group and MRI group appeared to agree with the statement that back pain impacted on their family interactions and childcare both before and after physiotherapy.

Regarding the question of whether participants felt relieved after learning about their diagnosis, a higher proportion of the MRI group felt relieved (89%) prior to physiotherapy in contrast to greater uncertainty (4 agreed, 3 disagreed) among the control group (43%). However, equal proportions agreed with the statement following physiotherapy intervention.

4.3.4. Standardised outcome measures

With respect to the baseline measurements, both groups showed similar levels of disability based on scores on the Roland Morris Disability Questionnaire (RMDQ). However, scores on other measures were higher in the MRI group. Following physiotherapy, both groups indicated higher levels of disability on the RMDQ and a higher risk of persistent pain (Orebro). Furthermore, back pain beliefs (BPB) displayed a marginal increase in the control group compared to the 10% decrease in the MRI group (see Table 12).

Table 12 Results of Standardised Questionnaires

MRI group or Control			RMDQ	FABQ-W	FABQ-P	Orebro	BPB	RMDQ	FABQ-W	FABQ-P	Orebro	BPB
			Baseline					After Physiotherapy				
MRI 9 (56%)	N	Valid	9	9	9	9	9	6	6	6	6	6
		Missing	0	0	0	0	0	3	3	3	3	3
	Mean		8.88	19.24	16.22	57.66	29.66	9.16	15.55	10	59.66	26.33
	Median		7.00	22	16	56.00	29.00	9.50	18	10	57.00	28.50
	Std. Deviation		5.41	9.14	4.81	11.63	4.61	3.86	13.65	8.71	12.50	5.50
	Percentiles	25	4.00	12.50	12.00	50.50	27.00	5.50	16.25	9.50	48.50	20.25
		50	7.00	22.00	16.00	56.00	29.00	9.50	22.00	16.00	57.00	28.50
		75	13.00	26.50	20.50	68.00	30.50	12.00	32.25	18.00	72.00	31.00
Control 7 (43%)	N	Valid	7	7	7	7	7	6	6	6	6	6
		Missing	0	0	0	0	0	1	1	1	1	1
	Mean		8.57	14.71	18.42	62.00	26.57	9.00	9.28	12.42	69.50	27.16

	Median		9.00	13	22	59.00	26.00	8.50	10	12	71.00	25.50
	Std. Deviation		4.43	4.64	12.32	10.59	5.62	4.29	4.71	9.37	10.44	6.73
	Percentiles	25	5.00	6.00	12.00	52.00	23.00	4.75	7.00	8.00	57.75	21.75
		50	9.00	22.00	13.00	59.00	26.00	8.50	14.00	11.00	71.00	25.50
		75	13.00	26.00	20.00	68.00	31.00	14.00	21.75	13.25	80.00	32.75

4.3.5. Feasibility of the study

Non-MRI group

The participants in the control group were seen at the spine clinic during the randomisation period; then, they received physiotherapy. The average time between receiving treatment and completing the baseline measures booklet was four weeks.

MRI group

The participants in the MRI group were seen at the spine clinic during the randomisation period, and they underwent an MRI scan. The average time between undergoing MRI and discussing the results with their doctor was 6 weeks.

4.3.6. Response rate and loss to follow-up

Out of the 16 patients randomised, 12 (75%) completed the study. Three participants in the MRI group were lost to follow-up, where one underwent elective spine surgery, while two others failed to submit their post-physiotherapy questionnaire booklets. Only one patient in the control group was lost to follow-up.

4.3.7. Results of the process evaluation

Quantitative data

In all, 129 patients were screened over the 4 months recruitment period, 24 of whom (18.6%) satisfied the inclusion criteria stated at the outset of the project (Figure 3). Out of the 105 excluded patients, 74 (57.3%) underwent MRI

examination within the preceding 6 months, and 20 (15%) had a specific medical diagnosis (e.g. fracture, cancer and lumber stenosis) that excluded them from participation in the study. Finally, 11 of the screened patients (8.3%) were over the age of 65 years which was one of the exclusion criteria.

Of the 24 screened patients who satisfied the inclusion criteria, 8 (33.3%) did not want to participate in the study. Some patients who declined to participate did not state the reason (n = 5); others attributed their decision to the time-consuming nature of the outcome measure booklet (n = 2), and the remaining patient (n = 1) was dissatisfied with the concept of randomisation. As previously noted, 5 patients (41.6%) consented to participate in the process evaluation interview.

Qualitative interviews

Telephone interviews were scheduled with five of the trial participants and two of the referring physicians involved in the feasibility study for the purpose of collecting qualitative data about the trial process. Concerning the occupations of the participants; jobs included dentist, entrepreneur and office worker. An overview of the sociodemographic characteristics of the participants, including age, gender and occupation, is given in the tables below, along with other information such as duration of LBP, average pain intensity (for the five patients), length of work experience (for the two doctors), and group (see Tables 13 and 14). The findings of these interviews will be presented in the following three subheadings.

Table 13 Participants' sociodemographic characteristics

Participant code	Age (years)	Gender	Occupation	Duration of LBP (years)	Avg. pain intensity	Group
PT.1	24	Female	Dentist	2	4	MRI
PT.2	37	Male	Office worker	3	8	Non-MRI
PT.3	55	Female	Own business	3	9	Non-MRI
PT.4	43	Male	Own business	8	5	MRI
PT.5	40	Male	Office worker	3	5	MRI

Table 14 Doctors' sociodemographic characteristics

Participant code	Age (years)	Gender	Education	Occupation	Experience (years)
Doc.1	30	Male	University Degree	Assistant Consultant	6
Doc.2	38	Male	University Degree	Assistant Consultant	12

Acceptability

The responses from trial participants enrolled in this study suggest that a diagnosis based on imaging and seeing a doctor was still important to patients with LBP – even to those who enrolled in the trial.

'I do not think they will accept, according to my experience. I am a patient with lower back pain. Anyone who suffers from lower back pain wants first to be treated by a doctor, which means he needs imaging to see what is going on inside'. PT5

This perception extends to diagnostic accuracy, and it was most evident in patients in the non-MRI group. Indeed, one patient was concerned that without the evidence from MRI, the doctor may have difficulty in accurately making a diagnosis.

'If you are allocated to a non-MRI group, how is the doctor going to diagnose your case?' PT1

However, some patients were not concerned about the group to which they were allocated on the grounds that they had already undergone a number of MRI scans.

'Being in either group was not a big issue for me as I have had many MRIs before'. PT3

The patients' motives for taking part in the study and giving informed consent revealed, for at least one participant, the desire to participate as part of a moral

obligation for the public good influenced by their own data collection experiences.

'What made me join the study is that once I was a student at the university and we were faced with research and how to collect samples of participants participating in scientific research'.' PT1

At the same time, it is important to recognise that the implementation of a large-scale study may have an adverse impact on the degree to which patients are satisfied with the healthcare they receive. One doctor respondent in this study drew attention to this issue when the matter of feasibility was presented to him.

'Any patient wants to be in the group that is getting the most tests and diagnostics and treatment. I don't think patients will be satisfied.' Dr. 1

The other doctor participant also drew attention to patients wanting to maximize their healthcare benefits by asking for more scans.

'Patients come to the hospital and ask for all the services that they could have, including MRIs.' Dr. 2

Feasibility of outcome measures booklet

There was a clear outcome for this aspect of feasibility, namely the proportion of participants completing the questions in the follow up questionnaire booklet (see PT2's comment below). Twelve out of the 16 participants completed follow up measures (25% loss to follow up) and for those returned, 100% of questions were complete. Several difficulties were highlighted by the participants interviewed on the experience of completing the outcome measures. Firstly, the length of time required to complete the booklet

(amounting to approximately 25 minutes) was considered lengthy, and it was highlighted that there was repetition of questions in different parts of the booklet. However, given that most participants completed the measures, the findings would suggest no real practical difficulties in terms of questionnaire burden or sensitivity over and above those anticipated (e.g. repetition across measures).

'There was no problem filling in the outcome measures booklet; all questions were clear, and we had the chance to ask about anything that was unclear'. PT2

'It takes from 20-30 minutes to fill in; yes, it was long and there was some repetition of the questions between pages". PT5

Context

Three fundamental issues emerged after considering the contextual factors surrounding this study, namely the social, political, and economic factors. Firstly, the matter of research assistance; secondly, the existence of and access to a patient database; and thirdly, the length of time over which the research would need be conducted to recruit sufficient participants. As for the first contextual factor, despite the good will from the hospital to support research, there are infra-structure limitations and lack of research capacity. The minimal research assistance available for the present study was a major hindrance. The absence of additional help for recruitment and to support baseline data collection eliminated the option of conducting a multicentre study since additional human resource would have been required for the purpose of

the screening and identification and recruitment of participants and completing the baseline measures and randomisation.

'The only obstacle I foreseen is the lack of researchers or assistant researchers; hospitals are very supportive if you want to conduct research'. Dr.2

As for the second contextual factor, most clinical research projects rely on the ready availability of data pertaining to the sampled patients. A matter of special concern here is the existence of several numbers of files for every patient in the existing governmental healthcare institutions. Dr.2 underlined the impracticality associated with conducting a retrospective study, along with the fact that no patient database is available.

'We have no database for patients; if you want to conduct a retrospective study it is almost impossible' Dr.2

Regarding the third contextual factor, despite the good will from the healthcare practitioners, there might be a lack of research culture that acts as a barrier in government hospitals. Time limitations are always problematic when attempting to collect clinical data, especially for doctors. This is because they rarely receive exemptions from normal working duties for research purposes, and they have to do this in their free time.

'There is no allocated time for research. I was exempted from on-call duty just to finish my research paper'. Dr.1

'If you are looking for a large study with follow-up then we cannot give our own time to research'. Dr.2

4.4. Synthesis of the findings

The predefined criteria of progressing to large-scale RCT was examined in the qualitative and quantitative findings. The study was brief in order to achieve the targeted number of participants and to have no more than 20% loss to follow-up. Consequently, the study achieved the targeted percentage of consent rate (67%), however, one participant raised the issue of possible threat to acceptance in the qualitative interviews.

4.5. Discussion

The aim of this study was to evaluate the acceptability and feasibility of allocating NS-CLBP patients randomly to an MRI or non-MRI group .Despite the fact that 16 consenting patients were recruited to the study in 4 months, 8 more patients were required to reach the required total of 24. Hence, the study fell short of achieving the recruitment target by 34%, which may be attributed to the study setting being limited to one governmental hospital.

Ethical approval for a second hospital whose consultant had agreed to support the study was declined. This was a private hospital in Riyadh, who cited policy considerations as the reason that randomisation to a non-MRI group was not possible (Appendix 12). However, even had the permissions been granted it is likely that without additional resource in the form of an additional research assistant for patient identification, screening and recruitment, this would not have been possible, as this was an unfunded PhD study.

As for the recruitment centre involved in the present study, a sizeable reference hospital based in Riyadh, the capital of the Kingdom of Saudi Arabia, was chosen. Of note, the geographical setting of the study may not allow the

findings to be generalised to the general Saudi population. Nevertheless, individuals in different parts of the country are referred to the hospital, given its status as a secondary healthcare centre.

The brief period of time allocated for conducting the proposed research led to a variety of difficulties. The time limitation relates to the regulations of the author's PhD sponsors which allow only four months of data collection per trip to Saudi Arabia. Additionally, in the 4-month recruitment period there were 10 national holidays and the holy month of Ramadan, in which working hours decreased from 9 to 6 hours per day.

Despite the inability to recruit the proposed number of patients (n = 24), this study was successful in randomising those recruited (n = 16) into 2 groups (i.e. an MRI group and a non-MRI group Control group).

It is also notable that while the minimum permissible range of non-consent rate was not subjected to standardisation, 40% is certainly not acceptable (Bowling, 2014). The non-consent rate of 33% in the present study (n = 7), however, was acceptable, especially when compared to that in the available LBP literature (Pincus et al., 2015).

The risk of bias is regarded as considerable when the loss to follow-up exceeds 20% (Dumville et al., 2006). Hence, it is important to note that the lost to follow-up rate of the present study was 25% (n = 4). Despite the inability to discuss with the participants their reasons for withdrawing from the research, several contributing factors seem plausible. The sample was recruited from a Riyadh-based reference centre, so patients who were from other areas in Saudi Arabia

(especially rural areas) with limited access to physiotherapy might be unwilling to participate in the research as physiotherapy service is provided only in high level centres (secondary and tertiary) in Saudi Arabia. As for another possibility, we found that one participant considered the outcome measure booklet time-consuming and repetitive, and two patients refused to take part in this study because the booklet was lengthy, and finally, the lack of postal service communication in Saudi Arabia also prevented alternative options for pursuing the return of questionnaires, which were not completed at the end of PT intervention. One alternative way to overcome this limitation in postal service is the use of electronic communication by email or an online survey. However, this way might encounter some limitations in literacy generally and literacy in electronic communication.

Although few patients stated (in the process evaluation interview) their unwillingness to be allocated to the non-MRI group, the feasibility of randomising patients to the MRI group posed a number of problems. For instance, one patient participant suggested that CLBP patients are unlikely to forgo the chance to receive a concrete diagnosis for their condition by agreeing to participate in a randomised study. Another issue related to the non-uniform time periods between receiving an MRI scan and returning to the doctor. For the participants in this study this time period ranged from two to four weeks, so if the research were to be rolled out in several healthcare centres, larger sample sizes could adversely affect the time line of the study.

Furthermore, as an extension of the previous point, it is worth noting that the delay in the start of physiotherapy intervention in participants in the MRI group (compared to their counterparts in the non-MRI group) could introduce potential bias in the study findings. However, this is one consequence of routine scanning for people with LBP which is delaying physiotherapy treatment. Moreover, the unspecified nature of the treatment and education the patients in both groups undergo could affect the consistency and validity of the results. As highlighted in Chapter 3, an alternative strategy can be utilised by therapists when handling CLBP patients, particularly regarding the matter of education. On the one hand, some practitioners apply biopsychosocial approaches, whereas many therapists continue to implement biomedical education.

Screening prior to recruitment involved examination of patient files contained within the recruitment centre by one of the usual care team. Nevertheless, as mentioned previously, it is possible that patients received an MRI diagnosis at another healthcare centre, which is something the researcher would not have been able to control for or learn about. Data contamination is another critical concern, as highlighted by one of the patients, who stated that he was not concerned about being allocated to the non-MRI group having undergone numerous previous MRI exams. This point suggest further confirmation must be sought from the patient to ensure that no previous MRI imaging were done in any other hospital.

On comparative examination of the participants' baseline measures against the existing literature, disability scores were found to be consistent (Woby, 2007;

George and Beneciuk, 2015). However, initial work FABQ scores were significantly greater in the present study (by around 10%), which might be related to the limited sample size. On the other hand, one of the interesting results of the non-standardized questions highlighted that all patients in both groups agree that MRI scan is always needed to diagnose people with CLBP.

One of the limitations of the study was the absence of a formal technique for synthesising the qualitative and quantitative data. The reason for this is that ethical approval for the process evaluation was obtained later. Future studies should adopt a formal technique before the research is initiated (O'Cathain., et al 2010).

A subsidiary aim of this research was to carry out a power calculation to estimate appropriate values for a large-scale project. As noted by Hallberg and Richards (2015), there are several methods of power calculation to determine the sample size, but the present study's small sample, along with the high dropout rate, do not warrant a power calculation (Kraemer, 2006; Thabane, 2010). Nevertheless, it is plausible to draw on comparable studies that had a larger sample size (Bowling, 2014). The Roland Morris Disability Questionnaire RMDQ is one of the primary outcome measures used in this study and has been used in previous research to calculate the mean baseline and the minimal clinically important change required for calculating the sample size (Little,2008; Chiarotto,2016; George and Beneciuk, 2015). Using this measure, a sample of (n=136) in each arm would have 90% power to detect a difference in means of 2.5 points in RMDQ scores between the MRI and non-MRI groups. Assuming a

mean of 9.7 in non-MRI group and standard deviation of 5.6 point with 0.05 two-sided significant level. The sample size would need to be inflated 25% to account for the loss of follow up. Therefore, 340 participants with CLBP would be required. Based on this feasibility study and allowing 12 months for recruitment, would require at least seven centres with spine clinics to screen approximately 2,709 people with CLBP for eligibility.

The findings of this feasibility and process evaluation study provide valuable insights for researchers planning to conduct a clinical trial in chronic lower back pain treatment in Saudi Arabia. This feasibility study has unpacked some of the potential barriers that exist to conducting a large-scale RCT in Saudi Arabia. Furthermore, the consent rate suggests the feasibility of randomizing patients, which might suggest that offering physiotherapy alone at the spine clinic (as an alternative to spine surgery consultation), is plausible. Interestingly, from the qualitative data neither of the doctor participants suggested that the design would not work for them, but both expressed doubts about patients' acceptance of the design. When linking the above opinion about the design to the qualitative interviews presented in the previous chapter (Chapter Three) the same doctor has emphasised the role of physiotherapy treatment as a cornerstone of treatment in CLBP management.

'*Physical therapy and primary healthcare providers are very important cornerstones in the treatment of chronic back pain.' Dr.4*

Furthermore, it was suggested that referrals to the spine clinic might be mitigated for LBP patients if they received physiotherapy as part of their primary care.

'Seventy percent of the cases that we see here could be treated by family doctors and physiotherapy.' Dr. 2

It might seem that doctors are supportive of recommending physiotherapy alone as a primary treatment for LBP; however, they are only concerned with patients' satisfaction.

Furthermore, a larger cohort study may be needed initially to examine the feasibility and acceptability (to healthcare organisations, healthcare practitioners and patients) of providing early physiotherapy as an alternative to spine surgery consultation for CLBP patients.

On reflection, since MRI scanning is practiced almost routinely, as discussed in (Chapter Three), it may have been more logical to consider having a routine MRI as the control arm and providing early physiotherapy as an intervention arm, shifting the design of the RCT from that of a non-inferiority RCT to that of a superiority RCT. Therefore, a future study should consider this design. While many of the challenges identified in this feasibility study, in terms of infrastructure and resources may remain, and while the introduction of early physiotherapy would require a cultural shift on the part of the healthcare practitioners and provider organisations and potentially pose some implementation issues, it may prove more acceptable to potential participants and offer a more evidence based intervention more akin to existing clinical guidelines in the UK and elsewhere (NICE, 2016; Stochkendahl, 2018). This shift would require the objective of the large scale RCT to be modified to match the new design, aiming to answer the question of whether providing

physiotherapy as an alternative to spine surgery consultation will result in better physical and psychosocial outcomes for patients with CLBP in Saudi Arabia?

4.6. Conclusion

A definitive trial for the present study would invariably be faced with the following obstacles: time limitations, the need to find a greater number of recruitment centres, the need to employ a research assistant, and, in view of the previous point, the need for substantial funding. Additionally, as one patient participant voiced, randomisation might be less acceptable as an MRI scan is imperative for diagnosis of CLBP in Saudi Arabia. The estimated sample size required for large scale RCT is 340 participants with CLBP to be randomly allocated into early physiotherapy treatment vs usual spinal consultation.

4.7. Proposed logic model for decreasing the MRI rate of CLBP in Saudi Arabia

Frechtling (2007) described logic modelling as a practical way to represent theoretical data by presenting graphical/textual information on how a programme might work. Ideally, the development of a logic model will incorporate critical thinking by all the targeted stakeholders, or ‘resources’. In addition, a logic model is highly dynamic by nature and can be enhanced at any stage of its implementation (Frechtling, 2007). The following logic model is based mainly on a strategy for reducing MRI rates that was implemented successfully in the Saskatchewan Spine Pathway, Canada (Kindrachuk et al., 2014).

The problem:

Based on the findings of the qualitative study, healthcare practitioners raised concerns about the over-utilisation of MRIs for patients with LBP. It was also suggested that scanning was performed routinely for most LBP patients in secondary care centres. Routine use of MRIs can cause patients to feel dependent on their radiological diagnoses and request follow up MRI scanning for monitoring and surveillance. The current practice of over-utilisation of the service has been suggested to increase the direct per patient costs in a number of studies. (Fritz, 2012; Maeng , 2017). When compared to having early physiotherapy, having physiotherapy as early as possible is associated with better patient outcomes and greater satisfaction (Nordeman, 2006; Lau, 2008; Fritz, 2012; Maeng, 2017; Bianca, 2018). Moreover, the cost of care has been documented to decrease (Fritz, 2012; Maeng, 2017; Bianca, 2018; Samsson, 2015; Frogner, 2018).

Context:

The current MSK care pathway in Saudi Arabia as described in (Chapter one) indicates that LBP patients are referred to secondary care spine clinics in Saudi Arabia mainly from primary care centres. Patients in primary care have no physiotherapy intervention due to the lack of the services at the primary care level and the fact that services in secondary care are referral based.

The suggested program will be implemented as a pilot in one spine clinic. It should be noted that some potential challenges should be considered before the implementation of this programme. Firstly, as this is the first programme to

address this issue in Saudi Arabia and will require a qualified physiotherapist to implement, this might impose staff shortages in the physiotherapy department in the secondary care centre where the study will be implemented. Secondly, there is a need to authorise physiotherapists working in spine clinics with privileges to refer patients to different specialities, which might face administrative resistance due to inexistence of this privilege before.

Evidence-based intervention:

Implementation of physiotherapy as a first option in spine clinics showed promising results in the Saskatchewan Spine Pathway, Canada (Kindrachuk et al., 2014). The results suggested a marked decrease in MRI referral and reduced waiting time to see the spine surgeon for patient candidates for surgery. Correspondingly, another successful Canadian implementation programme showed similar results while maintaining 97% patent satisfaction (Rampersaud, 2014; Zarrabian, 2017). Both of these implementation programs yielded a marked reduction in the cost of care for LBP patients.

Therefore it is proposed to implement an adapted form of the Saskatchewan Spine Pathway as described below.

Goals & Objectives:

Goals:

- Decrease the rate of MRI referral.
- Promote accessibility to spine and physiotherapy services.
- Achieve a greater level of satisfaction from patients and staff.

Process Objectives:

- All musculoskeletal (MSK) physiotherapists will complete training in screening for risk factors of serious pathology that require referral to other service and in screening for risk of psychosocial factors.
- Trained physiotherapists will have the software training required to make referrals using the electronic referral system.
- Trained physiotherapists and spine surgeons will complete additional training in the biopsychosocial model, multidisciplinary team work communication.
- After completing the aforementioned training, patients visiting the spine clinic will first be seen by a trained physiotherapist. From there, they will be triaged as either candidates for spine surgeon consultation or not. Surgery candidates will be referred to a spine surgeon consultation, and the remaining patients will be screened for psychosocial risk factors using the STarT Back Screening Tool and subsequently referred to the appropriate service (i.e. physiotherapy or psychologically informed physiotherapy intervention)
- Prior to referral to the physiotherapy outpatient department, all patients will be educated on how to manage their back pain and on the importance of staying active by the screening physiotherapist. In addition, those identified as high or medium risk according to STarT Back will receive psychosocial support in the form of combined physical and psychological therapy provided in physiotherapy department.

Outcome Objectives:

The target number is estimated based on Canadian implementation studies (Kindrachuk, 2014;Rampersaud, 2014; Zarrabian, 2017).

- By the end of the pilot (6 months), 25% reduction in MRI referral
- By the end of the pilot (6 months), waiting time to see Spine Surgery to decrease to 21 days.
- By the end of the pilot (6 months), accessibility to physiotherapy intervention to decrease to 21 days.
- By the end of the pilot (6 months), 90% satisfaction of patients about the clinic.

Target Population:

The target population in the program is people with LBP referred from primary care centers to the spine surgery clinic in King Fahad Medical City (Secondary Care Centre) in Riyadh-Saudi Arabia.

Description of Strategies and Activities:

The overall aim of this program is to decrease the cost associated with overutilisation of MRI services and promote rapid access to physiotherapy and spine surgery services whilst maintaining good patient satisfaction levels (Table .15).

First Strategy; to provide training for MSK physiotherapist screening in the identification of candidates for surgery, other medical services and rapid physiotherapy.

This step is a cornerstone in the program, as early identification of surgery candidates could serve in reducing waiting times to see the surgeon. Moreover, early physiotherapy referral has been found to increase several patient outcomes.

The suggested method of testing this strategy is by surveying MSK physiotherapists before and after the training. The survey will include clinical scenarios of LBP patients and ask questions about appropriate decisions to make as a ‘first point of contact physiotherapist’. Additionally, focus groups or individual interviews with the trainees will explore what additional training is required and what obstacles the ‘first point of contact physiotherapist’ screener might face.

Second Strategy: To provide training for MSK physiotherapists and spine surgeons regarding the biopsychosocial model, multidisciplinary team work and communication.

Without adequate communication and a shared understanding of the program’s purpose and potential outcomes, in terms of patient benefit including better access to appropriate services and decreased work load on other healthcare workers the program might fail.

Similar methods of testing could be implemented to measure the awareness of trainees about the need for multidisciplinary team work and good interdisciplinary communication.

Third Strategy: To provide training for MSK physiotherapists and spine surgeons on best practice recommendations for educating LBP patients as recommended by evidence-based guidelines.

Each patient visiting the clinic will have a unified education based on the guideline recommendation delivered by the screening physiotherapist.

Organization:

The suggested program will initially be implemented in the Spine Surgery Clinic in King Fahad Medical City. Following successful implementation, the results will be presented to the higher authority of the Ministry of Health (MOH) to seek implementation of this program in all secondary care hospitals in Riyadh within one year and around Sound Arabia within three years.

Partners and Stakeholders:

For this program to be successful, it is essential for the physiotherapy department to work in partnership with the spine clinic. Joint stakeholder engagement is crucial for planning the implementation, arranging the education and staffing.

Initial evaluation:

Rationale:

A formative evaluation is necessary to collect baseline data for comparison of impact measured later in the evaluation process.

Methods and indicators:

Before the program starts, it is important to clearly identify how many physical therapists will be working in the screening clinic based on the number of patients the clinic sees per day and the number of days/ hours the clinic runs. This step will determine the staffing needs from the physiotherapy department.

It is also important to retrieve the previous 6 months' records from the spine clinic on the following indicators for comparison purpose.

- Percentage of patients referred to spine surgery.
- Percentage of patients referred to other specialities.
- Percentage of patients referred to physiotherapy.
- Percentage of patients referred to MRI.

Additionally, the cost of care associated with LBP with regards to health services utilisation, mainly for MRI scans, medication and medical visits will be collected for the previous 6 months for economic evaluation after the program.

Process Evaluation:

Rationale:

A process evaluation will be necessary to assess whether the activity outputs outlined in the logic model are contributing to the goals. Program monitoring and collection of activity outputs will take place throughout the program. Indicators will be used to monitor achievability of outcomes.

Methods and indicators:

One way of examining how the training provided to MSK physiotherapists is reflected in their practice is by surveying the therapist with the clinical scenarios adapted from the training received and measure their awareness.

The following indictors will be used to ensure the practice of screening in spine clinic is taking place:

- Percentage of patients referred to spine surgery.
- Percentage of patients referred to other specialities.
- Percentage of patients referred to physiotherapy.
- Percentage of patients referred to MRI.
- Satisfaction level of the patient.

Impact Evaluation:

The overall impact of implementing these improvements will be reflected in the cost of care. A separate economic evaluation of the costs for MRI, medication and medical visits will be compare before and after the program.

Table 15 Logic Model Process

Resources	Actions	Output	Outcome	Impact
• Hospital administration. • Spine surgeons. • Physiotherapists. • Physiotherapists trained in	• Limit referrals for MRIs for back pain to the spine clinic unless specific pathology is suspected.	• Early identification of patients who need further services All patients attending spine clinics screened for	• 25% fewer LBP referrals for MRI. • More appropriate MRI referrals • More appropriate Physiotherapy referrals	• Reduction in the direct cost of care associated with LBP.

electronic referral systems • Physiotherapy/ spine clinic stakeholder implementation group	• Train physiotherapists in red-flag identification and STarT Back screening. • Train Physiotherapists and spine surgeons in biopsychosocial model, multi-disciplinary team working and good communication. • Patients triaged by physiotherapist for spine surgeon referral or physiotherapy only. • First point of contact physiotherapist' screeners refer to different specialities. • Medium and high-risk patients receive both physical and psychologically informed physiotherapy.	psychosocial risk factors using STarT back tool. • All patients educated about back pain and self-management. • Specialty referrals triaged according to risk. • Improved team communication • Multidisciplinary working • Team approach to rehabilitation adopting biopsychosocial model	• Reduced waiting time to access physiotherapy (≤ to 21 days) • Greater patient satisfaction with services • Reduced waiting time to see spine surgeon (≤ 21 days) • Increased patient confidence in self-management of LBP? • Increased staff (PT and spine clinic staff) satisfaction • Promote evidence-based practice • Increased confidence in clinical decision making (PT and spine surgeon)	• More efficient use of secondary care services • More people in work and fewer days lost to sickness absence?

Chapter Five

Discussion

5.1. Introduction and overview of the thesis

This chapter will discuss the key findings of the component studies of the entire thesis. It will also discuss the limitations, the implications for future research, the clinical implications and the policy implications of the project. Subsequently, the conclusion will be provided.

5.2. Key findings

The key findings of each study are presented separately below.

Systematic review

Primary aim:

To identify the psychosocial factors associated with changes in pain and disability outcomes in CLBP patients treated by a physiotherapist

Key finding:

This study found evidence of a predictive association between psychosocial factors fear avoidance, self-efficacy and catastrophising and disability outcomes in CLBP patients following physiotherapy treatment. These factors were less likely to predict pain severity outcomes following physiotherapy intervention.

Qualitative interviews

Primary aim:

To explore the psychosocial factors associated with MRI diagnosis in people with NS-CLBP

Key findings:

Fear of movement and anxiety were reported to be the main psychosocial consequences of receiving the diagnosis of LBP with MRI. This impacted on daily living, social and work life activities.

These outcomes were influenced by the way LBP is managed in the Saudi healthcare system and patient demand for MRI scans as an explanation for their pain.

Delays in referrals for further specialist investigations or rehabilitation may promote chronicity and negativity influence health and participation outcomes.

There is a lack of shared philosophy within and between healthcare practitioners and services in the way LBP is managed and in how patient-education is delivered.

The study emphasised the need for better coordination and communication between different healthcare levels and services and early management of CLBP patients in primary care in Saudi Arabia.

It highlighted the importance of and need for national and local clinical guidelines specifically tailored for Saudi patients and healthcare practitioners.

Feasibility RCT and process evaluation

Primary aim:

To determine the feasibility of a definitive trial concerning the impact of MRI diagnosis on psychosocial, pain and disability outcomes in people with CLBP treated with physiotherapy by randomising patients to receive an MRI diagnosis

(intervention) plus physiotherapy rehabilitation or physiotherapy alone (Non-MRI/control group).

Key finding:

Although it was feasible to randomise patients to receive physiotherapy alone the recruitment target was not achieved: 16/24 participants were recruited in 4 months (12.4% of those screened); 33% declined. The process evaluation identified a number of key factors that may negatively affect a full trial: These were research resources, including limited availability of physicians' time for research, lack of research infrastructure e.g. to support recruitment to trials and limited research capacity in terms of the knowledge and skills of the healthcare team and limited funding. Interviews with five participants from both groups and physicians raised concerns about the acceptability and feasibility of randomly allocating patients to non-MRI group.

5.3. **Discussion of key findings**

This doctoral research project was carried out following the MRC framework for complex interventions and investigated the psychosocial characteristics associated with the MRI diagnosis of NS-CLBP patients. From the results presented in Chapter 2 (i.e. the systematic review), it is apparent that a predictive relationship is present between catastrophising, fear avoidance, self-efficacy and disability and the level of pain experienced after physiotherapy treatment. It is evident that in terms of the prevalence of chronic low back pain, the influence of biomechanical factors is not as great as for psychosocial characteristics. This finding is consistent with the conclusions of Kamper et al.

(2014), Koes et al. (2010), Van Tulder et al. (2006) and Waddell and Burton (2001).

Psychosocial factors can be used to anticipate poor treatment outcomes (George, 2015; Pincus, 2010), thereby posing a problem for physiotherapists. People with CLBP who exhibit these psychosocial factors are more likely to become disabled, but little is known about this association. In a cohort study conducted in the UK consisting of 531 candidates, 15% of the variance observed in pain severity was associated with pain-related anxiety, while anxiety accounted for 28% of the variance in disability (Campbell et al., 2013). Self-efficacy, fear, and psychological anxiety were identified, through a systematic analysis and 12 mediation studies, as significant factors that affect the development of neck and back pain and, ultimately, disability (Lee et al., 2015). Self-efficacy is a strong determinant as evidenced by a systematic analysis of 83 studies of chronic pain disorders (15616 candidates, 23 LBP studies) and identified as consistently related to pain severity, affective anxiety, and disability (Jackson et al., 2014). In effect, some current treatments used to manage chronic pain now focus on behavioural change rather than relieving pain, which was the traditional focus (Frost, 1995; NICE, 2016; Stochkendahl, 2018).

Anxiety was a common psychosocial characteristic highlighted by participants belonging to all three groups (i.e. patients, physiotherapists, and doctors), and the identified psychosocial factors are in line with the FAM. When applied to chronic musculoskeletal pain, this model defines how the fear of pain causes

patients to avoid some physical activities and expose themselves to disability, which has been exhaustively demonstrated (Vlaeyen and Linton, 2000; Leeuw, 2007). Recently, the model has been diversified to include the impact that maladaptive learning processes and self-limiting beliefs have on behaviour and pain perception. Researchers and clinicians now understand that pain cognition can have a greater effect on the occurrence and management of disability than the pain itself (Crombez et al., 2013). MRI could detect a condition that may not have been the principal cause of pain, such as lumber disc prolapse, and this does not necessarily need treatment (Nakashima et al., 2015). This increases patients' fear and anxiety, and they may even be intimated by the complex terms medical practitioners use when discussing MRI findings with them.

The qualitative interviews carried out for this project suggest a mismatch in healthcare delivery for people with LBP in general, more so in the over-utilisation of resources at the secondary care level for conditions that otherwise should have been handled in primary care. Furthermore, international guidelines recommend managing CLBP at the primary level (NICE, 2016; Stochkendahl, 2018). Respondent doctors and physiotherapists concurred with this recommendation and stated that the early treatment of CLBP is cost-effective and minimises the workload in secondary care.

However, patients demand for MRI and preference for where they receive treatment might contribute to the over-utilisation of resources at the secondary care level. In the current study of a medical centre in Saudi Arabia, doctors and physiotherapist respondents stated that inadequate access to medical services

and insufficient number of doctors may reduce LBP patients' trust in primary care. Moreover, indefinite pathways of care and diversity in the types of patient education provided by doctors and physiotherapists may also result in the under-utilisation of LBP facilities at the primary level in the current Saudi Arabian healthcare system. LBP patients in most industrialised countries prefer to control back pain through medical consultation or emergency treatment. In an analysis of 21 studies on chronic pain in 12 countries, most patients go to the emergency department of a medical facility to manage their LBP (Edwards et al., 2017). The authors estimated the that the incidence of LBP in ER departments is 4.39% (95% CI 3·67–5·18), which is close to the incidence of fever, shortness of breath, and chills (Edwards et al., 2017). However, no distinct reason has been identified to explain why patients with LBP tend to overlook primary care.

Moreover, respondent doctors at the secondary level of care further suggested that the ineffective utilisation of primary healthcare resources resulted in longer waiting periods for patient consultations. The higher chronicity of LBP, in turn, is relative to a prolonged consultation period (Macfarlane et al., 1999; Crook et al., 2002), which may cause work absenteeism and reduce a patient's productivity (Crook et al., 2002). The effects of improperly utilising healthcare resources are far-reaching, and over time, they might result in significant socioeconomic challenges.

The lack of physiotherapy services at the primary level was a primary concern raised by all the groups interviewed in this study. Furthermore, the healthcare

practitioner respondents proposed that physiotherapy should be the initial service offered to individuals with CLBP.

Providing physiotherapy to CLBP patients is an important component of effective primary care (Stochkendahl et al., 2018; NICE, 2016). The qualitative review suggested that physiotherapy provided in primary care could minimise the treatment period and resources required in secondary care. Empirical evidence demonstrates that physiotherapists are better equipped to extend effective managed care in primary care to patients experiencing musculoskeletal conditions in different countries (Holdsworth and Webster, 2004; Ludvigsson and Enthoven, 2012; Goodwin and Hendrick, 2016). Moreover, physiotherapy interventions have been shown to achieve high levels of satisfaction in LBP patients in primary care (Webster et al., 2008; Goodwin and Hendrick, 2016). However, no studies have been conducted on the patients' response to physiotherapy as the first point of contact in Saudi Arabia. Nor are there any published studies on the competency of current physiotherapists in managing musculoskeletal patients as the first point of healthcare contact in Saudi Arabia.

Healthcare professionals continue to request radiology scans to assist in the diagnosis of CLBP (Jenkins, 2015; Bishop, 2015) despite international guidelines discouraging the use of MRI for this purpose (Hartvigsen, 2018; Koes, 2010; Van Tulder, 2006; Waddell and Burton, 2001). The qualitative interviews in the current study were conducted in one health facility in Saudi Arabia and indicated the absence of both regional and national clinical

recommendations for CLBP patients, raising concerns regarding whether international guidelines have been applied in the country's other healthcare centres. This study focused on identifying factors that cause over-reliance on MRI as a diagnostic tool for CLBP patients. The study determined that a need for visual confirmation, and in some cases, the patient's preference, resulted in an increased rate of using this imaging technique among doctors in Saudi Arabia. A study conducted by McPhillips-Tangum et al. (1998) revealed that a significant number of CLBP patients emphatically demand MRI imaging and recurrent clinical visits, an attribute that was evident in one centre in Saudi Arabia's healthcare system. Healthcare practitioners reported that CLBP patients in Saudi Arabia request MRI imaging and make clinical visits as often as monthly to manage the condition, which also explains the over-utilisation of MRI imaging for CLBP. Most CLBP patients seem convinced that MRI imaging is essential for an accurate diagnosis (Jenkins et al., 2016), a result similar to the findings of Espeland and Baerheim (2003) who had previously proposed that patients' persistence in requesting diagnostic imaging is a key factor in physicians ordering unnecessary MRIs. However, this persistence is common among patients who have physical complaints classified as non-specific.

Patients pursue a justifiable reason for their pain, and when the only reason put forward is biomedical, they are more inclined to accept it (Serbic and Pincus, 2014; Bunzli, 2015). However, one limitation of MRI imaging is its provision of irrelevant results that patients may regard as consequential and this may heighten their anxiety levels. For example, a positive MRI result of a herniated disk is common in asymptomatic patients (Herzog, 2017; Wassenaar, 2012). A

patient may not, however, understand that this type of anomaly is common and view it an additional cause for distress. The qualitative interview study showed how patients relate the improvement in their condition to what they can see on the MRI scan

To determine the feasibility of recruitment in the feasibility study conducted, I set a minimum recruitment target of 24 participants. However, I was only able to recruit and randomise 16 participants. This failure can be attributed to two main reasons. Firstly. despite setting out to recruit from two centre, we recruited patients from only one centre, and the duration of the recruitment period was limited by funding restrictions imposed on students studying overseas by the Saudi Government. The attempt to use a second recruitment centre a private hospital, was unsuccessful for policy reasons. The recruitment period was limited to four months (April to the end of July 2017) during which there were 10 national holidays and the holy month of Ramadan.

Despite falling short of the targeted sample size (n = 24), 16 participants were successfully recruited and randomised into two groups: MRI group and non-MRI group. As noted in the process evaluation phase, the study faced several setbacks. Interviews with participants voiced concern about the acceptability of being allocated to a Non-MRI group. One participant saw this as relinquishing a chance to fully access healthcare resources at the centre in Riyadh since these resources may not be present in their local healthcare facilities. These patients felt that by being included in the non-MRI group, their CLBP condition would remain undiagnosed.

A loss to follow-up ratio surpassing 20% is considered a statistically significant risk of bias in the results (Dumville et al., 2006). It is therefore critical to note that the lost to follow-up ratio in this survey was 25% (n = 4). No attempt was made to understand the reasons for this loss of for participants who opted out to justify their choice. However, some factors might be responsible for loss of follow up. The choice of a Riyadh referral hospital is one such factor. Most patients visiting this facility would have initially visited another medical centre, probably one that is rural and lacks the necessary physiotherapy facilities. Such patients might find it difficult to participate in the study. Some patients may have found completing the outcome assessment booklet too difficult, for reasons of literacy or too tedious and time-consuming, thereby causing their withdrawal. The absence of communication amenities in the Saudi Arabian postal system, i.e. not enough post offices in rural areas, may have also contributed to their unwillingness to participate. These factors remain to be understood in a future study.

The feasibility of randomising patients into the MRI group was subject to several challenges. One relevant problem is the irregular time interval between undergoing MRI imaging and the subsequent clinical visit. Candidates in the sample identified the period to be within two to four weeks, a span that could be even greater if the study was conducted using a larger sample.

Moreover, it is important to note that the frequency of rescheduled physiotherapy interventions for individuals in the MRI category when compared to the non-MRI patients could result in biased results. The physiotherapy

interventions were also indeterminate, an aspect that could affect the rationality and consistency of the model. Chapter 3 describes auxiliary approaches that could be used by therapists in the diagnosis of CLBP patients, especially by providing the patient with relevant educational information. Some therapists use biopsychosocial methods, but a greater number provide biomedical educational information.

The medical records of prospective participants were reviewed before they were selected for inclusion in the sample. As previously mentioned, the researcher was unaware of whether the patients had undergone an MRI exam at another facility prior to recruitment. The integrity of the data collected may have been compromised, as observed when a patient expressed his lack of concern should he be included in the non-MRI group, as he had already been subjected to numerous MRI exams for his back. A future study would need to exclude such people, thus reducing the recruitment pool.

In summary, the feasibility study highlighted a number of issues that would affect the success of a definitive trial in Saudi Arabia. The drawbacks in research infra-structure and research capacity; policy, which prevents, research in private hospitals in Saudi Arabia and a major limitation: patients' choice. Patients are free to choose from various healthcare services and could switch between private and government hospitals and thus between arms of the trial, seeking scans or interventions that may influence the outcome of interest. Furthermore, the patients' recovery process could be catered to within a recruiting centre. Such nonlinear practices might be due to the lack of unified

guidelines pertaining to healthcare and the lack of a shared philosophy among different members of the healthcare team. In conclusion, although it was feasible to recruit and randomise patients into two groups these challenges would make it impractical to progress to large scale RCT.

5.4. **Limitations**

While this is the first project to explore how healthcare in Saudi Arabia is managing CLBP and to highlight the psychosocial consequences of using an MRI to diagnose CLBP patients, the project has several limitations that should be considered.

Most notably, data were obtained from a single, albeit large, governmental centre in Saudi Arabia, which could be considered a limitation for generalisation of the results to the general Saudi population. Nevertheless, individuals based in different parts of the country are referred to the hospital, given its status as a secondary healthcare centre. However, it would still have been beneficial to obtain data from a variety of governmental centres to increase accuracy and representation. There were also time constraints on the data collection process because the sponsor allocated a short, fixed amount of time to conduct the study.

5.5. **Policy implications**

At the beginning of 2016, the Saudi government announced Vision 2030, which focuses on the development of the country and its citizens. One of the

commitments of Vision 2030 was the promotion of physical and psychosocial well-being.

The impact of routinely scanning people with CLBP using MRIs might lead to a public health problem, affecting individuals with chronic back pain, their work, their families, and society. Although it could not be generalised to the whole country, the need for clinical guidelines and pathways of CLBP management in Saudi Arabia was voiced by multiple healthcare respondents in our qualitative interviews.

Multiple publications suggest that having clinical guidelines is ineffective unless implementation strategies are developed for them (Williams, 2010; Deyo, 2009). Some countries have focused on and implemented effective guidelines in CLBP management. In Denmark, Canada, and the UK, clinical practice has been improved by the implementation of guidelines that assist practitioners by providing informed decision criteria. Such an implementation policy was introduced in Denmark. This implementation sought to assess GPs' adherence to key performance indicators (KPI) driven by the clinical guidelines, as compared to their usual care. The KPIs included referral to a specialist, referral for imaging, screening for psychosocial risk factors and referral for psychosocial consultation (Riis, 2016; Jensen, 2017).

All the GPs on the implementation side received continued medical education (CME), and there was an emphasis on patient-physician communication and on communication between the disciplines (GPs, physiotherapists and occupational consultants).

The aim was to reduce referral to medical specialists, decrease the rate of referrals for imaging and increase the practice of psychosocial screening. After the CME initiative, each healthcare practitioner received a reminder of the key messages by email every three months for one year.

This education was supported by online educational resources on forums, Twitter and Facebook, which contained information about back pain, as well as clinical management guidelines.

On the implementation side, patients with low back pain had the ability to access online tests and video data aimed at changing their beliefs regarding back pain and emphasising the importance of staying active and self-management. This implementation strategy enabled Denmark to use primary care resources first, therefore minimising the use of secondary care resources, and the number of patients referred to the secondary level decreased substantially (Riis, 2016; Jensen, 2017).

In addition to the previously discussed (Chapter 3) ISAEC clinical pathway of management of LBP in Toronto, Canada, one upcoming pathway is the Saskatchewan Spine Pathway of Canada (Kindrachuk et al., 2014). Patients were referred to Saskatchewan Spine Clinic (SSC) from primary healthcare centres and triaged into two groups. The first group of patients received education, self-management instructions and/or physiotherapy, and were then followed up as required by a physiotherapist and not a spine surgeon.

The second group included patients more likely to benefit from surgical intervention, either during the first visit to SSC (due to red flag status) or after failure of conservative treatment.

The key indicators for the above implementation included pain, disability outcome measures and MRI utilisation. This approach is multifaceted and has been found to minimise patients' insistence on MRI imaging. The number of patients being referred to spine surgery also significantly reduced. The model also enabled an efficient referral system; only patients that required spinal surgery were referred to spine surgeons (Kindrachuk et al., 2014).

The latest successful example of effective implementation is the national clinical pathways for the diagnosis of radicular pain and LBP in the UK, which was introduced by NHS England in June 2014 and amended in February 2017 (NHS, 2014; England National Pathfinder Projects). Thirty relevant stakeholders consented to the strategy, which is gradually being introduced in the country's Clinical Commissioning Groups, each managing about 300,000 individuals. The groups are members of the NHS and regulate the distribution of NHS services throughout England. The initial pathway emphasises early identification of red flags and appropriate referral to a specialist at first contact in primary care, either via triage or via treatment by a practitioner with a nursing or physiotherapy background, who will act as the single point of contact for patients throughout this pathway. Patients are provided with appropriate education and self-management instructions if there is no red flag identified, and they are then be referred for the appropriate treatment option based on

SBST. The main aims of this pathway are as follows: early identification and referral of patients with red flag status; rapid identification of patients who might benefit from surgery; quick and easy access to evidence-based conservative management; and selective referral of patients who might benefit from a combined physical and psychological programme. This pathway has been found to yield positive results in decreasing unnecessary procedures and accelerating access for patients in need of further investigation (Lingard, 2016)

In conclusion, adaptation of existing and successfully implemented clinical pathways of care in Saudi Arabia could save time and resources for developing a new clinical pathway for people presenting with LBP. It is evident, however, that replicating policies over time increases their efficacy in the diagnosis and management of CLBP (Suman, 2015; Mesner, 2016). The major challenges is to recognise the unproductive strategies that are in place, eradicate them, and introduce newer, more efficient policies that are also more productive in the long-term utilisation of resources. However, other key challenge to be addressed are the lack of public awareness of factors pertaining to the development of CLBP and the influence of patient choice. These issues need to be addressed beyond the healthcare setting by amendments in public policy and public health awareness campaigns.

5.6. **Implications for future research**

While the feasibility RCT and process evaluation indicate that conducting a definitive RCT is not practical, further areas for research have been identified in this project. One of the qualitative interview findings is the patients' demand for

MRI exam. However, the doctors who participated in the interviews all practiced in one hospital. Hence, it is not possible to ascertain whether this is a national issue or limited to a single hospital. Therefore, the scope of the research could be expanded by interviewing more doctors from other hospitals. If these data could be obtained, it would increase the representativeness of the views of the patients and validate the findings of the current study.

Qualitative studies have shown that there is a need for early physiotherapy intervention. If physiotherapy is provided first to patients, it would reduce the workload at the higher levels of care as well as decrease the associated costs. However, this statement has no supporting evidence that specifically applies to Saudi Arabia since no research has been conducted on the cost implications of CLBP management in this country. Presently, there are no studies related to whether LBP patients are willing to undergo a physiotherapy session prior to other medical care.

There are inconclusive associations linking the psychosocial factors mentioned in this study to the use of diagnostic MRIs. Therefore, it could be beneficial to focus on the correlation between the psychosocial factors mentioned in this study and using MRI as the primary diagnostic tool, which could strengthen the data obtained in this study. Currently, a causal effect cannot be ascertained since there is no evidence.

The awareness of patient education for CLBP and chronic pain, in general, is worth investigating. The study highlights a variation in the type of patient education. Assessing healthcare practitioners' awareness of chronic pain

education and identifying the barriers to delivering evidence-based patient education concerning chronic pain conditions would be worthwhile. The level of awareness of current healthcare practitioners regarding the role of clinical guidelines is also worth investigating. Our data showed that such guidelines are acknowledged as an important factor in assuring quality; however, it should be noted that the data were obtained from one centre and cannot be generalised throughout Saudi Arabia. Furthermore, there is no evidence regarding whether medical and health science students are aware of the importance of clinical guidelines for LBP management.

5.7. **Clinical implications**

The findings from this doctoral programme of research have a number of clinical implications. First, findings from the qualitative interviews highlighted the need to initiate physiotherapy interventions as the first line of treatment. Despite having no supporting evidence on patients' acceptance or physiotherapist competency, this finding might support the initiation of physiotherapy services in primary care. Second, the study has also found an urgent need for guidelines in managing CLBP patients within the healthcare system in Saudi Arabia. Third, the systematic review determined the factors that are related to pain and disability among patients who have undergone physiotherapy sessions. This may guide physiotherapists in screening for psychosocial factors prior to initiating usual care.

5.8. **Conclusion**

No prior research has focused on the psychosocial impact of MRI use in the diagnosis of CLBP. This project highlighted a possible association between fear and anxiety in patients with CLBP after they receive a diagnostic MRI.

Due to the consistent findings by various studies of psychosocial factors including catastrophising, depression, fear of movement and self-efficacy, to be effective predictors of disability outcomes, regardless of the form of physiotherapy intervention, indicates these factors out to be included in future CLBP physiotherapy screening.

The qualitative interview of both people with CLBP and healthcare practitioner suggest an elevated fear and anxiety as a consequence of MRI diagnosis. Moreover, the interview data suggest a variation in the education of CLBP patients and the lack of local or national clinical guidelines for LBP management.

Given the parameters of the feasibility study, the sample size required for a large-scale RCT study is n=340, which will require recruiting from at least seven centres with spine clinic services. The need for more recruiting centres, lack of assistant researchers and lack of sufficient funding and infrastructure for research are the main barriers to the completion of a definitive RCT study. Additionally, the patient and physician participants' process evaluation interviews highlighted that patients may question their diagnoses if they were allocated to the non-MRI group, raising genuine concerns about acceptability and a risk of contamination. Therefore, recruiting and randomising the patients

into groups may be feasible but the presence of above barriers will make it impractical.

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Appendix 1

Patient Participant Information Sheet

Final version:02

16.07.2016

Title of Study: **The Relationship between MRI Diagnosis and Psychosocial Factors in Physiotherapy Treated Chronic Non-Specific Low Back Patients**

Study ID – Psychosocial-Factors

Name of Researcher(s): **Mr. Ahmed Alhowimel, Dr. Kate Radford, Dr. Neil Coulson**

We invite you to participate in an interview as part of a research study. Before you agree to do so, we would like you to understand why the research is being performed and what your participation would involve. Please take the time to read the following information carefully and talk to others about the study if you wish. A member of our team will review this information sheet with you and answer any questions you might have. If any details about the study are not clear to you, or if you would like more information, please let us know. We can be contacted using the telephone numbers listed at the end of this sheet.

What is the purpose of the study?

This study aims to explore the psychosocial changes in chronic low back pain patients after being diagnosed with MRI. This research specifically aims to explore the experiences of people with chronic lower back pain living in Saudi Arabia. We wish to identify and explore the psychosocial and functional factors associated with MRI diagnosis in people with chronic lower back pain following

physical therapy interventions, from the point of view of the people with chronic lower back pain following physical therapy interventions

We hope that physiotherapists, orthopaedic surgeons, and other healthcare professionals will thus benefit from a greater understanding of how to help in the recovery of people like yourself who have experienced chronic lower back pain.

In the longer term, we hope that the findings from this study can lead to better pathways of care for people with chronic lower back pain and assist in the development of appropriate guidelines for the management of chronic LBP in Saudi Arabia.

Why have I been invited to participate?

We are inviting you to take part in a one to one interview because you have previously undergone a MRI scan for your chronic lower back pain. The aim of the focus group discussion will be to explore the view of chronic low back pain patients of the psychological and social changes appeared after being diagnosed with MRI. We are inviting approximately 8-10 participants like you to participate in this study.

Do I have to take part?

It is up to you to decide whether you wish to participate in this study or not, and you should take some time to consider your decision. If you do decide to participate, we require that you sign a consent form and return it to Mr. Ahmed Alhowimel at the address provided below. You will also retain a copy of the consent form to keep along with this information sheet. You are free to withdraw from the study at any time, without providing a reason.

What will happen if I agree to participate?

If you wish to take part in this study, you will be contacted by telephone and a time will be arranged for the interview. We will do our best to arrange a time that is convenient for you and will confirm the time by telephone. The interview takes

approximately 30-45 minutes and will be held in a hospital conference room in Riyadh, Saudi Arabia.

The content of the interviews will be audio recorded and field notes taken in order to document inaudible or contextual information. This content will be transcribed and analysed to identify the psychosocial factors associated with MRI diagnosis in chronic low back pain patients.

Expenses

There will be no expenses associated with participation of this study.

What are the possible disadvantages and risks associated with participation?

We do not foresee any disadvantages or risks for participants in this study. We will do our best to arrange the interview to take place at a time convenient for you.

What are the potential benefits of taking part?

The information obtained from your participation in this study may contribute to the design of rehabilitation services for people with chronic lower back pain and provide physiotherapists, orthopaedic surgeons and other healthcare professionals with greater insight into the factors associated with MRI diagnosis in chronic low back pain patients. Moreover, the findings from this study may facilitate the development of guidelines for the management of chronic LBP in Saudi Arabia.

What happens when the study ends?

When the study ends, you will continue to receive your usual care from the hospital.

What if a problem arises?

If you have a concern about any aspect of this study, you can contact to the researcher (Mr. Ahmed Alhowimel, Principal Investigator, on 0553470558) who will do his best to answer your questions. If you remain unhappy and wish to make a complaint, please contact the hospital's Patient Affairs Department or main supervisor: Dr. Neil Coulson, Telephone: 0044 115 846 6642, Email: neil.coulson@nottingham.ac.uk. Additionally, you can contact the Research Ethics Committee Administrator, c/o The University of Nottingham, School of Medicine Education Centre, B Floor, Medical School, Queen's Medical Centre Campus, Nottingham University Hospitals, Nottingham, NG7 2UH, Telephone: 0044 115 8231063, E-mail: louise.sabir@nottingham.ac.uk.

Will my participation in the study remain confidential?

We will adhere to ethical and legal practices and all information related to you will be handled in confidence.

Any data collected from your participation in the study will be assessed by authorised persons from the University of Nottingham who are involved in the study. Other authorised persons may also review the data in order to verify that the study is being carried out correctly. All such personnel will maintain a duty of confidentiality to you as a research participant, and will do their best to meet this duty.

All information collected about you during the course of this research will be kept strictly confidential, stored in a secure and locked office, and in a password protected database. Such information will be anonymised, and a unique identifier will be used so that you cannot be associated with the data.

Your personal data (address, telephone number) will be retained for 6-12 months after the study concludes to allow us to inform you of the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). All other data (research data) will be kept securely for a period of seven years, during which all necessary precautions will be taken to maintain your confidentiality by all those involved in the study, with only members of the

research team having access to your personal data. After this time, your data will be disposed of securely.

Although the information we collect about you is confidential, should you disclose anything to us which we feel puts you or anyone else at risk, we may deem it necessary to report this information to the appropriate body.

What will happen if I don't wish to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights or medical care being affected. If you withdraw from the study, however, the information collected up to that point cannot be erased and may still be used in the project analysis.

What will happen to the results of the research study?

We will use these findings to study the relationship between MRI diagnosis and different psychosocial and function al outcomes in chronic low back pain patients. The findings from this study will be written as a dissertation and submitted to the University of Nottingham for the degree of Doctorate of Philosophy in Rehabilitation and Ageing. Furthermore, the findings will be submitted for publication to allow other healthcare professionals to benefit from the study. Note that you would not be identified in any such report or publication.

Who is organising and funding the research?

The study is organised by the Division of Rehabilitation and Ageing, School of Medicine, University of Nottingham, UK and funded by Prince Sattam Bin Abdulaziz University, Saudi Arabia.

Who has reviewed the study?

All research in the University of Nottingham is reviewed by an independent group of people, called a research ethics committee, to protect your interests.

This study has been reviewed and given favourable opinion by the ethics committee of The University of Nottingham, Medical School.

Further information and contact details

If you have any questions or concerns about the study or wish to discuss participation, you can contact the principal researcher at the following address:

Mr. Ahmed Alhowimel
Division of Rehabilitation and Ageing
B Floor, School of Medicine
Queens Medical Centre
University of Nottingham
Nottingham
NG7 2UH
Tel: 0044 115 823 0948
Mobile 1: 0553470558
Mobile 2: 0044 7482097847
Email: msxaa45@nottingham.ac.uk

Finally, thank you for reading this information sheet, which you should retain. If you agree to take part, we will ask you to sign a consent form, a copy of which you will receive.

Appendix 2

Healthcare Participant Information Sheet

Final version:02

16.07.2016

Title of Study: **The Relationship between MRI Diagnosis and Psychosocial Factors in Physiotherapy Treated Chronic Non-Specific Low Back Patients**

Study ID – Psychosocial-Factors

Name of Researcher(s): **Mr. Ahmed Alhowimel, Dr. Kate Radford, Dr. Neil Coulson**

We invite you to participate in an interview as part of a research study. Before you agree to do so, we would like you to understand why the research is being performed and what your participation would involve. Please take the time to read the following information carefully and talk to others about the study if you wish. A member of our team will review this information sheet with you and answer any questions you might have. If any details about the study are not clear to you, or if you would like more information, please let us know. We can be contacted using the telephone numbers listed at the end of this sheet.

What is the purpose of the study?

This study aims to explore the psychosocial changes in chronic low back pain patients after being diagnosed with MRI. This research specifically aims to explore the experiences of people with chronic lower back pain living in Saudi Arabia. We wish to identify and explore the psychosocial and functional factors

associated with MRI diagnosis in people with chronic lower back pain following physical therapy interventions, from the point of view of the people with chronic lower back pain following physical therapy interventions. We hope that physiotherapists, orthopaedic surgeons, and other healthcare professionals will thus benefit from a greater understanding of how to help in the recovery of people like yourself who have experienced chronic lower back pain. In the longer term, we hope that the findings from this study can lead to better pathways of care for people with chronic lower back pain and assist in the development of appropriate guidelines for the management of chronic LBP in Saudi Arabia.

Why have I been invited to participate?

We are inviting you to take part in a one to one interview because you have been directly involved in providing care for CLBP patients. The aim of the interview discussion will be to explore the view healthcare practitioners about the psychological and social changes appeared after being diagnosed with MRI. We are inviting approximately 6-8 participants like you to participate in this study.

Do I have to take part?

It is up to you to decide whether you wish to participate in this study or not, and you should take some time to consider your decision. If you do decide to participate, we require that you sign a consent form and return it to Mr. Ahmed Alhowimel at the address provided below. You will also retain a copy of the consent form to keep along with this information sheet. You are free to withdraw from the study at any time, without providing a reason.

What will happen if I agree to participate?

If you wish to take part in this study, you will be contacted by telephone and a time will be arranged for the interview. We will do our best to arrange a time that is convenient for you and will confirm the time by telephone. The interview takes approximately 30-45 minutes and will be held in a hospital conference room in Riyadh, Saudi Arabia.

The content of the interviews will be audio recorded and field notes taken in order to document inaudible or contextual information. This content will be transcribed and analysed to identify the psychosocial factors associated with MRI diagnosis in chronic low back pain patients.

Expenses

There will be no expenses associated with participation of this study.

What are the possible disadvantages and risks associated with participation?

We do not foresee any disadvantages or risks for participants in this study. We will do our best to arrange the interview to take place at a time convenient for you.

What are the potential benefits of taking part?

The information obtained from your participation in this study may contribute to the design of rehabilitation services for people with chronic lower back pain and provide physiotherapists, orthopaedic surgeons and other healthcare professionals with greater insight into the factors associated with MRI diagnosis in chronic low back pain patients. Moreover, the findings from this study may facilitate the development of guidelines for the management of chronic LBP in Saudi Arabia.

What happens when the study ends?

When the study ends, you will continue to receive your usual care from the hospital.

What if a problem arises?

If you have a concern about any aspect of this study, you can contact to the researcher (Mr. Ahmed Alhowimel, Principal Investigator, on 0553470558) who will do his best to answer your questions. If you remain unhappy and wish to

make a complaint, please contact the hospital's Patient Affairs Department or main supervisor: Dr. Neil Coulson, Telephone: 0044 115 846 6642, Email: neil.coulson@nottingham.ac.uk. Additionally, you can contact the Research Ethics Committee Administrator, c/o The University of Nottingham, School of Medicine Education Centre, B Floor, Medical School, Queen's Medical Centre Campus, Nottingham University Hospitals, Nottingham, NG7 2UH, Telephone: 0044 115 8231063, E-mail: louise.sabir@nottingham.ac.uk.

Will my participation in the study remain confidential?

We will adhere to ethical and legal practices and all information related to you will be handled in confidence.

Any data collected from your participation in the study will be assessed by authorised persons from the University of Nottingham who are involved in the study. Other authorised persons may also review the data in order to verify that the study is being carried out correctly. All such personnel will maintain a duty of confidentiality to you as a research participant, and will do their best to meet this duty.

All information collected about you during the course of this research will be kept strictly confidential, stored in a secure and locked office, and in a password protected database. Such information will be anonymised, and a unique identifier will be used so that you cannot be associated with the data.

Your personal data (address, telephone number) will be retained for 6-12 months after the study concludes to allow us to inform you of the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). All other data (research data) will be kept securely for a period of seven years, during which all necessary precautions will be taken to maintain your confidentiality by all those involved in the study, with only members of the research team having access to your personal data. After this time, your data will be disposed of securely.

Although the information we collect about you is confidential, should you disclose anything to us which we feel puts you or anyone else at risk, we may deem it necessary to report this information to the appropriate body.

What will happen if I don't wish to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights or medical care being affected. If you withdraw from the study, however, the information collected up to that point cannot be erased and may still be used in the project analysis.

What will happen to the results of the research study?

We will use these findings to study the relationship between MRI diagnosis and different psychosocial and function al outcomes in chronic low back pain patients. The findings from this study will be written as a dissertation and submitted to the University of Nottingham for the degree of Doctorate of Philosophy in Rehabilitation and Ageing. Furthermore, the findings will be submitted for publication to allow other healthcare professionals to benefit from the study. Note that you would not be identified in any such report or publication.

Who is organising and funding the research?

The study is organised by the Division of Rehabilitation and Ageing, School of Medicine, University of Nottingham, UK and funded by Prince Sattam Bin Abdulaziz University, Saudi Arabia.

Who has reviewed the study?

All research in the University of Nottingham is reviewed by an independent group of people, called a research ethics committee, to protect your interests. This study has been reviewed and given favourable opinion by the ethics committee of The University of Nottingham, Medical School.

Further information and contact details

If you have any questions or concerns about the study or wish to discuss participation, you can contact the principal researcher at the following address:

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B Floor, School of Medicine
Queens Medical Centre
University of Nottingham
Nottingham
NG7 2UH
Tel: 0044 115 823 0948
Mobile 1: 0553470558
Mobile 2: 0044 7482097847
Email: msxaa45@nottingham.ac.uk

Finally, thank you for reading this information sheet, which you should retain. If you agree to take part, we will ask you to sign a consent form, a copy of which you will receive.

Appendix 3

CONSENT FORM

15.07.2016

Title of Study: **The Relationship between MRI Diagnosis and Psychosocial Variables in Physiotherapy Treated Chronic Non-Specific Low Back Patients. A Mixed Method Study**

REC ref: *( )*

Name of Researcher: Mr. Ahmed Alhowimel, Dr. Kate Radford, Dr. Neil Coulson

Name of Participant:

Please initial

1. I confirm that I have read and understand the information sheet version number ……dated..... for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
3. I understand that relevant sections of my data collected in the study may be looked at by the research group and by other responsible individuals for monitoring and audit purposes. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐
4. I understand that the interview will be audio recorded using an audio digital recorder for data analysis and those anonymous direct quotes from the focus group or interview may be used in the study reports and publication purposes. ☐

5. I understand that all data will be anonymous and confidential apart from information being revealed during the interview which is of concern and may need reporting i.e. potential risks to another person or to myself or criminal behaviour. ☐

6. I give permission for the anonymised data set to be used to inform future projects and for education purposes. ☐

7. I agree to maintain the confidentiality of the interview. ☐
8. I understand that information about me recorded during the study will be kept in a secure database. If the data is transferred is will be made anonymous. Data will be kept for 7 years after the study has ended and then securely destroyed. ☐
9. Optional: I agree for my personal data being kept for 6-12 months after the end of the study so that I can be contacted about possible follow-up studies. ☐
10. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature

_____	_____	_____
Name of Person taking consent	Date	Signature

2 copies: 1 for participant, 1 for the project notes.

Appendix 4

Direct line/e-mail
+44 (0) 115 8232561
Louise.Sabir@nottingham.ac.uk

Faculty of Medicine and Health Sciences

Research Ethics Committee
C/o Faculty PVC Office
School of Medicine Education Centre
B Floor, Medical School
Queen's Medical Centre Campus
Nottingham University Hospitals
Nottingham
NG7 2UH

10th November 2016

Mr Ahmed Alhowimel
PhD Student
c/o Dr Neil Coulson
B112, Division of Rehabilitation and Ageing
B Floor, School of Medicine
QMC Campus
Nottingham University Hospitals
NG7 2UH

Dear Mr Alhowimel

Ethics Reference No: OVS18082016 – **please always quote**	
Study Title: The Relationship between MRI Diagnosis and Psychosocial Factors in Physiotherapy Treated Chronic Non-Specific Low Back Patients. A Mixed Method Study. **Short Title**: The Psychosocial Impact of MRI Diagnosis in Chronic Non-Specific Low Back Pain.	
Chief Investigator/Supervisors: Dr Neil Coulson, Associate Professor in Health Psychology, Dr Kathym Radford, Associate Professor in Rehabilitation Research (Long Term Conditions), Rehabilitation and Ageing, School of Medicine.	
Lead Investigators/student: Mr Ahmed Alhowimel, PhD Student, Rehabilitation and Ageing, School of Medicine.	
Type of Study: PhD, mixed methods, overseas, Saudi Arabia	
Proposed Start Date: 01/01/2017	**Proposed End Date**: 30/09/2017 9mths
No of Subjects: 64+	**Age**: 18+years
School: SoM	

Thank you for submitting the above application which was considered by the Committee at its meeting on 18th August 2016 and the following documents were received:

Short Title: The Psychosocial Impact of MRI Diagnosis in Chronic Non-Specific Low Back Pain.

- FMHS REC Application Form dated 28/7/2016
- Psychosocial-factors Protocol
- Participant Information Sheet 16.07.2016
- Consent Form 15.07.2016
- Topic Guide for Focus Groups/Interviews: Health Care Professionals
- Topic Guide for Focus Groups/Interviews: People with Chronic Non-specific low back pain.

These have been reviewed and are satisfactory and the study has been given a favourable opinion.

A Favourable opinion is given on the understanding that all appropriate ethical and regulatory permissions are respected and followed in accordance with all local laws of the country in which the study is being conducted and those required by the host organisation/s involved.

A favourable opinion is given on the understanding that the conditions set out over the page are followed:

Appendix 5

Kingdom of Saudi Arabia
Ministry of Health
King Fahad Medical City
(162)



المملكة العربية السعودية
وزارة الصحة
مدينة الملك فهد الطبية
(١٦٢)

IRB Registration Number with KACST, KSA: H-01-R-012
IRB Registration Number with OHRP/NIH, USA: IRB00010471
Approval Number Federal Wide Assurance NIH, USA: FWA00018774

November 21, 2016
IRB Log Number: 16-415E
Department: External
Category of Approval: EXEMPT

Dear Ahmed Alhowimel,

I am pleased to inform you that your submission dated November 13, 2016 for the study titled **'The Relationship between MRI Diagnosis and Psychosocial Factors in Physiotherapy Treated Chronic Non-Specific Low Back Patients: A Mixed method Study'** was reviewed and was approved. Please note that this approval is from the research ethics perspective only. You will still need to get permission from the head of department or unit in KFMC or an external institution to commence data collection.

We wish you well as you proceed with the study and request you to keep the IRB informed of the progress on a regular basis, using the IRB log number shown above.

Please be advised that regulations require that you submit a progress report on your research every 6 months. You are also required to submit any manuscript resulting from this research for approval by IRB before submission to journals for publication.

As a researcher you are required to have current and valid certification on protection human research subjects that can be obtained by taking a short online course at the US NIH site or the Saudi NCBE site followed by a multiple choice test. Please submit your current and valid certificate for our records. Failure to submit this certificate shall a reason for suspension of your research project.

If you have any further questions feel free to contact me.

Sincerely yours,





Prof. Omar H. Kasule
Chairman, Institutional Review Board (IRB)
King Fahad Medical City, Riyadh, KSA
Tel: + 966 1 288 9999 Ext. 26913
E-mail: okasule@kfmc.med.sa

Appendix 6

Topic guide for Semi-structure interview

As part of my PhD study on the relation between MRI diagnosis of people with chronic low back pain and different psychosocial variables, like depression and fear, please answer the following:

I. Semi-structured questions for people with chronic low back pain:

Personal systems/coping strategies:

Can you tell me about your back pain?

What is your understanding of your chronic low back pain?

What happened after the scan?

Did it change you view of the pain?

Have you received any education from your health care provider?

Healthcare System

Could you express your opinion on how the healthcare system deals with low back pain?

How long did it take you to be diagnosed radiologically? Have you been advised to delay the imaging?

How important you think radiological diagnosis is for chronic low back pain?

Are you aware of the low back pain clinical guidelines implemented in your area?

Workplace

How did the problem alter your performance at work?

Did you receive support form you co/workers and employer?

Semi-structured questions for Physiotherapist:

How important you think the MRI diagnosis for people with chronic low back pain?

Does it affect your view of people with low back pain?

Does it affect the overall patient outcomes after physiotherapy?

Do patient with radiological diagnosis behaves differently?

What sort of education is provided to low back pain patients and when?

Any specific terms that you are avoiding while delivering the education?

What advice should be given to people with low back pain?

Do you think the healthcare systems are over-utilising the imaging of chronic low back pain?

Are clinical guidelines helpful in your area?

Semi-structured questions for doctors:

How important you think the MRI diagnosis for people with chronic low back pain?

Does it change your initial diagnosis?

Does it alter the pain medications?

Does it facilitate early surgical interventions and how successful is it?

Do you find urgency from people with low back pain to undergo radiography?

What are your thoughts about common beliefs patients have and how far does it affect your management?

Any specific terms that you are avoiding while delivering the education?

What advice should be given to people with low back pain?

Do you think the healthcare system are over-utilising the imaging of chronic low back pain?

Are clinical guidelines helpful in your area?

Appendix 7

Participant Information Sheet

Final version:01

02.02.2017

Title of Study: The Relationship between MRI Diagnosis and Psychosocial Factors in Physiotherapy Treated Chronic Non-Specific Low Back Patients

Study ID – Psychosocial-Factors

Name of Researcher(s): Mr. Ahmed Alhowimel, Dr. Kate Radford, Dr. Neil Coulson

We invite you to participate in a feasibility randomised control trial study. Before you agree to do so, we would like you to understand why the research is being performed and what your participation would involve. Please take the time to read the following information carefully and talk to others about the study if you wish. Mr. Ahmed Alhowimel will review this information sheet with you and answer any questions you might have. If any details about the study are not clear to you, or if you would like more information, please let us know. We can be contacted using the telephone numbers listed at the end of this sheet.

What is the purpose of the study?

This study aims to assess the feasibility of randomising patients to two groups in term of patients' acceptance and physicians' acceptance. Moreover, we wish to identify the unintended changes in processes and outcomes and the aspects of the larger social, political, and economic environment that may influence intervention implementation

In the longer term, we hope that the findings from this study can lead to better understanding of undertaking similar studies in Saudi Arabia.

Why have I been invited to participate?

We are inviting you to take part in this study because you are having back pain since more than three months.

Do I have to take part?

It is up to you to decide whether you wish to participate in this study or not, and you should take some time to consider your decision. If you do decide to participate, we require that you sign a consent form and return it to Mr. Ahmed Alhowimel at the address provided below. You will also retain a copy of the consent form to keep along with this information sheet. You are free to withdraw from the study at any time, without providing a reason.

What will happen if I agree to participate?

If you wish to take part in this study, you will be contacted by a research time member who will randomly allocate you to MRI group; in which you will have MRI scan for your back and the results will be communicated to you by your doctor then you will have physiotherapy treatment. The other group will have no MRI, instated they will be referred directly to physiotherapy treatment. in both groups you will have to fill in a booklet of outcome measures before starting the physiotherapy and after completing your sessions.

Expenses

There will be no expenses associated with participation of this study.

What are the possible disadvantages and risks associated with participation?

We do not foresee any disadvantages or risks for participants in this study.

What are the potential benefits of taking part?

The information obtained from your participation in this study may contribute to the design of studies in rehabilitation services for people with chronic lower back pain and provide physiotherapists, orthopaedic surgeons and other

healthcare professionals with greater insight into the factors associated conducting studies in chronic low back pain in Saudi Arabia.

What happens when the study ends?

When the study ends, you will continue to receive your usual care from the hospital.

What if a problem arises?

If you have a concern about any aspect of this study, you can contact to the researcher (Mr. Ahmed Alhowimel, Principal Investigator, on 0553470558) who will do his best to answer your questions. If you remain unhappy and wish to make a complaint, please contact the hospital's Patient Affairs Department or main supervisor: Dr Neil Coulson, Telephone: 0044 115 846 6642, Email: neil.coulson@nottingham.ac.uk. Additionally, you can contact the Research Ethics Committee Administrator, c/o The University of Nottingham, School of Medicine Education Centre, B Floor, Medical School, Queen's Medical Centre Campus, Nottingham University Hospitals, Nottingham, NG7 2UH, Telephone: 0044 115 8231063, E-mail: louise.sabir@nottingham.ac.uk.

Will my participation in the study remain confidential?

We will adhere to ethical and legal practices and all information related to you will be handled in confidence.

Any data collected from your participation in the study will be assessed by authorised persons from the University of Nottingham who are involved in the study. Other authorised persons may also review the data in order to verify that the study is being carried out correctly. All such personnel will maintain a duty of confidentiality to you as a research participant and will do their best to meet this duty.

All information collected about you during the course of this research will be kept strictly confidential, stored in a secure and locked office, and in a

password protected database. Such information will be anonymised, and a unique identifier will be used so that you cannot be associated with the data.

Your personal data (address, telephone number) will be retained for 6-12 months after the study concludes to allow us to inform you of the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). All other data (research data) will be kept securely for a period of seven years, during which all necessary precautions will be taken to maintain your confidentiality by all those involved in the study, with only members of the research team having access to your personal data. After this time, your data will be disposed of securely.

Although the information we collect about you is confidential, should you disclose anything to us which we feel puts you or anyone else at risk, we may deem it necessary to report this information to the appropriate body.

What will happen if I don't wish to carry on with the study?

Your participation is voluntary, and you are free to withdraw at any time, without giving any reason, and without your legal rights or medical care being affected. If you withdraw from the study, however, the information collected up to that point cannot be erased and may still be used in the project analysis.

What will happen to the results of the research study?

We will use these findings to study the relationship between MRI diagnosis and different psychosocial and function al outcomes in chronic low back pain patients. The findings from this study will be written as a dissertation and submitted to the University of Nottingham for the degree of Doctor of Philosophy in Rehabilitation and Ageing. Furthermore, the findings will be submitted for publication to allow other healthcare professionals to benefit from the study. Note that you would not be identified in any such report or publication.

Who is organising and funding the research?

The study is organised by the Division of Rehabilitation and Ageing, School of Medicine, University of Nottingham, UK and funded by Prince Sattam Bin Abdulaziz University, Saudi Arabia.

Who has reviewed the study?

All research in the University of Nottingham is reviewed by an independent group of people, called a research ethics committee, to protect your interests. This study has been reviewed and given favourable opinion by the ethics committee of The University of Nottingham, Medical School.

Further information and contact details

If you have any questions or concerns about the study or wish to discuss participation, you can contact the principal researcher at the following address:

Mr. Ahmed Alhowimel
Division of Rehabilitation and Ageing
B Floor, School of Medicine
Queens Medical Centre
University of Nottingham
Nottingham
NG7 2UH
Tel: 0044 115 823 0948
Mobile 1: 0553470558
Mobile 2: 0044 7482097847
Email: msxaa45@nottingham.ac.uk

Finally, thank you for reading this information sheet, which you should retain. If you agree to take part, we will ask you to sign a consent form, a copy of which you will receive.

Appendix 8

Participant Information Sheet

01.09.2017

Title of Study: **The Relationship between MRI Diagnosis and Psychosocial Factors in Physiotherapy Treated Chronic Non-Specific Low Back Patients**

Study ID – Psychosocial-Factors

Name of Researcher(s): **Mr. Ahmed Alhowimel, Dr. Kate Radford, Dr. Neil Coulson**

We invite you to participate in an interview as parallel part to feasibility RCT study. Before you agree to do so, we would like you to understand why the research is being performed and what your participation would involve. Please take the time to read the following information carefully and talk to others about the study if you wish. Mr. Ahmed Alhowimel will review this information sheet with you and answer any questions you might have. If any details about the study are not clear to you, or if you would like more information, please let us know. We can be contacted using the telephone numbers listed at the end of this sheet.

What is the purpose of the study?

This study aims to assess the feasibility of randomising patients to two groups in term of patients' acceptance, physicians' acceptance and healthcare reliance. moreover, we wish to identify the unintended changes in processes and outcomes and the aspects of the larger social, political, and economic environment that may influence intervention implementation

In the longer term, we hope that the findings from this study can lead to better understanding of undertaking similar studies in Saudi Arabia.

Why have I been invited to participate?

We are inviting you to take part in process evaluation interview because you have participated in the feasibility RCT and this is a parallel study to assess the integrity of the feasibility RCT.

Do I have to take part?

It is up to you to decide whether you wish to participate in this study or not, and you should take some time to consider your decision. If you do decide to participate, we require that you sign a consent form and return it to Mr. Ahmed Alhowimel at the address provided below. You will also retain a copy of the consent form to keep along with this information sheet. You are free to withdraw from the study at any time, without providing a reason.

What will happen if I agree to participate?

If you wish to take part in this study, you will be contacted by telephone and a time will be arranged for you to take part in one to one interview. We will do our best to arrange a time that is convenient for you and will confirm the time by telephone. The interview will last approximately 20-40 minutes.

The content of the interview will be audio recorded and field notes taken in order to document inaudible or contextual information. This content will be transcribed and analysed to assess the integrity of the feasibility RCT.

Expenses

There will be no expenses associated with participation of this study.

What are the possible disadvantages and risks associated with participation?

We do not foresee any disadvantages or risks for participants in this study.

What are the potential benefits of taking part?

The information obtained from your participation in this study may contribute to the design of studies in rehabilitation services for people with chronic lower back pain and provide physiotherapists, orthopaedic surgeons and other healthcare professionals with greater insight into the factors associated conducting studies in chronic low back pain in Saudi Arabia.

What happens when the study ends?

When the study ends, you will continue to receive your usual care from the hospital.

What if a problem arises?

If you have a concern about any aspect of this study, you can contact to the researcher (Mr. Ahmed Alhowimel, Principal Investigator, on 0553470558) who will do his best to answer your questions. If you remain unhappy and wish to make a complaint, please contact the hospital's Patient Affairs Department or main supervisor: Dr Neil Coulson, Telephone: 0044 115 846 6642, Email: neil.coulson@nottingham.ac.uk. Additionally, you can contact the Research Ethics Committee Administrator, c/o The University of Nottingham, School of Medicine Education Centre, B Floor, Medical School, Queen's Medical Centre Campus, Nottingham University Hospitals, Nottingham, NG7 2UH, Telephone: 0044 115 8231063, E-mail: louise.sabir@nottingham.ac.uk.

Will my participation in the study remain confidential?

We will adhere to ethical and legal practices and all information related to you will be handled in confidence.

Any data collected from your participation in the study will be assessed by authorised persons from the University of Nottingham who are involved in the study. Other authorised persons may also review the data in order to verify that the study is being carried out correctly. All such personnel will maintain a duty of confidentiality to you as a research participant and will do their best to meet this duty.

All information collected about you during the course of this research will be kept **strictly confidential**, stored in a secure and locked office, and in a password protected database. Such information will be anonymised, and a unique identifier will be used so that you cannot be associated with the data.

Your personal data (address, telephone number) will be retained for 6-12 months after the study concludes to allow us to inform you of the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). All other data (research data) will be kept securely for a period of seven years, during which all necessary precautions will be taken to maintain your confidentiality by all those involved in the study, with only members of the research team having access to your personal data. After this time, your data will be disposed of securely.

Although the information we collect about you is confidential, should you disclose anything to us which we feel puts you or anyone else at risk, we may deem it necessary to report this information to the appropriate body.

What will happen if I don't wish to carry on with the study?

Your participation is voluntary, and you are free to withdraw at any time, without giving any reason, and without your legal rights or medical care being affected. If you withdraw from the study, however, the information collected up to that point cannot be erased and may still be used in the project analysis.

What will happen to the results of the research study?

We will use these findings to study the relationship between MRI diagnosis and different psychosocial and function al outcomes in chronic low back pain patients. The findings from this study will be written as a dissertation and submitted to the University of Nottingham for the degree of Doctor of Philosophy in Rehabilitation and Ageing. Furthermore, the findings will be submitted for publication to allow other healthcare professionals to benefit from the study. Note that you would not be identified in any such report or publication.

Who is organising and funding the research?

The study is organised by the Division of Rehabilitation and Ageing, School of Medicine, University of Nottingham, UK and funded by Prince Sattam Bin Abdulaziz University, Saudi Arabia.

Who has reviewed the study?

All research in the University of Nottingham is reviewed by an independent group of people, called a research ethics committee, to protect your interests. This study has been reviewed and given favourable opinion by the ethics committee of The University of Nottingham, Medical School.

Further information and contact details

If you have any questions or concerns about the study or wish to discuss participation, you can contact the principal researcher at the following address:

Mr. Ahmed Alhowimel

Division of Rehabilitation and Ageing
B Floor, School of Medicine
Queens Medical Centre
University of Nottingham
Nottingham
NG7 2UH
Tel: 0044 115 823 0948
Mobile 1: 0553470558
Mobile 2: 0044 7482097847
Email: msxaa45@nottingham.ac.uk

Finally, thank you for reading this information sheet, which you should retain. If you agree to take part, we will ask you to sign a consent form, a copy of which you will receive.

Appendix 9

CONSENT FORM

25.08.2017

Title of Study: **The Relationship between MRI Diagnosis and Psychosocial Variables in Physiotherapy Treated Chronic Non-Specific Low Back Patients. A Mixed Method Study**

REC ref:*( )*

Name of Researcher: Mr. Ahmed Alhowimel, Dr. Kate Radford, Dr. Neil Couls

Name of Participant:

Please initial

1. I confirm that I have read and understand the information sheet version number ……dated..... for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
3. I understand that relevant sections of my data collected in the study may be looked at by the research group and by other responsible individuals for monitoring and audit purposes. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐
4. I give permission to the primary investigator to contact me for an interview related to the process evaluation of the study. ☐
5. I understand that the interview will be audio recorded using an audio digital recorder for data analysis and those anonymous direct quotes from the focus group or interview may be used in the study reports and publication purposes. ☐
6. I understand that all data will be anonymous and confidential apart from information being revealed during the interview which is of concern and ☐

may need reporting i.e. potential risks to another person or to myself or criminal behaviour.

7. I give permission for the anonymised data set to be used to inform future projects and for education purposes. ☐

8. I agree to maintain the confidentiality of the interview. ☐

9. I understand that information about me recorded during the study will be kept in a secure database. If the data is transferred is will be made anonymous. Data will be kept for 7 years after the study has ended and then securely destroyed. ☐

10. Optional: I agree for my personal data being kept for 6-12 months after the end of the study so that I can be contacted about possible follow-up studies. ☐

11. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

2 copies: 1 for participant, 1 for the project notes.

Appendix 10

Psychosocial Factors Associated with an MRI Diagnosis of Chronic Non-Specific Low Back Pain

Outcome Measures Booklet

This booklet contains 6 sections for you to complete.

For each question, please choose the response that best applies to you. Please tick/circle the response as instructed. If you do not know which answer to give, please choose the one that seems best suited to you rather than not answering.

Even if you feel that some of the questions don't apply to you, for example, because you have made a full recovery, please try to answer them all so we get an overall picture.

The information you give us will be treated confidentially.

If you require any help or have any questions, please contact:

Mr Ahmed Alhowimel.

Tel: 0553470558

Email: ahmed.alhowimel@nottingham.ac.uk

Please return your completed questionnaire to Mr Ahmed Alhowimel or your treating physiotherapist.

Section one

The below questions are adapted from a qualitative study of the psychosocial consequences of MRI diagnosis of people with non-specific chronic low back pain.

These questions explore your understanding of low back pain. Please TICK the box that most closely corresponds with your belief.

To diagnose low back pain	Please TICK the box that most closely corresponds to your beliefs	
Magnetic resonance imaging (MRI) and computerized tomography (CT scan) are always needed.	Agree ☐	Disagree ☐
An x-ray is NOT always needed	Agree ☐	Disagree ☐
Diagnosis can be made by taking medical history and physically examining the patient without the need for additional tests.	Agree ☐	Disagree ☐
Laboratory tests such as glycaemia, cholesterol and urine are always needed.	Agree ☐	Disagree ☐
What is chronic low back pain?		
Pain in the lumbar region that usually improves in three weeks, with or without treatment.	Agree ☐	Disagree ☐
Untreatable pain in the lumbar region.	Agree ☐	Disagree ☐
Pain in the lumbar region requiring surgery.	Agree ☐	Disagree ☐

Pain in the lumbar region lasting more than 3 months.	Agree ☐	Disagree ☐
The explanation that I have received about chronic pain had been helpful.	Agree ☐	Disagree ☐
The information that I have received about back care has been helpful.	Agree ☐	Disagree ☐
Back pain impacted my family life and interaction with my kids.	Agree ☐	Disagree ☐

How tense or anxious have you felt since knowing your diagnosis? (please circle on the scale below)

|_____|_____|_____|_____|_____|_____|_____|_____|_____|_____|_____|

0 1 2 3 4 5 6 7 8 9 10

Calm and relaxed As tense as I've ever felt

I feel relieved after knowing my diagnosis. (Please Tick ONE box)

☐ Strongly agree ☐ Agree ☐ Not sure ☐ Disagree ☐ Strongly disagree

Section Two

In this section we are trying to assess the physical limitation caused by the back pain

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

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

As you read the list, think of yourself *today*. When you read a sentence that describes you today, put a tick against it, Remember, only tick the sentence if you are sure it describes you today.

		√
1.	I stay at home most of the time because of my back.	
2.	I change position frequently to try and get my back comfortable.	
3.	I walk more slowly than usual because of my back.	
4.	Because of my back I am not doing any of the jobs that I usually do around the house.	
5.	Because of my back, I use a handrail to get upstairs.	
6.	Because of my back, I lie down to rest more often.	
7.	Because of my back, I must hold on to something to get out of an easy chair.	
8.	Because of my back, I try to get other people to do things for me.	
9.	I get dressed more slowly than usual because of my back.	
10.	I only stand for short periods of time because of my back.	
11.	Because of my back, I try not to bend or kneel down.	
12.	I find it difficult to get out of a chair because of my back.	

13.	My back is painful almost all the time.	
14.	I find it difficult to turn over in bed because of my back.	
15.	My appetite is not very good because of my back pain.	
16.	I have trouble putting on my socks because of the pain in my back.	
17.	I only walk short distances because of my back.	
18.	I sleep less well because of my back.	
19.	Because of my back pain, I get dressed with help from someone else.	
20.	I sit down for most of the day because of my back.	
21.	I avoid heavy jobs around the house because of my back.	
22.	Because of my back pain, I am more irritable and worse tempered with people than usual.	
23.	Because of my back, I go upstairs more slowly than usual.	
24.	I stay in bed most of the time because of my back.	

Section Three

In this section we are interested to know the fear avoidance behaviours and its effect on your personal life and work.

Here are some of the things other patients have told us about their pain. For each statement please circle the number from 0 to 6 to indicate how much physical activities such as bending, lifting, walking or driving affect or would affect your neck pain.

	Completely Disagree			Unsure			Completely Agree
1. My pain was caused by physical activity.	0	1	2	3	4	5	6
2. Physical activity makes my pain worse.	0	1	2	3	4	5	6
3. Physical activity might harm my back.	0	1	2	3	4	5	6
4. I should not do physical activities which (might) make my pain worse.	0	1	2	3	4	5	6
5. I cannot do physical activities which (might) make my pain worse.	0	1	2	3	4	5	6

The following statements are about how your normal work affects or would affect your back pain.

	Completely Disagree			Unsure			Completely Agree
6. My pain was caused by my work or by an accident at work.	0	1	2	3	4	5	6
7. My work aggravated my pain.	0	1	2	3	4	5	6

8.	I have a claim for compensation for my pain.	0	1	2	3	4	5	6
9.	My work is too heavy for me.	0	1	2	3	4	5	6
10.	My work makes or would make my pain worse.	0	1	2	3	4	5	6
11.	My work might harm by back.	0	1	2	3	4	5	6
12.	I should not do my regular work with my present pain.	0	1	2	3	4	5	6
13.	I cannot do my normal work with my present pain.	0	1	2	3	4	5	6
14.	I cannot do my normal work until my pain is treated.	0	1	2	3	4	5	6
15.	I do not think that I will be back to my normal work within 3 months.	0	1	2	3	4	5	6
16.	I do not think that I will ever be able to go back to that work.	0	1	2	3	4	5	6

Section Four

In this section we are trying to find out the impact of back pain in your general health and your ability to return to work.

1- How long have you had your current problem? Please tick (√) ONE

☐ 0-1 Weeks ☐ 1-2 Weeks ☐ 3-4 Weeks ☐ 4-5 Weeks ☐ 6-8 Weeks
☐ 9-11 Weeks ☐ 3-6 Months ☐ 6-9 Months ☐ 9-12 Months ☐ Over 1 year

2- How would you rate the pain that you have had during the past week? Please Circle one number.

|_____|_____|_____|_____|_____|_____|_____|_____|_____|____ |
0 1 2 3 4 5 6 7 8 9 10

No Pain *Pain as bad as it could be*

Please circle one number which could describe your current ability to in each of these activities

3- I can do light work for an hour. Circle one

|_____|_____|_____|_____|_____|_____|_____|_____|_____|____ |
0 1 2 3 4 5 6 7 8 9 10

I can't do it because of pain *I can do it without pain*

4- I can sleep at night. Circle one

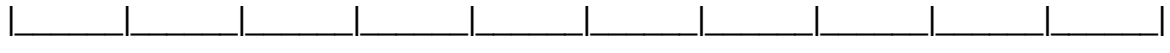
|_____|_____|_____|_____|_____|_____|_____|_____|_____|____ |
0 1 2 3 4 5 6 7 8 9 10

I can't do it because of pain *I can do it without pain*

5- how tense or noxious you felt in the past week? Circle one

|_____|_____|_____|_____|_____|_____|_____|_____|_____|_____|
0 1 2 3 4 5 6 7 8 9 10
Calm and relaxed *as tense as I've ever felt*

6- How much have you been bothered by feeling depressed in the past week? Circle one



0 1 2 3 4 5 6 7 8 9 10

not at at all *extremely*

7- in your view, how large is the risk that your current pain may become persistent? Circle one



0 1 2 3 4 5 6 7 8 9

10 *no chance*

very large risk

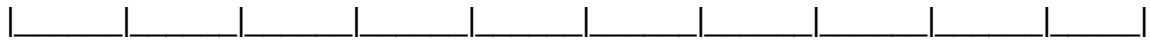
8- in your estimation, what are the chances that you will be working your normal duties in 3 months? Circle one



0 1 2 3 4 5 6 7 8 9 10

no chance *very large risk*

9- An increase in pain is an indication that I should stop what I am doing until pain decrease. Circle one



0 1 2 3 4 5 6 7 8 9 10

Disagree *completely agree*

10-I should not do my normal work with my persistent pain. Circle one



0 1 2 3 4 5 6 7 8 9 10

Disagree *completely agree*

Section Six

In the section we are trying to assess your belief abut back pain. Please TICK the box that most closely corresponds with your belief.

1- There is no real treatment for back trouble.

☐ Strongly agree ☐ Agree ☐ Not sure ☐ Disagree ☐ Strongly disagree

2- Back trouble will eventually stop you from working.

☐ Strongly agree ☐ Agree ☐ Not sure ☐ Disagree ☐ Strongly disagree

3- Back trouble means periods of pain for the rest of one's life.

☐ Strongly agree ☐ Agree ☐ Not sure ☐ Disagree ☐ Strongly disagree

4- Doctors cannot do anything for back trouble.

☐ Strongly agree ☐ Agree ☐ Not sure ☐ Disagree ☐ Strongly disagree

5- Bad back should be exercised.

☐ Strongly agree ☐ Agree ☐ Not sure ☐ Disagree ☐ Strongly disagree

6- Back trouble makes everything in life worse.

☐ Strongly agree ☐ Agree ☐ Not sure ☐ Disagree ☐ Strongly disagree

7- Surgery is the most effective way to treat back trouble.

☐ Strongly agree ☐ Agree ☐ Not sure ☐ Disagree ☐ Strongly disagree

8- Back trouble means you will end up in a wheelchair.

☐ Strongly agree ☐ Agree ☐ Not sure ☐ Disagree ☐ Strongly disagree

9- Alternative treatment is the answer to back trouble.

☐ Strongly agree ☐ Agree ☐ Not sure ☐ Disagree ☐ Strongly disagree

10-Back trouble means long period of time off work.

☐ Strongly agree ☐ Agree ☐ Not sure ☐ Disagree ☐ Strongly disagree

11-Medication is the only way to relieving back trouble.

☐ Strongly agree ☐ Agree ☐ Not sure ☐ Disagree ☐ Strongly disagree

12-One you have a back trouble there is always a weakness.

☐ Strongly agree ☐ Agree ☐ Not sure ☐ Disagree ☐ Strongly disagree

13-Back trouble must be rested.

☐ Strongly agree ☐ Agree ☐ Not sure ☐ Disagree ☐ Strongly disagree

14-Later in life, back trouble gets progressively worse.

- ☐ Strongly agree ☐ Agree ☐ Not sure ☐ Disagree ☐ Strongly disagree

Thank you for completing this questionnaire.

Please return your completed questionnaire to Mr Ahmed Alhowimel or your treating physiotherapist

Appendix 11

Framework for interviews with clinician: Topic Guide

Introduction

The purpose of these interviews is to assess the feasibility of conducting a randomised control trial by exploring healthcare workers' views of acceptability of the study design as well as the contextual factors that influence sustainability and outcome success.

- Thinking about the use of MRI for NS-LBP, do you feel that this tool is essential in the management of such cases? Please explain your answer.
- Does your organisation currently commission strategies for the decreased use of MRI? If so, please explain why.
- Are you aware of other organisations in Saudi Arabia that commission strategies for the decreased use of MRI? If so, please can you explain these tactics
- What factors do you think can influence the decisions of whether to order MRI for NS-CLBP?
- Is it acceptable to randomise patients into MRI groups and non-MRI groups? Please explain your answer.
- Is it feasible to randomise patients into MRI groups and non-MRI groups that work with other agencies, such as the Ministry of Health, within the private sector or at military hospitals? Please explain your answer.
- Think about larger context of the study: in your opinion, what are the social or political issues that could impact the study's design?
- Can you identify any social or political barriers that would *prevent* the feasibility study from being undertaken?
- Do you think your current clinical role encourages involvement in research practices?
- Considering the research environment, did you find you were supported when conducting the research? If so, what kind of support did you receive? Please explain.
- Are there any other comments you wish to add?

Framework for interviews with NS-CLBP Patients: Topic Guide

Questions will be asked on the following topics, some examples of which are given below.

My current research project explores the psychosocial impact of diagnosing people with non-specific chronic lower back pain (NS-CLBP) using an MRI at the University of Nottingham. I understand that you have NS-CLBP and were a participant in our

previous study. Your involvement was extremely helpful, so we wanted to say thank you. I understand that you have given your consent for us to contact you to ask a few follow-up questions.

Your name will not be mentioned within any published documents, meaning anything you say cannot be identified as coming from you directly. Any names of individuals or places that you may refer to during the interview shall also be anonymised when transcribed. All information provided by you will be confidentially preserved and shall only be used to develop a more detailed understanding of the topic.

Therefore, would you be willing to answer some questions?

Construct	Question	Prompts
NS-CLBP specifics	Tell me something about your back pain and how things have been going for you. •	• How does the LBP affect you? (physically, thinking skills, emotionally, socially) • How does the LBP affect your work situation? (relationships, capacity to work) •
Acceptability	What made you participate in this randomised study?	• Have you had any concerns about randomisation? • Do you think this method will be accepted by patients with LBP?

Recruitment - utility of materials/measures and recruitment methods *As a participant in the study, you were asked to complete questionnaire booklets at the recruitment stage and again after physiotherapy.*	Did you encounter any problems with the information you were given to read? Please explain.	• Did you encounter any problems completing and returning the questionnaires? Please explain. • Was it written in an understandable language? • In terms of time to complete the questionnaire, how long did it take you to fill it in? • Were you given any help with its completion? • Was there any question/s that you felt were inappropriate?
Context	Do you think that there will be difficulties in conducting this study?	• Regarding the waiting time for results and a referral for physiotherapy, was the waiting time appropriate for you? Please explain. • Considering the communication between you and the research team, were you comfortable being contacted several times during the study? • Have you received any conflicting information from the research team regarding the study?

Additional Comments

Is there anything else you would like to add or comment regarding your participation in the study?

Appendix 12

د. سليمان الحبيب
DR SULAIMAN AL HABIB
medical group المجموعة الطبية

DESK OF THE VICE PRESIDENT FOR PHYSICIANS' AFFAIRS

Corporate Ethics Committee Decision No. 2017-007

9th April 2017

To : **Dr. Ahmed Alhowimel**

From : **Prof. Abdullah Al Herbish**
VP - Physicians Affairs

Subject : **Psychosocial Factors Associated with an MRI Diagnosis of Chronic Non-Specific Low Back Pain**

Dear Dr. Alhowime;

I would like to inform you that the above-mentioned proposal for your study was discussed in HMG Ethics Committee. It is with regret that this has not been approved as it does not fit with the HMG policy.

Thank you for understanding.

Best regards.

Cc: Mr. Abdulmohsen Al Taweel