

**CHANGING PERCEPTIONS OF WORK ABILITY
IN PEOPLE WITH LOW BACK PAIN:
A FEASIBILITY AND ECONOMIC EVALUATION**

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Abstract

Background: Low back pain is a main cause of sickness absence and work disability in the UK. The economic impact of this is considerable and there is a growing urgency to address the occupational management of low back pain through a vocational focus on rehabilitation. However there is a lack of evidence as to how the needs of this client group can best be met.

Objective: The aim of this study was to test the feasibility of delivering an NHS vocational intervention to this client group, assess how acceptable the intervention was to the participants, and examine the costs involved.

Methods: The study followed an iterative process of development, evaluation and implementation. The study used survey and interview methods to investigate current NHS provision of work-related advice and support to this client group, and determine how the effectiveness of vocational interventions might be measured. The findings were used to inform the design and test the feasibility of an individually targeted vocational intervention and economic evaluation with patients concerned about their ability to work due to low back pain.

Results: The findings of this research demonstrated that there is limited advice and support available to people who are concerned about their ability to work due to low back pain, either from clinicians or in the workplace. Although routine multidisciplinary group rehabilitation reduced patients' concerns, its impact depended on the ability of the patient to apply condition management tools and techniques to the workplace. A total of 51 patients were recruited over a six month period to a feasibility randomised controlled trial with concurrent economic evaluation. Eighty-seven individual work support sessions were delivered. Outcome data was obtained for 38 participants at six month follow-up. Post-trial interviews were conducted with 22 of the trial participants. The intervention and the trial were acceptable to many of the participants, although not all were willing for the researcher to involve the workplace and some did not

engage. For some, the demands of work itself were an obstacle to accessing treatment.

Conclusions: This study showed that it is feasible to deliver an individually targeted NHS vocational intervention to this client group, that the protocol was acceptable to many of the participants, and that an economic evaluation could be conducted. However, the current design cannot be recommended for a definitive randomised controlled trial. Considerable methodological changes are needed to address the method of recruiting participants, the delivery of the intervention and the measurement tools used. Furthermore, routine rehabilitation may not be sufficiently reliable as a control. Finally, the impact of vocational interventions is likely to be limited unless partnership working between clinicians and employers becomes customary practice.

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- Coole C, Drummond A, Sach TH, Watson PJ. 2011. Assessing the feasibility of collecting health care resource use data from general practices for use in an economic evaluation of vocational rehabilitation for back pain. *Journal of Evaluation in Clinical Practice*, 17(1), 204-207.
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CHAPTER 1 INTRODUCTION

This research concerns the effect of rehabilitation on peoples' perceptions of their ability to work with low back pain. The study comprised a number of interconnected yet discrete elements, each building sequentially on the other. This chapter summarises the main research evidence and associated literature related to the subject of low back pain and work which was available when the study was conceived. It also identifies the limitations in this literature and presents the rationale for the study.

A narrative approach to reviewing the literature was chosen (Grant & Booth, 2009). There are limitations associated with this approach, for example it may be open to bias and there may be uncertainty as to the content of the literature that was excluded. However, in this research a wide range of topics were covered at different time points. A narrative approach was therefore used to provide an overview and critique of literature specific to each stage of the research at the time it was conducted, and presented in the introduction to each chapter.

1.1 The definition of low back pain

This study is concerned with musculoskeletal, or mechanical, low back pain. This excludes pain caused by serious spinal pathology or nerve root problems. In the majority of cases, the cause of musculoskeletal pain cannot be clearly identified and is described as non-specific pain; several structures may be involved including muscle, joints, discs and other connective tissue (Waddell, 2004).

1.2 The epidemiology of low back pain

Low back pain will affect most adults during their lifetime (Andersson, 1997). In 1998, 40% of adults in Great Britain reported that they had suffered from back pain lasting more than one day (Office for National Statistics, 1999).

Approximately 7% to 9% of adults in the UK consult their GP for low back pain in any one year (McCormick et al., 1995; Dunn et al., 2005). One in five patients

with low back pain will consult their GP (Papageorgiou & Rigby, 1991) and 75% of these will continue to experience symptoms one year later (Croft et al., 1998). Most people remain at work or return to work quickly, but recurrence is common (Wasiak et al., 2003). In 1998, of those aged 16-64 who were not employed, 13% gave back pain as one of the reasons (Office for National Statistics, 1999).

1.3 The management of low back pain

When this study was initiated, best practice clinical management of non-specific low back pain was based on guidelines published by Airaksinen et al (2006), and van Tulder et al (2006). These state that in the 'acute' phase (less than six weeks duration) patients should be managed by the clinician with referral for manipulation considered for those who are failing to return to normal activities. Multidisciplinary treatment programmes in occupational settings are recommended as an option for workers with sub-acute low back pain and who have been on sick leave for more than 4 - 8 weeks. For those with chronic low back pain (considered to be back pain lasting for longer than 12 weeks) cognitive behavioural therapy, supervised exercise therapy, brief educational interventions, and multidisciplinary (biopsychosocial) treatment are recommended. The guidelines recommend that patients should be advised to stay active and continue with normal activities. Educational advice and information that supports self-management should be provided. If working, patients should be encouraged to remain at work with temporary adjustments if required, or take minimal sick leave, returning to usual hours and duties as soon as possible. The biopsychosocial model (Engel, 1997) is widely accepted as best illustrating the physical, psychological, social and behavioural factors that underlie back pain disability (Waddell, 2004). Obstacles to recovery from non-specific low back pain have been classified using a coloured 'flags' system: red flags representing pain caused by serious spinal pathology such as tumour or fracture (Waddell, 2004); yellow flags representing psychological factors including unhelpful thoughts and beliefs about back pain, passive approaches to

treatment, fear of movement and distress (Kendall et al., 1997); blue flags representing perceptions about health and work such as perceptions of high job demands or a belief that work is harmful (Main & Burton, 2000); black flags representing contextual factors such as unhelpful sickness absence policies or lack of modified work (Main & Burton, 2000). Yellow, blue and black flags are often grouped together and referred to as 'psychosocial' obstacles to recovery.

1.4 The economic impact of low back pain

Low back pain is a major cause of work absence in the UK. In 2008, amongst manual workers, apart from minor illness and acute medical conditions, back pain was the main reason for both short and long term sickness absence. It was the fifth most common reason for both short and long term sickness absence in non-manual workers (Chartered Institute of Personnel and Development, 2008). In 2008/9 in Great Britain an estimated 3.5 million working days were lost through musculoskeletal disorders mainly affecting the back. These figures are similar to data collected between 2004/5 and 2007/8 (Health & Safety Executive, 2008/9). The economic impact is huge: the most recent estimate of the indirect costs of informal care and production losses due to low back pain per annum, conducted in 1998, was £10,668 million (Maniadakis & Gray, 2000).

Greater efforts to improve the management of work problems experienced by people with low back pain are therefore urgently required. In 2007, the government commissioned a review of the health of Britain's working-age population which estimated the annual economic costs of sickness absence and work disability to be in excess of £100 billion (Black, 2008). Mechanisms for reducing the rates of 7% of working age people on work disability benefits, and 3% off work sick were urgently sought.

In 2008 the government published its response to this review with a range of new health and employment initiatives and recommendations (Department for Work and Pensions, Department of Health, 2008). The initiatives included a revised sickness certificate and a series of 'Fit for Work' pilots which aimed to

explore the effectiveness of different models of multidisciplinary support for those with common health conditions such as low back pain.

1.5 Rehabilitation and low back pain

Musculoskeletal back pain, although a common health problem, can be manageable given the right care, support and encouragement (Waddell & Burton, 2004a). For patients presenting with acute low back pain, clinicians are recommended to provide reassurance, advise normal activity including work if possible and prescribe medication for pain relief (van Tulder et al., 2006).

Patients who fail to return to normal activity after 6 weeks may be referred for spinal manipulation, exercise and/or acupuncture (National Institute for Health and Clinical Excellence, 2009).

For those who are at risk of, or have developed long-term back problems, multidisciplinary rehabilitation and pain management approaches based on this model are recommended (Waddell & Burton, 2004a; National Institute for Health and Clinical Excellence, 2009; Airaksinen et al., 2006). Rehabilitation has been described as 'a process of active change arriving at an improvement in functional ability and greater participation in society through an active partnership with health professionals to achieve desired goals' (British Society of Rehabilitation Medicine, 2000).

A number of systematic reviews have been conducted which support a multidisciplinary approach to rehabilitation for low back pain and other chronic pain conditions (Karjalainen et al., 2003a; Scascighini et al., 2008; Guzman et al., 2001) although it is unclear as to the optimal content of treatment, and which health care professionals should provide it. Return to work and work retention are rarely primary outcomes in the studies reviewed, although a study by van Geen et al (2007) supports the long term effect of multidisciplinary back training on work participation. In order to evaluate the outcome of back pain rehabilitation in adults of working age, it is essential to consider vocational factors.

1.6 Vocational rehabilitation and low back pain

For most adults, employment has a vital role in the maintenance of good health. A recent review by Waddell & Burton (2006) has concluded that overall, the health problems associated with lengthy sickness absence and unemployment outweigh any health problems which may be associated with work itself. Work can also provide a structure, a sense of identity and self-esteem, financial security and independence, social participation and fulfilment (Waddell & Burton, 2006). Vocational rehabilitation is the term given to the process of 'helping people with health problems stay at, return to and remain in work' and requires the co-ordinated efforts of healthcare and the workplace (Waddell et al., 2008). It considers the interaction of physical, emotional, cognitive, environmental, organisational and social factors, and their effect on work ability. An extensive literature review of vocational rehabilitation and common health conditions has recently been conducted by Waddell et al (2008) who propose that vocational rehabilitation should be accessible to everyone of working age, at the appropriate level for their needs, using a stepped-care approach to match the level of intervention to individual need. Guidelines for the clinical and occupational management of musculoskeletal conditions, including back pain have recently been published, based on this stepped-care approach (Kendall et al., 2009).

A number of systematic reviews of studies of work-focused interventions for low back pain/musculoskeletal conditions/pain have been conducted (Schonstein et al., 2003; Franche et al., 2005; Williams et al., 2007; Kuoppala et al., 2008).

These reviews conclude that structured multidisciplinary rehabilitation programmes, based on cognitive behavioural principles, are effective for helping people with back pain to return to work. Co-ordination of vocational interventions and communication between the patient/employee, healthcare professionals and employers facilitates this process but is often non-existent (Frank et al., 1998; Sawney & Challenor, 2003). Scheel et al (2002) found that

although there was agreement between GPs and employers that return to modified work was effective in reducing long-term sick leave, obstacles such as limited GP time, lack of information and poor co-ordination meant that it was applied infrequently. Limited interaction between UK GPs and Occupational Health Physicians was demonstrated in a study by Beaumont (2003) who argued that overcoming these communication barriers would involve changes in attitude, culture and systems.

1.7 Limitations in the current evidence

1.7.1 Content, skill mix and duration of interventions

Findings from the studies included in the systematic reviews of low back pain vocational rehabilitation demonstrate the difficulty in drawing clear conclusions about the optimum content, or skill mix, or intensity of the interventions. Firstly, inclusion criteria are variable as to whether participants are sick-listed or not, and whether the setting of the intervention is occupational or clinical. The duration of the interventions can vary from as little as 2-3 hours (Hagen et al., 2000) to at least six weeks (Loisel et al., 1997). Some studies have supported the inclusion of a work-site visit (Loisel et al., 1997), where others have not (Karjalainen et al., 2003b). The intervention reported by Linton et al (2000) reduced sickness absence without any work interventions. Socio-economic variations both between and within different countries can affect outcomes. For example Bendix et al (1998) found that results varied according to whether participants were taken from a rural or urban population. The skill mix for vocational interventions also differs between studies. Waddell et al (2004) have reported that back pain rehabilitation usually involves health professionals from a number of disciplines but in two of the systematic reviews referred to earlier (Schonstein et al., 2003; Franche et al., 2005), the term 'multidisciplinary' was defined as comprising a physician and only one other discipline. Norrefalk (2003) has argued that the term 'multidisciplinary rehabilitation' lacks a clear definition.

1.7.2 Timing of interventions

There are weaknesses in the evidence linking duration of symptoms with the level of intervention. It has been suggested that structured vocational rehabilitation for low back pain is most effective once 4-6 weeks of sickness absence have elapsed; however, Waddell et al (2008) admit that this is a general assumption for which there is insufficient evidence. People may remain at work with, or without, seeking help. It is not known how long people are struggling with back pain before they take sick leave, or how many change or modify their occupation to accommodate their symptoms.

In reality, back pain rarely follows a linear course as specified by the current clinical guidelines. Back pain is frequently recurrent, with symptoms fluctuating even when pain is long-term. Classifications of 'acute' (<6weeks) 'sub-acute' (6-12 weeks) and 'chronic' (>12 weeks) duration of back pain (van Tulder et al., 2006) may therefore be inaccurate and/or misleading. Recent attempts to reach a consensus on the definition of duration have not been successful (Dionne et al., 2008). As a result there is a lack of consistency between the timescales used to measure different stages of back pain and the treatment recommendations given accordingly. Referring clinicians may therefore be unclear which service will best meet the needs of the individual patient.

1.7.3 The role of healthcare professionals in advising back pain patients about work

Studies have shown poor application of back pain guidelines by clinicians. Explanations for low back pain used by UK GPs and physiotherapists remain biomedical, potentially raising patients' anxieties and concerns about causal factors and diagnosis rather than providing reassurance (Bishop, PhD Thesis 2008). A published study by the same author found that the attitudes and beliefs of UK GPs and physiotherapists were associated with their self-reported clinical behaviour regarding advice about work; many held the belief that back pain necessitates some avoidance of activities and work (Bishop et al., 2008).

A number of studies have shown that GPs struggle to advise patients with low back pain about work: for example due to their own beliefs that painful activities should be avoided (Coudeyre et al., 2006), their inability to challenge the patient's conceptual model of back pain (Chew-Graham et al., 1999), lack of time and skills in addressing occupational factors and potential conflicts in the doctor-patient relationship (Breen et al., 2007). However, these studies do not address what GPs do when consulted by patients with work problems due to low back pain, and their perception of the extent of their role. In addition, few studies have explored this client groups' experiences of the work-related help or support that they expect or have received from GPs and clinicians.

In a review of qualitative research on return to work, MacEachen et al (2006) suggested that 'intermediary' players such as healthcare professionals have a potential role in facilitating return to work after musculoskeletal injury.

However, Waddell (2004) argues that most health professionals pay insufficient attention to their patients' work issues, that they have little knowledge of patients' work, and rarely any contact with the workplace. The impact of clinical guidelines recommending that health practitioners assess work-related factors and advise early return to work activities (van Tulder et al., 2006; Airaksinen et al 2006) may therefore be limited.

1.7.4 The complexity of work-related outcome measurement

If preventing work disability is a major goal in managing low back pain, then reliable, valid and standardised tools to measure outcomes are essential.

However, the measurement of work is not straightforward.

Firstly, sickness absence data may not be reliable. Barmby et al (2002) have argued that sickness absence is not purely a response to a medical condition. For example, workers who have access to wage compensation payments are more likely to be absent than those without, and the incidence of sickness absence is influenced to a large extent by the availability of sick pay. Economic uncertainty may lead to increased job insecurity and greater absence monitoring by

employers, which may reduce sickness absence (Elfering, 2006). Employees may use annual leave rather than increase their sickness record, or work at a reduced rate but remain at work. 'Presenteeism' is the term used to describe lost productivity resulting from decreased performance of workers with health problems who nevertheless attend their workplaces. It is thought to be more common in employees with chronic conditions (Munir et al., 2008), although further evidence of the concept is required (Paul et al., 2007).

Secondly, time to return to work is influenced by more than just health care; age, gender and other socio-economic factors are important (Amick et al., 2000). Differences in how workplace interventions are applied and the eligibility criteria for long term disability benefits will also affect return to work (Anema et al., 2009).

Thirdly, work status, for example being employed/unemployed or working full time/part time, is not necessarily a reliable measure of work ability (Wasiak et al., 2007). Using work status as an outcome needs to be clearly related to the health condition, because external factors such as age, family commitments, and the socio-economic climate may have an impact. Work status does not account for ongoing pain, disability and reduced performance. It may not measure adjusted hours/duties. Stay at work outcomes are less commonly reported (Waddell et al., 2008) despite the fact that back pain should be seen as a recurrent problem which may affect retention and career advancement, not sickness absence alone (Wasiak et al., 2007). Also, to achieve optimal health outcomes, withdrawal from employment or change of employment status, which may be unrelated to the health condition, may be a preferred option for some individuals.

Elfering (2006) concluded that work-related measures are not standardised in their method of measurement, do not use standardised terminology, and lack theoretical background. He argues that there are multiple elements involved in the measurement of work outcome, including psychosocial risk factors such as

work-related attitudes and behaviours and biomechanical risk factors such as physically demanding work. Therefore, although belonging to the workforce is a primary goal, and traditional measures of sickness absence days and work status are important, others are needed to encompass all the dimensions of work. Among those suggested are an individual's perceptions of current and future work ability, and measures of biomechanical and psychological factors that address obstacles to recovery, such as fear-avoidance, self-efficacy, physical loading. Fear-avoidance beliefs develop when people believe that they should avoid any activity that causes, or might cause pain and is considered a fundamental mechanism in disabling back pain (Vlaeyen & Linton, 2000). Self-efficacy concerns the belief that one can successfully perform a particular act – an expectation of what one can do. Those with higher self-efficacy are thought to be more confident in their control of pain, and to live up to their own expectations (Arnstein et al., 1999). Physically demanding work is often associated with back pain, although there is little evidence that it causes long term harm to the back. (Burton & Waddell, 2004)

1.7.5 Lack of UK-specific research

Very little independent research into multidisciplinary rehabilitation for low back pain, with or without vocational interventions has been conducted in the UK. The current evidence is largely based on studies from North America and Northern Europe and may not be applicable within the UK's occupational and healthcare settings. For example in Canada and the USA, workers' compensation insurance schemes fund wage replacement and rehabilitation. In the Netherlands employers are liable for up to two years of sick pay, at 70% of the previous salary, and the discussion and formulation of return to work plans are mandatory. In the UK however, there is no legal requirement for employers to rehabilitate employees who are off sick and no one body has core responsibility for providing this service (European Agency for Safety and Health at Work, 2007). Most published peer-reviewed research conducted in the UK concerns

physical therapy for back pain. Three UK studies have reported a reduction in sickness absence through physiotherapy interventions for back pain, but the work status of participants was not clearly recorded, so conclusions are difficult to draw (Moffat et al., 1999; Critchley et al., 2007; Manca et al., 2007).

Two vocational schemes aimed at common health problems including back pain have been piloted by the Department for Work and Pensions. The first, the Pathways to Work scheme, was based on a pilot study for participants who were work-disabled with low back pain (Watson et al., 2004) and developed into a mainstream service during the course of this current study.

The second, the Joint Rehabilitation and Retention Pilot (Department for Work and Pensions, 2006), was a randomised controlled trial for sickness absentees of between six and 26 weeks. Participants were randomly allocated to either a workplace intervention, a health intervention, a combined workplace and health intervention, or a control group. There was no significant difference in return-to-work rates between the groups. However, problems with poor trial design and organisation limited the conclusions that could be drawn.

Two studies of functional restoration programmes for chronic low back pain have been reported (Hunter et al., 2006; Sivan et al., 2008) with promising results. However, these were longitudinal studies rather than controlled trials, and the treatment programmes were funded through employer insurance schemes. Such programmes are only available to a small minority of the UK workforce.

The UK Best trial (Lamb et al., 2007) aimed to examine a treatment programme for back pain using a cognitive-behavioural group treatment approach compared with advice on active back pain management provided individually. The group intervention was to be delivered by one therapist, rather than a multidisciplinary team as is recommended for rehabilitation. However, the focus of the programme was on general back pain disability rather than work ability and there was no vocational intervention. Sickness absence days were to be a

secondary outcome measure, however the results had not been published at the time of this current study.

The effects of vocational interventions are dependent to a large extent on the healthcare and economic systems of individual countries (Airaksinen et al., 2006). There is therefore a need for large scale longitudinal studies into the efficacy of interventions for retaining people with low back pain in employment in the UK.

1.8 Cost-effectiveness of rehabilitation and low back pain

Low back pain is costly both in health-care resource use and lost productivity (Maniadakis & Gray, 2000). It is therefore important to assess the value for money offered by interventions such as vocational rehabilitation. Cost utility analysis examines cost-effectiveness by using health outcomes to calculate 'quality-adjusted life years' (QALYs). A recent systematic review of cost-utility evaluations (Dagenais et al., 2009) demonstrated that it is difficult to conclude which is the most cost-effective treatment for back pain due to the variation in methodology, types of intervention and clinical criteria. The majority of eligible studies in this review were from the UK; however few had collected data on lost productivity and did not include multidisciplinary/vocational interventions. There is some limited evidence from other systematic reviews that functional restoration and workplace-based interventions for injured workers can reduce the costs associated with work disability and sickness absence due to musculoskeletal pain (Schonstein et al., 2003; Franche et al., 2005). Cooper & Dewe (2008) highlight some of the difficulties in measuring the costs associated with worker ill-health, citing for example, absenteeism, employee turnover and replacement and presenteeism.

As Sach & Whynes argue (2003), indirect costs such as these should be included in economic evaluations, but even when they are, there is wide variation in the methods used. This variation can significantly affect the outcome of cost-

effectiveness studies. It has been agreed by a panel of senior researchers and patient representatives that economic evaluations, including work-related costs, are one of the top seven research priorities for trials of therapeutic management of musculoskeletal disorders (Foster et al., 2009).

1.9 Justification for this research study

In 2005 the UK government published its strategy for improving the health and well-being of the working age population (Department for Work and Pensions, Department of Health, Health & Safety Executive, 2005). The strategy states that one of the key objectives is to help employees obtain early and appropriate treatment so that where possible they can remain in work. Evidence reviews have concluded that healthcare should be work-focused, and vocational rehabilitation in the UK should build on existing resources (Waddell et al., 2008) and it has been reported that there is a strong case for the NHS being involved in the provision of work-related interventions to help people with low back pain enter, stay in or return to work (Black, 2008). However, current vocational assessment and intervention within the NHS is patchy (Waddell et al., 2008) and there is a lack of evidence as to how health professionals in the UK can best use their limited resources to address the occupational needs of people with persisting or recurrent low back pain.

A better understanding is required of the content and amount of vocational rehabilitation; how, when and where rehabilitation is best delivered, the costs involved and how the effectiveness of the interventions can be measured.

The results of new initiatives commissioned by the UK government to address health at work and sickness absence (Department for Work and Pensions, Department of Health, 2008) will not be available until at least 2013. These initiatives are not condition-specific. It is not known how they will co-ordinate with existing back pain services, or how they might be established and funded in the future.

Most working adults with low back pain will therefore, for the foreseeable future, receive rehabilitation for low back pain through existing NHS services, regardless of their work status and ability. As the NHS is required to become more 'work-focused', health care professionals need to gain a better understanding of how they can best address the occupational needs of patients with low back pain. The hypothesis for this study is that adding an individually targeted vocational intervention alongside NHS group rehabilitation may provide a cost-effective means of addressing the impact of back pain on work ability and retention of employment. Vocational rehabilitation is a complex intervention, with several interacting components (Medical Research Council, 2008). The Medical Research Council (2008) advises that complex interventions should be tested through an iterative approach. This should involve a series of pilot studies to target and evaluate each area of uncertainty before moving on to an exploratory and then a definitive evaluation.

1.10 The research plan

Research aims

There were four overall aims:

1. To investigate existing provision of work-related advice and support for patients with low back pain.
2. To inform the design and content of an individually targeted work-related intervention for use in a feasibility randomised controlled trial.
3. To identify appropriate and acceptable measurement tools and data collection methods for use in a feasibility randomised controlled trial.
4. To test the feasibility of delivering an individually targeted intervention alongside group rehabilitation in a randomised controlled trial with concurrent economic evaluation.

Chapter Plan

The research will be presented as follows:

Chapter 1:	Introduction
Chapter 2:	Questionnaire survey of GPs
Chapters 3 & 4:	Patient interviews: pre and post routine group rehabilitation
Chapter 5:	Questionnaire survey of GP Practice Managers
Chapter 6:	Pilot patient questionnaire
Chapter 7:	Feasibility randomised controlled trial with concurrent economic evaluation
Chapter 8:	Post-trial participant interviews
Chapter 9:	Conclusions and recommendations

Specific details regarding the relationship between the study aims, research questions, methods of data collection and the thesis chapters may be found in Appendix 1.

CHAPTER 2 QUESTIONNAIRE SURVEY OF GPs

GPs have a key role in the decision as to whether patients with low back pain remain at work, and are usually the first clinician that the patient will consult if they are experiencing difficulties. It was therefore important to investigate GPs' current practice and their views and experiences in managing the vocational needs of this client group, including that of referring patients to NHS group rehabilitation provided by the Nottingham Back Team. The findings would help to inform the design of the proposed feasibility randomised controlled trial.

2.1 Background

In the UK, the General Practitioner (GP) is the first point of contact for most patients seeking NHS healthcare and the 'gatekeeper' for access to treatment interventions. As reported earlier, 20% of those with low back pain will consult their GP (Papageorgiou & Rigby, 1991) and on average, approximately 7% to 9% of the UK adult population will consult their GP for low back pain in a year (McCormick et al., 1995; Dunn & Croft, 2005). GPs also have a statutory obligation for sickness certification from the seventh day of sickness absence, prior to which the worker can self-certify. Patients may not necessarily visit their GP for a sick note; they may consult to gain advice about whether, or how to, remain at work. However, as this review of the literature will show, there are a number of factors that influence GPs' ability to provide appropriate advice and support.

2.1.1 Application of back pain management guidelines

Several studies have shown that a wide range of factors influence the ease with which GPs apply the relevant evidence for back pain management. One of these is the desire to maintain the doctor-patient relationship. In a qualitative study of 20 GPs, the findings showed that GPs failed to challenge patients' medical model of back pain in their attempts to maintain what they perceive to be an effective

relationship, rather than recommending an active approach based on the biopsychosocial model, thus reinforcing illness behaviour (Chew-Graham & May, 1999). GPs may also respond differently according to the presenting problem. In a questionnaire survey using case vignettes (Campbell & Ogden, 2006), UK doctors were more likely to issue a sick note to a patient experiencing work-related stress because it was felt that the patient needed or deserved one. They were more likely to issue a sick note to a patient with back pain in order to maintain the relationship, rather than because they felt the patient was unfit for work. GPs may also be reluctant to initiate contact with employers due to issues over confidentiality and potential conflicts of interest, preferring patients or their employers to take the lead, and being guarded in what they wrote if approached by an employer (Mowlam & Lewis, 2005). GPs may find it difficult to balance their perceived role as the patient's advocate with the recommendations of clinical guidelines. Focus groups carried out with 67 GPs in Scotland found that GPs resented the effect of their certification role on their relationship with patients (Hussey et al., 2004). In a qualitative study of 21 UK GPs and their management of acute back pain, a major finding was the GPs' concerns about potential conflict between themselves and their patients arising from issues relating to work, certification and the attitudes of employers (Breen et al., 2007).

In addition, GPs' own attitudes and beliefs about back pain can negatively influence the advice they give to patients about activity and work. In a questionnaire survey of 60 Swedish GPs, 31% agreed that a decrease in pain was necessary before return to work, and 58% believed that back pain patients should not engage in monotonous or heavy work (Linton et al., 2002). A cross-sectional questionnaire survey conducted in France found that GPs' fear-avoidance beliefs about low back pain had a negative influence on their adherence to guidelines regarding physical and occupational activity in that they

were more likely to prescribe sick leave and less likely to advise maintenance of physical activity (Coudeyre et al., 2006).

2.1.2 Work-related advice

At the time of this research study, GPs could use the 'remarks' section on the sickness certificate to record advice that a patient need not refrain from work and/or that certain workplace adjustments might be appropriate (Department for Work and Pensions, Desk Aid 2). However, according to the literature reviewed, GP practice in the use of the 'remarks' section seemed to vary. The study by Hiscock and Ritchie (2001) suggested that GPs were not using this option whereas another study reported that some GPs did use it to inform employers that the patient could make a phased return (Mowlam & Lewis, 2005). Patients can return to work following a period of certification without the consent of the GP if their employer is in agreement, but again, practice appears to differ; the view of some GPs is that a certificate is necessary for patients to resume work on full duties (Mowlam & Lewis, 2005).

The length of a standard GP consultation is also perceived as an issue. Studies suggest that GPs may write a sick note because it is quicker than entering into a lengthy discussion with the patient about their work situation (Hiscock & Ritchie, 2001).

As reported earlier, guidelines suggest the provision of educational advice and information by clinicians. Although leaflets and books have a limited impact on their own, they are considered a useful supplement if consistent with verbal advice (Waddell, 2004). Some studies have shown that providing patients in primary care with information, based on the biopsychosocial model, may help to promote more positive beliefs about physical activity and pain. The Back Book for example has been shown to reduce fear-avoidance beliefs and disability when tested in primary care (Burton et al., 1999) although the effects on work status were not examined. A previous qualitative study of GP management suggested that GPs consider they have limited educational resources for low back pain

patients, and also lack awareness of local services to refer patients to (Breen et al., 2007), however, no previous studies have investigated what written information GPs provide to this patient group, or which additional services they rely on to help patients with their work problems.

2.1.3 GPs and occupational health

Two qualitative studies commissioned by the Department for Work and Pensions have concluded that GPs may be limited in their scope for advising on work issues without occupational health expertise. One examined the role played by GPs in the sickness certification process in which participants identified a need for an occupational health resource to which GPs could refer, as well as more employment-based occupational health services (Hiscock & Ritchie, 2001). The later study by Mowlam and Lewis (2005) also identified that GPs felt that they lacked the necessary expertise of occupational health physicians. However, the majority of UK employees do not have access to occupational health services and the nature of the services that are provided is variable. In 2006 the Faculty of Occupational Medicine reported that, at 34%, occupational health coverage in the UK was one of the lowest in the European Union compared with others such as Finland and the Netherlands with at least 90% coverage (Faculty of Occupational Medicine, 2006). GPs therefore remain the key resource for patients whose low back pain affects their ability to work. They also rely on other practitioners such as physiotherapists to provide advice and interventions such as manual therapy and exercise therapy.

2.1.4 Communication with the workplace

The benefit of early communication between healthcare providers with patients and their workplaces has been demonstrated by Kosny et al (2006) in a cross-sectional survey of Canadian workers with compensation claims for occupational musculoskeletal injuries. The authors identified that workers who reported that their healthcare provider had 'made contact with the workplace' were 70% more

likely to make an early return to work. However, other studies have shown that such communication is often limited. A Dutch cohort study reported on a questionnaire survey of occupational physicians involved with 300 low back pain patients who had been sick-listed for 3-4 months. The questions concerned the medical management of patients, obstacles to return to work and communication with the treating physicians. The occupational physicians considered that waiting times, treatment duration and the views of the treating physicians were obstacles for return-to-work. In only 19% of the patients was there communication between the occupational physician and the treating physician, which usually consisted of an exchange of information rather than an attempt at co-ordinated management (Anema et al., 2002). In a Delphi study of 25 UK 'stakeholders' the participants concluded that communication between Occupational Health and GPs was 'often very poor' (Beaumont, 2003). However, no previous studies have reported on the extent to which GPs communicate with employers regarding the management of patients' work problems.

2.1.5 GP referral to therapy and rehabilitation

As reported earlier, in addition to managing patients themselves, guidelines recommend that GPs may also consider referring low back pain patients for manipulation and/or supervised exercise. Even if GP referrals to therapists do not focus on work rehabilitation, they do anticipate that a beneficial outcome would facilitate work ability (Mowlam & Lewis, 2005). However, no previous studies have reported on the extent to which GPs communicate with therapists regarding their patients' work problems.

In the UK manipulation and exercise interventions are routinely available through NHS physiotherapy. Multidisciplinary treatment programmes however are less common, and rarely based in occupational settings as recommended by the guidelines. In the South Nottinghamshire area however, where this current study was located, GPs are able to refer patients directly with persisting or recurrent low back pain to multidisciplinary rehabilitation. The Nottingham Back

Team (now called the Nottingham Back and Pain Team) provides multi-disciplinary group rehabilitation for those with persisting or recurrent low back pain using a cognitive behavioural pain management approach. Statistically significant improvements in general function have been reported for those completing the programme (Baird et al., 2008). Nottinghamshire has a widely varying demographic profile; data from the Office for National Statistics show that at the time of the study, South Nottinghamshire (also known as Greater Nottingham) was reported to have a population of approximately 626,300 (Office for National Statistics, 2008a), fairly evenly divided between Nottingham City (296,600) and the boroughs of Rushcliffe, Broxtowe (including Hucknall) and Gedling. In terms of socio-demography as described by the 2007 Index of Multiple Deprivation (IMD, 2007) Nottingham City was the 13th most deprived area in England out of 355, compared with Rushcliffe (331st), Broxtowe (226th) and Gedling (208th). However, the extent to which GPs refer to this group programme is not known, nor their expectations of the team in the management of patients' occupational issues.

In summary, previous research questions the role of GPs as gatekeepers for people with work problems due to low back pain. In order to inform recruitment to the proposed feasibility randomised controlled trial, and to justify the need for a vocational intervention, we wished to identify how GPs in the South Nottinghamshire are perceived their role in managing this client group, their expectations and experiences of the help provided by other practitioners, in particular the Nottingham Back Team, and recommendations for how the needs of this client group might be better met.

Thus there were 4 research questions:

- 1. What are GPs' experiences of helping low back pain patients return to and stay at work?*
- 2. What are GPs' experiences of therapy/rehabilitation for patients with low back pain that affects their ability to work?*

3. *What are GP's experiences of the Nottingham Back Team, and their satisfaction with how the team addresses patients' work problems?*
4. *What improvements would GPs recommend to help them manage their patients' work problems?*

2.2 Methods

2.2.1 Design

A postal questionnaire survey design was chosen to address the research questions, drawing on relevant published literature and the expertise of the steering group. Much of the previous UK research in this field has used qualitative interview methodology; fewer quantitative studies have been conducted. Face-to-face interviews are expensive, and there is the potential of response and interviewer bias (Bowling, 2006). A survey of all referring GPs could potentially obtain data from a larger and more representative sample.

2.2.2 Questionnaire

2.2.2.1 Content and presentation of the early version

The original version of the questionnaire consisted of four sections and an additional space for comments, with a total of 70 questions covering six sides of A4. Respondents were told that the questionnaire concerned the management of patients with persistent or recurrent low back pain which was affecting their ability to work.

The first section concerned the actions GPs took when managing patients with back pain. This included the extent to which they asked or advised employed patients about their work and whether or not they referred patients to rehabilitation after they had reported problems for longer than six weeks. Similar questions concerned patients who were unemployed. Two questions referred to sickness certification, one concerning the use of the 'remarks' section to provide more specific recommendations regarding work, and the other to ascertain the

GPs' actions regarding expiry of the certificate. Further questions in this section concerned the extent to which GPs initiated or responded to either written or verbal communication with patients' therapists and employers regarding their work difficulties and the written advice and information GPs provide to employed and unemployed patients. The questions were separated by four feeder questions. Response options of 'always, often, rarely, never' were chosen to capture the frequency of GPs' reported actions.

The second section concerned the obstacles faced by GPs in helping patients with work problems. These covered a range of issues identified in the literature including those of available time, training, experience, continuity of care, knowledge of local services to refer to, waiting times for rehabilitation, access to specialist advice. Others concerned situations where conflict might arise with other stakeholders. The remaining questions in this section concerned patient-related obstacles such as litigation, job dissatisfaction, benefit dependency, demands at home and other health conditions. The questions were separated by two feeder questions. Dichotomous response options of 'mainly agree' and 'mainly disagree' were chosen in order to ease the speed of completion; frequency was perceived to be of less importance.

The third section concerned the frequency of communication with therapists and employers with the response options of 'frequently, sometimes, rarely, never'. Other questions concerned the experience of referring to the Nottingham Back Team with mixed response options of 'yes/no' and 'mainly agree/mainly disagree' as appropriate and a box to add comments regarding any reasons for dissatisfaction with the service provided. It was anticipated that the team would provide the control group in the second phase of the research study, and recruit patients to the study. It was therefore important to ascertain GPs' experiences of the team to demonstrate that there might be a need for an additional work-focused intervention, and that sufficient patients could be recruited.

Remaining questions referred to GPs' views about rehabilitation for the client group; for example accessibility and effectiveness, also using 'mainly agree/mainly disagree' response options.

The fourth section concerned GPs' demographics including length of experience, qualifications and training in occupational health and sickness certification, and the rural/urban description of the practice. The purpose was to ascertain the representativeness of responses.

An additional space was provided for further comment. A covering letter was designed that would accompany the questionnaire.

2.2.2.2 Piloting

The questionnaire and covering letter was piloted with a convenience sample of five local GPs who were identified through colleagues within the university, one of whom was employed by Nottingham City PCT, the remainder by Nottinghamshire County PCT. The pilot questionnaire was either emailed or posted to the GPs. Feedback was received either by email or in writing. Generally responses were positive, however the main criticism was that, although the questionnaire was well-presented, complete and well-written, it was far too long and that the feeder questions were too complicated. The second section concerning the possible barriers faced by GPs in managing work issues was considered to lack focus and some of the questions were unclear. The definition of 'rehabilitation' was queried on the basis that GPs might consider this to mean physiotherapy only, rather than the Nottingham Back Team. It was suggested that a choice should be given as to what action GPs might take depending on the duration of the problem, and to make a distinction between physiotherapy and the Nottingham Back Team. It was also felt that a qualifier should be included in the instructions that the questionnaire referred to patients without a 'red flag'; i.e. that there was no indication of pathology requiring further investigations. The relevance of questions regarding GPs' communication verbally with employers or therapists was queried as this was not considered to be common

practice. As a result of the feedback received a number of changes were made, as detailed below (2.2.2.3), and one GP commented further on the revised questionnaire.

Further piloting was considered, however at that time GP consortiums across the South Nottinghamshire area were in the process of commissioning new services for low back pain. There was considerable uncertainty as to the future of the Nottingham Back Team and as the team was a focus of the questionnaire and integral to the study as a whole, it was judged a priority to post the questionnaire as soon as possible.

2.2.2.3 Content and presentation of the final version

The final version of the questionnaire was reduced to three sides of A4 and printed on blue paper to distinguish it from other mail received by the participants (Appendix 2, pp. A4-A8). No changes were made to the covering letter.

The questionnaire was divided into three sections to reflect the first three research questions, with a space inviting participants to add comments and suggestions to address the fourth research question. As ease of completion was a main priority, for the majority of the questionnaire the format of the response options was limited to 'mainly agree/mainly disagree'. Respondents were instructed that the questions addressed the management of patients with persisting or recurrent low back pain without red flags so as to exclude patients for whom referral to a specialist might be considered. In order to reduce the length of the questionnaire, the majority of the questions referring to the general obstacles experienced by GPs were removed, whereas those referring to GPs' awareness and experience of therapy and/or rehabilitation were retained as these had a more local focus. Questions concerning the demographic of the practice location, and qualifications and experience of GPs were also removed in order to reduce the length of the questionnaire as they were not considered to be a priority.

The first section concerned the actions taken by GPs with this client group. Questions were included to address the actions of GPs according to the duration of their patients' symptoms. The timescales were chosen to reflect clinical guidelines: the early phase when the GP might be more likely to self-manage or refer to manual therapy, the sub-acute phase when active multidisciplinary assessment and/or rehabilitation would be considered and the chronic phase when referral for rehabilitation would be recommended. The purpose was to determine the extent to which GPs would involve other healthcare professionals/services in the management of their patients. Respondents were given three choices of response: referral to physiotherapy, referral to the Nottingham Back Team, or an open response. Where GPs had ticked an option this was recorded as a positive response. If they had failed to tick an option this was recorded as a negative response. Remaining questions were those referring to the use of sickness certification, the provision of written advice/information, the extent to which the GP took overall responsibility for managing their patients' work difficulties due to low back pain, and actions taken by GPs regarding communication with employers and therapists regarding work. The second section concerned GPs' experiences rather than their actions, including the extent of verbal and/or written communication received from therapists and employers. The remaining questions concerned GPs' experiences of therapy/rehabilitation with this client group and whether they should be provided by local health authorities.

The third section comprised the questions referring specifically to the Nottingham Back Team.

2.2.3 Ethics

Ethical approval was granted by the Nottingham 1 Research Ethics Committee, and the Research and Development Departments of the two Primary Care Trusts (PCTs) concerned. Consent of the participating GPs was not required.

2.2.4 Procedure

In order to ascertain the representativeness of the sample of returned questionnaires, and to target non-respondents, the practice code was written at the top of each questionnaire, with a unique identifying number for each GP. Each questionnaire was addressed personally and signed in order to improve the return rate. A covering letter was attached and stamped addressed envelope included. Participants were asked to return the questionnaire by a set date, three weeks after the date of posting. A follow up letter was sent to each GP who had not responded by the return date with a further copy of the questionnaire and an addressed envelope.

One copy of each of the returned questionnaires was stored at the University in a locked filing cabinet. A document containing the identifying number of each individual GP and GP practice was stored separately. GPs and GP practices were not identified individually in the analysis.

2.2.5 Sample

The questionnaire was sent to each of the 441 GPs in South Nottinghamshire who were able to refer to the Nottingham Back Team and who had not been involved in the piloting. South Nottinghamshire is served by two Primary Care Trusts (PCTs). Lists of the GPs currently recorded as being employed in each practice within the PCT were obtained by contacting either the executive office (Nottingham City PCT; 200 GPs) or the website (Nottinghamshire County Teaching PCT; 241 GPs) of the PCTs concerned.

2.2.6 Proposed data analysis

Data were entered onto SPSS version 15 and analysed using descriptive statistics. Text data from the comments section were entered into a word document. These were then categorised according to emerging themes (Braun &

Clarke, 2006). The identified themes were then agreed with one of the research supervisors (PJW).

2.3 Results

2.3.1 Response rate

A total of 241 questionnaires were received; a response rate of 54.6%. The majority (160) were received from the initial mailing. The response was distributed fairly evenly between the two PCTs and the GP clusters within each PCT as shown in Table 1. A total of 94 GPs used the free space to provide additional comments.

Table 1. Comparison of percentage response rates between PCTs and GP clusters.

Primary Care Trust (PCT)	GP Cluster	Questionnaire returned Per PCT/GP Cluster				Total Questionnaires posted	
		Yes		No		N	%
		N	%	N	%		
Nottingham City	Robin Hood	52	55.9	41	44.1	93	21.1
	City Central	10	50.0	10	50.0	20	4.5
	Norcomm	41	58.6	29	41.4	70	15.9
	Non-aligned	3	42.9	4	57.1	7	1.6
	Unicom	6	66.7	3	33.3	9	2.1
	uncoded	1				1	0.2
	Total	112	56.3	87	43.7	200	45.4
Nottinghamshire County	Principia	43	48.3	46	51.7	89	20.2
	NE Consortium	49	53.8	42	46.2	91	20.6
	NW Consortium	36	59.0	25	41.0	61	13.8
	Total	128	53.1	113	46.9	241	54.6
	Total questionnaires posted						441

2.3.2 GP management of patients according to duration of symptoms affecting patients' work

There were differences in the patient management strategies used by GPs in relation to the length of time that patients had experienced difficulty working

due to low back pain. The results are shown in Table 2. Three GPs referred to the 'back pain pathway' (this is a triage system that had been established locally to direct patients to the most appropriate service). A small number of GPs indicated that their decision would 'depend on the individual' rather than choosing or naming a specific optional method of management or chose more than one main option.

Table 2. GP management of patients according to duration of symptoms affecting patients' work.

If symptoms continue past 2 weeks I mainly....								
	Yes		No		Missing		'depends on individual'	
	N	%	N	%	N	%	N	%
Refer to physio	133	55.2	107	44.4	1	0.4	0	0
Refer to NBT†	36	14.9	204	84.6	1	0.4	0	0
Other*	72	29.9	164	68.1	1	0.4	1	0.4
*Other: one or more specified							N	
Advice							27	
Exercises							22	
Medication							34	
Literature							13	
Manage myself							31	
Refer to 'back pain pathway'							3	
If symptoms continue past 6 weeks I mainly....								
	Yes		No		'depends on individual'			
	N	%	N	%	N	%		
Refer to physio	145	60.2	96	39.8	0	0		
Refer to NBT†	92	38.2	149	61.8	0	0		
Other	7	2.9	231	52.4	3	1.2		
Other if specified							N	
Refer to specialist							2	
Depends on individual							2	
Continue to manage myself							1	
If symptoms continue past 12 weeks I mainly....								
	Yes		No		Missing		'depends on individual'	
	N	%	N	%	N	%	N	%
Refer to physio	56	23.2	181	75.1	4	1.7	0	0
Refer to NBT†	174	72.2	63	26.1	4	1.7	0	0
Other	22	9.1	210	87.1	4	1.7	5	2.1
Other: specified							N	
Refer to specialist							22	

† NBT = Nottingham Back Team

If patients had experienced difficulties for more than two weeks, the majority of GPs (55.2%) agreed that they 'mainly' referred to physiotherapy, with a lesser number (14.9%) 'mainly' referring to the Nottingham Back Team and a substantial number (29.9%) choosing to state an alternative strategy. The alternatives stated included one or more of the following: advice; medication; exercises; continued management by GP; providing literature. As problems persisted in duration an increasing proportion of GPs 'mainly agreed' that they would refer on to the Nottingham Back Team.

2.3.3 Actions taken by GPs to help patients manage low back pain which affects their ability to work.

Table 3 shows the results from responses to the statements concerning the actions taken by GPs to help patients manage low back pain affecting their ability to work. Less than a quarter of GPs 'mainly agreed' that they took overall responsibility for this area. Although most (but not all) GPs responded to written communication from employers and/or therapists about managing their back pain at work, few agreed that they initiated such contact themselves. The majority 'mainly disagreed' that they received verbal communication from either therapists or employers on this issue, however half 'mainly agreed' that they received written communication from therapists, and over a quarter from patients' employers. As regards sickness certification, the majority of GPs 'mainly agreed' that they advised patients that they could return to work before the expiry of the certificate, if able to, but only a third 'mainly agreed' that they used the 'remarks' section to make recommendations to employers on duties/hours.

Table 3. Actions taken by GPs to help patients manage low back pain which affects their ability to work.

Statement from questionnaire	mainly agree		mainly disagree		some-times		don't know		missing	
	N	(%)	N	%	N	%	N	%	N	%
I take overall responsibility for managing patients' work difficulties resulting from low back pain.	52	21.6	185	76.8	0	0	2	0.8	2	0.8
I respond to written communication from patients' employers about managing their low back pain at work.	215	89.2	21	8.7	0	0	0	0	5	2.1
I respond to written communication from patients' therapists about managing their low back pain at work.	216	89.6	21	8.7	0	0	0	0	4	1.7
I initiate written communication with patients' employers about managing their low back pain at work.	6	2.5	233	96.7	0	0	2	0.8	0	0
I initiate written communication with patients' therapists about managing their low back pain at work.	25	10.4	213	88.4	0	0	3	1.2	0	0
I receive verbal communication from patients' employers about managing their low back pain at work	7	3.0	232	96.2	0	0	0	0	2	0.8
I receive written communication from patients' employers about managing their low back pain at work	69	28.7	169	70.1	0	0	0	0	3	1.2
I receive verbal communication from patients' therapists about managing their low back pain at work	31	12.8	207	86.0	0	0	0	0	3	1.2
I receive written communication from patients' therapists about managing their low back pain at work	122	50.6	114	47.4	2	0.8	0	0	3	1.2
I explain to patients, if writing a sickness certificate, that they can return to work before it expires, if able to.	219	90.9	21	8.7	1	0.4	0	0	0	0
When writing sickness certificates, I use the 'remarks' section to make recommendations on work duties/hours.	85	35.3	153	63.5	3	1.2	0	0	0	0

Fourteen GPs (6%) made references in the comments section of the questionnaire to their role and responsibilities and those of other stakeholders in regard to the management of work issues. Examples of the sub-themes identified were:

1. That it was not their role;

'I feel the decision regarding suitability for work should be made by a dedicated occupational health professional. There is a clear conflict of interest for [a] patient's own GP to make the final decision on whether they are suitable for work'

2. That workplace healthcare may be limited;

'Employers have hugely variable attitudes to physical problems and work – we don't want you back until you're better is very common. Access to occupational health and 'work through it and we'll see if we can help' is unfortunately unusual'

3. That GPs did not have sufficient ability to advise on work issues;

'I don't feel I have the skills or training to assess patients back pain and its impact on the working environment. Also it is hard to decline a medical certificate, even though you feel the patient is fit for work, when they tell you they are unable to perform their job'

4. That providers of therapy/rehabilitation might have these skills;

'I would welcome written guidance that I can give to patients about the sort of activities and length of time it is reasonable for them to perform at work'

2.3.4 Written advice and information given to patients by GPs.

The responses to the questions regarding the written advice and information given to patients by the participants are shown in Table 4.

Less than half the GPs 'mainly agreed' that they provided written information to patients about managing their health problems at work, and nearly three-quarters 'mainly agreed' that they lacked up-to-date information on resources that may provide help to patients with work problems due to low back pain. The most frequently cited information was that provided by the Arthritis

Table 4. Written advice and information given to patients by GPs.

Statement from questionnaire	mainly agree		mainly disagree		Some-times		Missing																			
	N	%	N	%	N	%	N	%																		
I provide patients with written advice and information about managing health problems and back pain at work.	80	33.2	157	65.1	1	0.4	3	1.2																		
If you do provide this, please specify:																										
	<table border="1"> <thead> <tr> <th>Written advice/info.</th> <th>N</th> </tr> </thead> <tbody> <tr> <td>Arc information</td> <td>22</td> </tr> <tr> <td>The Back Book</td> <td>16</td> </tr> <tr> <td>On-line resources</td> <td>11</td> </tr> <tr> <td>'Back in Business'</td> <td>9</td> </tr> <tr> <td>'Treat Your Own Back'</td> <td>4</td> </tr> <tr> <td>'Back to Work'</td> <td>2</td> </tr> <tr> <td>Job Centre</td> <td>2</td> </tr> <tr> <td>Other (various)</td> <td>24</td> </tr> </tbody> </table>		Written advice/info.	N	Arc information	22	The Back Book	16	On-line resources	11	'Back in Business'	9	'Treat Your Own Back'	4	'Back to Work'	2	Job Centre	2	Other (various)	24						
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Other (various)	24																									
I lack up-to-date information on resources that may provide help to patients with work problems due to low back pain*	172	71.4	62	25.7	2	0.8	5	2.1																		

Research Campaign (now Arthritis Research UK), followed by the Back Book, and GP on-line resources reported as EMIS, PILS, (patient.co.uk). Seven GPs specifically requested more information that they could give to patients e.g. *'the longer the work-related problems go on, the harder it is inevitably to treat/manage them successfully. If there are any better leaflets recommended by the back team then please could you send some to us at our surgery'*

2.3.5 GPs' experiences of therapy/rehabilitation for patients with low back pain which affects their ability to work.

Table 5 shows the results from responses to the statements regarding GPs' experience of therapy/rehabilitation services for patients with low back pain that affects their ability to work. Only a quarter 'mainly agreed' that these were adequate. The vast majority 'mainly agreed' that these services needed to be more clearly defined, better co-ordinated and more accessible.

Table 5. GPs' experiences of therapy/rehabilitation for patients with low back pain which affects their ability to work.

Therapy/rehab to help low back pain patients with their work problems.....	Mainly agree		Mainly disagree		Some-times		Don't know		Missing	
	N	%	N	%	N	%	N	%	N	%
is adequate	61	25.3	166	68.9	1	0.4	4	1.7	9	3.7
needs to be more clearly defined	210	87.1	23	9.5	0	0	3	1.2	5	2.1
needs to be more accessible	217	90.0	16	6.6	0	0	2	0.8	6	2.5
needs to be available more promptly	223	92.5	12	5.0	0	0	2	0.8	4	1.7
provided by local health authorities	166	68.9	49	20.3	0	0	14	5.8	12	5.0
needs to be more effective	205	85.1	23	9.5	0	0	6	2.5	7	2.9
needs to be better co-ordinated	209	86.7	18	7.5	0	0	7	2.9	7	2.9

Thirty GPs (12%) made reference to lack of clarity regarding referral criteria and treatment pathways in the comments section of the questionnaire. Examples of the two main problems associated with the referral process were:

the number of different mechanisms;

'so many protocols, guidelines, special forms, new electronic pages/websites – no wonder we forget what's out there!'

'I am aware of the [rehabilitation] team but there seem to be many/varied/complex pathways re: referral of patients with back pain. Clear simple guidelines are needed'

and frequent changes in services;

'the provision seems to keep changing so it is difficult to keep up with the best system for each patient'

'by setting up more 'care packages' more 'teams' more

'assessment and treatment pathways' are not helping. It is just confusing patients let alone the frontline GPs'

As shown in Table 5, nearly all GPs 'mainly agreed' that services needed to be available more promptly, and twenty-two (9%) made reference to the problems associated with lengthy waiting lists in the comments section of the questionnaire. Examples of the problems perceived to be associated with delay were that patients may lose motivation to work;

'delays between referral and first appointment often mean patient already adopting 'sick role' and prompt appointments would nip this in the bud'

or fail to take up the therapy/rehabilitation being offered;

'I feel that in all areas there is an unacceptable delay, and it is too easy to encourage DNA's ('did not attend's)'

or lose employment;

'Probably get to see the [rehabilitation] team when it's too late i.e. already lost job'

The majority of GPs 'mainly agreed' that these services should be provided by local health authorities, but a larger proportion of GPs disagreed with, were unsure or did not respond compared to the other statements about service provision.

2.3.6 GPs' experiences of the Nottingham Back Team

Table 6 below summarises the results from responses to the statements concerning GPs' experiences of the Nottingham Back Team (NBT). The majority of GPs had referred patients to the NBT and/or had been consulted by patients referred to the team by other GPs. More than three-quarters 'mainly agreed' that they expected the team to help patients to manage their work problems, and were generally satisfied with the service that the NBT provided. Slightly fewer (68.9%) 'mainly agreed' that they were satisfied with communication from the team. Just over half 'mainly agreed' that they were satisfied with the service that the team provided in helping patients with their work problems.

Table 6. GPs' experiences of the Nottingham Back Team (NBT)

Statement	Yes		No		Not fully		N/A		Missing	
	N	%	N	%	N	%	N	%	N	%
I am aware of the service currently provided by the NBT	218	90.5	18	7.5	3	1.2	0	0	2	0.8
I have referred patients to the NBT	225	91.7	4	1.7	0	0	3	1.2	9	3.7
I have seen patients who have been referred by other GPs to the NBT	177	73.4	47	19.5	0	0	4	1.7	13	5.4
Statement	Mainly agree		Mainly disagree		Don't know		N/A		Missing	
I receive adequate communication from the NBT following assessment and/or treatment	166	68.9	53	22.0	2	0.8	5	2.1	15	6.2
I expect the NBT to help patients to manage work problems	211	87.6	15	6.2	0	0	5	2.1	10	4.1
I am satisfied with the service that the NBT provides generally	185	76.8	33	13.7	6	2.5	5	2.1	12	5.0
I am satisfied with the service that the NBT provides in helping patients manage their work problems	142	58.9	50	20.7	26	10.8	5	2.1	18	7.5

Forty-five GPs (18.7%) made comments specific to their experience of the team. Many of these illustrated the responses reported above, particularly requests for more information about referral to the team and the treatment offered:

'I didn't know they existed – what do they do?'

and the need for better, prompt feedback from the team regarding management plans and work-related advice:

'uncertain how much Back Pain Team addresses work problems – have never as far as I can recall, received any written feedback/advice from the back team about a patient's working life'

Although there were many positive comments about the team, others identified barriers to accessing the service including the length and location of the treatment programmes:

'Patients often can't manage seven sessions at NBT because of work – if possible a shorter course might be useful for these patients'

and that some patients were unable to engage in rehabilitation:

'Although I have replied that I am generally satisfied with the NBT service, I think this process is a bit hit and miss and I have patients who have apparently not been helped'

2.4 Discussion

Responses from the GPs in this survey indicated a wide variation in their approach to the management of patients who have work difficulties resulting from low back pain. There were mixed responses as to whether GPs would take overall responsibility for these problems; although more than one-fifth 'mainly agreed' that they did so, the majority 'mainly disagreed'.

Few GPs reported that they initiated communication with other key stakeholders such as employers and therapists about a patient's work difficulties. At the time of designing the questionnaire, evidence-based advice for GPs on the management of low back pain was available on-line in the UK known as PRODIGY guidelines. These included advice on helping patients with their work problems, for example discussing modification of duties with the patient's employer or occupational health department (Clinical Knowledge Summaries Previous Version). However, between May and September 2008 the PRODIGY guidance was converted to the Clinical Knowledge Summaries Topic Review Structure and now no longer covers 'the management of low back pain when this requires specialist care, for example the occupational health management of low back pain' (Clinical Knowledge Summaries). It would appear, therefore, that communication with a patient's workplace will continue to rely on the content of

the sickness certificate or rest with the patient. Shortly after this study was conducted, the UK government decided that GPs should continue to take the lead on assessing for fitness to work through a revised medical certificate, or 'fit note' (Department for Work and Pensions and Department of Health, 2008). The certificate is designed to encourage GPs to help their patients remain at or facilitate return to work by suggesting that modified work is considered by the employer. However, only one third of the GPs in this questionnaire study appeared to make use of the 'remarks' section on the original sickness certificate to communicate with employers which indicates that any suggestions made regarding work modification on the new 'fit note' may be limited.

The results of this study support other recent research demonstrating that the recommendations for enabling patients to remain at work are still not being followed. A UK postal survey of GPs and physiotherapists found that in response to a vignette describing a patient with non-specific low back pain more than a quarter of respondents would have advised sick leave (Bishop et al., 2008) although another study has suggested that GP certification behaviour is not necessarily specifically associated with low back pain, but may reflect a general predisposition to certify sickness for common health conditions (Watson et al., 2008).

This study has demonstrated that GPs remain unwilling or feel unable take overall responsibility for managing the work difficulties of patients with low back pain, which raises the question of who else might do so. As reported earlier, relatively few employees in the UK have access to Occupational Health services, and these are often not accessed until an employee has been off sick for some time. Precise data are not available, but a recent report has stated that at least 40% of employers do not even have a sickness policy (Black, 2008). In the South Nottinghamshire area covered by this survey, more than 99% of workplaces are small-to-medium-sized enterprises (less than 250 employees) (Office for National Statistics, 2008b). Although detailed information is not

available as to the exact number of employees in these workplaces, these figures show a prevalence of smaller organisations, which are least likely to offer occupational health support for employees with ill health. The ratio of accredited occupational health practitioners to small-to-medium-sized enterprises with greater than two employees is 1:1506 (Faculty of Occupational Medicine, 2006).

A recent review (Black, 2008) and scoping study have recommended that referral to a case-managed multidisciplinary programme should take place if a person has not returned to work after 4-6 weeks of absence (Campbell et al., 2007). As a result, since this questionnaire survey was conducted, the UK government is now piloting 'Fit for Work' services to provide personalised support. These are mainly targeted at those on sick leave, and the results will not be available for evaluation until at least March 2013 (Department for Work and Pensions, 2011).

Previous studies have shown that people who have health problems that affect their work do want to be able to access healthcare interventions that may improve their condition, rather than workplace management alone (Department for Work and Pensions Research Report No. 339, 2006). Healthcare professionals such as physiotherapists are frequently asked to provide advice and recommendations about activities, including work, although work outcomes are not commonly recorded by UK healthcare providers (Waddell et al., 2008) and there is currently little evidence for the effectiveness of physiotherapy in work outcomes for back pain. However, as the results of this study have demonstrated, GPs commonly offer out-patient physical therapy and/or rehabilitation to their patients with low back pain and are likely to continue to do so. Such services could have an important role in promoting work ability and retention. There is no indication within the recent UK government proposals (Department for Work and Pensions, Department of Health, 2008) to address, clarify or build on the role that physiotherapy and rehabilitation personnel might

have in liaising with employers and GPs, yet this might prove to be a cost-effective option.

It may be that other clinicians might be better qualified to manage sickness certification. A study commissioned by the Department of Work and Pensions conducted interviews, focus groups and a telephone survey with over 1,000 non-medical healthcare professionals found that 69% of non-medical healthcare professionals reported that they would not have difficulty in assessing fitness for certification purposes if provided with training and guidelines (Niven, 2005). Thus it might be more appropriate to train other professionals to assess and manage work problems, such as therapists, case managers or line managers. However, this study has also demonstrated that there are weaknesses within service provision that add to the difficulty experienced by GPs in their attempts to help patients with low back pain. Many GPs reported that they were not well informed as to the services available to them, and that treatment pathways and protocols were complex and constantly changing. The vast majority did not consider that existing service provision was adequate to meet the needs of their patients whose ability to work was affected by low back pain. They were particularly concerned about the negative impact of waiting times.

Only a third of GPs in this study reported providing written information to patients on the management of work-related back pain. For patients with chronic low back pain the effectiveness of individual education is less clear (Engers et al., 2008), but the new NICE guidelines for the early management of persistent low back pain have concluded that information should be provided to support verbal advice and guidance (National Institute for Health and Clinical Excellence, 2009). The most commonly cited source of information in this study, *The Back Book* (Burton et al., 1999), is based on a biopsychosocial approach and encourages an early return to work. Information produced by the Arthritis Research Campaign (now Arthritis Research UK) was also cited by several GPs and has an advantage over *The Back Book* in that it is available on-line. However

the section on advice related to work in the Arthritis Research UK information on back pain management is headed 'Should I give up work?' which could increase patients' concerns. In this study the majority of GPs were aware that they lacked information, and expressed a willingness to utilise the appropriate material. However, this information has been available for a long time. It would appear that GPs need more direction and encouragement to provide suitable material to patients although further research is required in this area to examine its effect on work. There is no evidence, for example, that information booklets decrease absenteeism (Marty & Henrotin, 2009).

Strengths and limitations of the study

The main strength of this study is that it highlights the challenges that are already faced by GPs at a time when the UK government is proposing to extend their role and thereby questions whether GPs will be able to meet these increased demands. The response rate, although low in general terms, compared well with other postal surveys of healthcare professionals (Cook et al., 2009). The GPs who responded were representative of the geographical area concerned, although they may not have been representative of the GP population nationally. Response bias may still have influenced the results in that the responders may have had a special interest in the subject and therefore be atypical. In addition, the majority of the GPs who took part in the pilot stage were employed by Nottinghamshire County PCT which may have contributed to the higher response rate from those practices. The length of the questionnaire, its salience, personalisation and use of reminders may have helped to achieve the response rate. Van Geest et al (2007) suggest that pre-notification contact can increase response rates, although this would have required additional resources. There was a time pressure to conduct the survey before local services were re-organised.

This study relied on self report rather than a longitudinal observation methodology; therefore although it was possible to ascertain that GPs reported

whether they did or did not engage in a particular activity, it was not possible to substantiate this engagement or to assess the usefulness of any approach undertaken. Closed dichotomous response options were chosen for the majority of the questions to enable ease of completion and increase the response rate, although these limited the degree to which definitive conclusions could be drawn. One of the weaknesses of structured questionnaires is that the response options may 'force' some respondents to select an answer that does not fully represent their view. Questions regarding communication between GPs, therapists and employers did not indicate the frequency that this took place and therefore caution is required in the analysis. For example, GPs may have 'mainly agreed' that they received written communication from employers, but this may indicate that if they do receive communication, it tends to be written rather than that they receive it on a regular basis. Keeping the original frequency response options of e.g. 'often, sometimes, rarely, never' may have led to a more accurate representation. Also, some of the questions in section B and all of those in section C were weighted in one direction which might have led to affirmation bias; alternating the weighting may have avoided bias.

The questionnaire did not refer specifically to GPs' experiences and expectations of stakeholders including physiotherapy and occupational health which might have improved the quality of the data, as would questions referring specifically to GPs' confidence in advising on workplace modifications. A question asking the GP as to whose role they considered it was to help manage patients' work problems, e.g. employer/GP/therapist/occupational health could have yielded richer responses. More extensive piloting may have identified these flaws and improved the design of the questionnaire. Piloting could have included semi-structured interviews to assist in the design of the questionnaire, and using cognitive interviewing techniques to ascertain GPs' experiences as they were completing it.

Other methods of collecting data could have included individual interviews or focus groups but were considered impractical given the time and financial constraints of the study. A survey also provided an opportunity to draw GPs' attention to the service provided by the Nottingham Back Team, which could have a positive effect on recruitment to the proposed feasibility randomised controlled trial.

2.5 Conclusion

The questionnaire survey identified that a large number of GPs required support to advise and manage patients who have work problems due to low back pain. It would seem that the help GPs offer may be variable and that they feel current provision is inadequate. There was little evidence that guidelines are being adhered to. This suggests that government initiatives which expect the General Practitioner alone to provide this service are unrealistic. Considerable training and a change in the GPs' perception of their role may be required; extending the role of other professionals to assess, advise and manage work problems may be more feasible. Most GPs were aware of, referred to, and were and satisfied with the service provided by the Nottingham Back Team, although there appeared to be less agreement as to whether they were satisfied with how the team manages patients' work problems, and agreement that service provision is inadequate. This study has shown that patients with low back pain are unlikely to receive sufficient work-related advice and support from their GP, and that although GPs do refer to multidisciplinary rehabilitation, this may not be fully addressing patients' work problems. These results lend support to recruiting participants to a feasibility randomised controlled trial with the Nottingham Back Team intervention as the control. However, this study did not investigate the work-related support actually experienced by patients from GPs and other healthcare practitioners, or the help they have received at the workplace. Consequently these factors will be explored further in Chapters 3 and 4.

CHAPTER 3 PATIENT INTERVIEWS: PRE and POST GROUP REHABILITATION

This chapter reports on interviews conducted with patients who have recurrent or persisting low back pain. As concluded from the GP questionnaire survey (Chapter 2), patients with low back pain receive limited advice and support from their GP regarding work. In order to design the proposed feasibility randomised controlled trial it was important to find out about the actual experiences of this client group of working with back pain, and the help that they may or may not have received in managing their back pain at work. Interviews were conducted with patients prior to, and following, group rehabilitation. This chapter describes the methodology used for both sets of interviews and also reports on, and discusses, the findings of the interviews conducted prior to patients attending group rehabilitation. For the purpose of clarity the findings of the interviews conducted following routine group rehabilitation are reported and discussed separately in Chapter 4.

3.1 Background

Much of the data on factors affecting the work ability of people with low back pain have been collected through quantitative research using questionnaires and sickness absence to measure outcomes (Franche et al., 2005). Qualitative research conducted on patients' experiences of work and low back pain has been carried out with either those returning to work after occupational injury (Shaw et al., 2002; Shaw & Huang, 2005; Soeker et al., 2008; Raak & Wahren, 2006) or those who have been work-disabled for several years (Patel et al., 2007; Magnussen et al., 2007). However, this tells us little about the experiences of those who continue to work with back pain, or the extent to which multidisciplinary rehabilitation might affect their ability to work.

The results of the questionnaire survey reported in Chapter 2 demonstrated that GPs may be limited in the extent to which they are able and willing to advise and

support patients with low back pain which affects their work ability. In order to design the feasibility randomised controlled trial it was necessary to ascertain the experiences of patients themselves, both before and after group multidisciplinary rehabilitation for back pain. In particular, it was necessary to know whether and how their concerns about work had been addressed and the work-focused interventions that might be required.

The aim was to address the following research questions:

- a. What are patients' experiences of working with low back pain?*
- b. What are patients' experiences of the help they may, or may not have received in managing their back pain at work, prior to group rehabilitation?*
- c. What are patients' experiences of group rehabilitation in addressing their ability to work with back pain?*

3.2 Method

A qualitative approach using thematic analysis was used (Braun & Clarke, 2006), within a mainly essentialist methodology, to report the experiences, meanings and reality of the participants, rather than a constructionist method which would be more reflective of discourses existing within society. It would have been possible to collect data through quantitative methods, for example a survey, but the themes and scope of the data would have been restricted to the knowledge and view of the researcher and thus have a narrower focus. Data were collected through individual semi-structured interviews to maintain the focus of the enquiry while providing some flexibility.

A partly theoretical or deductive perspective was taken in that a list of topic areas, question areas and prompts were prepared by the researcher as a guide for the interviews, based on reviews of relevant literature and through discussion with clinicians and service users from the project steering group. It is suggested that this method can enable the researcher to be more sensitive to subtleties

within the data (Tuckett, 2005). However, the framework was adaptable to allow other unanticipated themes or patterns to be explored and amendments and additions were made to the schedule in response to new topics arising as the interviews progressed.

Each participant was interviewed prior to, and approximately two months after completing, multidisciplinary rehabilitation. This was to allow sufficient time for the effects of group treatment to be consolidated and for any individual treatments following routine group treatment to have been completed. The researcher kept a reflective log of additional information related to practical issues arising from the interviews, amendments to the interview guide and ideas regarding possible themes.

3.2.1 Sampling

The overall aim was to provide data from a minimum of eight employed and eight unemployed participants. The sample size was chosen with the aim of reflecting sufficient diversity within the time, resources available and allowed for a 30% drop-out rate. Therefore twenty-four participants were to be recruited. Convenience sampling was used and participants were allocated into two groups; employed and unemployed. Participants were recruited from the Nottingham Back Team.

3.2.2 Inclusion criteria

Patients were included if (i) they had been offered routine rehabilitation with the Nottingham Back Team (ii) they had responded positively to a question at their assessment by the Nottingham Back Team clinician that they were concerned about their ability to work because of low back pain and (iii) they had done some kind of paid work in the previous five years. The third restriction was made to ensure that participants were able to reflect on recent work experience.

3.2.3 Exclusion criteria

Patients were excluded if they were non-English speakers. It was not practical to include non-English speakers as all of the study documentation was in English. This criterion was explained in the Participant Information Sheet (Appendix 3, pp A9-A14) and included in the protocol guidance for Nottingham Back Team clinicians.

3.2.4 Ethics

Ethical approval was obtained from the Nottingham 1 Research Ethics Committee and the Research and Development Departments of the Nottingham University Hospitals Trust and the Primary Care Trusts concerned.

3.2.5 Recruitment

Participants were recruited over an eight week period by clinicians from the Nottingham Back Team during routine initial assessment, following referral by the patient's GP or other designated healthcare professional. If the patient met the study criteria the clinician explained the study to the patient. If the patient agreed, the clinician gained written consent for the researcher to contact the patient by telephone within the next 48-72 hours. The clinician gave the Participation Information Sheet (Appendix 3, pp A9-A14) to the patient to take home and read. The patient was then contacted by the researcher, who answered any questions they had, and arranged a time and place for the first interview if the patient was still in agreement. Written consent to participate was obtained at the interview. Participants were made aware that the researcher was a healthcare professional.

3.2.6 Initial interview (pre-group rehabilitation)

The initial face-to face-interview took place prior to routine rehabilitation by the Nottingham Back Team. The interviews lasted approximately 45 minutes.

Participants were offered a choice of location; either at home, at work, or at the office base of the Nottingham Back Team.

The initial interview addressed the first and second research questions i.e. *What are patients' experiences of working with low back pain?* and *What are patients' experiences of the help they may, or may not have received in managing their back pain at work, prior to group rehabilitation?*

An interview guide was prepared based on a review of the literature and discussion with the study steering group (see Appendix 4, pp A15-A19).

Topic areas were as follows:

- Current work situation
- Experience of back pain at work
- Experience of help received
- Expectation of routine Nottingham Back Team rehabilitation

3.2.7 Follow-up interview (post-group rehabilitation)

The follow-up interview addressed the third research question i.e. *What are patients' experiences of group rehabilitation in addressing their ability to work with back pain?* and lasted approximately one hour. Participants were offered the same choice of location as for the first interview.

An interview guide was prepared to be used as prompts (see Appendix 5, pp A20-A23) based on a review of the literature, discussion with the study steering group and the findings of the initial interviews conducted pre-routine rehabilitation.

Topic areas were as follows:

- Current work situation
- Current ability to manage back pain at work
- Experiences of the Nottingham Back Team rehabilitation programme
- Recommendations/suggestions for improving services

3.2.8 Data analysis

Each interview was conducted, digitally recorded and transcribed verbatim by the researcher as the interviews progressed. Analysis followed the staged process as described by Braun and Clarke (2006). In the first two stages the scripts were read and re-read by the researcher, and initial codes identified line-by-line, then in the same way, each script was read and coded independently by a second researcher, one of the researcher's supervisors who has extensive clinical and research experience in work-related back pain. To manage the data systematically, a qualitative software package (NVivo 8) was used to help code each transcript, incorporating relevant data from the researcher's field notes. As the study proceeded, initial codes were refined following constant comparison of the interview scripts and reviewed and agreed with the second researcher. In the third stage, potential broad themes and sub-themes were identified through analysing, collating and/or collapsing codes. These themes were then reviewed and refined with the second researcher. Codes which did not appear to fit within the identified themes, or stand alone as themes, were discarded. Themes were then checked against the data to check that they were valid and represented the data set as a whole, and definitions were agreed with the second researcher.

3.3 Results (Pre-group rehabilitation)

A total of 50 patients met the inclusion criteria, of whom thirty-eight agreed to a follow-up call from the researcher. Of these, seven declined to be interviewed. A further three agreed but did not attend the interview. Therefore a total of twenty-eight patients participated in the study. Demographic details of the participants are shown in Table 7. As few unemployed participants were recruited, it was decided to interview a larger proportion of employed participants. Data saturation was considered to have been achieved at 26 patients when no new themes arose, however as two further participants had already consented, these interviews took place by telephone, and these data

were included in the analysis. By the end of recruitment only three unemployed participants had been recruited (two due to back pain, another due to redundancy).

Table 7. Pre-group rehabilitation interviews: demographic details of participants.

Sex	Male	16
	Female	12
Age	Mean age (S.D.)	44.7 yrs (10.82)
	Age range	22-64 yrs
Education level	Secondary school	11
	GCSE	4
	Further education	9
	Higher education	4
Length of back pain history	Mean (S.D.)	7.6 yrs (9.41)
	Range	3 months – 35 yrs
Previous treatment from clinicians other than GP	Yes	22
	No	6
Work status at recruitment	At work	19 (6 modified work)
	Off sick (due to back pain)	6
	Unemployed	3 (2 due to back pain)
Employer profile (of employed participants)	Large (>250 employees)	20
	Small (<20 employees)	3
	Self-employed	1
	Self/agency employed	1
Sick leave ever for back pain	Yes	22
	No	6
Sick leave in previous 6 months (employed participants)	None	11
	1-7 days	3
	1-6 weeks	5
	6-12 weeks	3
	13-17 weeks	0
	>18 weeks	3

There were three main themes identified through analysis of the interview scripts:

1. Concerns about working with back pain.
2. Help received from GPs and clinicians regarding work.
3. Work modifications.

These themes and their sub-themes can be seen in Table 8. These themes are reported with quotations to illustrate the findings.

Table 8. Pre-group rehabilitation interviews: themes and sub-themes identified from analysis of the interviews.

1	Concerns about working with back pain	
	i	Justifying back pain at work
	ii	Concern about future ability to work
	iii	Difficulty coping with flare-ups
	iv	Reluctance to use medication
	v	Concern about sickness records
2	Help received from GPs and clinicians	
	i	Doubts about what GPs have to offer those with back pain
	ii	Little evidence of effective advice about work from GP
	iii	GP and clinician management may increase concerns about work
	iv	GPs more inclined to write sickness certificates than help with work problems
	v	Lack of dialogue between GPs, clinicians and employers
3	Work modifications	
	i	Assistance from Occupational Health
	a	A service for employers rather than employees
	b	Advice may be overcautious
	c	Influence may vary and may depend on perceived causation
	d	Modifications left to manager to implement
	ii	Assistance from employers/managers
	a	Help depends on the individual manager
	b	May be over-cautious in their support
	c	Managers with back pain perceived to be more sympathetic
	iii	Patient control
	a	Easier to modify workload if in control
	b	The pros and cons of working for oneself
	c	Fewer options if working alone
	d	Colleague support

3.3.1 Concerns about working with back pain

Participants expressed a number of concerns about working with back pain which have been summarised in the following five sub-themes.

3.3.1.1 Justifying back pain at work

The majority of patients felt cautious about disclosing the fact that they had back pain (e.g. asking for help, applying for different work, taking sick leave) because they might be labelled a fraud, or as disabled which they perceived could prevent them from working, or unreliable due to having a health problem:

..people think that you're swinging the lead, because it's not a visible thing.... I remember at my sickness interview – you can see the disbelief in the manager's eyes... (Participant15 male aged 37)

Therefore if people did have to disclose their back pain, they were keen to justify their symptoms by what they felt would be a more acceptable explanation. If patients were in dispute with their employers, or considering a compensation claim for a work-related injury they were particularly keen to seek investigations in order to receive a diagnosis/attribute a cause:

I went to Occupational Health – I had nothing to hide – I took all my records - I'm not making anything up – I had evidence, I had a MRI scan – I'm not lying. (Participant 12 female aged 30)

Some felt that their condition should therefore be better validated by a specific diagnosis on the sickness certificate:

I mean that first sick note said back pain. Well that can mean... a bit of backache – do you know what I mean? And to me it's really important that my work know what's going off. And even though I'd explained to my boss that I've got a bulging disc, he put lumbago – well that's backache isn't it?! (Participant 17 female aged 37)

For the participants in this study, the uncertainty of what was wrong with their back was a common theme, together with the desire to attribute a cause. Some had received diagnoses by healthcare professionals, and several had had scans and x rays. Others had developed their own explanations, usually involving some kind of structural change to the spine, in an attempt to explain their symptoms. The terms 'wear and tear', 'degeneration' and 'arthritis' were used by several of the interviewees. Patients linked their condition to a history of heavy physical

work or attributed it to a specific traumatic event in the past and several thought that age was a contributory factor:

.. I've worked for 15 years with old people and my GP said that there was significant wear and tear at the base of my spine and I do sometimes think 'has that had anything to do with it?' because at the end of the day I'm only 37. (Participant 17 female aged 37)

See I'm not sure whether the pain that I've got is aggravated by the job I do – or if I'm getting old. And sometimes, as I'm doing my work it goes off anyway. So I'm not sure. (Participant 8 male aged 53)

3.3.1.2 Concern about future ability to retain work

For many of the participants, being unsure what was wrong with their backs led to uncertainty about their future working capacity. These uncertainties centred on the possibility of having to retire earlier than planned, not being able to enjoy their retirement if they carried on working, having to stop work, experiencing increased pain at work, having to retrain or not be able to continue their chosen career.

I can retire in a year's time....but I wasn't even thinking of that – because with the friends I work with...some of them are 62, 63. You know, just doing 16 hours, a bit less, and I thought 'well I could do that until I've had enough'. Never thought of all this happening. (Participant 18 female aged 58)

... I've still got another 21 years left at work. And obviously, the concern is, if me back's killing me now, what am I going to be like in later times. And am I still going to be earning the money to pay the mortgage? (Participant 20 male aged 43)

For many therefore, the expectation was that their working capacity would be likely to decrease over time.

3.3.1.3 Difficulty in coping with flare-ups

There was uncertainty relating to the unpredictable and variable nature of the pain, which seemed to be outside the patients' control:

I'd lost confidence in my back because it can just go any time.. and when you are walking around, or climbing in or out of a car, you've always got in the back of your mind... 'oh is it going to flare up again?' (Participant 15 male aged 37)

and the impact that flare-ups of pain had on their ability to get to work, or to work consistently. There was concern about whether employers would continue to tolerate recurrent episodes:

I said to my GP 'look they're getting fed up at work you know, when this happens' (a flare-up), the pressure that is put on you when you do take time off is crazy really' (Participant 19 male aged 56)

Other studies have reported on the fact that chronic pain fluctuates, rather than being constant (Patel et al., 2007; Corbet et al., 2007), and is outside of the control of the patient. For some patients, the inconsistency of severely painful episodes which are followed by periods when the pain is hardly noticeable may lead the patient to question the validity of any medical explanations they have received, or doubt the validity of their own subjective feelings of pain (Lillrank, 2003). Unless the normality of fluctuating symptoms is explained by clinicians to patients and their employers, patients may not feel comfortable in asking for help.

3.3.1.4 Reluctance to use medication

Analgesia is one of the few treatment interventions available directly from the GP (and to some extent pharmacists) for which there is strong evidence for helping to manage acute and chronic back pain thus enabling return to normal activity, including work. It was certainly seen as a main role of the GP by the participants in this study to prescribe medication, yet many questioned its value.

Just – well you go to the doctors and all you get to do is take painkillers and stuff like that (Participant 19 male aged 56)

Many were uncertain about the side-effects, effectiveness or the safety of the medication they had been offered to help control their pain, and the impact on their work:

*...I know from other peoples' experiences you start on one painkiller, and then you have to go higher and higher and higher –...I'd rather work through the pain rather than keep relying on painkillers
(Participant 14 female aged 57)*

*..we read the side-effects, and it's 'don't drive, don't operate heavy machinery, don't do this, don't do that' – and it's like I can't take it, because I drive to work, operate a fork-lift....so I can't take them can I?
(Participant 20 male aged 43)*

3.3.1.5 Concern about sickness records

For many participants there was uncertainty about the extent to which having time off work with their back pain was or might be viewed negatively, depending on their experience of their employer's absence management policy and procedures. Worries were expressed about disciplinary measures being taken which might affect their job security, or attempts to find alternative work:

..I know people that have been off for a long time...and they're cautioned going back – and I don't really want that on my record because if it did come that I was ever made redundant, or I wanted to change my job companies look at that (sickness record), and it does make you reluctant to have time off sick..(Participant 17 female aged 37)

This office worker describes the effect of company bonus schemes on her decision whether or not to take time off:

*the company's got this thing where they're trying to drop the number of absentees there are, and if by the end of the year those figures come down, we get a bonus. It's a bit like dangling a carrot to us I suppose.
(Participant 25 female aged 46)*

For many, back pain is a recurrent problem, with acute flare-ups which generally settle quickly. However, some employers would only 'take back pain seriously' if

a person had a sickness certificate for back pain – taking occasional days off due to back pain would not be seen as legitimate reason for absence.

.....Now If I'd taken the odd day off - they'd say 'you can't be off for a bad back like this, having a day off then 'I feel better' so I'll go back to work and then next week...off again.....this is another reason why my GP's kept me off work - because they'll look at my record and say 'Oh she's had a day off here, and a day off there, supposed to have a bad back'
(Participant 11 female aged 57)

To avoid having to take sick leave, several interviewees had chosen to use or considered using annual leave instead. One 35 year old staff nurse described how she had used her annual leave in the past instead of absenting with back pain. When she had taken sick leave, her symptoms were easier to manage, but she then felt that she could not be seen going out of her house as others might doubt the authenticity of her pain.

3.3.2 Help received from GPs and other clinicians

The participants had consulted a range of clinicians about their back pain, including GPs, pain specialists, physiotherapist and chiropractors. Their experiences of the advice and support received from these consultations is summarised in the following five sub-themes.

3.3.2.1 Doubts as to what GPs have to offer those working with back pain

There was little evidence that the participants expected GPs to offer them advice about work. Many perceived that there was little to be gained by consulting their GP about back pain. Some had sought private investigations or physical therapy instead. They saw the main role of the GP as prescribing medication and providing sickness certificates. This participant described how she had previously managed a long history of recurrent back pain:

I didn't go to the doctors much with it because I thought, 'it's a bad back, you know, there's no point'. (Participant 24 female aged 55)

A 22 year old participant reported that she had not received any advice about work from her GP, and had delayed consulting him previously as a result of advice from family and friends. She had changed to a job that would accommodate her back pain:

..everybody said 'don't bother going to your doctor about it, they can't do anything, just rest up a bit'. (Participant 27 female aged 22)

Another believed others were better placed to manage back pain and had sought a consultation and investigations through private healthcare:

I don't want to be critical of my GP but my understanding is they're not the right people to deal with back problems. I don't mean that disrespectfully, I mean that because it has to be passed on somewhere. (Participant 23 male aged 56)

Participants varied in their relationship with their GP. The frequency with which patients had consulted their GP is not known. Some had rarely needed to consult their GP or had chosen not to as a result of previous experiences. Some reported a very good relationship, others less so. Several reported different experiences within the same practice or by changing practices. Few expressed dissatisfaction with their GP, but there was a general belief that GPs could offer little in the way of help.

3.3.2.2 Little evidence of effective advice about work from the GP

When they had consulted their GP, many participants reported that they had not received any advice or support in relation to work that they had found effective. It seemed that some GPs were more inclined to offer help than others. One participant who worked for a large public employer described how her GP had not considered it to be his role:

I went in, he was a young doctor, he says 'we haven't got time to deal with things like this. It's not up to us, you should have been to Occupational Health'. (Participant 24 female aged 55)

An office worker reported that his back pain had been ignored by his manager. His GP's response was to encourage him to stay at work, but in the absence of tailoring this advice to the workplace the participant felt that this simply demonstrated a lack of appreciation of his condition. He reported how he had been able to remain in work because he had a part-time job:

*GP – he just said if you could stick at your job it's better for you. I think I learnt later that they have no idea about back problems.....I haven't been off sick with my back – because I do part-time anyway so I try and take it easy during the day, and then I can keep at work.
(Participant 7 male aged 43)*

Another example of advice out of context of the workplace is offered by this self-employed participant following his first episode of back pain:

*I rang the GP and said 'Look, I don't know what's happened – I think I've done my back in – what should I do?...' He says 'Nothing, have a paracetamol'. For six and a half months I didn't do any work at all.
(Participant 2 male aged 43)*

As a result, this participant reported that he then delayed consulting his GP further because he was upset at the GP's response. He had continued to self-manage, working at a reduced rate for more than two years until eventually referred for rehabilitation.

3.3.2.3 GP and clinician management may increase concerns about work

Several participants described how GPs and other clinicians advised avoidance of work or particular tasks, implying that work would exacerbate their condition or could place them at risk, rather than form an essential part of their recovery.

*'What did the chiropractor say about work?' 'No'. He said 'no - don't go back'. Because I don't think he really understood what I did.
(Participant 26 female aged 51)*

Another participant describes work-related advice from her physiotherapist:

She said I would be OK to go back to work, but don't do any heavy lifting ...after I've completed the programme I should be OK, and I will have learnt ways to deal with lifting. (Participant 21 female aged 41)

It seemed that rather than making contact with the employer and advising on temporary modifications, clinicians gave generally vague and negative advice, such as 'take it steady' and 'be careful' or implied that work was harmful, even in this case where the physiotherapist was based at the workplace:

The first time I went to see him (physiotherapist) he said 'D'you think you ought to be here'? (Participant 8 male aged 53)

Those in manual work were more likely to receive warnings:

He (GP) asked me what job I did, and he says 'Have you looked for a job that's lighter work?' And as I says to him 'you do your job because you enjoy it. If I wanted a job doing light work I would have found one a long time ago'. (Participant 22 male aged 35)

3.3.2.4 GPs are more inclined to write sickness certificates than help patients manage work problems

It seemed that GPs were more inclined to provide sickness certification than interventions aimed at work retention. This building worker describes refusing the offer:

It's the same old scenario. He said take time off. He could have quite happily wrote me a note off (sickness certificate).

Nevertheless, remaining at work had an impact on other aspects of his life:

*I just keep going. I just deal with it at the weekends.
(Participant 20 male aged 43)*

Another participant described how he had to take the initiative in requesting that his GP recommend him for modified duties (this was the only example given of a GP using the 'remarks' section on the current sickness certificate which can be used to advise the employer regarding work tasks):

...he wanted to put me off sick then but I said 'No I want to stay at work' and I told him to give me a note which would put me on light duties for four weeks where I refrain from any heavy duties and I'd take it to my boss (Participant 3 male aged 44)

Some felt they had to comply with their GP's wishes. For this participant, lengthy certification had become a routine method of management:

He normally gives me a paper (sickness certificate) for about four weeks and then I have to go back and see him.(Participant 11 female aged 57).

Others had been signed off work by the GP while waiting for the results of tests, investigations and treatment interventions:

He signed me off for two weeks at first and said 'let's wait till we get the results of the MRI' and when the results came he said 'I'm going to refer you to the back team' and he sent me a paper (sickness certificate) for six weeks. (Participant 17 female aged 37)

3.3.2.5 Lack of dialogue between GPs, clinicians and employers

There was little evidence of dialogue between GPs and other clinicians and employers, leaving the participants responsible for channelling and interpreting information between the two sectors. This could leave them with concerns as to whether their employers would believe their condition was valid:

Sometimes I wish...my doctor and employers would get in touch with each other because – when I ring up work, you know, I feel sometimes – I bet they don't believe me. (Participant 11 female aged 57)

In only one case had a GP contacted a participant's employer about the management of her back pain at work. This was in writing and the participant reported it had no impact. Two participants reported that therapists had written letters for them to give to their employers recommending alterations to workstations, but there was no direct contact, and their action had not fully resolved the problem:

He wrote a letter. I showed that to the manager. Things have improved slightly – they've bought me a new chair. It's not ideal, but it's better than the one I had. I did want to have a separate monitor with a keyboard raised up and – but that hasn't come to fruition yet. I'm still waiting on that. (Participant 25 female aged 46)

For this participant, therapists had been successful in helping her get a more comfortable chair, but underlying organisational obstacles were not addressed:

The problem is, the physio recommended that every half an hour I have a break.. But that can't happen in my job because of the nature of it – I can't turn my computer off (Participant 12 female aged 30).

Most were not opposed in principle to contact being made between healthcare practitioners and the workplace. This participant felt that contact between his physiotherapist and his employer may have helped him to retain his previous job:

It probably would have been nice just to have a bit more communication. Whether he would have acted on it or not, I don't know. But if it's coming from somebody else as an outsider saying 'look we're monitoring him and this is what's up, he's got to go on lighter duties'. Or have an assistant or something like that for the real heavy work, and he is on the mend, blah, blah, blah, he'd probably look at it in a different way. (Participant 22 male aged 35)

However one participant was more doubtful due to the nature of the relationship with his manager, and thought that any contact from healthcare professionals would 'upset' the manager.

3.3.3 Work modifications

Although few of the participants had experienced support with work modifications from GPs and other clinicians, most had modified their work in some way. Their experiences are summarised in three main themes and described below.

3.3.3.1 Help from Occupational Health

a) A service for employers rather than employees

The majority of the participants in this study worked for large employers (>250 employees) who are more likely to provide an occupational health service. Some of those who had accessed occupational health reported positive experiences and examples of practice which reflected current occupational guidelines:

It's like I had to refer myself to OH – and that's the only time I've got anywhere. They said I am better off going back to work if at all possible.

(Participant 26 female aged 51)

However, several participants were unsure whether there was such a service, or what it might have offered them. It was usually accessed through referral by (and at the discretion of) the line manager; a service that the employee might be 'sent to' or that the employer was 'willing' for the employee to access. Agreeing to attend was seen as a necessary procedure to be followed, for example:

I've been to occupational health at work, and basically been compliant throughout the whole thing. (Participant 10 male aged 43.)

The view that occupational health was employer-orientated could result in a lack of trust. Employees might have doubts over confidentiality, or whether it might affect their job security if a judgement was made that they were not fit to work.

This participant describes why she had chosen not to use a telephone help-line:

It says that it's private and confidential, but I do know for a fact that it goes back to your managers. Which to me is wrong.

(Participant 25 female aged 46)

Occupational health was generally perceived as an absence management procedure, associated with 'return to work' interviews following a period of sick leave, rather than a service for supporting people to remain at work. Two participants on sick leave for six weeks at the time of the interview expected to be referred for their first consultation on their return, not before.

In the time between her clinical assessment and the study interview the following participant had been retired on ill health by her employers, having been off sick for a year. Modified work did not appear to have been considered by occupational health, despite her motivation to return to work:

Well, I had to go and see a private doctor from XXXX and then another one. I had to see two separate ones. And they did all the same that everyone else has done. They all say that it wouldn't be advisable for me to do the job... probably they are right because I'm still a little bit nervous in case that goes again. Nobody's ever told me it won't, you know, so I suppose.. if it did happen, and they'd let me go back to work – everybody's frightened of suing. I think I could have probably gone back to it myself. (Participant 18 female aged 58)

Of those who had received consultations, these were generally conducted away from the work-site. Only one participant described a visit by an occupational physician to look at his work environment; another participant, a staff nurse, had been promised a visit but it had not taken place. Assessment of participants' ability to do their job was generally through discussion rather than observation; some also reported a limited test of physical function such as bending. One participant questioned the validity of an assessment which had been conducted by telephone.

b) Advice may be over-cautious

From the descriptions that participants gave, the advice received as a result of the consultations varied in its adherence to occupational guidelines. Guidelines recommend temporary modifications to enable a graded return to normal duties, without raising fears about further pain, or causing 'damage' to the back. However it seemed that some participants had been advised to avoid certain duties rather than being gradually exposed to normal activities. This was particularly the case in tasks thought to be more closely associated with back pain, and where back pain was perceived to have started at work.

Two participants had become involved with Occupational Health following accidents at work. One had had to contact them himself, but appreciated their support and found them effective in advising him on a phased return to full duties, although the underlying message seemed to be that he should be careful about lifting and six months later he was still on 'light' duties:

Occupational Health came in at work, and they said "no, don't do anything, just do 'light' duties" – you know – computer stuff – recommended to HR what I should do and things – and said keep on light duties for another – month I think he said and then he's going to come in and assess the jobs and things and say whether or not he thinks that they're suitable. (Participant 6 male aged 29)

The other participant was still on 'light' duties over a year later and was in the process of applying for disability benefits. In her case their advice on modifications had also helped her remain in employment, but not return to full duties, and implementation seemed to largely rest with her manager.

Another participant had referred herself to Occupational Health as she was keen to return to work after four months sick leave. Their advice on modifications had helped her to return to work, but again, implementation of their advice largely rested with the manager, and advised restricted lifting with no apparent indication of when this arrangement should change:

They actually wrote and said that I should be fine going back to work, part-time...I'm not allowed to pick up 10kg or something – the (occupational health) doctor put it on the letter. (Participant 26 female aged 51)

Less common was the experience reported by a care worker who had felt reassured by her consultation that modifications were not required:

I saw (occupational health physician) and you know he talked through everything with me, examined me, and he wrote a letter to my manager and sent me a copy, and said that I could carry on with normal work activities. He felt that my back wouldn't stop me doing anything, but if I did something to aggravate it, it wouldn't make it worse – I'd just be in extra pain for a few days. (Participant 5 female aged 43)

However, this participant had taken minimal sick leave for her back pain. She had been given this advice through a consultation triggered by a period of eight weeks sick leave due to depression, not back pain.

c) Influence may vary and depend on perceived causation

There were different experiences in the extent to which the advice of occupational health would be taken up by employers. For example, one participant had been on sick leave for over six months as she was struggling to drive to work because of her back pain. She had attended more than one occupational health consultation. Her public sector employers were either unable or unwilling to act on the advice they had been given. At the time of the interview she was involved in legal proceedings against her employers over the application of reasonable adjustments as defined by the Disability Discrimination Act (1995) and had been off sick for seven months. She describes one of the consultations:

He said 'the sensible solution would be to relocate her to an office closer to her home, otherwise the problem will not go away'. I had a meeting briefly after the report and she (her manager) said 'well, there's nothing I can do, there's no jobs there'. Problem is, employers can just ignore what they say (Participant 12 female aged 30)

The two participants whose back pain had followed workplace accidents indicated that the response of their employers was associated with the perceived cause of their pain:

But he's been actually pretty good (Occupational Health Physician) – he's given quite good advice I think and given them a bit of a kick as well actually – when he came in he just looked around and said 'Oh God that's awful – you shouldn't be doing that' – and took the boss into the office – and it was quite nice really that there was...

'There was someone looking out for you?'

Yes. (Participant 6 male aged 29)

And:

I think they're more understandable (understanding) because it's been done at work. They're more lenient. I think if I'd have done this – say I was gardening at home and I'd done it, then I think they'd have been more inclined to have let you go, more so than try and help you to work through it. (Participant 24 female aged 55)

d) Modifications left to manager to implement

It appeared rare for occupational health personnel to meet with anyone other than the patient. Usually the patient was left to act as a conduit between occupational health, their employer and their GP. In the two instances where workplace injuries were perceived to have taken place, occupational health did meet with the manager/employer; otherwise communication between the parties was by written report or letter. However written communication does not provide an opportunity for all those involved to clarify or discuss any advice or recommendations given, and how it might be implemented or evaluated. This participant described how there seemed to be an expectation from both the physician and the manager that the participant was responsible for the transmission of information:

He said 'email me your latest thing from the last meeting you had, I'll look at it, review it and then forward it to her (the manager) and then she can read that then she's got everything there'. I think...he wants to check what I'm saying and make sure that things are recommended correctly, rather than them asking me, I say something and it goes wrong. So I said 'the best answer is to go through the right channel'. (Participant 6 male aged 29)

This participant highlights a similar lack of clear, effective communication:

I haven't been back to see her since that initial consultation. It was a series of consultations and on one of them the boss wanted to sit in, I had no objection, but the Occupational Health officer did, so it didn't happen and the boss wasn't pleased about that and she basically gave me a good grilling – 'well, what did she say – what are you going to do – what's going to happen?' (Participant 10 male aged 43)

3.3.3.2 Help from employers/managers

As has been described, Occupational Health had played a limited role in modifying work for the participants in this study. Day to day management of the employee's back pain at work therefore largely rested with the worker themselves, their colleagues and their supervisors or line managers. It was common for the interviewees to talk about receiving the support of their colleagues, but perceptions and experiences of managers were mixed:

a) Help depends on the individual manager

Some participants had received help from their managers in making minor adjustments which had enabled them to remain at work. One 22 year old described how she had recently started work as a member of a small team in the postal department of a large company before her symptoms became more troublesome. She had changed from her normal occupation (fashion design) due to a combination of stress and back pain, where modifications had been unavailable. Her manager and colleagues in this new job had agreed that when she was in more discomfort they would take a greater share of the heavier manual handling tasks, and were happy for her to take more of their share of computer-based tasks in return. This informal and flexible arrangement had enabled her to feel productive rather than a burden to her colleagues. Similarly, a librarian described how temporary work adjustments agreed with her manager had meant that she was able to reciprocate:

Well it's a team effort really – I'm doing things that other people aren't. If anybody needs to do my allocation of shelving I'm doing something for them in return. (Participant 21 female aged 41)

However, if duties were reduced indefinitely, with no extra cover, workers might feel that they were burdening their colleagues. There were doubts as to how long their colleagues support might continue. This participant had injured her back at work, and modified duties had been arranged, but she felt that she was not fulfilling her part in the team:

I feel as though I'm useless. I just poodle about doing what I can, where I can. And the men go 'Oh, bloody come out the way' if I try and do something. But they're not going to carry on doing that are they?
(Participant 24 female aged 55)

This sense might be heightened by the possibility that their colleagues could question the validity of their pain:

..because we work as a team it's like - do they think I'm swinging the lead? But it's like letting the team down, because you want to be able to do your quota, not put more strain on the other side of the team.
(Participant 15 male aged 37)

Inability or unwillingness of employers to address low staffing levels could limit attempts to modify their workload. For this participant, low staffing levels were compounded by a culture that made it difficult to ask for modifications in the form of postural changes. This participant had to maintain an uncomfortable sitting position:

'During the day, can you get up and move if you wanted to?'
Oh yeh, if I wanted to yeh, but it's the pressure of sort of having to - if I was to do that it'd be 'where are you going? You've got work to get done, you ain't got time to go talking' and stuff like that! 'Oh I don't mind you moving around, but you get those ten units done for the post'. So you've still got to sit still.'

Although he felt that his employers would be more amenable to modifying his job through the purchase of equipment:

Oh there'd be no problem in buying a different chair - they're very good like that. (Participant 19 male aged 56)

Whereas other office-based employees described receiving workstation assessments and modifications, this participant had not found her employers (a multinational company) at all helpful in providing her with suitable display screen equipment:

They don't like to spend money where they think they can get away with it. I mean the chair – I just really, really forced the issue, because I said to the manager – I just can't cope with coming to work, sitting in a chair that's causing me more pain when I get home. And even now, the lap top – this is not the one I originally had- and I did say to them when the other one broke down – maybe now I'll get the monitor and a keyboard separate – 'Oh well, we've got a spare one floating round at xxxxx Road, you'll have to have that lap top'. (Participant 25 female aged 46)

This office worker again had experienced little support from his manager:

I did inform the boss about it and - because one time I was lifting from the ground and I felt something jolt in my back and I was in agony and he just said 'well why didn't you report straight away?' – because I didn't do that and – he was trying to blame me, that I'd done it elsewhere – 'it's not our fault'. (Participant 7 male aged 43)

Whereas this participant's employers had agreed to her taking regular breaks from sitting which had not affected her productivity:

I do get up every hour and walk round, and every half hour when it's really painful. Everybody's aware of why I'm doing it. Even though I'm away from my desk for 15-20 minutes an hour, I'm still exceeding my targets. So it's not impacting – I mean people who are there at their desk all the time are not hitting their targets so - I'm constantly exceeding mine. (Participant 4 female aged 44)

b) May be overcautious in their support

Some managers could be overcautious, perhaps due to a sense of responsibility and their own anxieties about back pain, and encourage participants to modify their workload. Participants reacted differently in these situations; some seemed relieved that their problems were being taken account of:

They've been very good. My immediate manager has been excellent. He's been very good. If I go in and say I can't manage it, it's 'well, leave it then'. (Participant 24 female aged 55)

While others were less inclined to accept:

She is very good. She says to me today 'what are you carrying that ladder for?' I said – 'feel the ladder, it's a lightweight ladder, two step'. She says 'Oh but you shouldn't have been carrying it'. I says 'I've got to do my job, you've got to let me do my job. If I can't do my job, there's no point in my being here'. (Participant 26 female aged 51)

Lack of adequate help in effective work modifications could lead to further sickness absence, even with the best of intentions. Another participant had been signed off for six weeks following a previous attempt to remain at work on 'light' duties, which failed after he went straight back to his usual duties without a gradual return.

c) Managers with experience of back pain perceived to be more sympathetic

As back pain is a common health condition, it is quite likely that managers will also have some experience of back pain. Participants generally felt that their manager was more sympathetic as a result of their own experience of pain:

I spoke to my boss – he said 'yes, take it easy'. My boss, he's got long term back pain, and last time he was off with his back he had to wear a support belt and everything, and he understands what it's all about. (Participant 3 male aged 44)

There was a sense that other managers may not be as tolerant of workers with back pain:

I'm lucky that my line manager he has a back problem as well so he knows what I go through. (Participant 4 female aged 44)

3.3.3.3 Patient control

a) Easier to modify workload if in control

In this study some participants were able and/or had chosen to modify their own duties and/or hours on an informal basis, either by themselves, or by involving their colleagues.

This council worker, with a long history of back pain had pursued a combination of self-management, taking a few days off work and accessing private manual

therapy to remain in work. The nature of his job meant that he was able to adjust his tasks and workload to remain at work most of the time:

As I say, I have flare-ups, but because I manage my own day, if it ain't the best then I'll stay in the office all day. It just means I'm not climbing in and out of vans all day. (Participant 15 male aged 37)

The ability to modify his workload was also a key factor in work retention for this finance consultant. His flare-ups were now becoming more frequent, but he had been able to manage these by working flexibly:

No I haven't taken sick leave. I work with it in the sense that say I can't get into the car, go to the office, go up the stairs, I will stay here, do some calculating, phone calls. You could argue that the way I work is self-employed. (Participant 23 male aged 56)

Some participants reported quite minor alterations to their working methods that had helped them to manage the more physically demanding parts of their jobs, as this care assistant describes:

So I do alter the way I do that a little bit. If I'm moving footplates on wheelchairs, everybody else just bends over – I actually get down on the floor on my knees, and they've provided me with a kneeling pad so I'm not hurting my knees on the floor. (Participant 5 female aged 43)

This building trade worker also described how he had been able to slow down his pace of work:

I take me time more. I used to go like a bull at a gate, so now I take me time a lot more. It has helped me back. Other than that, nothing else has changed. (Participant 20 male aged 43)

b) Pros and cons of working for oneself

However, working for an unsympathetic boss, and the inability to control his workload had led this participant to start up his own business:

I'm going to pace meself with what jobs I'm doing. Not take me time as such, cos I'm always used to working at nine hundred mile an hour – but I'll be able to limit meself – do a couple of jobs a day instead of six, seven, eight jobs a day. (Participant 22 male aged 35)

Other participants agreed that there were advantages to being self-employed. One participant with a three year history of back pain had been working part-time as a freelance IT consultant, as well as running his own property development company. Because of difficulty managing his back pain, he had given up the consultancy in order to concentrate on the latter. Although he was worse off financially, it meant that he was able to have more control over his daily routine, and delegate to his employees:

If I hadn't been self-employed - because of the property business that I've got - but if I was actually working for somebody - I'd probably be unemployed by now. (Participant 2 male aged 43)

c) Fewer options if working alone

Another participant worked in catering both privately, and for an agency. To some extent she could choose how much work to take on, however once she had accepted a booking she was generally working alone without the possibility of adjustments. She considered that asking clients for help would have lessened their confidence in her ability to complete the job.

When you're actually doing a job and you're doing a good job, if you let them start seeing well I'll have to sit down for five minutes they'll think - 'oh she's not very reliable, we won't book her again we'll get somebody else'. (Participant 14 female aged 57)

d) Colleague support

Others were able to ask colleagues for help on an informal basis when their symptoms were more troublesome. This seemed to work well when the help was available from a team, as this participant describes:

Oh they're very good. If there's days when I can't bend down - or I sit there in the chair like this - they do things for me. (Participant 11 female aged 57)

However for those who worked with just one other colleague, such informal arrangements appeared to carry greater risks to job retention:

I've always gone to work, and who I work beside has been brilliant – you know when my back's been playing up he'll say don't lift those up, I'll do that. If he wasn't there I wouldn't be able to do it.

(Participant 17 female aged 37)

3.4 Discussion

The findings of this interview study demonstrate that although most of the participants had seen clinical specialists as well as their GP, they had received little work-focused support and guidance. Consultations had failed to resolve underlying concerns about their health condition that contributed to their concerns about their ability to work. There was little evidence of communication between healthcare providers and the workplace. Few participants had received effective or sufficient support from occupational health services, if available. Of those who had remained at work, most were making informal modifications to accommodate their symptoms, either independently or jointly with their colleagues and line manager.

Issues of diagnosis, ageing and physical work

Most participants perceived that their back condition might be viewed negatively by others in the workplace. Other studies have reported on the stigma associated with low back pain; for example that having time off work with a bad back has acquired 'moral stigma' because of media reports associating it with fraudulent benefit claims (Holloway et al., 2007); those with the condition may perceive that their condition will be doubted by employers and colleagues (Soeker et al., 2008) particularly when they feel they cannot perform their usual work tasks yet able to carry out basic daily living activities. This fear of being perceived as a 'cheat' can compound the anxieties of coping with the condition itself (Lippel, 2003). Participants therefore wanted to be able to explain their symptoms, but attaching a diagnosis to low back pain is difficult as most is due to 'non-specific' pathology (Koes et al., 2006). The term 'non-specific LBP' was not used by any of the participants. It was common for the participants to have

seen several clinicians about their back pain, in some cases over several years. As Sawney and Challenor report (2003), patients are inclined to believe the first diagnosis they are given and labels then become difficult to remove. Inappropriate or mistaken beliefs about the cause of back pain have been identified as an obstacle to recovery (Kendall et al., 1997). The results of our study show that the message that back pain is normal and self-manageable is either not being given by clinicians or not being heard by patients. As Holloway et al argue (2007) the 'paradigm shift' in the treatment model for low back pain to self-management, rather than cure, is relatively recent, and patients (and their employers) may not understand it. Previous studies have shown that patients themselves may become frustrated by the lack of what they perceive to be a meaningful diagnosis (Corbett et al., 2007; Lillrank 2007). Unless clinicians are able and willing to explain the changing nature of back pain management directly to employers, it remains the patient's responsibility to interpret the information and advice given by clinicians. Those who have received biomedical explanations and specific diagnoses in the past are likely to be particularly confused and in greater need of advice explaining the nature of 'chronic' pain and the role of heavy physical work and age in back pain. Many participants perceived that a history of physical work, and increasing age were associated risk factors, although in reality there is little evidence to support these beliefs (Burton & Waddell, 2004). This perception is particularly important as the age of retirement is to increase in line with life expectancy (Department for Work and Pensions, 2006) and that the quality of work life impacts on quality of life in retirement (Feldt et al., 2009). If patients believe that their pain is associated with 'wear and tear' or 'arthritis' or 'degeneration', they may also believe that their health condition will naturally worsen with age. Age-related explanations may be used by clinicians with the intention of reassuring patients as to the benign nature of their condition, but may be interpreted by patients as implying progressive deterioration (Holloway et al., 2007).

The use of medication

Although medication is a key evidence-based tool in symptom management in low back pain (Airaksinen et al., 2006; van Tulder et al., 2006; National Institute for Health and Clinical Excellence, 2009), the participants in this study expressed uncertainties about their medication, including its possible impairment of their ability to work. In comparison with other studies of primary care back pain management (which have for example examined the advice given by GPs to patients about activity including work) there have been few studies of how the subject of medication is approached within the consultation. A review by Broekmans et al (2009) has concluded that medication adherence is poor in patients with chronic pain and a further study (Campbell & Cramb, 2008) has also shown that dissatisfaction with medication is common in this client group. Banbury et al (2008) argue the need for healthcare professionals, particularly GPs and pharmacists, to aim for greater concordance when prescribing medication for back pain. Their study demonstrated that patients with low back pain had little knowledge about how to take medication, perceived it as ineffective, were worried about side-effects, and concerned about masking of symptoms, and possible addiction. In addition, McCracken et al (2006) demonstrated that perceptions of others' negative attitudes toward the use of analgesia can affect patients' adherence. Some studies have indicated that effective medication can increase productivity in chronic health conditions (Goldfarb et al., 2004), but the use of opioids, particularly 'strong' opioids has been associated with work loss in low back pain (Volinn et al., 2009]. There is very little research published on the role of milder medications in vocational rehabilitation for low back pain. Attitudes towards medication, and its use in work retention for back pain would seem to be an area that needs to be addressed.

Sickness absence

The majority of participants had taken sick leave for back pain, but as others have argued (Hansson et al., 2006; Hooftman et al., 2008), this decision is not taken lightly. In this study most of the participants were reluctant to take sick leave, not only because of their concerns about negative attitudes to back pain, but also due to absence management policies that appear punitive to those with chronic, fluctuating conditions, particularly those who take short term absences. They therefore seem to be doubly disadvantaged and problems may then become hidden from the employer. There is some evidence that presenteeism may be increasing as a result of rigid absence policies (Munir et al., 2008). Although its effect on productivity is difficult to establish, it has been argued that presenteeism may have a detrimental effect on future health (Bergstrom et al., 2009). The economic costs of this may be considerable. For example, in a recent report, the costs of presenteeism for mental health problems were estimated at £605 per employee annually (Sainsbury Centre for Mental Health, 2007). A large number of employers use absence records when selecting for redundancy and appointing staff, and this is naturally of great concern to the individual employee. The Chartered Institute of Personnel and Development (2009) advises employers to be aware that they should monitor employees' performance and behaviour, not just their attendance levels, for indications that they might be unwell, particularly in the current economic climate when greater job insecurity due to the recession may be responsible for reduced sickness absence. Employers may not always find the right balance between supporting employees with health problems, and taking action against those who try to take advantage of occupational sick pay (Chartered Institute of Personnel and Development, 2009). However, employers also need to be aware of the reasons why workers with low back pain may be reluctant to disclose their condition, and provide greater opportunities for supporting openness. The finding that people of

working age are reluctant to take sick leave for back pain is supported by recent epidemiological evidence (Bowey-Morris et al., 2011).

The role of GPs and other clinicians in advising on work

Many of the participants had remained in work despite, rather than due to, the recommendations they had received either from their GP or other clinicians they had consulted. There was little expectation that healthcare providers might address their problems in the workplace. Studies of back pain prevalence have demonstrated that only between 30% and 40% of those with back pain will consult a GP (Department of Health, 1999; Picavet et al., 2008) but little is known about why they choose not to do so. The study findings suggest that employees may remain at work with back pain without visiting the GP, believing that GPs have little to offer. Patients may therefore not consult their GP until the situation at work has deteriorated and is more difficult to resolve. Alternatively they may consult other healthcare professions instead, particularly for manual therapy which is recommended as a core intervention for non-specific low back pain (National Institute for Health and Clinical Excellence, 2009). A recent study by Pincus et al (2010) suggests that low back pain comprises 70% of the caseload of private musculoskeletal practitioners, and that these tend to be patients with long term recurrent symptoms rather than acute episodes. A study by Foster et al (1999) concluded that low back pain accounted for at least 50% of physiotherapists' outpatient workload; this proportion may increase further as the government intends to increase the provision of self-referral to NHS physiotherapy (Department for Work and Pensions, Department of Health, 2008).

Work modifications

There is a wealth of evidence that temporary modifications can aid work retention (Franche et al., 2005) and reduce the recurrence of sickness absence (van Duijn & Burdorf, 2008). However, the effect of such workplace interventions on health outcomes is unclear (van Oostrom et al., 2008). Furthermore,

although most people who experience back pain remain at work, or return to work within a few weeks, we do not know if they are successfully managing their duties. Some, as the findings from this study have shown may work at reduced capacity, rely on the help of colleagues, remain on adjusted duties or hours, have periods of absence for a secondary illness such as depression, or change occupation. If modifications are unavailable or ineffective, healthy and productive work may prove unsustainable.

The role of GPs and other clinicians in work modifications

Few participants reported being assisted or advised on modified work, and those who did described it as vague and not fully integrated into the workplace. Simply advising a patient to stay at work, although reflecting clinical guidelines to remain active, may be of little practical help to some patients, and misconstrued as a lack of understanding by the healthcare professional of what it means to remain at their workplace with back pain. In this study sickness certification was the main way in which GPs managed difficulties at work, even in workers who expressed a willingness to remain at work. These findings reflect the results of the GP questionnaire survey reported in Chapter 2 where it was concluded that most GPs do not see the management of patients' work problems as their role. Participants in this study had received care from both private and public healthcare providers but the lack of appropriate or effective work advice remained constant. Some authors have suggested fear-avoidant beliefs of GPs and other clinicians are a factor: those who perceive low back pain as mainly a biomechanical condition are more likely to advise people to refrain from work or avoid certain tasks (Coudeyre et al., 2006; Bishop et al., 2008). This is seen in public and private practitioners (Pincus et al., 2010) and the experiences of the participants in this study.

One participant gave an example of a GP making a direct attempt to influence the employer and in two other cases, therapists had tried to improve patients' workstations, but all reported limited success. Unfortunately a patient's employer

is under no obligation to act on advice given. As with the findings of the questionnaire survey reported in Chapter 2, GPs appeared to expect patients to receive help from occupational health. The roles and responsibilities of healthcare professionals in relation to their patients' employment are poorly defined in the UK. Physical therapists may expect workplace assessments and modifications to be the role of health and safety officers or occupational therapists (Pincus et al., 2010). Laypersons/patients on the other hand, may see themselves as responsible for managing musculoskeletal disorders (Larsson & Nordholm, 2008) and/or have varied expectations of the help that GPs and clinicians can provide. UK healthcare professional bodies have signed a Consensus Statement, pledging to 'do all we can to help people enter, stay in or return to work' (Black, 2008), but as yet, with no clear lines of responsibility or pathways of communication, patients seem to be left to rely on their own resources.

The role of occupational health in work modifications

Participants' experience of modified work was therefore largely centred on the workplace rather than any interventions from clinicians. Those who could manage their own workload or a choice of tasks had an obvious advantage. Some of these modifications were simple, and used flexibly when the need arose. Only a minority of the participants in this study had received support through occupational health services, often following a period of sickness absence. Self-referral was unusual. Experiences of occupational health varied; modifications may not have been considered or have been inappropriate or ineffective. Implementation largely rested with the line manager; there were few examples of face-to-face communication between all the parties concerned, leaving the details to the interpretation of the manager and the employee. Those whose symptoms had followed a workplace accident seemed to have received more attention, perhaps due to employers' fears of compensation claims. Such concerns may lead to an over-cautious approach. In the UK the extent of

occupational health services is determined by the costs that employers are willing/able to bear. Employees' perceptions of the confidentiality and affiliation of occupational health are also important. Reducing the number of sickness absence days that 'trigger' a referral to occupational health may lead to more effective management of musculoskeletal disorders (Department for Work and Pensions, Department of Health, Health & Safety Executive, 2005), however if the service is viewed solely in connection with disciplinary procedures, employees may be reluctant to access it. Previous UK research suggests that the implementation of occupational health guidelines, particularly prompt intervention, may be hindered by organisational obstacles. A study by McCluskey et al (2006) found that the procedure for processing sickness certificates led to unnecessary delay in notifying occupational health of sickness absence.

The role of the manager in work modifications

Line managers have a vital role in supporting employees with health conditions such as low back pain. Their beliefs and attitudes, and the support and guidance available to them, can either facilitate or impede the employee. A recent study of line manager competencies (British Occupational Health Research Foundation, 2010) recognises that line managers are 'the key to work adjustments and implementation of work redesign initiatives' and that they require support in this role. The report concludes that managers do not need to be knowledgeable about health conditions to be effective, however, it would seem from our findings that some basic understanding of pain mechanisms may be helpful in clarifying whether tasks are 'harmful' to the back.

In this study, participants considered that managers were more sympathetic if they had also experienced back pain. However, sympathy in itself did not necessarily lead to appropriate management. If a manager believes that pain should be avoided, and that heavy work is inherently dangerous, their approach may be overcautious and result in permanent restrictions. The ease with which work modifications can be made has been described as 'adjustment latitude'

(Johansson & Lundberg, 2004). There is a risk however, that if workers are able to, and choose to avoid certain tasks because they think they are unsafe or will make their condition worse, then it may become a permanent arrangement and lead to reduced capacity. These 'representations' (thoughts, attitudes and beliefs) that an individual has of their condition are one of the key factors in the 'margin of manoeuvre' model described by Durand et al (2009). The findings of this study suggest that the representations held by managers and other stakeholders are also important. Much research has studied the effect of fear-avoidance beliefs of patients, GPs and other clinicians (Linton et al., 2002; Coudeyre et al., 2006). The thoughts, attitudes and beliefs of employers, line managers and work colleagues are of equal importance, but feature less in the literature.

Participants' experiences of line managers were mixed. In her study, Foster (2007) concluded that 'employees are reliant upon the goodwill of individual line managers for successful adjustments, turning what should be a legal obligation into a personal lottery'. Research conducted for the British Occupational Health Foundation (2010) found that the relationship with the manager prior to sickness absence had a bearing on return to work, and suggested that the attitudes of managers were perceived by employees as varying according to the health condition. In a study of university employees, Munir et al (2005) found that only 50% of those with chronic health conditions had disclosed their condition to their boss. As suggested earlier, employees with back pain who are concerned about being seen as fraudulent or unreliable may be unwilling to disclose their condition. Their need to maintain an identity of independence and ability, and/or not wanting to appear pre-occupied with their pain may be a barrier to seeking support (Campbell & Cramb, 2008) and they may perceive themselves as primarily responsible for managing their condition at work (British Occupational Health Research Foundation, 2010; Larsson & Nordholm, 2008). However, interventions designed to empower employees with chronic diseases suggest

that it is possible to train employees to negotiate work accommodations (Varekamp et al., 2009).

Modifications should be temporary and involve a gradual return to full hours and duties. However the line manager may then be faced with conflicting demands if productivity levels are subsequently reduced. The effect on other workers also has to be considered. The participants in this study did not want to be a 'burden' to their colleagues, and felt more comfortable about receiving help if they were able to reciprocate in some way. Some workplaces are better able to offer modifications than others due to staffing levels and the variety of work tasks. Other research has shown that fewer options are available when the work is highly specialised, or physically demanding (Baril & Berthelette, 2000). It may be difficult for employers to see the long term 'business case' for offering modifications and as organisations become 'leaner' there is a risk that lower staffing levels increase individual workloads with fewer options for adjustment. Where modifications had been made by employers, more attention seemed to be paid to adjusting equipment, such as seating, rather than grading tasks and activities. Employees and employers need to be able to consider a wide range of different types of modification, but the study by Foster (2007) concluded that managers were more likely to favour the provision of equipment, rather than adjustments to work itself that could result in changes to employment conditions and work organisation.

Limitations and strengths

Qualitative studies should have credibility, dependability and transferability (Graneheim & Lundman, 2004). In this study, information was collected using semi-structured interviews based on previous research findings which provided a theoretical basis and so greater credibility to the topic guide. Individual interviews were chosen to encourage each participant in sharing their individual experiences and perceptions without being influenced by the presence and views of other participants as might have arisen in a focus group setting (Lehoux et al.,

2006). A more inductive approach to data collection and analysis, for example grounded theory (Glaser 1992; Strauss & Corbin, 1998) or interpretative phenomenological analysis (Smith & Osborne 2003) may have revealed more latent themes. However, it was not the purpose of this study to develop theory, or to explore in depth the meaning that participants' experiences had to them as individuals, but instead to provide a broad understanding of the issues involved. Dependability was increased by having the same interviewer who transcribed each interview verbatim. This process also facilitated familiarity with the data. Interview transcriptions, coding and suggested themes were repeatedly checked, compared and revised with another researcher which also increased credibility and dependability. Transferability was facilitated by providing a detailed description of: the method of selection, the process of analysis and the characteristics of the participants (without revealing their identity), and by the inclusion of appropriate quotations.

It may be considered a weakness of the study that the themes were not confirmed by the participants; however they would not have had full access to the data set, or the same knowledge of the literature to guide the analysis. Bias could have arisen because the researcher had recently been working as a clinician and this was known by the participants. This knowledge may have influenced their contribution to the interview as they may have wanted to convince the researcher of the legitimacy of their illness story; a 'moral plot' (Werner et al., 2004). To minimise these issues, the researcher requested that any questions about back pain were dealt with after the interview had been completed.

Convenience sampling was chosen because of restraints on time and resources and this restricts the generalizability to people working with low back pain and not, as originally envisaged, to unemployed people with low back pain. The diversity of the sample also limits the potential to understand in

depth/distinguish between the experiences of different sub-groups in terms of for example age, gender, occupation.

There were comparatively few participants self-employed or employed by small-to-medium enterprises compared with large employers. The reason for this is unclear. It may be that the pressures of working for oneself or for a small employer impose actual or perceived obstacles to accessing treatments or taking part in a research study, or it may reflect UK norms in that the majority of the working population is employed by large enterprises: statistics show that whilst small enterprises (<50 employees) account for more than 99% of businesses, large employers (public and private) account for almost 60% of the workforce (Department of Business Innovation and Skills, 2009). This would appear to be an area where further research is indicated.

There were also very few unemployed participants, and a weakness of the study is that data were not collected that could have demonstrated the representativeness of the sample. The majority had taken sick leave, some for several weeks, and some were unemployed. The participants may therefore not be representative of those who are managing their back pain more successfully at work and so limit the extent to which the findings can be generalised to a wider population.

Although not the aim of this study, a comprehensive understanding of the factors involved in work retention would include other factors, for example the context and influence of the participants' home situation.

3.5 Conclusion

This interview study has found that although the participants had received a range of healthcare interventions for their back pain these had failed to alleviate their concern about their work ability, which was closely connected with uncertainty about the condition itself. They were concerned about managing flare-ups, the use of medication to manage symptoms and taking sick leave. Few

had access to support from occupational health services, and for those who did, the support was variable. Management of their condition at work largely rested with the resources of the employees themselves, their colleagues and their supervisors/line managers. Communication between the employee, their employer and clinicians was limited, with the employee as the main conduit for advice and information. The results of Chapter 2 demonstrated that GPs do not see that it is their role to provide work-related advice and support with regard to managing their back pain at work. This study has demonstrated that it is also the patients' experience, and that any help they receive from individual healthcare practitioners or at work is also likely to be limited. However, none of the participants had received multidisciplinary rehabilitation using a cognitive-behavioural approach as clinical guidelines recommend for this client group. The extent to which rehabilitation can address their concerns about work would inform the design of the intervention in the proposed feasibility randomised controlled trial by indicating whether, when and what further support is needed. Thus the next chapter reports on the participants' experience of routine multidisciplinary group rehabilitation.

CHAPTER 4 PATIENT INTERVIEWS: POST-GROUP REHABILITATION (RESULTS)

This chapter reports on and discusses the findings of the interviews conducted with members of the study sample described in Chapter 3, **after** they had attended group rehabilitation. The methodology is as described in section 3.2. The interview schedule can be seen in Appendix 5, page A20 – A23.

4.1 Participants in the post-group rehabilitation interviews

Of the original 28 patients who participated in the pre-group rehabilitation interviews, 19 participated in the interviews following group rehabilitation. Of the nine who did not participate, eight were known to be at work, one of these on modified duties. Seven had not attended routine rehabilitation for the following reported reasons: three due to work commitments, two due to difficulty accessing treatment (due to administrative/ communication problems); one due to holidays/work commitments; one due to family circumstances. As these participants had not attended the rehabilitation programme, they were not interviewed a second time. Of the two remaining participants, one had attended rehabilitation but declined to be interviewed due to work commitments. The other participant could not be contacted. She had been off sick at recruitment. It is not known whether this participant attended rehabilitation. The three participants who were unemployed at the pre-rehabilitation interviews remained unemployed, although the participant who had been made redundant was in the process of applying for another job. Another participant was in the process of being retired on ill health at the pre-rehabilitation interview. Her employment had since been terminated; she was receiving Employment Support Allowance and actively looking for work.

Demographic details for 19 participants are shown in Table 9.

Table 9. Demographic details of participants in the post-rehabilitation interviews (n=19)

Sex	Male	10
	Female	9
Age	Mean age (S.D.)	43.6 yrs (11.8)
	Age range	22-64 yrs
Education level	Secondary school	7
	GCSE	1
	Further education	8
	Higher education	3
Length of back pain history	Mean (S.D.)	6.25 yrs (8.12)
	Range	3 months – 26 yrs
Previous treatment from clinicians other than GP	Yes	16
	No	3
Work status at follow-up interview	At work	14 (5 modified work)
	Off sick	1
	Unemployed	4 (3 due to back pain)
Employer profile (of employed participants)	Large (<250 employees)	14
	Small (<20 employees)	0
	Self-employed	1
	Self/agency employed	0
Sick leave taken for back pain	Yes	12
	No	7

4.2 Results

There were five main themes identified through analysis of the interview scripts.

These reflected the experiences of how group rehabilitation had addressed participants' concerns about working with back pain as reported in Chapter 3.

These themes and their sub-themes can be seen in Table 10 and are reported with quotations to illustrate the findings.

Table 10. Themes and sub-themes of post-rehabilitation interviews.

1.	Changing cognitions
i	Confidence and control
ii	Self-responsibility
iii	Adaptation/acceptance
2	Help with work
i	Inconsistent/indirect
ii	Doubts as to whether the team could help
iii	Unresolved concerns
3	Self-management tools applied at work
i	Exercise
ii	Pacing
iii	Medication
4	Treatment approach
i	Content and delivery of information
ii	Group setting
5	Obstacles to accessing treatment
i	Work itself
ii	Referral practice

4.2.1 Changing cognitions

Many participants reported that they felt less concerned about their ability to work since attending routine rehabilitation because of changes in their thoughts and beliefs about, and their attitude towards managing, their back pain.

4.2.1.1 Confidence and control

Some participants' concerns about work had reduced due to the general increase in confidence and sense of control they had gained through group rehabilitation. This included one participant who had been retired on ill health before she had attended the programme and was now looking for work, and another who had returned to work on modified duties. This confidence could relate to increased confidence in managing flare-ups:

I feel confident if it goes again I know what to do about it. Not like last time. (Participant 3 male aged 44)

It also reduced concerns about injuring the back. This participant had gradually started to do more lifting at work after using the gym during the programme:

..... I was just worried that I'd injure myself, hurt myself...just going in the gym and thinking, well I've been on a rowing machine – that's bending and pulling on my back – and I can still walk afterward you know! So maybe lifting that thing – I can do it. (Participant 6 male aged 29)

4.2.1.2 Self-responsibility

Many of the participants referred to a sense of their own responsibility and role in helping themselves to manage their back pain and stay at work. This included keeping up with exercises that would improve and maintain their general health and being more proactive in seeking help regarding their work problems:

'It's my problem. It does help that you've got to care about yourself. Yes it did help. I know I've got to live with it. I can't sit down and wait for money from the government. (Participant 16 male aged 24)

But we can't do nothing much about it, but it's realising that yes, this has happened and we'll manage it. Like I'm having to sort out my Access to Work to get a proper workstation assessment done. (Participant 12 female aged 30)

4.2.1.3 Adaptation/acceptance

Participants talked about the extent to which they had accepted that they had a long term condition for which there was no cure, that it was not necessarily going to get any worse, and that they could manage it more effectively:

I think it just made me – it helped me come to terms with the pain and accept it. (Participant 4 female aged 44)

I think my mind set's changed about it – thinking I've just got to get on with it you know... I know that I can't do no more damage.....so I think I've sort of accepted that really. (Participant 28 female aged 35)

However for some this meant adapting a reduced level of activity rather than a sense of feeling able to do more and to return to previous work activities. This participant was not intending to return to work in IT:

Basically I'm just applying everything they tell me and it's actually – rather than me try to get back to my lifestyle, prior to the injuries that I've had, I'm actually doing it the other way round now...although I was in IT for a long time, I don't think it's actually good for my situation. I can't do the things I used to. I've learned not to expect things to be the same, and I have to alter my life around it. (Participant 2 male aged 43).

Others still considered that previous work tasks were responsible for their back condition:

There's a lot of jobs I've had to do over the years. You don't care how much damage you're doing to yourself. (Participant 3 male aged 44)

It's a wonderful thing your body isn't it, but there's obviously a lot of – because we abuse it by and large? I think mine started in the RAF as a cook with these big mixing bowls... I think that's what's done me, and all the square bashing, cos you used to go through all these combat situations – don't know if that did it – the wear and tear... (Participant 13 male aged 64)

4.2.2 Help with work received from the rehabilitation team

The team had made some efforts to liaise with employers in some cases but this was mainly at the request of the patient. Some participants would have appreciated more liaison with their workplace than they had received. Others considered it would not have made any difference. Help was inconsistent, largely indirect and reliant on the active support of the employer. Although patients could attend a one-off work-related group session run by the team, this was not accessed by any of the participants.

4.2.2.1 Inconsistent/indirect

One participant had returned to work during the programme and reported having received good support from her employers. At her instigation the team had written to her employers with advice on taking breaks. Another participant had been able to share information about the treatment approach with her employer:

She was pleased that something was being done for me, and I could go back every week and tell her what I'd done, and she thinks I got a lot out of it as well. I've been able to pass on information to some other members of staff. (Participant 5 female aged 43)

However, others who had received less support from their employers would have appreciated more contact. This participant's employers appeared more concerned about the time he was taking off work:

My manager's really good, it was HR who said 'no, he's got to make up his time'. But no-one has even asked me about the programme. It's a bit of a shame really. I thought they could use that for their benefit – might get a lot of benefits out of it for the whole workforce.

*'Was there any contact between the team and your employers?'
It would have been helpful for them to have contacted the HR department. (Participant 15 male aged 37)*

Participants reported instances where other patients on the programme had received support regarding work, although these could not be substantiated, and the outcome was unknown:

Yeah we all had work problems..like one lady who – she worked on the trains, and they was pushing to finish her because they said she couldn't do the job....she was quite upset, so they was giving her quite a lot of information separate, in her group, individually, a lot of information about things she could do. (Participant 24 female aged 55)

However others appeared not to have had sufficient help:

Well, my employers, they really helped me out, but one of the ladies that did go there (to the treatment programme), she actually lost her job while she was there. (Participant 11 female aged 57)

This participant had a new temporary contract within the same company he worked for at the time of the initial interview. This new role involved more sitting than in the job he had prior to the treatment programme which he was struggling with. He did not feel that he had received enough individual support:

'Do you think it would have made any difference if the back team had contacted your employer?'

Yeah, if they'd rung HR to find out at the end, how things work you know in some way like – 'well these are the issues with this person – how can you benefit him as a company – how you can help him'. Because I felt like I was doing all the pushing. If there was some support – some professional support – that would have helped prompt the employer I think. They would have listened more, instead of thinking 'oh, there's another employee moaning again'. (Participant 7 male aged 43)

For participants who had returned to work on 'light' duties, arrangements to grade up to usual duties seemed to rest with them. In one case his key worker had suggested that his occupational health provider could contact the team however this was not taken up by the employer:

I said to Occ Health – 'you can phone my key worker'. He said 'I can't do that, it's not legal, I'm not allowed to do that.' I spoke to HR – they said 'well I don't know why!' (Participant 3 male aged 44)

This participant also received less help than he had anticipated. He remained on sick leave following a flare up of pain after starting the programme and considered that more direct, individual support would have helped.

I was led to believe that part of the treatment was for the team to liaise with employers, and from week one the manager was demanding a letter...It just was not addressed at all. The phone wasn't picked up once, not once. Something was sent, but like I said it was just a standard letter picked out of the folder, it was just general.(Participant 10 male aged 43)

This participant confirms that work issues were approached indirectly. This participant perceived the approach to work to be general with little opportunity for individual attention:

*...they didn't really approach the problems at work. You – cos you sat and talked to them individually...you had about a five minute one-to-one. You could have a bit longer if you wanted, where you spoke about anything, you know, and what you wanted to achieve, and what you'd achieved that week. But it wasn't directly done for work.
(Participant 24 female aged 55)*

4.2.2.2 *Doubts as to whether the team could help*

Although some participants indicated that they did not receive sufficient help with work issues, there was some doubt as to the impact this might have made. For example one participant remained worried about her sickness absence records but was not keen for the team to raise this with her line manager as it might cause other problems:

No - because that would all come down on my manager's head then. He's under a lot of pressure. I wouldn't want anyone to do anything that put the focus on him not doing it. (Participant 4 female aged 44)

Others felt that contact by the team would not have made any difference because their employers would have paid little, if any, attention to it:

*Yeh it's one of them things. They couldn't really do anything. I would hope that they could have done something, but I suppose they couldn't really have done anything. If they can't listen to my own GP are they going to listen to anyone from the programme?
(Participant 12 female aged 30).*

... I mean, they'd send a letter and it would go to the personnel department and they'd just sort of look at it - they'd probably inform the manager. I think that's as far as it goes, cos - it'd probably be different if it was a small place I worked for, but being in a big company, you're just a number. (Participant 8 male aged 53)

Although it seemed as though there were some modifications that could have helped. One nurse who had returned to work but was still struggling with frequent flare-ups considered that her employers were sufficiently supportive and did not need support with work issues, but when pressed admitted that certain physical demands could be reduced, such as better staffing levels and equipment provision. However she was reluctant to consider modifications:

I'm thinking in the long term now – what can I do for the future - thinking about what job I could do – obviously I can't do this long term I don't think.....My duties have more or less stayed the same to be honest because I wouldn't want them to change in all honesty.. I wouldn't want any special treatment or any desk duties or anything like that.

(Participant 28 aged 35)

4.2.2.3 Unresolved concerns about working with back pain

Some participants, even though they found the programme helpful, and were more confident about managing their back pain, still had some unresolved concerns about continuing in their current jobs:

Concerned? Not as bad as I was, you know. I still think every so often is this the best thing to be doing?' – the job I'm actually doing for- I don't know. I know they say it doesn't mean that you're damaging your back, the pain, but really.....it can't be good...I just think it's (her job) going to get too much if I'm not careful.....but I just think if it gets any worse it's going to be awful really...

(Participant 28 female aged 35)

Reservations remained with some regarding applying for work and disclosing their history of back pain:

'Do you think it might affect you getting a job?'

The fact that I've said 'Oh yeah, I'm not very good' – they might think I'm more trouble than I'm worth – I might be asking for special treatment. (Participant 27 female aged 22)

Others had unanswered questions and remaining concerns about work causing further injury:

You see I'd quite like to change my job. I'd like to go back to working with children again, but I'm not going to be able to pick them up am I? I was a nanny - there's no way with the pain I have now that I could do it. (Participant 4 female aged 44)

However, none of the participants had attended the optional one-off session that the team provided for those with work problems. Some were unaware of it, others felt it was not aimed at them.

4.2.3 Application of self-management tools to work

Participants reported on the extent to which they had been able to apply different elements of the treatment programme to help them manage their work.

4.2.3.1 Exercise

Exercise was referred to by several participants as one tool that they thought would help them remain at work. This might be through exercises they could incorporate into work:

...she was telling us how to do core muscles – now, for some reason, if I’m bending over, I use that as an excuse to bring in a bit of exercise. So if I’m standing, I’m turning my core muscles on, and if you’re lifting something, you’ve actually done a small workout.

(Participant 2 male aged 43)

...and the exercises...because I’ve got no balance, and yeah, that’s helped with work because...if I’m leaning into the van with one leg on the floor, I’m wobbling, which is affecting your back. So – yeah it has helped with work in a roundabout way, but not specifically.

(Participant 24 female aged 55)

Or by using exercise more generally, for example by keeping more flexible and active. Exercise was not referred to by participants as having been prescribed by the team to address specific work problems.

4.2.3.2 Pacing

Participants referred to the benefits of ‘pacing’ their work activities, mainly in terms of taking more time over tasks and taking more regular breaks, or working in smaller ‘chunks’:

It’s a whole different attitude – it’s not like using it as an excuse for being lazy – you were probably doing too much in the first place – so it’s a case of getting the balance right there. So take your time. A job takes as long as it takes. (Participant 3 male aged 43)

I’m more aware – with driving and things like that, not to stay in the same position for too long. (Participant 15 male aged 37)

Although this wasn't possible for all participants to apply at work:

...you can't slow it down, that's the speed, you've got to get it out and done as quick as possible – there's no way of really going 'just a minute'. It's great saying 'pace things' but sometimes you can't. That worked more for being at home. (Participant 6 male aged 29)

4.2.3.3 Medication

Participants described how medication was helping them to manage their pain at work, either by changes that the team had recommended to prescriptions, the dosage or the frequency of medication, and through addressing their concerns about medication:

....and they gave me slow-release ones as well, which was a bit more helpful, because I was able to take them before the shift – just a simple thing like that really. (Participant 28 female aged 35)

...instead of thinking 'well I can't take those two at dinner time because by the time I get home I'll have a blinding headache', well I can now, so therefore I can keep the pain at bay a lot better....so now I can keep the pain at bay all day. (Participant 24 female aged 55)

4.2.4 The treatment approach

None of the participants had experienced group multidisciplinary rehabilitation before. The majority had enjoyed the informality and had enjoyed the experience. The knowledge gained had helped to reduce concerns about working with back pain. Participants talked about their experiences of and responses to the group approach to treatment.

4.2.4.1 Content and delivery of information

The comprehensiveness of the information received, and the method of delivering and explaining it was commented on:

And any question you asked, no fault at all, can't fault them at all – they were very open to questions....very open, any suggestions, or if you'd got any problems you could talk to them. (Participant 18 female aged 58)

And they really did make an effort to keep that light atmosphere. Which I found was very important. Cos there's nothing worse than if someone's in front of a class with a teacher and they go 'ssh sh' and you're bored with it. (Participant 24 female aged 55)

4.2.4.2 The group setting

It seemed that the opportunity to compare themselves with others was helpful to the participants, both in validating their condition, and challenging their own perception of the severity of it and learning from each other:

Well, if like you'd got concerns, like I think - well all of us did in the group, then you listened to other people, and the pains and things that they're experiencing, and you'd think to yourself 'well mine's probably not as bad'. (Participant 8 male aged 53)

I think it was a good way of going to something and going - 'Oh I'm not really that bad!' I don't know if that was the idea, whether they just get someone in with - that's really bad, so everybody else goes 'actually mine ain't too bad!' But the group thing where you talk about it, I don't want this to sound bad, but it was good to see people with worse conditions than you in a way - you think to yourself 'what am I whingeing about?' (Participant 6 male aged 29)

Although two participants did not feel they had benefited:

I think what I was worried about was they didn't take you as an individual. (Participant 7 male aged 43)

Unfortunately for me it didn't work. (Participant 10 male aged 43)

4.2.5. Obstacles to accessing treatment

Although many of the participants had found the treatment programme helpful in addressing some of their concerns about working with back pain, there were factors influencing the ease with which patients were able to access it.

4.2.5.1 Work itself

Participants discussed how work itself might be a barrier to attending treatment, including those seeking work. Some had been required to take annual leave to attend the programme, or to make up the time by doing extra shifts:

What has changed though was the approach from work. Whereas when they said it was all OK (for him to attend), I had to make my time up in the end, every time I came. (Participant 15 male aged 37)

Taking time away from work was not necessarily easier for self-employed participants:

I initially cancelled the first one because of my work, and the second time I was going to ring and cancel it but they sent me a letter saying that if you do that once, second time you do it you're out – and I thought about it, and I thought – I've got a load of work to do, I can't really do this and have to do the work as well. But then I thought, all my life I've been doing this, I'll go there, I'll try the one session, if I don't like it I won't go back. (Participant 2 male aged 43)

Work commitments were also an obstacle for participants who may have benefited from attending the optional work-related session run by the team:

at the end of the course they were saying if you're still worried about working and things, you can go on an extra course, like a programme, to go and talk to some people, and discuss about work – which – I didn't go to that –unfortunately-because of work, it was just a bit difficult to get there. (Participant 6 male aged 29)

...there was something happening in week four where they were running something, but I was at work, so I couldn't go. It was advice for keeping in work, and doing certain things. (Participant 7 male aged 43)

4.2.5.2 Referral practice

Another obstacle was that referrers did not necessarily know about the existence of the programme or refer patients promptly, and that referral was influenced by their own perspective or management approach. Referral might be delayed until the results of investigations were available; in some cases by as much as six months. There was a wide variation in the timing of referral:

Some of them hadn't had pain for long. A lady I got to know, she'd only been in pain since Christmas, and there was me, I'd had it four years. There was another lady there that had had it all her life. If I'd had that (the information) sooner I probably wouldn't have had so much rough deal as I've had. I'd have had my pain under control quicker, instead of suffering. It's stopped me doing things you know.
(Participant 5 female aged 43)

Even GPs who had referred participants did not necessarily know what they were referring to, or seemed to see the programme as a necessary stepping stone rather than useful in its own right:

..the GP said you must go to them, because you have to be in the system to get further treatment – but now I've been to them I don't need any more treatment...the only negative I can think of is it cost me three years in my own time. (Participant 2 male aged 43)

For some there was surprise at the speed of gaining an appointment, once they had been referred, whereas others had waited for longer to gain a place on the programme:

....I went for the assessment last July – didn't actually start the course until October – it was a case of waiting times and all that rubbish...
(Participant 10 male aged 43)

4.3 Discussion

The interviews reported in Chapter 3 described the concerns that participants had about working with back pain, and the limited work-related help they had received from their GP, other clinicians and their employers. However, the participants had not at that stage received treatment for their back pain through group rehabilitation. The findings of the follow-up interviews reported in this Chapter have demonstrated that many participants reported feeling less concerned about their ability to work after attending group rehabilitation. This was mainly due to changes in participants' understanding of, and their attitudes and beliefs towards, their health condition, and their ability to apply pain management techniques at work.

Confidence in managing back pain at work

Participants described an increase in confidence, feeling 'in control' and seemed to have accepted responsibility for managing their back pain as a long-term health condition. These changes reflect the concepts of fear-avoidance, self-efficacy and locus of control that underpin cognitive-behavioural approaches to back pain management (Waddell, 2004) and for some it seemed that this general self-management approach could be successfully applied to work. However there was ambiguity as to whether participants had actually increased their functional ability as a result of treatment or had rather come to accept the 'status quo' of their back pain. This may simply reflect that the participants had varying levels of chronicity of back pain, or that a combination of rehabilitative and pain management approaches are used within the treatment programme. Accepting responsibility for the self-management of back pain may be considered a positive outcome by patients and healthcare providers, but if patients are unable to make necessary adaptations at work themselves (which may include temporary or permanent adjustments to hours, duties and environments as well as relationships with colleagues and managers) then concerns about work are likely to continue. In this study, some participants had received support from the team, but there was no consistency of approach and the responsibility lay with the participants to instigate the support. Although the team did run an optional extra session for patients who had work-related problems, the participants had either not heard of it, were unable to access it, or did not feel it was aimed at them. There were no instances of employers contacting the team, even for those participants who were off sick, therefore concerns identified in the initial interviews reported in Chapter 3 about sickness records and justifying their condition at work had not been addressed directly by the team.

Self-management tools

Several participants reported that self-management tools learned during the programme, such as exercise, could help with work. Usually this was described

in terms of general symptom management rather than being prescribed specifically to help participants with their work tasks. A review by Hayden et al (2005) concluded that in adults with sub-acute low back pain, graded activity programmes improved rates of sickness absence, but these programmes were based within the workplace. For other forms of exercise the evidence is not clear. A randomised controlled trial comparing a brief information/advice intervention with an additional physical exercise programme found no effect on return to work rates (Hagen et al., 2010), although an earlier meta-analysis reported strong evidence that exercise significantly reduced sick days in the first year after treatment (Kool et al., 2004). The authors of a reported randomised controlled trial for chronic low back pain patients in Scotland have questioned the value of the exercise component in a combined education/exercise group programme (Ryan et al., 2010); however work outcomes were not collected. For the participants in this study, exercise included activities such as swimming and the gym, as well as muscle strengthening exercises. Where participants described applying exercises at work, it seemed to be through their own initiative rather than a specific treatment plan.

It seemed that concerns expressed in the initial interviews regarding the use of analgesia had reduced as a result of the programme. As discussed in Chapter 3, there is little research regarding the effect of medication on back pain and work ability, unlike, for example, rheumatoid arthritis. A recent Swedish research study has reported on the reduction in work disability of patients with rheumatoid arthritis as a result of medication use (Oloffson et al., 2010). As Nicholas (2004) describes, practitioners' approaches to the use of medication for pain can vary. Some advocate its use in order to capitalise 'on improved analgesia by an increase in physical and psychosocial functioning' (Collett, 2001). However, others disagree (Nicholas, 2004), arguing that seeking pain relief through a drug encourages patients to remain pain-focused and less willing to take responsibility for self-management. It may be that, as Turk has

suggested (2001), combined modalities may be more effective, however further research is needed to test this hypothesis regarding work outcomes.

Pacing was also referred to by participants as a means of helping them to cope at work. The concept of pacing is based on operant conditioning (Fordyce, 1976) where activity is guided by time or amount, rather than pain. However, the term means different things to different people (Birkholtz et al., 2004). It is not clear in the literature whether pacing aims to increase activity levels or manage pain. The aim may be to introduce tasks in a graded manner so that patients can build up skills, confidence and tolerance for an activity (Strong et al., 2002). Others may use it as a general coping technique of taking rest breaks as reported by McCracken and Samuel (2007) who found that pacing was positively related to avoidance behaviour and disability, and Gill and Brown (2009) have argued that an evidence-base is lacking. More recently, a randomised trial comparing different treatment methods for chronic fatigue syndrome found that cognitive behavioural therapy and graded exercise therapy were more effective than pacing (White et al., 2011). Pacing was described as an adaptive approach rather than being aimed at increasing activity levels. In a recent study, Tveito et al (2010) recommend that in order to retain workers with back pain, future interventions should focus on pacing of work, however they do not define the term. A study of adherence to treatment methods following a London-based cognitive-behavioural treatment programme for persistent pain has suggested that some participants may use pacing as a 'safety behaviour', keeping their activity levels low rather than increasing them (Curran et al., 2009). The participants in our study mainly indicated that pacing was a general method used to take breaks during the working day so as to reduce the incidence of flare-ups rather than as a means of increasing activities. This can thus be viewed as a form of work modification, which as one participant described, may not be possible in some workplaces, or is dependent on the participant taking the initiative.

Work as an obstacle to accessing treatment for health conditions

For some of the participants in this study, work itself was perceived as a barrier to attending the treatment programme. There is little research on this topic to draw upon. Some employers may be prepared to offer leave, but there is no obligation in law. If employees are considered to meet the requirements of the Disability Discrimination Act (1995) (now the Equalities Act), then it may be considered a 'reasonable adjustment' to permit an employee leave to attend treatment; however it would still be the employer's decision as to whether that leave was paid. Employers may be more inclined to support employees seeking treatment if they considered that it would benefit them. A recent review has concluded that there is some evidence that multidisciplinary interventions which involve some form of workplace involvement are likely to be cost-effective to the employer for employees with back pain who are on long-term sick leave (Carroll et al., 2010). The results of a trial conducted in the Netherlands also support this (Lambeek et al., 2010a), however, the participants in that trial were all full or partially absent from work. In Scotland a pilot study of a case-managed occupational health programme for employees included those struggling at work due to a health problem; only one third of participants were absent. The authors concluded that the pilot was cost-effective in terms of quality of life and sickness absence, however there was no comparator group, and all health problems were included (Hanson et al., 2007).

Limitations of the gatekeeper role in access to rehabilitation.

There was a wide variety in the speed with which participants had been referred, and in the length of time they had to wait for the programme to start. This finding reflects the results of the GP questionnaire survey in Chapter 2 where GPs reported the difficulty they experienced in keeping up to date with the changes in service provision and referral pathways. In the UK a major inquiry commissioned by The King's Fund (2011) concluded that while the majority of GP care is good, such variations in practice need to be addressed. There is

limited literature on GP referral patterns to rehabilitation for back pain. Pitt et al (2008) in a qualitative study of Australian GPs reported that referral of patients with osteo-arthritis to self-management programmes was limited by the GPs' knowledge about the content and availability of programmes and their attitudes towards patient involvement in them. In a German study of referral practices, Schulte et al (2010) report on long delays in referral to healthcare professionals for pain, particularly to specialist pain centres, and that a non-systematic pathway of referral is likely to fail a number of patients who have limited access to information about services. Bouton et al (2008) in a survey of French GP management of chronic low back pain in general practice found that patients waited a long time to be referred to multidisciplinary care, and recommended that GPs should be encouraged and helped to organise this process earlier. However, the authors indicated that the referral pathway to such care was a recent development, whereas in this current study, multidisciplinary rehabilitation had been available for eight years, and the findings suggest that for patients who had been able to apply self-management techniques at work, early referral could increase their confidence in their work ability.

Communication with the workplace

The findings of the post-treatment interviews indicated little direct communication taking place between employers and the treatment providers, and where this did take place it was largely at the participants' initiative. Although the need for better communication between stakeholders has been reported (Beaumont, 2003; Sawney & Challenor, 2003) there are surprisingly few studies that have examined how communication between employers and healthcare providers actually takes place. Pransky et al (2004) have emphasised the importance of good communication between healthcare and employers in return to work, but argue that communication across all of the models of disability prevention and management is often unidirectional and impersonal. They recommend that an interactional, rather than a linear model of

communication is required. The support from participants' employers in this study was very variable. Even those who were aware of the participant attending treatment seemed unwilling to make contact with the team.

Group approach to treatment

Many participants had enjoyed the treatment programme and had found it a positive experience. Although cognitive-behavioural approaches are commonly used in treating chronic pain, there is little research which has explored the advantages or disadvantages of this type of treatment being delivered in a group setting. Group treatments are underpinned by social learning theory (Bandura, 1971) which supports behaviour change through learning by observing and modelling others. According to Keefe et al (2002) the group setting provides an opportunity for patients to be in touch with others who have similar problems. As Main et al argue (2008), this 'normalises the pain experience and maximises opportunities to draw on the experiences of group members'. However, Main et al also warn that the group setting may be a disadvantage if patients' concerns and anxieties are not addressed, and others agree that success depends on how the therapy is practised (Linton, 2005; Dysvik & Stephens, 2010). Only a few studies have compared the specific therapeutic value of being in a group over individual therapy for back pain (Main et al., 2008) and the evidence does not favour one approach above another (Rose et al., 1997; Turner-Stokes et al., 2003; Nykanen & Koivisto, 2004).

There is also little research into the advantages of group treatment in helping patients improve their ability to work. Joyce et al (2010) conducted a qualitative study of patients off sick for more than six months with mental ill health, cardiovascular disease or musculoskeletal conditions who had participated in Condition Management Programmes. They found that an important theme was the stimulation, support and motivation that participants had experienced from the group interventions, however the effect of this finding on work outcomes was not reported. Linton and Andersson (2000) demonstrated a significant reduction

in sickness absence resulting from a group treatment programme, but this was compared with the provision of written information to patients rather than individual treatment.

In this study the group experience was helpful in normalising pain, but conclusions could not be drawn as to the extent the group process actually helped regarding work ability. Many commented positively on the comprehensiveness of the treatment programme, yet several had residual concerns about work.

Limitations to the study

As was the case in the pre-treatment interviews, the topic guide was based on findings from previous research studies to provide a theoretical basis. This was enhanced by the findings of the pre-treatment interviews so that the themes identified could then be reflected on in the post-treatment interviews. However, there were some limitations to the study.

The researcher was unable to interview all of the participants who attended the programme thus there may have been some selection bias and data saturation may not have been reached. Interviewing participants two months following treatment may not have allowed sufficient time for the effects of the treatment programme to have been consolidated. The interview schedule was revised as the interviews progressed which meant that new themes which were raised in later interviews would therefore not have been addressed in the earlier ones, and may not have been developed adequately. Another limitation was the skill required to guide the participants to share their perceptions and experiences specifically with regard to work; participants tended to reflect on their experiences in general terms, even when the questions were specific to work. Knowing that the researcher had a healthcare background may also have led them to comment in favour of the programme.

4.4 Conclusion

The findings of this study suggest that multidisciplinary group rehabilitation can help patients with low back pain to feel more confident in managing their back pain at work, although without a comparison group, it is not known whether this is due to the treatment they received or whether the participants naturally improved over time.

Many of the participants felt that they had benefited from the treatment approach and that their concerns about work had been addressed within the group setting. Some had received work-related advice and support from the team on a more individual basis, but not in any structured way, with little evidence of direct contact with employers. Other participants felt that their needs regarding work required more individual support or had unresolved concerns about their future ability to retain employment. There was no real opportunity for clinicians to access the workplace, or to offer advice and support on work modifications. Likewise, although some employers had shown an interest in the treatment programme, they had not initiated any contact with the clinicians to ask for advice and support, and one had refused. None of those interviewed had accessed the optional work-focused group session run by the team: some felt it was not required, others were unable to attend due to work, or were unaware of it.

Efforts to reduce concerns about work through rehabilitation were targeted towards improvement of the patient's ability to self-management of their back pain, rather than to advise or offer support on workplace modifications. The reason why work issues were not addressed to a greater extent is not known. It may be that clinicians feel they lack the relevant experience, that it is not their role, or that it is not a priority. As discussed in Chapter 1, work outcomes are not a routine measure within the health service. From the patients' perspective, if the emphasis of treatment is that patients should learn to manage their own back pain, then they may feel reluctant to ask for help, or may not know what

help might be available, or may be unsure of the extent to which it might change the work situation. Finally, work itself can be perceived as a barrier to accessing rehabilitation and access to rehabilitation relies on the knowledge and management approach of the referrer.

This study has confirmed that the provision of work-related advice and support is not a structured or key feature of multidisciplinary group rehabilitation provided by the Nottingham Back Team. Although group rehabilitation may address some work-related concerns experienced by those with back pain as identified in Chapter 3, this largely depends on the ability of the participant to effect change themselves. Some participants may therefore benefit from an individually targeted treatment approach to the management of their work-related problems resulting from low back pain, in addition to group rehabilitation. The interview findings have also informed the content of the intervention, for example, by providing the opportunity for participants to discuss their individual concerns about work; offering direct contact with participants' employers and GP regarding the management of their back pain at work; assessing the need for, and advising on work modification; educating and informing participants as to current evidence regarding the work-relatedness of back pain; helping participants apply the tools of pacing and exercise more effectively to their work; increasing participants' confidence and ability to disclose the nature of their back pain; facilitating their take-up of group rehabilitation; delivering the intervention promptly so as to address work-related problems as early as possible rather than waiting for group rehabilitation to start.

The individual intervention would be tested in the proposed feasibility randomised controlled trial in parallel to routine group rehabilitation. In order to evaluate the effectiveness and cost-effectiveness of such work-related interventions, appropriate measurement tools are required. Chapters 5 and 6 report on the exploration of outcome measures that might be tested in the feasibility randomised controlled trial.

CHAPTER 5 QUESTIONNAIRE SURVEY OF GP PRACTICE MANAGERS

This chapter reports on the practicality of collecting data on healthcare-resources used by patients with low back pain. The data would contribute to the economic evaluation used in the proposed feasibility randomised controlled trial. GPs are the 'gatekeepers' to National Health Service care, and patient records held by general practices are a key source of data on healthcare resource use. It was therefore important to establish whether healthcare resource-use data could be collected from general practitioner (GP) practices as the findings would inform the design of data collection in the feasibility trial. A questionnaire survey of GP practice managers was conducted to investigate this.

5.1 Background

Economic evaluations estimate the costs and benefits of two or more competing interventions in order to inform resource allocation decision making about the likely value for money. In a fixed-budget national health service, it is important to undertake such evaluations in order to maximise the efficient use of resources and patient outcomes. The cost of back pain to the UK economy is considerable in respect of both direct and indirect healthcare. Maniadakis and Gray (2000) estimated that in 1998 approximately 37% of direct healthcare costs associated with low back pain were from physiotherapy and other allied specialists, 31% from the hospital sector, and 14% from primary care, with the remaining costs distributed between medication, community care and imaging. A review by Picavet et al (2008) reported that between 30% and 45% of those with back pain have had contacts with primary health care within the period of a year. Although the majority of low back pain sufferers do not have contact with healthcare, those that do have a higher resource-use than the general population. In a national survey of general practices in the Netherlands, patients with low back pain had a higher frequency of contact with GPs, medical

specialists and physiotherapists than patients who did not have low back pain (Picavet et al., 2008). In addition to consultations with a range of healthcare professions, other direct medical costs include medication, pain-relieving injections, surgery and investigations such as MRI scans and X rays. Establishing accurate and feasible methods of data collection of healthcare resource-use is therefore essential in studies measuring the effectiveness of back pain rehabilitation. However, previous studies have questioned the quality of economic evaluations in the field of spinal disorders due to poor methodology (Korthals de Bos et al., 2004).

Resource-use data for health economic evaluations can be collected in a number of ways, and through a combination of methods, including patient questionnaires, clinical report forms or from patient records. A few studies, as described below, have published results of investigations into the use of these alternative methods, but findings are mixed as to the most reliable method. Self-report is commonly used but may not be accurate due to, for example, poor completion rates and recall error. In a retrospective study, Patel et al (2005) compared data collected from UK GP practices with that collected from 303 patients who had consulted the practices in the previous six months. The results showed good agreement. However, in a randomised controlled trial comparing the cost-effectiveness of anti-depressants, Mistry et al (2005) compared GP records with patient questionnaire data for 324 UK patients. The authors concluded that reliance on GP records was necessary due to the incompleteness of patient questionnaires. A later comparative study by Byford et al (2007) found that although GP records provided more accurate data than patient report on practice-based contacts, they were less reliable in providing information on contacts with other health services.

Medical records have an advantage over self-report in that they should be more accurate. In a study comparing patient-report through telephone survey with

medical record data, Brown and Adams (1992) found that laboratory reports and similar management databases were more accurate than self-report. Patients may not be familiar with terminology used (e.g. name of medication, the profession of the clinician they have been referred to (e.g. rheumatologist) or misunderstand the type of investigation or test they have had. Self-report questionnaires are cheaper and simpler, and can cover a broader range of economic outcomes such as out-of-pocket expenses (Patel et al., 2005). However, their validity will be influenced by the length of the recall period, the saliency of events, sociable desirability of response, the chronicity of the condition, and the demographic characteristics and literacy of the respondent (Evans & Crawford, 2000).

Very few economic evaluations describe how healthcare resource-use data collection tools have been developed, or have compared them with self-report for low back pain. A retrospective study comparing the management and referral of 900 low back pain patients at three UK general practices compared case notes and self-report (McKinnon et al., 1997). The authors reported substantial differences between the two methods regarding consultation and investigations. A Dutch study of 205 fibromyalgia and low back pain patients compared patient-completed cost diaries with insurance company data. The study found that self-reported specialist care contacts compared well, but not physiotherapy contacts (Goossens et al., 2000). In 2004, a large UK multi-centre trial reported on the cost-effectiveness of physical treatments for back pain in primary care (UK Beam Trial Team, 2004) and also collected healthcare resource use data from the participants, however it is not clear whether the data were recorded by diaries or by questionnaire. In a more recent study, Whitehurst et al (2007) compared GP records with a self-report questionnaire on healthcare resource use in order to validate their data collection methods and found good reliability. However, they compared only 10% of their sample and the comparison was limited to whether or not the patient had received at least one GP consultation or referral to

secondary health care in the 12 month period rather than the total number. It did not compare other data such as the number and type of treatments and investigations, or prescribed medications. As Evans and Crawford suggest (1999), not all elements of treatment are recalled to the same degree. For example, in their review they concluded that medication use tends to be recalled with less accuracy than hospitalisation. Both McKinnon et al (1997) and Whitehurst et al (2007) examined resource use over a period of 12 months. In an often recurrent and fluctuating condition such as low back pain, long follow-up periods will have greater validity, but memory may only be accurate for 2-3 months (Brown & Adams, 1992) and self-report may be less accurate after this time.

Therefore in order to inform the economic analyses of the proposed feasibility randomised controlled trial we wished to test the practicality of collecting information on resource use data from GP patient records in our locality. In the proposed feasibility randomised controlled trial the economic evaluation would include the estimation of the comparative costs and outcomes of the interventions from a national health service perspective, the patient perspective being presented separately. The trial would seek to capture any change in health care resource use following the intervention. The data would be used to compare levels of healthcare resource-use over a set period of time, i.e. six months after rehabilitation between those receiving the intervention and those not. Data would be collected retrospectively.

There were two research questions to be addressed in this part of the study:

- 1. Do GP practices collect data on healthcare resource use of patients with low back pain?*
- 2. Would GP practices be willing/able to extract this data on selected study participants at a future stage in the study?*
If yes, would they require payment for undertaking this task, and what might be the cost?

5.2 Methods

5.2.1 Research Design

A postal questionnaire survey design was chosen to address the research questions in order to obtain data from a larger and more representative sample than would have been possible from face-to-face interviews. The questions were developed from a review of relevant literature, the advice of a data analyst from one of the referring GP consortiums and a consensus of the steering group of the study which included a health economist and GP.

5.2.2. Content and presentation

The questionnaire was divided into three sections to reflect each research question in turn. The questionnaire was printed on cream paper to help distinguish it from other mail and from the GP questionnaire survey which had recently been conducted (Appendix 6, pp. A24-A27).

Questions covered two main areas:

1. The type of data collected by the practice which are related in some way to low back pain

Questions were divided into four sections: dates of consultations conducted at the surgery (including GP, practice nurse, physiotherapist, counsellor); prescriptions including medications associated with disturbance to sleep, mood and side-effects (name of medicine, date prescribed, strength, dose and number of days supplied); investigations (blood tests, X rays, Dexa and MRI scans) and referral to secondary care (e.g. physiotherapy, multidisciplinary rehabilitation, pain clinic, rheumatology, orthopaedics). There was a space for comments after each of the four sections.

2. The extraction of data on individual patients for use at a future stage of the study

Further instructions explained that the timescale would involve data that had been collected on individual patients during the six months before, and the six months after treatment by the Nottingham Back Team, over a ten month period

in 2009. It was anticipated that this would involve a maximum of four patients per practice.

Questions were divided into six sections: whether it would be possible for the practice to extract some/all of the data; the approximate charge per patient; the maximum number of patients this might include; and the amount of notice the surgery would require. Practices were also asked whether there was a maximum number of patients that they would be willing to extract data for, and if they were unable to extract the data themselves, whether they would permit the researchers to collect it. There was space for further comments at the end.

5.2.3 Piloting

The questionnaire was piloted with two practice managers. Neither of the practice managers reported any difficulty in completing the questionnaire which was therefore unchanged.

5.2.4 Ethics

Ethical approval was granted by the Nottingham 1 Research Ethics Committee and the Research and Development Departments of the two Primary Care Trusts (PCTs) concerned. Consent of the participating Practice Managers was not required.

5.2.5 Sample

The questionnaire was sent to each of the 114 referring practices in South Nottinghamshire who were able to refer to the Nottingham Back Team. Lists of the practices were obtained by contacting either the executive office (Nottingham City PCT; 63 practices) or the website (Nottinghamshire County Teaching PCT; 51 practices) of the PCTs concerned.

5.2.6 Procedure

Each questionnaire was given a practice code in order to ascertain the representativeness of the sample of returned questionnaires and to target non-respondents. The questionnaires were not personally addressed as it was not possible to establish the name of the practice managers at each of the 114 practices. A covering letter was attached and stamped addressed envelope included. Practice managers were asked to return the questionnaire by a set date, three weeks after the date of posting.

A follow-up letter, a further copy of the questionnaire and an addressed envelope was sent to each practice that had not responded by the return date. Three weeks after the date of the second mailing follow-up phone calls were made to each practice that had still not responded, and a third copy of the questionnaire sent on request.

One copy of each of the completed questionnaires was stored at the University in a locked filing cabinet. A document containing the identifying number of each GP practice was stored separately. GP practices were not to be identified in any reports.

5.2.7 Proposed data analysis

Data were entered onto SPSS version 15 and analysed using descriptive statistics. Text data from the comments sections were entered into a word document. These were then categorised according to common themes.

5.3. Results

A total of 51 questionnaires were returned; a response rate of 45%. The majority (63%) were returned from the first mailing. Table 11 shows that the response was greater from Nottinghamshire County Teaching PCT.

Table 11. Practice manager questionnaire return rates per PCT.

PCT	Returned	Not returned
Nottingham City	25 (40%)	38 (60%)
Nottinghamshire County Teaching	26 (51%)	25 (49%)

Table 12 shows the responses to questions regarding the data collected by the practice. The majority of practices reported that they did collect dates of consultations related to low back pain conducted with the GP (84%) and the practice nurse (73%). However, this was dependent on attendance: e.g.

- *If a patient does not keep an appointment, how do we know if they were coming with LBP?*

Dates of appointments with other staff at the practice such as physiotherapists and counsellors were less frequently collected, and there was substantial missing data in this part of the questionnaire. Some replies indicated that it

Table 12. The type of data related to low back pain collected by the GP practice.

Data collected by practice	Yes		No		Missing †	
	N	%	N	%	N	%
Dates of surgery appointments with GP	43	(84.3)	5	(9.8)	3	(5.9)
Dates of surgery appointments with practice nurse	37	(72.6)	5	(9.8)	9	(17.6)
Dates of surgery appointments with physiotherapist	18	(35.3)	22	(43.1)	11	(21.6)
Dates of surgery appointments with counsellor	13	(25.5)	22	(43.1)	16	(31.4)
Date of prescription	45	(88.3)	2	(3.9)	4	(7.8)
Name of medicine	45	(88.3)	2	(3.9)	4	(7.8)
Number of tablets prescribed	44	(86.3)	2	(3.9)	5	(9.8)
Strength of dose	45	(88.3)	2	(3.9)	4	(7.8)
Number of days supplied	45	(88.3)	2	(3.9)	4	(7.8)
Blood tests	42	(82.4)	4	(7.8)	5	(9.8)
X rays for back pain	45	(88.3)	2	(3.9)	4	(7.8)
MRI scans	41	(80.4)	3	(5.9)	7	(13.7)
Dexa scans	38	(74.5)	5	(9.8)	8	(15.7)
Referral for further assessment/treatment	46	(90.2)	2	(3.9)	3	(5.9)

†'Missing' defined as question not answered by respondents

was not clear whether the appointments referred to in the questionnaire (e.g. physiotherapy) were those held at the surgery. Some respondents commented that records depended on whether other health professionals kept the practice informed of appointments made and attended by patients e.g.

- *Dependent upon receiving information from other services – does not always appear!*
- *Info returned to practice when letter written by hospital consultant – often delayed by several weeks.*

There was much more agreement as to the data collected regarding prescriptions related to low back pain, with 86% of practices recording the date of prescription, name of medicine, number of tablets to be taken per day, number of days supplied and the strength of each dose.

Additional comments were made with reference to factors that could influence the accuracy of data collection e.g.:

- *Scripts may be variable (e.g. up to four times per day as needed)*
- *Prescribing is on the computer but only linked with back pain if on a repeat prescription*
- *It may not always be clear whether the medication was prescribed specifically for low back pain e.g. may also have OA hip etc.*

The majority of practices reported that they collected data on blood tests (80%); dxa scans (71%); X rays (86%) and MRI scans (76%), although this would depend on who had requested the investigations e.g.:

- *Only if ordered by the practice or reported to practice by consultant if they ordered them.*

The majority of practices (90%) collected data on referral for further assessment/treatment for low back pain.

Table 13 shows the responses to questions regarding the feasibility of data extraction. Three-quarters of the practices agreed that it would be possible to extract all/some of the data for individual patients. However there was variation as to whether the practice would charge for this, what the approximate charge might be, how much notice would be required and the maximum number of patients that the practice would be willing to extract the data on e.g.:

- Unfortunately the practice is very busy but would have no objection to someone from the department extracting data.
- Happy to negotiate terms.
- We do not systematically collect data in this way
- Depends on numbers. Costs of staff met.

Overall there was a wide range of responses to this section of the questionnaire. Some practices were unwilling or unable to extract data themselves or to allow a researcher to do so. Others were willing, but would charge a fee or would negotiate terms. Seven of the 21 who agreed that they could extract the data said that they would do this at no charge.

Comments made on some questionnaires or in telephone calls made to the practices to follow up non-response showed that some questionnaires would have been completed by administrative staff, whereas in other practices the questionnaire was passed to the GPs to complete, but this had not transpired e.g.

- Practice manager can't complete – Doctors don't want to complete!

Table 13. The feasibility of data collection. N=51 respondents (%)

Data collection	Yes		No	Unsure		Missing
Would it be possible to extract some/all of the data?	38 (74.5)		8 (15.7)	0 (0)		5 (9.8)
Would there be a charge?*	17(33.3)		7 (13.7)	11 (21.6)		16 (31.4)
*If yes, what might be the approximate charge per patient?	£1-£5	£10	£20	>£20	Unsure	Missing
	2 (3.9)	5 (9.9)	2 (3.9)	2 (3.9)	14 (27.4)	26 (51.0)
Notice needed to extract data	1-2 wks		3-4 wks	6-8 wks		Missing
	15 (29.4)		12 (23.6)	7 (13.7)		17 (33.3)
Maximum number of patients willing to extract data for	1-10	11-20	21-30	>30	Unsure	Missing†
	11(21.6)	2 (3.9)	3 (5.9)	4 (7.8)	13 (25.5)	18 (35.3)
Would you be willing to allow the researchers to pay someone else to collect the data?	Yes		No	Unsure		Missing†
	19 (37.2)		14 (27.5)	4 (7.8)		14 (27.5)

†'Missing' defined as question not answered by respondents

5.4 Discussion

This study demonstrated some of the difficulties associated with collecting retrospective healthcare resource use data from GP records for use in an economic evaluation of vocational rehabilitation for back pain. Although computerised GP records are now commonplace, extraction of data on individual patients for research studies does not appear to be readily available. Local research networks provide an opportunity to facilitate high quality health services research (Frew et al., 2001) but will include only a proportion of GP practices and inclusion in the network does not assure data collection for every research study. This raises a wider question of who actually owns the data held by the GP, and who should have access to it, particularly within the context of the development of electronic care records (NHS Care Records Service).

A major consideration is the complexity of pragmatic trials; resources used by patients include a range of services combining primary and secondary care, both of which need to be considered in the evaluation (Mistry et al., 2005) and this study has identified some of the complexities involved. Firstly it cannot be assumed that all practices record all the consultations that take place at the surgery. This study showed that details of consultations with other health professionals within primary care may be less accurately recorded than those with the GP and/or practice nurse. Secondly, although computerised records of prescriptions are held, the prescribed medication may not be linked specifically to low back pain. Thirdly, as reported earlier in the study by Byford et al (2007) GP records might not be able to provide accurate data on other healthcare services. In this study for example, practices were more confident in their ability to keep accurate records of investigations requested directly by the GP, but not if scans or X rays had been requested through secondary care. GPs rely on other service providers to inform them of patient contacts, so underestimation in the records is more likely.

The results of this survey indicated that it would be possible to extract some, if not all, of the required data through study participants' general practices for a research study. However, this study aimed to conduct a feasibility randomised controlled trial recruiting patients through secondary care. It would not be possible to know in advance which patients, and therefore which general practices, this would involve, and whether they would be those able and/or willing to provide the necessary data. The uncertainty as to the notice needed and costs required by different practices to extract the data added further obstacles and was unlikely to be feasible in a randomised controlled trial recruiting a large number of patients of whom only a few would be from each practice.

Future research might help to indicate what would encourage GPs to participate. If the main concern is patient confidentiality a recognised agreement and procedure for handling sensitive data need to be developed. If resource issues are a factor, these could be overcome if they were to be identified and included in research bids. Lack of knowledge about, or interest in research might suggest a need for education for GPs in order to encourage them to become more involved. Negative experiences of being involved with research in the past may need to be addressed.

There were some limitations to this study. The response rate was low; over 50% of practices in the South Nottinghamshire area were not represented. This may have been due to a number of reasons: the practice manager may not have had easy access to the required information, some practices may have been managed by the GPs (they had recently been approached regarding the GP Questionnaire Survey and this may have influenced their motivation to participate in a second survey) and the survey took place over the school summer holiday period when practice staff were more likely to be on leave. Another limitation was the large amount of missing data, which may also have been due to the fact that the practice managers were unable to access the

information required. More extensive piloting may have facilitated the design of response options which could have clarified if this was in fact the case.

Furthermore, four of the respondents had used crosses (x) rather than ticks (✓) to indicate their responses. In these cases, additional comments made by the responders and the pattern of responses demonstrated that their intention had been affirmative, however this factor could potentially have led to inaccuracies in analysing the data and might also have been avoided through more rigorous piloting and clearer instructions.

Alternatively, a series of semi-structured interviews could have been conducted with a sample of GP practices representing different sizes and organisational structure. This may have provided a greater depth of understanding of the possibilities and limitations of collecting healthcare resource-use data from the practices.

5.5 Conclusion

This study has shown that collecting direct healthcare resource-use data from GP practices for an economic evaluation of a feasibility randomised controlled trial would not be practical. Only a small minority of practices would be able and willing to engage in providing information on individual patients at no, or minimal, cost which would have limited the number and location of patients who could be recruited within the timescale and resources of the study. In addition, although data on GP consultations and medications were collected by the vast majority of surgeries, data on secondary healthcare use was less readily available. An alternative method of collecting data on healthcare resource-use would therefore be required for the proposed feasibility randomised controlled trial. The next chapter reports on the feasibility of collecting data through self-report.

CHAPTER 6 PILOT PATIENT QUESTIONNAIRE

This chapter reports on the piloting of a patient questionnaire conducted with the same patient sample as that in the interviews reported in Chapters 3 and 4.

In the Introduction (Chapter 1) it was noted that appropriate outcome measures are needed to evaluate the effects of healthcare interventions and to determine the sample size and power of definitive trials. They can also facilitate comparisons between different healthcare systems and interventions. Key measures that would be required in the proposed feasibility randomised controlled trial included those concerning participants' ability to work, psychological and psychosocial obstacles to work and measures required for an economic evaluation. There is a wide range of standardised subjective work-related measurement tools reported in the literature but few have been used in the UK healthcare setting, and there are no standardised tools that measure objective work outcomes. It was therefore important to test a selection of measurement tools with low back pain patients to inform the decision as to how this data would be collected in the proposed feasibility randomised controlled trial. These tools would include measures of outcome, used to determine whether interventions produce the desired result and process measures, used to identify or predict the factors leading to improvement.

6.1 Background

6.1.1 Measuring work

The ability to work is a key measure of health but, as Amick (2000) has argued, although health and work interact with each other, very little data exists on whether and how clinicians are evaluating the effects of this interaction when treating patients. This is of particular importance in back pain, where 85% of the costs are indirect, resulting from sickness absence, work loss and early retirement (Elfering, 2006). Over ten years ago, Deyo et al (1998) recommended that these dimensions should be included in outcome measures of

rehabilitation in low back pain, and yet healthcare often fails to address such outcomes, particularly in the UK (Waddell et al., 2008). One major challenge is that many of the measures lack standardised terminology and measurement, and theoretical background (Wasiak et al., 2007; Elfering, 2006). Previous studies of low back pain and work have focused on people on sick leave, with 'return to work' or 'number of days sick' as the primary outcome. This study aimed to include both employed (including those on sick leave or not) and unemployed persons, and these outcomes alone would not be sufficient. Return to work is an inappropriate outcome for people who are already at work. Number of days' sick leave is not an appropriate measure for people who have modified their work due to back pain rather than taking sick leave. Neither measure reflects the fact that a person may remain unemployed due to the lack of job availability rather than the person's ability to work.

Work outcomes encompass more than one dimension. Examples include: occupational status, productivity, work attitudes, role functioning (Amick et al., 2000), sickness absence, functional capacity evaluations, risk factors for work disability (Elfering, 2006), work sustainability, career advancement (Wasiak et al., 2007). It is therefore recommended that multiple data sources are used, including those which assess work-related 'yellow flags' or psychosocial obstacles which may be predictive of return to work, such as fear-avoidance. The fear-avoidance model was introduced to explain why a minority of people with acute musculoskeletal pain will develop a chronic pain problem (Vlaeyen & Linton, 2000). Pain-related fear has been found to be predictive of return to work and sick leave (Storheim et al., 2005; Boersma & Linton, 2005). Finally, in the UK there is no objective means of measuring individual work-related outcomes such as sickness absence for the purpose of healthcare research and data have to be collected directly from the individual.

6.1.2 Measures required for an economic evaluation

As reported earlier in the thesis, this study aimed to examine the feasibility of conducting an economic evaluation alongside the proposed feasibility randomised controlled trial. An economic evaluation is defined as the comparative analysis of alternative courses of action in terms of both their costs and their consequences (Drummond, 2005). Costs may include direct costs (e.g. healthcare resource use, social services), indirect costs (e.g. sickness absence, reduced productivity, early retirement), informal costs (e.g. cost of unpaid informal care) and transfer payments (e.g. social security benefits). Results from the Practice Manager Questionnaire Survey reported in Chapter 5 demonstrated that it would not be possible to collect healthcare resource use by objective means in this study, and that this data, as with data on indirect costs, would therefore need to be collected from the individual participants.

Consequences can be measured in monetary terms (cost-minimisation study, cost-benefit analysis), in natural units e.g. life-years gained, level of disability (cost-effectiveness analysis), or in quality-adjusted life years (cost-utility analysis). The feasibility randomised controlled trial would not be using natural units to measure consequences, therefore cost-utility analysis would be the most appropriate method. Cost-utility analyses use health-related quality of life measures, also known as preference-based measures of health to calculate quality-adjusted life years (QALYs). QALYs can enable direct comparisons to be made with other interventions and the measures are completed by the patient.

6.1.3 Patient consultation in the design of measurement tools

In their IMMPACT report on pain-related outcome measures Turk et al (2006) recommend that patient groups should be consulted about the adequacy and meaningfulness of measurement instruments. Patients should be involved in the design and piloting of such measures in order to test validity, but the 2006 IMMPACT report identified that no attempt had been made to consult patient groups about the acceptability of current outcome measures. Whereas feasibility

refers to ease or convenience, acceptability has been defined as the suitability or favourability (Feeley et al., 2009). Therefore in order to identify the most appropriate measures, and data collection method for use in the proposed feasibility randomised controlled trial and economic evaluation, a range of measurement tools were tested for ease of completion and face validity with a sample of patients with low back pain.

There were three research questions:

- a) *Were the participants able to understand the instructions for completion of the measures?*
- b) *Was the content of the measures relevant to the participants?*
- c) *How easily were the participants able to complete the measures?*

6.2 Method

A questionnaire was designed which contained a number of measurement tools based on a review of the literature, discussion with academic colleagues and with the study steering group (Appendix 7, pp A28-A47). The questionnaire was to be piloted with the patients participating in the initial (pre-routine rehabilitation) interviews reported in Chapter 4.

6.2.1 Content of the questionnaire

6.2.1.1 Demographic details

Questions on gender, date of birth, length of back pain history, occupation, sickness/disability benefits, sick leave for back pain previous to the last 6 months, living arrangements, marital status and highest level of education reached were included to examine the representativeness of the sample. These topics were selected by the researcher as a result of reviewing previous studies and discussion with the research team.

6.2.1.2 Work Ability measures

Patients' self-perceived work ability is an important outcome in vocational rehabilitation (Elfering, 2006; Wasiaak et al., 2007; Kuoppala 2008), however a literature search found no standardised measures of perceived work ability that could be applied to both employed and unemployed patients. Minor adjustments were therefore made to the wording of two work ability scales: the Work Ability Index (Tuomi et al., 1998) and the Graded Reduced Work Ability Scale (Haldorsen et al., 1998) so that they might be suitable for completion by both groups of participants.

The Work Ability Index (WAI)

The Work Ability Index is a widely used measure of perceived work ability, developed by the Finnish Institute of Occupational Health (Tuomi et al., 1998). Evidence of satisfactory internal validity has been provided (Nygard et al., 1991, Eskelinen et al., 1991) and of test-retest reliability (de Zwart et al., 2002). The scale has been recommended for use as a standardised tool in outcome research in back pain (Elfering, 2006). The index was originally designed for studies of ageing employees and is a predictor of work disability in this group (Tuomi et al., 1991) but has since been shown to be predictive of long-term sickness of younger age groups (Kujala et al., 2006) and sickness absence (Nygard et al., 2005; Bergstrom et al., 2007). It has been used to measure outcomes in multidisciplinary rehabilitation programmes (Braathen et al., 2007) and occupational health (Hanson et al., 2007; Taimela et al., 2008). As both the summary measure of the WAI, and all of its seven items have reliably predicted work disability, retirement and mortality (Ilmarinen & Tuomi, 2004, Alavinia et al., 2009), the item asking respondents to report on the number of current diseases diagnosed by a physician was omitted to reduce the length of the questionnaire.

To make the WAI applicable to those who were no longer working, it was

necessary to generalise the wording in two of the questions, for example changing 'your work/current job' to 'work' or 'working'.

The Graded Reduced Work Ability Scale

The Graded Reduced Work Ability Scale was constructed for the Norwegian Ministry of Health and Social Affairs and consists of six items, five with a five-point scale grading the perceived work ability of patients in relation to the complaints for which they have been sick-listed (Haldorsen et al., 1998). The sixth question asks whether other complaints are affecting their health and well-being. The scale has been used to study predictors of return to work in low back pain. Haldorsen et al (1998) reported on a prospective study of 260 patients treated with a light mobilisation programme for low back pain. Subjective ratings of reduced work ability produced a prediction rate of 65% for the non-returners. Hagen et al (2005) used three items of the scale (reduced ability to work, the belief that work will aggravate the condition, and whether other complaints are affecting health and well-being) as one of the measures to identify prognostic factors for the effect of a brief intervention on return to work in a randomised controlled trial of 457 patients with sub-acute low back pain. Beliefs about reduced ability to work had a strong modifying effect on return to work at three month follow-up. When used in a study of fibromyalgia, high internal consistency of the scale was reported (Kurtze et al., 1999).

As participants in this study would not necessarily be on sick leave, the wording of the questions was changed from 'the complaint you have been sick-listed for' to 'your back pain'.

6.2.1.3 Fear-avoidance measures

There are two commonly used measures, the Fear-Avoidance Beliefs Questionnaire (Waddell et al., 1993) and the Tampa Scale of Kinesiophobia (Kori et al., 1990) and both were included in the pilot questionnaire so that a comparison could be made.

The Fear-Avoidance Beliefs Questionnaire

The FABQ is specific to low back pain and consists of two sub-scales; one concerns physical activity (5 items of which 4 are scored), the other concerns work (11 items of which 7 are scored). Each uses a 7 point Likert scale. The work scale in particular has been shown to be a good predictor of work status and disability (Fritz et al., 2001; Fritz & George., 2002). Test-retest and internal consistency is high but has been validated only for those who are, or have recently been employed (Waddell et al., 1993). It was therefore unclear whether it would be feasible as a measure for unemployed patients in this study.

The Tampa Scale for Kinesiophobia

The Tampa Scale for Kinesiophobia (Kori et al., 1990) has the advantage of not being employment status-specific, however it is not directly related to work or low back pain. The Dutch versions of the scale have been shown to demonstrate good internal consistency and test-retest reliability (Swinkels-Meewiss, 2003). The shortened version of the scale was used (Woby et al., 2005) consisting of eleven items rather than the original seventeen, which retains similar psychometric properties to the original.

6.2.1.4 Measurement of direct and indirect costs

A series of questions concerning employment and healthcare resource use were designed by the researcher and her steering group, drawing on Thompson and Wordsworth (2001). Questions referred to the participants' experiences in the previous six months, as this would be the end-point for the feasibility trial.

Questions concerning work included hours of work, the extent to which participants had worked reduced hours and duties due to back pain, sickness absence (or annual leave taken) due to back pain, financial claims related to back pain (claims against their employer, insurance claims or for welfare benefits), individual and household income. A further question aimed to measure presenteeism (being at work but performing less well due to a health problem).

If not working, participants were asked their main occupation, and whether they were in receipt of benefits.

Questions concerning healthcare resource use included services accessed and treatments used in relation to back pain.

6.2.1.5 Health-related quality of life measures

The most widely used preference-based measures of health used in cost-utility analysis are the EuroQol, or EQ-5D (Brooks, 1996) and the SF-6D (Brazier et al., 2002). Both have been found to have test and re-test reliability (Brazier et al., 2004) and are widely used in spine research (Nemeth, 2006).

EQ-5D

The EQ-5D has two components. The first contains five dimensions (mobility, self-care, usual activity, pain/discomfort and anxiety/depression) rated at three levels which provide a utility score ranging from 0 (death) to 1 (perfect health). A negative value of -0.59 can be scored for some health states. The second component is a 20cm Visual Analogue Scale of self-rated health status; this component was not used in the study as it is not used to measure utility. In a study of seven patient groups, including 265 patients with low back pain, ceiling effects were identified, and clustering in the top category of each dimension (Brazier et al., 2004). An advantage of the EQ-5D is that a large amount of reference data are available (Nemeth, 2006). However, a study comparing the quality of life of 633 low back pain patients with that predicted by the EQ-5D Spanish version (Zamora et al., 2007) found that the values given by the general population were lower than those of the patients, and suggest that the scale should not be used with patients, although no comparative study has been conducted in the UK.

SF-6D

The SF-6D is made up of six dimensions (physical functioning, role limitations, social functioning, pain, mental health and vitality) rated on between four and six levels and provides a utility score ranging from 0.296 to full health (Brazier

et al., 2002). Brazier et al (2004) identified floor effects, a smaller range and lower variance in values than the EQ5-D. It is considered to be more refined than the EQ-5D (Brazier et al., 04). There are fewer published studies of this measure but it is expected that it will be used more widely (Marra et al., 2004). As studies have shown that the SF-6D and EQ-5D have strengths and weakness, both were included in the questionnaire so that a comparison could be made in terms of ease of completion and face validity, and to examine the appropriateness of the instruments in relation to low back pain.

6.2.2 Ethics and consent

Ethical approval was obtained from the Nottingham 1 Research Ethics Committee and the Research and Development Departments of the Nottingham University Hospitals Trust and the Primary Care Trusts concerned. Written consent was obtained in conjunction with that obtained for the patient interviews (see **3.2.5**).

6.2.3 Procedure

A form of cognitive interviewing was used to collect the data. This method is used to establish 'how target audiences understand, mentally process and respond to the materials they are presented with' (Willis, 2005). Two of the techniques used are 'think aloud' where participants are encouraged to verbalise their thoughts about the questionnaire during completion, and 'verbal probing' whereby the researcher prompts the participant to describe their experiences. Cognitive interviews can enhance the reliability and validity of a questionnaire, and have been used in this field (Lerner et al., 2001). To conduct this process, training of the participants is advised (Willis, 2005), However, this would have required additional interview time. It was felt that this additional demand would affect recruitment to the study, thus no training was provided.

Each participant who took part in face-to-face initial interviews was asked to complete the questionnaire and comment on it, with prompts by the researcher using a topic guide (see Appendix 4, pg A19). This took place immediately after

the interview had been completed and took approximately 40 minutes to complete. Verbal comments made by participants as they completed the questionnaire were recorded digitally by the researcher, who kept supplementary written notes of her observations.

6.2.4 Data Analysis

Data collected digitally were transcribed by the researcher, entered onto a qualitative software management system (Nvivo 8) and combined with the supplementary notes taken by the researcher. Content analysis was used by the researcher to identify themes corresponding to each section of the questionnaire.

6.3 Findings

Twenty-five of the original twenty-eight participants completed the questionnaire. One participant did not have time to complete it. It was not possible to complete the questionnaire with the two participants who were interviewed by telephone. The demographic details of the participants are shown in Table 14.

Table 14. Demographic details of the participants in the questionnaire pilot (n-25)

Sex	Male	13
	Female	12
Age	Mean age (S.D.)	45.6 yrs (10.02)
	Age range	22-64 yrs
Education level	Secondary school	11
	GCSE	4
	Further education	7
	Higher education	3
Length of back pain history	Mean (S.D.)	8.3 yrs (9.72)
	Range	3 months – 35 yrs
Previous treatment from clinicians other than GP	Yes	21
	No	4
Work status at follow-up interview	At work	16 (5 modified work)
	Off sick	6
	Unemployed	3 (2 due to back pain)
Employer profile (of employed participants)	Large (<250 employees)	17
	Small (<20 employees)	3
	Self-employed	1
	Self/agency employed	1
Sick leave taken for back pain	Yes	16
	No	9

The findings were as follows:

6.3.1 Work Ability measures

Work Ability Index (WAI)

Four participants expressed no difficulty in completing the measure and made no adverse comments. However, other participants were unclear as to what was meant by 'mental' and 'physical' work, or 'regular daily activities'. Seven participants who were off sick or on adjusted duties had more difficulty in estimating their work ability numerically.

Graded Reduced Work Ability Scale (GRWAS)

Six participants expressed no difficulty in completing the measure and made no adverse comments. However, nine participants questioned the definition of 'other' work, the term 'complaints' and whether 'continue to work' included adjusted work.

6.3.2 Fear-Avoidance measures

Fear Avoidance Beliefs Questionnaire (Work) (FABQ(W))

Seven participants expressed no difficulty in completing the measure, and made no adverse comments. However the definition of 'normal' work was questioned by three whose work had been adjusted. Four thought that the past tense of the second question: '*my work aggravated my pain*' was not particularly relevant to them. The question regarding compensation was unclear, however this question is not used in the scoring of the questionnaire.

Tampa Scale of Kinesiophobia (TSK)

Seven participants expressed no difficulty in completing the measure and made no adverse comments. However, three participants questioned the definition of 'exercise', and six questioned what 'it' referred to in the second question (*If I were to try to overcome it, my pain would increase*). Six disputed the terms 'dangerously' (*I wouldn't have this much pain if there weren't something potentially dangerous going on in my body*) and 'accident' (*My accident has put my body at risk for the rest of my life*) as they felt these terms did not apply to their experience or perceptions of their back pain.

6.3.3 Measurement of direct and indirect costs

Employment factors

None of the participants were able to complete this part of the questionnaire without guidance and prompting from the researcher. Some found the instructions difficult to follow; others found it difficult to complete because they had more than one job, whereas the questionnaire referred to one job, or their

work status had changed within the previous six months, which the response options did not allow for. Several had difficulty in estimating their own reduced productivity as a result of back pain, but more found it easier to express this as a percentage rather than in time. Some had difficulty in accurately remembering when events such as sickness absence had occurred. Only one participant refused to answer the question on income.

Healthcare resource use

Only one participant expressed no difficulty in completing the measure, and made no adverse comments. Some found the instructions difficult to follow; others needed help to identify the treatment providers they had accessed. Many had difficulty in reporting accurately the medication they had used. Some of those who were interviewed at home were able to identify this more easily if they had the medication to hand. The fact that many participants used their medication irregularly cast doubts over the accuracy of data that might be collected by this means.

6.3.4 Health-related quality of life measures

SF-6D

Five participants expressed no difficulty in completing the measure and made no adverse comments. However, six reported that their symptoms would vary within the 'previous 4 weeks' stated in the instructions. Six also questioned the choice of functional activities given as examples in the first three questions, or the definitions of 'work', 'normal work' and 'housework'. Eight had difficulty either in understanding the meaning of the fourth question (*during the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health? - were limited in the kind of work or other activities?*), or because their work situation had changed within the 4 week period. Six had difficulty understanding the meaning of the fifth question (*during the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular*

daily activities as a result of any emotional problems (such as feeling depressed or anxious? – accomplished less than you would like?) or in understanding whether the question was linked to their back pain.

EQ-5D

Seven participants expressed no difficulty in completing the measure, and made no adverse comments. Seven participants commented that it did not reflect the variability of their symptoms in that their answers would be different according to the day it was completed. Eleven commented that there was an insufficient range of response options or that they lacked sufficient detail.

6.4 Discussion

Cognitive interviewing is normally only used to aid the development of a questionnaire rather than to test the psychometrics of established measures. In this pilot work we explored both standardised questionnaires and non-standardised measures. Difficulties were identified with both. The findings from this study demonstrated that each of the standardised measures used had strengths and limitations in face validity, acceptability and ease of completion. This suggests that there may be fundamental weaknesses in these measures and supports the conclusions of McClimans (2010) that not only do researchers have an imperfect understanding of the constructs involved in patient-related outcome measures (and therefore lack a gold standard), but that the questions they ask are often imperfectly understood.

At the time of the pilot, there was little evidence that cognitive interviewing had been used to either develop or evaluate the measures used in the questionnaire, although in one qualitative study Mallinson (2002) reported that the validation of the SF-36 health status questionnaire had failed to identify some important problems with the scale. More recently, Pool et al (2009) explored how patients with neck pain understand and interpret the questions in the Tampa Scale of Kinesiophobia. They also identified problems with the meaning of specific terms

such as 'dangerous' and 'injury', and certain assumptions that made it difficult for respondents to answer. McClimans (2010) argues that the combination of qualitative assessment within quantitative measures should be on-going in order to create better measures.

Questions on healthcare resource use and employment factors were drawn from an existing source, commonly used in health economics (Thompson & Wordsworth, 2001), but are concerned only with days off work. This pilot work demonstrated that collecting data that captures the nuances of, for example, work status and productivity within set timescales may be too complex to measure accurately by postal questionnaire.

Limitations of the study

One weakness of the study was that participants discussed the questionnaire with the researcher as they were completing it. Although this method did allow for an immediate response, it may have influenced the manner in which participants completed the questions, and they may have been more or less inclined to answer in a certain way. A more authentic response may have been gained if the participants had completed the entire questionnaire without any intervention from the researcher, and then reflected on their experiences whilst referring back to the questions. Missing responses or mistakes in understanding may have been more accurately identified. Also the time to complete could have been measured together with a more precise opinion from the participants' of the questionnaire as a whole.

The participants had taken part in individual interviews with the researcher prior to completing the questionnaire. This may have influenced the extent to which participants felt comfortable with the process. Likewise, through the interview, the researcher had gained an understanding of the participants work situation, and may therefore have influenced the extent that she prompted and/or questioned participants' responses.

6.5 Conclusion

This pilot work identified areas of concern regarding the selection of measures to be used in the proposed feasibility randomised controlled trial. The findings suggested that both the EQ-5D and SF-6D had strengths and limitations in face validity and acceptability with this client group; their validity and reliability would be compared further in the feasibility economic evaluation. Again, some participants had experienced difficulty in completing the WAI and GRWAS, but neither was more favourable, and it was decided to include both in the trial questionnaire. Overall the FABQ(W) appeared to have greater face validity and was easier to complete than the TSK, and it was decided to use it in preference to the TSK. As the ease of completion of the sections on healthcare resource use and employment status was poor, it was decided to ask these questions by telephone in the trial where verbal prompting by the interviewer might facilitate more accurate responses.

CHAPTER 7 FEASIBILITY RANDOMISED CONTROLLED TRIAL AND ECONOMIC EVALUATION

7.1 Introduction

This chapter reports on a feasibility randomised controlled trial, informed by the study findings reported in Chapters 2-6. The aim was to find out whether it would be feasible to conduct a definitive trial to test whether group back pain rehabilitation with an individually targeted vocational intervention was more effective than group back pain rehabilitation alone. The feasibility of conducting a concurrent economic evaluation would also be examined.

The objectives were to examine:

- The recruitment and retention of participants
- The delivery of the protocol
- The feasibility of the proposed outcome measures
- The feasibility of estimating an effect size of the intervention in order to adequately power a future definitive randomised controlled trial
- The feasibility of conducting an economic evaluation

7.2 Method

7.2.1 Design

A feasibility randomised controlled trial design was selected. A randomised controlled trial (RCT) is considered the first choice when assessing the effectiveness of treatment interventions. An RCT can safeguard against bias, and reduce the effects of known and unknown variables (Bowling, 2001). It can increase the probability that any differences observed are due to the intervention. However the Medical Research Council framework (Medical Research Council, 2008) advises that complex interventions such as rehabilitation should be tested through an iterative approach to reduce the uncertainties in planning a definitive study, and determine whether, and how best to proceed. The three major objectives of piloting an RCT intervention have

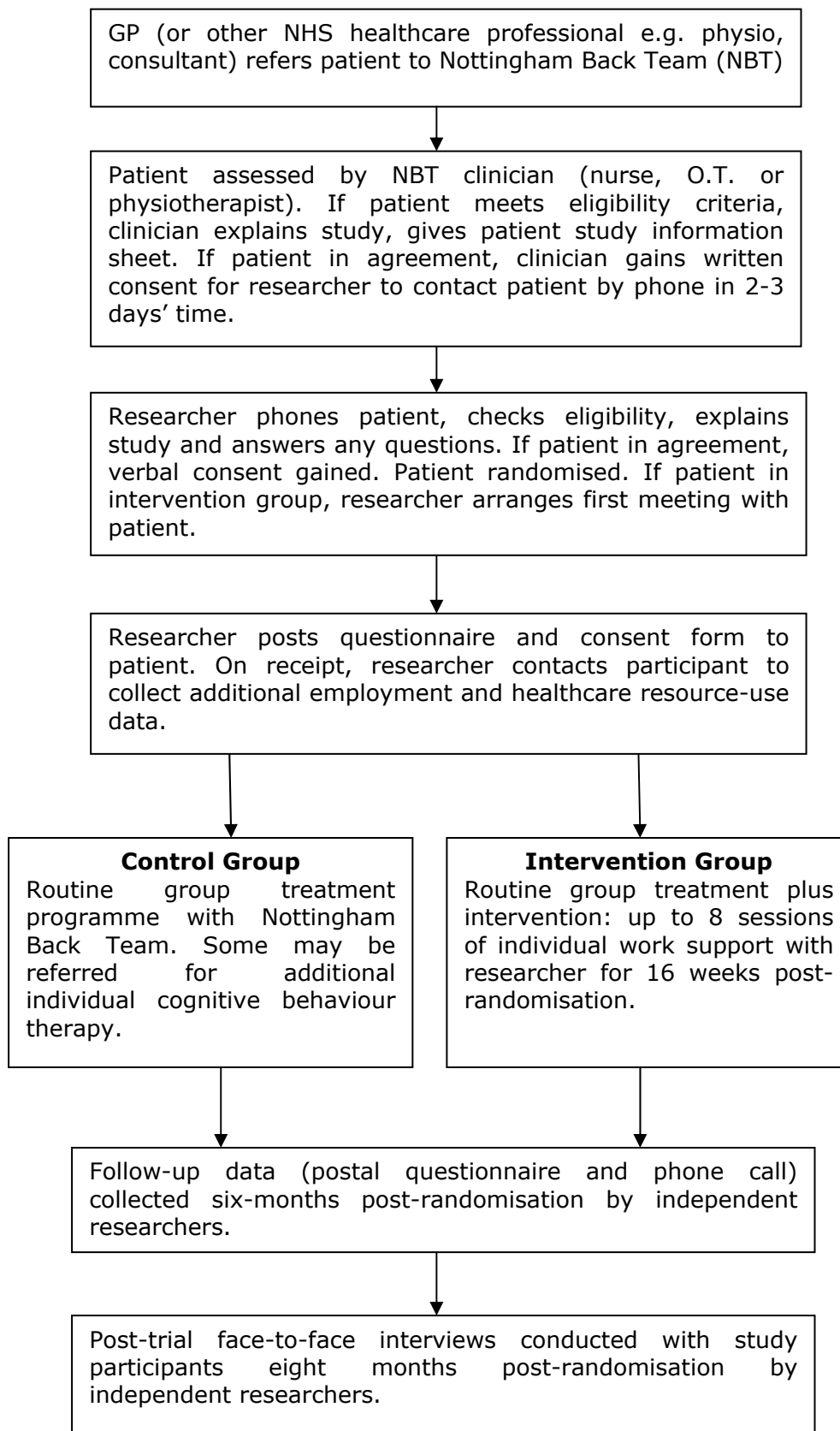
been described by Feeley et al (2009) as the assessment and feasibility of the intervention; the feasibility and acceptance of the design and procedures; the facilitation of determining effect sizes for use in sample-size calculations. The use of the terms 'feasibility' and 'pilot' vary in the literature. In their commentary paper, Thabane et al (2010) use the terms interchangeably. However, Arain et al (2010) argue that the terminology should be clarified and recommend the definitions used by the National Institute of Health Research Evaluation, Trials and Studies Coordinating Centre (NETSCC). These describe a pilot study as a miniature version of the main study to check that all the components of the main study can work together, and it therefore resembles the main study. In contrast, a feasibility study is undertaken at an earlier stage to examine the parameters needed to design the main study. As there were many uncertainties in this study, a feasibility design was therefore chosen. A pragmatic approach was used to maximise the study's external validity and generalisability (Alford, 2007).

As reported in Chapter 5 (Practice Manager Survey), the total costs associated with the care and treatment of back pain for the year 1998 have been reported as £1,632 million, however the total employment-related costs are estimated as being between £5,018 and £10,668 million (Maniadakis & Gray, 2000).

Therefore in order to estimate the full economic impact of back pain, the cost analyses for the feasibility economic evaluation would be carried out from a societal, as well as a healthcare perspective.

The design of the feasibility randomised controlled trial is illustrated in Figure 1.

Figure 1. Design of the feasibility randomised controlled trial.



7.2.2 Sampling frame

As this was a feasibility study, a formal sample size calculation was not indicated. A target number of participants was decided, based on the time and resources available, and the numbers of patients attending routine group rehabilitation who were likely to be concerned about their ability to work. In the earlier interview study (Chapter 3), 41 patients were recruited, having expressed a concern about their ability to work due to back pain. This had provided a study sample of 28 participants, 25 of whom were employed. Sixteen of the employed participants attended rehabilitation. On this basis, it was estimated that it would take approximately 20 weeks to recruit 70 patients to provide a sample of 50 patients (25 in each arm) allowing for 30% drop-out/loss to follow-up.

The majority of patients recruited to the earlier interview study in this phase were employed, rather than unemployed. In addition, a 'Pathways to Work' (Department for Work and Pensions, Pathways to Work) service had recently been established in Nottingham by the Department of Work and Pensions and a private provider. This service was designed to offer intensive vocational support to those unemployed and claiming incapacity benefits due to common health conditions. It was anticipated that patients unemployed due to low back pain in Nottingham would be offered this support. On the basis of these findings, and the different problems and requirements of employed and unemployed patients, it was decided that the feasibility randomised controlled trial would therefore only recruit patients who were in paid employment.

7.2.3 Recruitment

Potential participants were identified by the Nottingham Back Team's clinicians during their routine assessment.

Inclusion criteria: patients were included if

- They had experienced low back pain for more than six weeks.
- their GP was located in South Nottinghamshire.
- they were employed.

- they were concerned about their ability to work due to back pain. This was determined by asking patients to complete a written screening question prior to the start of the assessment. The question asked the patient to tick a box if they were concerned about their ability to work because of low back pain.
- they had been offered rehabilitation by the Nottingham Back and Pain Team.

Exclusion criteria; patients were excluded if

- they had already received or were in receipt of an individual NHS vocational rehabilitation programme for back pain.
- they were unable to read, write and speak in English sufficiently to participate in the intervention and to complete questionnaires.

7.2.4 Consent

If the patient met the above criteria, the clinician explained the study to the patient. If the patient agreed, the clinician then gained written consent for the researcher to contact the patient by telephone after two days. The clinician gave the patient the information sheet to take home and read (Appendix 8, pp A48-A52). The patient was then contacted by the researcher by telephone, who answered any questions the patient had, and gained verbal consent to randomisation. Written consent was then obtained by post.

7.2.5 Randomisation

Each participant was randomised to one of the two treatment arms in the ratio 1:1 based on a computer-generated pseudo-random code using random permuted blocks of varying size, created by the Nottingham Clinical Trials Support Unit. The researcher then contacted the participant by telephone to inform them of their group allocation. If the participant was in the experimental group the principal investigator arranged the initial work assessment interview

with the participant. If not, the participant continued with routine group rehabilitation.

7.2.6 Treatment groups

7.2.6.1 Routine treatment (Control)

Routine treatment consisted of multidisciplinary group rehabilitation provided by the Nottingham Back and Pain Team. Treatment was based on a cognitive behavioural model with a pain-management approach, combining education and physical conditioning. At the start of the study, group sessions were for 3 hours once weekly over 7 consecutive weeks. However, during the study, the team introduced two further group treatment options, a four week programme (2 hours per week) and a ten week programme (3 hours per week). This decision was made by the team in order to address differing needs of patients and was outside of the control of the study. Patients could also be referred to individual cognitive behavioural therapy/psychology. Group allocation was determined by general level of function and psychological indicators rather than work status. Although work issues might be addressed within the group programme there was no individually targeted vocational intervention, and work outcomes were not routinely collected. Concerns regarding work might be addressed by the key worker during the group programme, who might advise on general management strategies but vocational interventions did not follow any standard procedure.

7.2.6.2 Individual work support (Intervention)

Participants were offered routine group rehabilitation but in addition received a specific work-focused intervention. This began as soon as possible after randomisation, both to standardise the intervention and to be able to address work-related problems promptly, and was completed within 16 weeks post-randomisation.

Objective of the intervention

The purpose of the intervention was to increase participants' self-perceived work ability by identifying and addressing their concerns about working with low back pain.

Theoretical basis of the intervention

The intervention was guided by cognitive-behavioural/rehabilitative and adaptive/ergonomic theory. For example, concerns about working with low back pain might be addressed by seeking to change factors intrinsic to the individual such as their physical ability, their knowledge base and their thoughts and beliefs about back pain. Concerns might also be reduced through changing factors extrinsic to the individual such as informing/educating their employer, modifying work tasks, environmental adjustments.

Content of the intervention

The content of the intervention was informed by the findings of the earlier interviews, best practice in the rehabilitation and occupational management of back pain (Carter & Birrell, 2000; Waddell, 2004; Waddell & Burton, 2004a), and the experience and clinical expertise of the researcher. It was tailored to the needs of the individual participant and could include:

- Communication with relevant others involved with the patient and the management of their back pain at work (e.g. GP, employer) providing information on current occupational, and general back pain management guidelines where appropriate.
- Assessment of work tasks and environment, including a work visit and ergonomic evaluation including analysis of tasks, environments, work organisation, job design and risk assessments.
- Identification of obstacles to the effective management of back pain at work, including psychological factors (e.g. loss of confidence), physical difficulties (e.g. limited standing tolerance), personal perceptions of work

(e.g. high job demands) and attitudes of others (e.g. managers, colleagues).

- Tailored interventions e.g. adjustments to work tasks and schedules, environmental adaptation, simulated work tasks, training in communication strategies and assertiveness techniques, information on evidence-based guidelines and recommendations for managing back pain at work, signposting/referral to other agencies and specialists e.g. mental health services and employment services.
- Participants were offered a maximum of eight face-to-face treatment sessions of up to 90 minutes each. The sessions took place at an agreed location e.g. at an out-patient clinic, at the patient's workplace, at the patient's home. Additional communication regarding work matters could also take place between the researcher and the patient by letter, telephone and/or email if appropriate. After each meeting, the researcher wrote to the participant to summarise what had taken place together with the agreed arrangements for the next meeting. If a participant did not attend an appointment then the researcher followed this up with a letter and/or telephone call to enquire whether the participant wished to rearrange the appointment. Two weeks before the end of the sixteen week intervention period, the researcher wrote to each participant to remind them that the intervention was coming to an end and invited them to contact the researcher if they wished to discuss any further concerns and/or to arrange another meeting.

7.2.7 Blinding

It was not possible to blind the study participants the researcher or the Nottingham Back and Pain Team clinicians providing routine group rehabilitation to treatment allocation.

7.2.8 Baseline data and outcome measures

Baseline measures were collected shortly after randomisation. This was a pragmatic decision in order to ensure that the intervention began at a standardised time point, i.e. before routine rehabilitation had started. As it was possible that patients might begin routine rehabilitation within a few days of recruitment, it was decided to randomise first so that there would be the minimum delay in arranging the first meeting between the researcher and participants in the intervention group. Baseline data were collected by the researcher who also delivered the intervention. Endpoint data were collected by independent researchers at six months post-randomisation and was anonymised before being entered into SPSS and analysed by the researcher.

The design of data collection was informed by the findings of the work carried out in earlier stages of the study. The Practice Manager survey (Chapter 5) had identified that data on healthcare resource use would have to be collected from the participants rather than through the GP practice. The Pilot Questionnaire (Chapter 6) had concluded that collecting complex data on healthcare resource use, work status and productivity might be best conducted by telephone interview to enable prompts and clarification of questions to be provided to the participants where required.

Data was therefore collected through three means:

7.2.8.1 Postal questionnaire

A postal questionnaire was designed (Appendix 9, pp A53-A73), based on the questionnaire piloted with patients earlier in the study (Chapter 6). Baseline and outcome measures included the following demographic data: date of birth, sex, ethnicity, marital status, living arrangements, highest level of academic qualification achieved, length of back pain history, physical job demands (based on a tool developed by Halpern et al (2001)), patient preference regarding treatment, individual and household income and current and completed compensation claims. The following work-related standardised outcome

measures were included: the Work Ability Index (Tuomi et al., 1998) – [Questions 1;2;4;5;6], the Graded Reduced Work Ability Scale (Haldorsen et al., 1998) and the Work scale of the Fear-Avoidance Beliefs Questionnaire (Waddell et al., 1993). Other core outcome measures commonly used to evaluate treatments for back pain were included: the Roland and Morris Disability Questionnaire (Roland & Morris, 1983), the Pain Self-Efficacy Questionnaire (Nicholas, 1989), the Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983) and the Pain Numeric Rating Scale (Jensen & Karoly, 2001). Cost-utility would be evaluated through the two preference-based health-related quality of life measures piloted with patients previously (Chapter 6): the EQ-5D (Brooks, 1996) and the SF-6D (Brazier et al., 2002).

7.2.8.2 Telephone interview

Data concerning employment status and sickness absence and healthcare resource use were collected by telephone (see Appendix 10, pp 74-76). This method was used so that complex questions could be clarified with the participant by the researcher, and to reduce the size of the postal questionnaire. Employment-related data included current occupation, employment status, size of employer and hours worked/not worked/hours on adjusted duties due to back pain.

7.2.8.3 Case records

Data was collected from participants' case records held by the Nottingham Back Team as to the number of treatment interventions received from the team and any specific work-related support or advice documented.

7.2.9 Data analysis

Data analysis was mainly descriptive and included the demographics of the study population, recruitment of participants, drop-out and loss to follow-up, patient feedback, researcher observations and documentation. Baseline measurements were examined visually for any important differences between the groups. Large

differences (more than 10%, on advice from statistician) should be taken into account in a definitive trial, for example by stratifying the groups at randomisation if that characteristic was thought to have a strong association with the outcome, or identified as a possible confounder in regression analyses. Completed measures were examined for patterns of missing data, spread of scores, responsiveness to change and floor/ceiling effects. Floor/ceiling effects of > 15% would be reported, as these are considered to be significant (Terwee et al., 2007). The difference and variability between the groups in the outcome measures were reported using median scores and inter-quartile ranges, means and standard deviations. Even where questionnaire data are normally distributed, they can rarely be considered true interval data thus reporting medians and inter-quartile ranges is considered more appropriate than means and standard deviation (Field, 2009). However, reporting both values would allow comparison with other published studies. Further analysis was to be dependent on the number of participants recruited and retained in the study; the endpoints for a feasibility study are factors that affect successful trial conduct, rather than tests of significance. However, if appropriate, scores would be examined for any effect size, and compared to any differences due to patient preference as to the study group they were randomised to. This decision would be guided by the sample size, the number of participants retained in the study, and any observed trends as to the outcomes for each group.

The difference and variability between the two groups in the EQ-5D and the SF-6D would be reported. If non-dominance occurred (i.e. if the costs were greater and the intervention more effective, or the intervention was cheaper and less effective) an incremental cost-utility ratio (ICUR) would be carried out.

The Human Capital Approach (Pritchard & Schulpher, 2000) was used to quantify productivity losses i.e. by multiplying the cumulative number of missed work days (or percentage of perceived reduced daily productivity) by participants' pre-tax daily/weekly salary. Daily/weekly wage was calculated by taking the mid-

point of participants' reported individual income band, less 35% (to account for national insurance contributions, pensions and tax), then by dividing the remaining amount as follows:

- productivity loss/wage per week = above total divided by 52
- productivity loss/wage per day = weekly productivity
loss/wage divided by number of days worked per week

Direct healthcare costs (UK £2009) were obtained from the following sources:

- Costs of treatment interventions and investigations were derived from national published unit cost data (NHS reference costs, 2009), costs of health staff from the unit costs of health and social care (PSSRU, 2009), medication costs from the British National Formulary (2009) and local costs of routine rehabilitation from personal communication with the Nottingham Back and Pain Team manager.

The following assumptions of time frames/amounts were made in estimating costs where participants were unable to give precise data. Documenting assumptions made at the beginning of an evaluation are needed to guide sensitivity analyses (Fox-Rushby & Cairns, 2005):

- six months = 26 weeks
- 'a few days' = three days
- 'often' = 50% of the time
- 'when required' = 0.25 of usual dose

Where participants were unable to give a precise response, but were able to provide a range (e.g. 1-2 GP visits) the 'worst case scenario' data (i.e. in this example two visits) was used in the analysis.

7.2.10 Ethics

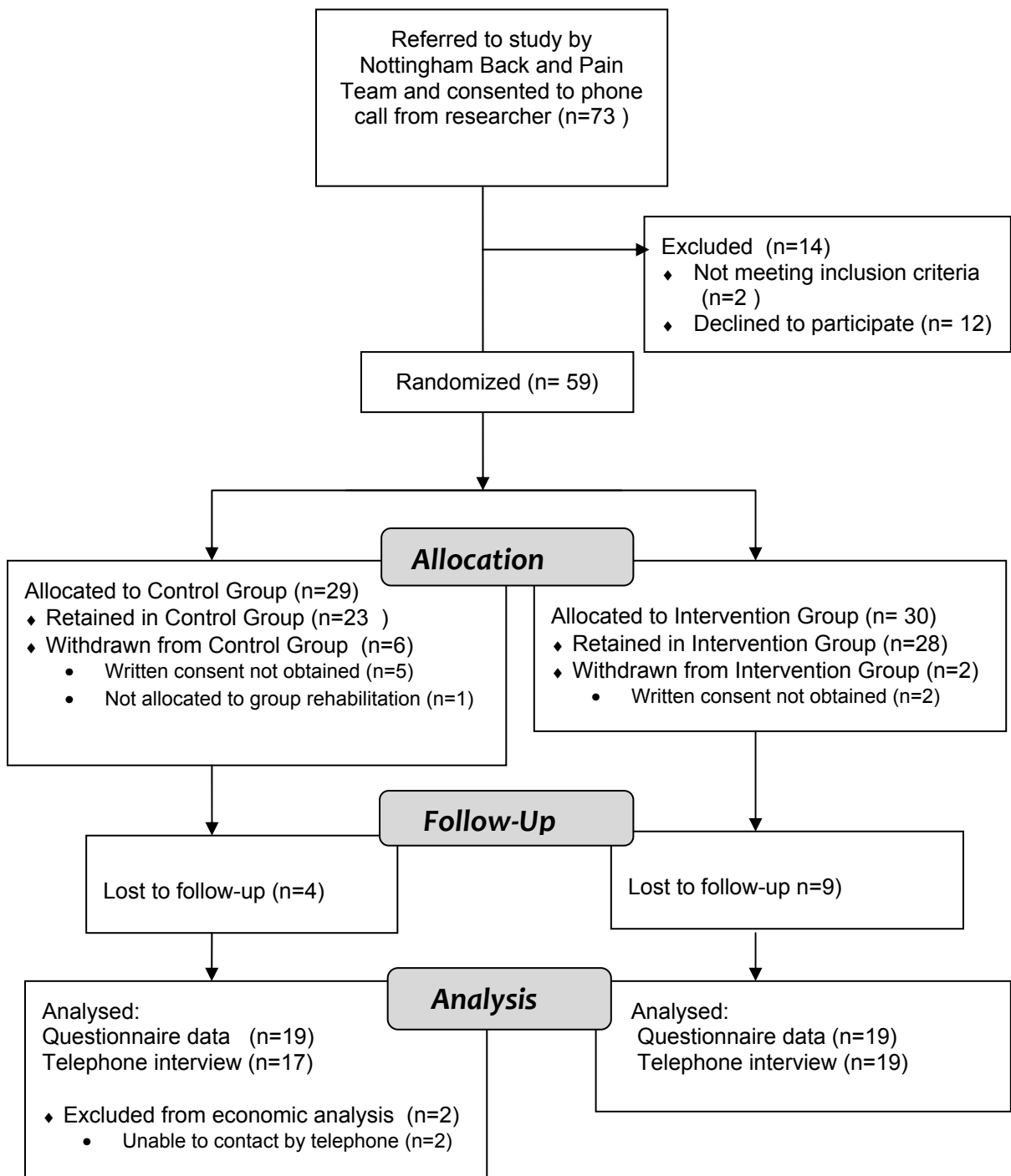
Ethical approval was obtained from Derbyshire Research Ethics Committee and Research and Development approval was obtained from the Nottingham University Hospital NHS Trust Research and Development Directorate.

7.3 Results

7.3.1 Recruitment of participants

Recruitment and randomisation took place between May and October 2009. The flow of participants through the study is summarised in Figure 2. Of the 73 patients referred by the Nottingham Back and Pain Team, two did not meet the criteria and twelve declined. The remaining 59 patients were randomised. Eight patients were withdrawn from the study following randomisation; seven failed to return their written consent, one had been offered individual treatment rather than group treatment. Of the 51 participants who remained, 28 were in the intervention group and 23 in the control group. Of these, 22 in the intervention group and 16 in the control group received at least one routine treatment session. Six month questionnaire and telephone interview data was collected from 19 participants in the intervention group. Six month questionnaire data was collected from 19 participants in the control group, and telephone interview data from 17 in the control group.

Figure 2. CONSORT diagram summarising the flow of participants



7.3.2 Characteristics of the sample

7.3.2.1 Demographic characteristics

The groups were well balanced with regard to the majority of demographic characteristics as shown in Table 15. The mean age was 48 years in the control group and 41 years in the intervention group. Both groups had an average back

pain history of 7.3 years. There was a higher proportion of women in the control group (56%), and equal number of men and women in the intervention group. The majority of participants in each group were married, of white English ethnic origin, had an individual pre-tax income of less than £20,000, expressed a preference for the intervention, and had experienced a gradual onset of their back pain. There were differences between the groups greater than 10% with regard to the following characteristics; a greater proportion of those in the control group lived alone and had no formal qualifications and a greater proportion of those in the control group reported that their back pain was associated with an accident at work. Also, although a minority were, or had been, involved in insurance claims related to their back pain, three participants in the control group had completed disability benefit claims related to their back pain, compared with none in the intervention group.

7.3.2.2 Occupational characteristics

The groups were less well balanced at baseline with regard to occupational characteristics as shown in Table 16. There were differences between the groups greater than 10% with regard to the following characteristics: a greater proportion of those in the control group worked for less than 16 hours per week, a greater proportion of the control group reported working normal hours and duties at baseline and a greater proportion of those in the intervention group were employed in large enterprises (>250 employees). In addition, although the measure of physical job demands was similar between groups using the scale devised by Halpern et al (2001), a greater proportion of the control group considered that their job involved a lot/a great deal of physical effort than the intervention group.

Table 15. Demographic characteristics of the sample.

	Control N=23 (45%)			Intervention N=28 (55%)		
	Mean	S.D.	Range	Mean	S.D.	Range
Age	48.30	10.14	28-65	41.46	11.93	18-59
Back pain history (months)	88.43	84.53	2-300	88.04	103.78	2-420
	N	%		N	%	
Gender						
Male	10	43.5		14	50.0	
Female	13	56.5		14	50.0	
Ethnicity						
White English	22	95.6		25	89.3	
Black Caribbean	1	4.4		2	7.1	
Pakistani	0			1	3.6	
Marital status						
Never married	2	8.7		7	25.0	
Married	14	60.9		16	57.1	
Divorced	6	26.1		5	17.9	
<i>Missing</i>	1	4.3		0		
Highest academic qualification						
Secondary school	9	39.1		5	17.9	
GCSE/equivalent	4	17.4		3	10.7	
Further education	5	21.8		16	57.1	
Higher education	4	17.4		4	14.3	
<i>Missing</i>	1	4.3		0		
Living arrangements						
Alone	4	17.4		1	3.6	
With adults	10	43.5		14	50.0	
With children	1	4.3		3	10.7	
With adults and children	7	30.5		10	35.7	
<i>Missing</i>	1	4.3		0		
Preference for arm of study						
Intervention	13	56.5		16	57.2	
Routine treatment	2	8.7		0		
No preference	8	34.8		12	42.8	
Individual income (pre-tax)						
Less than £20,000	16	69.6		17	60.7	
£20,000 - £39,999	5	21.8		8	28.6	
£40,000 or more	1	4.3		3	10.7	
<i>Missing</i>	1	4.3		0		
How back pain started						
Gradually	12	52.2		14	50.0	
Suddenly (not an accident)	4	17.4		7	25.0	
Accident at work	6	26.1		2	7.1	
Accident (not at work)	1	4.3		5	17.9	
Insurance/benefit claims						
None	20	87.0		24	85.6	
Under consideration	0			1	3.6	
Involved	0			1	3.6	
Completed	1	4.3		1	3.6	
<i>Missing</i>	2	8.7		1	3.6	
Disability benefit claims/appeals						
None	17	73.9		25	89.2	
Under consideration	1	4.3		1	3.6	
Involved	0			1	3.6	
Completed	3	13.0		0		
<i>Missing</i>	2	8.7		1	3.6	

Table 16. Occupational characteristics of the sample.

	Control N=23 (45%)			Intervention N=28 (55%)		
	Mean	S.D.	Range	Mean	S.D.	Range
Physical job demands (0-30)	8.78	5.21	0-26	8.50	3.74	2-16
(Halpern)	N	%		N	%	
Physical effort involved in job						
Very little/not much	3	13.0		10	35.8	
Some	6	26.2		9	32.1	
A lot/a great deal	13	56.5		9	32.1	
<i>Missing</i>	1	4.3		0		
Employment status due to back pain						
Normal hours/duties	13	56.5		11	39.3	
Adjusted hours and/or duties	5	21.7		13	46.4	
On sick leave	5	21.8		4	14.3	
Hours worked per week						
0 - 16	4	17.4		1	3.6	
17 - 39	13	56.5		16	57.1	
40 and above	6	26.1		8	28.6	
variable	0			3	10.7	
Days sick leave for back pain in previous six months						
None	13	56.6		13	46.5	
1-29	5	21.7		8	28.5	
30 and over	5	21.7		7	25.0	
Employer characteristics (1st or only job*)						
Self-employed	3	13.0		3	10.7	
<50 employees	3	13.0		3	10.7	
51-250 employees	3	13.0		1	3.6	
>250 employees	14	61.0		21	75.0	
Concern about ability to continue working due to back pain						
Very little/not much	5	21.7		6	21.5	
Some	6	26.1		9	32.1	
A lot/a great deal	12	52.2		13	46.4	
Claim against employer						
None	21	91.4		25	89.2	
Involved	1	4.3		1	3.6	
Completed	0			1	3.6	
<i>Missing</i>	1	4.3		1	3.6	
Occupational groups (1st or only job*)						
Managers/senior officials	0			3	10.7	
Professionals	2	8.7		2	7.1	
Associated professional/technical	3	13.0		2	7.1	
Administrative & secretarial	1	4.3		4	14.3	
Skilled trades	3	13.0		6	21.5	
Personal services	5	21.7		4	14.3	
Sales & customer services	2	8.7		4	14.3	
Process, plant & machine operatives	3	13.0		0		
Elementary occupations	4	17.4		3	10.7	

*three participants in the intervention group and one in the control group had two jobs.

7.3.2.3 Standardised outcome measures

The majority of outcomes of standardised measures were evenly distributed as can be seen in Table 17. Perceptions of work ability were overall slightly higher in the control group on the Work Ability Index but slightly higher in the intervention group on the Graded Reduced Work Ability Scale. However there were differences between the groups greater than 10% with regard to the following measures: there was a higher level of perceived disability (RMDQ) and work-related fear-avoidance (FABQWork) in the control group.

Table 17. Standardised outcome measures at baseline.

	Control 23 (45%)					Intervention 28 (55%)				
	Mean	S.D.	Median	Range	IQR	Mean	S.D.	Median	Range	IQR
Mean back pain in previous 6 months (0-10: lower scores indicate less pain)										
	5.52	1.79	5.33	3-10	2.33	5.67	1.66	6.0	1.6 – 8.3	2.3
						<i>Missing: 1</i>				
Roland & Morris (0-24: lower scores indicate less disability)										
	11.7	5.29	12.0	2-20	10.0	10.0	3.14	9.50	3-16	4.0
Pain Self-Efficacy Questionnaire (0-60 lower scores indicate lower self-efficacy)										
	33.1	10.9	33.0	13-56	15.0	33.5	9.55	32.5	14-50	15.5
HADS Anxiety (0-21 lower scores indicate less anxiety)										
	8.52	3.34	8.0	2-18	3.0	8.86	3.62	8.0	3-16	6.0
HADS Depression (0-21 lower scores indicate less depression)										
	6.78	3.10	7.0	2-13	5.0	6.93	3.10	6.50	1-16	5.0
Fear-Avoidance Beliefs Questionnaire: Work (0-42 lower scores indicate less fear-avoidance)										
	23.1	8.26	22.0	6-36	14.0	18.8	8.53	19.0	2-35	10.0
						<i>Missing: 1</i>				
Graded Reduced Work Ability Scale (5-25: lower scores indicate greater work ability)										
	17.3	3.72	17.0	10-24	5.0	16.7	3.16	16.0	10-22	5.0
Work Ability Index question 1 (0-10: higher scores indicate greater work ability)										
	6.13	2.58	7.0	1-9	4.0	5.79	2.47	6.0	0-9	2.0
Work Ability Index question 2 (2-10: higher scores indicate greater work ability)										
	6.85	1.24	7.0	4-9	2.0	6.51	1.38	6.0	4-10	2.25
Work Ability Index question 4 (1-6: higher scores indicate greater work ability)										
	3.43	1.24	4.0	1-5	2.0	3.21	0.99	3.0	2-5	2.0
Work Ability Index question 5 (1-5: higher scores indicate greater work ability)										
	3.35	1.37	4.0	1-5	3.0	2.93	1.27	3.0	1-5	2.0
Work Ability Index question 6: (1,4,7: higher scores indicate greater work ability)										
	5.30	1.52	4.0	4-7	3.0	5.93	1.46	7.0	4-7	3.0

7.3.3 Feasibility of the interventions

7.3.3.1 Routine treatment

Allocation of routine treatment is shown in Table 18. The majority of the 51 participants were allocated to the seven week group programme. Six of each

group were allocated to the four week group programme and one participant in the intervention group was allocated to the ten week group programme.

Table 18. Allocation of routine rehabilitation

Level of routine rehabilitation	Control n=23		Intervention n=28	
	allocated (%)	taken up (%)	allocated (%)	taken up (%)
4 week programme	6 26%	2 9%	6 21%	5 18%
7 week programme	17 74%	13 56%	21 75%	16 57%
10 week programme	0	0	1 4%	1 4%
Total	23 100%	15 65%	28 100%	22 79%

The proportion of routine treatment attended by the study participants is shown in Table 19. Fourteen participants (27%) did not attend the programme, six in the intervention group and eight in the control group. The same proportion of each group (61%) attended more than half/all of the group sessions. Three participants in the control group, and two in the intervention group reported that they did not attend due to work commitments.

Table 19. Proportion of routine rehabilitation attended

Proportion of routine rehabilitation attended	Control n=23		Intervention n=28 (%)		Total n=51 (%)	
All	4	17%	6	21%	10	20%
More than half	10	44%	11	40%	21	41%
Less than half	1	4%	5	18%	6	12%
DNA	8	35%	6	21%	14	27%
Total	23	100%	28	100%	51	100%

Three participants, all in the intervention group, had received specific advice/support with work issues through routine treatment during the 16 week study intervention period, as documented in the team's patient records: one had been advised to use a lumbar roll in sitting at work, one had been advised to gradually pace lifting at work, another had requested that the team send a letter to his employer detailing the results of the treatment programme. Two

participants, both in the intervention group had been referred for individual cognitive behaviour therapy which was ongoing at six month follow-up.

7.3.3.2 Intervention group

Each of the 28 participants in the intervention arm of the study attended at least one consultation with the researcher. The number of meetings was decided jointly between the participant and researcher. Participants were encouraged to contact the researcher as necessary during the 16 week study period. Details of the number, location, duration and time of face-to-face contacts are shown in Table 20.

Table 20. Number, location, duration and time of face-to-face contacts in intervention group.

Location	sessions attended (N)	DNA (N)	evening sessions (N)	Mean time per session	Number of face-to-face contacts with researcher (intervention group)	
					No. of contacts	No of participants
					1	4 (14%)
Home	39	3	16	59 mins	2	12 (43%)
Research base	17	1	N/A	66 mins	3	5 (18%)
Workplace	15	0	1	53 mins	4	1 (3.5%)
Clinic	14	1	N/A	46 mins	5	0
Job Centre	1	1	N/A	90 mins	6	3 (11%)
Cafe	1	0	0	30 mins	7	2 (7%)
Total	87	6	17		8	1 (3.5%)
					Total	28

N/A: location not available in evenings

There were a total of 87 face-to-face contacts, an average of three for each participant. The majority were conducted at the participants' homes with 19% conducted in the evening (between 5pm and 9.30pm). Fifteen meetings were held at participants' place of work. The majority of participants (43%) attended two face-to-face meetings with the researcher. Six participants attended between six and eight meetings each.

The range and content of work support varied according to the concerns and needs of each participant as identified between the participant and the

researcher. Examples of treatment objectives identified can be seen in Table 21. Although eight participants received workplace visits, only one participant accepted the researcher's offer to meet with her employer, in order to arrange a graded return. Three accepted the researcher's offer to write directly to their employer regarding the management of their back pain at work, four others preferred to take letters to give to their employers themselves. Letters written to employers invited the employer, with the employee's consent, to contact the researcher regarding the management of the employee's back pain at work, but only one return contact by the employer was made through this route and did not encourage further participation. A further participant on sick leave at recruitment did not believe that her employers would consider making adjustments, did not intend to return to work and did not want the researcher to contact her employers. However she did take up the researcher's offer to meet

Table 21. Content of the intervention.

Treatment objectives	Examples
Communication strategies at work.	Disclosure of back pain at work, asking for help, discussing back pain at interviews, coping with perceptions of others' attitudes.
Symptom management at work.	Work modifications e.g. pacing work activities, activity scheduling to aid performance at work, flare-up management, sleep and stress management, use of medication.
Changing cognitions about working with back pain.	Reassurance, explanation of diagnoses, relationship between symptoms, diagnoses and work demands, education in pain mechanisms, addressing fear-avoidance.
Information to support working with back pain	Equipment, workstation adjustment, legislation & guidelines e.g. roles of Occupational Health, Health & Safety Executive, Disability Discrimination Act, Access to Work, Disability Employment Adviser, benefits e.g. Tax Credits
Support with work issues	Work visits and work assessment. Liaison with employers (written and face-to-face), planning graded returns, addressing concerns about sickness absence.
Function related to work tasks	Simulated work tasks, exercises to increase tolerance of work tasks e.g. sitting, standing, lifting, kneeling.
Support not directly related to work	Liaison with treatment providers, explanation of different treatment interventions, encouragement and support in attending routine treatment.

with the Disability Employment Adviser to discuss the options of support that were available to her through the JobCentre and employment services.

Four participants indicated that they might be in favour of the researcher visiting their workplace, but the visits were not completed. One participant cancelled the visit he had arranged due to a flare-up; one reported difficulty in arranging a suitable time with her manager; one decided that the visit was no longer necessary as she was receiving adequate support at work and another was admitted to hospital for abdominal surgery. All four participants either disengaged from the study or were lost to follow-up.

All participants were unaware of guidelines and recommendations in managing back pain at work as produced by the Health and Safety Executive (HSE Guidance Topics: Back Pain) and Faculty of Occupational Medicine (FOM) and the responsibilities of employers in arranging adjustments. One participant had received assessment through 'Access to Work'. Access to Work is a system of funding available through the Department of Work and Pensions and provides financial support to employers for extra costs which may arise if a health condition or disability affects job performance (Access to Work). The remainder were unaware of the legal responsibilities of employers, or services which might be available through the JobCentre.

The time interval between allocation and uptake of routine treatment varied between participants. One participant in the intervention group had already started routine treatment before the first meeting could be arranged with the researcher. Another did not start routine group treatment until five months after randomisation, one month after the end of the 16 week intervention.

The delay in take-up of, or non-attendance at routine treatment had an effect on the treatment objectives for some participants. In these cases, a greater proportion of the intervention was concerned with reassurance and explanations

e.g. of diagnosis and prognosis, pain mechanisms and general back pain management which would have been included in routine treatment.

7.3.3.3 *Response rates and loss to follow-up*

Nine participants in the intervention group were lost to follow-up. One had been admitted for spinal surgery; a second underwent surgery for another, unrelated condition. A third had not pursued the intervention or routine treatment because of work pressures. Two other participants were in the process of moving house at the time of the six-month data collection; one having not taken up routine treatment, the other having dropped out of treatment. A sixth had apparently successfully completed routine treatment and had engaged in the intervention, but at follow-up had been signed off sick and was awaiting further investigations. Although these factors are not causal, they may have influenced participants' willingness to remain in the study.

Four participants in the control group were lost to follow-up. Of these four, three had not attended any sessions of routine treatment, including one who had emigrated during the study period and one who had moved with no forwarding address. The remaining participant did not complete routine treatment.

7.3.4 Feasibility of data collection

Response rates to data collection are shown in Table 22. Postal questionnaires were returned by 38 participants (19 control; 19 intervention) at six months post-randomisation. Occupational outcomes at six months were obtained by telephone interview from 36 participants (17 control; 19 intervention).

Table 22. Response rates to data collection.

Baseline	Control 23		Intervention 28	
	N	%	N	%
Returned questionnaire unprompted	11	47.8	26	92.9
Returned qu're with telephone prompt	8	34.8	2	7.1
Returned qu're with telephone prompt and 2 nd copy	4	17.4	0	0.0
Total questionnaires returned	23	100.0	28	100.0
Total telephone interviews completed	23	100	28	100
Six months				
Returned questionnaire unprompted	13	56.5	9	32.1
Returned qu're with telephone prompt	2	8.7	1	3.7
Returned qu're with telephone prompt and 2 nd copy	4	17.4	9	32.1
Total questionnaires returned	19	82.6	19	67.9
Telephone interview completed	17	73.9	19	67.9

7.3.4.1 Standardised outcome measures

There were no missing data for the RMDQ or HADS. Only one item was missed regarding 'mean pain'. There was no missing data for the WAI or the GRWAS at baseline, but one participant in the control group who had been made redundant and not anticipating returning to work did not complete either scale at 6 months. Floor or ceiling effects of more than 15% were not found for the total scores of any of the measures used.

There were no floor or ceiling effects for the scaled WAI items 1,2,4. Item 5 of the WAI (total sick days in the previous 12 months) had a ceiling effect of more than 15% at baseline and at six months. Item 6 has a categorical response.

Two items of the GRWAS had floor effects of more than 15% at baseline, and four items had floor and/or ceiling effects of more than 15% at six months.

One participant did not complete the entire FABQ Work scale at baseline. At six months two participants failed to answer several questions and their scores were classed as 'missing'. Floor and/or ceiling effects in excess of 15% were found for six of the seven items at baseline and at six months.

Floor effects of 31% were found for the question regarding medication in the PSEQ at baseline. At six months, nine of the ten PSEQ items had ceiling effects of more than 15%, but the question on medication had a floor effect of 23%

indicating that many participants felt less confident in coping with their pain without medication compared with other aspects of living with back pain.

7.3.4.2 Telephone interviews

It was possible to contact most of the participants by telephone, but required several attempts, and some calls had to be made in the evening as participants were generally working during the day. If it was not convenient for the participant, a subsequent time/day was arranged. It was not possible to contact two participants.

It was difficult to gain accurate data for some items on the telephone questionnaire. Participants who were self-employed and/or ran their own businesses found it more difficult to state their average hours per week, and some employed participants worked more hours than they were contracted for. Some who had taken sick leave in the previous six months had difficulty recalling exactly how many days this had amounted to. It was particularly difficult to estimate sickness absence when a staged return to work had been implemented, and to record and compare data such as hours of work and sickness absence accurately if participants' employment status had changed during the six month period. For example, one participant had left his job working for a large employer where he had been on long term sick leave to become self-employed. Recording work adjustments was not straightforward. Some participants were able to work flexibly to accommodate their symptoms. Some made informal adjustments to tasks, for example a mobile hairdresser asked her clients to rinse their own hair and a nurse avoided washing patients single-handed when she could. Others reported formal adjustments to hours and/or duties arranged with their employer.

7.3.4.3 Six month data

Postal questionnaires were returned by 38 participants (19 control; 19 intervention) at six months post-randomisation. The scores for the standardised

outcome measures can be seen in Table 23. These results showed no consistent trends as a result of the intervention. The control group had lower median scores for pain, disability (RMDQ) and depression (HADS) but higher scores for fear-avoidance (FABQWork) than the intervention group. The control group had higher median scores for work ability on two measures (GRWAS, WAI Question 5) whereas the intervention group had higher median scores for self-efficacy (PSEQ) and work ability on one measure (WAI Question 1).

Table 23. Six month outcomes (standardised measures)

	Control N=19 (50%)					Intervention N=19 (50%)				
	Mean	S.D.	Median	Range	IQR	Mean	S.D.	Median	Range	IQR
Mean back pain (0-10: lower scores indicate less pain)	5.33	2.03	5.0	2.3-9.7	2.67	5.19	1.74	5.67	2-9	2.33
RMDQ (0-24: lower scores indicate less disability)	7.32	5.64	6.0	0-19	11.0	8.79	6.28	7.0	0-24	10.0
PSEQ (0-60: lower scores indicate less self-efficacy)	39.7	12.8	42.0	12-60	18.0	39.5	14.7	43.0	3-60	19.0
HADS Anxiety (0-21: lower scores indicate less anxiety)	7.47	3.69	8.0	1-14	5.0	8.42	4.29	8.0	0-16	6.0
HADS Depression (0-21: lower scores indicate less depression)	5.53	4.21	4.0	0-15	6.0	6.58	4.61	6.0	0-16	8.0
FABQWork (0-42: lower scores indicate less fear-avoidance)	20.7	8.78	20.0	0-36	12.7	18.6	9.82	18.5	2-33	15.2
	<i>Missing: 1</i>					<i>Missing: 1</i>				
GRWAS (5-25: lower scores indicate greater work ability)	14.8	4.18	14.5	7-22	6.25	15.5	6.47	16.0	5-25	10.0
	<i>Missing: 1</i>									
WAI Q1 (0-10: higher score indicates greater work ability)	6.78	2.26	7.50	3-10	3.0	7.00	2.60	8.0	6-10	3.0
	<i>Missing: 1</i>									
WAI Q2 (2-10: higher score indicates greater work ability)	6.86	1.28	7.0	4-9	2.0	6.97	2.07	7.0	2-10	2.0
	<i>Missing: 1</i>									
WAI Q4 (1-6: higher score indicates greater work ability)	3.89	1.23	4.0	2-6	2.0	3.47	1.22	4.0	1-5	2.0
	<i>Missing: 1</i>									
WAI Q5 (1-5: higher score indicates greater work ability)	3.44	1.38	4.0	1-5	3.0	2.95	1.39	2.0	1-5	2.0
	<i>Missing: 1</i>									
WAI Q6 (1,4,7: higher score indicates greater work ability)	6.00	1.78	7.0	1-7	3.0	6.21	1.36	7.0	4-7	3.0
	<i>Missing: 1</i>									

Occupational outcomes were obtained by telephone interview from 36 participants (17 control; 19 intervention). The results are shown in Table 24. A greater proportion of the control group were working their normal hours and

duties than the intervention group, and two participants in the intervention group were on sick leave at the time of the interview. Sickness absence rates for the previous six months were similar in each group.

Table 24. Occupational outcomes at six months

	Control N=17 (47%)		Intervention N=19 (53%)	
	N	%	N	%
Employment status due to back pain				
Normal hours/duties	13	76.5	9	47.4
Adjusted hours and/or duties	3	17.6	7	36.8
On sick leave	0		2	10.5
Made redundant in last six months	1	5.9	0	
Employment support allowance	0		1	5.3
Days sick leave for back pain in previous six months				
None	9	52.9	10	52.6
1-29	7	41.2	7	36.8
30 and over	1	5.9	1	5.3
Employment support allowance	0		1	5.3

As the sample was small and there was a 25% loss to follow-up, it was not considered appropriate to measure effect sizes.

7.3.5 Feasibility of the economic evaluation

Data for the economic evaluation was available for 19 patients in the intervention group and 17 participants in the control group (two participants in the control group had returned the postal questionnaires but were unable to be contacted by telephone by the independent researchers). Results for cost measurement and cost utility are shown separately.

7.3.5.1 Cost measurement outcomes

a) Personal healthcare costs

Costs included over-the-counter medication and supplements including gels and creams, TENS machines, heat pads and treatment (osteopathy, physiotherapy and massage). Results for the control group can be seen in Table 25. The following participants were unable to estimate the costs of items used: two of

the five participants who reported using paracetamol; one of the four patients who reported using ibuprofen; both participants who reported using heat pads. The total for the available estimated personal healthcare cost for the control group was £612.36.

Table 25. Personal healthcare costs (control: N=17)

Personal healthcare	No. pts reported using	No. pts able to estimate costs	Mean estimated reported cost per user	Range of estimated costs	Total reported costs
Paracetamol	5	3	£21.75	26p-£35	£65.26
Nurofen	1	1	£4.00	£4.00	£4.00
Ibuprofen	4	3	£22.39	£2.16-£35.00	£67.16
Co-codamol	1	0	0	0	0
Glucosamine	1	1	£30.94	£30.94	£30.94
Gel/cream	0	0	0	0	0
TENS	4	4	£37.50	£20 - £50	£150.00
Heat pads	2	0	0	0	0
Osteopathy	2	2	£60.00	£60.00	£120.00
Physio	0	0	0	0	0
Massage	1	1	£175.00	£175.00	£175.00
Total costs					£612.36

Results for the intervention group can be seen in Table 26. The following participants were unable to estimate the costs of items used: three participants who reported using paracetamol; one participant who reported using co-codamol; two participants who reported using gels/creams. The total for the available estimated personal health care cost for the intervention group was £1035.99.

Table 26. Personal healthcare costs (intervention: n=19)

Personal healthcare	No. pts reported using	No. pts able to estimate costs	Mean estimated reported cost per user	Range of estimated costs	Total reported costs
Paracetamol	6	3	£38.67	£2.00 -£104.00	£116.00
Nurofen	0	0	0	0	0
Ibuprofen	2	2	£31.00	£10.00 - £52.00	£62.00
Co-codamol	2	1	£104.00	£104.00	£104.00
Glucosamine	0	0	0	0	0
Gel/cream	4	2	£12.50	£9.00 - £16.00	£25.00
TENS	4	4	£39.25	£20.00 - £60.00	£156.99
Heat pads	4	4	£63.50	£5.00 -£210.00	£254.00
Osteopathy	0	0	0	0	0
Physio	2	2	£204.00	£90.00 -£228.00	£318.00
Massage	0	0	0	0	0
Total costs					£1035.99

b) Direct healthcare costs

Data was available for 36 participants (control:17; intervention:19). Costs included medication, consultations, investigations and treatment. Medication costs for the control group can be seen in Table 27. One participant reported using 'Trampatch' for which a cost could not be found in the BNF. The total for the available direct healthcare medication cost for the control group was £867.59.

Table 27. Direct healthcare costs: medication (control: N=17)

Medication	No. pts reported using	Range of costs	Total costs
Paracetamol	2	£1.92 - £17.47	£19.39
Ibuprofen	3	£2.54 - £3.82	£14.05
Co-codamol 8/500	5	£15.28 - £61.15	£168.14
Co-codamol 30/500	1	£7.83	£7.83
Diclofenac	2	£0.51 - £9.28	£9.79
Naproxen	1	£49.96	£49.96
Acupan	1	£19.03	£19.03
Codeine	1	£8.23	£8.23
Tramadol	4	£10.62 - £53.69	£96.52
Trampatch - 2 patches/wk	1		NOT KNOWN
Amitriptyline	1	£28.39	£28.39
Pregablin	1	£418.60	£418.60
Omeprazole	1	£27.66	£27.66
		Total costs	£867.59

Medication costs for the intervention group can be seen in Table 28. One participant reported using Oromorph for which a cost could not be found in the British National Formulary. The total for the available direct healthcare medication cost for the intervention group was £1108.45.

Table 28. Direct healthcare costs: medication (intervention: N=19)

Medication	No. pts reported using	Range	Total cost
Paracetamol	2	£5.82 - £23.30	£29.12
Ibuprofen	1	£11.46	£11.46
Co-codamol 8/500	3	£3.78 - £15.28	£33.40
Co-codamol 30/500	1	£62.00	£62.00
Kapake	1	£4.20	£4.20
Diclofenac	1	£1.43	£1.43
Naproxen	2	£7.25 -£7.74	£14.99
Acupan	1	£113.56	£113.56
Codeine	1	£8.53	£8.53
Tramadol	2	£42.95 -£85.90	£128.85
Amitriptyline	3	£7.10 - £21.29	£35.49
Temgesic	1	£57.20	£57.20
Oromorph	1 (2.5-5mg/day)		NOT KNOWN
Pregablin	1	£418.60	£418.60
Gabapentin	2	£20.75 - £41.50	£62.25
Lyrica	1	£106.95	£106.95
Zopiclone	1	£6.48	£6.48
Omeprazole	1	£13.83	£13.83
Diazepam	1	£0.11	£0.11
Total cost			£1108.45

Costs of consultations, investigations and treatment for the control group can be seen in Table 29. The total costs for the control group were £2,432.00.

Table 29. Direct healthcare costs: consultations, investigations and treatment (control: N=17)

Consultations, investigations, treatment	No. pts reported	Range / no. sessions	Total consultations	Total cost
GP (per 11.7min) £35	9	1-6	20	£700.00
Hospital consultant (per contract hr) £129	1	1	2	£258.00
Acupuncture (O/P) (per treatment) £136	1	1	4	£544.00
Physiotherapy (per treatment) £42	4	1-10	15	£630.00
MRI scan (per scan) £200	1	1	1	£200.00
X ray (per Xray) £50	2	2	2	£100.00
Spinal injection (per injection) £187	0	0	0	0
Liver ultrasound (per scan) £60	0	0	0	0
Blood test (per procedure) £10	0	0	0	0
Total cost				£2,432.00

Costs of consultations, investigations and treatment for the intervention group can be seen in Table 30. The total costs for the intervention group were £3,802.00.

Table 30. Direct healthcare costs: consultations, investigations and treatment (intervention: N=19)

Consultations, investigations, treatment	No. pts reported	Range/ no. sessions	Total consultations	Total cost
GP (per 11.7min) £35	7	1 - 12	44	£1540.00
Hospital consultant (per contract hr) £129	2	2-3	5	£645.00
Acupuncture (O/P) (per treatment) £136	0	0	0	0
Physiotherapy (per treatment) £42	1	2-7	18	£756.00
MRI scan (per scan) £200	1	1	1	£200.00
X ray (per Xray) £50	0	0	0	0
Spinal injection (per injection) £187	2	1-2	3	£561.00
Liver ultrasound (per scan) £60	1	1	1	£60.00
Blood test (per procedure) £10	1	4	4	£40.00
Total cost				£3802.00

c) Routine treatment costs

Data was available for 51 participants (control: 23; intervention: 28). Results for the control group can be seen in Table 31. The mean cost per participant who attended routine treatment was £783.33.

Table 31. Routine group treatment (control: N=17)

Group treatment	No. pts attending	Total cost
4 week programme (£200)	2	£400.00
7 week programme (£900)	10	£9,000.00
10 week programme (£1,100)	0	0
DNA	5	0
Total		£9,400.00

Results for the intervention group can be seen in Table 32. The mean cost per participant who attended routine treatment was £758.82. Costs for routine group treatment were inclusive of any additional individual CBT/psychology.

Table 32. Routine group treatment costs (intervention: N=19)

Group treatment	No. pts attending	Total cost
4 week programme (£200 each)	4	£1,000.00
7 week programme (£900 each)	12	£10,800.00
10 week programme (1,100 each)	1	£1,100.00
DNA	2	0
	Total	£12,900.00

d) Individual work support (intervention) costs.

Data on individual work support was available for all 28 participants in this group, but for the economic evaluation only data for the nineteen participants remaining in the study was used. The results can be seen in Table 33. Costs included face-to-face treatment time with the researcher, non-contact time (including participants who did not attend appointments) and travel costs.

Table 33. Individual work support costs (intervention: N=19)

Individual work support	Total amount	Cost	Total
Patient contact	71.5 hours	£44 per hr	£3,146.00
Non-contact	87 hours	£44 per hr	£3,828.00
Travel		40p per mile	£222.18
Total			£7,196.18

e) Productivity costs due to back pain

Data was available for 36 participants (control: 17; intervention: 19).

Costs included those related to sickness absence, perceived reduced productivity whilst at work due to back pain and costs of reduced hours on days worked due to back pain. Results for the control group can be seen in Table 34.

Seven participants had taken sick leave and were able to report the number of days. Fourteen participants reported days when they were less productive whilst at work due to back pain, although one was unable to give the precise number of days. The researcher assumed that this was 50% of the time. Thirteen of the fourteen participants were able to estimate the amount of reduced average productivity as a percentage. Seven participants reported that on some days at work they had worked fewer hours due to back pain, of whom two could

estimate how many hours less. One participant had been made redundant during the six month period. The total for the available estimated productivity cost for the control group was £7,797.74.

Table 34. Productivity costs due to back pain (control: N=17)

	No. pts reporting	No. pts possible to estimate costs for	Range	Cost
Sickness absence days				
	7	7	2 days – 3 weeks	£1,725.00
Days when less productive at work, and percentage less productive				
	14	13	2 days – 130 days 15% - 50%	£5,606.89
Days when at work but working less hours				
	7	2	2 days – 78 days 3 hours – 5 hours	£465.85
Total Cost				£7,797.74

Results for the intervention group can be seen in Table 35. Nine participants had taken sick leave and eight were able to report the number of days. One participant reported 'a few days' which the researcher assumed as 3 days. Eleven participants reported days when they were less productive whilst at work due to back pain, although one was unable to give the precise number of days. The researcher assumed that this was 50% of the time. A twelfth participant reported that back pain affected her ability to work approximately one day per week, but that she was able to delegate to others, so did not feel that it affected her productivity and she was not included. All eleven were able to estimate the amount of reduced average productivity as a percentage. Four participants reported that on some days at work they had worked fewer hours due to back pain, of whom two could estimate how many hours less. One participant had finished work on health grounds during the six months and was claiming Employment Support Allowance, but the exact start date was not collected and this data was not included in the analysis. The total for the available estimated productivity cost was £11,897.95.

Table 35. Productivity costs due to back pain (intervention: N=19)

	No. pts reporting	No. pts possible to estimate costs for	Range	Cost
Sickness absence days				
	9	9	3 days – 8 weeks	£7,160.40
Days when less productive at work, and percentage less productive				
	14	13	3 days – 20 days 5% - 60%	£4,485.59
Days when at work but working less hours				
	7	2	2 days – 5 days 2.5 hours – 4 hours	£251.96
Total Cost				£11,897.95

f) Total healthcare and productivity costs

The total healthcare and productivity costs for each group can be seen in Table 36. The total healthcare and productivity cost for the intervention group were £16,830.88 more than the control group. The total healthcare and productivity cost per participant in the intervention group was £755.12 more than the control group.

Table 36. Total costs for healthcare and productivity

	Control (17)	Intervention (19)
	Total	Total
Personal healthcare	£612.36	£1,035.99
Direct healthcare (meds)	£867.59	£1,108.45
Direct healthcare (excluding. rehab)	£2,432.00	£3,802.00
Direct healthcare (rehab)	£9,400.00	£12,900.00
Direct healthcare (intervention)	0	£7,196.18
Total healthcare costs	£13,311.95	£26,042.62
Productivity costs	£7,797.74	£11,897.95
Total cost	£21,109.69	£37,940.57
Mean cost per participant	£1,241.75	£1,996.87

7.3.5.2 Results for cost utility

Thirty-eight participants had returned the postal questionnaire at follow-up which included the EQ-5D and the SF-6D. There was no missing data for the EQ-5D at baseline; at six months, one participant did not complete question 2 (self-

care). At baseline one participant did not complete two of the questions related to physical activity, another did not complete one question on pain.

At six months, two participants did not complete two of the physical activity questions.

Full data was available for 37 participants with the EQ-5D and for 36 participants with the SF-6D. QALY scores were computed for both measures, and compared using independent t-tests. The results are shown in Table 37. These show different directions for the scores in that there was a QALY gain for the intervention group as measured with the EQ-5D, and a QALY loss for the intervention group as measured with the SF-6D. Differences were small not statistically significant, results for both measures were close to zero, and the confidence intervals also crossed zero. No further analysis was conducted.

Table 37. Results of independent t-tests comparing QALYs per group for EQ-5D and SF-6D

QALY	Study Arm	N	Mean	SD	Mean difference (95% CI)
EQ-5D	control	19	.003658	.0983936	0.0119532 (-.075567 to .0516612)
	intervention	18	.015611	.0922092	
SF-6D	control	18	.007196	.0960793	-0.001985 (-.015112 to .0190811)
	intervention	18	.005211	.0295839	

As the results for the health related quality of life measures were divergent, the raw scores were compared to identify differences in the results for the individual dimensions measured by the instruments. One participant at baseline, and two participants at six months reported 'full health' (maximum total score) on the EQ-5D. No participants reported maximum or minimum total scores on the SF-6D.

EQ-5D

The scores and percentages for the EQ-5D are shown in Table 38. No participants reported extreme problems for the dimensions of mobility and self-care either at baseline or six months. More than 60% of participants reported 'no

problems' in self-care at both time points. More than 30% of participants reported no problems in mobility. More than 27% of participants in the intervention group and more than 40% of participants in the control group reported not feeling anxious or depressed. The majority reported some problems with self-care, moderate pain or discomfort and feeling moderately anxious or depressed. More than 20% of participants in each group reported extreme pain or discomfort at each time point.

Table 38. Results for the EQ-5D

Dimension	Response option	Control (N=19)						Intervention (N=18)					
		Baseline			6 months			Baseline			6 months		
		N	%	N	%	N	%	N	%	N	%	N	%
Mobility	No problems walking about	7	36.8	8	42.1			6	33.3	11	61.1		
	Some problems walking about	12	63.2	11	57.9			12	66.7	7	38.9		
	Confined to bed	0	0	0	0			0	0	0	0		
Self-Care	No problems with self-care	12	63.2	12	63.2			15	83.3	14	77.8		
	Some problems washing/dressing	7	36.8	7	36.8			3	16.7	4	22.2		
	Unable to wash/dress self	0	0	0	0			0	0	0	0		
Usual Activities	No problems with usual activities	6	31.6	6	31.6			1	5.5	6	33.3		
	Some problems with usual	11	57.9	11	57.9			16	89.0	12	66.7		
	Unable to perform usual activities	2	10.5	2	10.5			1	5.5	0	0		
Pain/Discomfort	No pain/discomfort	0	0	1	5.3			1	5.5	1	5.5		
	Some pain/discomfort	15	78.9	13	68.4			12	66.7	13	72.2		
	Extreme pain/discomfort	4	21.1	5	26.3			5	27.8	4	22.2		
Anxiety/Depression	Not anxious/depressed	8	42.1	9	47.4			5	27.8	5	27.8		
	Moderately anxious/depressed	10	52.6	10	52.6			9	50.0	11	61.1		
	Extremely anxious/depressed	1	5.3	0	0			4	22.2	2	11.1		

SF-6D

The scores and percentages for the SF-6D dimensions of physical functioning, role limitations and pain are shown in Table 39.

Physical functioning: more than 60% of participants were limited a lot in vigorous activities. There was a greater variation for moderate activities; but overall the majority were limited a little. No participants in the control group reported that they were limited a lot with bathing/dressing, either at baseline or six months. More than 50% reported that they were not limited at all.

Role limitations: For physical role limitations there was a spread of scores, but with the majority in the middle of the scale, reporting being limited either some of the time, a little of the time or most of the time at baseline. For emotional role limitations there was a greater spread of scores. For the control group, the greater proportion had problems a little of the time or some of the time compared with the intervention group. More than 30% of the control group were limited none of the time at both time points.

Pain: Overall, scores were spread across the categories. No participants reported 'none' for bodily pain at baseline or at six months. The greater proportion was moderate or severe for both groups at each point. The greater proportion of both groups reported pain moderately interfering with usual activities at each point.

Table 39. Results for the SF-6D: dimensions of physical functioning, role limitations and pain.

Dimension	Response option	Control (N=18)				Intervention (N=18)			
		Baseline		6 months		Baseline		6 months	
		N	%	N	%	N	%	N	%
Vigorous activities	Limited a lot	13	72.2	11	61.1	14	77.8	14	77.8
	Limited a little	5	27.8	6	33.3	4	22.2	3	16.8
	Not limited at all	0	0	1	5.6	0	0	1	5.6
Moderate activities	Limited a lot	7	38.9	3	16.7	5	27.8	6	33.3
	Limited a little	6	33.3	11	61.1	11	61.1	9	50.0
	Not limited at all	5	27.8	4	22.2	2	11.1	3	16.7
Bathing/dressing self	Limited a lot	0	0	0	0	0	0	3	16.7
	Limited a little	9	50.0	7	38.9	9	50.0	2	11.1
	Not limited at all	9	50.0	11	61.1	9	50.0	13	72.2
Physical health limiting usual activities in past 4 weeks	All of the time	2	11.1	2	11.1	1	5.6	2	11.1
	Most of the time	4	22.2	1	5.6	9	50.0	3	16.7
	Some of the time	8	44.5	5	27.8	5	27.7	7	38.9
	A little of the time	4	22.2	9	50.0	3	16.7	2	11.1
	None of the time	0	0	1	5.6	0	0	4	22.2
Emotional health limiting usual activities in past 4 weeks	All of the time	1	5.6	0	0	1	5.6	0	0
	Most of the time	2	11.1	0	0	9	50.0	5	27.8
	Some of the time	4	22.2	8	44.5	5	27.7	6	33.3
	A little of the time	5	27.8	2	11.1	3	16.7	3	16.7
	None of the time	6	33.3	8	44.5	0	0	4	22.2
Bodily pain in past 4 weeks	None	0	0	0	0	0	0	0	0
	Very mild	1	5.6	1	5.6	0	0	3	16.7
	Mild	1	5.6	3	16.7	2	11.1	4	22.2
	Moderate	8	44.4	10	55.5	7	38.9	7	38.8
	Severe	6	33.3	2	11.1	8	44.4	1	5.6
	Very severe	2	11.1	2	11.1	1	5.6	3	16.7
Pain interfering with usual activities in past 4 weeks	Not at all	0	0	1	5.6	1	5.6	3	16.7
	A little bit	2	11.1	6	33.3	2	11.1	5	27.8
	Moderately	8	44.4	8	44.4	11	61.1	6	33.3
	Quite a bit	5	27.8	3	16.7	3	16.6	2	11.1
	Extremely	3	16.7	0	0	1	5.6	2	11.1

The scores and percentages for the SF-6D dimensions of mental health, vitality and social activity are shown in Table 40.

Mental health: The greater proportion of each group reported that they had been very nervous a little of the time or none of the time. More than 20% of participants reported being very nervous none of the time. Regarding feeling downhearted and depressed, the greater proportion reported feeling downhearted and depressed a little of the time.

Social Functioning: In regard to the effect of health on social activities, the greater proportion reported problems some of the time, or less often, with more than 25% of the control group reporting problems none of the time.

Vitality: Scores were spread across almost all categories.

Table 40. Results for the SF-6D: dimensions of mental health, vitality and social functioning.

Dimension	Control (N=18)						Intervention (N=18)						
	Baseline			6 months			Baseline			6 months			
	N	%		N	%		N	%		N	%		
Have you been very nervous during the past 4 weeks <i>Mental health</i>	All of the time	0	0	0	0	0	0	0	0	0	0	0	5.6
	Most of the time	2	11.1	0	0	0	2	11.1	0	0	2	11.1	16.7
	Some of the time	2	11.1	2	11.1	2	2	11.1	2	2	6	33.3	11.1
	A little of the time	8	44.5	9	50.0	9	8	44.5	4	6	33.3	4	22.2
	None of the time	6	33.3	7	38.9	7	4	22.2	8	6	33.3	4	22.2
Have you had a lot of energy during the past 4 weeks <i>Vitality</i>	All of the time	0	0	1	5.6	1	0	0	0	0	0	1	5.6
	Most of the time	2	11.1	0	0	0	2	11.1	0	0	3	16.7	27.8
	Some of the time	4	22.2	10	55.5	10	4	22.2	6	8	44.6	6	33.3
	A little of the time	12	66.7	6	33.3	6	4	22.2	3	4	22.2	3	16.7
	None of the time	0	0	1	5.6	1	0	0	3	3	16.7	3	16.7
Have you felt downhearted and depressed past 4 weeks <i>Mental health</i>	All of the time	0	0	0	0	0	0	0	0	0	0	0	0
	Most of the time	3	16.7	0	0	0	5	27.8	2	5	27.8	2	11.1
	Some of the time	5	27.8	4	22.2	4	4	22.2	5	4	22.2	5	27.8
	A little of the time	7	38.8	8	44.5	8	6	33.3	7	6	33.3	7	38.9
	None of the time	3	16.7	6	33.3	6	3	16.7	2	2	11.1	4	22.2
How much has your health interfered with social activities in the past 4 weeks <i>Social functioning</i>	All of the time	0	0	1	5.6	1	0	0	0	0	0	1	5.6
	Most of the time	3	16.6	1	5.6	1	3	16.6	4	6	33.3	4	22.2
	Some of the time	5	27.8	3	16.6	3	5	27.8	3	5	27.8	3	16.6
	A little of the time	5	27.8	5	27.8	5	5	27.8	5	5	27.8	5	27.8
	None of the time	5	27.8	8	44.4	8	2	11.1	5	2	11.1	5	27.8

7.4 Discussion

There were four main findings from the trial. Firstly, it was possible to recruit patients and randomise them to the study. Secondly, the protocol could be delivered; it was possible to provide the work-focused intervention alongside group rehabilitation. Thirdly, the majority of the standardised outcome measures were feasible. Finally, it was feasible to conduct an economic evaluation: it was possible to collect a large proportion of data from participants through the methods chosen, although the data could not be confirmed objectively from GP or employment records. In addition the health outcome measures used both had a high completion rate, however each had different psychometric properties and the QALY values did not correspond with each other.

Additional observations were made in relation to the research questions identified in the introduction to this chapter and are discussed below.

Recruitment

Although it was possible to recruit patients, the original target was not achieved. There were several possible reasons. Firstly, at the time of the study, GP 'clusters' in South Nottinghamshire were commissioning alternative back pain services which may have reduced the number of referrals to the team, Secondly, although the researcher trained the clinicians in the procedure for identifying and referring potential participants, the clinicians may have differed in their approach to potential participants at the initial assessment. Identifying patients independently either before or after the assessment could have avoided this, but would have delayed the recruitment process. Thirdly, patients who were at work and having to consider taking time out for routine treatment may have decided that they did not have the time to take part in a research study as well. However, data is not available to support these suppositions and therefore limits the conclusions that can be drawn. Other studies have reported longer recruitment times. In their study of integrated care for sick-listed patients with chronic back pain, Lambeek et al (2010b) recruited 134 participants over

approximately 4.5 years. Lamb et al (2010) in their multicentre trial of group treatment for low back pain recruited 701 participants over 2 years, but across seven different regional sites. Bultmann et al (2009) in their trial of co-ordinated and tailored work rehabilitation for workers on sick leave due to musculoskeletal disorders recruited 119 participants over twelve months, approximately 50% fewer than anticipated from a pilot study. In the current study data was not collected on why potential participants declined to be referred to the study as this was considered an additional burden on the clinicians and patients at the initial assessment.

Retention

The overall retention of participants in the study was just less than 75%, and is a limitation of the study. Loss to follow-up of more than 20% is considered to be a source of bias (Dumville et al., 2006). Loss to follow-up was greater in the intervention group than in the control group. The reasons for this are unknown, although all but one of those lost to follow-up either did not attend or had dropped out of routine treatment. As participants had been referred to the study by the clinicians providing routine treatment, it may be that these participants felt less engaged in the study as a result. This indicates that greater efforts would be needed to retain participants in a definitive trial. Recruiting participants independently of routine rehabilitation may have improved retention. Although the researcher did try to maintain contact with participants, this was mainly by letter. Booking a number of appointments with the researcher in advance, which could later be cancelled if unnecessary may have helped to retain participants as may regular follow-up phone calls. Greater attention to agreeing an acceptable method and frequency of communication with each participant may be necessary. Six month data was collected by independent researchers who had not previously had any contact with the participants. Some participants may therefore have felt less obliged to return questionnaires at six months.

Randomisation

Although the groups were reasonably well-balanced in terms of age, gender and history of back pain there were some differences between groups at baseline. These were lone living arrangements, educational attainment, hours worked, work status, an accident at work reported as the cause of back pain, the size of the enterprise worked for, a physically demanding job, completed financial compensation claims due to back pain, perceived disability and work-related fear avoidance. Those characteristics identified as being associated with work disability, were work-related fear avoidance (Fritz et al., 2001) perceived disability (Turner et al., 2008) educational attainment (Pietikainen et al., 2011), physically demanding work (Shaw et al., 2007) and compensation claims (Waddell, 2004). These could be confounding factors in a definitive trial, and the possible effect on differences found between the treatment arms might need to be minimised by stratifying the randomisation, or adjusting for in multivariate analysis. However, the differences might be due to the small sample and/or because randomisation took place prior to the baseline data collection.

Delivery of the intervention

Although it was possible to deliver the intervention, the intensity varied. Some participants were keen to access help. Others seemed to expect or need little support. This may be because they entered the study for altruistic reasons; at least 20% of each group at baseline had reported 'very little' or 'not much' concern about their ability to work due to low back pain. The screening question used at the initial clinical assessment by the Nottingham Back Team did not ask the extent to which the patient was concerned. It may also be the case that the term 'concerned' was inappropriate. Other studies have used participants' own perception of their ability as entry criteria. For example, Linton and Andersson (2000) used the person's own perception of being at risk of a chronic problem developing. Similarly, Karjalainen et al (2003) used the person's own perception that back pain was making working life difficult. Both studies were aimed at

participants with acute or sub-acute low back pain rather than those with longer term problems, however in this current study, prior testing of the screening question may have identified whether the terminology used was appropriate. It may also have been the case that participants' concerns had lessened as a result of their assessment and/or their anticipation of the help they would receive through routine treatment. Some may have felt under obligation to the clinician because they had been offered treatment. Again, data was not collected which may have supported these possible explanations.

A number of intrinsic factors may have influenced participants' decisions to request or decline additional treatment sessions. These include the extent to which treatment was perceived as helpful, the time they had available, their level of engagement with group rehabilitation, their understanding of the protocol and their ability/willingness to approach the researcher.

There was some overlap between the content of routine treatment and the intervention. This was partly due the delay between GP referral and starting routine treatment. A limitation of the study is that data on the length of any delay for each participant were not collected, however the longest any participant waited was five months. Where there was a delay in participants attending routine treatment, generic pain management treatment approaches were more likely to be included in the intervention. This may have diluted the effect of the intervention and would be a factor to consider in the design of a definitive trial. However, the intervention did provide a greater opportunity to apply the components of group treatment to the work setting than may be possible during group treatment. Concerns about work could be addressed promptly, rather than waiting for routine treatment to start. The management of non-work-related issues may be a necessary component of vocational rehabilitation which suggests that providers require a good understanding of the condition. In addition, clinicians and participants were not blinded and there may have been some contamination during routine treatment; clinicians may have

paid more or less attention to work issues than would normally be the case. However, as reported, few participants had received documented advice or support regarding work issues as part of routine treatment.

Selecting the appropriate treatment approach was sometimes problematic when participants had either not begun or completed routine treatment. It was not possible to anticipate how participants would respond to routine treatment. Some might improve both in their function and cognitions and for example have less need for adaptations or support. Others might make less improvement and require a more adaptive approach in order to retain employment. One participant had received an Access to Work assessment (Access to Work). Access to Work provides support with extra costs which may arise if a health condition or disability affects job performance. The UK government intends to improve the way that this funding is delivered so that it can better support those with fluctuating conditions (DWP & DoH, 2008), but it is unclear the extent to which this and other services could, or should be, available to those with back pain compared with other musculoskeletal conditions, for example rheumatoid arthritis (Gilworth et al., 2001).

Some participants in the intervention group may have been open to, and benefited from, more encouragement from the researcher in maintaining contact with the participant, and in liaising with other stakeholders. However, recipients of healthcare may be unused to practitioners liaising with or contacting other stakeholders regarding their work. They may be uncertain of what this may lead to, particularly from a research project trialling a new intervention; employees may be apprehensive as to the outcome. In a study of employed women with inflammatory arthritis, ergonomic assessments were conducted outside the workplace in part because some participants did not wish to disclose or draw attention to their condition (Lacaille et al., 2008). The emphasis on self-management of back pain may also inadvertently reinforce the view that

workplace management of the condition is also the patient or employee's responsibility. Other research has suggested that those with 'serious' chronic diseases may need to learn skills to help them solve work-related problems (Varekamp et al., 2009) whereas those with common health conditions such as low back pain are considered to be 'essentially manageable'. However in our study many participants were unaware of avenues of help and support, and the responsibilities of employers. Some patients felt able to effect their own adjustments in relation to their work, but others needed more direct help. The time-limit of the intervention period also affected the extent to which the intervention could be taken; there was a risk of raising issues regarding the work situation that could not be resolved within the timescale of the study. In delivering this intervention, the roles of researcher, clinician and case manager were each required to a greater or lesser extent and the potential for conflict in attempting to combine these roles needs to be acknowledged. For example, a researcher is bound by a protocol, is motivated primarily to maintain each individual in a study and should be unbiased. A clinician is motivated primarily to treat the individual patient according to his/her own clinical judgement. A case manager is expected to be more impartial and resource aware, and to balance the needs of both the patient and other stakeholders such as the employer (Hanson et al, 2006).

Arranging suitable times and locations to meet with participants was sometimes difficult. Although the researcher could access an office or clinic during the daytime, if participants were working during the day then meetings had to be arranged at their home. It was then difficult to find a private space. Email was a useful option where participants were comfortable in communicating by this means.

It may be that a period of sixteen weeks is not long enough to address a chronic problem with fluctuating symptoms or that some participants did not engage with the intervention or the researcher. A set number of meetings with the

researcher had not been built into the protocol as it was not known how many would be necessary. It may have helped to retain participants by booking advance appointments over the course of the intervention period, which could be cancelled as required. The intervention had not previously been tested, and lack of prior evaluation may have influenced the outcome.

Routine group treatment as a control

It seems that relying on 'routine treatment' as a comparator or control group can be unreliable as services undergo change; in this study for example, different intensities of group rehabilitation were being introduced by the service in order to best meet the needs of the client group. In addition, as indicated in Chapter 4, not all patients who are concerned about working with back pain will necessarily take up the offer of group treatment and work itself can be perceived as a barrier to accessing treatment. In a recent multi-centre trial of group cognitive-behavioural therapy for low back pain, the majority of participants were retired (Lamb et al., 2010). It may be that for those who are unable to access or engage with the group treatment, such an intervention needs to be delivered in a different format. For some, multidisciplinary treatment may need to be delivered on an individual basis. Although a group format is advocated to normalise pain experience and maximise the possibilities of learning from other group members (British Pain Society, 2007), there is little evidence that it is more effective (Rose et al., 1997; Turner-Stokes et al., 2003; Nykanen & Koivisto, 2004). For patients who do take up the offer of routine treatment, work-focused interventions would seem to be best integrated within a multidisciplinary team, but which has the flexibility to respond to patients' individual needs, for example intervening before or after the treatment programme if necessary.

Two participants in the intervention group had received individual cognitive behaviour therapy/psychology in addition to routine group treatment. Although the reason for referral was not directly associated with work problems, and did

not incur additional costs, it may nevertheless have influenced six month outcomes, and would therefore need to be addressed in the analysis of a definitive trial.

Feasibility of the proposed standardised outcome measures

Baseline scores for the outcome measures used in the study were compared with those reported in other studies of back pain rehabilitation. Participants' mean scores showed slightly higher levels of pain intensity (Pain NRS) and perceived disability (RMDQ) and lower scores for pain self-efficacy (PSEQ) than those reported by Lamb et al (2010) in their recent study of group behavioural treatment for low back pain. However they showed slightly lower levels of pain intensity and perceived disability than those reported by Lambeek et al (2010b) in their study of integrated care for sick listed patients with chronic low back pain. The GRWAS has been reported in only two papers (Haldorsen et al., 1998; Hagen et al., 2005). Neither paper reported the raw scores, and this research student has been unable to find any further information about the scale despite attempts to contact the authors and the University of Bergen, Norway. The mean scores for anxiety and depression (HADS) were both slightly higher than those reported in a recent trial of low back pain in primary care (Hill et al., 2011), but within 'normal' or 'mild' score bandings. Scores for fear-avoidance related to work (FABQWork) demonstrated similar levels of fear-avoidance as those reported by Grotle et al (2006) in a sample of patients with chronic low back pain. Median scores for the five chosen items of the WAI were approximate to those reported by Larsson et al (2008) in their study of female employees with musculoskeletal symptoms. However, mean scores for Question 1 (also known as the Work Ability Score) showed a higher level of perceived work ability than reported in studies of patients on sick leave (Brathen et al., 2007) and Ahlstrom et al (2010) which reported baseline means of 3 and 4. In this current study, the means were between 5.8 and 6.1. The single Work Ability Score has been reported to correlate with the whole index, with 0-5 points considered 'poor'; 6-

7 points 'moderate', 8-9 points 'good' and 10 points 'excellent' (Gould et al., 2008).

The GRWAS, Pain NRS, HADS and RMDQ all had high completion rates and low floor/ceiling effects and are considered feasible to use in a definitive trial. The FABQ was less acceptable and responsive due to the large amount of missing data and high percentage of floor/ceiling effects and cannot therefore be recommended. The high percentage of floor effects for the question concerning medication in the PSEQ suggests that the scale may not be a valid measure with this client group.

In this study, the same patient questionnaire and telephone interview questions were used at baseline and at six month follow-up. Although this meant that changes in all the measures could be accounted for, some of the data were redundant e.g. demographic and personal information, and standardised measures such as those concerning pain, function and mood. Such data were useful only in comparing baseline characteristics; with hindsight this may have placed an unnecessary burden on the respondents and may have affected response rates and loss to follow-up.

The feasibility of estimating an effect size in order to power a definitive trial

It would have been possible to estimate an effect size from the results of this feasibility study; some of the results showed an improvement for the intervention group in some of the work related measures, including Question 1 of the Work Ability Index, which has been used as a stand-alone measure in other studies (Ahlstrom et al., 2010; Nygard et al., 2005). A power analysis is the main method used to ascertain the sample size needed for a randomised controlled trial. The purpose is to ensure that the sample size is large enough to make a valid test of the study hypothesis and is estimated by using the standard deviation of the measurement tool and the effect size between the groups under investigation (Bowling, 2001). The effect size can be calculated using the mean difference between follow-up scores or change from baseline, or by linear

regression (Vickers & Altman 2001). However, in this study it was not considered appropriate to estimate an effect size for the intervention for the purposes of powering a definitive trial; the sample was smaller than intended, there had been a 25% loss to follow-up and although the results showed an improvement for the intervention group in some of the work-related measures, these were small and inconsistent. In addition, there were a considerable number of methodological issues which would need to be addressed in a main study, and any subsequent changes might invalidate the effect size. Kraemer et al (2006) warn against the use of pilot studies to conduct power calculations for this reason. An alternative method as suggested by Bowling (2001) would be to base the power calculation on the findings of previous studies. For example, the results reported by Braathen et al (2007) and Larsson et al (2008) could be used, however the eligibility criteria of the participants were different to those in this current study. In addition, as reported earlier, there are a range of key outcomes in work rehabilitation and it may be more appropriate to select more than one measure on which to calculate a sample size for a future trial.

Feasibility of measurement tools and data collection of the economic evaluation

All 36 participants whose data was used in the economic evaluation returned the postal questionnaire which included complete details of their individual income, the EQ-5D and the SF-6D.

Some participants had difficulty estimating time off work, for example if they had been on a graded return, or if they worked variable hours for example in a seasonal job such as landscape gardening. Not all were able to provide precise responses, and the accuracy of the data cannot be guaranteed. Details regarding, for example the type of injection, or medication prescribed was not always sufficient to determine the cost. The complexities of allocating costs when job circumstances and income level had changed within the study period were also difficult to account for, including one participant in the control group who had been made redundant, and one in the intervention group who had

moved onto Employment and Support Allowance. Collecting meaningful data on adjusted work also presents difficulties as adjustments vary in degree and in level of formality. In Chapter 5 it was concluded that gathering this data by questionnaire would be too complex, and would extend the postal questionnaire to an unacceptable length, however for some participants this data proved difficult to collect by telephone, despite the opportunity for the researchers to give prompts and clarifications. In this study, the researchers had not previously collected this data; more experience may have helped the quality of their questioning. Also it was not possible to contact two participants by telephone and their full data was therefore not available.

If research studies continue to rely on patients to provide healthcare resource use, and the need for economic evaluations grows then further studies are recommended to find the most acceptable and accurate methods of data collection, such as face-to-face interviews or diaries, in order to minimise the number of uncertainties. Two large UK randomised controlled trials of primary care back pain management, the UK Beam Trial (UK Beam Trial Team, 2004) and the STartBack trial (Hill et al., 2011) have both relied on participant report to collect healthcare resource use data, rather than from the GP surgeries, even though the surgeries had been recruited to the studies. Unless the findings of this current study are specific to Nottinghamshire, these suggest that there is a need to corroborate patient data with GP records more closely if the cost-effectiveness observations are to be accepted. Mixed methods using a combination of patient report and GP record data might be another option to consider. Guzman et al (1999) in their study of comparative methods of collecting data on healthcare use following occupational low back pain found that a questionnaire completed face-to-face with a trained interviewer had a better return rate than diaries or provider reports, although it was more expensive. These findings underline some of the difficulties in collecting data for use in economic evaluations and that multiple elements are involved (Elfering, 2006;

Wasiak et al., 2007). In addition, baseline data was collected by the researcher who delivered the intervention which may have led to bias.

Direct healthcare and productivity costs

In this study, and in contrast with the figures stated in the introduction to this Chapter, the direct costs of healthcare were greater than the indirect costs of productivity. However, when the costs of routine rehabilitation and the trial intervention were excluded, productivity costs were greater than those of healthcare. It has also been suggested that the costs of presenteeism outweigh those of absenteeism (van Leeuwen et al., 2006; Cooper and Dewe, 2008). In this study, the costs of absenteeism were greater than for presenteeism in the intervention group, but in the control group the costs of presenteeism were greater. This is likely to be due to the fact that more participants in the intervention group reported more sickness absence, and for longer duration. Measuring productivity is complex. It is not possible to prove that simply being at work guarantees productivity, and that we work at 100% when we are well. People who work part-time may take fewer sick days as they are able to recover on 'non-work' days. Others may work additional hours to compensate for reduced productivity due to back pain. The Human Capital Approach that was used in this study may over-estimate productivity costs as it is not known to what extent a worker's absenteeism or presenteeism actually affects productivity. Asking an employer may be more accurate but is not feasible. There is little research published on the measurement of presenteeism in back pain studies. Sogaard et al (2010) argued that presenteeism could double costs of lost production in rheumatoid arthritis but is often excluded from studies due to methodological challenges. The costs of both absenteeism and impaired presenteeism are difficult to estimate. The costs of absenteeism depend upon the extent of for example incurred costs of covering for the person and lost sales/output. Nicholson et al (2006) argue that the cost of absence varies across jobs depending on how easily the worker can be replaced, the extent to which

the worker functions as part of a team and the time sensitivity of the worker's output. These factors are described as 'multipliers' which they suggest can construct a more accurate estimate of the value of lost output. They suggest a median multiplier of 1.28; the cost to the firm of missed work is therefore often greater than the wage. Pauly et al (2007) developed these methods further to include presenteeism. Again, the characteristics of the individual job are crucial; in some instances employers considered it easier to allow workers who are unwell to remain at home because it is more difficult to make up for their impairments if they are at work. Estimates of the impact of presenteeism were much less precise than absenteeism and the results uncertain because workers may 'make up' on lost productivity on their return, or urgent work may be taken over by others. In this case the Friction Cost Approach may be more accurate than the Human Capital Approach which may overestimate costs (Filipovic et al., 2011). Beaton et al (2009) reviewed 21 measures of at-work productivity loss in arthritis, which they argued revealed an 'ambivalent' set of results, and the need to define and contextualise the measurement of worker productivity more effectively.

Comparison of EQ-5D and SF-6D

This was a small sample, nevertheless some observations were made in comparing the two measures.

There was minimal missing data, indicating that the measures were easy to complete. In line with previous studies however, the small amount of missing data for the SF-6D was in those questions regarding physical activities (Barton et al., 2008) indicating that there may be weaknesses in the design of these questions.

The ceiling effects shown in four of the five dimensions of the EQ-5D support the findings of Brazier et al (2004). In addition there was evidence for floor effects for pain indicating that the EQ-5D may not be sufficiently responsive for this client group.

Brazier et al (2004) identified evidence for floor effects in the SF-6D. In this study, there was some evidence for floor effects but this was particularly so for the questions on vigorous and moderate activity and to a lesser extent for pain, whereas there was evidence for ceiling effects in the dimensions of mental health and social functioning. Brazier et al (2004) have suggested that researchers should choose on basis of appropriateness of the descriptive system in terms of severity of the problem. The SF-6D questions refer to the 'previous 4 weeks'. This timescale may be more appropriate for conditions where symptoms fluctuate rather than the EQ-5D questions which refer to 'your own health state today'. In this study, the EQ-5D showed a greater QALY gain when compared with the SF-6D, as has been hypothesised by Sogaard et al (2009). However, a study by Grieve et al (2009) found that where the patients' baseline health was relatively good, the SF-6D records a greater utility gain than the EQ-5D. These different findings do not explain the divergence in QALY scores in this study, which may be due to the small sample size. However the findings of this study do appear to support the argument that the two measures are not interchangeable.

7.5 Conclusion

In conclusion, it would be feasible to conduct a definitive trial of individual work support alongside group rehabilitation for employees who are concerned about their ability to work, and to conduct an economic evaluation in parallel. However, the following methodological changes should be considered:

- Recruitment of participants independently of rehabilitation clinicians.
- Recruitment criteria to include a measure of participants' level of concern about their work ability.
- Randomisation stratified by hours worked and sickness absence history.

- Individual work support to pre-arrange a set number of treatment sessions with each participant that could be cancelled or re-arranged as necessary.
- Provision of an accessible out-of-hours office base for the researcher to meet with participants.
- Exclusion of the FABQWork and PSEQ as outcome measures with this client group.
- Collection of economic data through additional means including face-to-face interviews, cost diaries and categorical options for continuous data.
- Independent collection of both baseline and outcome data.

However, these methodological changes would increase the recruitment period and costs of the study. Furthermore they would not resolve the following issues which could affect the impact of the intervention:

- Delay in access to group rehabilitation due to referral practices and waiting times.
- The format of routine group rehabilitation is subject to change and therefore may not be a sufficiently reliable comparator.
- Potential participants may have difficulty in attending group rehabilitation due to the demands of their work.
- The willingness of participants to involve the workplace and of participants' employers to involve the researcher.

This chapter has reported on the quantitative data collected during the feasibility randomised controlled trial, and the researcher's experience in delivering the intervention. In order to evaluate the feasibility randomised controlled trial fully it was important to explore and report on the experience of the patients who participated. This is the purpose of the next chapter.

CHAPTER 8 POST-TRIAL PATIENT INTERVIEWS

8.1 Introduction

In order to inform the decision as to whether a definitive randomised controlled trial would be feasible and acceptable, the perceptions and experiences of a sample of the trial participants were explored through semi-structured interviews. There were four research questions:

- a) *what or who had helped the participants to remain in work?*
- b) *which elements of routine treatment and the vocational intervention did the participants consider to be useful, or not useful, in changing perceptions of work ability?*
- c) *what were participants' views and experiences of the study organisation and the timing, location, duration and content of the vocational interventions?*
- d) *what were participants' views and experiences of the methods of data collection, and the ease of completion and acceptability of the measures used?*

8.2 Method

8.2.1 Design

A qualitative approach using thematic analysis was used (Braun & Clarke, 2006). Data were collected through individual semi-structured interviews conducted by two independent researchers to reduce the risk of bias.

Each participant was interviewed approximately eight months after randomisation. This was to allow sufficient time for the effects of the study to be consolidated and to avoid any bias through halo effects, yet while the experience of participating in the study was still relatively fresh in the minds of the interviewees. The researchers kept a reflective log of additional information related to theoretical and practical issues arising from the interviews.

8.2.2 Sampling

The overall aim was to provide data from a minimum of twenty patients that best represented the age and gender of the participants, the routine treatment they had received and the size of enterprise they worked in. It was considered that this sample size would be sufficient to gain the breadth and depth of the majority of participants' experiences within the available timescale and resources of the study.

8.2.3 Recruitment

Participants were recruited by the same independent researchers who conducted the six month follow-up telephone interviews. After completing the telephone data collection interview, the researcher asked the participants if they would be willing to take part in a face-to-face interview. If they were in agreement, the researcher arranged a convenient time and place to meet in order to conduct the interview. Participants were offered a choice of location; either at home, at work, at the office base of the Nottingham Back Team, or at the University of Nottingham.

8.2.4 Interviews

The interviews were recorded using a digital voice recorder, and took place in a private area which was convenient to the participant. The interviews lasted approximately 45 minutes. A list of topic areas was prepared by the researcher and her supervisors as a guide for the interviews (see Appendix 11 pp A77-A83).

Topic areas were as follows:

- Current occupation
- Concerns about working with back pain
- Help received in returning to/staying at work
- Take-up of routine treatment
- Experience of the intervention
- Experience of participating in the study

8.2.5 Data analysis

Data were transcribed by the researcher. The interview guide and the data itself were reviewed after each interview by the researcher and one of her supervisors.

Data were managed with the aid of a qualitative software programme.

To manage the data systematically, a qualitative software package (NVivo 8) was used to help code each transcript, incorporating relevant data from the researcher's field notes. As the study proceeded, initial codes were refined following constant comparison of the interview scripts and reviewed and agreed with the second researcher. In the third stage, potential broad themes and sub-themes were identified. These themes were then reviewed and refined with the second researcher. Codes which did not appear to fit within the identified themes, or stand alone as themes, were discarded. Themes were then checked against the data to check that they were valid and represented the data set as a whole.

8.3 Results

A total of 23 participants agreed to be interviewed. There were unavoidable delays in appointing the independent researchers, consequently there was less time and opportunity to select a representative sample of the participants.

Convenience sampling was therefore employed. One participant failed to attend two appointments and therefore a total of 22 participants were interviewed. The demographic characteristics of the sample are shown in Table 41.

Table 41. Demographic characteristics of the sample.

		Intervention	Control
Gender	Male	6	3
	Female	5	8
Age	Range	28-65	30-59
	Mean (SD)	50.5 (10.46)	48.7 (7.77)
Workplace size	Self-employed	1	1
	Small (<50)	1	2
	Medium (>50; <250)		
	Large (>250)	9	7
	Small/large (2 jobs)	0	1
Routine treatment			
	4 week	4	1
	7 week	6	5
	10 week	1	0
	DNA	0	5

There were two main themes identified from analysis of the interview data, each with further sub-themes as shown in Table 42.

Table 42. Themes identified from analysis of the data.

1.	Experiences of the study	
	i	Experiences of the intervention
	a	Timing and location
	b	Personal/individualised
	c	Workplace support
	d	Practical help/advice
	e	Signposting/information
	f	Limitations
	ii	The organisation of the study
	iii	Data collection
	a	Questionnaire
	b	Telephone interview
2.	Help in staying at work	
	i	A GP that listens and helps in the way I expect
	ii	Feeling able to ask for help
	iii	The right help at the right time
	iv	Helping yourself
	a	Tools/techniques learnt through routine rehabilitation
	b	Personal resources
	c	Acceptance of uncomfortable working conditions

8.3.1 Experiences of the study

8.3.1.1 Experiences of the individual intervention

The majority of those interviewed had found the delivery and content of the individual intervention helpful and gave positive feedback about their experience:

a) Timing and location

Flexibility in the timing and location of the intervention was appreciated by participants. For some who worked shifts, daytime meetings could be arranged at the participant's home. Others could arrange for meetings to be held at work, or at a clinic in the daytime if home was not suitable:

It was pretty much easier to come here (clinic) than at my house or anything and had the dog running round and everything else – you could concentrate on what you were trying to do.'
(Participant 10 intervention group, male)

Meetings could be arranged outside of their normal working hours, and outside of the work environment if preferred:

And the fact that she was able to come to the house as well, because I was, you know starting to build up the hours, and it was difficult to do it during the day, and the fact that she was able to come here in an evening, every couple of weeks or so, was invaluable really.
(Participant 8 intervention group, male)

Some participants indicated that they would have appreciated longer than the maximum eight sessions, whereas others were satisfied with one or two sessions. For some the timing was appropriate in that it coincided with routine treatment, whereas others would have appreciated help earlier. Others seemed to expect or need little support. This may be because they entered the study for altruistic reasons. As shown in Table 2 Chapter 7, at least 20% of each group at baseline had reported 'very little' or 'not much' concern about their ability to work due to low back pain. As this participant indicated, she felt that although she had a supportive workforce, she recognised that others may not:

If I need it I know where to go and ask, so I don't feel I can't cope with that myself, but that doesn't mean that others in a totally different work environment to what I'm in wouldn't have big issues.

(Participant 59 intervention group, female)

b) Personal/individualised

That the intervention offered a personal one-to-one approach was seen as beneficial because it gave participants more opportunity to discuss work problems in more detail and allowed for a greater understanding of the issues involved. Participants described feeling 'fortunate' to have the individual advice of an 'expert' that 'you felt there was always someone you could go to' and that the group setting had limitations 'it's difficult to talk when you're in a group'. This school technician describes how she felt the targeted intervention led to a greater appreciation of her job:

You was given that personal one-to-one. You weren't just generalising. Because she went there, she knew my problems, at the workplace.

(Participant 48 intervention group, female)

c) Workplace support

Communication between the researcher and the workplace was perceived as helpful, even though it was not necessarily acknowledged by the employer:

She raised issues with like the floor being so slippy at work.....she wrote them letters with some advice and stuff about going back to work...and how we were affected by sick leave....I mean the employer never really spoke to me about the letters or anything like that, but I knew they were there. (Participant 10 intervention group, male)

And

..the letters to my work, when I needed them, concerning my gradual return to work and, you know, the reassurance that gave me, that – you know – I had the backing when I needed it.

(Participant 8 intervention group, male)

Workplace visits were seen as useful in that they gave an opportunity for the researcher to gain a more accurate assessment and understanding of the job demands and environment:

She'd met me at work and went round work and she could see where the problems was which was very very helpful, that was. That's what I would recommend, that somebody came to your workplace and saw the problems that you had and then could look at it with fresh eyes and say well do you think of perhaps doing this and - you know.
(Participant 48 intervention group, female)

In one case the researcher met with a participants' employer in order to arrange a graded return and appreciated having the researcher to take on an advocacy role:

At first the chair (that had been recommended) wasn't really pushed, and then (the researcher) came and I had a phone call with that, and it was pushed in a nice way, without me having to get all...!
(Participant 4 intervention group, female)

Another participant felt that in hindsight, more contact with her workplace might have been helpful than she had wanted at the time:

Maybe I should have asked her to come into work and perhaps had a three-way conversation, perhaps with my ward manager.....she actually did offer to come in and have look round but I think I always opted to see her at home. (Participant 49 intervention group, female)

d) Practical help/advice

The practical help and advice received from the researcher on how work could be modified was also commented on by participants. Pacing techniques were identified as helpful, for example taking short breaks and varying activities, generally slowing down their approach to work:

You just have to slow down a bit and pace it. Which I think you know that's where (the researcher) probably hit it on the head - 'have you ever thought about pacing the work?' Cos I've never been that one - I'd say come on let's get it done. But yeh, I tend to do a bit more pacing now.
(Participant 33 intervention group, male)

Adaptations and equipment were useful in some cases such as computer software to remind sedentary workers to get up and move around, or equipment that might help to make the job easier:

The step ladders that I was being used were like something out of the ark you know, but like she said I needed something to put both feet on to stand and a handle yeh, and she even went on the internet and looked up for me and brought em'. (Participant 48 intervention group, female)

e) Signposting and information

Participants appreciated obtaining information on other services and help available to them, including the application of workplace legislation and guidance for employees with health conditions and disabilities:

*She helped me a lot to find out what I would have to do if I stayed on sick for six months, and she rang up ESA [Employment and Support Allowance] to find out what I would need so I knew exactly where I was going if I wasn't going to go back.....and she also arranged the meeting with the DEA [Disability Employment Adviser], so we could sit and discuss what options there were at work, or what might happen after I'd finished on sick, and what procedure I needed.
(Participant 26 intervention group, female)*

And how to access help more effectively at work:

*....She made me think about things – maybe try not to feel guilty about talking to my head, saying I'd got a right to still work, because I'd got this feeling that – Oh I can't work any more – you know what I mean at that point – and she gave me a lot of confidence. Yeah.
(Participant 4 intervention group, female)*

Or when looking for work:

*She did say to me you need to go and look at what these jobs entail.....that was useful because you don't think – you go on the job description that's in the paper - but it doesn't actually occur to you to go into an actual workplace and say 'well, can I have a look and see exactly what you do?' before I apply for it.
(Participant 26 intervention group, female)*

f) Limitations

Although the intervention was received positively by most, for some, problems remained. Not all patients had engaged with the intervention. This participant reported that he had discontinued the intervention following a family bereavement, but did not appear to have found it helpful:

Yeah it was interesting – and – telling me different things about back pain – like what the back team was telling you about trying to stop the activity before the pain got – you know – at its worst and that type of thing – as I say, all these things are all right in theory aren't they.....

(Participant 57 intervention group, male)

Most of those interviewed had found the intervention helpful in terms of practical advice and support, but some had experienced further flare-ups which they had struggled with at work, or remained apprehensive about how they would manage if one arose:

Just recently because of this last flare up, and it is really – and it is – been – like going on for a month, it's not getting better, so 'til I go see the osteopath tomorrow- it is worrying me because I do stand a lot.'

(Participant 48 intervention group, female)

In some instances the modifications suggested could not be implemented because they involved environmental changes which required investment from the employer:

Some of the things were changes – recommended changes, such as an air bed you know to transfer a patient from bed to trolley – that's up to the ward manager, so you can only put suggestions forward.

(Participant 49 intervention group, female)

8.3.1.2 The organisation of the study

Of those participants who were interviewed, the majority gave positive feedback about the way the study had been organised and the information they had received, whether they had been in the control group or not. Participants generally thought the information sheet sufficiently detailed, however on further questioning some interviewees, mainly from the control group, seemed not to

have a full understanding of the difference between the intervention and control groups. Participants were in some cases receiving treatment from other services such as pain clinics, and had difficulty distinguishing between the services and clinicians they were seeing, for example this patient who had disengaged from the intervention:

I don't know much about the study – I'm getting confused. Because I'm with the pain team, and I had the pain management course didn't I – and what are you? (Participant 13 intervention group, male)

8.3.1.3 Data collection

a) Questionnaire

In the main, participants were satisfied with the questionnaire, and considered it to be relevant:

The questions were easy very relevant, particularly specifically what are you doing in your day at work, which was really useful. Nobody's really asked me that before, yeah. (Participant 38 control group, male)

*To me a lot of it was relevant because every question described exactly how I was. I mean they were going on about pains and discomforts and how we manage at work, and I think it was going through that I could see meself written it, so I could answer the questions very easily.
(Participant 6 control group, male)*

However there was some reserve about the items regarding personal circumstances:

*I don't know what the personal income thing has got to do with it.
(Participant 4 intervention group, female)*

The ability of the questionnaire to reflect the day to day variation in their condition was questioned, and there was concern as to whether an accurate picture was being provided:

*..because pain's very abstract, so you've got to go with your gut feeling with it – so no it wasn't difficult, it just makes you think, and you're just sometimes wondering whether you're being accurate enough with it.
(Participant 59 intervention group, female)*

I did find that – it really did get to me a bit – all the time I’m trying to be truthful, but then thinking well is that right – is it a good day or – have I got to give you my bad days, and things like that.

(Participant 48 intervention group, female)

b) Telephone interview

Most participants were satisfied with the data collected by telephone, and found the opportunity to clarify questions helpful:

Well it was easy. Cos – you asked me specific questions, and if there was something you needed to clarify, or I did, we just – yeh I thought that was fine. (Participant 31 control group, female)

although there were problems with recall and with quantifying absence from work indicating that some of the responses may not have been accurate:

A lot of things are happening in your life – unless you write it down in your diary – I mean I have to get me diary and...just over the phone – is a little bit to think about, but you answer what you can.

(Participant 48 intervention group, female)

And:

Sometimes it was difficult to calculate it when you’re on a gradual return, because it’s only so many hours, so – you know do you – sometimes it’s difficult to say it in days, because you are back at work, but only working maybe four or six of the eight hours you’re meant to be working.

(Participant 8 intervention group, male)

8.3.2 Help in remaining at work

This main theme combines factors associated with remaining at work raised by participants from both the individual intervention and control groups.

8.3.2.1 A GP that listens and helps me in the way that I expect

Few interviewees in either the intervention or the control group had received help from their GP specific to work. However, those GPs who had listened and taken actions that the participants favoured or expected were perceived as aiding work retention, although these were not directly associated with work:

Has your GP given you support with your work?

Yeh he was really good. He talked me through it, helped me with meds initially because of the back spasms and stuff like that, got me over the pain, and he was the one that got me onto the course as quickly as possible. (Participant 10 intervention group, male)

One participant however did describe how his GP had also provided some apparently useful practical advice, although the participant did not seem to feel this was particularly helpful. He did not seem able to put the advice into context perhaps because the GP did not have time to explain it more fully and/or because the participant had been unable to attend routine treatment:

What help has your GP given you about work?

None really, just painkillers. [partner: 'He told you about exercises'.] He's gave me exercises to do, and he told me about that Back Pain thing clinic thing. And that's about it really.....just explained best ways to sit and how to go about, make sure I stop more often, make sure even if it's just before I get to a destination, stop and just have a stretch before I get there. (Participant 9 control group, male)

Advice from GPs to avoid or reduce work could nevertheless be viewed this as helpful – perhaps because the participants concerns were given credence:

When I had the facet joint injections she signed me off for a month, and at the time I thought Ooh, that seems a long time, but she said I needed that time to concentrate on getting better. And in the end it got extended to about eight weeks that I was off. And erm, she – the GP supported me all the way through that with the relevant doctors notes and things, so that was important. (Participant 8 intervention group, male)

Where GPs did not take time to listen, or take the action that the participant felt to be important, such as explaining symptoms, or better advice about remaining at work they were seen as less helpful:

Have they [at the GP surgery] helped you with remaining at work specifically?

Erm, well, (sighs) it's just – they haven't really said a lot, because I've been – how many times have I been? When I told the doctor about me not being able to get up, she asked if I'd like an X ray – and I did go to have that done. But it came back clear, so I don't know, I've not had any answers really. (Participant 53 control group, female)

And

My GP was happy to write a sick note for me, but I didn't really want to be off sick unless I really had to be, and they would give me more painkillers if I needed them, but other than that – I mean they're very nice, but absolutely no help at all.... You know you have a quick slot. I guess they have a lot of people with back pain, and mine must have been fairly minor compared with a lot of people they see – that was my reasoning. (Participant 38 control group, female)

Participants might change their GP in order to get the help they want, which may or may not be successful:

What help has your GP given you about work?

You know, I thought, because the doctor I had was hopeless so I thought 'right I'll change doctors, might get a better doctor', but she's just the same, she says 'oh I'll put you on sick. I can't go on sick. (Participant 31 control group, female)

GPs differed in their approach to the new 'fit note'.

GP was rubbish! I went to the GP and I said my sick note runs out on such-and-such, and it's called is it a fitness to work now, and I told him I could do some sort of office work - so can you sign me fit to go back to do something like that. And he said to me – 'do you get paid while you're off'? And I says well, 'yeh'. And he just said 'well stay off then and be happy!' But what I did, he signed me off for a month, and in the meantime I changed GP practice. And she was a lot better, and er – she actually put on it something like er – 'talk to the patients!' You know – don't do your normal nursing job but go in and talk to the patients or go and do something like that. So she was a lot better. More open to getting me back to work. (Participant 49 intervention group, female)

8.3.2.2 Feeling able to ask for help at work

This theme involved a number of sub-themes: how back pain was perceived at work, how common an experience it was, the visibility of the problem, personality, burdening others who might also have the same problem. Feeling able to ask for help at work was an important factor in remaining at work with back pain. This participant in the control group described how attending the

treatment programme had given her more confidence in requesting support from colleagues:

How did they (the back team) help with your work problems then?

I think they gave me the confidence to say 'can I do this bit and then you do that bit because of my back pain', for example if you're washing someone. Before I wouldn't say anything I would just try and do it but if it didn't happen I'd just keep quiet, but now I've got a bit more confidence to say 'Oh I've got back pain can we please just swap roles' or something. (Participant 5 control group, female)

Compared with another participant, who had not wanted to request time off to attend routine treatment:

I think probably, looking back now, I think probably they would have done...it's always a struggle for cover in the classroom I'm in, so - it is - I just didn't like to ask basically. (Participant 53 control group, female)

Others reported that the lack of visibility of back pain affected the help they might receive from colleagues:

It's difficult because you can't see my injury. I mean maybe privately some of them I think would be thinking 'well why isn't she working as many night shifts as I am' – or 'why doesn't she not have do long shifts and I don't have to?' (Participant 38 control group, female)

Participants reported feeling uncomfortable about being treated differently when requesting, or being given help:

We went into a meeting and I didn't feel I was able to take my special chair in because I didn't want people to – you know – I felt a bit awkward basically – and the lady at the back team said 'you know you shouldn't feel like that, if you want to take your chair in then you should do it and make people aware that there is a problem'. (Participant 8 intervention group, male)

I just felt that I didn't want to be the only person there that wasn't able to just do things when you were asked. (Participant 26 intervention group, female)

This participant described how the help provided by his employer had helped with work retention, but not his relationship with his colleagues as it had increased their workload:

What's your employer done to help you stay at work?

Gives me less handballs things, jobs, and he's got a new truck with better air seats and that.

And how helpful have your colleagues been?

Not really! They get more handball jobs now, so they haven't really been any help. (Participant 9 control group, male)

Some were confident that they could ask for help from their employers, whereas others avoided telling them at all such as this participant had recently left her previous job as a carer to start work as a cleaner:

Has your employer been helpful?

*Well, this one doesn't know about it - I didn't tell 'em.
(Participant 6 control group, female)*

8.3.2.3 Being able to access the right help/information about work at the right time

a) The lack of appropriate information about working with back pain

Participants discussed their lack of awareness about where to get help, or that information provided was not easily obtained or did not meet their needs.

*Yeh, yeh – but – what other information is there [about help with work]?
There's nothing – about – where else you can go, you know, if you've got any problems or anything like that, there's no – other, there's nothing on it – I know it says your GP, but where else – can you go? You know, for more information. (Participant 31 control group, female)*

This participant reported how he had managed to keep employed by claiming Mobility Allowance which had enabled him to drive to work:

*Er well the DLA, Disability Living Allowance, that – the wife found out about that one day after we come back from town and it (his back) wasn't very good, that was in 2007. So – she'd seen the leaflet somewhere and we got a form and done it that way – and that was an ordeal getting that, a real ordeal. Took us a year to get that through.
(Participant 41 control group, male)*

This self-employed landscape gardener had not known where to go to access help:

Well I haven't had any [help] really. I mean the government always want people to try and keep working and stuff, but you know, when your back goes I mean what else can you do? Why is it not in a leaflet or – where you go to the back - to the clinics?

(Participant 57 intervention group, male)

Information about working with back pain/health conditions/disabilities was perceived as generally helpful, but the content was not necessarily seen as relevant. This participant was regularly using taxis to get to work as she was no longer able to use the bus and the researcher had suggested that she could find out if Access to Work funding would be available to her:

I mean I did look at the website, and it's funny isn't it, because I don't see myself as somebody who's got a disability, erm, but then when it talks about disability on the thing – but (the researcher) did say well it is sort of a disability – er – and I think yeh – it is disabling, cos it stops me doing what I would normally do!

(Participant 49 intervention group, female)

Or appropriate. This participant describes her reaction to an advisory booklet:

"Don't go and lie down", well of course you go and lie down – but you get up, fair do's, but I mean – it was the way they phrase it. It was really patronising! As if you were all - because you'd said you'd got backache that you were trying to con everybody!

(Participant 48 intervention group, female)

There was generally little awareness of help available through the Department of Work and Pensions which could have been useful to access earlier:

I suppose if I'd known, I could've gone to see (the DEA) in hindsight.

(Participant 26 intervention group, female)

b) The potential need to access help again in the future

Although many participants were managing reasonably well at work, concerns remained for the majority about their future ability to work: whether their condition would worsen over time, how they would cope with a severe flare-up,

whether they would have to look for an alternative job or work part-time. These concerns had been identified as a theme in the pre-rehabilitation interviews (Chapter 4); this time they were expressed whether or not participants had received routine treatment and/or the intervention. They ranged in intensity:

Right now I'm confident that I can carry on at the moment without any problem. In the future like I says, it could get to the stage where it's going to get bad and I can't work. (Participant 6 control group, female)

Erm probably less [concerned] I think..... Yeh I think I'm pretty confident that everything's er go go go. (Participant 33 intervention group, male)

At this present time it's not a concern at all....The only thing is at the back of my mind if it does come up again, you know, the recovery period to get back to where I am now. (Participant 10 intervention group, male)

Yeh, more, more concerned now yeh. Cos I had a long spell when it settled down. but the last one I had was - nearly as bad as the first one I had - so - when I have it like that I can't do anything, hopeless. (Participant 57 intervention group, male)

Even participants who had very supportive employers were not necessarily confident that this would continue:

So while everybody's being good about it, I have concerns about it in the future - is someone going to say 'Oh it's such a long time ago now, you're going to have to try and do things. So - we'll see I suppose. I don't know. (Participant 38 control group, female)

As this participant describes, these concerns may be a normal reaction to any health condition that has had an impact on work:

But you can't help - it's just natural to just worry and wonder whether you can continue to work. (Participant 59 intervention group, female).

8.3.2.4 Helping myself to stay at work

Participants described some of the tools and techniques they used to remain at work, including those learnt through routine treatment. These findings support some of those identified through the post-routine rehabilitation interviews

(Chapter 4) such as the use of medication, exercise, pacing, and the application of knowledge and understanding, but also the impact of personality, motivation and acceptance of work-related pain.

a) Tools/techniques/lessons learnt through routine rehabilitation

So what, or who, has helped you remain at work?

I think the back programme I did really helped me not to worry about it and I think that was making the pain worse – the actual anxiety about it all, and they helped me to see that actually if I just do lots of exercises and stretches, that can resolve a lot of the pain. I think they made you understand the back pain better and sort of reassured you about it.

(Participant 5 control group, female)

Would you say that the group treatment that you had, did that help with your work?

It gave me the psychological back ground, physical background and also the methods of increasing my flexibility which may impact upon easing the pain. The two main aspects to me which were beneficial were understanding it, and that was a major objective of the course, and also how individuals can cope with back pain.

(Participant 18 intervention group, male)

So although you didn't find the actual group treatment directly applicable to your work, do you think you were able to take away things and apply them to your work?

Yes yes I was, in the mind set wise you know? Yes it was – it did give you that – that - what can I say – the notion that you can get out there and do some more rather than just sit at home which is what I was doing at the time – but well not sitting – but you can get out there and do more.

(Participant 41 control group, male)

b) Personal resources

Participants commented on how one's own motivation and personal resources were important in remaining at work. Personal characteristics were considered to be a factor. Participants described having a 'strong work ethic' and 'determination' or the ability to 'adapt to it and be very positive in living with it'.

The need to earn money was also important 'I just carry on regardless - basically

- *it's a case of having to!* and *I've got to do it. I can't get any benefits or anything, so gotta work*’, and for structured activity: *I just can't stand being at home, not by meself*’ and *I was getting stir crazy – I needed something, you know, something to get up for in the morning!*’.

Some had modified their home life in order to remain at work:

I've had to change me ways a lot more. Like now, I used to get up in the mornings and go to work. Just literally get up, get dressed and go to work. Whereas now I get up an hour before so I'll get chance to do stretches and get meself flexible enough so that I'm alright for work. (Participant 9 control group, female)

At the end of the day I can't go out as much as I used to at all because I need to lie down if I've had a busy active day, then I can't just go and you know sit in a restaurant or a pub for the evening, I have to lie down and just not do much social in the evening. If I've got a reasonable amount of driving in the day then I can't do anything in the evening I have to just re-plan. (Participant 38 control group, female)

...because I work part-time thank goodness I've got like Wednesday to rest or the weekend, cos you know like I don't work Friday so I have a long weekend, so I have to try and work round that, cos that's the only thing I can think of. (Participant 48 intervention group, female)

c) Acceptance of uncomfortable working conditions

For some patients, back pain was perceived to be a common experience in the type of work they were engaged in. There was an expectation therefore that most people ‘worked through it’ in order to remain in work. However this approach could lead to the necessity of taking sick leave during severe flare ups because modifications were perceived as impossible. In some cases this meant having to give up the job when it got too much.

This participant describes how health conditions such as back pain were an accepted part of the building industry:

We're like that in the building trade, broken arms and all sorts – - we just keep going, you know, until we – you know - drop basically! I've had a few days off with it, but nothing you can really talk about, you know it's nothing that you probably don't get ordinarily in the building trade anyway you know. (Participant 1 control group, male)

A chef in a large public sector organisation describes a similar experience:

*Because of the nature of the job you're always standing up and it's a repetitive movement type job, roll the pastry and stuff, you're using your back all the time, and lifting stores and things like that. I think it's kind of considered you're gonna have it at some stage.
(Participant 10 intervention group, male)*

For this teaching assistant, the nature of the job led her to believe that some sick leave was unavoidable.

How do people in your job cope if they have back pain – other than yourself?

Well, we have to have time off really. Because of the nature of what we do. (Participant 4 intervention group, female)

Others described how they considered that their jobs could not be modified further, either due to low staffing levels, the culture of the workplace, or the physical work environment:

*Because it's an infant school. We have these little tiny chairs and I cannot – I still can't sit on one of those because it really hurts my leg.
(Participant 4 intervention group, female)*

I'm not allowed to go to any other areas to have a break, you know, because that's where the canteens and the rest areas are. Because of the nature of the job with the medicines and everything, there's no eat or drink allowed in the department. No walking sticks or walking aids allowed in the department. (Participant 57 control group, male)

*Well they've got to change lots of things at work, but they just haven't got the money to do it. We've been in the new build six years. And the children still haven't got anywhere to put their coats, and hats. And we've been waiting, waiting – health and safety – got to keep waiting.
(Participant 48 intervention group, female)*

8.4 Discussion

These post-trial interviews added to the overall findings of the feasibility randomised controlled trial reported in the previous chapter. They confirmed that the protocol was deliverable and acceptable to many of those interviewed, but that improvements were indicated in the organisation of the study, the content and timing of the intervention and the data collection methods used. They also confirmed that greater attention needs to be given to how individual interventions can promote effective dialogue with participants' workplaces. In addition they upheld and supplemented themes identified in the first phase of the study concerning the experiences of working with back pain and of routine rehabilitation.

There were several important factors connected with the trial. Firstly, the majority of NHS healthcare services for those with musculoskeletal disorders are delivered during office hours. The findings of this study suggest that for those who are employed, there is a need for more flexible services, both in time and location. There are some patients, for example, who are unable to arrange appointments at work, or in working hours, but would also have difficulty in meeting with a therapist at their home. In addition, even patients who engage with multidisciplinary rehabilitation have on-going concerns about working with back pain and work situations are not stable - some patients may need further support in future, indicating the need for open-access services. However, such flexibility in service provision incurs additional costs, and may not be cost-effective.

Participants appreciated the individualised, personal aspect of the intervention. This may in part be due to a 'Hawthorne effect' (Roethlisberger & Dickson, 1939) but also because by nature an individual's work situation is complex and unique and therefore work problems are difficult to address within a group setting. Patients may feel reluctant to discuss their work problems in detail

within the group, and/or be unable to apply the generalised techniques of pain management such as activity scheduling to their work.

As reported in the earlier interview studies, participants seemed to have received little in the way of direct work-related help from their GP. Their responses indicated that their opinion of the GP was influenced by how well the GP's management matched the participant's expectations. This finding is supported by other studies, most recently by Wrapson & Mewse (2011) who suggest that the patient has considerable input into the decision-making process of return to work. The limited time of a GP consultation was also a common theme.

Feeling able to ask for help was identified as an important factor in staying at work. In this study, some participants felt able to do this or gained the confidence to do so through rehabilitation and/or the intervention, whereas others appreciated the 'advocacy' role of the research therapist in requesting help more directly on their behalf, either through written communication or – less frequently – by meeting with the employer.

Not all patients will feel comfortable about inviting a healthcare practitioner into the workplace. It is not common practice in the UK, as the employer has no obvious incentive to liaise with clinicians and both the employer and employee may feel that they are inviting scrutiny. In other studies conducted in countries where employers have a financial investment in rehabilitation, workplace visits are more frequently reported (Lambeek et al., 2010)

According to the participants, remaining at work was also dependent on individual characteristics and motivations, such as a strong work ethic, financial need and the ability to cope with pain in the workplace. These factors have also been reported in a recent paper by de Vries et al (2011), although their sample was drawn from the general population, rather than from patients.

In this study, simple and low-cost interventions were found to be helpful in many cases. However there was also a message that in some occupations it was the norm to expect, and to work with, back pain, and that taking a few days leave

during a flare up was common and considered acceptable. There is a view that endurance behaviour may eventually lead to avoidance behaviour and reduced ability in the long term (Karsdorp & Vlaeyen, 2009) which some participants implied. In jobs where modifications are difficult to arrange such as those with repetitive physical demands and/or challenging environments, i.e. those with limited adjustment latitude, employers may consider it more cost-effective to assume a certain amount of sick leave rather than make expensive adjustments. Information about services and initiatives to support employed people with back pain seem not to be easily available to those who need them, or the language used may be off-putting. For example, information on 'Access to Work' refers to those with disabilities and health conditions (Access to Work). The terms are not clearly defined; participants may not see themselves as disabled and think that the information does not apply to them. Literature aimed at those with acute or first episodes of back pain may not be seen as appropriate by those who have persisting or recurrent symptoms.

Although the organisation of the study was generally acceptable, the interview findings indicated that the protocol could have been described more clearly, particularly for the control group who were less likely to understand what they were not receiving. Some misunderstanding may have arisen because the participants were initially referred by the Nottingham Back Team clinicians, and had difficulty in distinguishing the two arms of the study. A detailed description of the study was required in the Participant Information Sheet for consent purposes, but perhaps could have been worded more concisely. As reported earlier, a greater proportion of the control group had no academic qualifications. The patient questionnaire was generally acceptable and relevant, although the purpose of including questions regarding personal information, particularly income, should perhaps have been explained by an introductory paragraph. The unease that some participants experienced over the 'accuracy' of their responses

echoes the concerns expressed in the earlier interviews, implying that the credibility of their health condition might be in doubt.

Limitations of the study

The main limitation of the post-trial interviews was the delay in appointing the independent researchers which meant that a less representative sample of participants was available to be recruited for interview than had been anticipated. Therefore although it was possible to recruit the number planned, data saturation may not have been reached. Another important consideration was that the views of participants who were lost to follow-up were not available. Also some participants may not have had the time, or did not wish to take part in a face-to-face interview, but may have agreed to be interviewed by telephone. It may also have been possible to collect some data through a postal questionnaire. Finally, although both researchers were given the same training experience, they may have differed in their approach to the interviewees and the quality of the data gathered.

8.5 Conclusion

In conclusion, the majority of trial participants who agreed to be interviewed reported that they had found the individual work support acceptable and useful in helping them to remain in work. They had benefited from the flexible delivery that did not interfere with work, the direct focus on work issues and communication with their employers. However, other participants seemed to have had less need for individual support, had not engaged with the intervention at the time it was offered or had continued to experience problems at work. Greater attention to the management of future 'flare-ups' of back pain at work is indicated.

As was found in the post-routine rehabilitation interview study (Chapter 4), most participants who had attended routine group rehabilitation had found it indirectly helpful in addressing their concerns about work. The organisation of the study

and methods of data collection were acceptable to most, although collecting data by telephone may result in some inaccuracy due to difficulty in recall combined with a limited time for participants to consider their responses.

CHAPTER 9 CONCLUSIONS AND RECOMMENDATIONS

9.1 Introduction

This thesis has reported on the development of and findings from the first feasibility randomised controlled trial of a vocational intervention specific to low back pain to be conducted in the UK. Although it cannot be concluded that a definitive trial based on this current study design is recommended, the research has made a considerable contribution to knowledge in the field and has identified important factors to be considered in planning future research with this client group. In this final chapter, conclusions and recommendations will be presented with reference to the overall findings, recently published research and current practise in relation to management of work-relevant low back pain.

9.2 Contributions to knowledge provided by this study

9.2.1 Workplace support for workers with low back pain

This study has demonstrated that the advice and support currently available to people who are concerned about their ability to work due to low back pain is limited. Those affected may remain at work, or take minimal sick leave, largely through their own efforts or the support of their colleagues and/or line manager. Few can, or know whether they can, access workplace support through occupational health, and there is a reluctance to disclose the condition at work due to perceived stigma and concerns about job security. In addition, any advice and support workers do receive will also be guided by the attitudes and beliefs about back pain management of those in the workplace, which may not be appropriate.

9.2.2 Work-related advice and support from routine healthcare

This study found that the help and support that GPs offer to patients who are concerned about their ability to work due to back pain is variable and generally limited. Most GPs do not consider that the management of patients' work-related problems is their responsibility nor raise their patients' work-related issues with patients' employers or with other clinicians to whom they refer. GPs report that they are not clear about where else they can refer patients, to obtain necessary help and consider that the services available are inadequate and over-subscribed. They would like relevant written information to give to patients and to be better informed about current service provision.

The study also demonstrated that patients generally do not expect their GP to help them with their work problems, and may therefore not consult them until they have been having problems for some time. Even though people with low back pain may consult other clinicians privately, such as manual therapists, they do not receive sufficient help regarding work issues. They are largely unaware of the support available through the employment services.

This study found that 'best practice' multidisciplinary group rehabilitation for low back pain could provide patients with tools and techniques that could help them to manage their symptoms at work and thus reduce their concerns. However, the impact largely depended on the ability of the individual to apply these strategies; there was little individual targeting of work issues, and minimal contact with patients' employers.

9.2.3 Individually targeted work-focussed healthcare

This study was able to demonstrate that an individually targeted work focussed intervention could be delivered alongside routine multidisciplinary group rehabilitation, and was acceptable to many of the participants. Many appreciated the flexible approach to delivery that did not interfere with work, the direct focus on work issues and the opportunity for greater communication with their

employers. The tailored approach resulted in some participants seemingly being helped by just one or two sessions, whereas others felt they had benefited from more, and in some cases for longer than the sixteen week period. However, not all participants were willing for the researcher to involve the workplace and some participants did not appear to engage with treatment.

9.2.4 Measurement tools

In this study, a range of work-relevant measures were evaluated including standardised measures of perceived work ability and fear-avoidance, non-standardised measures of sickness absence, work modification and reduced productivity. Other standardised measures included those required for an economic evaluation including health-related quality of life, and non-standardised measures of healthcare resource use. The measures of the main outcome, work ability were considered feasible, but not the fear-avoidance measure (FABQWork). Neither of the two measures of health-related quality of life could be recommended above the other, and would need further evaluation and comparison with this patient group. Due to the difficulties in the completion of non-standardised measures of work and health-care resource use, a combination of diaries and face-to-face data collection is suggested. In this study, the limited availability of accurate healthcare resource data was demonstrated and it is recommended that in order to conduct meaningful economic analyses this needs further attention.

Other commonly used low back pain measures were also evaluated in this study. The findings suggested that one measure in particular, the PSEQ, may not be useful due to floor effects obtained for a specific question on medication use.

9.2.5 The feasibility of a definitive trial of individual work support

In this study, a number of methodological changes are indicated before the intervention can be tested in a definitive randomised controlled trial. These changes affect the method of recruitment, the design and delivery of the

intervention and the choice and collection of outcome measures. In addition, the intervention would be best investigated as an integral component of a group rehabilitation programme rather than as an additional intervention for some individuals. An outline design for a definitive trial is illustrated in figure 3 and is described below. However, due to the considerable changes in methodology involved, further feasibility studies would be required to inform the design.

Recruitment

In this study, clinicians identified potential participants at their initial Nottingham Back Team clinical assessment following referral by their GP (or less often, another NHS practitioner) which may have led to bias. This method also meant that potential participants in need of work-relevant support were dependent on the referral practice of the GP and that they had to wait for their appointment with the rehabilitation team. This delayed the start of intervention. It is therefore suggested that participants are recruited directly from their GP, or by self-referral. However, this method of recruitment would need to be piloted.

Eligibility

In this study, some of the participants reported that although they were concerned about their ability to work due to low back pain, that they were not greatly concerned. It is suggested that further evaluation of this screening question is conducted and compared with alternatives. A further criteria might be that participants agree to the researcher contacting their employers where appropriate, however this may be a difficult judgement for potential participants to make, and may reduce the ecological validity of the study.

Control group

In this study, the control was routine multidisciplinary group rehabilitation. However, not all participants were able to access the group treatment programme due to work demands and routine treatment was not reliable as a control. It is therefore suggested that participants are offered the option of individual multidisciplinary rehabilitation, and that the group rehabilitation is a

research arm of the study, rather than routine treatment. However, the feasibility of delivering the programme on an individual basis would need to be established.

The intervention

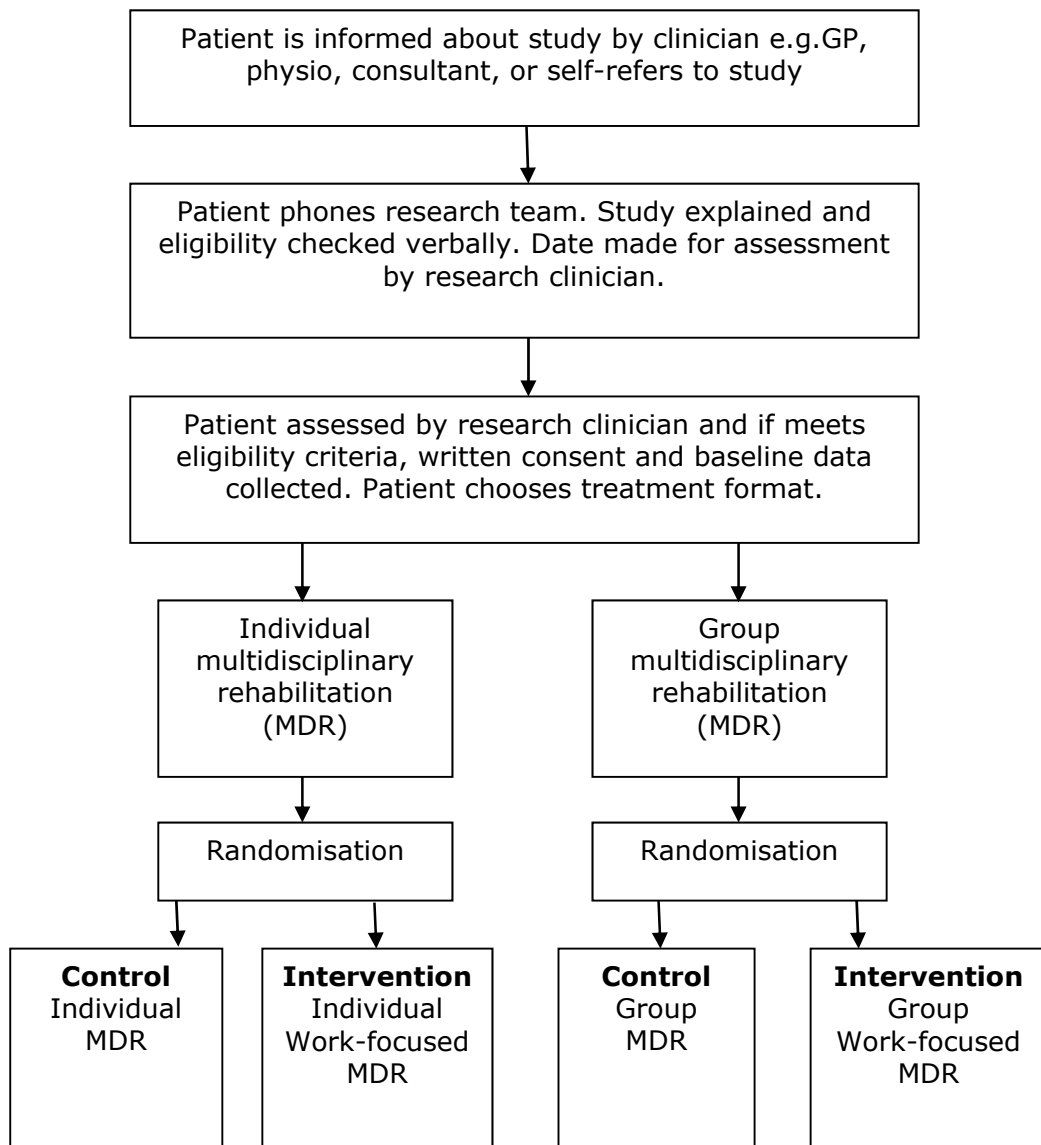
In this study, some participants had not maintained contact with the researcher over the duration of the intervention. Although the reasons for this are not clear, it may be that a more formal approach to arranging treatment sessions would help participants to remain engaged. It is suggested that, for example, a set number of sessions are booked in advance that the participant can cancel or change as they wish. However, the feasibility of this method would need to be tested. Some participants had experienced further flare-ups of pain that they were struggling to manage at work after the intervention had finished. The intervention could be extended, but it is suggested that equal attention needs to be given to the content of the intervention and how flare-ups can be addressed more effectively than was the case in this study. It has to be acknowledged that in cases where the management of flare-ups is limited by work demands that cannot be temporarily modified, and where communication between the researcher and the employer is not feasible, then the impact of the intervention may be limited despite increasing its duration.

In this study, because some participants had to wait longer than anticipated to take up a place on the treatment programme, generic pain management approaches formed a greater part of the intervention than had been anticipated. It is therefore suggested that the VR intervention is integrated within a work-focused multidisciplinary treatment programme and compared with a control arm which has no such intervention. This would avoid dilution of the effect of the intervention. However, the content, duration and feasibility of an integrated work-focused treatment programme would need to be established.

Outcome measurement and data collection

Baseline data would be collected at the assessment meeting with the research clinician prior to randomisation. Due to the complexities of collecting accurate work-related and healthcare resource-use data, it is suggested that follow-up data is collected via a combination of participant diaries, postal questionnaire, telephone and/or face-to-face interview. The measures of work ability used in this current study are feasible but the concept and measurement of work ability needs further investigation (see 9.3.9).

Figure 3. Outline proposal for a definitive trial



9.3 Justification for further research with reference to recent evidence, current practice and the study findings

9.3.1 The epidemiology of work-related back pain

Low back pain continues to be a major reason for GP consultation in the UK. One in seven of all consultations are estimated to be for a musculoskeletal problem, and an estimated one in four of the registered population consult for a musculoskeletal problem with the back, predominantly the lower back being the most common problem site for all age groups except children (Jordan et al., 2010). However, this recent evidence gives an incidence of 5% of adults consulting their GP for back pain compared with estimates of 7%-9% as reported from earlier studies in Chapter 1.

Latest data on work-related back pain available through the Health and Safety Executive (HSE, 2011) indicate a downward trend in sickness absence over the course of the study when compared with data reported in Chapter 1. For the year 2010/11 in Great Britain an estimated 2.5 million working days were lost through musculoskeletal disorders mainly affecting the back, compared with 3.5 million working days in 2008/9. According to the most recent survey of sickness absence published by the Chartered Institute of Personnel and Development (CIPD, 2011), among manual workers, back pain is now the third most common cause of short term absence, and the fourth most common cause of long-term absence, whereas in 2008 back pain was the second most common cause for both short and long-term absence. However, among non-manual workers, back pain remains the fifth most common cause for short and long-term absence, as it was in 2008. A recent study has demonstrated that sickness certification for back pain is more common than other conditions. In a study of GP records for 148,176 patients, more certificates were issued for back pain than any other condition; one for every three consultations (Wynne-Jones et al., 2010a). Thus it would seem that further research studies of work-related back pain are justified.

9.3.2 The economic impact of low back pain

It is difficult to judge the current economic impact of low back pain in the UK as there have been no further estimates since the study conducted in 1998 by Maniadakis and Gray (2000) and no data have been published on presenteeism due to low back pain. However, a recent study by Lambeek et al (2011) reports a decrease in the total cost of back pain in the Netherlands from 4.3 billion Euros in 2002 to 3.5 billion Euros in 2007. On the basis of this data there appears to be a downward trend in the impact of low back pain on healthcare resource use and the economy. However, the reasons for this are not known, nor whether the trend will continue. It may for example be due to improved application of evidence-based guidance in the management of back pain, both within healthcare and at the workplace, or it may be as a result of the effect of the economic downturn and/or changes in welfare systems where people may be less likely to take sick leave, or to be able to claim work-related benefits. It may also be due to changes in how data are collected, or how likely workers are to report back pain compared with, for example, stress. However, as Lambeek et al (2011) conclude, the costs remain substantial with the indirect costs of lost production and work disability continuing to make up the greater proportion (88%). Although a direct comparison of costs cannot be made between countries with different healthcare and social security systems, the ratio is likely to be similar internationally (Dagenais et al., 2009), and cost-effective interventions that can aid work retention and productivity are still urgently required (Palmer et al., 2011). This current study has drawn attention to the complexities of collecting the data required for economic evaluations, and has made recommendations as to how this might be addressed in future studies.

9.3.3 Low back pain management guidelines

In May 2009 new guidelines were introduced in the UK concerning the early management of persistent non-specific back pain lasting for between 6 weeks and one year (National Institute of Health and Clinical Excellence, 2009). As in

the guidelines reported in Chapter 1 these recommend that patients should continue with normal activities, but the management of work is not addressed specifically as this was not a requirement of the guidance.

Previous evidence-based guidance on the management of musculoskeletal problems including low back pain has been combined and published in one document for both clinicians and employers (Kendall et al., 2009). This guideline promotes collaborative working and consistency of approach between healthcare and the workplace and highlights the role of healthcare professionals in work-focused management using a stepped-care approach. In summary, these advise that GPs and other clinicians should reassure patients, encourage normal activity, provide evidence-based diagnosis and treatment, and advise the patient and employer on work-related matters. If problems continue, then cognitive behavioural management, employer liaison and suggestions for work modification are recommended. For persistent problems, communication with the workplace should be maintained together with the provision of multi-disciplinary treatment delivering cognitive pain-management and vocational rehabilitation. The results from this study suggest that, in the UK at least, greater efforts are required by both clinicians and employers to follow these guidelines.

9.3.4 Vocational rehabilitation for back pain

As discussed in Chapter 1, the majority of studies reporting on return to work and work retention have been published outside the UK, and little has changed during the course of this study. In their recent systematic review, Palmer et al (2011) identified 42 randomised controlled trials and cohort studies of interventions to manage musculoskeletal-related sickness absence and work loss, of which 50% were specific to low back pain. None were from the UK, and the authors concluded that benefits of interventions were small with considerable uncertainty as to their cost-effectiveness. Two UK randomised controlled trials of interventions for low back pain have been published since this review, the first being the UK Best trial (Lamb et al., 2010). As reported in Chapter 1, this aimed

to trial a cognitive-behavioural group treatment programme compared with an active management consultation for back pain. However, although the intervention showed a statistically significant improvement in perceived disability, the only work-related outcome measure collected was sickness absence and this was not reported. More recently, a large randomised controlled trial of stratified low back pain management in primary care has been published (Hill et al., 2011). Sickness absence was significantly lower at 12 months for each stratified group of patients. However, this analysis was of the 298 responders who reported being currently employed at 12 months, compared with 524 participants employed at baseline, therefore the effect of the intervention on work ability is difficult to judge. The evidence-base for UK-specific research for work-related back pain remains limited.

9.3.5 Recent UK government initiatives regarding health and work

The most relevant UK government initiatives to this study have been the development of the GP 'Fit Note' and the 'Fit for Work' pilots, established in response to Dame Carol Black's review of the health of the UK working age population (Black, 2008). The Fit Note was introduced in April 2010 to encourage GPs to take a greater role in enabling their patients to remain in work, however, as the findings of this current study have demonstrated, there are concerns as to the extent to which this can be achieved. A study by Wainwright et al (2011) reported that despite the introduction of the fit note, GPs considered that the maintenance of the doctor-patient relationship, and the lack of engagement with the employer, limits its potential value with chronic pain patients. Two studies conducted by the Department for Work and Pensions have explored GPs' attitudes to sickness certification and the fit note. The first, Research Report 733 (Hann & Sibbald, 2011) found that GPs felt they had a proactive role in helping patients return to work, but that they needed good local services to which they could refer patients for work-related advice and support and did not know what services were available. This echoes the findings of the current study in that GPs

do not see it as their role to provide this advice and support and questions their role as a gatekeeper to services. One of the disadvantages of the intervention reported in this current study is that patients could only access it if they had been referred to group rehabilitation by a clinician (usually the GP). A more recent study by Fylan et al (2011) found that GPs' lack understanding of, and confidence in using, the fit note to advise on work modifications. GP training in fit note completion was based on a pilot study where 45% of participating GPs remained 'not particularly' or 'not at all' confident on advising on modifications or adjustments after the training (Chang & Irving, 2008). There has been no evaluation of whether training has made any difference to practice, and GPs are not obliged to attend.

In a more recent cross-sectional postal survey of 878 UK GPs more than three-quarters of the sample agreed that occupational health nurses should be able to issue sickness certificates and almost 60% suggested that physiotherapists should (Wynne-Jones et al., 2010b). An Allied Health Professions (AHP) Fit Note is shortly to be introduced, however there is no evidence to support its use. Furthermore, any advice is not binding on employers and neither fit note is designed to facilitate further communication between the parties.

A review of sickness absence by Black and Frost (2011) has concluded that GPs do not have the required expertise to use the fit note to advise patients on their ability to perform specific jobs, and that fit note guidance be limited to the person's ability to perform 'any' work. For those who have been absent for more than four weeks, it is suggested that patients are instead referred to an Independent Assessment Service for functional assessment and advice on return to work. How such a service will compare with the 'Fit for Work' pilots is not clear. The Fit for Work pilots were introduced in eleven primary care sites in 2010, offering early intervention and multidisciplinary support for those at risk of long-term sickness or work disability. However they are not due to be evaluated until 2013 and none have been designed as randomised controlled trials thus

limiting the extent of any conclusions that can be drawn as to their effectiveness. Whether or not these services will evaluate the effect on specific health conditions such as work-related back pain is unknown. As this study has shown, people continue to struggle at work with back pain while taking minimal sick leave; there is no attention given to how GPs and clinicians can manage those who do not meet the criteria for referral to Independent Assessment Services. This study has indicated that both individual work support and group rehabilitation may increase perceptions of work ability in employed patients and might be a cost-effective option.

9.3.6 Case management

The intervention in this study was delivered by an occupational therapist with a post-graduate qualification in ergonomics and clinical experience in delivering back pain management/rehabilitation. This could therefore be considered to be in part an extended practitioner role, and in part a case management role. There has been a growing emphasis on the case management approach to managing workers with common health problems such as musculoskeletal disorders. The role of case management is to 'integrate clinical and occupational management with the needs of the individual to facilitate early return to work (or work retention)' (Hanson et al., 2006). The case manager can function as a 'broker', 'generalist' or 'primary therapist' although Hanson et al (2006) argue that there is a potential for conflict of interest when using the primary therapist as the case manager. Hanson et al (2007) used an occupational health case-management approach in a pilot study based in NHS Fife and NHS Lanarkshire showing improvements in health and return-to-work, however the approach has yet to be tested in a randomised controlled trial. Some of the Fit for Work pilots are using a case management model. For example, Working Health Services in Scotland (Hanson et al., 2011) have delivered case management both through dedicated case managers and by clinicians adopting a case management function. Their evaluation did not compare the effectiveness of the approaches; case managers

had more contacts with clients than the clinicians who adopted the role, however this may simply have been as a result of clinicians' caseload. One of the advantages of a clinician adopting the case management role is that they can apply specialist knowledge to the health condition and its management at work promptly, as in this current study, rather than having to refer on to another individual and/or service. One of the disadvantages is that the clinician is less likely to have current knowledge of support services for example debt management, or of employment law. These considerations have been raised in relation to other health conditions for example long term mental health (Holloway et al., 1991) but further evaluation is required in common health conditions such as low back pain. It may be that a model of 'stepped care' would be appropriate, where clinicians can provide certain levels of work-related advice and support themselves, or can gain further expertise through additional training. Further research is recommended to investigate what this training should consist of, and how it will be evaluated.

9.3.7 Integrated management

The case management model as presented by Hanson et al (2006) is a form of integrated management; i.e. combined health and workplace management. Lambeek et al (2010) have reported on a randomised controlled trial of integrated care for patients with chronic low back pain in the Netherlands who have been sick-listed for at least 12 weeks. Their integrated model combined a workplace visit and intervention delivered by occupational therapists, with graded activity based on cognitive behavioural principles delivered by physiotherapists, and was effective on return to work. However, as with Hanson's model (2006), this relied on the active involvement and support of an occupational health physician (all employees have an occupational physician in the Netherlands). As reported in this thesis, provision of this level of occupational health is not common practice among UK employers. The Sickness Absence Review (Black & Frost, 2011) makes little reference to occupational

health, but recommends that their services are included within the Independent Assessment Services. How such services will interact with individual employers and workplaces is unclear. In this current study, one of the obstacles to delivering a vocational intervention was that interaction between clinicians and employers is not customary UK practice. The Sickness Absence Review describes 'reports' being provided to GPs, or to be 'given' to employees to give to their employer. As argued elsewhere in this thesis, this uni-directional approach will not address the problems that may arise when employers are unable or unwilling to make the necessary adjustments to support return to work. Neither does it tackle the problem of those remaining at work and not taking sick leave. This current study suggests that workers may benefit from interventions before four weeks sick leave has elapsed. Further research to investigate how employers and clinicians can communicate and interact effectively, with or without a fit note, in the interest of the worker is recommended.

9.3.8 Group approaches

As reported in the study, participants overall felt that they had benefited from the group approach, yet evidence to support such approach over individual multidisciplinary rehabilitation is limited, and equivocal. However, two recent qualitative studies have reported on participants' experiences of occupationally-orientated group rehabilitation. Joyce et al (2010) conducted a qualitative study of patients with mental ill health, cardiovascular disease or musculoskeletal conditions who had participated in Condition Management Programmes as part of the Pathways to Work initiative (Department for Work and Pensions, Pathways to Work). A main theme was the stimulation, support and motivation that participants had experienced from the group. However the effect of this finding on work outcomes was not reported. In a Norwegian study of patients who were interviewed three years after participating in group rehabilitation for musculoskeletal and/or psychological conditions, group membership was stated to be an important factor in facilitating return to work (Haugli et al., 2011).

Participants in both programmes had been on long-term sick leave, so are not directly comparable to this study, however, further evaluation of individual and group occupational rehabilitation approaches appears warranted.

9.3.9 Work ability

In this study, work ability was one of the main outcomes of interest, because of the limits of sickness absence as an outcome measure. However, although subjective estimates of work ability are considered to be good predictors of future work ability and disability (Tuomi, 1997) recent literature concludes that the term is still too poorly defined (Gould et al., 2008; Tengland, 2011).

Tengland suggests that two definitions are needed, one for specific jobs requiring particular expertise, and another for the ability to manage some kind of work.

One of the disadvantages of the use of the Work Ability Index (Tuomi et al., 1998) as an outcome measure of work ability in people with low back pain is that it neither specifies the type of work, nor relates the concept to the health condition under investigation. The advantage of the Graded Reduced Work Ability Scale (Haldorsen et al., 1998) is that it can be related to the health condition of interest, and includes questions that relate to the respondent's perceived ability to conduct 'any' or 'other' work. The findings of this study suggest that it may be measuring a different concept from that of the Work Ability Index. Unfortunately it has not been widely used, and further evaluation of the scale, and its comparability with the Work Ability Index is suggested.

9.3.10 Future studies of multidisciplinary rehabilitation and work ability

The results of this study demonstrate that greater flexibility in the provision of back pain rehabilitation is required if it is to become more work-focused. The option of individual multidisciplinary treatment needs to be available, with times and locations that are accessible to employed patients. Not all patients who are offered group treatment are willing or able to take it up, or to access it promptly. Where multidisciplinary group rehabilitation is provided, our findings suggest

that vocational interventions should be integrated within the service, rather than additional to it. Such a model might then be compared with routine multidisciplinary group rehabilitation in a trial. However, at present, few group programmes of this nature are available. A further recommendation is for greater clarity in defining the role of clinicians in vocational interventions; the impact of work-focused healthcare may be limited by the attitudes and beliefs of patients and employers towards involving health practitioners in the workplace. Caution is therefore advised in interpreting the results of international studies and in comparing them to those conducted in the UK where the employer has no obligation to liaise with clinicians or to support rehabilitation, and few employees have access to the support of an occupational physician. The impact of healthcare on the organisational and cultural 'black flags' that pose considerable obstacles to the effective management of back pain at work (Kendall et al., 2009) will therefore remain limited. Strategies to explore effective means of communication and interaction between clinicians, patients and their employers are recommended. Finally, the study has shown that the collection and measurement of valid and reliable work-related outcomes is complex and requires further attention.

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APPENDIX 1

The relationship between the study aims, research questions, methods of data collection and thesis chapters

Study aims	Research questions	Method of data collection	Chapter(s)
<p>1 To investigate existing provision of work-related advice and support for patients with low back pain.</p>	<p>-What are GPs' experiences of helping low back pain patients return to and stay at work? -What are GPs' experiences of therapy/rehabilitation for patients with low back pain that affects their ability to work? -What are GPs' experiences of the Nottingham Back Team and their satisfaction with how the team addresses patients' work problems? -What improvements would GPs recommend to help them manage their patients' work problems?</p>	<p>GP questionnaire survey</p>	<p>2</p>
<p>2 To inform the design and content of an individually targeted work-related intervention for use in a feasibility randomised controlled trial</p>	<p>-What are patients' experiences of working with low back pain? -What are patients' experiences of the help they may or may not have received in managing their low back pain at work, prior to routine group rehabilitation? -What are patients' experiences of routine group rehabilitation in addressing their ability to work with low back pain?</p>	<p>Patient interviews pre-group rehabilitation</p>	<p>3 3,4</p>
		<p>Patient interviews post-group rehabilitation</p>	<p>3 (methods) 4 (results)</p>

3	To identify appropriate and acceptable measurement tools and data collection methods for use in a feasibility randomised controlled trial.	<ul style="list-style-type: none"> -Do GP practices collect data on the healthcare resource-use of patients with low back pain? -Would GP practices be willing/able to extract this data on selected study participants in a feasibility randomised controlled trial? -If so, would they require payment for undertaking the task, and what would be the cost? 	Practice manager questionnaire survey	5
4	To test the feasibility of delivering an individually targeted intervention alongside group rehabilitation in a randomised controlled trial with concurrent economic evaluation.	<ul style="list-style-type: none"> -Are the participants able to understand the instructions for completing a selection of measurement tools? -Is the content of the measurement tools relevant to the participants? -How easily are the participants able to complete the measurement tools? -Is it possible to recruit and retain participants? -Is it possible to deliver the protocol? -Are the proposed outcome measures feasible? -Is it feasible to estimate an effect size of the intervention in order to adequately power a future randomised controlled trial? -Is it feasible to conduct an economic evaluation? -What or who had helped the participants to remain in work? -Which elements of routine treatment and the intervention did the participants feel to be useful, or not useful, in changing their perceptions of work ability? -What were the participants' views and experiences of the study organisation and the timing, location, duration and content of the vocational interventions? -What were the participants' views and experiences of the methods of data collection, and the ease of completion and acceptability of the measures used? 	Pilot patient questionnaire	6
			Feasibility randomised controlled trial and economic evaluation	7
			Post-trial patient interviews	8

APPENDIX 2

GP Questionnaire



Working Well with Back Pain GP Questionnaire

Instructions

This questionnaire is in 3 sections. The questions concern the management of patients with **persisting or recurrent low back pain** (without red flags) which affects their ability to work.

Please underline the answer which best applies to you.

Section A: How do you help patients to manage low back pain which affects their ability to work?

1. If symptoms continue past 2 weeks I mainly:
 - a) refer to physiotherapy OR
 - b) refer to the Nottingham Back Team OR
 - c) other (please specify)

2. If symptoms continue past 6 weeks I mainly:
 - a) refer to physiotherapy OR
 - b) refer to the Nottingham Back Team OR
 - c) other (please specify)

3. If symptoms continue past 12 weeks I mainly:
 - a) refer to physiotherapy OR
 - b) refer to the Nottingham Back Team OR
 - c) other (please specify)

4. When writing sickness certificates, I use the 'remarks' section to make recommendations on work duties/hours mainly agree mainly disagree

5. I explain to patients, if writing a sickness certificate, that they can return to work before it expires, if able to mainly agree mainly disagree

6. I provide patients with *written* advice and information about managing health problems and back pain at work (e.g. JobCentre Plus, Work Directions, Arthritis Research Campaign) mainly agree mainly disagree

If you do provide this, please specify.....

- | | | | |
|---|---|---------------------|------------------------|
| 7. I initiate <u>written</u> communication with patients' employers about managing their low back pain at work | ✓ | <i>mainly agree</i> | <i>mainly disagree</i> |
| 8. If received, I <i>respond</i> to written communication from patients' employers about managing their low back pain at work | | <i>mainly agree</i> | <i>mainly disagree</i> |
| 9. I initiate <u>written</u> communication with patients' therapists about managing their low back pain at work | | <i>mainly agree</i> | <i>mainly disagree</i> |
| 10. If received, I <i>respond</i> to written communication from patients' therapists about managing their low back pain at work | | <i>mainly agree</i> | <i>mainly disagree</i> |
| 11. I take overall responsibility for managing patients' work difficulties resulting from low back pain | | <i>mainly agree</i> | <i>mainly disagree</i> |
| 12. I lack up-to-date information on resources/services that may provide help to patients with work problems due to low back pain | | <i>mainly agree</i> | <i>mainly disagree</i> |

Section B: What is your experience of therapy/rehabilitation for patients with low back pain which affects their ability to work?
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- | | | | |
|---|--|---------------------|------------------------|
| 1. I receive <u>verbal</u> communication from patients' <u>employers</u> about managing their low back pain which affects work | | <i>mainly agree</i> | <i>mainly disagree</i> |
| 2. I receive <u>written</u> communication from patients' employers about managing their low back pain which affects work | | <i>mainly agree</i> | <i>mainly disagree</i> |
| 3. I receive <u>verbal</u> communication from patients' <u>therapists</u> about managing their low back pain which affects work | | <i>mainly agree</i> | <i>mainly disagree</i> |
| 4. I receive <u>written</u> communication from patients' therapists about managing their low back pain at work | | <i>mainly agree</i> | <i>mainly disagree</i> |
| 5. Therapy/rehabilitation to help low back pain patients with their work problems is <u>adequate</u> | | <i>mainly agree</i> | <i>mainly disagree</i> |
| 6. Therapy/rehabilitation to help low back pain patients with their work problems need to be <u>more clearly defined</u> | | <i>mainly agree</i> | <i>mainly disagree</i> |
| 7. Therapy/rehabilitation to help low back pain patients with their work problems needs to be <u>more accessible</u> | | <i>mainly agree</i> | <i>mainly disagree</i> |
| 8. Therapy/rehabilitation to help low back pain patients with their work problems needs to be <u>available more promptly</u> | | <i>mainly agree</i> | <i>mainly disagree</i> |
| 9. Therapy/rehabilitation to help low back pain patients with their work problems should be <u>provided by local health authorities</u> | | <i>mainly agree</i> | <i>mainly disagree</i> |
| 10. Therapy/rehabilitation to help low back pain patients with their work problems needs to be <u>more effective than at present</u> | | <i>mainly agree</i> | <i>mainly disagree</i> |
| 11. Therapy/rehabilitation to help back pain patients with their work problems needs to be <u>better co-ordinated</u> than at present | | <i>mainly agree</i> | <i>mainly disagree</i> |

Section C: What is your experience of the Nottingham Back Team?

- 1. I am aware of the service currently provided by the Nottingham Back Team yes / no
(if you answered 'no' then please go to 'comments' below)
(if you answered 'yes' please continue)
- 2. I have referred patients to the Nottingham Back Team yes / no
- 3. I have seen patients who have been referred by other GPs to the Nottingham Back Team yes / no
- 4. I receive adequate communication from the Nottingham Back Team following assessment and/or treatment mainly agree mainly disagree
- 5. I expect The Nottingham Back Team to help patients to manage their work problems mainly agree mainly disagree
- 6. I am satisfied with the service that the Nottingham Back Team provides generally mainly agree mainly disagree
- 7. I am satisfied with the service that the Nottingham Back Team provides in helping patients to manage their work problems mainly agree mainly disagree

Please add any comments / suggestions

.....
.....
.....
.....
.....
.....
.....
.....

(comments space continues over)

THANK YOU FOR TAKING THE TIME TO COMPLETE THIS QUESTIONNAIRE

Please return the completed questionnaire to the researcher in the **stamped addressed envelope provided** , to:

Carol Coole
Research Occupational Therapist
University of Nottingham
Division of Rehabilitation and Ageing
B Floor, Medical School
Queens Medical Centre
Nottingham NG7 2UH

APPENDIX 3

Participant Information Sheet (patient interviews)



Working Well with Back Pain

We would like to invite you to take part in a new research study for people of working age with low back pain in Nottingham. Before you decide whether to take part, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish.

Part 1 tells you the purpose of this study and what will happen to you if you take part.

Part 2 gives you more detailed information about how the study will be carried out.

Participant Information Sheet

Part 1

What is the purpose of the study?

Many people struggle at work because of back pain, and worry about whether they will be able to carry on working. Some people have to take sick leave, or even stop work because of back pain.

We are trying to find out whether the type of treatment given by the Nottingham Back Team can help keep people well at work. (This includes people who are unable to work at the moment).

Why have I been invited?

You have been invited because you have indicated a concern that your back pain affects your ability to work, or might do so in the future. We are inviting everyone in a similar situation who is assessed by the team over the next few weeks. We are hoping to get 24 people to take part in the study.

Do I have to take part?

It is up to you to decide. You have some time to think about it. With your agreement, we have passed your telephone details to the researcher, Carol Coole. She will contact you within the next two to three days and ask if you would like to join the study. She will also be able to answer any further questions you have.

Even if you give your consent to participate in the study, you are free to withdraw from the study at any time, without giving a reason. This will not affect the standard of care you receive.

What will happen to me if I take part?

You will receive the usual seven-week treatment programme run by the Nottingham Back Team. You will be interviewed by the researcher on two occasions. The first interview will take place before the treatment programme starts, and the second will take place within two months of completing the programme. Each interview will last for approximately one hour. Both interviews will be audio-taped. The interviews will be arranged at a time and place convenient to you, in a private area, either at your home, or workplace, or at the Mobility Centre at Nottingham City Hospital.

If the interview takes place at the Mobility Centre at the City Hospital, you will be sent information on travel and parking.

At the **first interview**, the researcher will discuss your work situation with you, and any problems or concerns you have about working with back pain. This will include any expectations you might have as to how the treatment programme might help you to work with back pain. You will also be asked to complete a questionnaire about the following topics:

1. Your current work status
2. Whether you are receiving any work-related benefits (e.g. sick pay, incapacity benefit)
3. Your ability to work
4. Number of sick days, or days on adjusted work/hours
5. Your general health
6. How back pain affects you

You will also be asked your opinion about how easy or difficult the questionnaire was to complete.

At the **second interview**, we will ask about your experiences of the treatment programme, including whether it has helped your ability to work with back pain, what you found most helpful or unhelpful, and what else would help.

What will I have to do?

If you want to join the study, tell the researcher (Carol Coole) when she contacts you by telephone. She will then arrange to interview you at a time and place convenient to you, before the treatment programme starts.

What are the possible benefits of taking part?

We cannot promise that the study will help you, but the information we get from this study may help improve the treatment of people with low back pain, to help them stay working.

Are there any problems with the study?

At present is not feasible to include non-English speakers, as this is a pilot study. However, the results will help us design a larger study, which will include non-English speakers.

Will it cost me anything to take part?

No, any meetings with the researcher that incur travel costs will be reimbursed. However, if you choose, the researcher can visit you at home, and outside working hours if you are at work.

Will my taking part in the study be kept confidential

Yes. We will follow established ethical and legal practices, and all information about you will be handled in confidence. The details are included in Part 2
If the information in Part 1 has interested you, and you are interested in taking part in the study, please read the additional information in Part 2 before making any decision.

Part 2

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

If you withdraw from the study, we will use the data collected up to your withdrawal. You may continue to be treated by the Nottingham Back Team in their group programme.

If you withdraw from the Nottingham Back Team group treatment programme at any stage, you will not have any further contact with this study. Your data up to the time you withdraw from treatment will still be used.

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised.

What if there is a problem?

If you have any concerns about the study, ask to speak to the researcher who will do her best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. The contact numbers are given below*.

NHS bodies are liable for clinical negligence and other negligent harm to individuals covered by their duty of care. NHS institutions employing researcher are liable for negligent harm caused by the design of studies they initiate.

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised.

Will my GP know about me being involved in the study?

Yes. Your GP will know that you are being treated by the Nottingham Back Team, and about the research study. Your GP will not be informed of any personal details that you give to the researcher.

Will anyone else know about me being involved in the study?

If another healthcare professional, apart from your GP, has referred you to the Nottingham Back Team, we will inform them that you are involved in the study. This other healthcare professional will not be informed of any personal details that you give to the researcher.

What will happen to the results of the research study?

It is intended that the results of the study will be published formally in scientific journals. We will send all participants in the study a summary of the results. You will not be identified in any report/publication.

Who is organising and funding the research?

The research is being funded by a charity called the Arthritis Research Campaign (arc), who will pay the salary of the researcher. There is a 'steering group' which meets regularly to advise the researcher. The group includes experienced research therapists, a local GP, and a patient who has been treated by the Nottingham Back Team.

Who has given permission for the study to be carried out?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by the Nottingham 1 Research Ethics Committee

Further information and contact details

Carol Coole
Research Occupational Therapist
University of Nottingham
Division of Rehabilitation and Ageing
B Floor, Medical School
Queens Medical Centre
Nottingham NG7 2UH
Tel. 0115 8230247
Carolyn.coole@nottingham.ac.uk

*** NHS Complaints Procedure**

If you are unhappy with the study, and wish to make a complaint, you can contact any of the following:

- **Patient Advice and Liaison Service (PALS)** at Nottingham City Hospital:
Freephone – 0800 052 1195 or
Drop-in at the PALS office on South Corridor, Junction S6 at Nottingham City Hospital (weekdays 9.30-4.30) or
Email – pals@nuh.nhs.uk or
Write to PALS, Freepost, NEA 14614, Nottingham NG7 2UH
- **NHS Direct** 0845 4647
- To make a formal complaint, write to:
Chief Executive
Peter Homa
NUH NHS Trust
QMC Campus
Derby Road
Nottingham
NG7 2UH

APPENDIX 4

**Patient interview guide (pre-group rehabilitation)
including pilot questionnaire**

Working Well with Back Pain

Interview Schedule 1: Pre-treatment

Welcome and introduction (to employed/unemployed patients)

- “Thank you for agreeing to meet with me today
- This session will be in two parts. Firstly I shall be asking you questions about your back pain and your employment. Then I will ask you to complete a questionnaire, and ask you your opinion of the questionnaire. Altogether, this should last about an hour and a half.
- It is important that you know that everything you say during this interview will be treated confidentially. Your name will not be mentioned on any published documents, and therefore anything you say cannot be identified as coming from you. Your participation in this interview will not affect your work, or any benefits you might be on, or any services you receive, including your treatment with the Nottingham Back Team
- It is difficult to engage in a conversation with someone and take notes at the same time – are you happy for me to record this interview? The tapes will only be used by the University to report and analyse results. They will not be passed on to your employer if you have one, or the Department for Work and Pensions, your GP, or any other agencies. Your name will not be recorded on the tape. The tape will be stored securely at the University of Nottingham.
- Do you have any questions before we start?”

Employed patients

Topic area	Question area	Prompts
Current work situation	Tell me about the job that you are doing at the moment	<ul style="list-style-type: none"> - job title - hours/shifts - length of time in job - main duties - job satisfaction - size of business/employer
Experience of back pain at work	How does back pain affect your ability to work?	<ul style="list-style-type: none"> - difficulties encountered, physical, cognitive, psychological, emotional, social - attitudes of/relationships with colleagues/employer - effect of work on back pain - sickness absence, injury claims - perceived work ability, current and future - workplace back pain management strategies used
Other barriers to work	What other things affect your ability to work?	<ul style="list-style-type: none"> - age - flare-ups of pain - home situation - other physical/mental health problems - worry about the pain, fear of disability, not coping - money worries
Experience of help received	What help have you had with managing your back pain and work?	<ul style="list-style-type: none"> - employers, occupational health, workplace physio - GP, physio (NHS/private), hospital consultants - Job Centre, DEA, Job Brokers - content, type, amount of help given - expectation/experience of help received
Expectation of treatment with Nottingham Back Team	How do you think the NBT might be able to help you improve your ability to work?	<ul style="list-style-type: none"> - reduce symptoms, increase fitness, manage pain better - contact with employers/visits/advice/training - expectations of, preferences for work interventions - reduce sick leave, improve work ability - change in duties/hours of work

Unemployed patients

Topic area	Question area	Prompts
Work history	What work have you done in the past?	<ul style="list-style-type: none"> - when last employed, reasons for leaving - is back pain cause of unemployment - type of work - current work plans if any/intention to work in future
Management of back pain at work	How has back pain affected your ability to work in the past, and your ability to work in future?	<ul style="list-style-type: none"> - difficulties encountered, physical, psychological, emotional, social - attitudes of/relationships with colleagues/employer - effect of work on back pain - sickness absence, injury claims - perceived work ability, current and future
Other barriers to work	What other things affect your ability to work?	<ul style="list-style-type: none"> - flare-ups of pain - age - home situation - other physical/mental health problems - worry about the pain, fear of disability, not coping - money worries - lack of skills, qualifications, experience
Experience of help received	What help have you had with managing your back pain and work?	<ul style="list-style-type: none"> - employers, occupational health, workplace physio - GP, physio (NHS/private), hospital consultants - Job Centre, DEA, Job Brokers - content, type, amount of help given - expectation/experience of help received
Expectation of treatment with Nottingham Back Team	How do you think the NBT might be able to help you improve your ability to work?	<ul style="list-style-type: none"> - reduce symptoms, increase fitness, manage pain better - contact with employment services, GP - expectations of, preferences for work interventions - reduce sick leave, improve work ability - change in duties/hours of work

To both employed and unemployed patients: **Interview Schedule for Pilot Questionnaire**

“Thank you for telling me about your experiences of working and back pain. Is there anything else that you’d like to say that we haven’t discussed?”

- I’m going to give you the questionnaire now.
- I want to know what you think about the questionnaire, what you like and don’t like about it, and how we could improve it.
- There are eight sections.
- I’d like you to complete each section at a time, and tell me what you think about it.
- You are welcome to make comments about each section while you are completing it.
- I will also ask you some questions about each section.

Topic area	Prompts
Instructions	How easy was it to follow the instructions? How clear were the instruction? How well were you able to understand what you were meant to do?
Question/answer format	How well did you understand all the questions? How easily were you able to answer all the questions? How was it to remember the details of what had happened in the previous 6 months? How difficult was it to differentiate between your back pain, and interventions for other health conditions, e.g. when you have seen your GP? Were any of the questions difficult to answer? Were there any questions you did not want to answer?
Content	How well did the questions apply to you? How relevant were the questions to you? Do you think some sections were better than others in expressing the problems you have? Which? Did you feel that the questions reflected the impact back pain has had on work and healthcare? Why/why not? What else would you liked to have been asked?
General impression	What did you think about the length, layout, presentation, readability, space for comments

APPENDIX 5

Patient interview guide (post-group rehabilitation)

Interview Schedule 2: Post-treatment

Welcome and introduction (to employed/unemployed patients)

- “Thank you for agreeing to meet with me again today
- I’m going to ask you about the treatment programme you have had with the Nottingham Back Team. It will last about one hour.
- As before, the interview will be taped. Everything you say during this interview will be treated confidentially. Your name will not be mentioned on any published documents, and therefore anything you say cannot be identified as coming from you. Your participation in this interview will not affect your work, or any benefits you might be on, or any services you receive, including your treatment with the Nottingham Back Team. The tapes will be stored securely at the University of Nottingham.
- Do you have any questions before we start?”

a) If patient was employed at first interview

Topic area	Question area	Prompts
Work situation	Tell me about your work situation now.	<ul style="list-style-type: none"> - same job, different job, no job, reasons - hours/duties/adjustments - size of business/employer - changes since first interview/since treatment
Management of back pain at work	How does back pain affect your ability to work now?	<ul style="list-style-type: none"> - what do you now find difficult about working - sick leave since first interview - relationship with/attitudes of employer/colleagues - perceived current/future work ability - any changes since treatment
Other barriers to work	What other things affect your ability to work?	<ul style="list-style-type: none"> - flare-ups of pain - age - home situation - other physical/mental health problems - worry about the pain, fear of disability, not coping - money worries

Experience of NBT treatment programme	How has the treatment programme affected your back pain, and your ability to work?	<ul style="list-style-type: none"> - experience of treatment compared with expectations - what was helpful/unhelpful - effect of therapists, key worker, exercises, - information/education, other patients, work problems - group session, individual therapy - content, type, amount of help given re: work - what was it like being part of a group - were there other people who had difficulty working - did being in a group make a difference to your ability to work now - change in referral method, self-referral, faster referral - better awareness of GP - separate group treatment for people with work problems - more education in the group programme on managing work problems - more individual help with work problems - more contact with employers and job centres - longer-term support - what else would help you return to/stay in work?
Recommendations/suggestions for improvement	How do you think the NBT could improve the service they offer to people with back pain that is affecting their ability to work?	

a) If patient was unemployed at first interview

Topic area	Question area	Prompts
Work situation	Tell me about your work situation now.	<ul style="list-style-type: none"> - if now working, details of job, how came about - hours/duties/adjustments - changes since first interview/since treatment - if no change – reasons
Management of back pain at work	How does back pain affect your ability to work now?	<ul style="list-style-type: none"> - what do you now find difficult about working - sick leave since first interview - relationship with/attitudes of employer/colleagues - perceived current/future work ability - any changes since treatment

<p>Other barriers to work</p>	<p>What other things affect your ability to work?</p>	<ul style="list-style-type: none"> - flare-ups of pain, unpredictability - age - home situation - lack of skills, qualifications, experience - attitudes of employers - other physical/mental health problems - worry about the pain, fear of disability, not coping - money worries, benefits system
<p>Experience of NBT treatment programme</p>	<p>How has the treatment programme affected your back pain, and your ability to work?</p>	<ul style="list-style-type: none"> - experience of treatment compared with expectations - what was helpful/unhelpful - effect of therapists, key worker, exercises, - information/education, other patients, work problems - group session, individual therapy - content, type, amount of help given re: work - what was it like being part of a group - were there other people who had difficulty working - did being in a group make a difference to your ability to work now
<p>Recommendations/suggestions for improvement</p>	<p>How do you think the NBT could improve the service they offer to people with back pain that is affecting their ability to work?</p>	<ul style="list-style-type: none"> - change in referral method, self-referral, faster referral - better awareness from GP - separate group treatment for people with work problems - more education in the group programme on managing work problems - more individual help with work problems - more contact with employers and job centres - workplace teaching about back pain management - longer-term support - what else would help you to return to/stay in work, ?

APPENDIX 6

GP Practice Manager Questionnaire



*Working Well with Back Pain
Practice Manager Questionnaire*

Section 1. This section asks about the data collected by your practice

Please indicate below, which of the following data your practice collects which are related in some way to low back pain:
Please place tick the box if your practice keeps a record of this data for each patient, and a cross if it does not. Please add any comments which you feel may be relevant.

I. Consultations at the surgery related to low back pain

- | | | | |
|---|--------------------------|---|--------------------------|
| a) Dates of appointments with GP | <input type="checkbox"/> | b) Dates of appointments with Practice nurse | <input type="checkbox"/> |
| Whether attended / UTA / DNA | <input type="checkbox"/> | Whether attended / UTA / DNA | <input type="checkbox"/> |
| c) Dates of appointments with Physio | <input type="checkbox"/> | d) Dates of appointments with Counsellor | <input type="checkbox"/> |
| Whether attended / UTA / DNA | <input type="checkbox"/> | Whether attended / UTA / DNA | <input type="checkbox"/> |
| e) Dates with other professional | <input type="checkbox"/> | f) Dates with other professional | <input type="checkbox"/> |
| specify..... | | specify..... | |
| Whether attended / UTA / DNA | <input type="checkbox"/> | Whether attended / UTA / DNA | <input type="checkbox"/> |

Comments:

.....
.....
.....

(cont.)

Section 1 Continued

As before, please indicate below, which of the following data your practice collects which are related in some way to low back pain:

Please place tick the box if your practice keeps a record of this data for each patient, and a cross if it does not. Please add any comments which you feel may be relevant.

2. Prescriptions related to low back pain

(This could include medication for pain, inflammation, anxiety, depression, sleep disturbance, muscle tension, and medications for managing side-effects)

Date of Prescription(s)	<input type="checkbox"/>	Name of medicine(s)	<input type="checkbox"/>
Number of tablets to be taken per day	<input type="checkbox"/>	Strength of each tablet	<input type="checkbox"/>
Number of days supplied	<input type="checkbox"/>		

Comments:

.....
.....

3. Investigations related to low back pain

Blood tests	<input type="checkbox"/>	X rays	<input type="checkbox"/>
Dexa scans	<input type="checkbox"/>	MRI scans	<input type="checkbox"/>

Comments:

.....
.....

4. Referral for further assessment / treatment for low back pain

e.g. Physiotherapy, Nottingham Back Team, Pain Management, Pain Clinic
Spinal Disorders Unit, Rheumatology

Comments:

.....
.....

Section 2. This section asks about extracting the data collected.

If some or all of the above data is collected by the practice, would it be possible to extract the data for individual patients, as requested by the researcher, and with the consent of the patient?

(The timescale would be data that had been collected during the 6 months before, and 6 months after treatment by the Nottingham Back Team, over a 10 month period, in 2009. We would anticipate this would involve a maximum of 4 patients per practice).

- a) Would it be possible to extract some/all of the data?.....(yes/no) **If no, go to question f**
- b) Would there be a charge per patient?(yes/no)
- c) If 'yes', what might be the approximate charge per patient? £
- d) How much notice would you need to extract the data?days/weeks
- e) We are interested in testing the feasibility of collecting this kind of data. In any future study, what might be the maximum number of patients you would be willing to extract this data for?
Maximum number of patients:.....
- f) If you were unable to extract the data yourself, would you be willing to let us pay someone who does have the necessary skills to collect the data?(yes/no)

Comments:

.....
.....

Thank you for taking the time to complete this questionnaire

Please return the completed questionnaire to the researcher
in the **stamped addressed envelope provided**, to:

Carol Coole
Research Occupational Therapist
University of Nottingham
Division of Rehabilitation and Ageing
B Floor, Medical School
Queens Medical Centre
Nottingham NG7 2UH

APPENDIX 7

Pilot Patient Questionnaire

Date:

Patient Identification Number:



The University of
Nottingham



0870 850 5000
www.arc.org.uk
Committed to curing arthritis

Working Well with Back Pain

Questionnaire for participants

This booklet contains eight sections for you to complete. The information will be treated confidentially.

We want to know what you think about the questionnaire: what you like and don't like about it, and how we could improve it. After you have completed each section, the researcher will ask you for your comments, which will be recorded on audiotape. The tape and questionnaire will be stored securely at the University of Nottingham.

Thank you for taking the time to complete the questionnaire.

Section A. This section asks about your health.

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

- I have no problems in walking about
- I have some problems in walking about
- I am confined to bed

Self-Care

- I have no problems with self-care
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

Usual Activities (e.g. work, study, housework, family or leisure activities)

- I have no problems with performing my usual activities
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

Pain/Discomfort

- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

Anxiety/Depression

- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed

Section B: This section asks about how you feel, and how well you are able to do your usual activities.

Please only **tick one box** per question.

The following questions are about activities you might do in a typical day. Does <u>your health</u> <u>now limit you</u> in these activities? If so, how much?		Yes, limited a lot	Yes, limited a little	No, not limited at all
1	<u>Vigorous activities</u> , such as running, lifting heavy object, participating in strenuous sports			
2	<u>Moderate activities</u> , such as moving a table, pushing a vacuum cleaner, bowling or playing golf			
3	Bathing or dressing yourself			

During the Past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

		All of the time	Most of the time	Some of the time	A little of the time	None of the time
4	Were limited in the kind of work or other activities?					

During the Past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

		All of the time	Most of the time	Some of the time	A little of the time	None of the time
5	Accomplished less than you would like					

6 How much bodily pain have you had in the past 4 weeks?

None Very mild Mild Moderate Severe Very severe

7 During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

None Very mild Mild Moderate Severe Very severe

These questions are about how you feel and how things have been with you during the Past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks.....

		All of the time	Most of the time	Some of the time	A little of the time	None of the time
8	Have you been very nervous?					
9	Did you have a lot of energy?					
10	Have you felt downhearted and depressed?					

11. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time Most of the time Some of the time A little of the time None of the time

4. Estimated work impairment due to health conditions

Is your health condition a hindrance to your ability to work?

Circle more than one alternative if needed

There is no hindrance/ I have no diseases/conditions	6
I am able to do my job, but it causes some symptoms	5
I must (or would have to) sometimes slow down my work pace or change my work methods	4
I must (or would have to) often slow down my work pace or change my work methods	3
Because of my condition, I feel I am able to do only part-time work	2
In my opinion, I am entirely unable to work	1

5. Sick leave during the past year (12 months)

How many whole days have you been off work, or unavailable for work, because of a health problem (disease or healthcare or for examination) during the past year (12 months)?

None at all	5
At the most 9 days	4
10-24 days	3
25-99 days	2
100-365 days	1

6. Own prognosis of work ability two years from now

Do you believe that from the standpoint of your health, you will be able to work two years from now ?

Unlikely	1
Not certain	2
Relatively certain	3

7. Mental resources

Have you recently been able to enjoy your regular daily activities ?

Often	1
Rather often	2
Sometimes	3
Rather seldom	4
Never	5

8. Have you recently been active and alert ?

Often	1
Rather often	2
Sometimes	3
Rather seldom	4
Never	5

9. Have you recently felt yourself to be full of hope for the future ?

Often	1
Rather often	2
Sometimes	3
Rather seldom	4
Never	5

Section D. This section asks you how much your back pain affects your ability to work.

1.

<i>To what extent is your ability to do your ordinary work reduced by your back pain?</i>	A great deal	<input type="checkbox"/>
	A lot	<input type="checkbox"/>
	Some	<input type="checkbox"/>
	Not much	<input type="checkbox"/>
	Very little	<input type="checkbox"/>

2.

<i>To what extent is your ability to carry out <u>other</u> work reduced by your back pain?</i>	A great deal	<input type="checkbox"/>
	A lot	<input type="checkbox"/>
	Some	<input type="checkbox"/>
	Not much	<input type="checkbox"/>
	Very little	<input type="checkbox"/>

3.

<i>If you continue to work, to what extent will that affect your back pain?</i>	A great deal	<input type="checkbox"/>
	A lot	<input type="checkbox"/>
	Some	<input type="checkbox"/>
	Not much	<input type="checkbox"/>
	Very little	<input type="checkbox"/>

4.

<i>To what extent does your back pain affect your health and well-being?</i>	A great deal	<input type="checkbox"/>
	A lot	<input type="checkbox"/>
	Some	<input type="checkbox"/>
	Not much	<input type="checkbox"/>
	Very little	<input type="checkbox"/>

5.

<i>To what extent do other complaints affect your health and well-being?</i>	A great deal	<input type="checkbox"/>
	A lot	<input type="checkbox"/>
	Some	<input type="checkbox"/>
	Not much	<input type="checkbox"/>
	Very little	<input type="checkbox"/>

6.

<i>To what extent do you think your back pain will affect your ability to work in two years time?</i>	A great deal	<input type="checkbox"/>
	A lot	<input type="checkbox"/>
	Some	<input type="checkbox"/>
	Not much	<input type="checkbox"/>
	Very little	<input type="checkbox"/>

Section E. In this section we want you to tell us about your work situation over the last 6 months

1. Have you had a paid job **over the last 6 months?**

Yes What is/was your job title?.....
(please continue to question 2)

No **please go straight to question 6**

2. When you are doing your normal job and hours (without any adjustments because of your back pain), how many hours would you work in a typical week?

Number of hours: Over how many working days?

3. Are you self-employed? (please tick the box that applies)

Yes No

4. Your recent work situation

Please choose a statement below that best describes your main work situation over the last 6 months. <u>Tick only one box.</u>		
a	I have been working my usual hours and duties over the last 6 months	<input type="checkbox"/>
b	<p>I am working my usual hours, but over the last 6 months I have been unable to do some/all of my usual duties, and/or have had to ask for help because of my back pain.</p> <p><i>On how many days when you have been at work have your duties been affected by back pain?</i></p> <p>..... days</p> <p><i>On those days when your duties have been affected by back pain, how many fewer productive hours are you providing because of your back pain? (compared to someone else doing your job who is in perfect health.)</i></p> <p>..... hours per day</p>	<input type="checkbox"/>
c	<p>I am doing all my usual duties, but I have been unable to work my usual hours over the last 6 months because of my back pain</p> <p><i>How many hours less have you worked per week?</i> hours</p>	<input type="checkbox"/>
d	<p>I am working, but over the last 6 months I have been unable to work my usual hours AND have been unable to do some/all of my usual duties, and/or have had to ask for help because of my back pain.</p> <p><i>How many hours less have you worked per week?</i> hours</p> <p><i>On how many days when you have been at work have your duties been affected by back pain?</i></p> <p>..... days</p> <p><i>On those days when your duties have been affected by back pain, how many fewer productive hours are you providing because of your back pain? (compared to someone else doing your job who is in perfect health.)</i></p> <p>..... hours per day</p>	<input type="checkbox"/>
e	I am off sick because of my back pain	<input type="checkbox"/>
f	<p>I am doing 'Permitted Work' while on benefit, because of my back pain</p> <p><i>How many hours per week?</i> hours</p>	<input type="checkbox"/>
g	<p>I have stopped work during the last 6 months due to my back pain</p> <p><i>Please go to question 7</i></p>	<input type="checkbox"/>

5. Your sick leave

The following questions are about time off sick from work due to **back pain**. Please answer every question

(Remember that this information will be treated confidentially)

a	How many working days/hours of sick leave have you taken over the last 6 months because of your back pain? <i>Days: Hours:..... (if none, put '0')</i>
b	How many separate episodes of sick leave have you taken over the last 6 months because of back pain? (an episode could be one day, or several days in a row. For example, if you were off sick for one day each week over 4 weeks, this would count as four episodes. Or, if you normally worked Monday to Friday, and were off sick on the Friday and the following Monday, this would count as one episode) <i>Number of episodes</i>
c	For how many of these episodes have you received a sickness certificate from your GP? <i>Number of episodes</i>
d	How many of these episodes have lasted for more than 10 consecutive work days? <i>Number of episodes</i>
e	Over the last 6 months , have you taken annual leave instead of taking sick leave? Yes / No (please circle your answer) If so, how much? <i>Days Hours</i>

6. Please could you indicate which income band your approximate annual after-tax individual income would fall within.

(Remember that this information will be treated confidentially)

Less than £10,000	<input type="checkbox"/>	£40,000 - £49,000	<input type="checkbox"/>
£10,000 - £19,999	<input type="checkbox"/>	£50,000 - £59,000	<input type="checkbox"/>
£20,000 - £29,000	<input type="checkbox"/>	£60,000 - £69,000	<input type="checkbox"/>
£30,000 - £39,000	<input type="checkbox"/>	£70,000 or above	<input type="checkbox"/>

7. Please could you indicate which income band your approximate annual after-tax household income would fall within.

(Remember that this information will be treated confidentially)

Less than £10,000	<input type="checkbox"/>
£10,000 - £19,000	<input type="checkbox"/>
£20,000 - £29,000	<input type="checkbox"/>
£30,000 - £39,000	<input type="checkbox"/>

£40,000 - £49,000	<input type="checkbox"/>
£50,000 - £59,000	<input type="checkbox"/>
£60,000 - £69,000	<input type="checkbox"/>
£70,000 or above	<input type="checkbox"/>

8. Your main occupation if not working

If you do not currently have a paid job, please choose a statement below that best describes your main occupation over the last 6 months . Tick only <u>one</u> box. State whether this is due to back pain (yes or no)			Is this due to back pain? (please delete)
a	I am a carer/homemaker	<input type="checkbox"/>	Yes / No
b	I am a student/training	<input type="checkbox"/>	Yes / No
c	I am not working but I am actively looking for work or further training/education	<input type="checkbox"/>	Yes / No
d	I am not working, but I am considering looking for work or further training/education in the future	<input type="checkbox"/>	Yes / No
e	I am not working, and am not considering work or further training/education in the future	<input type="checkbox"/>	Yes / No

9. If you have not been in paid work over the last 6 months, what was your last job title?

.....

10. If you are not in paid work, when was your last day of paid work?

.....

11. Benefits received

<p>How many of the following benefits have you received, <u>mainly</u> or <u>partly</u> <u>due to back pain</u> over the last 6 months? Tick <u>any</u> of the boxes that apply.</p> <p>(Remember that this information will be treated confidentially)</p>		
a	Statutory Sick Pay	<input type="checkbox"/>
b	Sick Pay through your employer (full salary or half salary)	<input type="checkbox"/>
c	Incapacity Benefit	<input type="checkbox"/>
d	Income Support Premium because you are unable to work	<input type="checkbox"/>
e	Working Tax Credit with disability premium	<input type="checkbox"/>
f	Job Seekers Allowance	<input type="checkbox"/>
g	Disability Living Allowance	<input type="checkbox"/>
h	Industrial Injuries Disablement Benefit	<input type="checkbox"/>
i	None of the above	<input type="checkbox"/>

12. Has your back pain led to you being involved in any financial claims during **the last 6 months**? Please tick the box which applies for (a) (b) and (c).

Type of claim	None	Planning	Involved	Completed (if so, for what sum?)
(a) Claim against employer				
(b) Insurance claim				
(c) Claim/appeal for benefits				

13. Have you taken time off work due to low back pain in the past – **previous to the last 6 months**?

Yes No

Section F – In this section we want you to tell us which health services and medication you have used for your back pain over the last 6 months.

1. Because of your back pain, in the last 6 months, have you been to see your GP, or any other health care professional at the GP surgery?

Yes (please complete the table below to tell us some details)

No (continue with question 2)

Health care professional	Number of visits you made to the doctors surgery over the past 6 months
<u>Doctor</u> Name: Practice:	
Practice nurse:	
Physiotherapist:	
Counsellor:	
Other (specify):	

2. During the last 6 months, have you been to see any other health professional for your back pain? (Do not include any visits to your doctors surgery)

Yes (please complete the table below to tell us some details)

No (continue with question 3)

Health Professional	Was this NHS or was it Private?		
	NHS (please state number of visits)	Private (please state number of visits)	If private please state cost of visits
Hospital Consultant Please state department:			
Osteopath			
Chiropractor			

Health Professional	Was this NHS or was it Private?		
	NHS (please state number of visits)	Private (please state number of visits)	If private please state cost of visits
Acupuncturist			
Homeopath			
Walk-in Centre			
A & E			
Other (specify):			

3. During the last 6 months, have you received any of the following investigations or treatments (e.g. blood test, X rays, MRI scans, injections, surgery), or been admitted to hospital because of your back pain?

Yes (please complete the table below to tell us some details)

No (continue with question 4)

Date (if known)	Hospital and department	Number of days in hospital if relevant	Type of treatment/investigation

4. During the last 6 months has your doctor prescribed any medication (painkillers, anti-inflammatory drugs, etc) for your back pain? Please include anti-depressants if you have become depressed as a result of your back pain.

Yes (please complete the table below to tell us some details)

No (continue with question 5)

Name of medicine	Number of tablets to be taken per day	Strength of each tablet	Number of days supplied
<i>For example: Ibuprofen</i>	<i>For example: 6</i>	<i>For example: 200mg</i>	<i>For example: 5</i>

5. During the last 6 months, have you bought any over-the-counter medicines, or other treatments or equipment, to help treat your back pain?

Yes (please complete the table below to tell us some details)

No

(please include painkillers, anti-inflammatory drugs/gels/creams/sprays etc; herbal or complementary remedies including massage; and equipment e.g. TENS machine)

Item or other remedy bought	Total cost (£)

Section G. This section asks you about the concerns you have about having pain.

Below is a list of statements people experiencing pain are sometimes concerned about. Please read through the questions and rate your strength of agreement for each one according to the scale below.

	Strongly Disagree	Disagree	Agree	Strongly Agree
	1	2	3	4
1	I'm afraid that I might injure myself if I exercise			<input type="checkbox"/>
2	If I were to try to overcome it, my pain would increase			<input type="checkbox"/>
3	My body is telling me I have something dangerously wrong			<input type="checkbox"/>
4	People aren't taking my medical condition seriously enough			<input type="checkbox"/>
5	My accident has put my body at risk for the rest of my life			<input type="checkbox"/>
6	Pain always means I have injured my body			<input type="checkbox"/>
7	Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening			<input type="checkbox"/>
8	I wouldn't have this much pain if there weren't something potentially dangerous going on in my body			<input type="checkbox"/>
9	Pain lets me know when to stop exercising so that I can't injure myself			<input type="checkbox"/>
10	I can't do all the things normal people do because it's too easy for me to get injured			<input type="checkbox"/>
11	No one should have to exercise when he/she is in pain			<input type="checkbox"/>

Here are some things which other patients have told us about their pain. For each statement please circle any number from 0 to 6 to say how much your normal work affects, or would affect *your* back pain.

	Completely disagree	1	2	3	4	5	6	Completely agree
1. My pain was caused by my work or by an accident at work	0	1	2	3	4	5	6	
2. My work aggravated my pain	0	1	2	3	4	5	6	
3. I have a claim for compensation for my pain	0	1	2	3	4	5	6	
4. My work is too heavy for me	0	1	2	3	4	5	6	
5. My work makes (or would make) my pain worse.....	0	1	2	3	4	5	6	
6. My work might harm my back	0	1	2	3	4	5	6	
7. I should not do my normal work with my present pain	0	1	2	3	4	5	6	
8. I cannot do my normal work with my present pain	0	1	2	3	4	5	6	
9. I cannot do my normal work until my pain is treated	0	1	2	3	4	5	6	
10. I do not think that I will be back to my normal work within 3 months	0	1	2	3	4	5	6	
11. I do not think that I will ever be able to go back to that work	0	1	2	3	4	5	6	

Section H. Personal information

Sex: Male Female

Date of birth:/...../.....
Day Month Year

How long have you had low back pain?YearsMonths

Because all replies are anonymous, it will help us to understand your answers better if we have a little background data on your previous education. Please tick the box which best describes at what stage you completed your education.

Secondary school (no formal qualifications)

GCSE, 'O' levels or equivalent

Further education, e.g. 'A' levels, diploma, or equivalent

Higher education, e.g. degree or equivalent

THANK YOU FOR TAKING THE TIME TO COMPLETE THIS QUESTIONNAIRE

APPENDIX 8

Participant Information Sheet (feasibility randomised controlled trial)



Working Well with Back Pain

Participant Information Sheet

A research study for people of working age with low back pain is taking place in Nottingham. The aim is to find out how services like the Nottingham Back and Pain Team can best help people who are concerned about their ability to work.

We would like to invite you to take part in this study. Before you decide whether to take part, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish.

What is the purpose of the study?

Many people struggle at work because of back pain, and worry about whether they will be able to carry on working. Some people have to take sick leave, or even stop work because of back pain. There has been very little research done in the UK in this area, and we are keen to find out how the NHS can best help people who are having difficulty working due to a health condition. We want to find out whether the type of treatment given by the Nottingham Back and Pain Team can help keep people well at work, and whether giving extra individual help will make a difference.

Why have I been invited?

You have been invited because you have indicated a concern that your back pain affects your ability to work. We are inviting everyone in a similar situation who is assessed by the team over the next few weeks. We are hoping to get 50 people to take part in the study.

Do I have to take part?

It is up to you to decide. You have some time to think about it. With your agreement your telephone details will be passed to the researcher, Carol Coole. She will contact you two days after you have completed and returned the reply slip, and ask if you would like to join the study. She will also be able to answer any further questions you have. Even if you give your consent to participate in the study, you are free to withdraw from the study at any time, without giving a reason. This will not affect the standard of care you receive.

What will happen to me if I take part?

You will receive the treatment that has already been offered to you by the Nottingham Back and Pain Team. You will be allocated into one of two groups. The allocation will be carried out randomly by computer.

If you are allocated into the first group, you will receive Treatment as Usual. If you are allocated to the second group, you will receive extra Individual Work Support.

(continues over)

The details are given below:

Treatment as Usual

If you are in the Treatment as Usual group, you will continue with the treatment you have been offered by the Nottingham Back and Pain Team. You will still be able to discuss any problems about work with members of the staff during your treatment. You can ask them to write to your employer if you wish. There is also a separate, one-off 3 hour group session held in the City Centre approximately every 8 weeks for any Nottingham Back and Pain Team patients who have work problems.

Individual Work Support

If you are in the Work Support Group, you will continue to receive the treatment you have been offered by the Nottingham Back and Pain Team (Treatment as Usual). You will also be offered extra individual support, advice and information to help address the concerns you have about work in greater depth. This will include:

- A full assessment of your usual work tasks (including a visit to the workplace if appropriate).
- Identifying the concerns that you have about work due to your back pain and helping you to overcome the problems you are having. This will vary for each person, but could include for example:
 - Asking for help e.g. from employers and colleagues
 - Making adjustments to working positions, equipment, work schedules etc
 - Building up your physical ability to cope with particular activities e.g. standing, moving and handling, driving
 - Managing flare-ups of pain at work
 - Meeting with your employers to discuss their concerns, and helping them to understand your condition
 - Planning a return to work if you are off sick
 - Looking at alternative work
 - Information about/referral on to other agencies and specialists
- Providing you, and your employers with the latest information and legislation about the management of back pain at work, including health & safety regulations, occupational health guidelines etc.
- Communicating/liasing/meeting with the key people involved e.g. your manager, employer, occupational health, GP etc.

We do understand that you may have hesitations about the nature of any contact with your workplace. Please be reassured that contact would be only be made with your full consent.

This work support will be given by the researcher who is an experienced occupational therapist and qualified ergonomist. You will be offered up to eight meetings with the researcher, over a period of 16 weeks (you may not want - or need all eight). The first meeting will take place as soon as possible after you have entered the study. The meetings can take place at your home, at your workplace, or at the Mobility Centre at the City Hospital, (or at another agreed location that would be more convenient). Each session meeting would last between 30 and 90 minutes. Some of the work support might also take place over the phone, or by post, or email, if that is more convenient.

All participants:

When you join the study, you may be sent a **questionnaire** to complete and return to the researcher, Carol Coole, in a stamped addressed envelope. The questionnaire asks about your back pain, your general health, and your work. The researcher, Carol Coole, will also ask you some additional questions on these subjects by **telephone**.

This information will be collected again, by postal questionnaire and telephone interview, six months later by a suitably qualified and independent researcher. This researcher will also

collect information on the number and type of interventions you have received from the Nottingham Back and Pain Team as documented in their treatment notes, and any interventions received from Carol Coole.

Approximately seven months after joining the study, you will be invited to take part in an individual **interview** by the independent researcher. This is to find out what you thought was helpful, or unhelpful about the treatments and interventions you received, and any suggestions or recommendations for how they might be improved. The interview will last up to one hour, and will be recorded using a digital voice recorder with your permission. The interview will be arranged at a time and place convenient to you, in a private area, either at your home, or workplace, or at the Mobility Centre at Nottingham City Hospital.

What will I have to do?

If you want to join the study, tell the researcher (Carol Coole) when she contacts you by telephone. She will then tell you which group you have been allocated to.

What are the possible benefits of taking part?

We cannot promise that the study will help you, but the information we get from the study may improve the treatment of people with low back pain, and help them to stay in work.

Are there any problems with the study?

At present it is not feasible to include non-English speakers, as this is a pilot study. However, the results will help us design a larger study, which will include non-English speakers.

Will it cost me anything to take part?

No, any meetings with the researcher that incur travel costs will be reimbursed. If you choose not to travel, the researcher can visit you at home, and outside working hours if you are at work.

Will my taking part in the study be kept confidential?

Yes. We will follow established ethical and legal practices, and all information about you will be handled in confidence.

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

If you withdraw from the study, the information collected up to then cannot be removed, and may still be used in the study. You can continue to be treated by the Nottingham Back and Pain Team if you wish.

If you withdraw from the Nottingham Back and Pain Team programme at any stage, you will still be able to continue with the study.

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised.

What if there is a problem?

If you have any concerns about the study, ask to speak to the researcher who will do her best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. The contact numbers are given at the end of this document.*

(continues over)

NHS bodies are liable for clinical negligence and other negligent harm to individuals covered by their duty of care. NHS institutions employing researcher are liable for negligent harm caused by the design of studies they initiate.

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised.

Will my GP know about me being involved in the study?

Yes. Your GP will know that you are being treated by the Nottingham Back and Pain Team, and about the research study. Your GP will not be informed of any personal details that you give to the researcher.

Will anyone else know about me being involved in the study?

If another healthcare professional, apart from your GP, has referred you to the Nottingham Back and Pain Team, we will inform them that you are involved in the study. This other healthcare professional will not be informed of any personal details that you give to the researcher.

What will happen to the results of the research study?

It is intended that the results of the study will be published formally in scientific journals. We will send all participants in the study a summary of the results if you wish. You will not be identified in any report/publication.

Who is organising and funding the research?

The research is being funded by a charity called the Arthritis Research Campaign (arc), who will pay the salary of the researcher. There is a 'steering group' which meets regularly to advise the researcher. The group includes experienced research therapists, a local GP, and a patient who has been treated by the Nottingham Back and Pain Team.

Who has given permission for the study to be carried out?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by the Derbyshire Research Ethics Committee.

Further information and contact details for the study:

Carol Coole, Research Occupational Therapist

Division of Rehabilitation and Ageing, Queens Medical Centre, Nottingham NG7 2UH

Tel. 0115 8230247 email: carolyn.coole@nottingham.ac.uk

*** NHS Complaints Procedure**

If you are unhappy with the study, and wish to make a complaint, you can contact the following:

- **Patient Advice and Liaison Service (PALS)** at Nottingham City Hospital: Freephone – 0800 052 1195 or
- **NHS Direct** 0845 4647

APPENDIX 9

Patient Questionnaire

Patient Identification Number:



The University of
Nottingham

Nottingham University Hospitals 
NHS Trust



Working Well with Back Pain

Questionnaire for participants

The questions in this booklet ask you about:

- **Your back pain**
- **Your general health**
- **Your work**
- **Personal details**

The information you give will be treated confidentially.

Please read the instructions given on each page.

Unless the instructions state otherwise, please answer as to how you are today.

Thank you for taking the time to complete the questionnaire.

Please return the completed questionnaire
in the stamped addressed envelope provided to:

Carol Coole
Research Occupational Therapist
Working Well with Back Pain
Division of Rehabilitation and Ageing
B Floor, Medical School
Queen's Medical Centre
Nottingham NG7 2UH

These questions are about your back pain.

1. How long have you had back pain?

.....YearsMonths

2. How long have you been concerned about your ability to work due to back pain?

..... YearsMonths

3. How did your back pain start? (please tick one box)

Gradually

Accident at work

Accident (not at work)

Suddenly (not due to an accident)

4. How would you rate your pain on a 1-10 scale **today**, that is right now, where 0 is "no pain" and 10 is "pain as bad as it could be"?

(please circle one number only e.g. 3)

No pain

Pain as bad as
it could be

0 1 2 3 4 5 6 7 8 9 10

5. In the past 6 months, how intense was your pain **at its worst** on a 1-10 scale where 0 is "no pain" and 10 is "pain as bad as it could be"?

(please circle one number only e.g. 3)

No pain

Pain as bad as
it could be

0 1 2 3 4 5 6 7 8 9 10

6. In the past 6 months, how intense was your pain **at its best** on a 1-10 scale where 0 is "no pain" and 10 is "pain as bad as it could be"?

(please circle one number only e.g. 3)

No pain

Pain as bad as
it could be

0 1 2 3 4 5 6 7 8 9 10

These questions are about your back pain.

Below are some sentences that people have used to describe themselves when they have back pain. When you read them, you may find some stand out because they describe you. Circle the number of each sentence that applies to you today e.g. 4

- 1 I stay at home most of the time because of my back
- 2 I change position frequently to try and get 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 more often
- 7 Because of my back I have to hold on to something to get out of an easy chair
- 8 Because of my back I try to get other people to do things for me
- 9 I get dressed more slowly than usual because of my back
- 10 I only stand up 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 most of the time
- 14 I find it difficult to turn over in bed because of my back
- 15 My appetite is not very good because of my back pain
- 16 I have trouble putting on my socks (or stockings) because of the pain in my back
- 17 I only walk short distances because of my back
- 18 I sleep less well because of my back pain
- 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 bed-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

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

0 1 2 3 4 5 6
Not at all confident Completely confident

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

0 1 2 3 4 5 6
Not at all confident Completely confident

7. I can cope with my pain without medication.

0 1 2 3 4 5 6
Not at all confident Completely confident

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

0 1 2 3 4 5 6
Not at all confident Completely confident

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

0 1 2 3 4 5 6
Not at all confident Completely confident

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

0 1 2 3 4 5 6
Not at all confident Completely confident

Here are some things which other patients have told us about their pain. For each statement please circle any number from 0 to 6 to say how much your normal work affects, or would affect your back pain.

	Completely disagree	1	2	3	4	5	6	Completely agree
1. My pain was caused by my work or by an accident at work	0	1	2	3	4	5	6	
2. My work aggravated my pain	0	1	2	3	4	5	6	
3. I have a claim for compensation for my pain	0	1	2	3	4	5	6	
4. My work is too heavy for me	0	1	2	3	4	5	6	
5. My work makes (or would make) my pain worse.....	0	1	2	3	4	5	6	
6. My work might harm my back	0	1	2	3	4	5	6	
7. I should not do my normal work with my present pain	0	1	2	3	4	5	6	
8. I cannot do my normal work with my present pain	0	1	2	3	4	5	6	
9. I cannot do my normal work until my pain is treated	0	1	2	3	4	5	6	
10. I do not think that I will be back to my normal work within 3 months	0	1	2	3	4	5	6	
11. I do not think that I will ever be able to go back to that work	0	1	2	3	4	5	6	

These questions are about working with back pain.

Please tick one box in each section

1.

<i>To what extent is your ability to do your ordinary work reduced by your back pain?</i>	A great deal	<input type="checkbox"/>
	A lot	<input type="checkbox"/>
	Some	<input type="checkbox"/>
	Not much	<input type="checkbox"/>
	Very little	<input type="checkbox"/>

2.

<i>To what extent is your ability to carry out <u>any</u> paid work reduced by your back pain?</i>	A great deal	<input type="checkbox"/>
	A lot	<input type="checkbox"/>
	Some	<input type="checkbox"/>
	Not much	<input type="checkbox"/>
	Very little	<input type="checkbox"/>

3.

<i>If you continue to work, to what extent will that affect your back pain?</i>	A great deal	<input type="checkbox"/>
	A lot	<input type="checkbox"/>
	Some	<input type="checkbox"/>
	Not much	<input type="checkbox"/>
	Very little	<input type="checkbox"/>

4.

<i>To what extent does your back pain affect your health and well-being?</i>	A great deal	<input type="checkbox"/>
	A lot	<input type="checkbox"/>
	Some	<input type="checkbox"/>
	Not much	<input type="checkbox"/>
	Very little	<input type="checkbox"/>

5.

<i>How many of your work activities and duties are affected by your back pain?</i>	A great many	<input type="checkbox"/>
	A lot	<input type="checkbox"/>
	Some	<input type="checkbox"/>
	Not many	<input type="checkbox"/>
	Very few	<input type="checkbox"/>

6.

<i>How concerned are you about your ability to continue working due to back pain?</i>	A great deal	<input type="checkbox"/>
	A lot	<input type="checkbox"/>
	Some	<input type="checkbox"/>
	Not much	<input type="checkbox"/>
	Very little	<input type="checkbox"/>

7.

<i>Does your work involve a lot of physical effort?</i>	A great deal	<input type="checkbox"/>
	A lot	<input type="checkbox"/>
	Some	<input type="checkbox"/>
	Not much	<input type="checkbox"/>
	Very little	<input type="checkbox"/>

8.

<i>Do other health conditions affect your health and well-being?</i>	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
	Don't know	<input type="checkbox"/>

These questions are about your general health.

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

- I have no problems in walking about
- I have some problems in walking about
- I am confined to bed

Self-Care

- I have no problems with self-care
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

Usual Activities (*e.g. work, study, housework, family or leisure activities*)

- I have no problems with performing my usual activities
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

Pain/Discomfort

- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

Anxiety/Depression

- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed

These questions are about your general health.

Please only tick one box per question.

The following questions are about activities you might do in a typical day. Does <u>your health</u> <u>now limit you</u> in these activities? If so, how much?		Yes, limited a lot	Yes, limited a little	No, not limited at all
1	<u>Vigorous activities</u> , such as running, lifting heavy object, participating in strenuous sports			
2	<u>Moderate activities</u> , such as moving a table, pushing a vacuum cleaner, bowling or playing golf			
3	Bathing or dressing yourself			

During the Past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

		All of the time	Most of the time	Some of the time	A little of the time	None of the time
4	Were limited in the kind of work or other activities?					

During the Past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious?)

		All of the time	Most of the time	Some of the time	A little of the time	None of the time
5	Accomplished less than you would like					

6 How much bodily pain have you had in the past 4 weeks?

None Very mild Mild Moderate Severe Very severe

7 During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

None Very mild Mild Moderate Severe Very severe

These questions are about how you feel and how things have been with you during the Past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks.....

		All of the time	Most of the time	Some of the time	A little of the time	None of the time
8	Have you been very nervous?					
9	Did you have a lot of energy?					
10	Have you felt downhearted and depressed?					

11 During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time Most of the time Some of the time A little of the time None of the time

These questions are about your general health.

Read each item and tick the reply that comes closest to how you have been feeling IN THE PAST WEEK. Do not take too much time over your replies; your immediate reaction to each item will be more accurate than a long thought out response.

I feel tense or "wound up":

- Most of the time
- A lot of the time
- From time to time, occasionally
- Not at all

I still enjoy the things I used to enjoy:

- Definitely as much
- Not quite so much
- Only a little
- Hardly at all

I get a sort of frightened feeling as if something awful is about to happen:

- Very definitely and quite badly
- Yes but not too badly
- A little, but it doesn't worry me
- Not at all

I can laugh and see the funny side of things:

- As much as I always could
- Not quite as much now
- Definitely not so much now
- Not at all

Worrying thoughts go through my mind:

- A great deal of the time
- A lot of the time
- Not too often
- Very little

I feel cheerful:

- Never
- Not often
- Sometimes
- Most of the time

I can sit at ease and feel relaxed:

- Definitely
- Usually
- Not often
- Not at all

I feel as if I am slowed down:

- Nearly all the time
- Very often
- Sometimes
- Not at all

I get a sort of frightened feeling like butterflies in the stomach:

- Not at all
- Occasionally
- Quite often
- Very often

I have lost interest in my appearance:

- Definitely
- I don't take as much care as I should
- I may not take as much care
- I take as much care as ever

I feel restless as if I have to be on the move:

- Very much indeed
- Quite a lot
- Not very much
- Not at all

I look forward with enjoyment to things:

- As much as I ever did
- Rather less than I used to
- Definitely less than I used to
- Hardly at all

I get a sudden feeling of panic

- Very often indeed
- Quite often
- Not very often
- Not at all

I can enjoy a book, or radio, or TV programme:

- Often
- Sometimes
- Not often
- Very seldom

4. Is your health condition a hindrance to your ability to work?

Circle **more than one** alternative if needed

There is no hindrance/ I have no diseases/conditions	6
I am able to do my job, but it causes some symptoms	5
I must (or would have to) sometimes slow down my work pace or change my work methods	4
I must (or would have to) often slow down my work pace or change my work methods	3
Because of my condition, I feel I am able to do only part-time work	2
In my opinion, I am entirely unable to work	1

5. Absence from work due to ill health during the past year (12 months)

How many whole days have you been off work, or unavailable for work, because of a health problem (disease or healthcare or for examination) during the past 12 months?

None at all	5
At the most 9 days	4
10-24 days	3
25-99 days	2
100-365 days	1

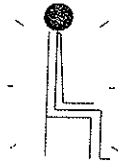
6. Do you believe that from the standpoint of your health, you will be able to work two years from now?

Unlikely	1
Not certain	2
Relatively certain	3

These questions are about your usual work.

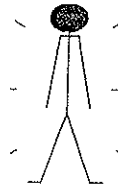
For each question please tick one box that best describes your usual work.

1. Does your work involve **sitting in one position** for 30 minutes or more without a break?



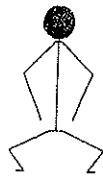
- Never
Occasionally
Half the time
Always / most of the time

2. Does your work involve **standing in one position** for 30 minutes or more without a break?



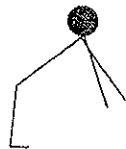
- Never
Occasionally
Half the time
Always / most of the time

3. Do you **squat** as part of your job?



- Never
Occasionally
Half the time
Always / most of the time

4. Do you carry out tasks which involve **bending forwards** in an uncomfortable position?



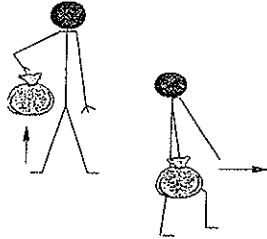
- Never
Occasionally
Half the time
Always / most of the time

5. Does your work involve **stretching downwards** below knee level?



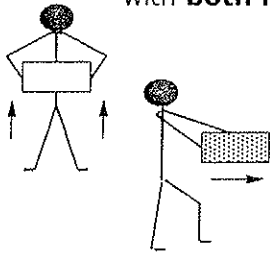
- Never
Occasionally
Half the time
Always / most of the time

6. Does your work involve **lifting or carrying** weights of 25lb (11kg) with only one hand? (equivalent to the weight of a full small suitcase)



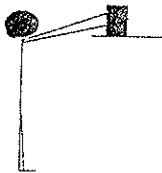
- Never
- Occasionally
- Half the time
- Always / most of the time

7. Does your work involve **lifting or carrying** weights of 50lbs (22kgs) with **both hands**? (equivalent to the weight of a full large suitcase)



- Never
- Occasionally
- Half the time
- Always / most of the time

8. Does your work involve **lifting or carrying** weights of 25lbs (11kgs) **at or above shoulder level**? (equivalent to the weight of a full small suitcase)



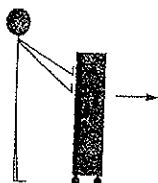
- Never
- Occasionally
- Half the time
- Always / most of the time

9. Does your work involve **lifting or carrying** weights of 50lbs (22kgs) **on one shoulder**? (equivalent to the weight of a full large suitcase)



- Never
- Occasionally
- Half the time
- Always / most of the time

10. Does your work involve **pushing** weights of 100lbs (44kgs)? (equivalent to the weight of a washing machine)



- Never
- Occasionally
- Half the time
- Always / most of the time

Personal Information.

Please could you provide us with the following information:

1. Sex: Male Female 2. Date of birth:/...../.....
Day Month Year

3. What is your ethnic origin? (please tick one box only)

White

- English Scottish Welsh
 Other British, please specify
 Irish
 Any other White background, please specify

Mixed

- White and Black Caribbean
 White and Asian White and Black African
 Any other Mixed background, please specify

Asian or Asian British (Asian English, Asian Scottish or Asian Welsh)

- Indian Pakistani Bangladeshi
 Any other Asian background, please specify

Black or Black British (Black English, Black Scottish or Black Welsh)

- Caribbean African
 Any other Black background, please specify

Chinese or Chinese British (Chinese English, Chinese Scottish, Chinese Welsh)

- Chinese
 Any other Chinese background, please specify

Any other background (not listed above)

- Please specify

Personal Information (continued)

Questions 6 and 7 ask about your income. This information will help us in understanding the economic costs of back pain. Please remember that this information will be treated confidentially.

6. Please could you indicate which income band your approximate individual income would fall in, **before** tax has been deducted. Tick one box only

Less than £10,000	<input type="checkbox"/>
£10,000 - £19,999	<input type="checkbox"/>
£20,000 - £29,000	<input type="checkbox"/>
£30,000 - £39,000	<input type="checkbox"/>

£40,000 - £49,000	<input type="checkbox"/>
£50,000 - £59,000	<input type="checkbox"/>
£60,000 - £69,000	<input type="checkbox"/>
£70,000 or above	<input type="checkbox"/>

7. Please could you indicate which income band your approximate household income would fall in (i.e. combined with spouse/partner), **before** tax has been deducted.

Less than £10,000	<input type="checkbox"/>
£10,000 - £19,000	<input type="checkbox"/>
£20,000 - £29,000	<input type="checkbox"/>
£30,000 - £39,000	<input type="checkbox"/>

£40,000 - £49,000	<input type="checkbox"/>
£50,000 - £59,000	<input type="checkbox"/>
£60,000 - £69,000	<input type="checkbox"/>
£70,000 or above	<input type="checkbox"/>

8. Has your back pain led to you being involved in any financial claims during **the last 6 months?**

Please tick one box for each (a) (b) and (c).

Type of claim	None	Under consideration	Involved	Completed (if so, for what sum?)
(a) Claim against employer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(b) Insurance claim	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(c) Claim/appeal for benefits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Personal Information (continued)

Please remember that this information will be treated confidentially.

9. Please tick one box which best describes your highest academic qualification.

Secondary school (no formal qualifications)

GCSE, 'O' levels or equivalent

Further education, e.g. 'A' levels, diploma, or equivalent

Higher education, e.g. degree or equivalent

10. What is your marital status? (please tick one box)

never married (includes co-habiting)

married (includes remarried and separated)

divorced

widowed

11. What are your living arrangements? (please tick one box)

alone

with adults

with children

with adults and children

12. This study is comparing two types of treatment:

1. Usual treatment
2. Usual treatment plus extra support for work problems

Patients taking part in the study have been allocated randomly to each group, because we don't know which treatment works best. We would like to know, if you had been given the choice, which treatment you would have preferred to receive, or whether you had no preference.

Please place a tick in one of the boxes below which best describes your preferred treatment:

I would have preferred to have usual treatment

I would have preferred usual treatment plus extra support for work problems

I have no preference

Now please give today's date: ____ / ____ / 20____

THANK YOU VERY MUCH FOR TAKING THE TIME TO COMPLETE THIS QUESTIONNAIRE

Please return the completed questionnaire
in the stamped addressed envelope provided to:

Carol Coole
Research Occupational Therapist
Working Well with Back Pain
Division of Rehabilitation and Ageing
B Floor, Medical School
Queen's Medical Centre
Nottingham NG7 2UH

APPENDIX 10

Telephone interview schedule

Working Well with Back Pain

Schedule for Telephone Interview (baseline and 6 months)

Introduction

- Thank you for agreeing to this telephone interview today
 - It is important that you know that everything you say during this interview will be treated confidentially. Your name will not be recorded in connection with your replies and therefore anything you say cannot be identified as coming from you.
 - Do you have any questions before we start?
1. Are you still in the same job as you were 6 months ago?
 2. Are you self-employed, or do you work for someone else?
 3. If you are employed, about how many other people are employed by the company?
 4. How many days and hours would you work in a typical week in your usual work?
 5. Over the last 6 months, have you been able to do all of your usual hours and duties?
 6. Have there been any days when you have been unable to do some or all of your usual duties and/or have had to ask for help because of your back pain?
 - How many days in the last 6 months?
 - On those days, how much less productive do you think you have been compared to someone in perfect health? (hours over the day, or percentage of time)
 7. Have there been any days in the last 6 months when you have been unable to work your usual hours because of your back pain?
 - How many days in the last 6 months?
 - How many hours less did you work?
 8. Have you taken any sick leave because of your back pain over the last 6 months?
 - How many hours/days/episodes?
 - How many of these did you have a sick note for?

9. Have you taken time off work due to back pain in the past – previous to the last 6 months?

10. Over the last 6 months, have you been to see any health care professionals, including your GP about your back pain?
 - e.g. physio, counsellor, nurse, osteopath, chiropractor, consultant, A & E, walk-in centre, etc
 - private or NHS?
 - How many visits/if private, how much
 - Have you had any interventions e.g. blood tests, X rays, scans, injections, surgery? Which hospital? Number of days in hospital?

11. During the last 6 months, has your GP prescribed you any medication for your back pain (may include antidepressants) If so:
 - Name of medicine and strength of tablet
 - Number of tablets taken per day
 - Number of days taken

12. During the last 6 months have you bought any over-the-counter medicines or other treatments or equipment to help treat your back pain?
 - Items bought and cost

APPENDIX 11

Post-trial patient interview schedule

Working Well with Back Pain

Schedule for Post-trial interview (with independent researcher)

Welcome and introduction

- Thank you for agreeing to meet with me today. I want to find out your experience of taking part in this research study. This will help in planning further research in the future.
- Everything you say during this interview will be treated confidentially. Your name will not be mentioned on any published documents, and anything you say cannot be identified as coming from you. Your participation in this interview will not affect your work, or any benefits you might be on, or any services you receive. Any comments you have about the team, or about the people involved research study will not be personally identifiable. I am an independent interviewer – I am not employed by the back team. I am not a member of the team that are carrying out the research study.
- It is difficult to engage in a conversation with someone and take notes at the same time – are you happy for me to record this interview? The recording will only be used by the University to report and analyse results. It will not be passed on to anyone else. Your name will not be recorded. The recording will be stored securely at the University of Nottingham.
- Do you have any questions before we start?

Topic area	Question areas	Prompts
Introductory question	Are you working at the moment?	<p><i>What job are you doing at the moment?</i></p> <p><i>Is that the same job that you were doing when you joined the study?</i></p> <p><i>If not- what changed and why?</i></p>

<p>Concern about working</p>	<p>How concerned are you now about your ability to work, and to remain at work, with back pain (<i>and/or leg pain</i>)?</p> <p>Do you have any concerns about keeping at work in the <u>future</u> because of your back? If so, <u>what</u> are they?</p> <p>Does working with back pain affect your life outside work? If so what?</p>	<p>More or less concerned than at start of study?</p> <p>Concerns about staying in same job? Having to get a different job – either because of back pain or due to economic situation?</p> <p>How will you manage to stay at work if you have a flare-up of your back pain?</p>
<p>Help in returning to/staying in work</p>	<p><u>If at work</u> What/who has helped you remain at work? Why? Why not?</p> <p><u>If not at work, or in a new job now</u> What might have helped you stay in your previous job?</p> <p><u>If off sick</u> What would help you get back to work?</p> <p>Do other people in your line of work have back pain – is it a common problem – if so why?</p>	<p>What has your employer done to help you stay at work with back pain? What have you said to your employer about your back pain? (if not disclosed – why?)</p> <p>What help has your GP given you <u>about work</u>? What have you said to your GP about your back pain? (if not disclosed – why?)</p> <p>How helpful have your colleagues been? What have you said to your colleagues about your back pain? (if not disclosed – why?)</p> <p>What about occupational health? Is it available? Has it been accessed? How helpful? What did they do?</p> <p>To what extent have you had to rely on your own efforts to stay at work?</p>

	<p>How are people with back pain viewed where you work – are people understanding, sympathetic – or not?</p> <p>What changes could be made to help you stay in your job?</p>	<p>What else could be done to help keep you working? Anything anyone can help you with – through work or the health service?</p> <p>Modifications to tasks, environment, hours, breaks, equipment?</p>
<p>Take up of <u>routine group treatment</u></p>	<p>Did you go to the <u>group treatment</u> programme run by Nottingham Back and Pain Team?</p> <p>Why? Why not?</p>	<ul style="list-style-type: none"> - If not – what were your reasons – e.g. too busy, forgot, unsure of the arrangements, personal circumstances, didn't think it would help? - Employer supportive? Allowed time off?
<p>Experience of <u>routine group treatment</u></p>	<p>How useful was the group treatment from the Nottingham Back and Pain Team in addressing your concerns about work?</p> <p>How did they help you with your work problems?</p> <p>What was most useful in helping you manage at work?</p> <p>What else might have been helpful – or should have been included as regards your concerns about work?</p>	<ul style="list-style-type: none"> - content, type, amount of help given re: work More direct contact with your work?

<p>Experience of individual work support if received.</p>	<p>In this research study, some people were offered extra support to help them with their concerns about work. This support was from Carol Coole. You may have met with her here, or at work, at home, or at Queens Medical Centre. She wasn't part of the group treatment.</p> <p>Were you offered this?</p> <p>Would you have wanted it?</p> <p>How useful was it?</p> <p>What was useful? Why?</p> <p>Did it meet your expectations?</p> <p>What else might have been helpful?</p>	<ul style="list-style-type: none"> - How much difference did it make? - Visit to workplace - Help with solving problems - Meetings with employers - Advice for/education of employers - Referral to other services
	<p>What did you think about:</p> <p>What did you think of the number of sessions you had with Carol Coole, did you have enough?</p> <p>Was it convenient?</p> <p>Were you able to make use of any of the information and advice you were given about work? How did you use it to help you manage at work?</p>	<ul style="list-style-type: none"> - Was 16 weeks too long/too short? - Were the sessions too long/too short - Were these convenient? - Was the support given too early/too late? - What did other people think about it – your family, employer, colleagues, GP etc?

Topic area	Question area	Prompts
The research study	<p>What did you think of the way the study was organised? (make it clear this is different from the Nottingham Back Team treatment)</p> <p>Did you get enough information about the study at your first appointment with the back team?</p> <p>Did Carol give you enough information about it when she rang you? (show information sheet)</p>	<ul style="list-style-type: none"> - Did you get enough information at the assessment? - What did you think of the Information Booklet? - How might the organisation of the study have been improved? - Could it have been explained better?
Collecting information	<p>What did you think of the questionnaire? (independent researcher to have copy of questionnaire to hand for prompting)</p> <p>What did you think of the questions you had to answer by phone? (independent researcher to have copy of telephone interview questions to hand for prompting)</p>	<ul style="list-style-type: none"> - How easy/difficult was it to complete? - How relevant was it? - What about the length and layout? - What do you think could have been left out? - What else could have been included? - What was it like to answer the questions on the phone? Did you mind, could you answer them easily enough? How convenient was it?
Closing question: Experience of the study and recommendations/suggestions	<p>Is there anything else you'd like to mention that we haven't covered?</p> <p>Are there any other comments or suggestions you would like to make about the study?</p>	<ul style="list-style-type: none"> - What would you change? - What would you have preferred?

	<p>Are there any other comments or suggestions you would like to make about how people might be helped to stay at work with back pain?</p>	<p><i>Have you had enough help regarding work?</i></p>
<p>Thank you</p>	<p>Thank you very much for taking part in this interview, and for taking part in the study. When all the results have been collected and analysed, you will be sent a summary of the findings if you would like that (Pt will have indicated on consent form).</p>	