TREATMENT SATISFACTION AND DISSATISFACTION IN PATIENTS WITH CHRONIC LOW BACK PAIN

A thesis submitted for the degree of Doctor of Philosophy

by

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Abstract

This thesis explores treatment satisfaction and dissatisfaction in patients with chronic low back pain (CLBP).

Chapters 1 and 2 provide background on CLBP, and treatment satisfaction and dissatisfaction.

Chapter 3 presents study 1, the systematic review which identified research concerning treatment satisfaction and dissatisfaction in patients with CLBP. Findings indicated a need to define the concept, and establish appropriate measurement based on patient input and evidence to support the reliability and validity of items.

Chapter 4 presents study 2, a qualitative study. Ten patients with CLBP taking medication and/or receiving physiotherapy were interviewed. A conceptual model of CLBP and a thematic map of treatment satisfaction and dissatisfaction were developed. Satisfaction was related to being ‘happy’ or ‘pleased’, and maintaining normal functioning. Treatment not working, causing discomfort, or negatively affecting health-related quality of life, as well as inconvenience of medication, lack of information, not feeling involved in treatment decisions, lack of trust and confidence in healthcare professionals, and being misdiagnosed or undiagnosed, were associated with dissatisfaction.

Chapter 5 documents the development of the CLBP Treatment Satisfaction Questionnaire, based on patient input from study 2. Cognitive debriefing showed items were relevant and understood by patients.

Chapter 6, study 3, explored the psychometric properties of the questionnaire. The longitudinal design involved data collection from 249 patients, some of whom participated in follow-ups. Results indicated that treatment satisfaction/dissatisfaction involves an appraisal of the following seven domains: ‘Information Provided about Back Pain and Treatment, ‘Burden of Back Pain’, ‘Impact of Back Pain and Treatment on Relationships’, ‘Satisfaction with the Treatment Process’, ‘Problems with Side Effects of Medication’, ‘Adherence to Physiotherapy’, and ‘Medication Acceptability’. Some evidence of reliability and validity are presented.

This thesis concludes with Chapter 7, a discussion of the main findings of the studies, strengths and limitations, and recommendations for future research.

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Abbreviations

ADLs	Activities of Daily Living
ANOVA	Analysis of Variance
BEST	Bio-Energetic Syncronisation Technique
BPS	British Psychological Society
CAM	Complementary and Alternative Medicine
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CLBP	Chronic Low Back Pain
EDSQ	Eye Drop Satisfaction Questionnaire
EOS	End of Study
ESP	Extended Scope Practitioner
ES	Effect Size
FA	Factor Analysis
FDA	Food and Drug Administration
GP	General Practitioner
HCP	Health Care professional
HIV	Human Immunodeficiency Virus
HMSO	Her Majesty’s Stationery Office
HRQoL	Health-Related Quality of Life
HSE	Health and Safety Executive
ICC	Intraclass Correlation Coefficient
ICT	Iron Chelation Therapy
IPA	Interpretive Phenominological Analysis
KMO	Kaiser-Meyer-Olkin Measure
LBP	Low Back Pain
MD	Missing Data
MLR	Multiple Linear Regression
MRI	Magnetic Resonance Imaging
NC	Not Classified
NCQA	National Committee for Quality Assurances
NHS	National Health Service
NSAIDs	Non-Steroidal Anti-Inflammatory Drugs
NSAIMs	Non-Steroidal Anti-Inflammatory Medicines

OPCS	Office of Population Censuses and Survey
PCA	Principal Components Analysis
PETS	Problematic Experiences of Therapy Scale
PGI	Patient Global Impression
PMP	Pain Management Programme
PPI	Present Pain Intensity Scale
PRO	Patient-Reported Outcome
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
RMDQ	Roland and Morris Disability Questionnaire
SATMED-Q	Treatment Satisfaction and Medicines Questionnaire
SD	Standard Deviation
SF-36	Short Form 36-Item Health Survey
SF-MPQ	Short Form Pain McGill Questionnaire
SICT	Satisfaction with Iron Chelation Therapy
SMOG	Simplified Measure of Gobbledygook
SPSS	Statistical Package for Social Scientists
SSRIs	Selective Serotonin Reuptake Inhibitors
SWAM	Satisfaction With Antipsychotic Medication
TCAs	Tricyclic Antidepressants
TENS	Transcutaneous Electrical Nerve Stimulation
TSQM	Treatment Satisfaction Questionnaire for Medication
VAS	Visual Analogue Scale

Chapter 1 - An Overview of Chronic Low Back Pain

The aim of this Chapter is to provide an overview of chronic low back pain (CLBP) including definitions of CLBP, prevalence and aetiology of CLBP, predisposing factors of CLBP, the management and treatment options of CLBP, as well as direct and indirect cost implications of CLBP.

1.1 Definition of CLBP

Low back pain is defined as pain, tension in the muscles, or stiffness between the rib cage and the top of the thighs, with or without sciatica (leg pain) (see for example, Loney & Stratford, 1999). There is an ever-growing body of literature on low back pain, but there is less information about CLBP (Andersson, 1999). One possible reason for this is that the symptoms of CLBP are quite varied and are sometimes described as feelings of shooting, stabbing, tingling or numbness. The pain can be localized or related to another part of the body (Stop Pain, 2008. What are the Symptoms? section, para. 1). In addition to back pain, many individuals experience limited range of motion, some cannot function as they would like to, and some may experience fever or weight loss indicative of illness (Stop Pain, 2008. What are the Symptoms? section, para. 1). Psychological symptoms may also occur, and depression has been shown to be three or four times more prevalent in patients with CLBP compared to the general population (Sullivan, Reesor, Mikail, & Fisher, 1992).

Though there is ambiguity and a lack of consensus regarding the transition from acute to chronic pain (Cedraschi et al., 1999; Andersson, 1999; Skevington, 1996), the duration of symptoms is characteristic of CLBP. For example, some suggest ‘chronicity’ is back pain that lasts beyond the expected period of healing (Andersson, 1999), or that which lasts more than seven weeks (Andersson, 1999; Spitzer, Leblanc, & Dupuis, 1987).

Others have referred to CLBP as pain lasting at least half the days in a 12-month period in single or multiple episodes (Von Korff, 1994). However, more commonly, CLBP is defined as ‘persistent’ or ‘sustained’ low back pain lasting more than three months or twelve weeks (Frank, 1993; Nachemson & Bigos, 1984; Frymoyer, 1988; Bogduk & McGuirk, 2002; Bogduk, 2004; Wheeler, 1995).

Warning signs for individuals with CLBP include severe pain that gets worse over several weeks instead of better, as well as the following symptoms: difficulty passing or controlling urine; numbness around the back passage or genitals; general numbness, pins and needles, or weakness in both legs; and unsteadiness on feet (Roland, Waddell, Moffett, Burton, & Main, 2007).

1.2 Prevalence of CLBP

Almost half the adult population in the U.K. (49%) reported experiencing low back pain lasting for at least twenty-four hours over the last year (Palmer, Walsh, Bendall, Cooper, & Coggon, 2000), and it is estimated that 80% of the adult U.K. population will experience back pain at some stage in their life (Maniadakis & Gray, 2000). Further, a Department of Health study showed that two and a half million people in the U.K. reported back pain that lasted throughout the year (i.e. chronic) (The Department of Health Statistics Division, 1999). These figures show that CLBP is a significant public health problem.

1.3 Aetiology of CLBP

CLBP is usually classed by clinicians as ‘specific’ or ‘non-specific’ (Nordin, Balague, & Cedraschi, 2006). A ‘specific’ diagnosis infers that there is a causal link between the pain experienced by the individual and a structural problem (e.g. systemic disease, infection, injury, trauma, or structural deformity) (Nordin et al., 2006). Individuals may have experienced pulled or strained muscles, ligaments, tendons, or ruptured discs. These may be cumulative effects of (for example) poor posture, and/or improper lifting techniques over periods of weeks, months, or years (Hunter, 1998; Mckenzie, 1986; Key, 2000). A definite somatic cause of low back pain is identified in about 10% to 20% of cases (Cedraschi et al., 1999). In clinical practice, ‘red flags’ are used to indicate possible underlying pathology and includes nerve root problems (Table 1) (Koes, van Tulder, & Thomas, 2006; Kendall, 1999).

Table 1: ‘Red Flag’ Conditions Indicating Possible Underlying Spinal Pathology or Nerve Root Problems (Koes et al., 2006)

Red Flags
• Onset age <20 or > 55 years
• Non-mechanical pain (unrelated to time or activity)
• Thoracic pain
• Previous history of carcinoma, steroids, HIV
• Feeling unwell
• Weight loss
• Widespread neurological symptoms
• Structural spinal deformity
Indicators for nerve root problems
• Unilateral leg pain > low back pain
• Radiates to foot or toes
• Numbness and paraesthesiae [sensation of tingling or prickling]
• Straight leg test induces more leg pain
• Localised neurology (limited to one nerve root)

In the absence of these red flags, a ‘non-specific’ diagnosis is provided to indicate there is no precise structure causing the pain (e.g., lumbago, myofascial syndromes, muscle spasms, back sprain, or back strain) (Nordin et al., 2006). No clear pathology of back pain can be identified in approximately 85% of individuals seeking care (Nachemson, Waddelll, & Norlund, 2000). Healthcare professionals (HCPs) have created a list of ‘yellow flags’ factors that help identify individuals at risk of chronic pain and disability. Examples of ‘yellow flags’ are low mood, workplace issues, or signs of psychosocial barriers to recovery (Koes et al., 2006; Kendall, 1999; Davidson, 2003) (see section 1.4).

1.4 Predisposing Risk Factors of CLBP

Predisposing risk factors are any characteristics that might make an individual susceptible to a condition (Drummond, Obrien, Stoddart, & Torrance, 1987). There are three main types of predisposing factors (primary, secondary, and tertiary) that differ according to the population that they impact (Gatchel, Polatin, & Kinney, 1995). Primary predictors identify the percentage of an ‘uninjured population’ who are likely to incur a LBP incident. However, since the focus of this thesis is on CLBP, primary predisposing factors are generally beyond the scope of this review. This review focuses on secondary predictors, which identify individuals with an acute LBP incident who are most likely to develop chronic problems, and tertiary predictors, which relate to factors that determine the likelihood of treatment success or failure in an individual with CLBP (Gatchel et al., 1995).

Gatchel et al (1995) studied secondary factors in a prospective study in 324 acute low back patients that explored CLBP disability problems (as measured by job-work status at six months follow-up) using clinical predictors of psychopathology (pain and disability, and whether individuals had experienced at least one personality disorder). The logistic regression model accurately identified 87% of cases of CLBP disability and concluded that age, race, pain, disability, and personality disorders were linked to not working due to the original back injury. Specifically, individuals who were older, with higher pain levels, non-Caucasian, and those with at least one personality disorder were more likely to be in the disabled group. In addition, a post hoc exploration of medical reviews of patients' charts showed that the severity of initial acute back injury may be related to not returning to work after six months, although these results did not reach statistical significance. One possible reason for not reaching statistical significance is that the post hoc analysis groups (disabled versus non-disabled group) comprised 20 randomly selected patients each, and consequently the sample size may not have warranted sufficient power to determine statistical significance between groups. Another explanation for this is that the analysis was performed retrospectively, and a physician who had been uninformed about the return-to-work status of patients was required to rate physical signs of severity on a five-point Likert scale, from one (minor) to five (severe). Consequently the physician rating as a proxy of patients' experiences may not have been an accurate reflection of severity of back injury.

Other secondary variables include proficiency in English (Lacroix et al., 1990), wage level (Volinn, Van Koevering, & Loeser, 1991; Deyo & Tsui-Wu, 1987), educational level (Deyo & Tsui-Wu, 1987; van Tulder, Assendelft, Koes, & Bouter, 1997), obesity (van Tulder et al., 1997), the workplace environment such as the type of chair used (Link, Nicholson, Shaddeau, Birch, & Gossman, 1990), prolonged sitting (Ratzon, Jarus, Baranez, Gilutz, & Erez, 1998), and time spent seated at work due to computerisation (Link et al., 1990). Occupational factors such as job dissatisfaction, and unavailability of light duty on return to work are also related to chronicity (van Tulder et al., 1997).

Tertiary predisposing factors are those that determine the likelihood of treatment success or failure in an individual with CLBP (Gatchel et al., 1995). Individuals' beliefs that the pain is stable and unchanging has been linked to poor adherence with physical and psychological treatments (Williams & Thorn, 1989), and Harkapaa (1991) found that when individuals believe they have control over their pain, they are more likely to participate in and benefit from rehabilitation programs. Similarly, those who believe that their pain is controlled by powerful others (e.g. doctor or family member) rather than chance are also more likely to adhere to pain management programmes (Gibson & Helme, 2000). In addition, individuals' beliefs about the cause of their pain and the potential effects of treatment are likely to affect the outcome of treatment (Schwartz, DeGood, & Shutty, 1985).

It should be noted that there are other factors associated with CLBP that can broadly be termed 'psychological' and include personality, psychiatric, behavioural and cognitive aspects. However, these factors are beyond the scope of this thesis.

1.5 Management of CLBP

1.5.1 Treatment Models Used in CLBP

The two most commonly used treatment models in CLBP are the medical model and the biopsychosocial model (Nordin et al., 2006). The medical model proposes that illness is the result of a disturbance to some biological process, such as a chemical imbalance in the brain (See Marks, Murray, Evans & Willig (2000) and Ogden (2000) for reviews). Applying the medical model to CLBP, as well as other illnesses involves the following steps: 1) recognising patterns of symptoms and signs by history and examination; 2) identifying the underlying injury or disease by diagnosis; 3) treating underlying injury or disease by specific therapy; and 4) expecting the patient to recover once the disease or injury is addressed (Nordin et al., 2006). However, the medical model has been critiqued as insufficient to explain the complexities of health and illness (e.g., as cited in Engel (1977) and Engel (1980)).

The medical approach is reductionist, suggesting that complex phenomena (such as CLBP) can be understood in terms of their most basic components. Since illness is seen as a consequence of biological changes that are beyond an individual's control, individuals are not responsible for their illness but are victims of external influences that cause internal changes (see Ogden (2000) for review). The medical model also assumes that health and illness are qualitatively different and independent of each other rather than a continuum, and that the mind and body function independently. The mind is incapable of affecting physical matter (such as muscles and bones), and physical matter are independent of changes in state of mind. For example, under this model, CLBP may cause depression, but depression is not related to either the onset or progression of CLBP.

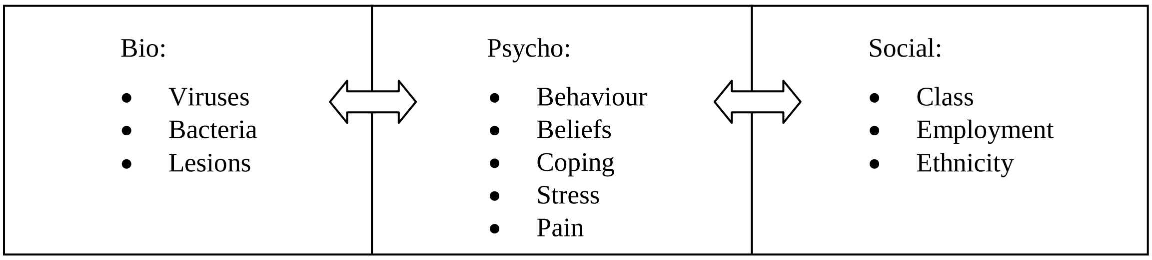
There are two other specific problems with the medical model in CLBP. Firstly, the medical model assumes that prevention or treatment should aim to alter bodily functions (for example, by using medications or surgery). Secondly, the medical model, though widely accepted in the developed world, does not account for very real pain in patients without physical signs, and may, in fact, assume that the patient is malingering (e.g. Ogden (2000)).

Unlike the medical model, the biopsychosocial model attempts to integrate the psychological (the 'psycho') and the environmental (the 'social') elements with the biological medical model (the 'bio') (Figure 1) e.g. Engel (1977). The *bio* factors that contribute to CLBP could include structural defects of the vertebrae. The *psycho* contributing factors could include cognitions such as catastrophising (a tendency to think the worst), emotions such as fear of movement, and behaviours such as restricting activity.

The social aspects include social norms of behaviour, pressures to change behaviour and social values on health, social class, and ethnicity.

The biopsychosocial model for CLBP recognises: 1) the non-specific nature of back pain; 2) identifies underlying psychosocial factors; 3) treats those factors with non-traditional interventions such as behavioural therapy; and 4) empowers patients to take responsibility for managing their CLBP with possible frequent recurrence (Nordin et al., 2006).

Figure 1: The Biopsychosocial Model of Health and Illness (Ogden, 2000)



Since illness is a consequence of a combination of biological, psychological and social factors, the biopsychosocial model assumes that individuals are not passive and thus they are not perceived as victims. For example, the recognition that an individual’s behaviour may contribute to their health and illness places more responsibility on the individual. The biopsychosocial model suggests that rather than focusing on the biological factors alone, the whole individual needs to be treated. Treatment may include, for example, behaviour change, focusing on changing an individual’s beliefs, coping strategies, and adherence to medication regimens. Further, unlike the medical model, the biopsychosocial model suggests that health and illness are not qualitatively different but exist on a continuum, and also that the mind and body interact with and affect each other. Finally, under this model, psychological factors are not only consequences of illness but may also contribute to its aetiology (see Ogden (2000) for review).

Critics have suggested that the biospsychosocial model remains predominantly biomedical and that empirical evidence is needed to establish its theoretical basis (see Ogden (2000) for review). However, whilst there may be precise causal pathways, complicated psychological theories and approaches continue to play an important role in understanding, treating and caring for individuals with CLBP.

1.5.2 Approaches of CLBP Relief

Nearly 40% of individuals with back pain in the UK consulted a GP for help, and 10% visited a complementary therapist (osteopaths, chiropractors, and acupuncturists) (The Department of Health Statistics Division, 1999). How to best achieve CLBP relief and restoration has been debated for at least 30 years (Chew & May, 1999). Clinical aims include relieving pain, improving functioning, developing coping strategies for pain and reducing side effects from medications (Waddell, 1992). There are three main approaches to CLBP relief: monotherapies, multidisciplinary therapy, and reductionism (Bogduk, 2004).

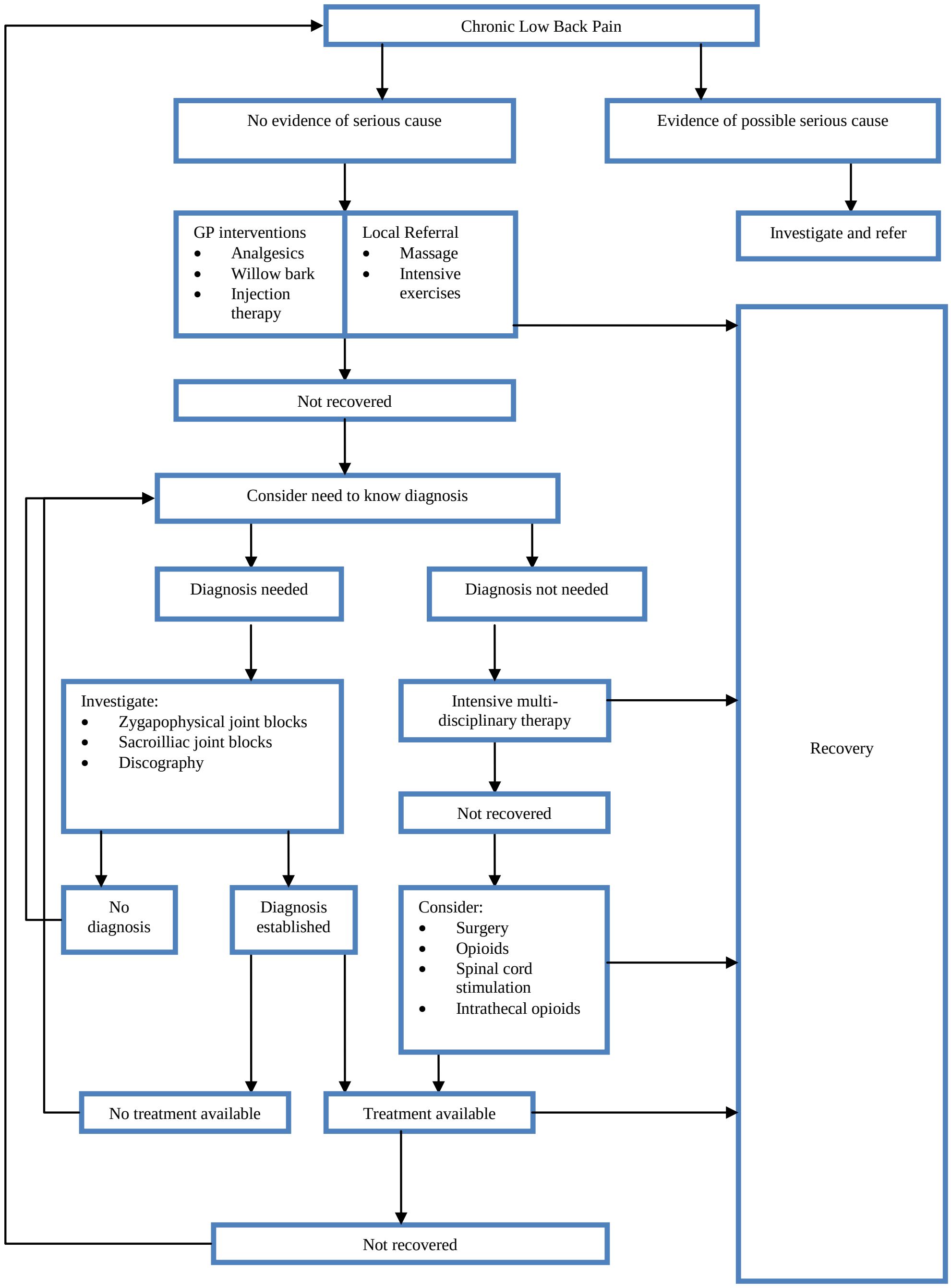
A monotherapy is a particular single intervention prescribed by a healthcare professional (HCP) as sole treatment (Bogduk, 2004). These may range from non-opioid analgesic medications (such as paracetamol, non-steroidal anti-inflammatory drugs (NSAIDs)), opioid analgesic medications and antidepressants, to physiotherapy, chiropractic, osteopathy and back surgery, as well as complementary and alternative therapies (such as acupuncture and tai chi).

Multidisciplinary therapy comprises various combinations of exercises, education, and behavioural therapy. Most programs address physical disabilities and patients’ beliefs about their pain and behaviour (Bogduk, 2004).

Reductionism pursues diagnosis of a specific physical/biological cause of CLBP with the goal of implementing a target-specific treatment (Bogduk, 2004; Bogduk & McGuirk, 2002). One of the outcomes of this approach is its reliance on surgery as a treatment for CLBP.

Bogduk (2004) presented guidance regarding the management of CLBP which is outlined in Figure 2. It should be noted that whilst this guidance provides a good overview of CLBP general practice management, it is not exhaustive and there are methods used in general practice that are not portrayed in Figure 2 such as magnetic resonance imaging (MRI) scans. Further details of the main monotherapies and multidisciplinary therapy are provided in sections 1.5.3 and 1.5.4.

Figure 2: Guidelines for General Practice Management of CLBP (Bogduk, 2004)



1.5.3 Monotherapies

Medications for CLBP Relief

Please note that unless otherwise stated, the information outlined below comes from the British National Formulary (British Medical Association & Royal Pharmaceutical Society of Great Britain, 2009).

Non-opioid analgesics used in CLBP relief include paracetamol. Other commonly used medications for CLBP are non-steroidal anti-inflammatory drugs (NSAIDs), combined analgesics (such as paracetamol with codeine phosphate), skeletal muscle relaxants, and opioid analgesic medications (Chou & Huffman, 2007; Cherkin, Wheeler, Barlow, & Deyo, 1998; Bernstein, Carey, & Garrett, 2004; Luo, Pietrobon, Curtis, & Hey, 2004; Luo, Pietrobon, & Hey, 2004). Benzodiazepines, systemic corticosteroids, and antidepressant medications can also be used in patients with CLBP (Chou & Huffman, 2007).

1) *Paracetamol*

Paracetamol is often used for short term pain relief and is not associated with any anti-inflammatory effects. Although side effects are rare, they include rashes and blood disorders, and following over-dosage, liver damage and possibly renal damage.

2) *NSAIDS*

Other non-opioid analgesics include NSAIDs, also known as non-steroidal anti-inflammatory medicines (NSAIMs). In single doses, NSAIDs have an effect comparable to paracetamol, providing short term pain relief. In regular full dosage, NSAIDs have a lasting anti-inflammatory effect and are therefore often used for continuous or regular pain associated with inflammation. Pain relief starts shortly after taking an NSAID and a complete analgesic effect can be obtained within a week. However, the anti-inflammatory effect may take up to three weeks to be achieved. NSAIDs tend to cause gastro-intestinal effects, nausea, diarrhoea, and possibly bleeding and ulceration. NSAIDs include aspirin, ibuprofen, diclofenic, and naproxen.

3) *Opioid Analgesics*

Opioid analgesics are usually used for the relief of moderate to severe pain. If used frequently, there is potential for dependence and tolerance. Common side effects reported include nausea, vomiting, constipation, and drowsiness. Large doses of opioid analgesics may cause respiratory depression and hypotension. Opioid analgesics include morphine, buprenorphine, codeine, and fentanyl amongst others.

4) *Skeletal Muscle Relaxants*

Skeletal muscle relaxants are used to alleviate chronic muscle spasm or spasticity associated with neurological damage. A major disadvantage is that they cause reduced muscle tone, which can ultimately lead to increased disability. Other potential side effects include sedation, dizziness, confusion, agitation, disorientation, and visual disorders. Skeletal muscle relaxants include baclofen and tizanidine.

In CLBP, benzodiazepines are also used as muscle relaxants that are usually prescribed as anti-anxiety medications. They have to be prescribed in the smallest dosage possible to provide an acceptable level of symptom relief due to the potential for dependency. Paradoxical effects are experienced by patients and range from talkativeness and excitement to aggression and anti-social behaviours. Withdrawal effects may occur up to three weeks after stopping a long-acting benzodiazepine and may include insomnia, anxiety, loss of appetite and body weight, and tremor.

5) *Corticosteriods*

Corticosteroids are steroidal anti-inflammatory medications for pain relief that come in the form of gels, tablets, and injections (for example, prednisolone). Corticosteroids are associated with a number of potential side effects such as sleep disturbance, increased appetite, weight gain, and psychological effects including increased or decreased energy levels. Other side effects include mania, psychosis, heart failure, peptic ulceration, and diabetes.

6) *Antidepressants*

Antidepressants are usually used to help deal with depression including that associated with physical illness such as CLBP. It can also be used as a sedative for pain relief. The major classes of antidepressants include selective serotonin reuptake inhibitors (SSRIs), as well as tricyclics (TCAs) and associated antidepressants. Examples of SSRIs include fluoxetine, paroxetine, escitalopram, citalopram, and sertraline. SSRIs typically have fewer side effects than TCAs. However, SSRIs are associated with gastro-intestinal side effects such as nausea, vomiting, abdominal pain, diarrhoea, and constipation. There are many other potential side effects including decreased sexual functioning and some bleeding disorders. Suicidal thoughts have been linked to SSRIs, but to date their causality has yet to be established with certainty.

Compared to conventional tricyclic antidepressants (TCAs) such as amitriptyline, TCA related antidepressants are associated with fewer side effects such as dry mouth, and constipation. Conventional TCAs are also associated with convulsions, abnormal heart rhythms, and heart block. Other side effects associated with TCAs and related anti-depressants include urinary retention, blurred vision, dizziness, confusion, and sexual dysfunction.

Physiotherapy for CLBP Relief

The cause and type of pain affects the type of physiotherapy chosen for CLBP relief. Physiotherapy includes advice and early activity, mobilisation or manipulative therapy, McKenzie therapy (program of assessment, treatment and prevention strategies including exercise), specific stabilisation exercises, general exercise and stretches, ergonomic advice, and postural advice (Australian Physiotherapy Association, 2003).

Chiropractics and Osteopathy

Chiropractics help individuals with CLBP by manipulating body structures such as the spine to relieve symptoms such as pain. Similarly, osteopathy is focused on the association between structure and function, with the view that pain and difficulty in functioning (even in other parts of the body) are a consequence of problems with structure. Osteopaths use manipulative techniques such as massage to relax tense muscles, or stretching to improve joint mobility. However, chiropractics are more focused on diagnostic procedures such as X-rays, MRI scans, and blood or urine tests (BackCare, 2008; BackCare, 2004).

Back Surgery

Back surgery is usually performed by an orthopaedic surgeon or neurosurgeon. Few individuals require back surgery, which is performed in selected individuals who continue to experience pain despite taking conventional treatments. There are three main types of back surgery: 1) discectomy, which involves removing part of the intervertebral disc; 2) decompression techniques, which involve removing any tissue that is compressing the nerve; and 3) stabilisation or fusion, which involves the fusion of two or more adjacent vertebrae to provide the spine with more stability. Although relatively low risk, several problems could occur and and must be weighed before proceeding with back surgery; these include problems associated with anaesthetic medications and the possibility of operator error (BackCare, 2004).

Complementary and Alternative Medicine Therapy for CLBP Relief

Complementary and alternative (CAM) therapies are sometimes used by individuals as an adjunct to conventional therapy to help with CLBP relief. One CAM therapy, the Alexander Technique, focuses on balance, posture, and movement. It is based on the concept that we function as a whole, and focuses on learning to prevent harmful habits which include placing too much tension on one's posture and movements or tightening muscles too much (BackCare, 2004). Other CAM therapies include acupuncture, massage and tai chi (Hart, 2008).

Other Monotherapies

There are several other monotherapies available. These include transcutaneous electrical nerve stimulation (TENS) whereby electrodes are positioned in areas where individuals are experiencing pain. Problems reported with TENS include minor skin irritation and dermatitis (Chou & Huffman, 2007; BackCare, 2004). Alternatives include electromyographic feedback, which involves teaching individuals with CLBP to control the tension in their muscles by receiving feedback regarding the electrical activity of their muscles, and practical, physical, and thinking relaxation techniques (BackCare, 2004). Further, some individuals with CLBP use lumbar supports, or treatments such as ice or heat applications (in the form of gel packs, wheat cushions, body belts, or electric pads) to help them temporarily relieve their back pain (BackCare, 2008).

1.5.4 Multidisciplinary Therapy and Support Groups for CLBP

Although there is no standard operational definition of multidisciplinary therapy, the term usually refers to various combinations of exercises, education, and behavioural therapy. However, one of the main characteristics of multidisciplinary therapy is that it addresses physical disabilities, patients' beliefs about their pain and resulting behaviour (Bogduk, 2004).

In some cases, patients are referred by their GP to specialist pain clinics that focus on the assessment and management of pain, as well as living a fuller life while coping with pain. The treatments offered vary and not all hospitals have specialised pain clinics. Often there will be a consultant anaesthetist who will prescribe pain medications or give injections to manage CLBP. Alternatively, there may be a more multidisciplinary team comprising doctors, psychologists, physiotherapists, nurses, occupational therapists and others (BackCare, 2006).

A Pain Management Programme (PMP) is a psychologically based rehabilitative treatment for people with CLBP for whom other treatments have not been successful. PMPs are often delivered in a group setting with a multidisciplinary approach. PMPs vary in approaches. Some focus on educating patients regarding pain, as well as self-management, coping and living with pain. Others offer CAM therapies (BackCare, 2006). In some parts of the UK, patient support groups are run in conjunction with local pain clinics, or are affiliated with groups linked to other organisations (BackCare, 2006). Others focus on behavioural treatments such as cognitive behavioural therapy to help manage pain intensity (Centre for Reviews and Dissemination, 2009).

1.6 Direct and Indirect Costs Associated with CLBP

Back pain is associated with enormous costs. These are often broken down in to two types. Direct costs are costs associated with the resources expended for healthcare, primarily medications and treatments. Such costs can sometimes also include individuals' out of pocket expenses, or resources from other statutory agencies or voluntary bodies. Indirect costs refer to individuals' time (or their families' time, or society's time and cost) consumed by healthcare. These costs can include work time and productivity losses such as lost wages (Drummond et al., 1987).

In the UK, the total direct healthcare costs for back pain are £1.6 billion per year (Maniadakis & Gray, 2000). The National Health Service (NHS) spends more than £1 billion on back pain related costs; this includes £512 million on hospital costs for back pain patients, £141 million on GP consultations for back pain, and £150.6 million on physiotherapy treatments for back pain. In private healthcare, £565 million is spent on back pain per year (Maniadakis & Gray, 2000). In terms of indirect costs, it is estimated that musculoskeletal disorders including back pain cost UK employers between £590 million and £624 million per year (HMSO, 1997).

Also, in the UK, nearly five million working days were lost as a result of back pain in 2003-2004. These findings were used to calculate that on any single day, 1% of the working population are on sick leave due to back problems (HSE, 2005). Further, it has been reported that back pain is the second most common reason for long term sick leave in most of the UK, and it’s the most common reason for those in manual labour jobs (Department for Work and Pensions, 2002).

1.7 Summary

CLBP is widespread, and its treatment is complicated by the fact that its aetiology is often unknown. It is evident that CLBP is a complex condition best considered through a model that takes into account the many interconnected physical, psychological and social factors associated with the condition. Despite the numerous treatments available for CLBP, it remains burdensome and costly to patients, healthcare systems and society. Consequently, it is essential to look at CLBP from the patient’s perspective. The main focus of this dissertation will be to explore patient satisfaction with two common treatments for CLBP: medication and physiotherapy. Chapter 2 provides background information on the concept of patient satisfaction with treatment.

Chapter 2 - An Overview of Treatment Satisfaction and Dissatisfaction

The aim of this Chapter is to provide an overview of issues pertaining to patient satisfaction and dissatisfaction with treatments. Definitions and conceptual issues of patient satisfaction with treatment will be considered followed by methodological aspects in terms of whether the concept is perceived as a dependent or independent variable, and uni-dimensional or multi-dimensional concept. Other methodological considerations include designing satisfaction questions, whether questionnaires are generic-, condition-, or treatment-specific concept, and issues related to psychometric properties of instruments. Other challenges in patient satisfaction measurement as well as factors associated with satisfaction and dissatisfaction with treatment will be considered.

2.1 The Purpose of Investigating Patient Satisfaction or Dissatisfaction

Exploring patient satisfaction has three main purposes. 1) It can help establish the patient’s perspective of health care services; 2) as a ‘process’, patient satisfaction can help identify problems and help to develop strategies to overcome such issues; and 3) satisfaction can be used to evaluate health care (Sitzia & Wood, 1997). Patient satisfaction is important because it provides user input in the planning and assessment of health services, and because satisfaction relates to health and illness behaviour. Therefore, satisfaction is often perceived as one of the goals of healthcare (Thompson & Sunol, 1995).

2.2 Definitions of Satisfaction and Dissatisfaction

Although the term ‘patient satisfaction’ is widely used, it appears to be rarely understood (Sitzia & Wood, 1997), and there is little in the literature to operationally define the concept (Rofail, Gray, & Gournay, 2005; Williams, 1994). However, some commonly cited definitions view patient satisfaction as an emotional response and cognitive appraisal process of aspects of healthcare based on an individual’s experience.

For example, patient satisfaction has been defined as an evaluation that involves "*a comparison of the individual's healthcare experience to a subjective standard*" (Pascoe, 1983 p.189). Similarly, it has been suggested that to convey satisfaction or dissatisfaction is an "*attitudinal response*" to patient's opinions about their clinical experiences (Kane, Maciejewski, & Finch, 1997 p. 715). Patient satisfaction has also been defined as "*affective"* and *"expressed as an attitude or feeling towards a product such as pleasure or displeasure*" (Ross, Frommelt, Hazelwood, & Chang, 1987 p. 22).

2.2.1 Patient Satisfaction with Healthcare

Satisfaction is a subjective rating and thus involves an individual's evaluation of particular aspects of care (Ware, Snyder, Wright, & Davies, 1983). These include interpersonal aspects (features of interaction between healthcare provider and individual receiving services, for example, respect and friendliness), technical quality (competence of healthcare providers and adherence to standards for diagnosis and treatment), accessibility/convenience (factors that impact receiving medical care), continuity (maintaining consistency with regard to the healthcare provider or location of care received), physical setting (such as how pleasant the atmosphere is), financial considerations (factors related to paying for medical services), and efficacy (the results of medical care) (Ware et al., 1983).

Patient satisfaction with health care has also been defined as "*the individual's positive evaluations of distinct dimensions of health care*" (Linder-Pelz, 1982 p. 580). Linder-Pelz's definition posits that patient satisfaction is a uni-dimensional concept (a single concept) composed of five social-psychological determinants: 1) occurrences (what actually happens, or the individual's perception of what occurred); 2) value (evaluating the health care experience); 3) expectations (beliefs regarding the likelihood that certain attributes are linked with an event, and the anticipated outcome of that association); 4) interpersonal encounters (an individual's rating of healthcare experience compared to all other similar encounters); and 5) entitlement (the belief that one has proper grounds for seeking/claiming a particular outcome) (Linder-Pelz, 1982). Sitzia and Wood (1997) refined this model further by moving interpersonal encounters and entitlement under the expectations heading. Further, whilst patient expectations, values, and perceived occurrences were independently associated with patient satisfaction, these variables explained less than 10% of the total variance of patient satisfaction (Jackson, Chamberlin, & Kroenke, 2001) (see section 2.6 for potential covariates of patient satisfaction).

Instead of a uni-dimensional concept, Fitzpatrick (1984) proposed three independent models of satisfaction – the need for the familiar, the goals of help seeking and the importance of emotional need – each associated with one determinant. "*The need for the familiar*" states that social expectations (such as cultural differences) determine the degree of satisfaction. However, a review by Sitzia & Wood (1997) suggested findings were ambiguous (e.g. Jain et al., 1985; Madhok, Bhopal, & Ramaiah, 1992). Closer examination of the studies they cited suggests that the association between cultural differences and satisfaction is not so clear. For example, the Jain et al. study (1985) cited by Sitza and Wood that explored attitudes of Asian patients to the delivery of healthcare in GP settings suggested that the doctor's nationality may be important to some patients. However, the results were problematic in that the question asked to assess satisfaction ('have you thought of leaving your present doctor') may not have sufficiently addressed the issue, and these findings cannot be used as conclusive evidence of an association between cultural differences and satisfaction.

"*The goals of help seeking*" model suggests satisfaction is not the main focus for individuals; instead, they seek a solution to their health problems (Fitzpatrick, 1984). However, anecdotal evidence suggests that individuals with good health status may be unhappy or dissatisfied, and individuals with poor health status may be happy or satisfied (Ross et al., 1987). Further, because patients' perceptions about change in health status are not usually measured in satisfaction studies (Wensing, Grol, & Smits, 1994), it's difficult to assess the adequacy of the model.

"*The importance of emotional need*" is the third model and is based on the emotional experience that individuals have both because of uncertainty and anxiety due to health problems, as well as the fact that many individuals are only able to assess healthcare professionals' competency from a non-technical perspective. Consequently, this model proposes that individuals judge satisfaction according to affective behaviour and communication skills. According to Sitzia and Wood (1997) evidence for this model seems to have emerged in part from Ben-Sira's work (1976), in which satisfaction with treatment from GPs was strongly related to perceptions of interest and devotion from the doctor rather than technical skills or administrative aspects (Ben-Sira, 1976).

Whilst it is apparent that there have been several attempts to define patient satisfaction, the definitions are relatively vague and thus the question of what actually constitutes patient satisfaction remains unanswered. Further, the above definitions relate to patient satisfaction with healthcare, or aspects of healthcare rather than specific to treatment (see section 2.2.2).

2.2.2 Treatment Satisfaction

Though there are few definitions of patient satisfaction with treatment, it can be defined operationally, as in terms of antipsychotic medication: "*Treatment acceptability (positive orientations towards treatment) and medication insight (self knowledge, awareness, and understanding) into the need for medication and its potential side effects*" (Rofail et al., 2005 p. 1068). The operational definition can be reliably and validly measured using the Satisfaction With Antipsychotic Medication (SWAM) scale (Rofail et al., 2005). For example, an advisory team agreed that the content of the SWAM scale was relevant and important to patient satisfaction with antipsychotic medication, and that the scale demonstrated clear face validity. In addition, a number of HCPs who reviewed the questionnaire felt that it was useful. The SWAM scale contains two scales, Treatment Acceptability and Medication Insight. Both have good internal consistency with Cronbach's alpha of 0.92 and 0.84 respectively.

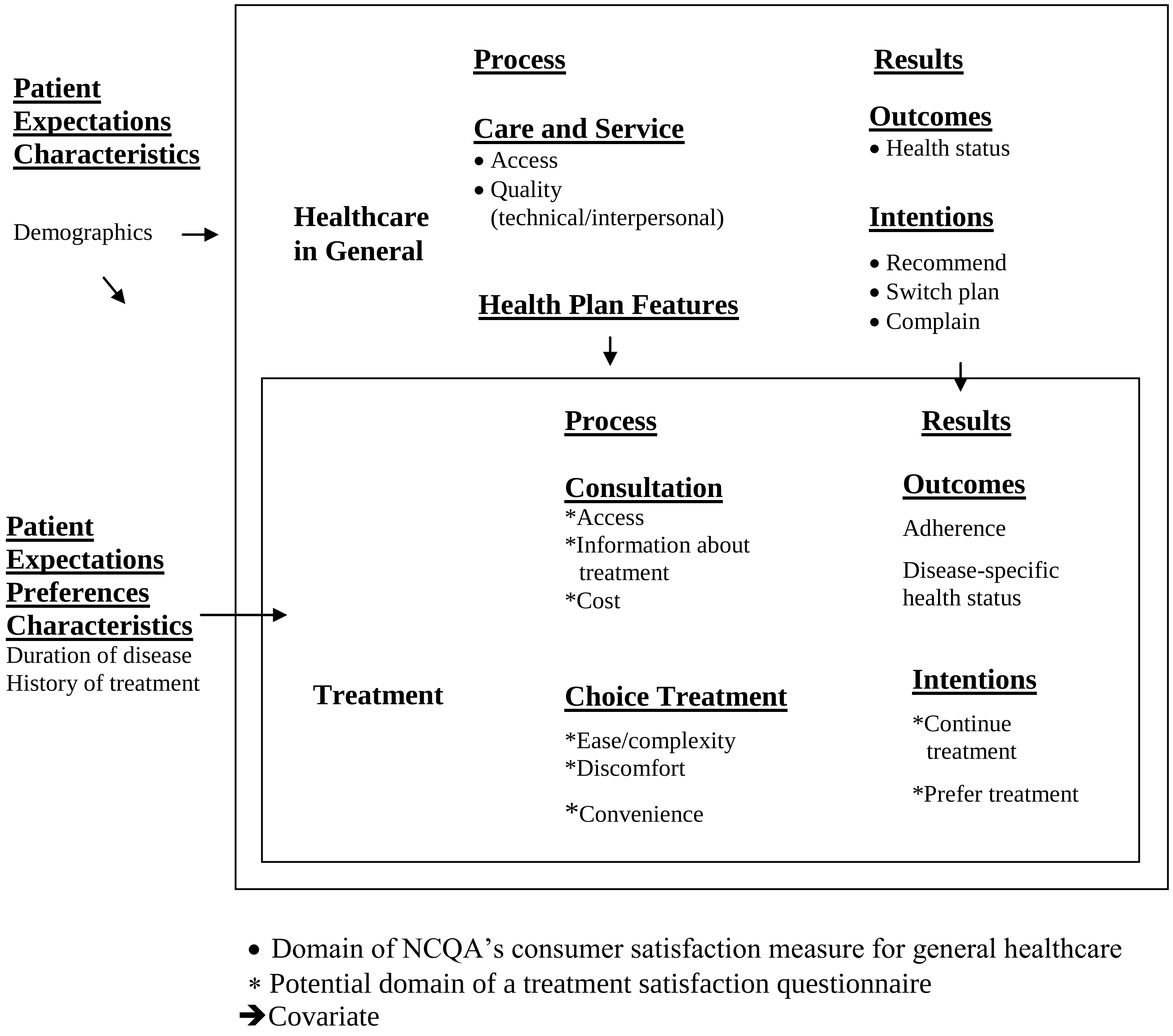
2.3 Conceptual Frameworks and Models of Patient Satisfaction

There are a number of conceptual frameworks or models of patient satisfaction. The most commonly cited in satisfaction studies – a conceptual framework of treatment satisfaction, the cognition-affect model of satisfaction, the assimilation-contrast model of perceptions, and the zone of tolerance model – are reviewed below.

2.3.1 A Conceptual Framework of Treatment Satisfaction (Weaver et al., 1997)

Weaver et al. (1997) proposed a conceptual framework of treatment satisfaction (Figure 3) that suggests that treatment satisfaction for a specific condition is a subset of general healthcare experience (Weaver et al., 1997). The framework was developed to further Pascoe's view of patient satisfaction (see section 2.2) (Pascoe & Atkinson, 1983); therefore, Weaver et al's conceptual framework includes patient characteristics that represent patients' subjective standards such as expectations, or those that may affect the standard such as previous experiences. Weaver et al. (1997) suggest that the framework is complimentary to Wilson and Cleary's (1995), which focuses on health status.

Figure 3: Conceptual Framework of Treatment Satisfaction (Weaver et al., 1997)



- Domain of NCQA's consumer satisfaction measure for general healthcare

∗ Potential domain of a treatment satisfaction questionnaire

➔Covariate

The first part of the figure depicts to the '*general healthcare experience*'. Patients' expectations of general healthcare and demographic characteristics influence this stage. The process includes care, service, and features of the health plan. Within general healthcare, '*Results*' include outcomes such as health status and intentions. Satisfaction is also an outcome but is composed of items or domains that have bullets next to them in Figure 3. Weaver et al. identified these items and domains based on the National Committee for Quality Assurance's (NCQA) Member Health Survey (Davies, Ware, & Kosinski, 1995). The NCQA recommend that health plans use patient satisfaction to evaluate care and refer to a handful of patient satisfaction questionnaires and consumer satisfaction surveys assess patient satisfaction.

Weaver et al. (1997) refer to Wilson and Cleary's definition of health status, which states that as an outcome, health status includes: a) biological and physical factors; b) symptom status; c) functional status; d) general health perceptions; and e) overall quality of life (Wilson & Cleary, 1995). They propose that 'satisfaction with outcomes' is an individual's evaluation of those outcomes on, for example, a five-point likert rating scale: "poor, fair, good, very good, and excellent" (Weaver et al., 1997).

The second part of Figure 3 considers the 'treatment experience' in parallel to the 'general healthcare experience.' Patients' expectations of treatment, their preferences for a particular treatment, and the actual characteristics of treatment all influence the treatment experience. The 'treatment experience'also includes consultation with the doctor. In this model, 'choice' can be either unilateral, involving either the doctor or the patient, or a joint decision where patients are involved in treatment decisions by being informed and having their preferences taken into consideration. For example, a patient may make a *unilateral* decision to take over-the-counter medications for pain, while another doctor and patient might make a *joint* decision to discontinue a drug regimen based on a mutual discussion of side effects and patient preferences. 'Results' of the 'treatment experience' include outcomes such as 'adherence', 'disease-specific health status', and 'intentions'. In this model, treatment satisfaction is an outcome that is represented by items and domains that have an asterisk in Figure 3. Weaver et al. state that the question 'which treatment do you prefer?' could form part of a treatment satisfaction measure.

The conceptual framework of treatment satisfaction provided by Weaver et al. (1997) provides a good contribution to this field especially in that it attempts to distinguish between 'satisfaction as an outcome' of general healthcare versus 'treatment satisfaction'.

However, though the framework builds in part on Pascoe's conceptualisation of patient satisfaction (see section 2.2) and considers the NCQA's Member Health Survey, it is primarily based on researcher intuition. Further, whilst there is some evidence in the literature to support associations between some of the variables and treatment satisfaction (e.g. Awad and Feine (1998)) (see also section 2.6), more empirical work is necessary to confirm the conceptual framework, including consideration for the potential joint effects of the proposed variables on treatment satisfaction.

In addition, Weaver's conceptual framework does not provide a sufficient operational definition of treatment satisfaction. Though an indication of the salient concepts is provided, whether the conceptual framework is exhaustive and captures all or the main important concepts remains questionable. This becomes more evident when considering that patients' views are often different to clinicians' or researchers', and are formed in different ways (Zandbelt, Smets, Oort, Godfried, & de Haes, 2004).

Further, it remains unclear whether the salient concepts of treatment satisfaction are equally weighted in terms of importance. For example, are treatment characteristics such as 'ease/complexity' equally as important as 'discomfort' and 'convenience', and is there anything else that has not been considered that is equally or even more important during the 'process'?

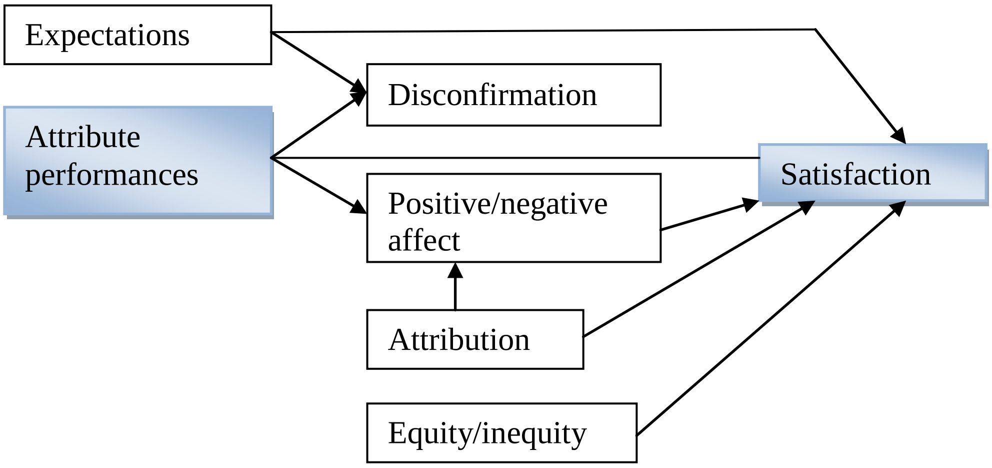
In addition, there is no reference to dissatisfaction with treatment (see section 2.5.1). Perhaps this was not addressed since the model implies that satisfaction and dissatisfaction are on a continuum, with higher patient ratings of the relevant concepts representing satisfaction and lower patient evaluations of the salient concepts indicating dissatisfaction. This oversight may be reflective of this field in general, in that it focuses on positive rather than negative aspects (Markson et al., 2001). Sitzia and Wood (1997) explain that such bias may be a consequence of the fact that a preponderance of satisfaction research has emerged from consumerism and is often driven by health services research and clinician intuition (Sitzia & Wood, 1997).

Another consideration relates to expectations, which in this conceptual framework are perceived as determinants of the general healthcare experience and also of the treatment experience, but are not necessarily included as part of a treatment satisfaction questionnaire. As this work notes in section 2.6.4, there are several issues to consider in relation to expectations, including ambiguity in defining the concept and the notion that there may be different types of expectations (e.g. Stimpson and Webb (1975) and Fitzpatrick (1984)).

2.3.2 Cognition-Affect Model of Satisfaction (Oliver, 1993)

Oliver (1993) proposed a cognition-affect model of satisfaction (Figure 4) in which satisfaction is a result of a comparative process between expectations and attributes performance (e.g., perceptions of treatment performance). There is a disconfirmation paradigm that suggests that the greater the discrepancy between initial expectations and treatment performance, the more apparent the satisfaction or dissatisfaction, depending on the direction of the discrepancy.

Figure 4: Cognition-Affect Model of Satisfaction (Oliver, 1993)



The model also indicates a direct link between treatment performance and satisfaction. Both positive affect (such as joy and interest) and negative affect (such as anger, disgust, and contempt) domains are mediators of satisfaction via treatment performance and ‘attribution’. For example, satisfaction is expected to be higher when individuals attribute favourable outcomes to themselves and unfavourable outcomes to others (Thompson & Sunol, 1995). In addition, equity is seen as a distinct moderating factor on satisfaction, and thus satisfaction is expected to be higher when individuals perceive fair treatment (Oliver & Swan, 1989).

Oliver’s cognition-affect model of satisfaction is predominantly a theoretical model of psychological processes. There is some empirical evidence to suggest that the best predictors of satisfaction are dependent on the sample and type of satisfaction. For example, Oliver found that ‘disconfirmation’ was the best predictor for a sample of individuals buying cars (based on consumerism), whereas ‘affect’ was the best predictor for those in education attending a course in marketing (Oliver, 1993). However, the model has not been empirically tested in its entirety.

Further, the model assumes that individuals bring with them expectations and have an ability and willingness to judge the quality of the relationship (Weaver et al., 1997) There is also some debate in the literature with regard to whether expectations are indeed related to satisfaction (see section 2.6.4) and, as noted earlier, further research is necessary to define the term expectations (e.g. Stimpson and Webb (1975); and Fitzpatrick (1984)).

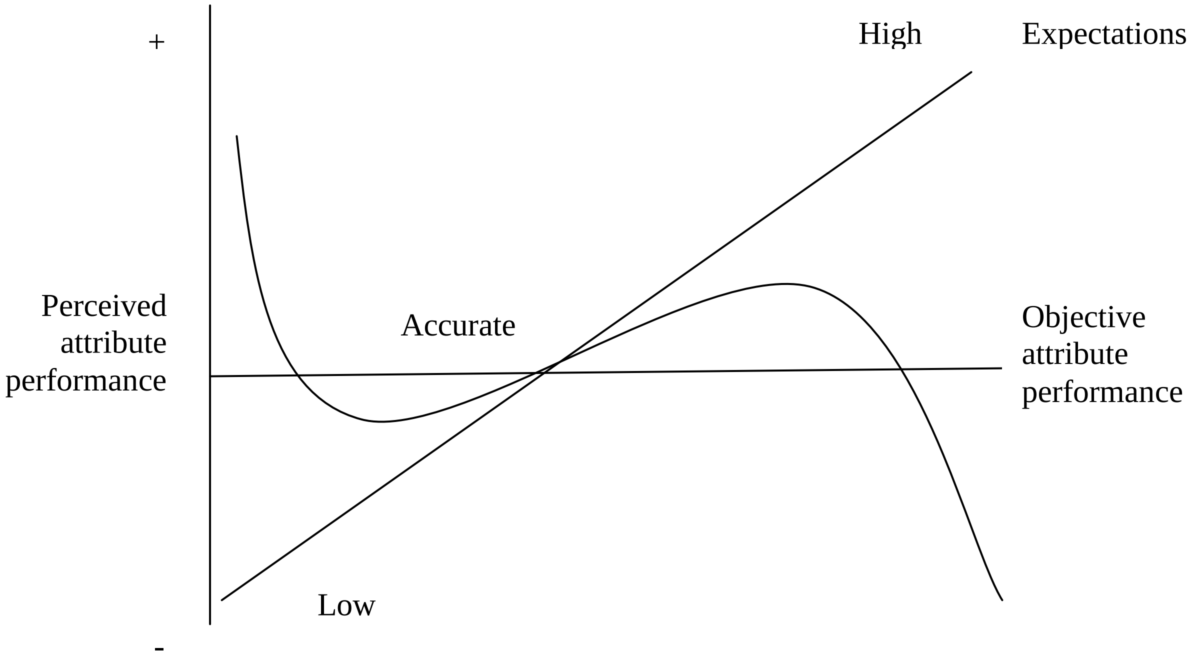
Furthermore, whilst the model focuses on psychological processes, it does not consider concepts such as convenience, preferences and intentional behaviours such as adherence. Indeed, in health care, adherence to treatment appears to depend in part on the patient’s satisfaction with the treatment or medical service received (see section 2.6.10).

Also, the question of what actually constitutes patient satisfaction remains unclear. For example, the model indicates that expectations are both mediating and moderating factors of satisfaction, but satisfaction is a separate concept and what exactly is it and how should it be measured are undetermined.

2.3.3 Assimilation-Contrast Model of Perception (Anderson, 1973)

Anderson's satisfaction model of assimilation-contrast is shown in Figure 5. The assimilation effect occurs in cases where perceptions of attribute performance slightly differ from initial expectations, and consequently individuals are more likely to displace their perceptions towards their expectations. The contrast effect is the opposite, whereby individuals start to exaggerate the increasingly large variation between their perceptions and expectations (Anderson, 1973; Ross et al., 1987).

Figure 5: Assimilation-Contrast Model of Perceptions (Anderson, 1973)



The main advantage of the assimilation-contrast model is that it does not consider satisfaction as a linear effect. Consequently, it provides some justification for why satisfaction measures often show little variance in scores with the exception of extreme situations (Weaver et al., 1997). This model has not been tested empirically in its entirety.

2.3.4 The Zone of Tolerance Model (Parasuraman, Berry, & Zeithaml, 1991)

The Zone of Tolerance Model proposes that the range between adequate and desired levels of expectations is the zone of tolerance (Parasuraman et al., 1991). Like other models of satisfaction, this model does not define terms such as expectations and what constitutes adequate or desired, although its advantage over some of the other models is that it distinguishes between outcome expectations and process expectations (Thompson & Sunol, 1995).

In summary, whilst there have been several attempts to develop frameworks and models to provide a graphical representation of the concept of patient satisfaction and its relationship to other concepts, these models do not adequately define key terms such as expectations and patient satisfaction, and they have yet to be empirically proven in their entirety. This limitation means that quantifying patient satisfaction reliably and validly is problematic, especially in terms of determining which topics should be covered under the umbrella term of 'treatment satisfaction' versus factors that may influence the concept but which are perhaps not part of the concept. The ambiguity incurred from operationally defining 'treatment satisfaction' leads one to question the validity and reliability of instruments used to measure patient satisfaction with treatment, and thus the results reported using such instruments. The following sections consider treatment satisfaction topics, methodological issues of patient satisfaction with treatment, and factors associated with patient satisfaction with treatment.

2.4 Treatment Satisfaction Topics

Weaver et al's 1997 literature review on treatment satisfaction identified a wide range of treatment satisfaction topics in both broad ranges of chronic diseases as well for specific conditions (Weaver et al., 1997). A search on "treatment satisfaction" identified 19 articles from 1400 abstracts that contained multi-dimensional instruments that measured treatment satisfaction (Weaver et al., 1997). Initially, 57 treatment satisfaction topics were identified in one or more of the 19 instruments. Of the 57 topics identified, 40 were reflective of Weaver et al's treatment satisfaction definition and conceptual framework (see section 2.3). Closer examination revealed that of the 40 treatment satisfaction topics, 17 were appropriate across a broad range of chronic diseases such as rheumatoid arthritis or coronary heart disease, or to a specific treatment such as insulin-dependent diabetes (Table 2). The study also identified other topics that may be appropriate to several conditions, such as information about non-medical aspects of the disease such as home help, safety, time required to learn to use appliance or undergo treatment, reliability, patients' sense of participating in treatment, independence, recommendation of the treatment to others, appropriateness, sense of responsibility for treatment, cost of treatment, how realistic was treatment, duration of treatment, number of doses required, and confidence in accuracy (Weaver et al., 1997).

Table 2: Treatment Satisfaction Topics Included in One or More of the 19 Instruments (Weaver et al., 1997)

Satisfaction Topic	**Number of Times Topic Mentioned in one or more of the 19 Instruments**
Overall satisfaction with current treatment	9
Effectiveness or results of treatment	9
Information about the disease	7
Discomfort from treatment, including side effects	6
Design/appearance product	6
Convenience of treatment	6
Desire to continue treatment	5
Ease/bothersomeness of treatment	4
Information about treatment	4
Flexibility of treatment e.g. when and where	3
Operation of appliance in general	3
Convenience when not in use (e.g. to carry or store)	2
Patients’ confidence in ability to use	2
Which of the treatments is preferred	2
How easy the treatment is to buy	2
Satisfaction with plan of care	2
How fast treatment worked	2

Though Weaver et al. (1997) identified topics related to treatment satisfaction, the literature review did not establish the importance of the satisfaction topics listed in Table 2. They did cite one study in the review that reported that efficacy, safety, how quickly treatment works, and side effects were important compared to topics such as ease of treatment and cost (Luciani, Osterhaus, & Gutterman, 1995); however, the Luciana et al. (1995) study was specific to migraine therapy, and it’s unclear whether there are other treatment satisfaction topics not captured in this study.

Further, Weaver et al.’s (1997) research was based on the factors (domain names) of instruments that were reported in published literature. However, there appears to be inconsistency in the factors (domain names) and associated items (questions) between studies. For example, there is diversity in the number of items in satisfaction instruments that contribute to a domain such as ‘convenience’; some use an overall convenience item while other instruments measure the various components that may relate to convenience often with no rationale for one way or another. Further, factors may be inconsistently named or defined. Therefore, further research is required on this topic, with closer examination into the items and factors of satisfaction instruments.

2.5 Methodological Issues of Patient Satisfaction with Treatment

2.5.1 The Difference between Patient Satisfaction and Dissatisfaction with Treatment

It should be noted that there are many patient satisfaction studies but far fewer that focus on dissatisfaction. They share the common trait that whilst we all know what satisfaction or dissatisfaction is, limited conceptual work has been performed to truly understand and define the concept. This means that there is even ambiguity regarding whether it is the same concept or different. Nevertheless, there seems to be some acceptance that they can be seen as on a continuum (Collins & O'Cathain, 2003). There is some evidence to indicate factors associated with dissatisfaction including social class, as well as aspects of care such as waiting times, communication, and patient information (Sitzia & Wood, 1997).

2.5.2 A Dependent or Independent Variable

Patient satisfaction can be viewed as an independent variable that might influence one's behaviour (Linder-Pelz, 1982) such as adherence, and hence the efficacy of treatment (see sections 2.6.9 and 2.6.10). Alternatively, it can be viewed as a dependent variable (Linder-Pelz, 1982), whereby patient satisfaction might be influenced by different factors such as age, educational background, and previous or current experiences with treatment (see sections 2.6.1 to 2.6.11). However, the direction of associations is not always clear, and establishing a causal relationship is determined by various factors such as study design. For example, patient satisfaction studies are often cross-sectional and are limited in controlling environments and potential confounding variables, making it difficult to establish a cause and effect relationship.

Linder-Pelz noted that in either case, researching patient satisfaction as an independent or dependent variable aims to provide practical data rather than being concerned with building or testing theories (Linder-Pelz, 1982). This still appears to be the case. Where theories have been developed, these have rarely been supported entirely by empirical data. For example, Weaver et al. (1997) combined the Zone of Tolerance model by Parasuraman et al 1991 with the Assimilation-Contrast model by Anderson (1973), but as a combined model the theory of satisfaction has not been tested empirically (see section 2.3).

2.5.3 Uni-dimensional Concept and Measurement

Sections 2.2 and 2.3 point out that defining satisfaction and establishing a conceptual model of what constitutes satisfaction is complex. The ambiguity of whether satisfaction is a uni-dimensional concept (e.g. Linder-Pelz 1982) that is influenced by various factors or a multi-dimensional concept that is also influenced by various factors (e.g. Fitzpatrick 1983) has resulted in ambiguity regarding how to measure the concept. Adding to the complexity of these issues is whether the components that comprise patient satisfaction are themselves multidimensional or uni-dimensional. Ware et al. noted that multi-item scales generally result in greater variability in scores compared to single-item measures (Ware et al., 1983).

In any case, the issue of whether satisfaction is uni- or multi- dimensional may in part explain the inconsistency in findings among studies. For example, a systematic literature review exploring patient satisfaction with treatments in CLBP showed that although the majority of studies indicated that patients are satisfied, there was significant diversity among studies in terms of study design and how patient satisfaction was assessed (see Chapter 3).

2.5.4 Methods for Designing Satisfaction Questions

As is the case for measurement, the question of how to design satisfaction questions is complicated by the ambiguity surrounding the subject in general. The three main methods of developing satisfaction questions – qualitative research with input directly from patients, adapting existing questionnaires, and using literature and expert opinion to create a new measure – are discussed in detail below.

Although patient satisfaction with treatment is a subjective concept (Ware et al., 1983), it must be emphasised that the methods employed to develop satisfaction items and questionnaires do not always use information directly from patients (Weaver et al., 1997; Bond & Thomas, 1991). For example, only one of 19 studies cited by Weaver et al. (1997) in their review asked patients open-ended questions about their choice for a particular treatment. This study included both positive and negative reasons, and developed a question based on each of the characteristics mentioned by patients. In order to ensure comparison of treatments, characteristics that were specific to a particular treatment were excluded (Lewis, Bradley, Knight, Boulton, & Ward, 1988). However, Lewis et al. (1998) failed to specify which items they excluded on these grounds, and it's possible that the items that were excluded may have been pertinent to the concept of treatment satisfaction from the patient perspective in individuals with insulin-dependent diabetes.

The importance of qualitative research in the development of questions is increasingly recognized as important, not only by researchers, but also by regulators; in fact, the FDA has made this a key guideline (Weaver et al., 1997; Aharony & Strasser, 1993; Food and Drug Association, 2009). Such recommendations and guidance documents have resulted in instruments such as the SWAM Scale (Rofail et al., 2005), the Satisfaction with Iron Chelation Therapy (SICT) Instrument (Abetz, Baladi, Jones, & Rofail, 2006; Rofail et al., 2008), the Eye Drop Satisfaction Questionnaire (EDSQ) (Nordmann et al., 2007), and the Alzheimer's Disease Caregiver Satisfaction Questionnaire (Abetz et al., 2009). The qualitative research that emerges from patient interviews or focus groups allows reviewers to establish whether topics were omitted during instrument development that may have been important to patients. Using information from qualitative research also allows developers to check the phrasing of questions to ensure that they are meaningful to patients (Weaver et al., 1997).

Some treatment satisfaction questionnaires have been created by adapting existing instruments from the literature (Weaver et al., 1997). While this is a common shortcut, these studies usually don't provide sufficient rationale for including an instrument in a study. For example, in cases where existing treatment satisfaction questionnaires have been used, there is little assurance that the items encompass all of the relevant concepts based on rich qualitative data from patients, or whether the recall period is appropriate to patients (see for example, Pincus, Vogel, Savage, & Newman, 2000). As a consequence, the chosen instrument(s) may have unacknowledged limitations. For example, if the instrument is not discriminative or sensitive to change, this may have implications on the results.

Satisfaction questions can also be developed using published literature, as well as expert opinion or clinical judgement (Rofail et al., 2005; Weaver et al., 1997). For example, a recent cross-sectional study was designed to explore satisfaction and subjective experiences with treatment using antipsychotic medication in patients with schizophrenia (Gray, Rofail, Newey, Allen, & Gournay, 2005). The questionnaire used in the study was developed by a researcher identifying concepts in the literature related to patients' experiences with antipsychotic medication and creating questions to be reviewed by healthcare professionals (e.g. psychologist, psychiatric nurse) as well as a patient who was taking medication at the time. A draft questionnaire was created and piloted in patients who were not included in the main study. This standard method elicited verbal and non-verbal feedback regarding the clarity of the items, tested patients' reactions to the questions, and was used to refine the question order and content (Gray et al., 2005). Another example used a similar method; this study used a literature review followed by cognitively debriefing items with an expert panel composed of clinicians and patients to develop the Treatment Satisfaction and Medicines Questionnaire (SATMED-Q) (Ruiz et al., 2008). Some studies have used questionnaires developed specifically for the purpose of the study without any validation (Simoens, Lobeau, Verbeke, & van Aerschot, 2009; Braig, Beutel, Toepler, & Peter, 2008).

2.5.5 Generic and Treatment-Specific Satisfaction Instruments

There is no ‘gold standard’ for measuring patient satisfaction with treatments (Rofail et al., 2005). However, like other patient-reported outcomes (e.g. health-related quality of life), instruments can be categorised as either generic or specific measures.

Generic measures should be applicable regardless of condition, treatment, sex, age, education, socio-economic status or culture (Fayers & Hays, 2005; Hayes & Morales, 2001). They are global in content and cover domains relevant to – in this case – satisfaction. The psychometric validity and responsiveness of generic instruments are demonstrated in general populations. An example of a generic treatment satisfaction questionnaire is the Treatment Satisfaction Questionnaire for Medication (TSQM) (Atkinson et al., 2004; Atkinson, Kumar, Cappelleri, & Hass, 2005).

In contrast, condition-specific instruments are comprehensive and pertinent for the target population, and their psychometric validity and responsiveness are demonstrated in the target population. In addition to condition-specific instruments, there are also treatment-specific instruments (Weaver et al., 1997). Examples of disease and treatment-specific instruments include the Satisfaction with Iron Chelation Therapy (SICT) questionnaire for patients with iron overload, and the SWAM scale for patients with schizophrenia receiving antipsychotic medication (Rofail et al., 2008; Rofail et al., 2005).

2.5.6 Psychometric Properties of Satisfaction Instruments

Weaver et al.’s (1997) literature review of treatment satisfaction measurement reported that several researchers considered the psychometric properties of satisfaction instruments. The main measurement attributes and number of studies were documented, and as shown in Table 3, seven studies (out of 19 included in the review) reported the construct validity of satisfaction instruments and 10 documented the responsiveness to change over time.

Table 3: Psychometric Properties from the Instrument Review Criteria by the Medical Outcomes Trust Scientific Advisory Committee and the Number of Studies that Assessed Psychometric Properties (Weaver et al., 1997)

Attribute		**Number of Studies***
I	Conceptual and measurement model (scale and subscale structure)	5
II	Reliability	
	A. Internal consistency (Cronbach’s alpha or KR-20)	3
	B. Reproducibility	
	a. Test-retest	3
	b. Inter-observer (interviewers)	0
III	Validity	
	- Content (review by laypersons and experts)	3
	- Construct (logical relationships between measures or individuals)	7
	- Relationship to criterion measure	0
IV	Responsiveness or sensitivity to change	10≠
V	Interpretability (qualitative meaning of the scores)	0
VI	Burden	
	1. Respondent	18
	2. Administrative	0
VII	Alternative forms (administration modes or proxy versions)	0
VIII	Language and/or cultural adaptations (conceptual equivalence, linguistic equivalence, and psychometric properties)	0

*19 total studies included in Weaver’s review

≠ Responsiveness was not measured in a randomised controlled trial in 4 of 10 studies

Whilst Weaver et al’s study was not systematic or exhaustive, Table 3 demonstrates that some measurement attributes are not considered during the development and psychometric validation of treatment satisfaction questionnaires. Potential gaps are apparent for discriminative (known groups) validity and administrative burden. Further, whilst Table 3 provides a good overview of the measurement attributes that have been considered by researchers in treatment satisfaction, further research is warranted into whether the results documented reached pre-defined criteria. For example, of the three studies that explored internal consistency, it would be useful to consider how many studies achieved Cronbach’s alpha of ≥ 0.7 (see for example, Kline, 2000), and if relevant, to closely examine possible reasons for not reaching the accepted criterion for internal consistency.

2.5.7 Other Challenges in Patient Satisfaction Measurement

Previous research that assessed patient satisfaction with treatment has generally used cross-sectional or longitudinal survey designs using self-report questionnaires to elicit information about satisfaction as a secondary or exploratory outcome (see for example Table 4 in section 3.4.3). A literature review of patient satisfaction with antipsychotic medication found that none of the questionnaires had been used on more than one occasion, and there were no studies exploring the clinical utility of the questionnaires or the psychometric properties of the measures (Rofail et al., 2005). Further, questionnaires differed in the number of items included and the rating scales. Notable examples include Helewell et al (1999), who measured patient satisfaction with an antipsychotic (quetiapine) using a seven-item questionnaire and a five-point rating scale from ‘very dissatisfied’ to ‘very satisfied’, and Koivumaa Honkanen et al (1999), who used a ten-item questionnaire (Helewell, Kalali, Langham, Mckellar, & Awad, 1999; Koivumaa Honkanen, Honkanen, Antikainen, Hintikka, & Vinamaki, 1999). Although the latter rated satisfaction from 1 to

10, scores were dichotomised as “satisfied” or “dissatisfied” for statistical analysis. Whilst collapsing categories into extreme cases can be advantageous in simplifying data for presentation or in cases where few observations exist within some categories, it is generally not advised. This is because with categorical data (even ordinal data), it should not be assumed that the difference between scores on a scale are the same (for example, between ‘satisfied’ and ‘very satisfied’ (Collins & O'Cathain, 2003)), and doing this may increase the chance of error.

Further, the study designs often used to measure patient satisfaction (e.g. observational or cross-sectional) mean that it is not possible to directly attribute the observed outcome to the process of treatment since social, economic, and other factors may influence the course of illness (Coulter, 1991).

2.6 Factors Associated with Satisfaction and Dissatisfaction with Treatment

There are many factors associated with patient satisfaction including patient demographic and clinical/treatment characteristics, information provided, beliefs, patient expectations, doctor-patient communication, effectiveness or efficacy of treatment, adherence to treatment, and psychological or social factors. These are presented in further detail below.

Rofail et al. (2005) performed a literature search of patient satisfaction with antipsychotic medication from January 1980-January 2003, using the key words ‘satisfaction’, ‘patient’, ‘consumer’, ‘user’, ‘antipsychotic’ and ‘treatment’. A total of eighty papers were identified that included the terms ‘patient satisfaction’ and ‘antipsychotic medication’ in the title or abstract. Based on this review, there was no study that considered all the factors in the literature associated with patient satisfaction, or even identified the key factors associated with satisfaction (Rofail et al., 2005). Thus, further research is warranted in order to determine the main factors associated with satisfactaion as well as the interaction of factors with each other.

2.6.1 Demographic Characteristics

Research indicates that patient satisfaction may be associated with patients' demographic characteristics such as age, ethnicity, education, and socio-economic status. For example, one study found that older people are more satisfied with healthcare than younger people (Williams, 1994; Hall & Dornan, 1990). However, results on ethnicity and patient satisfaction are not so definitive. For example, Pasco and Atkinson (1983) found that 'whites' on the whole were more satisfied than 'non-whites' (Pascoe & Atkinson, 1983). However, in a meta-analysis of published patient satisfaction surveys, ethnic origin did not appear to be related to patient satisfaction (Hall & Dornan, 1990). In addition, higher degrees of satisfaction are associated with lower levels of education (Hall & Dornan, 1990; Anderson & Zimmerman, 1993).

Note that although patient satisfaction appears to be associated with patient demographic characteristics, patients' gender has generally not been associated with patient satisfaction (Hall & Dornan, 1990; Sitzia & Wood, 1997) and there is a lack of literature showing an association of patient satisfaction with socioeconomic status.

2.6.2 Clinical and Treatment Characteristics

There are few studies in the literature demonstrating an association between patient satisfaction and clinical or treatment characteristics. For example, there is a lack of data exploring aspects such as type of medications (e.g. non-opioid analgesics versus opioid analgesics), dosage, and frequency of administration. However, there is some evidence to suggest that duration of disease, mode of administration of treatment, and whether individuals experience side effects from their treatment are associated with patient satisfaction. For example, Lewis et al. (1988) showed a positive association between treatment satisfaction and duration of diabetes. In haematology, several studies have demonstrated that overall, patients are satisfied and prefer oral-iron chelation therapy (ICT) compared to conventional infused-ICT (Cappellini et al., 2007; Vichinsky et al., 2008; Payne et al., 2007; Scalone et al., 2008; Rofail et al., 2008). Further, in rheumatology, Huskisson et al. (1992) found an association between overall satisfaction and the absence of pain and side effects.

2.6.3 Information and Knowledge

To date, satisfaction research has not focused extensively on the association of satisfaction with patient information and knowledge. However, there is some indirect evidence that they might be associated. For example, since information and knowledge have been shown to be associated with adherence to medication regimens (Myers & Midence, 1998), which is also related to satisfaction (see section 2.6.10), the level of information provided regarding treatment could also affect patients' level of satisfaction.

2.6.4 Patient Expectations

There is some evidence to suggest that expectations are associated with satisfaction, the notion being that patients with lower expectations tend to be more satisfied (Sitzia & Wood, 1997). For example, patient satisfaction was assessed using a survey with 2- week and 3-month follow-up in a general medicine walk-in clinic in the U.S. Findings showed that for each assessment, unmet expectations markedly decreased satisfaction (Jackson & Kroenke, 1997).

Further, models of satisfaction (see section 2.3) often refer to expectations (Anderson, 1973; Parasuraman et al., 1991; Oliver, 1993; Thompson & Sunol, 1995).

A mathematical equation of satisfaction using measurements of an individual's expectations regarding certain attributes, and the individual's appraisal of those attributes was proposed (Linder-Pelz, 1982). Satisfaction was the result of meeting or exceeding one's expectations. However, it has also been demonstrated that expectations have an independent influence on patient satisfaction, regardless of whether those expectations were fulfilled. This led to the conclusion that the fulfilment of expectations might have little to do with reported satisfaction (Linder-Pelz, 1982).

However, 'expectations' as a concept lacks a standard operational definition and there has been little research to establish what constitutes expectations (Stimpson & Webb, 1975). This is important, since if expectations are part of treatment satisfaction and there is general consensus that the concept of expectations is ambiguous and lacks clear definition, then the relationship between treatment satisfaction and expectations is questionable.

Further, as suggested by Fitzpatrick, there is a need to establish whether expectations are an identifiable concept (Fitzpatrick, 1984). Also, there are several potential confounding variables that may influence the relationship between expectations and satisfaction, such as individual's values, attitudes, and socio-economic status (Sitzia & Wood, 1997).

Expectations also seem to vary according to knowledge and prior experience, and therefore are likely to change rather than remain stable (Fitzpatrick, 1984). In addition, patients with no experience of receiving services may not have formed any expectations (Williams, 1994) so proposing that expectations may be an underlying mechanism of satisfaction is questionable in this instance. Williams was sceptical of expectations, further suggesting that individuals may question the legitimacy of their own expectations in light of information from healthcare professionals or complicated treatments (Williams, 1994).

For example, one may argue that individuals do not have sufficient knowledge of what to expect in aspects such as treatment.

With regard to research related to patients’ expectations of treatment for CLBP, there have been some interesting findings from a number of studies (see for example, Rives & Douglass, 2010; Verbeek, Sengers, Riemens, & Haafkens, 2004; McIntosh & Shaw, 2003; Liddle, Baxter, & Gracey, 2007; Yardley et al., 2009). For example, in one study (Liddle et al., 2007), key themes and categories related to patients’ expectations of treatment included: individually specific advice and exercises, supervision and follow-up to check progress, support and understanding from practitioner, proactive versus passive approach, a quick fix, and pain relief.

Other studies have shown similar findings, and patients with CLBP generally expect information and advice regarding back pain management, and their previous experiences led them to expect that treatments would be ineffective especially since they continue to experience pain and have difficulties with their normal activities (see for example, Verbeek et al., 2004; Rhodes, McPhillips-Tangum, & Markham, 1999).

In another study which explored beliefs contributing to attitudes for an intervention (using the Alexander technique and exercise) in low back pain, results showed that patients had a number of pre-intervention expectations such as expected outcomes of doing the intervention (behavioural beliefs), expected attitudes of others (normative beliefs), and expected ability to carry out recommended activities (control beliefs) (Yardley et al., 2009). In this study, patients experiences post-intervention were also documented and themes identified included specific outcomes regarding for example, partial or total pain relief, experienced attitudes of others, and experiences of ability to carry out recommended activities (Yardley et al., 2009). Patient perceptions and experiences of treatment are further considered in section 2.6.5.

2.6.5 Patient Perceptions and Experiences of Treatment

Patients’ perceptions and experiences with a condition and its treatment also seem to be associated with overall treatment satisfaction (see for example, McPhillips-Tangum, Cherkin, Rhodes, & Markham, 1998; Glenton, Nilsen, & Carlsen, 2006; Cherkin, Deyo, Berg, Bergmann, & Lishner, 1991). For example, with regard to patients experiences, it has been reported that patients requiring help for their LBP from primary care physicians are often dissatisfied not only with the information and care that they receive, but also their treatment (Cherkin et al., 1991). These findings inspired a qualitative study to further explore patients’ subjective experiences and reasons for repeated medical visits in chronic back pain (McPhillips-Tangum et al., 1998). Reasons for repeated medical visits included having difficulties performing normal activities or experiencing activity limitations and increased pain (or ‘flare ups’). There was a general need for participants to discover the cause of the pain, and often participants in the study reported seeking a diagnostic test that would help find a physical cause to their underlying pain. Results also indicated that participants were frustrated and confused when their questions were unanswered by HCPs which was associated with dissatisfaction with the care received. Further, even when treatment was delivered, it was sometimes considered unsatisfactory with participants often seeking alternative and new types of treatment. The authors suggested that clear and confident diagnosis and treatment programmes may help improve patient outcomes such as satisfaction (Thomas, 1987), and agreement between the patient and HCP was likely to be a stronger predictor of outcomes than clinical measures (Bass, 1986). However, this hypothesis warrants further exploration.

There is a preponderance of literature to document the negative impact and burden incurred to patients from CLBP (see for example, Smith & Osborn, 2007; Bacon et al., 1994; Pain in Europe, 2003; Keeley et al., 2008; Roland et al., 2007; Vlaeyen, Kole-

Snijders, Boeren, & van Eek, 1995; Woby, Watson, Roach, & Urmston, 2004; Liddle et al., 2007). However, there is some evidence to indicate that patients' experiences extend beyond just presence and intensity of pain, and its impact on every day activities, functioning, and level of disability incurred. For example, one qualitative study indicated that patients' experiences of CLBP included loss of function and impact on their social roles, but also included the uncertainty of aetiology and diagnosis, as well as impact on their self and identity (Smith & Osborn, 2007). The impact seemed to be worse for patients who felt they had a derogatory self image who in turn felt that they directed their negative feelings towards others (Smith & Osborn, 2007).

In another qualitative evaluation of evidence-based information presented in the form of a website for back pain sufferers, results showed that individuals were quite sceptical of the information presented, and expressed lack of trust with regard to research and researchers (Glenton et al., 2006). This was tied to the fact that research evidence seemed to be constantly changing, and also that often the researchers disseminated conflicting information. It is thought that the lack of trust and confidence in research may transition to a similar sense with HCPs and perhaps the healthcare system itself (Glenton et al., 2006). Conflicts of interest also appear to be somethingconsidered by patients receiving managed care for low back pain (Lo, 1999). For example, patients may question whether the tests employed by HCPs are truly not indicative of a CLBP problem or whether the HCP is trying to save money on behalf of themselves, their practice, or even the healthcare system in general (Lo, 1999).

Also, a study regarding patients' experiences, opinions and expectations for clinical management indicated that in general patients had experienced a number of diverse treatments that did not work for them (Liddle et al., 2007). Patients valued the advice and treatment provided to them, but they often questioned the appropriateness of treatment especially since a diagnosis was rarely provided yet patients often experienced varying degrees of pain and related symptoms. Consequently, patients often do not adhere to medication regimens and exercises as recommended by their HCP, and this in turn may affect the efficacy of the treatment (Liddle et al., 2007).

2.6.6 Involvement in Treatment Decisions

There is some evidence to indicate that lack of involvement in treatment decisions is significantly related to treatment dissatisfaction (see for example, Gray et al., 2005). This finding suggests that patients' perceptions regarding their treatment may be a determinant of patient satisfaction.

2.6.7 Therapeutic Relationship

A definition of a therapeutic relationship is a connection of trust and rapport between a HCP and patient involving: collaboration, empathy from the therapist, as well as mutual understanding and respect (Cole & McLean, 2003). The therapeutic relationship is sometimes referred to as a 'helping relationship' and the terms are often used interchangeably with the 'therapeutic alliance' (Leach, 2005). A definition of a therapeutic alliance emphasises active collaboration between a HCP and a patient (Ackermam & Hilsenroth, 2003).

There are various models that have been proposed to describe the therapeutic relationship between HCPs and patients. In particular, five main models are often referred to: the working alliance, the transferential/countertransferential relationship, the developmentally needed relationship, the I-you relationship, and the transpersonal relationship (Clarkson, 1990).

Specifically, the working alliance is considered to develop within the context of a business contract between a HCP and patient (such as times, fees, role and limits of responsibility). HCP’s encourage the development of a working alliance via for example active listening, and practice should be indicative of competence and trust to the patient. Being part of a working relationship requires that HCP make a good assessment of the patient, and that they emphasise that they can commit to helping to the patient. The woking alliance is portrayed in terms of bond of mutual understanding regarding what the patient is attending for, and reassurance that this is the place to get it (Clarkson, 1990).

The transferential/countertransferential relationship relates to how past experience can distort the way a patient perceives and relates to others. The HCP aims to identify with patients when and how they may be distorting their perception of the HCP to develop a process from ‘here and now’ to ‘there and then’. At the same time, HCPs try to tease out countrtransferential responses to the patient with particular attention regarding what could be represented to the patient, versus what could be considered by them as a HCP (Clarkson, 1990).

The developmentally needed relationship relates to what the patient may need from the treatment that they did not get during their childhood years. In particular, the process of empathising in a new way can be considered a way of fulfilling a gap from childhood years. It should be noted that the greater the patient’s needs (i.e. the gap), the more the HCP should consider the appropriateness of the therapy, as well as whether other kinds of help are also required (Clarkson, 1990).

The I-you relationship focuses on intimacy and is characterised by the HCP’s openness, the patient’s openness, and the process between the two. The I-you relationship model encourages consideration regarding how HCPs and patients may be blocking themselves from intimacy at a specific time in the relationship. Further, intimacy is not something that should be demanded (Clarkson, 1990).

The fifth model relates to the transpersonal relationship and is the idea that there may be something beyond current understanding and which provides a sense of hope. This model places emphasis on being aware that the topic of ‘spirituality’ may emerge from time to time during consultations between a HCP and patient, but that the role of the HCP should not extend to spiritual guidance (Clarkson, 1990).

Whilst these five models of the therapeutic relationship are well known within the field of psychotherapy, research specific to CLBP has focused more on the dynamics of the consultation in the context of the social interaction between HCP and patient (Derebery, 2003; Lo, 1999). The consultation process usually involves negotiations between HCP and patient about the meaning of symptoms, which can determine the outcome of the patient. Given that most patients with CLBP experience ‘pain’, they often consider their pain of organic physical nature (rather than psychological) (see for example, Derebery, 2003; Chew & May, 1997; Derebery, 2003; Chew & May, 1997). However, in CLBP the pathology is not often apparent particularly for non-specific CLBP, and GP’s need to diagnose the patient as an initial step of the consultation process. Consequently, responding to and managing patients with CLBP can be difficult (Chew & May, 1997; Derebery, 2003; Chew & May, 1997; Derebery, 2003), and patients with CLBP are often perceived as “a problem patient and a problem situation” (Nordin et al., 2006).

In a qualitative study conducted in North-West England, when asked about making a diagnosis for CLBP one GP mentioned “...how do you put it? Mechanical, due to bad posture, bad working practices, bad sitting, just to bad back care.” However, some GPs did not report pathology as the primary cause of consultations about CLBP, with one reporting: “(the) need for sick notes, any excuse to get money off the tax payer, avoidance of work...” The mismatch of explanatory models between doctor and patient causes frustration to both patients and GPs resulting in difficulties for GPs regarding whether to adopt a patient- or doctor-centred approached (Chew & May, 1997; Chew & May, 1997).

Further, the back pain may be causing considerable suffering to the patient. This may be for a number of reasons such as anxiety about health status, loss of function, or even a negative economic impact, which could increase a patient's distress levels. A GP could misinterpret such issues as a worse pathology than may be the case, thus leading to further testing, referrals, prolonged lost time at work and excessive treatment. This can ultimately lead to general patient dissatisfaction (Derebery, 2003).

In addition, often HCPs inform patients with CLBP to remain active when experiencing back pain and that bed rest will make the pain worse (Bogduk, 2004; Roland et al., 2007). The benefits of activity include that it will help develop muscles, keep the individual supple, give stronger bones, make patients fit and feel good, and releases natural chemicals that reduce pain (Roland et al., 2007). However, such key messages that HCP's disseminate do not fit well with the patient's explanatory model of pain especially since movement may also induce the pain intensity (Bogduk, 2004). Consequently, patients may not adhere to HCPs recommendations and this may in turn impact further on CLBP.

Other research related to the therapeutic relationship has explored how GP's often adopt a more autonomous rather than collaborative approach to managing patients with CLBP (see for example, MacNeela, Gibbons, McGuire, & Murphy, 2010). Reasons for an autonomous approach are in part explained by GP's expectations related to uncertainty regarding symptoms and doubts related to the possibility that patients are malingering or 'faking it'. Nevertheless, a shared-decision approach is generally recommended (see for example, Charles, Gafni, & Whelan, 1999; Heritage & Maynard, 2006; May, 2007). Also, whilst GPs are interested in the patient as individuals, their perspective of the patient's subjective experiences are often quite different to patient's actual experience and they generally place less emphasis than patients on the importance of experiences such as anger and frustration (see for example, Barry, 2002; Smith & Osborn, 2007).

It should be noted that there is some evidence to suggest an association between aspects of the therapeutic relationship and outcomes such as satisfaction (see for example, Leach, 2005; McCaffrey, Pugh, & O'Conner, 2007; Strutt, Shaw, & Leach, 2008; Cromarty, 1996). Such aspects include:

- Patient’s perception of HCP’s behaviour and attitude (Cromarty, 1996)
- Patient’s perception of HCP’s competence (effective, thorough, knowledgable) (Strutt et al., 2008; Cromarty, 1996)
- Effective communication skills (see section 2.6.8 also) (Leach, 2005; Cromarty, 1996)
- Establishing good patient rapport including making time for rapport (Leach, 2005)
- Building trust and confidence (Leach, 2005)
- Empathising (caring, reassuring, listening, continuity) (Strutt et al., 2008; McCaffrey et al., 2007)
- Generating a friendly, relaxed and secure atmosphere (Strutt et al., 2008)
- Manner in which treatment is delivered (such as being gentle and treating the root cause) (Strutt et al., 2008)
- Adequate consultation time (not rushed, short waiting times) (Strutt et al., 2008; Leach, 2005; Cromarty, 1996; McCaffrey et al., 2007)
- Adopting a collaborative consultation style (rather than authoritarian, technical, or parental) (Leach, 2005)

- Information-giving (explanation, advice) (Strutt et al., 2008; Leach, 2005; Cromarty, 1996)
- Level of understanding achieved (Cromarty, 1996)
- Patient’s perception of HCP’s responsiveness (whether the HCP is perceived to understand and accept a patient’s concerns and to provide appropriate treatment and care) (Reis et al., 2008)

Closer examination of empirical studies provides further evidence to support an association between the therapeutic relationship and satisfaction or dissatisfaction. For example, one study showed a general level of dissatisfaction with conventional treatments but particularly with being rushed, not being listened to, and feeling dismissed as a complainer (McCaffrey et al., 2007).

In addition, there are various factors which may increase or worsen the therapeutic relationship and consequently, these factors may indirectly contribute to treatment satisfaction or dissatisfaction. For example, indications of a good therapeutic relationship include increased flow of conversation, disclosure of sensitive information, relaxed body language, increased eye contact, and improvements in listening and responding (Leach, 2005). However, a poor therapeutic relationship may be presented in terms of long periods of silence, less conversation or very brief responses, lack of eye contact, and defensive body language (Leach, 2005).

Further, in a study that qualitatively explored what patients think about during their consultations (Cromarty, 1996), results showed that patients had a desire for understanding and considered the HCP’s willingness to help, as well as their ability and their available time. These findings suggest that patients consider the therapeutic relationship and evaluate the adequacy of various aspects which may in turn be related to treatment satisfaction.

A similar study explored patients' views of the doctor-patient relationship, and findings revealed three stages that seem to be related to creating the relationship (Gore & Ogden, 1998). The first is 'developing a relationship' and patients appeared to approach this in several ways. For example, some patients described knowing instantly that they would bode well with the doctor, whilst others described trying out several doctors in the practice, or searching for a doctor that would help them with specific requirements. For some patients who had been unsure about a new doctor, they tried to overcome their initial reservations and were relieved that they had not gone to a different practice too quickly. The second stage is 'validating the relationship' where patients seemed to pay particular attention to evidence of caring to help determine whether they liked their doctor. For example, some patients used these insights as in indication of the doctor's future behaviour, whilst some compared their doctor with others to consider the value of the relationship, whereas some patients generally accepted their doctor. In addition, there seemed to be key events that influenced the relationship, such as making a diagnosis, or receiving an important treatment. Caring and help during a crisis were also key events, whilst some patients described resolving a conflict between themselves and the doctor which had resulted in bringing them closer together. Also, accepting dissatisfaction for what would otherwise be considered a good relationship was another important aspect and included accepting problems with the appointment system, lack of availability, and wanting a more caring and listening doctor. The third stage was described as 'consolidating the relationship' with the doctor and involves a process of testing and setting boundaries. Some patients viewed conflict as necessary, whilst others considered conflict something to avoid. Specifically, some patients described exploring the HCP's knowledge boundaries, to gauge whether the HCP would allow the patients own knowledge to contribute to the consultation. Other patients described trying to establish the HCP's willingness to allow active participation from the patient (Gore & Ogden, 1998).

As developing, validating and consolidating a relationship with the HCP is often part of the treatment process, it is expected that these aspects may also contribute towards treatment satisfaction or dissatisfaction. However, further research is warranted to explore this.

2.6.8 Doctor-Patient Communication

Evidence suggests that doctor-patient communication is associated with patient satisfaction. For example, empathy and active listening are associated with increased patient satisfaction, and patients expect confirmation from HCPs that their pain is real (Verbeek et al., 2004). However, quantifying doctor-patient communication is problematic given the many ways doctors communicate about an individual's situation and health problems. Some of the most pertinent ways are through partnership building (establishing a rapport by empathising and actively listening), asking questions, information exchange, encouragement, non-verbal communication, and use of communication aids (Williams, 1999). The terminology used and various features of verbal communication are also important (Williams, 1999). For example, the type of questions that could be asked to initiate a response should progress from open to closed questions so that as much information as possible is extrapolated from the individual. However, if the questions are likely to invoke an emotional response, then objective to subjective questioning may be more appropriate (Williams, 1999). Also, an empathetic doctor-patient relationship includes the elicitation of feelings, paraphrasing, reflecting, using silence, encouragement, and non-verbal behaviour as well as listening to what the patient says and what is not said (Williams, 1999).

2.6.9 Effectiveness of Treatment

Effectiveness of treatment is the extent to which treatment does what it is intended to do under normal circumstances or in real world settings (Drummond et al., 1987). A review by Weaver et al. (1997) (see section 2.4 for details) stated that existing literature is inconclusive regarding the relationship between treatment satisfaction and effectiveness of treatment (Weaver et al., 1997) due to conflicting evidence. They provided evidence to support the link from studies such as Lewis et al., who demonstrated a positive relationship between treatment satisfaction and perceived blood glucose control (Lewis et al., 1988), and Huskisson et al. who showed an association between overall satisfaction and absence of pain and side effects in patients with rheumatoid or osteoarthritis (Huskisson et al., 1992), versus Castelin and Kerr who did not find such an association in patients with cardiac problems (Castelin & Kerr, 1995).

On reflection, it does not seem to be relevant to examine treatment satisfaction covariates between studies on several grounds. Firstly, study designs may differ significantly and the way that satisfaction is quantified in one study may not be comparable with another.

Also, one study refers to for example treatment satisfaction in patients with diabetes, and another measures satisfaction in patients with cardiac problems. The nature of patients is thus very different and whilst there are some similarities with regard to for example, that in both cases patients have to live with a continuous medical problem and are often advised about their diets, there are also very apparent differences. For example, individuals with diabetes may take regular insulin injections whereas people with cardiac problems are often faced with taking tablets (they do not take injections or blood sugars), and according to the severity of their condition may have to adjust their lifestyle.

Consequently, concepts such as treatment satisfaction and efficacy/effectiveness may vary significantly by condition.

2.6.10 Adherence to Treatment

Few studies have tried to define adherence (for a review see Myers & Midence, 1998), however, a definition of adherence by Haynes et al. is often cited and states that adherence is "*the extent to which a person's behaviour (in terms of taking medications, following diets, or executing lifestyle changes) coincides with medical and health advice*" (Haynes, Taylor, & Sackett, 1979). Recently, a study in 107 patients with β-thalassemia, sickle cell disease, or myelodysplastic syndromes taking ICT provided data to support an association between satisfaction with ICT and adherence (Rofail et al., 2008). There were four independent variables that significantly predicted adherence (R^2=42.3%): age, perceived effectiveness of ICT, low burden of ICT, and low side effects of ICT (Rofail et al., 2008).

Whilst Rofail et al. (2008) demonstrated an association between treatment satisfaction and adherence, it should be noted that the concept of adherence is complex. Rofail et al (2008) assessed adherence using three questions. These were, in general, in the last four weeks, how often did you: 1) have trouble remembering to take your iron chelation therapy?; 2) think about stopping iron chelation therapy; and 3) follow the chelation therapy regimen exactly as recommended by your doctor? These questions were rigorously developed, emerging from data elicited from in-depth patient interviews refined according to patient and clinical expert input (Abetz et al., 2006; Rofail et al., 2008).

2.6.11 Psychological States

Sitzia & Wood (1997) noted that there has been little research into the relationship between psychological states (e.g. anxiety) and satisfaction. Further research into this connection is needed.

2.7 Treatment Satisfaction Definitions, Conceptual Frameworks, Methodological Issues and Associated Factors: The Significance to CLBP

This Chapter included definitions, conceptual frameworks, methodological issues and factors associated with treatment satisfaction within a wider context, not specific to CLBP which is the focus of this thesis. The rationale for this approach was that there is an ever increasing body of literature that pertains to treatment satisfaction in general, and which may provide useful insights when exploring the concept to a specific indication such as CLBP. For example, Oliver's theory of consumer satisfaction (Oliver, 1993) presented in section 2.3.2 has frequently been referred to, but is not specific to CLBP. Nevertheless, based on this model, it could be inferred that satisfaction or dissatisfaction with treatment in CLBP may be a result of the discrepancy between patient expectations and the actual patient experience in terms of the performance of the treatment such as whether it worked and whether any side effects were incurred etc.

Similarly, in section 2.2.2 a definition of treatment satisfaction specific to antipsychotic medication (Rofail et al., 2005) was provided as well as other more general definitions of treatment satisfaction. One of the reasons for this was to demonstrate how definitions based on patient input are often richer and more detailed than those based on clinical and researcher intuition. In addition, some aspects of satisfaction with antipsychotic medication may be relevant to CLBP such as treatment acceptability. However, it is important to note that other aspects relevant to antipsychotic medications may be less relevant to CLBP. For example, medication insight which is defined as self knowledge, awareness and understanding into the need for medication and its potential side effects, is an important concept for patients with schizophrenia receiving antipsychotic medication where the nature of the condition includes cognitive impairment and lack of insight into their condition. However, medication insight may not be as relevant to patients with CLBP where the condition is mainly characterised by severity of pain and associated functional impairment. Therefore, whilst an overview of treatment satisfaction in general is useful, its relevance in context of CLBP needs careful consideration. Ideally, further exploration of the treatment satisfaction literature specific to CLBP and input from patients with CLBP is warranted (see Chapter 3 and Chapter 4, respectively).

2.8 Summary

In summary, this Chapter outlines the problematic nature of current research into treatment satisfaction. Satisfaction can be viewed as a research problem in terms of defining what constitutes treatment satisfaction and establishing appropriate measurement of the concept based on reliable and valid instruments. Satisfaction can also be viewed as a treatment problem in terms of levels of satisfaction associated with continuing and adhering to treatment. It can also be a useful indication of best practice (for example, are patients involved in treatment decisions), providing a reference point for clinical practice. Findings also suggest that there are numerous factors associated with treatment satisfaction including but not limited to demographic, clinical and treatment characteristics, information provided, knowledge, beliefs, expectations, doctor-patient communication, and effectiveness of treatment.

Future research should consider existing definitions and frameworks of treatment satisfaction but also work to resolve the ambiguities around the concept. A systematic review of the literature is warranted that is focused on a particular indication and with particular attention to chronic conditions such as CLBP. The review should describe empirical studies that meet pre-specified inclusion criteria with attention to study designs, samples, as well as to definitions and conceptual frameworks of treatment satisfaction, and attention to the development and psychometric properties of instruments.

Chapter 3 - Study I – Treatment Satisfaction and Dissatisfaction in Patients with Chronic Low Back Pain: A Systematic Review

3.1 Introduction

There are many forms of CLBP treatment that offer varying levels of relief (see Chapter 1). Though adherence in CLBP is complex, there are negative consequences to non-adherence such as increased healthcare expenditure and social costs including burden on carers (Myers & Midence, 1998).

There is an expanding body of evidence to suggest that increased patient satisfaction would increase adherence to recommended treatment regimens (see for example, Rofail et al., 2008; Myers & Midence, 1998) (see section 2.6.10). Treatment satisfaction is therefore an important variable to assess as part of routine clinical practice and would aid the effective management of patients' treatment programmes, as well as help to improve and maintain patient well-being. The assessment of treatment satisfaction may also be useful in any CLBP survey or clinical trial.

There are various definitions of satisfaction (see section 2.2). A generally accepted definition is that satisfaction or dissatisfaction is an attitude or opinion expressed by patients about their clinical experiences (Kane et al., 1997). However, it is controversial whether the concept is a multidimensional or a unitary concept. For example, some have proposed that satisfaction is a unitary concept influenced by determinants such as values (Kane et al., 1997; Sitzia & Wood, 1997), whereas others have suggested that satisfaction is multidimensional, comprised of two or more domains (factors), such as 'treatment acceptability' and 'medication insight' (Rofail et al., 2005). The focus of this thesis is on CLBP, and there is also a need to synthesise the literature on treatment satisfaction within this field.

3.2 Objectives

The objective of this systematic review was to explore treatment satisfaction and dissatisfaction in patients with CLBP. Specifically, to:

1. Establish definitions and conceptual frameworks or models of treatment satisfaction in CLBP including:
    - Whether treatment satisfaction in CLBP is a uni-dimensional or multi-dimensional concept.
    - Whether treatment satisfaction in CLBP has been used as a dependent or independent variable.
2. Identify factors associated with treatment satisfaction in patients with CLBP.
3. Provide an overview of questionnaires available to assess satisfaction or dissatisfaction with treatments in CLBP.
4. Establish the quality of treatment satisfaction studies.
5. Establish the level of treatment satisfaction in patients with CLBP.

3.3 Methods

Using guidelines defined by the University of York NHS Centre for Reviews and Dissemination (Centre for Reviews and Dissemination, 2009), a systematic search strategy was implemented. In order to ensure as comprehensive and unbiased a search as possible, a variety of search methods (both computerised and manual) were implemented.

3.3.1 Electronic Databases

The following five electronic databases were searched:

- PUBMED (index of medical literature)
- PsycINFO (index of psychological literature)
- EMBASE (indexes journals in biomedical and pharmacological literature)
- CINAHL (Cumulative Index to Nursing and Allied Health Literature)
- Web of Knowledge

A key specialist database was also searched:

- PROQOLID (Patient-Reported Outcomes Quality of Life Instruments Database)

3.3.2 Search Strategy

A search of published studies between January 1990 and December 2009 was conducted using the following keywords:

- chronic low back pain **OR** CLBP

  AND

- treatment **OR** therapy **OR** medication **OR** analgesic **OR** opioid **OR** physiotherapy **OR** physical therapy

  AND

- satisfaction **OR** dissatisfaction

3.3.3 Hand Searching

The following journals considered to be most relevant to today’s treatment scenario in CLBP and were hand searched separately for October, November and December of 2009 to identify publications that may not yet have been entered into databases:

- Pain
- Physiotherapy
- SPINE

3.3.4 Inclusion Criteria

The inclusion criteria were designed to capture articles that measured treatment satisfaction or dissatisfaction in CLBP. To be eligible for inclusion, an article had to specify the following in the title or abstracts of articles:

- patients with CLBP
- original data describing patient satisfaction and/or dissatisfaction with treatments for CLBP
- empirical quantitative data of patient satisfaction and/or dissatisfaction with treatments

3.3.5 Exclusion Criteria

Studies were excluded in the following cases:

- CLBP was not the primary focus
- the focus was on a broadly defined LBP patient population (see for example, Kalauokalani, Cherkin, Sherman, Koepsell, & Deyo, 2001)

- patients had acute or sub-acute back pain and there was no chronic comparison group (see for example, Curtis et al., 2000)
- data of sub-groups (e.g. acute, sub-acute and chronic patients) were pooled for analyses
- treatment was surgery or other invasive methods such as injections, implantable drug delivery systems, or acupuncture (N.B. where the issues related to satisfaction/dissatisfaction are likely to extend beyond those related to medication and/or physiotherapy e.g. fear of needles, fear of blood or puncturing of the skin, concerns about the future related to a non-reversible procedure, fear of going under anaesthetic, incidence and severity of side effects associated with anaesthetic surgeon’s competence, potential complications of surgery, attitudes and behaviour of surgeons and nursing staff, adequacy of hospital facilities, etc. In addition, treatment with surgery and other invasive methods were beyond the scope of this thesis whereby the main focus is on medications/physiotherapy and satisfaction with these treatments.)
- results did not document treatment satisfaction scores
- results focused on other types of satisfaction or dissatisfaction such as job satisfaction, life satisfaction, and marital satisfaction
- qualitative studies
- review papers
- posters
- letters or commentaries
- foreign language studies and non-English papers

Only studies which met all of the pre-defined inclusion and none of the exclusion criteria were included.

3.3.6 Description of Studies

Information was extracted about the aim, design and method, treatment or therapy, sample size, outcome measures, statistical analysis, and main findings including statistical significance.

3.3.7 Data Synthesis and Analysis

Studies were qualitatively reviewed with consideration given to methodological strengths and weaknesses. Meta-analysis was not performed since a preliminary review of studies revealed that there are limited data and study designs varied too much.

The quality of the articles was assessed in two parts. The first part used a 'hierarchy of evidence'. Specifically, studies were categorised according to the attributes of their design. An amalgamation of two hierarchies was used, which increases progressively downwards (Centre for Reviews and Dissemination, 2009; Greenhalgh, 1997). The categorisation of each study was conducted by two independent researchers (DR and a trained researcher), and any discrepancies were resolved by discussion.

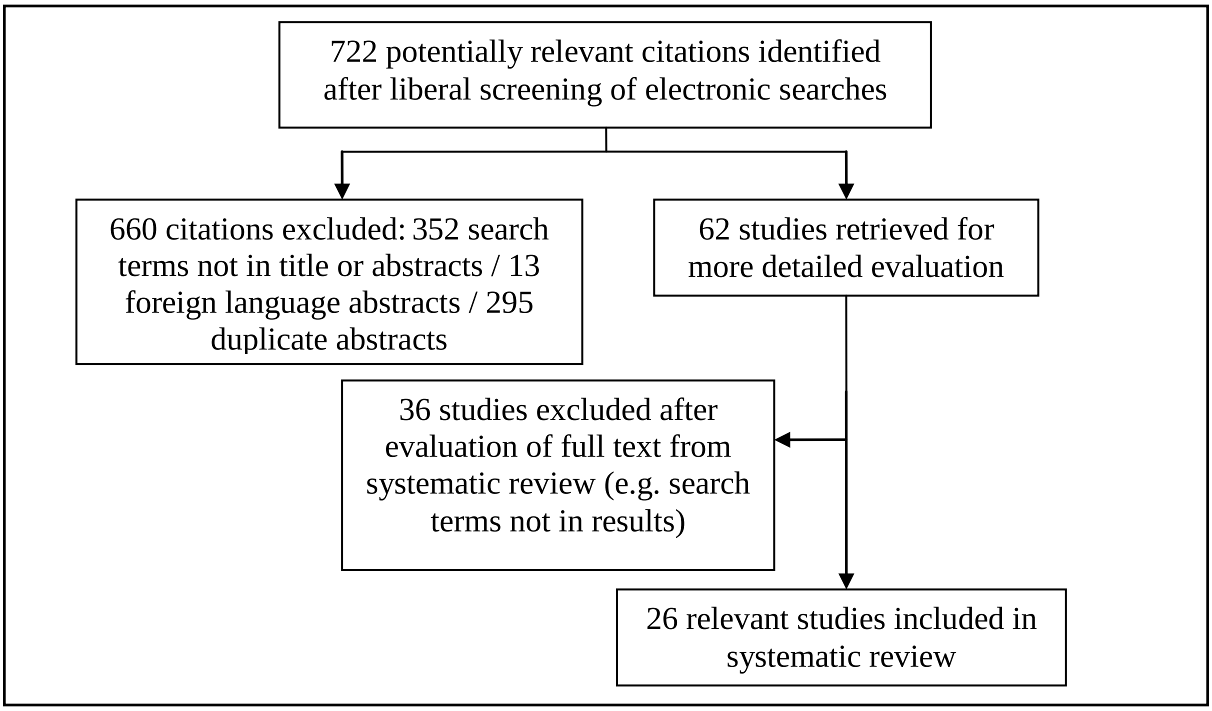
The second part involved using a 10-item checklist that was developed for a systematic review of patient satisfaction in antipsychotic medications (Walburn, Gray, Gournay, Quraishi, & David, 2001) and modified for this review. Originally, the items for this checklist were derived from two main sources (Centre for Reviews and Dissemination, 2009; Greenhalgh, 1997), and focused on variables most often highlighted in critical appraisal. The ten items were whether studies had explicit a priori aims, definitions of the size of the population under investigation, sample size calculation, justification that sample was representative of population, specification of inclusion/exclusion criteria, demographic details, justification of reliable and valid satisfaction instruments, an original questionnaire, response/drop-out rates, and discussion about the generalisability of results.

3.4 Results

3.4.1 Selection of Studies

The search strategy produced 722 articles. Of these, 660 were excluded (reasons included search terms not in title or abstract (n=352), non-English abstracts (n=13), and duplicates from use of various electronic databases (n=295)). Sixty-two abstracts met the inclusion criteria for containing satisfaction data and these were retrieved for more detailed evaluation. Closer examination excluded 36 studies after evaluation of full text because they did not meet the pre-specified inclusion and exclusion criteria (see section 3.3.4).

Figure 6: Flow Diagram of Study Selection Process



3.4.2 Description of Included Articles

The final list of reviewed articles is presented in Appenidix A. Table 4 summarises the design, participants, treatments/interventions and satisfaction measures used in the studies described in the included articles. All the studies included in this systematic review explored satisfaction in patients with CLBP (see sections 3.4.7 to 3.4.9).

CLBP was defined in different ways. For example, CLBP was referred to as pain lasting ≥ three months or ≥ 3 months constant/intermittent LBP (See for example, Licciardone et al., 2003; Barker, Elliott, Sackley, & Fairbank, 2008; Buchner, Zahlten-Hinguranage, Schiltenwolf, & Neubauer, 2006) or in some instances ≥ 3 months continual/recurrent LBP (See for example, Mannion, Muntener, Taimela, & Dvorak, 1999). However, one study defined CLBP as having had pain for ≥ 6 weeks (Nyiendo, Haas, & Goodwin, 2000). As well as duration of chronicity, impact on activities of daily living or functioning was a main criteria of inclusion for three studies (Wallace, Skowronski, Khanna, Tudor, & Thipphawong, 2007; Buchner, Neubauer, Zahlten-Hinguranage, & Schiltenwolf, 2007; Carey, Garrett, & Jackman, 2000). For example, one study specified that patients must be experiencing disabling symptoms (Carey et al., 2000), another required that patients were also on sick leave for six weeks or more (Buchner et al., 2007), and another that patients had experienced CLBP and activity limitations everyday for the last three months (Wallace et al., 2007). There were two studies that also included other groups of patients such as neck pain (Buchner et al., 2006) or acute pain (Haas, Sharma, & Stano, 2005). These studies were included because the results of each group were separate from the CLBP group. However, results on neck pain and acute pain were not extrapolated or reported as they are beyond the scope of this review.

The treatments and interventions studied were diverse (Table 4) and included medical/GP care, chiropractic care, osteopathy, physiotherapy, and surgery. For example, one study explored the benefits of back school (Shirado et al., 2005) and another focused on patients' perceptions of yoga (Groessl, Weingart, Aschbacher, Pada, & Baxi, 2008).

3.4.3 Quality of Studies

The quality of studies was mixed. Study performances as assessed by the checklist ranged from 3-7 out of 10 (mean number of lost points was 4.23, indicating an overall low quality of studies). The studies performed best for ‘explicit a priori aims’ (included in all studies), followed by ‘inclusion/exclusion of studies’ (included in 92% of studies). Only 19% of studies provided a sample size calculation to indicate the number of participants required to determine significant differences between groups, and only 12% of studies discussed the generalisability of results. None of the studies demonstrated that the study sample was representative of patients with CLBP Table 5.

Table 4: Characteristics of Included CLBP Studies

Study*	**Design**	**Participants**	**Treatments/Intervention**	**n**	**Satisfaction Outcome Measures**
Barker 2008	RCT.	Patients with CLBP > 3 months.	TENS/ FairMed device (to deliver sensory discrimination training).	60	Global rating of improvement and satisfaction, the Patient Global Impression of Change (PGIC) scale.
Buchner 2006	Cohort study.	Patients with CLBP > 3 months.	Multidisciplinary therapy as inpatients.	231	Level of satisfaction with therapy (5-point Likert-type scale: 5 = very satisfied; 1 = completely dissatisfied).
Buchner 2007	Cohort study	Patients with CLBP ≥ 3 months and sick leave for 6 weeks or more.	Multidisciplinary therapy as inpatients.	405	Level of satisfaction with therapy (5-point Likert-type scale: 5 = very satisfied; 1 = completely dissatisfied).
Buchner 2007	Cohort study.	Patients with CLBP ≥ 3 months who had sick leave for 6 weeks or more.	Multidisciplinary therapy as inpatients.	387	Level of satisfaction with therapy (5-point Likert-type scale: 5 = very satisfied; 1 = completely dissatisfied).
Carey 2000	Cohort study.	Patients with CLBP and persistent disabling symptoms > 3 months.	Chiropractic/ medical care.	96	A study specific question administered by telephone about overall satisfaction with care over the course of the patient's LBP. No further details provided.
Chown 2008	Cohort study.	Patients with CLBP > 3 months.	Group exercise/ physiotherapy/ osteopathy.	154	Questions regarding satisfaction with medical treatment on five-point Likert-type scale. No further details provided.
Goodwin 2000	Cross-sectional survey.	Patients with CLBP.	Multidisciplinary therapy in outpatients.	105	A patient satisfaction questionnaire was used with 10cm visual analogue scales to assess relative satisfaction with the individual components of the rehabilitation programme. The questions covered the introduction, understanding back pain, pain theories, sleep and beds, gym, hydrotherapy, part of a group, physical abilities, organisation, and staff. A score of 10 represented the most positive view towards that question, and scores less than 7 depicted areas of dissatisfaction.
Groess 2008	Cohort study.	Veteran patients with CLBP > 6 months attending a clinical yoga program.	Clinical yoga program.	49	Patients rated health benefits received from the yoga program, their yoga instructor, and the ease of participation on 0-10 visual analogue scales (0 being the worst and 10 indicating more satisfaction).
Haas 2005	Cohort study.	Patients with a primary complaint of CLBP of mechanical origin.	Chiropractic / medical care.	837	Patient satisfaction was evaluated on a 100-point scale, with higher scores indicating greater patient satisfaction.

Study[*]	**Design**	**Participants**	**Treatments/Intervention**	**n**	**Satisfaction Outcome Measures**
Hazard 1994	Cohort study.	Patients with CLBP, minimum 4 months work loss from back pain and absence of a clear, surgically correctable lesion.	Functional restoration and behavioural support.	90	Global treatment satisfaction questions. Scales ranged from 0=least satisfaction to 10=most satisfaction. No further details provided.
Holm 2003	Before-and-after study.	Patients with CLBP.	None specified. [Possible enrolment into an RCT to compare conservative treatment and spinal infusion].	42	Back satisfaction was measured using a single question designed to measure patients' overall back disability today.It was designed originally for a study to evaluate patients after shoulder surgery.
Katz 2005	RCT.	Patients with CLBP ≥ 3 months or more.	Bupropion sustained release (anti-depressant medication) / placebo.	60	Global satisfaction with pain relief item using Likert-type scale responses (1=very dissatisfied, 2=dissatisfied, 3=neither dissatisfied nor satisfied, 4=satisfied, 5=very satisfied).
Licciardone 2003	RCT.	Patients with >3 months of constant or intermittent, non-specific CLBP.	Osteopathic manipulative treatment / chiropractic manipulation / no intervention control group who continued their usual care.	91	Global satisfaction question using Likert-type scale responses. Higher scores represent less satisfaction with back care. No further details provided.
Macario 2008	Before-and-after study.	Patients with chronic discogenic LBP > 12 weeks	Spinal decompression using DRX9000	94	Global satisfaction question: 'How satisfied were you with DRX9000 treatment?' Response scale ranged from 0=Not satisfied to 10 very satisfied.
Mannion 1999	RCT.	Patients with >3 months of continual or recurrent episodes of CLBP.	Physiotherapy / muscle reconditioning using training devices / low-impact aerobics.	148	Study-specific questionnaire exploring patient satisfaction with therapy. Items were: 1) 'Happy with group to which randomised', 2) 'Impression changed during therapy', 3) 'Enjoyed coming to therapy', 4) 'Recommend therapy to others with similar problems, 5) 'Continue with this therapy if given the chance', 6) 'Therapist competence', 7) 8) Therapist friendliness', 9) 'Therapist advice in performing everyday tasks', and 10) Therapist interest in patient and their back problems'. Responses involved various Likert-type scales ranging from 1 to 5 (e.g. 1 = disappointed, 3=indifferent, 5=satisfied, or 1=worsened, 3=unchanged, 5=improved).
Molinari 2001	Cohort study.	Servicemen with CLBP history ≥ 1 year.	Instrumented posterior lumbar interbody fusion surgery / non-operant treatment.	14[†]	Three satisfaction questions scored on a 16-point scale with 15 representing maximum satisfaction and 0 representing total dissatisfaction. Scores totalled to provide an overall procedure

Study[*]	**Design**	**Participants**	**Treatments/Intervention**	**n**	**Satisfaction Outcome Measures**
					satisfaction score. No further details provided.
Niemisto 2005	RCT.	Patients with CLBP (with or without sciatica).	Multidisciplinary (chiropractic/exercise/GP) / GP care.	204	Satisfaction with care. No further details provided.
Norris 2008	RCT.	Patients with CLBP > 3 months under the care of a private physiotherapy company.	Integrated back stability programme / control.	59	Eight study specific questions explored patients experience and includuing an item: ‘Taking into account all your daily activities, your level of pain, and your functional impairment, do you consider that your current state is satisfactory?’ Responses involved marking a line between a 7-point bipolar rating scales. A score of 7 indicated the maximum positive experience, a score of 1 the maximum negative, and a score of 4.5 indicated a neither positive nor negative experience.
Nyiendo 2001	Cohort study.	Patients with CLBP > 6 weeks.	Chiropractic / medical care.	835	The Cherkin and MacCornack satisfaction questionnaire (Cherkin & MacCornack, 1989) administered by telephone and mailed at follow-up. Items covered: Doctor’s concern, doctor’s confidence and patient’s confidence. The response scale ranged: ‘very satisfied’, ‘satisfied’, ‘neutral’, ‘dissatisfied’ and ‘very dissatisfied’.
Nyiendo 2000	Cohort study.	Patients with recurrent CLBP ≥ 6 weeks.	Chiropractic / medical care.	138	Nine-question telephone interview modelled on the Cherkin and MacCornack satisfaction questionnaire (Cherkin & MacCornack, 1989) and a study specific mailed questionnaire for follow-up. Items included patient’s assessment of physician’s concern, patient’s impression of physician’s confidence, and patient’s own level of comfort, scored on a scale of 1=strongly disagree to 5= strongly agree. Satisfaction with information, treatment and overall medical care were scored on a scale of 1 = very satisfied to 5 = very dissatisfied.
Pincus 2000	Before-and-after study.	Patients with CLBP > 3 months.	GP / osteopath.	60	Adapted questionnaire used to assess patient satisfaction among the chronically ill (Linn & Greenfield, 1982). Three subscales were included: 1) competence (training, diagnosis, thoroughness in examination and tests, planning treatment), 2) quality of care (personal relationships, listening, caring), and 3) efficacy (improvement in health, reduction in symptoms). Each subscale

Study[*]	Design	Participants	Treatments/Intervention	n	Satisfaction Outcome Measures
					was measured on a 7-point scale, with anchors (extremely dissatisfied/extremely satisfied). A score of global satisfaction with back-pain management was also obtained.
Rainville 1997	Cohort study.	Patients with CLBP > 4 months.	Exercise and spine rehabilitation.	192	Patient satisfaction was assessed with a 10-item questionnaire covering scheduling, business services, physician services, therapist services, team-work, communication, education, home exercise instruction, quality of care, and effectiveness of care. Responses ranged from 1=excellent, 2=very good, 3=good, 4=fair, and 5=poor. Responses to the 10 questions were totaled.
Shirado 2005	Cohort study.	Patients with CLBP > 4 months who attended a low back school.	Back school – multidisciplinary team.	182	Global satisfaction question using 4 response categories: very satisfied, satisfied, not satisfied and not disappointed (equal), unsatisfied.
Smeets 2006	RCT.	Patients with non-specific CLBP > 3 months.	Active physical treatment / cognitive-behavioural therapy / combined treatment / waiting list control group.	223	Treatment satisfaction was measured by using a 100mm visual analogue scale for the overall treatment provided to the patient.
Torstensen 1998	RCT.	Patients with CLBP sick-listed for more than 8 weeks and less than 52 weeks.	Medical exercise therapy / conventional physiotherapy / ordinary activity level.	208	Treatment satisfaction questions rated on a 4-point scale: 1=completely satisfied, 2=partly satisfied, 3=not satisfied and 4=dissatisfied. No further details provided.
Wallace 2009	Cross-sectional survey.	Patients with CLBP and activity limitations every day for the previous 3 months.	None specified.	624	Six dichotomous (yes/no) questions were used to assess patients' satisfaction with their most recent provider for CLBP. The questions were: 1) 'Were you satisfied with your contact with the doctor or practitioner?' 2) Did you have an adequate explanation of your problem?' 3) 'Did you feel he/she was concerned about you?' 4) 'Did you feel he/she understood what was bothering you?' 5) Did the doctor or practitioner spend enough time with you?' 6) Would you want to see the same doctor or practitioner the next time you see a practitioner for your back problem?' Patients who gave affirmative answers to all six questions were identified as 'satisfied' with their last visit (dichotomous dependent variable of satisfied or not satisfied).

[*] Only first author reported; † n for comparative group/s not included; RCT: Randomised controlled trial.

Table 5: Quality of Included CLBP Studies

Study[*]	Explicit a priori aims	Definition of population under investigation	Sample size calculation	Justification that sample is representative of population	Inclusion/ exclusion criteria	Demographic details	Justification of reliable/ valid satisfaction instruments	Original item/ questionnaire	Response/ dropout rate specified	Discussion of generalisability	Total Score[**]
Barker 2008	+	+	+	-	+	+	+	-	+	-	7/10
Buchner 2006	+	+	-	-	+	+	+	-	-	-	5/10
Buchner 2007	+	+	-	-	+	+	-	+	+	-	6/10
Buchner 2007	+	+	-	-	+	+	+	-	+	-	6/10
Carey 1998	+	+	-	-	+	+	-	+	+	-	6/10
Chown 2008	+	+	-	-	+	+	+	+	+	-	7/10
Goodwin 2000	+	+	-	-	+	+	-	+	-	-	5/10

Study[*]	Explicit a priori aims	Definition of population under investigation	Sample size calculation	Justification that sample is representative of population	Inclusion/ exclusion criteria	Demographic details	Justification of reliable/ valid satisfaction instruments	Original item/ questionnaire	Response/ dropout rate specified	Discussion of generalisability	Total Score[**]
Groessi 2008	+	+	-	-	-	+	+	+	+	-	6/10
Haas 2005	+	+	-	-	+	+	+	-	+	+	6/10
Hazard 1994	+	-	-	-	+	+	-	+	+	-	5/10
Holm 2003	+	-	-	-	+	+	+	-	+	-	5/10
Katz 2005	+	+	+	-	+	+	+	-	+	-	7/10
Licciardone 2003	+	-	-	-	+	+	-	+	+	+	6/10
Macario 2008	+	+	+	-	+	+	-	+	+	-	7/10
Mannion 1999	+	-	-	-	+	+	-	+	+	-	5/10
Molinari 2001	+	+	-	-	+	-	-	-	-	-	3/10

Study[*]	Explicit a priori aims	Definition of population under investigation	Sample size calculation	Justification that sample is representative of population	Inclusion/ exclusion criteria	Demographic details	Justification of reliable/ valid satisfaction instruments	Original item/ questionnaire	Response/ dropout rate specified	Discussion of generalisability	Total Score[**]
Niemisto 2005	+	+	-	-	+	+	+	-	-	-	5/10
Norris 2008	+	+	-	-	+	-	+	+	-	-	5/10
Nyiendo 2001	+	+	-	-	+	-	+	-	+	-	5/10
Nyiendo 2000	+	-	-	-	+	+	-	+	+	-	5/10
Pincus 2000	+	+	-	-	+	+	+	-	-	+	6/10
Rainville 1997	+	-	-	-	+	+	-	+	+	-	5/10
Shirado 2005	+	+	-	-	+	+	+	+	+	-	7/10
Smeets 2006	+	+	+	-	+	+	-	+	+	-	7/10
Torstensen	+	+	+	-	+	+	-	+	+	-	7/10

Study[*]	**Explicit a priori aims**	**Definition of population under investigation**	**Sample size calculation**	**Justification that sample is representative of population**	**Inclusion/ exclusion criteria**	**Demographic details**	**Justification of reliable/ valid satisfaction instruments**	**Original item/ questionnaire**	**Response/ dropout rate specified**	**Discussion of generalisability**	**Total Score**[**]
1998											
Wallace 2009	+	+	-	-	+	+	-	+	+	-	6/10
TOTAL	26/26	20/26	5/26	0/26	24/26	21/26	13/26	16/26	19/26	3/26	-

[*] Only first author reported + Present - Absent

[**] If study met all criteria, total score 10 points

3.4.4 Design

The majority of studies were longitudinal cohort designs (39%, n=10) (Buchner, Neubauer, Zahlten-Hinguranage, & Schiltenwolf, 2007; Carey et al., 2000; Groessl et al., 2008; Haas et al., 2005; Hazard, Haugh, Green, & Jones, 1994; Molinari & Gerlinger, 2001; Nyiendo et al., 2000; Nyiendo, Haas, Goldberg, & Sexton, 2001; Rainville, Sobel, Hartigan, & Wright, 1997; Shirado et al., 2005). Others were randomised controlled trials (31%, n=8) (Barker et al., 2008; Katz, Pennella-Vaughan, Hetzel, Kanazi, & Dworkin, 2005; Licciardone et al., 2003; Mannion et al., 1999; Niemisto et al., 2005; Norris & Matthews, 2008; Smeets et al., 2006; Torstensen et al., 1998), before and after studies (See for example, Macario, Richmond, Auster, & Pergolizzi, 2008) and cross-sectional surveys (See for example, Wallace, 2009).

3.4.5 Samples

All but one study specified the definition or diagnostic criteria used for CLBP (Nyiendo et al., 2001), but the criteria used to select CLBP populations varied. One potential consequence of small differences in diagnostic criteria is large differences in selected populations.

3.4.6 Descriptive and Inferential Statistical Analyses

All the studies included in this review used both descriptive and inferential statistics for statistical analyses. Descriptive statistics are concerned with the presentation, organisation, and summarisation of data (Norman & Streiner, 1994). Common descriptive statistics used in patient satisfaction with treatments in CLBP studies included measures of central tendency such as mean, median, and mode, and measures of dispersion such as range, minimum, maximum, and standard deviation.

Inferential statistics enable generalisation from a sample of data to a larger group of individuals (Norman & Streiner, 1994). Common inferential statistics used in patient satisfaction with treatments in CLBP studies included regression analyses (See for example,Mannion et al., 1999), analysis of variance (See for example, Licciardone et al., 2003; Mannion et al., 1999; Nyiendo et al., 2001), and chi^2 test (See for example, Licciardone et al., 2003).

3.4.7 Definitions and Conceptual Frameworks of Patient Satisfaction with Treatments in CLBP

Of the 26 studies included in this systematic review, none operationally defined patient satisfaction or dissatisfaction with treatments in CLBP, or proposed a conceptual framework or model of what comprises patient satisfaction with treatments. Often, there appeared to be no distinction between satisfaction and dissatisfaction, and the way that satisfaction and dissatisfaction were measured generally implied equality between the concepts. Further, none of the studies stated how the concepts were used, although sometimes this could be inferred. For example, no study discussed whether satisfaction was considered an independent or dependent variable, and studies did not state whether the concept was perceived as uni-dimensional or multidimensional but this information could be extrapolated from closer observation of the measures used or statistical analyses.

3.4.8 Questionnaires Used to Measure Patient Satisfaction with Treatment in CLBP

All 26 studies reported satisfaction data from patients' perspectives, all using a patient-reported assessment. There were three studies that used a telephone interview which may have influenced results because for example, even with pre-specified responses it required interpretation of responses for coding (Nyiendo et al., 2000; Nyiendo et al., 2001; Carey et al., 2000).

Based on the findings of this systematic review, there is no consensus or ‘gold standard’ for measuring treatment satisfaction or dissatisfaction in CLBP. The Cherkin and McCornack Satisfaction Questionnaire was used in 8% of studies (n=2) (Nyiendo et al., 2000; Nyiendo et al., 2001). This instrument covers aspects relevant to patients’ satisfaction with care and contains 11 items (see section 3.4.9). In addition, one study (Pincus et al., 2000) adapted a 27-item osteopathic and GP management satisfaction questionnaire originally developed by Linn & Greenfield (1982). One important consideration is that the adapted 27-item questionnaire was originally developed in patients with chronic illness and further details are not provided regarding for example, types of chronic illness and number of patients, if any, with CLBP which is the focus of this thesis. Whilst there are some similarities between patients with CLBP and those with other chronic indications (such as that they may both experience pain which may cause some form of disability), there may be key differences. For example, someone with chronic pain induced from having for example, cancer, may have a very different experience of pain, or may rationalise their pain and any limitations they experience in the context of survival, whereas an individual with CLBP may not face issues related to survival and therefore may perceive their pain and its impact on daily activities very differently.

In addition, five studies used study specific questionnaires (Carey et al., 2000; Goodwin & Goodwin, 2000; Mannion et al., 1999; Molinari & Gerlinger, 2001; Rainville et al., 1997). See Table 4 for details on the content of satisfaction items or factors. In general, these study-specific questionnaires measured satisfaction with various components of treatment such aspects of the therapeutic relationship or a particular rehabilitation programme. Also, the content was usually unidimensional measurement and so many aspects of treatment satisfaction related to the focus of this thesis were omitted such as satisfaction with the treatment process (e.g. involvement in treatment decisions), and often minimal details were provided.

Further, satisfaction assessments differed in the number of items included, and the rating scales. Notable examples include studies that measured patient satisfaction modelled on the Cherkin & MacCornack satisfaction questionnaire and a 5-point Likert-type scale (Nyiendo et al., 2000; Nyiendo et al., 2001), and 13 studies that used a single global satisfaction item of various kind (Barker et al., 2008; Buchner et al., 2006; Buchner et al., 2007; Buchner et al., 2007; Barker et al., 2008; Hazard et al., 1994; Holm, Friis, Storheim, & Brox, 2003; Katz et al., 2005; Licciardone et al., 2003; Macario et al., 2008; Shirado et al., 2005; Smeets et al., 2006; Torstensen et al., 1998). Closer examination of the global satisfaction items revealed the diversity between studies using satisfaction ratings, since they focused on different aspects of CLBP and its treatment. For example, one global satisfaction rating was specific to pain relief (Katz et al., 2005) while another measured back satisfaction (Holm et al., 2003).

In fact, this potential problem was not just limited to global satisfaction ratings and CLBP studies appear to assess satisfaction with many different aspects ranging from pain relief (Katz et al., 2005), back satisfaction (Holm et al., 2003), satisfaction with the rehabilitation programme (Goodwin & Goodwin, 2000), satisfaction with therapy (Buchner et al., 2006; Buchner et al., 2007; Buchner et al., 2007; Mannion et al., 1999), and satisfaction with care (Carey et al., 2000). This makes comparisons between studies particularly difficult.

In addition, the response scales also varied for global satisfaction assessments from 5-point Likert-type scales (See for example, Buchner et al., 2006; Buchner et al., 2007; Buchner et al., 2007), to scales that ranged from 0-10 or 0-100 (See for example, Groessl et al., 2008; Haas et al., 2005) where higher scores indicate a level of satisfaction. Some global satisfaction assessments had 4 categorical options such as ‘very satisfied’,

‘satisfied’, ‘not satisfied and not disappointed’, and ‘unsatisfied’ (See for example, Shirado et al., 2005).

Comparing satisfaction results across these 26 studies is complicated because the studies did not focus on satisfaction and because the design of the studies and measurement of satisfaction varied so greatly. However, some key points did emerge when the satisfaction results were compared, as shown in Table 6. Most studies reported a positive level of satisfaction. Nevertheless, it is not apparent from this review whether these positive results were a true reflection of patients’ scores or if some have ceiling effect (perhaps a consequence of the way studies measured satisfaction). Also, in general, chiropractic care appeared to be favoured by patients over medical care (Nyiendo et al., 2001; Nyiendo et al., 2000).

It should be noted that whilst there are numerous global ratings of satisfaction items used in CLBP studies, these generally require patients to average their opinion of for example, ‘satisfaction with therapy’ into one single question at each timepoint. Chapter 2 demonstrates the various aspects that may be related to patient satisfaction with treatment (e.g. information/knowledge provided, involvement in treatment decisions, therapeutic relationship, patient perceptions and experiences with treatment etc.) and therefore the appropriateness of global ratings could be questionable depending on the intended purpose. For example, can patients truly average all of that information into a single item, and if they can, is there consistency between patients in terms of what they consider in making their global evaluation? Whilst global ratings are brief and easily administered, the inconsistency incurred when patients make their assessments possibly based on different criteria, may ultimately impact on reproducibility of scores (Feinstein, 1987). In addition, global ratings of satisfaction are subject to ceiling effects and can disguise or hide aspects of dissatisfaction (Lebow, 1974; Locker & Dunt, 1978). Further, global ratings are generally known to be less informative than for example, disease-specific or treatment-specific questionnaires which are multidimensional (Locker & Dunt, 1978; Hudak & Wright, 2000). Consequently, global rating assessments are sometimes used to aid interpretation. This notion is documented in the FDA PRO guidance which recommends the use of global ratings in general (not specific to treatment satisfaction) to help interpretation by the definition of responders (Food and Drug Association, 2009). Therefore, although a global rating of treatment satisfaction may in general not be suitable as an only assessment, it may be helpful in some studies in addition to other measures to aid interpretation of results.

Table 6: Patient Satisfaction Data in Included CLBP Studies

Study*	**Positive (+) Satisfaction Data**	**Neutral (0) Satisfaction Data**	**Negative (-) Satisfaction Data**
Barker 2008	In the FairMed group, 27% of patients stated that they were more able to cope with pain at 3weeks; in the TENS group, it was 45%.	73% of the FairMed participants stated no change in their ability to cope with pain compared to 44% in the TENS group.	11% of TENS group participants stated that they were less able to cope with pain at 3 weeks.
Buchner 2006			Using a 5-point Likert scale, the mean satisfaction with therapy score for patients with CLBP was 2.85 (SD ± 1.61).
Buchner 2007		Using a 5-point Likert-type scale, satisfaction with therapy scores between the three age groups ranged from 3.10 to 3.48 (SD ± 1.43 to 1.58) at 6 month follow-up.Results between different age groups were not statistically significant.	
Buchner 2007		Using a 5-point Likert-type scale, satisfaction with therapy scores between the three groups of chronicity ranged from 3.13 to 3.45 (SD ± 1.40 to 1.58) at 6 month follow-up. Results between groups of chronicity were not statistically significant.	

Study[*]	Positive (+) Satisfaction Data	Neutral (0) Satisfaction Data	Negative (-) Satisfaction Data
Carey 2000	At 22 months, patients were asked about their overall satisfaction with care. Care was rated as ‘very good’ or ‘excellent’ by 25% of patients with unremiting CLBP compared to 38% of those with remitting CLBP.		
Chown 2008	Results on the 5-point Likert-type scale were collapsed. At baseline, the majority of patients were ‘somewhat/very satisfied’ with group exercise, physiotherapy and osteopathy: 39%, 42%, and 40% , respectively. The proportion of patients stating ‘somewhat satisfied’ or ‘very satisfied’ with overall medical treatment increased for all treatment groups (group exercise/physiotherapy/ osteopathy) between baseline and 6 weeks. 63%, 79%, 87%, respectively.		
Goodwin 2000	The following elements of the programme scored positively - above 7 on 0-10 VAS scales: the introduction, understanding back pain, pain theories, open discussion about pain, ergonomics, exercise principles, stress and relaxation, gym, hydrotherapy, part of a group, physical abilities, psychological abilities, staff and organisation.		The following elements scored negatively - below 7 on 0-10 VAS scales: healthy back video, sleep and beds, and mentoring.
Groessl 2008	On VAS scales of 0-10, mean scores for the health benefits received from the yoga program, the yoga instructor, and the ease of participation were 5.97, 9.09, and 6.03, with higher scores indicating more satisfaction.		
Haas 2005	On a scale of 0-100, results indicated that patients with CLBP receiving chiropractic care had significantly higher patient satisfaction than patients receiving medical care: mean 86.4 SD 19.9 vs. mean 71.3 SD 22.7, respectively, p<0.01.		
Katz 2005	On a scale of 1 to, satisfaction with pain relief was 3.43 (SD 1.06) for patients receiving bupropion compared to 2.78 (SD 1.07) for patients receiving placebo. This difference reached statistical significance.		
Licciardone 2003	Both osteopathic manipulative treatment (p=0.001) and sham manipulation (p=0.02) participants reported significantly greater satisfaction with their back care than the no intervention control participants.		
Macario 2008	On a scale of 0 to 10, mean satisfaction scores with DRX9000		

Study[*]	Positive (+) Satisfaction Data	Neutral (0) Satisfaction Data	Negative (-) Satisfaction Data
	treatment (for spinal decompression) was 8.55 (median 9, range 5 to 10).		
Mannion 1999	The majority of the patients declared their satisfaction on hearing which group they had been assigned to, and few of them changed their impression for the worse during the course of the treatment. This was observed for all three groups.		
Molinari 2001[†]	The non-operative group had an average satisfaction score of 9.6 of 15 (SD 2.8). The operative group had an average satisfaction score of 13.9 of 15 (SD 1.8). The difference in satisfaction scores between the groups reached statistical significance.		
Niemisto 2005	At 2 years, the combination group (receiving combined manipulation, stabilising exercises and physician consultation) had higher satisfaction with care compared to the consultation group.		
Norris 2008	Mean values of all patient satisfaction questions showed positive experience (>4.5 points).		
Nyiendo 2001	There was a sharp contrast favouring chiropractic in the proportion of patients that reported satisfaction with care at 1 year; the trend was apparent on all 10 satisfaction questions (p<0.0001). Differences between chiropractic and medical care were found in patients' confidence that the treatment was working (36% vs. 74%) and in the proportion of patients who would see a physician of the same type in the future for a CLBP problem (61% vs. 83%). For both groups, patients were least satisfied with 'sufficient information provided about the cause of their pain' (40% vs. 73%).		
Nyiendo 2000	Satisfaction was higher for patients attending chiropractors than medical physicians. In particular, patients expressed greater satisfaction regarding information on treatment program provided, and overall medical care.		
Pincus 2000	Levels of satisfaction were high (for competence, quality of care, and efficacy) for GP management and osteopath; however, there were significantly higher scores for satisfaction with osteopathic treatment compared to GP treatment in the same surgery.		
Rainville 1997	Satisfaction scores were analysed according to types of compensation		

Study*	**Positive (+) Satisfaction Data**	**Neutral (0) Satisfaction Data**	**Negative (-) Satisfaction Data**
	involvement (e.g. patients receiving Workers' Compensation, Social Securuity Disability, or private disability policy benefits). Where items scores ranged from 1to 10 (excellent to poor), mean item and total satisfaction scores were similar between those with and without compensation involvement (16.4 and 16.7, respectively).		
Shirado 2005	Eighty-five patients (48.6%) were satisfied with the back school 12 months after enrollment. Fifty-eight patients (33.1%) were satisfied.	Twenty patients (11.4%) were not satisfied/not disappointed (equal) with the back school 12 months after enrolment.	Twelve patients (6.9%) were unsatisfied/disappointed with the back school 12 months after enrolment.
Smeets 2006	Satisfaction scores for three different percentiles of the baseline Roland and Morris Disability Questionnaire (RMDQ) were presented. Satisfaction was significantly higher in the active physical therapy group compared to the waiting list control group when the patient had a lower level of functional limitations at pre-treatment. For the ninetieth percentile score (RMDQ = 19) this difference was not significant. CBT and combined therapy showed a significantly higher level of satisfaction compared to the waiting list group, and the higher the baseline RMDQ-score, the greater this difference became. No differences were evident between CT and CBT.		
Torstensen 1998	A total of 34.2% (26 patients) in the medical exercise therapy group (MET), 32.2% (19 patients) in the conventional physiotherapy (CP) group, and 6 patients 9.5% (6 patients) in the ordinary activity level group were 'completey satisfied' with their treatment. Many patients were 'satisfied' with their treatment: 28 in the MET group, 21 in the CP group, and 24 in the ordinary activity group.	There were 9 patients in the MET group, 14 in the CP group, and 25 in the ordinary activity group were 'partly satisfied' with their treatment.	There were 4 patients in the MET group, 5 in the CP group, and 8 in the ordinary activity group who were 'dissatisfied' with their treatment.
Wallace 2009	Atotal of 69% of the sample was completely satisfied with all elements of their care and 63% did not intend to seek care from another health-care provider.		
Number of studies	**21/24**	**5/24**	**5/24**

*Only first author reported

N.B. Hazard 2001/Holm 2003 are not included since papers document correlations/associations only.

3.4.9 An Overview of the Cherkin and MacCornack Questionnaire

As mentioned previously, the Cherkin and MacCornack questionnaire has been used in two out of 26 CLBP studies and therefore warrants further exploration (see section 3.4.8). On closer examination of the development paper (Cherkin et al., 1991), the questionnaire contains 11 items and was compiled to measure patient satisfaction with care for LBP rather than treatment satisfaction for CLBP. Firstly, the nature of patient satisfaction with care is a much broader and all-encompassing concept than treatment satisfaction (see sections 2.2.1 and 2.2.2). Also, patients with LBP include those with acute, subacute, and chronic pain (see section 1.1). Those with for example acute pain may have very different experiences compared to those with chronic pain both in terms of the clinical nature of their pain and its impact on daily functioning, as well as the management of pain (Grichnik & Ferrante, 1991), and therefore aspects of treatment satisfaction could also be very different. For example, acute pain is often incurred by a specific injury or disease, whereas, chronic pain may or may not emerge as a consequence of an injury and is often related to psychological states. Consequently, the treatment for acute pain is usually to target the underlying cause whereas chronic pain often requires a multidisciplinary approach (see section 1.5).

The Cherkin and MacCornack questionnaire was administered by telephone two to four weeks after patient's back pain visit. The process involved the interviewer reading 17 statements to patients about the care they had received from their physician. This method is not ideal given the potential bias that could be incurred in for example the way that statements are read to patients, as well as social desireability bias due to patient's desire to please the interviewer (Sitzia & Wood, 1997).

The items of the questionnaire covered information adequacy, physician caring, and technical quality of care, and were developed based on another study which indicated family physician's and chiropractor's perceptions regarding patients concerns about care (Cherkin & MacCornack, 1989). Therefore, the items were developed based on clinical expert opinion rather than patient's perceptions. Whilst the family physicians and chiropractors may have been involved in the day-to-day management of patients with LBP and therefore well informed of the daily challanges patients may face, developing a questionnaire informed by HCPs rather than patients (or perhaps both) may have resulted in missing important concepts.

Also, as mentioned in section 2.5.4 the qualitative research that emerges from patient interviews or focus groups allows reviewers to establish whether topics were omitted during instrument development that may have been important to patients. Using information from patient qualitative research also allows developers to check the phrasing of questions to ensure that they are meaningful to patients (Weaver et al., 1997). However, this level of information was not documented in the development paper of the Cherkin and MacCornack Questionnaire.

In the development paper there are also no details given regarding the actual questions asked to family physicians, or how item generation was actually performed. Also, it appears that that there were no cognitive debriefing exercises or pilot testing to establish whether patients truly understood what was required of them from each question. Cognitive debriefing would have provided further support for the face and content validity of the questionnaire and allowed an opportunity to pilot test the questionnaire including generating evidence to support that the response options are meaningful to patients and suitable for each item.

Item responses were on a Likert-Type scale from 'strongly agree' to 'strongly disagree'. Factor analysis was performed which yielded three subscales labelled: Information, Caring, and Effectiveness. However, the development paper does not document the percentage of variance that each factor contributed. Also, there is no clear indication of why three factors were extrapolated (for example, there is no scree plot or descriptive information to show the eigenvalues), and the factor loading matrix is not presented.

In addition, whilst Chronbach's alpha was performed for three subscales and results exceeded Nunnally's threshold of 0.70, and the construct validity of the scales were explored by correlating the scale scores with variables one would expect to be associated with patient satisfaction (all of which were statistically significant), the psychometric properties were not explored any further e.g. discriminant validity and test-retest reliability. In addition, there was no attempt to show that the questionnaire was sensitive to change over time.

With the above in mind, whilst the Cherkin and MacCornack Questionnaire has been used in clinical practice to inform treatment decision making for chiropractic care in patients with LBP, there is insufficient evidence from the development paper to support its utility and adequacy as a measure of treatment satisfaction in patients with CLBP receiving medication and/or physiotherapy.

3.4.10 Factors Associated with Patient Satisfaction

Four studies documented how satisfaction was related to other concepts (Hazard et al., 1994; Wallace et al., 2007; Nyiendo et al., 2001; Pincus et al., 2000). Factors associated with satisfaction included:

- pain (Hazard et al., 1994)
- disability (Hazard et al., 1994)
- age (Pincus et al., 2000)
- employment status (Hazard et al., 1994)

- narcotic use (Wallace et al., 2007)
- doctor type (Nyiendo et al., 2001)

One study also reported factors that did not seem to be associated with satisfaction (Pincus et al., 2000). These were: osteopath's competence, quality of care, efficacy, and number of appointments, demographic characteristics (sex, work status, and ethnicity), and psychological factors (depression, anxiety and coping style). However, there were mixed results between studies. For example, whilst Hazard (1994) found an association between satisfaction and pain/disability, Pincus (2000) found no association between satisfaction and symptoms including duration, pain intensity and disability.

3.5 Discussion

3.5.1 Summary

The last Chapter provides an overview of patient satisfaction and dissatisfaction in general. In this Chapter, this study investigated patient satisfaction and dissatisfaction with treatments for CLBP. There were five specific objectives discussed below.

The first objective was to establish definitions and conceptual frameworks or models of satisfaction and dissatisfaction with treatments in CLBP, including whether satisfaction was a uni-dimensional or multi-dimensional concept, and whether it had been used as a dependent or independent variable. Results indicated that there are few data in the literature concerned with patients' satisfaction with treatments for CLBP. Of the studies that exist, none focused on operationally defining the concept or establishing whether the concept is uni-dimensional or multi-dimensional. Consequently, there is a need to establish conceptually what patient satisfaction and dissatisfaction with treatments in CLBP is and how it relates to other concepts such as adherence.

The second objective of this study was to identify factors associated with treatment satisfaction or dissatisfaction in CLBP. Whilst there were some associations identified, there were mixed results between studies. For example, whilst Hazard (1994) found an association between satisfaction and pain/disability, Pincus (2000) found no association between satisfaction and symptoms including duration, pain intensity and disability. Therefore, further research is warranted to establish with greater certainity factors associated with the treatment satisfaction or dissatisfaction.

The third objective was to provide an overview of questionnaires used to measure treatment satisfaction or dissatisfaction. The Cherkin and MacCornack questionnaire was the most popular satisfaction assessment having been used in 2 out of 26 studies (8%). However, none of the studies including those who used the Cherkin and MacCornack Satisfaction questionnaire, provided rationale for its utility. Further, although the domain coverage and content of questionnaires were often briefly described, the psychometric properties of the instruments used were not documented. Thus it is questionable whether the studies were really assessing treatment satisfaction in CLBP or some other concept.

The Cherkin and MacCornack questionnaire had been used in two studies. Closer reflection of the questionnaire indicated that it was developed to measure patient satisfaction with family physician and chiropractic care in LBP rather than treatment satisfaction in CLBP. Further, it was developed using clinical expert opinion rather than patient input and there was no information regarding how the items of the questionnaire were developed. The questionnaire had not been cognitively debriefed or piloted with patients. Further, whilst there was some attempt to perform factor analysis of the items of the questionnaire, the information in the papers was insufficient to establish the appropriateness of the analyses and decisions made. Moreover, whilst there was some evidence of internal consistency and concurrent validity, there were no details regarding discriminant validity, test-retest reliability or sensitivity to change over time. Since no comprehensive and well developed instrument measuring treatment satisfaction in patients with CLBP could be found in the literature, there is a need to construct and validate one whose items are developed using rich qualitative interviews with patients with CLBP, with explicit details regarding the open-ended questions posed to patients, how the qualitative analyses were performed, and then cognitively debriefing the questionnaire in patients with CLBP. Following this, psychometric testing should be performed to confirm that questionnaire is truly measuring treatment satisfaction.

The fourth objective was to establish the quality of satisfaction studies. The designs used varied from the lower levels of the hierarchy of evidence, such as cohort studies, to the higher levels, such as double blind prospective randomised controlled trials (RCTs). While such longitudinal designs could be used to assess, for example, change in satisfaction scores over time, such data were rarely reported. When testing the clinical efficacy of treatment, several factors should be considered. Amongst the most important to patients are pain and functional impairment which are often primary and secondary endpoints in studies. The limited satisfaction data may in part demonstrate a lower priority placed on the patient's perspective. However, assessing treatment satisfaction as a supportive endpoint is also important given that it is associated with adherence to treatment, which in turn is likely to impact efficacy and therefore pain and functional impairment. Further, the mixed quality of studies makes comparisons and generalisations problematic.

Finally, the fifth objective was to establish the level of patient satisfaction or dissatistfaction with treatments in CLBP. What data there are to examine patient satisfaction with treatments in CLBP, illustrate predominantly positive but some negative attitudes towards treatment. The positive finding of the majority of studies suggests that such studies may be susceptible to the Hawthorne effect, since often data collection was within a clinical setting. Therefore, participants may have responded in a way they hoped would give them a preferred image in the eyes of the researcher. Future research should implement strategies to minimise such biases, such as conducting the study in a non-clinical setting, or being interviewed by an independent researcher who is not informed of the primary aims of the study, thereby enabling a more ‘real’ measure of patient satisfaction.

This systematic review suggests that there appears to have been no conscious efforts to distinguish between satisfaction and dissatisfaction, and to date the way that satisfaction and dissatisfaction have been measured generally imply equality between the concepts. However, these issues warrant further exploration based on rich qualitative data that emerge from in-depth interviews with patients who have CLBP, as well as clinician and researcher insights. In addition, there is a need to develop a valid and reliable measure of satisfaction with treatments in CLBP that is also based on rich qualitative data from in-depth patient interviews. Using this valid measure, further research could test hypotheses regarding factors associated with patient satisfaction and dissatisfaction.

3.5.2 Strengths and Limitations

It is important to acknowledge that the findings of this literature review are based predominantly on published studies found by searching electronic databases, such as PUBMED and PsycINFO, as well as from selective hand searches. Other instruments that measure patient satisfaction with treatment in CLBP may exist, and which were not part of this review.

Further, meta-analyses could not be performed in this literature review due to insufficient data and the diversity of study designs. However, the literature review was conducted systematically; the inability to perform meta-analyses does not diminish the robustness of the interpretation of the findings and the recommendations made. Thus, this literature review has fulfilled its purpose in providing an overview of treatment satisfaction and dissatisfaction in CLBP including consensus around satisfaction definitions, and whether good questionnaires exist to quantify the concept.

3.5.3 Conclusions

It is important to comprehensively assess patients' satisfaction with treatment in both routine clinical practice and CLBP clinical trials and surveys. Current instruments are not based on an operational definition of what constitutes patient satisfaction with treatment or a conceptual framework that clarifies relationships among the complex set of factors associated with this concept. Though the well-regarded Cherkin and McCormack Satisfaction Questionnaire has been used in two studies to assess satisfaction with overall care and treatment, the studies did not justify its use as a measure nor did they define patient satisfaction. Further, in cases where assessment tools have been used, the psychometric properties have rarely been reported and documented as they relate to patients with CLBP.

The findings of this systematic literature review highlight the need to develop an instrument specific to patient satisfaction with treatments in CLBP, that is based on a standard operational definition and a conceptual framework, and that has good psychometric properties. As outlined in Chapters 4-6, development and psychometric validation of such an instrument is currently underway.

Quantifying patient satisfaction allows health professionals to target aspects of patients' treatment that distress them (such as experiencing side effects), and therefore may assist in the improvement and maintenance of the patient's health. Moreover, analysing patient satisfaction with medication could indicate if best practice is being carried out (such as whether patients feel involved in treatment decisions, or if side effects are effectively managed by healthcare professionals) and provide a point of reference for clinical practice and future research. Finally, by reliably and validly measuring patient satisfaction and dissatisfaction with treatments in CLBP, analyses can be performed to explore how the concept is related to other concepts such as health-related quality of life and adherence to treatment regimens.

Chapter 4 - Study II – Treatment Satisfaction and Dissatisfaction in Patients with Chronic Low Back Pain: A Qualitative Study

The initial objectives of this study were to explore patients' subjective experiences with CLBP and its treatments, and their satisfaction and dissatisfaction with treatments. The researcher (DR) also planned to use the rich qualitative data extrapolated from interviews to develop a new instrument to assess satisfaction and dissatisfaction with treatment (medication and physiotherapy) for CLBP relief (see Chapter 5).

4.1 Introduction

The ultimate objective of the study was to obtain rich qualitative data to develop a disease-specific (CLBP) questionnaire that measures patient satisfaction and dissatisfaction with treatments (medication and/or physiotherapy). With this in mind, the purpose of the semi-structured interviews was to gain insight into and understand the subjective experiences of patients with CLBP receiving treatment (medication and/or physiotherapy) naturalistically – that is, to collect qualitative data based on spontaneous responses to open-ended questions rather than using pre-specified codes, summaries, or probes (Willig, 2001).

There are a number of different methods of sampling for qualitative research; these include convenience samples (the least rigorous method, also known as accidental sampling), theoretical sampling (Marshall, 1996) whereby ideally, the process of data collection and conceptualisation in qualitative research continues until 'saturated', that is, new data does not add to the developing theory (Guest, Bunce, & Johnson, 2006), and purposive sampling (also known as judgement sample), which is the most common. In qualitative research, purposive sampling is intended to enhance understandings of experiences encountered by individuals or a particular group of individuals. With purposive sampling, the intention is to select particular cases (e.g. individuals or groups) that provide the best insights to help address the research question (Devers & Frankel, 2000). There are many different strategies that can be employed for purposive sampling including but not limited to extreme case sampling (using cases that are rich in detail because they are unusual or specific in some way), maximum variation sampling (captures key themes across participant variations such as individuals of different age, gender, and employment), and homogenous sampling (identifies a small sample with similar traits to describe a group of individuals in detail such as patients with CLBP) (Collins, Onwuegbuzie, & Qun, 2006).

4.1.1 Method of Analysis

There are several methods that could be used to analyse qualitative data including, but not limited to, interpretive phenomenological analysis (IPA), discourse analysis, grounded theory, and thematic analysis. The most appropriate method is dependent on several factors but should be informed by the research question (Willig, 2001). If the primary purpose of this research had been to gain insight into patients' psychological worlds, then IPA would have been considered. Similarly, if the primary purpose of this study had been to explore the basic social processes, then grounded theory may have been used (Willig, 2001).

However, in this study, thematic analysis (Braun & Clarke, 2006), a widely-used qualitative analytic method that is increasingly being used in health-related research, was deemed the most appropriate method. Thematic analysis allows an analyst to find repeated patterns of meanings (themes) in a dataset. Whilst other qualitative methods also allow the identification of themes in a dataset, in this case, the primary purpose of the interviews was to use the data to develop a questionnaire. Further, thematic analysis is useful to establish a rich thematic description of the entire dataset, so that predominant themes can be identified. It is also a particularly useful technique when working with individuals whose views on a topic are unknown, and can help generate unanticipated insights. Indeed, Chapter 3 revealed a paucity of understanding in current literature about the concept of patient satisfaction or dissatisfaction with treatments in CLBP.

Various factors influence findings using thematic analysis, including the research questions asked, whether an inductive or theoretical approach is adopted, the rationale for semantic or latent levels of coding, and the epistemological positioning (i.e., an essentialist/realist versus constructionist approach) (Braun & Clarke, 2006; Willig, 2001). Thematic analysis has six key stages (Braun & Clarke, 2006). These key stages can occur one after the other and data can be collected before analysis begins, although thematic analysis can equally be used when data collection and analysis occur simultaneously. The key stages are familiarising yourself with your data, generating initial codes, searching for themes, reviewing themes, defining and naming themes, and producing the report.

Stage 1: Familiarising yourself with the data

- Transcribing the data, reading and re-reading the data, recording initial ideas.

Stage 2: Generating initial codes

- Systematically coding interesting features of the data in the entire data set, collating data relevant to each code.

Stage 3: Searching for themes

- Establishing codes into themes, gathering all data relevant to each potential theme.

Stage 4: Reviewing themes

- Checking whether the themes work in relation to the coded extracts and the entire dataset, generating thematic ‘map’ of the analysis.

Stage 5: Defining and naming themes

- Reviewing the analysis to refine the specifics of each theme and considering the overall story that the analysis tells, generating clear definitions and names for each theme.

Stage 6: Producing the report

- Selecting compelling extract examples, final analysis of selected extracts, referring to the research question and existing literature, producing a report of the analysis.

At this juncture, it's important to note some key points. Because qualitative research aims to elicit rich contextual information based on in-depth methods (usually) using small sample sizes, it has often been criticised by quantitative researchers for not being able to generalise findings from a representative statistical sample to the wider population from which the sample was drawn (Willig, 2001). However, the goal of qualitative methods are not to make claims about trends or provide information about prevalence and statistical distribution (Willig, 2001). Rather, qualitative methods often make analytical generalisations (Miles & Huberman, 1994) allowing insights in terms of description and explanation of a specific case and consideration for how selected cases fit within general constructs (Curtis, Gesler, Smith, & Washburn, 2000). Further, qualitative research is typically concerned with internal generalisability which is the extent to which conclusions drawn are generalisable within the particular setting or group studied rather than external generalisability which is moving beyond the group, setting or context (Maxwell, 1992) (see section 4.1.2).

It is also important to recognise that even within a realist paradigm that is predominantly data driven, reflexivity during the research process and findings (i.e. to reflect on one's own standpoint in relation to the concept of interest) helps demonstrate the potential influence on the validity of the research (see section 4.5.2).

4.1.2 Validation

The ‘correctness’ or ‘precision’ of interpretation is key to the validity of qualitative research. This includes establishing whether the interpretations truly represent the features of a particular case (internal validity), and whether the concepts are applicable to other groups within the population (external validity) (Ritchie & Lewis, 2003).

Establishing internal validity is achieved in several ways. For example, thematic analysis is a six-step process (see 4.1.1) that involves a ‘constant comparative process’ (Silverman, 2000). Usually, the thematic analysis is also supported and verified by two experienced researchers to confirm consensus in the interpretation. In addition, qualitative research usually supports its validity by citing verbatim quotations to support the analyses (Willig, 2001). Quotations are provided for many themes throughout the analyses to illustrate and support linkages or explanations.

External validity is often considered in terms of triangulation, which involves different ways of looking at the same concept. The literature recommends different forms of triangulation, including multiple analysis using different analysts, triangulation using different qualitative methods (e.g. face-to-face in-depth interviews versus focus groups), and ‘methods triangulation’ (Banister, Burman, Parker, Taylor, & Tindall, 1999). ‘Methods triangulation’ is common and relies on generating data via alternative quantitative analysis. This study was intended as the basis for quantitative analysis. The study reported in Chapter 6 will serve for triangulation and validation of the themes and concepts that emerge from the current study.

An alternative method for establishing whether the themes and concepts identified are applicable to other groups within the population (external validity) is through respondent validation, or taking the research evidence back to the participants. Because this method would have required additional time from the participating patients, this was judged unfeasible and unnecessary given that triangulation was planned to validate the observations from this study.

4.2 Objectives

The specific objectives of this study were to:

- Interview patients with CLBP who take medication and/or receive physiotherapy for CLBP relief in order to explore patients' subjective experiences with treatment including their satisfaction and/or dissatisfaction with various aspects of their treatment
- Collect rich quantitative data in order to design a questionnaire to assess satisfaction and dissatisfaction with treatments (medications and physiotherapy) in CLBP

4.3 Methods

Ethical approval was obtained from Stockport Ethics Research Committee (Ref:06/Q1401/41). The approval letter is in Appendix B.

4.3.1 Participants

Ten patients with CLBP participated and varied in age from 45 to 55 years (mean age 50 years). There were 8 women and 2 men. Patients were recruited from one NHS Trust in the North of England (Stepping Hill Hospital) via physiotherapists.

In this qualitative study, purposive sampling was performed using a homogenous sampling strategy whereby patients attending a pain clinic and/or receiving physiotherapy for CLBP were screened. They were considered eligible if they met all of the inclusion criteria and none of the exclusion criteria, which were pre-specified on a screening script (Appendix C). The inclusion criteria were:

- Patient diagnosed with CLBP (defined as pain lasting longer than 12 weeks, affecting the lower back, between the bottom of the ribs and top of the legs);
- Patient was receiving treatment for CLBP, or advised by their doctor to do so;
- Patient was 18 years or older;
- Patient was able to understand and communicate in English.

The exclusion criteria were:

- Patient had known cognitive impairment;
- Patient had a case-note diagnosis of co-morbid learning disabilities;
- Patient was currently using alcohol or illegal drugs;
- Patient had brain injury or any other organic disorder.

4.3.2 Interview Agenda

A semi-structured interview agenda was developed for patients with CLBP receiving treatment based on information from literature reviews and discussions with HCPs from a variety of backgrounds (including an extended scope physiotherapist in the orthopaedic clinic, a GP, physiotherapists, psychologists, and nurses). The interview agenda contained open questions but probes were designed in cases where patients provided very little or no response to questions. This method has been commonly cited in studies (Willig, 2001).

Ultimately, the content of the interview agenda was based on two independent researcher's opinions (DR and LM) according to the research question, and was designed to start with general questions and to move onto more personal matters when rapport had been established. With this in mind, the interview started with a short introduction regarding the content of the interview itself, explaining the areas that would be discussed and reassuring participants about confidentiality. The interview agenda was organised into four main sections relating to the main topics of interest. These ranged from (1) general discussion about demographic, clinical, and treatment details to more specific discussions about (2) CLBP, (3) treatments for CLBP relief, and (4) their opinions regarding satisfaction and dissatisfaction with treatments for CLBP relief.

The questions were formulated following careful consideration of alternative versions before the interview. Questions were descriptive, structural (to identify categories and frameworks of meaning from the patient perspective), and evaluative (for example, establishing feelings about CLBP and its treatment) (Spradley, 1979). In sections 2 – 4 of the interview guide, patients were asked several open-ended questions covering topics such as 'what does pain mean to you?', 'what does CLBP mean to you?', 'What does the term 'chronic' mean to you?' and 'what is the cause of your CLBP?' Questions also explored symptoms of CLBP. A number of discussion prompts were provided for each section, relating to issues such as duration, frequency and impact of CLBP

In addition, patients answered open-ended questions about their expectations of treatment, why they take treatment and their involvement in treatment decisions, as well as questions about adherence to medication and exercise regimens, and what 'satisfaction' and 'dissatisfaction' with treatments meant to them.

The interview agenda was piloted with three CLBP patients who were receiving treatment for CLBP relief. The results of the first pilot test showed that some of the questions needed to be repositioned within the interview guide to facilitate the flow of the interview. For example, the questions relating to CLBP and chronicity were reorganised so that patients were asked "What does 'pain' mean to you?" first, followed by "What does 'CLBP' mean to you?" and then "What does the term 'chronic' mean to you?"

These subtle changes were implemented for a second pilot test (n=2), where results indicated that there was some overlap in the questions being asked. While some overlapping questions were retained, since the researchers felt that some slightly different questions might elicit different responses from different patients, the interview agenda was further refined to minimise duplication of discussion topics and ensure that if a topic was discussed spontaneously earlier in the interview, it was not probed later. These changes helped limit the interview to a manageable length for both patient and interviewer.

A third pilot test was performed with these changes implemented (n=2), and results indicated that the guide could elicit spontaneous responses from patients related to the topics of interest and within a reasonable timeframe (45 minutes).

The final interview agenda included questions about CLBP, questions exploring experiences with treatments for CLBP relief, and opinions regarding satisfaction and dissatisfaction with treatments for CLBP relief (Appendix F). If patients did not have experience with a particular type of treatment (e.g. injection therapies) then questions relating to that treatment were skipped. The questions ‘do you ever experience CLBP?’, ‘how long have you experience CLBP?’ and ‘are you currently taking any medication for your CLBP?’ were used as warm ups and lead-ins to the interview. This was followed by questions such as ‘what does ‘pain’ mean to you?, ‘what does ‘CLBP’ mean to you?’ and ‘what symptoms do you experience from your CLBP?’, to more treatment-specific questions such as ‘why do you take treatment for CLBP?’, ‘do you feel involved in treatment decisions?’, followed by ‘please describe what taking medication for CLBP involves on a daily basis from your perspective’. Satisfaction-specific questions included ‘what does satisfaction with treatment mean to you?’, ‘what does dissatisfaction with treatment mean to you?’ and ‘are you satisfied with your treatment for CLBP?’ The interview ended with a general closing question, ‘are there any other points that you would like to mention in relation to our discussions on treatment(s) for CLBP relief, its impact on your life, satisfaction, or adherence?' Questions about patient demographic characteristics were also included as part of the interview agenda.

4.3.3 Other Study Documents

Information and consent forms were developed for the patient interviews (see Appendix D and E, respectively). These contained information about the purpose and conduct of study, confidentiality, the purpose of the study results, and ethical approval. Contact details were also provided should the HCP's or patients have any questions or problems.

4.3.4 Procedure

A non-probabilistic, purposive sampling approach was used. The Head of the Physiotherapy Department systematically screened patients attending the outpatient department according to a pre-specified screening script that included the inclusion and exclusion criteria (Appendix C). A trained researcher performed all patient interviews (DR). At the start of the interview, patients were given a patient information sheet and consent form to sign (Appendix D and E). They were assured of their anonymity and were informed that they had the right to withdraw at any time. They were also informed that any decision to do so would not affect the treatment and care that they receive in any way. Once the patient was comfortable, the tape recorder was switched on and they were asked to repeat their consent to participate for recording purposes.

The interviews lasted between 40 and 75 minutes, depending on how much each patient wanted to say. The interviewer was female and all interviews were conducted in an enclosed office within Stepping Hill Hospital to ensure confidentiality. All patients were asked identical questions in the same sequence, but the interviewer probed inductively on key responses, and probes were used only if a patient's response to the initial question did not cover certain topics of interest. All interviews were audio-taped and transcribed verbatim by the researcher to allow greater familiarity with the data prior to analyses. A tracking form was used to ensure the data generated from a specific interview was identifiable via patient identification numbers, thus ensuring anonymity. This tracking form was stored on a password-protected laptop computer.

Thematic analysis was supported and verified by two experienced researchers who confirmed consensus in the interpretation. There were two occasions where the analyses were discussed and interpretations amended as necessary. Any discrepancies were resolved via discussion until consensus was obtained between the researchers (see section 4.3.5). By example, whether anxiety and depression were separate independent themes or sub-themes of emotions.

4.3.5 Data Analysis

A number was assigned to every patient in the order in which interviews were conducted. The data were transcribed verbatim by DR, and the transcripts were checked against the tapes for accuracy. Data were managed using an Excel spreadsheet and ATLAS.ti 6 software, which is qualitative data analysis software. ATLAS.ti allows the researcher to locate, code, and annotate findings in datasets, to weigh and evaluate their importance, and to develop visual representations of associations between themes.

Each data item in each transcript was studied repeatedly and given equal attention during the coding process, which was thorough, inclusive and as comprehensive as possible. The coding process was performed without trying to fit data into a pre-existing coding frame. Rather, the relevant extracts from the dataset were collated to form themes. Themes were then checked against each other and also against the original dataset to ensure that they were coherent, consistent, and distinctive. The process was predominantly inductive in that the themes identified were strongly linked to the data themselves, and thus data-driven. Also, the themes were semantic themes in that they were identified within the explicit or surface meanings of the data, and the researcher was not looking for anything beyond what a patient said. As themes were identified, there was gradual progression from description, where the data were organised and summarised into patterns, to an interpretative process that theorised about the significance of the patterns as well as their broader meanings and implications, often in relation to previous research. The extracts were also checked to ensure that they matched the analytic claims. As recommended by Braun and Clarke (2006), during the analysis process, the researcher continually considered whether the analysis told a convincing and well-organised story about the data and the topic.

Throughout the analysis process, issues regarding various aspects of the process itself required defining and refining. For example, a theme was considered a level of patterned response related to the research question. The researcher was flexible and used their judgement as necessary. Other issues that were considered throughout the process included consideration regarding the epistemology which was an essentialist/realism positioning in that a general unidirectional relationship was assumed between meaning, experience, and language. The analysis process is outlined in Table 7.

Table 7: Process of Analysis

DR transcribed interviews and read through each interview transcript to generate codes relating to CLBP, treatments for CLBP, and aspects related to satisfaction and/or dissatisfaction with treatments for CLBP.
DR read and compared the codes to identify themes within these such as the ‘impact of CLBP and its treatment’, and ‘satisfaction with treatment’.
Quotes relating to each theme were assembled. DR and two experienced researchers independently reviewed these and discussed definitions of themes and the data within these. During this process, some changes were implemented to definitions.

DR re-coded all transcripts for these themes.
DR coded for sub-themes within themes. For example, sub-themes of ‘impact of CLBP and its treatment’ included ‘physical functioning’, ‘emotional impact’, ‘confidence’, ‘self-esteem’, ‘sleep’, and ‘relationships’. Examples of sub-themes of ‘satisfaction with treatment’ included ‘efficacy’, ‘side effects from medications’, ‘health-related quality of life’, ‘preferences’, ‘convenience’, ‘adherence’, ‘information provided’, and ‘involvement in treatment decisions’.
The process of coding for sub-themes included developing a conceptual model of CLBP and treatments for CLBP relief (Figure 7) as well as a thematic map of treatment satisfaction from patients’ perspective (Figure 8). This process involved shifting themes to sub-themes and vice-versa within Figure 7 and Figure 8.
Tables of data extracts and quotes representing the themes were generated in Excel. In addition, questions for a new questionnaire to measure satisfaction/dissatisfaction with treatments for CLBP relief were developed and tabulated to corresponding themes.
DR and an experienced researcher examined Figure 7 and Figure 8 to gain understanding of themes and sub-themes and agree on the main issues. The tables documenting the items generated for the newly-developed questionnaire were also examined. Disagreements were discussed and amendments were made as necessary.

4.3.6 Sampling and Saturation

Since there are few guidelines regarding non-probablistic sampling, purposive sampling was established inductively, and the sample size relied on a ‘saturation’ approach, which is the point at which no new information or themes are identified from interviews (Guest et al., 2006). Thus, the first seven interviews were compared with the last three interviews to examine whether saturation had been achieved in the overall sample of patients with CLBP receiving treatment.

4.4 Results

4.4.1 Demographic Characteristics

Patients' ages ranged from 45 to 55 years. The overall mean age was 50 years. There were eight women and two men. The majority of patients had no qualifications (n=7), two had O-levels, and one was a qualified nurse. Nine patients were unemployed, one was phased back to work and was working part-time as a staff nurse. All patients reported that their work was limited by their CLBP.

Various symptoms were recorded on patients' case notes, including pain in lower back; numbness in back; constant ache and intense pain; lack of strength in back; and unable to walk long distances. Duration since first diagnosis varied from six months to 30 years.

Patients were receiving a number of different medications for CLBP relief including non-opioid analgesics (such as paracetamol or cocodamol) (n=6), NSAIDs (ibuprofen or diclofenic) (n=7), opioid analgesics (codeine or dihydrocodeine) (n=4), benzodiazepines (diazepam) (n=3), and tricyclic antidepressants (amitriptiline) (n=3). Most were taking these medications as required. Side effects reported in patients' case notes included dizziness, dysphagia, nausea, and dysarthria.

In addition to taking medications for CLBP relief, all patients were seen and assessed individually by a physiotherapist and if they were demonstrating yellow flags (a belief that pain meant damage or harm, they were fear-avoiding and tending to be very passive in treatment) they were invited to attend the back programme. The back programme consisted of eight sessions (twice weekly) comprised of education regarding the causes of back pain, posture and positioning, and pacing, as well as exercises, and relaxation techniques.

4.4.2 Patients' Subjective Experiences with CLBP and its Treatment

The following themes were extrapolated from the data until the data was saturated and no more themes emerged. Common words used by patients with CLBP to describe their CLBP included "slicing", "twinge", "pins and needles", "stabbing", "numbness", "swelling" and "burning". The duration, severity, and tolerability of CLBP were very prominent topics during discussions with patients.

A central theme that emerged from the interviews was the impact of CLBP and its treatments on patients. Particularly interesting was how widely CLBP impact on patients' daily lives varied. The impact ranged from physical functioning and social functioning to influences on appearance, emotions, mood, self-esteem, confidence, sleep, relationships, and sex. Figure 7 provides a proposed conceptual model of CLBP and its treatments from the patient perspective.

Physical Impact

Physical functioning was a particular burden to patients, who not only described problems with standing up or standing all day but also difficulties with standing after only five minutes. Other issues with physical functioning included difficulties bending down, leaning over, and sitting still. Being able to function normally and carry out everyday activities were important to patients.

- *"Standing during the day is very difficult especially after five minutes" (ID01).*
- *"I couldn't even walk let alone go to the pharmacist..." (ID03).*
- *"I am still hoping to get back to normal. You know at some stage I will be fully functioning, and go back to work, and just do normal things like everybody else" (ID04).*

Social Functioning

Social functioning was also described as an aspect of their lives that had changed and was impaired due to their back pain. Many patients noted that they were more socially active before being affected by CLBP. They explained that they can't partake in physical sport or socialise in the evening. On the rare occasions that they do go out, they go more to watch than to participate in various events. One patient explained how even going to the cinema or for a meal was problematic because the chairs are uncomfortable.

- *"I can't do indoor bowling and ballroom dancing. If I go out I just sit. For example I go to watch the dancing. I still go where I would normally go but I don't do it. Even when I felt better I didn't go out because I didn't feel right, so just stayed in" (ID10).*

Although generally patients with CLBP described a negative impact on their social functioning, one patient described how they could still do the things they used to do*:*

- *"I've been involved in the church and that has helped me a lot, and I walk a dog with a friend. And I go to a choir still" (ID03).*

Appearance

Patients described problems with maintaining their appearance, with one explaining that they did not have the same interest, and another describing the pragmatic problems she encounters with trying to do her hair.

- *"Well just look at my hair! I can't do my hair because it hurts my back trying to do it. Every time I try it catches right in the middle of my back" (ID02).*

Emotions

The impact of CLBP on emotions was important for patients and ranged from feeling embarrassed about the pain to unhappy, sad or depressed. One patient said it was particularly hard to be positive at work.

Anxiety and worry about the uncertainty of the future and fear of movement were other emotions patients referred to in relation to their CLBP.

- *"I was anxious because I wanted to go back to work and I couldn't because I knew I wasn't fit enough" (ID09).*
- *"I'm scared to do too much to set the pain off" (ID02).*

Patients described being in a bad mood, and specifically referred to being annoyed by having to stop and rest. They were particularly frustrated at not being able to do what they wanted to, or by comparing their current condition to how they were before they had CLBP. Being irritable and miserable were also negative consequences of having CLBP.

- *"I've been fed up, frustrated and cross. Miserable but not desperate" (IDO2).*
- *"Irritability, and frustration because I was quite fit before. Also, I can't do what I used to do" (ID03).*

Self Esteem

Self esteem and confidence were other aspects that patients felt were compromised due to their CLBP. In relation to self-esteem, one patient described struggling to get acknowledged at work due to CLBP and suggested that this had affected self esteem.

- *"I was struggling to get acknowledged so that didn't do anything for my self esteem anymore" (ID03).*

Confidence

Closer examination of the issues related to confidence reveal that patients talked a lot about how uncertain they were of themselves, and particularly how cautious having CLBP has made them.

- *"I never do anything without thinking about how I'm going to do it, even the ironing" (ID02).*

Discussions also centred on lack of self confidence and how that was related to what they felt or what they could do.

- *"It knocks your confidence so much and I don't feel the same about yourself" (ID10).*

Sleep

Patients with CLBP discussed how the quality of their sleep was negatively impacted, and noted that waking up in the night due to the back pain was a problem, as well as difficulties sleeping or trying to get back to sleep.

- *"Generally not sleeping well and something always aches in my back in the morning. But it doesn't last all day (ID07).*

Relationships

Relationships were a sensitive issue, but patients noted that their partners were frustrated by the CLBP, did not always show empathy, or could not understand the pain and impact of the back pain experienced. Relationships impacted by CLBP include those with partners, siblings, parents, and work colleagues. Further, some individuals with CLBP were concerned about bothering others who were close to them since they had their own problems, and one patient explained how sometimes they didn't want anyone near them because of the back pain.

- *"I was beginning to think that everybody was thinking I was just playing on it, including my husband" (ID03).*
- *"My mum and my dad are nearly 90 years, and they have their own problems. So whenever they ask me I just say I am fine. Because they have their own problems" (ID04).*
- *"I think there were times when it does affect you so much that you don't want any one near you, you don't want to know" (ID05).*

Sex Life

During discussions, some patients tried to justify lack of sex as a consequence of age and characterised it as an old habit that has phased out over time.

- *"I don't know but my wife has noticed that probably my sex life has been affected because I hardly do it anymore because of the pain and all the surroundings that goes with it" (ID04).*
- *"You can forget sex with my back. When you get to my age there's no one nice anyway" (ID02).*

Factors Associated with CLBP

Some patients discussed issues related to the diagnosis of CLBP, with some indicating that their condition had gone undiagnosed and others suggesting they had been misdiagnosed or, in some, cases even indirectly accused of malingering.

- *"Because I was misdiagnosed, I was treated for being depressed for quite a while actually, I mean, that's always bothered me" (ID05).*

- *"When they got the diagnosis wrong then that was quite stressful" (ID09).*
- *"The doctors don't have a clue. Because they didn't have it they don't know. The doctor said we need to get you back to work. That made me feel as if he thought I was faking it" (ID01).*

Trust and Confidence in Clinicians

Some patients reported concerns about trust and confidence in clinicians in identifying their CLBP.

- *"I saw two locums at open clinics and they haven't a clue and so I didn't trust the clinicians" (ID01).*

Work

Patients talked about how impaired physical functioning limited their ability to work, and how absence at work resulted in changes that they didn't want to happen and that almost hindered their career.

- *"I can't get through my work because I physically can't keep going" (ID01).*
- *"I had 8 weeks off work and when I got back they change my job. I didn't want them to change my job. It was all arranged previously, I had sponsorship, training…I had plans and they all got changed" (ID02).*

Coping

Some patients briefly mentioned that their back pain resulted in an inability to cope and said that either one has to put up with the pain or to find some way of dealing with it.

- *"Pain means to me that it makes you feel miserable, not able to cope, and gets things out of perspective" (ID02).*

- *"You either put up with it or find a way of coping with it" (ID03).*

Locus of Control

The majority of patients with CLBP described an external locus of control, expressing the belief that the problem of back pain was for health professionals; one patient suggested that the health professionals know best and they [the patient] are ignorant.

- *"I just leave it to them. My problem is in their hands and I leave it up to them to come up with a solution" (ID04).*
- *"They know what's best for me. I'm ignorant" (ID02).*

Fear of Dependency

Patients explained that they were taking or had taken various treatment options to try and help them with their CLBP. Most commonly mentioned were non-opioid analgesic medications such as paracetamol or NSAIDs on an as-required basis. Other medications included opioid analgesics and anti-depressants. There was a general reluctance to take medication regularly and patients expressed concerns about dependency. Some patients described not taking their medication as recommended by their doctors due to fear of dependency and tolerance.

- *"I am worried about dependency. I don't want to rely on them" (ID04).*
- *"I only use it when it gets particularly bad. And as I said I take some pain killers and hope for the best really. Because I don't want to rely on tablets all my life" (ID09).*

Side Effects of Medication

A main consequence of taking medications for CLBP relief was negative side effects. Many patients referred to feeling spaced out, and one described not knowing what time of year it was. Other descriptions of side effects included feeling light-headed, dopey, unaware of things, and like a zombie. Some patients said that the side effects were intolerable and made them stop taking their medication or alter the amount of medication they took. Others said that regularly taking medication resulted in feeling out of control and negatively impacted their quality of life.

- *"The medicines made me not know if it was Christmas or Easter" (ID02).*
- *"You get zombified if you take them all the time. You don't feel in control" (ID05).*
- *"I decided not to take them because I was dopey all the time and I didn't have any quality of life or anything" (ID08).*

Other medication side effects cited included loss of appetite, difficulty getting to sleep, and gastric side effects such as heart burn and stomach ache. Clearly, the bother associated with side effects varied among patients, but it clearly affected their ability to perform everyday activities.

- *"They upset my stomach. I get a lot of heart burn, a lot of horrendous hear burn" (ID07).*
- *"The side effects are gastric" (ID03).*

Information about Side Effects

Another key theme related to treatment was information about side effects. Patients claimed that no one had informed them of the possible side effects of taking CLBP medication.

- *"I made a decision not to take them unless I was absolutely desperate. No one explained to me how drugs make you feel. I couldn't eat breakfast, and I was unable to sleep anytime after 2pm. Diazapam is habit forming and I was afraid of that" (ID02).*

Effectiveness of Medication

The primary reason for taking medication was to end the back pain and feel better again. Effectiveness of medication was important to patients, who expressed concerns that the treatment was not working but instead contributing towards the problems they were experiencing.

- *"I take treatment to make me feel better and get right again" (ID01).*
- *"Treatment not working, not helping, hindering. Causing more discomfort" (ID03).*

4.4.3 Satisfaction and Dissatisfaction with Treatments for CLBP Relief

In addition to understanding patients' subjective experiences with CLBP and treatments for CLBP relief, the purpose of the in-depth interviews was to also explore the concept of satisfaction and dissatisfaction with treatment from the patient perspective. Figure 8 provides a thematic map of the key themes that were associated with the concept of satisfaction or dissatisfaction with treatment (medications and physiotherapy).

Satisfaction with Treatments for CLBP Relief

Generally, satisfaction with treatment is positive aspects of treatment where patients described being happy or pleased with treatment. One patient in particular stated that they were satisfied with their treatment since receiving the correct diagnosis. In addition, the majority of patients referred to satisfaction with treatment as maintaining general health, being able to return to normal functioning or at least being able to do everyday activities and work as they were once able to do.

- *“Satisfaction with treatment means you are satisfied with the treatment you receive and you’re happy with it” (ID02).*
- *“Well satisfaction with treatment is having everything that you want and being happy, healthy and something like that” (ID05).*
- *“Satisfaction with treatment means when I am 100% satisfied with my body. Like I said because the pain has been there a long time, and it’s probably going to be there for the rest of my life. So, satisfaction to me is just, going back to work, feeling fit, I can do daily things, you know daily activities. It doesn’t have to be something extreme. You know I’m not going to do a bungee jump or something like that, I don’t expect to do something like that. My satisfaction is just going about doing my daily life as normal as possible” (ID04).*

Dissatisfaction with Treatments for CLBP Relief

Patients often referred to dissatisfaction with treatment in terms of treatment not being efficacious, in other words, the treatment is unable to stop or minimise their back pain so that they can return to normal functioning and continue everyday activities or work. In this respect, the negative impact that back pain has had on health-related quality of life seems to be particularly related to dissatisfaction with treatment, but especially reduced physical and social functioning. If the treatment was not working, causing discomfort, or hindering them, then this was also related to dissatisfaction. For example, patients referred to experiencing side effects and finding the side effects intolerable or unbearable, sometimes to the extent that they have to stop taking the medication. These aspects of treatment were all associated with dissatisfaction. The inconvenience of taking medication was also a key factor.

Lack of information about back pain, its treatments and potential consequences were also components of dissatisfaction with treatment. Not feeling involved in treatment decisions, lack of trust and confidence in healthcare professionals, being misdiagnosed or undiagnosed, feeling that healthcare professionals were not listening to them, and the general feeling that healthcare professionals were not empathetic about their CLBP were also all associated with dissatisfaction with treatment.

- *"The side effects would affect my satisfaction. Everybody in my class come off the medications because you don't feel right. I don't like the tablets because I am not as ill without them" (ID01).*
- *"Not being listened to. Long waiting lists to get seen to things. Long referral processes. Treatment not working, not helping, hindering. Causing more discomfort. Like the physio would make me feel worse, for four days I was in pain afterwards. So at the time it wasn't helping. It was causing me more pain than I arrived with" (ID03).*
- *"I never felt involved. I trust them now they know" (ID02).*
- *"No one explained to me how drugs make you feel" (ID08).*
- *"Dissatisfaction with treatment would mean if you didn't get the time or if the treatment wasn't appropriate* or inconvenient, *if their attitude wasn't good. If your left waiting too long or if they weren't interested and just going through the motions" (ID10).*

Having to pay for treatment privately due to long referral and waiting times was a contributing factor for one patient with CLBP.

- *"I mean I paid privately to get treatment purely because you know the waiting list was so long that I would have ended ten times as worse before I would have got some treatment" (ID05).*

In addition, closer examination of the discussions that took place in interviews reveal that satisfaction or dissatisfaction with treatments for CLBP relief were part of a much bigger concept – satisfaction with healthcare — which seemed to encompass referral times, waiting times, general communication about treatments, as well as a sense of empathy from HCPs.

Figure 7: Conceptual Model of Chronic Low Back Pain and Treatment

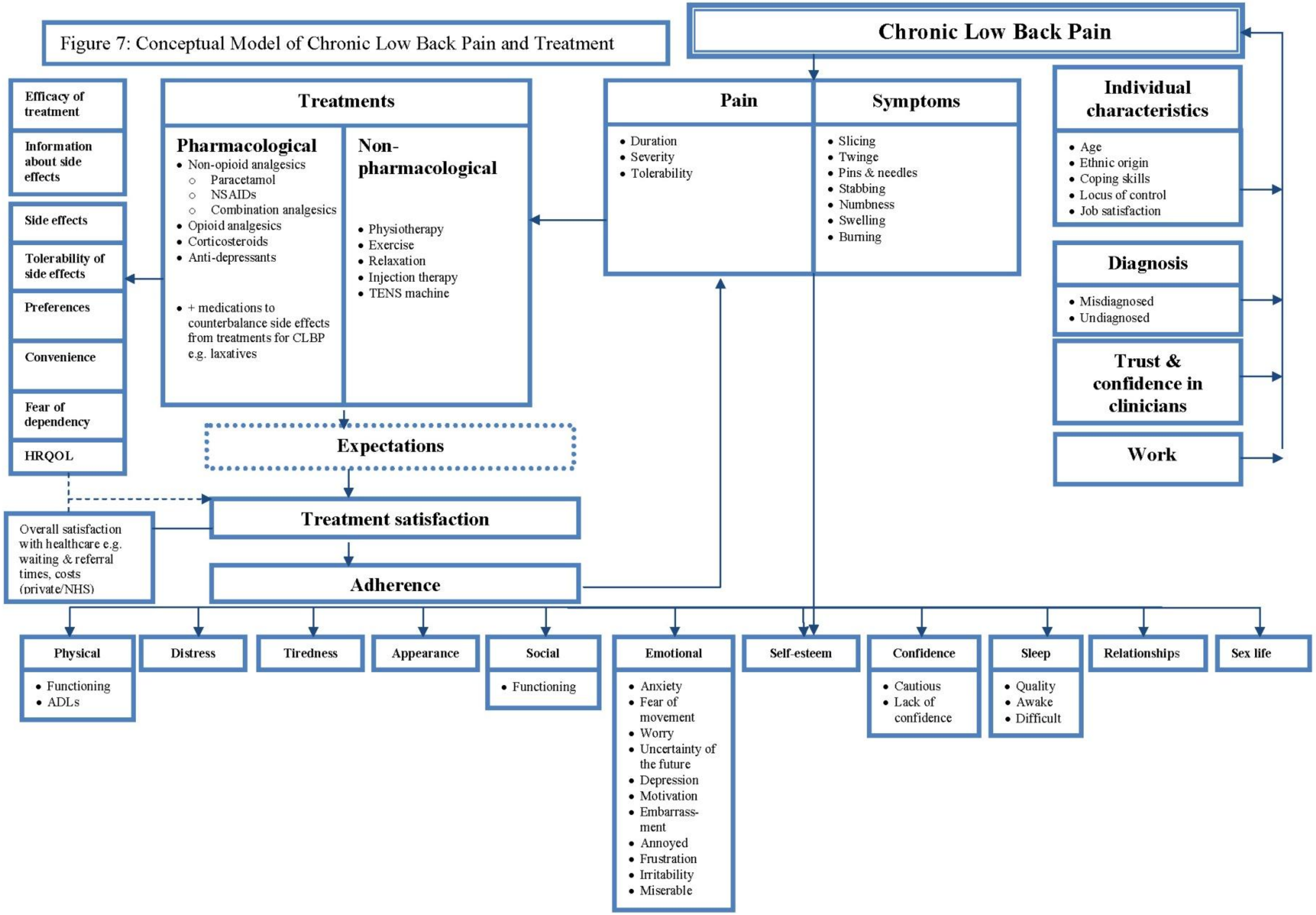
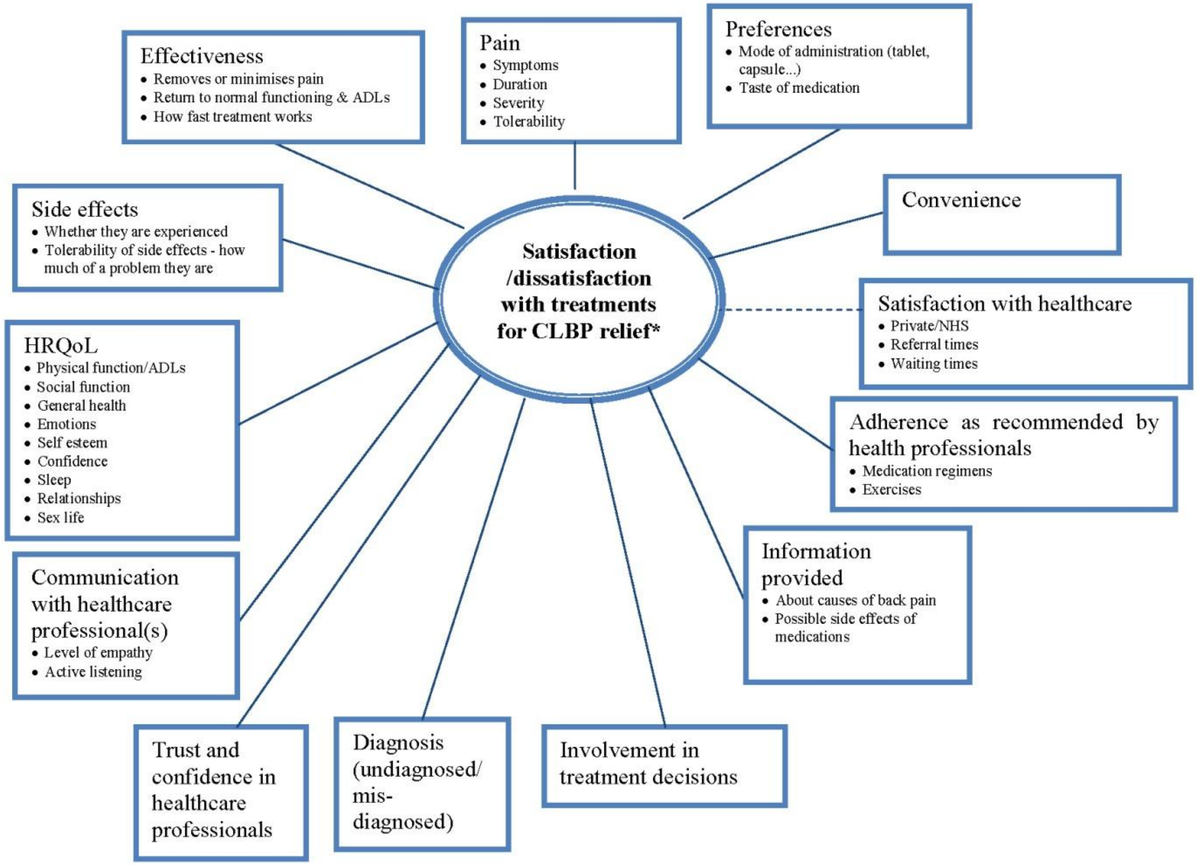


Figure 8: Thematic Map of Satisfaction/Dissatisfaction with Treatment for CLBP Relief from Patients' Perspective



*Satisfaction/dissatisfaction with treatment is viewed on a continuum, which as a dependent variable involves a multidimensional appraisal process of each of the main themes in Figure 8. As an independent variable, it can influence adherence to treatment regimens, which in turn may influence satisfaction/dissatisfaction with treatment.

4.4.4 A Summary of Data Driven Themes

Table 8 and Table 9 respectively provide summaries of data driven themes and sub-themes associated with patients' subjective experiences of treatment for CLBP relief and their satisfaction and dissatisfaction with treatments for CLBP relief.

Table 8: Summary of Data Driven Themes and Sub-Themes Associated with Patients' Subjective Experiences with Treatment for CLBP Relief

Impact of CLBP and its treatments (medication and physiotherapy)	
Pain	• Duration • Severity • Tolerability
Symptoms	• Slicing • Twinge • Pins and needles • Stabbing • Numbness • Swelling • Burning
Physical	• Functioning • Activities of daily living
Social	• Functioning
Emotional	• Anxiety • Fear of movement • Worry • Uncertainty of the future • Depression • Motivation • Embarrassment • Annoyance • Frustration • Irritability • Miserable

Impact of CLBP and its treatments (medication and physiotherapy)	
Confidence	• Cautious • Lack of confidence
Sleep	• Quality • Difficulty • Awake
Tiredness	
Relationships	
Sex life	
Distress	
Self esteem	

Table 9: Summary of Data Driven Themes and Sub-Themes Associated with Satisfaction and Dissatisfaction with Treatments for CLBP

Satisfaction and Dissatisfaction with Treatments for CLBP	
Pain	
Symptoms	
Effectiveness	• Removes or minimises pain • Return to normal functioning and can perform activities of daily living • How fast treatment works
Side effects	• Incidence • How much of a problem they are
Health-related quality of life (see Table 8)	• Physical functioning / ADLs • Social functioning • General health • Emotions • Distress • Self esteem • Confidence • Tiredness • Sleep

Satisfaction and Dissatisfaction with Treatments for CLBP	
	• Relationships • Sex life
Preferences	• Mode of administration (tablet, capsule...) • Taste of medication
Convenience	
Information provided	• About the causes of back pain • Possible side effects of medications
Adherence as recommended by HCPs	• Medication regimens • Exercises
Involvement in treatment decisions	
Diagnosis	• Undiagnosed • Misdiagnosed
Trust and confidence in HCPs	
Communication with HCPs	• Level of empathy • Active listening
Satisfaction with healthcare	• Private/NHS • Referral times • Waiting times

4.5 Discussion

The findings of this study suggest that satisfaction and dissatisfaction with treatments is a multidimensional concept and provide some support for a model similar to Fitzpatrick’s (1984) ‘multidimensional’ perception of satisfaction. When exploring the concept of satisfaction with treatment (medication and/or physiotherapy) in patients with CLBP, patients’ responses to open-ended questions generally described positive aspects of treatment, such as receiving the correct diagnosis, and being ‘happy’ or ‘pleased’ with treatment. Maintaining general health and returning to normal functioning such as carrying out everyday activities or going to work are very important concepts that form part of satisfaction with treatment.

Patients were even more descriptive about dissatisfaction with treatment, which was generally perceived as the opposite of satisfaction with treatment and thus supports the view that satisfaction and dissatisfaction are on a continuum (Collins & O'Cathain, 2003). Dissatisfaction includes negative aspects of treatment such as being misdiagnosed or undiagnosed, a lack of trust and confidence in clinicians, lack of information (about back pain, its treatments, and potential consequences of treatment). Communication by healthcare professionals is important, and dissatisfaction with treatment seems to also be related to perceived lack of empathy and lack of active listening by HCPs to the patient.

These findings are consistent with those of a systematic review which cited aspects of treatment for back pain about which patients have expectations or express satisfaction in qualitative studies (Verbeek et al., 2004). Like this study, Verbeek et al found that associated treatment aspects included ‘diagnoses/finding cause of pain’ where patients stated that there wasn’t really an initial diagnosis and clinicians weren’t really certain what was going on. ‘Confidence based relationship’ was another aspect of treatment where patients reported lack of faith in their HCPs. ‘Information/instructions’ was key, since patients reported that they needed more knowledge and direction regarding what to do. Verbeek et al. (2004) findings regarding communication with HCPs and listening are also confirmed in this study.

Limited efficacy of treatment is a major theme of dissatisfaction with treatment. Patients report dissatisfaction when treatment doesn’t succeed in removing or minimising the back pain and does not enable the patient to return to normal functioning, thus limiting their HRQoL. These results are consistent with Lewis, Bradley, Knight, Boulton, and Ward

(1988), whose results demonstrated an association between treatment satisfaction and efficacy/effectiveness in terms of perceived glucose control in diabetes.

In this study, experiencing intolerable side effects were also an important theme related to dissatisfaction with treatment. These findings are in line with Huskisson et al., (1992), who found that overall satisfaction was associated with absence of pain and side effects in rheumatoid arthritis.

This study also revealed that convenience of treatment regimens and the mismatch of medication compared to patient preferences in terms of for example mode of administration were also associated with the concept. Dissatisfaction was also associated with non-adherence to treatment regimens as recommended by doctors. These results are supported by previous research which indicated that patients with iron overload receiving infused iron chelation therapy were less satisfied than those receiving oral iron chelation therapy, and that satisfaction with iron chelation therapy was significantly associated with never thinking about stopping chelation therapy (a proxy for adherence) (see for example, Rofail et al., 2008; Cappellini et al., 2007; Payne et al., 2007). However, it should be noted that the direction of the association between satisfaction and adherence warrants further exploration since it’s not clear whether treatment satisfaction as an independent variable influences adherence to medication regimens, or whether it is adherence as an independent variable that influences satisfaction and dissatisfaction with treatment. The role of efficacy and other concepts in the associations also require further exploration.

Findings from these in-depth interviews also suggest that patients are perhaps not as satisfied with their treatment as they may initially indicate. For example, the majority of patients indicated that they were satisfied with their treatments for CLBP relief. However, further discussion revealed that patients still experienced CLBP and that this appeared to significantly impact their everyday lives in terms of physical functioning, activities of daily living, emotional impact, social functioning, and relationships. These findings come as no surprise, since another study reported similar results in patients receiving antipsychotic medications (see for example, Gray et al., 2005).

The findings from this study provide support for other CLBP studies, such as with regard to patients' actual experiences of CLBP and its treatment in terms of intensity of pain and impact on quality of life which is well documented in the literature (see for example, Roland et al., 2007; Keeley et al., 2008; Pain in Europe, 2003). Further, the actual experiences patients report in this study are similar to other CLBP studies that have used a qualitative approach. For example, patients with CLBP seem to describe their experiences of treatment regarding limited efficacy and this is similar to patients' descriptions of failed treatment approaches (Liddle et al., 2007), and also patients in this study describe lack of trust and confidence in clinicians which is similar to another study which showed lack of trust in research, and researchers and possibly also HCPs (Glenton et al., 2006).

Unexpectedly, expectations were mentioned by only one patient in this study in relation to satisfaction with treatment. Closer examination of the interview transcript and the discussions between the interviewer and the patient revealed that the patient did not mention expectations spontaneously in response to any of the open-ended questions. In light of this and given that it was only mentioned briefly by one patient in response to being probed by the interviewer, expectations were not added to the final thematic map of satisfaction and dissatisfaction with treatments in CLBP. Further research to test this decision is warranted. The literature on expectations and satisfaction is ambiguous (see section 2.6.4). Although several studies suggest expectations are related to satisfaction with treatment (Jackson & Kroenke, 1997; Sitzia & Wood, 1997), expectations, like satisfaction, lacks an operational definition and there is a lack of consensus opinion regarding what constitutes patient expectations. Further, some researchers have questioned patients' abilities to form an opinion of what to expect from treatment, especially if they are treatment-naive or have not received health services before (Williams, 1994). With this in mind, the relationship between satisfaction and expectations requires further exploration.

Despite this, it is important to acknowledge that there are a number of studies that qualitatively document LBP patients' expectations from treatment (Liddle et al., 2007; McIntosh & Shaw, 2003; Rives & Douglass, 2010; Verbeek et al., 2004; Yardley et al., 2009). On reflection, one of the possible reasons why expectations did not emerge as a major theme in this study may be due to the questions in the interview guide which focused more on patients overall experiences and the notion of satisfaction and dissatisfaction. For example, a closer examination of Liddle et al. (2007) shows that they asked a number of open questions related to patients' expectations during the focus groups. For example, 'what are your expectations from treatment?' and 'how did you decide if your expectations are met or not?' Therefore future studies could consider defining the concepts of satisfaction and dissatisfaction further as they relate to expectations and the extent to which they have been met. Future studies should pay particular attention to the questions put to patients.

Finally, it is apparent from this study that satisfaction and dissatisfaction with treatment is part of a larger concept of satisfaction with healthcare; such findings support Weaver et al.'s (1997) treatment satisfaction conceptual framework. However, evidence from this study reveals that the boundaries between the two concepts are not explicit to patients, and further research is warranted to establish empirical evidence to support the concepts and their association.

4.5.1 Strengths and Limitations

Some strengths and limitations of this study warrant comment. We can assume a certain degree of patient homogeneity because a homogenous sampling strategy was used, and thus patients were chosen based on some common criteria; in this case they were patients with CLBP taking medication and/or receiving physiotherapy to help them with their back pain problems. Further, the more similar the patients were in their experience as it related to the research concept of interest, the sooner it can be expected to reach saturation (Guest et al., 2006). In this study, the similarities appeared to be sufficient to produce a fairly exhaustive dataset within ten interviews.

The results of this study cannot be generalised to patients' receiving physiotherapy alone, as all patients were taking medication and a few had mentioned that they were using other methods to help them with their back pain. Also, whilst the data that emerged from this study was based on robust methods and thus the findings can stand alone, it is important to re-emphasise that the main purpose of this study was to use the data to develop a questionnaire (see Chapter 5).

Furthermore, there were a few concepts such as 'the motivation to continue taking medication' and 'flexibility of taking treatment if you are travelling' appear in the satisfaction literature (see Weaver et al., 1997) but did not emerge as key themes in this study. One reason for this may be that the sample was not diverse enough, or that these concepts are not specific to patients with CLBP receiving medication and/or physiotherapy. Note, though, that the satisfaction topics identified in Weaver et al., (1997) were found in a comprehensive literature review rather than the in-depth patient interviews used in this study that are recommended for development of conceptual models and questionnaires (see for example, Acquadro et al., 2003; Food and Drug Association, 2009).

In addition, it should be noted that there appears to be some overlap between the conceptual model of CLBP and its treatments and the thematic map of satisfaction and dissatisfaction with treatments for CLBP, and the proposed associations within each are not definite causal links. Thus, further empirical work is necessary to test the validity and reliability of the proposed conceptual model and thematic map. The conceptual model and thematic map do not show which concepts are more important than others and further studies should explore this question as well.

One aspect requiring further consideration is that the use of a purposive homogenous sampling strategy may in part explain a sample comprised of mainly females, of narrow age range and occupational background. Thus, additional studies could explore subgroups and identify thematic variability within a sample to establish the cohesiveness of themes/subthemes and its association to sample heterogeneity. Further, studies using other purposive sampling strategies could be considered and may provide alternative insights into patients' subjective experiences. For example, maximum variation sampling could help to establish central themes across patient variations such as patients with CLBP of different ages, or those with different occupational backgrounds. Alternatively, extreme case sampling could help consider patients' subjective experiences or the concept of treatment satisfaction in cases which are unusual or special in some way. For example, one might expect that patients with CLBP who were misdiagnosed or undiagnosed on several occasions are likely to have different experiences.

It is important to acknowledge that the interview guide contained some closed questions that resulted in yes or no answers, and which were then followed up by, if yes, why, or if no, why not? Whilst such questions make it easy for patients to answer, the control of the interview generally remains with the interviewer and such questions may limit the detail and richness of data or result in shorter answers compared to open questions. Open questions usually provide the interviewees with control of the conversation, and encourage patients to think and reflect as well as provide opinions and feelings. Also, they are often considered more objective and less leading than closed questions.

Finally, to ensure confidentiality and for the convenience of patients, the interviews were performed in an enclosed office within Stepping Hill Hospital. However, whilst the room was quiet thus helping to facilitate discussions, it is rather official, and not the most relaxing and comfortable of environments. Consequently, such an environment may not necessarily help to get the most out of patients in terms of detailed discussions. Other environments such as interviewing in their home settings may be considered more comfortable for some patients. If the interviews were performed in patients' homes then some patients may have felt that the information provided to the interviewer was private compared to a hospital setting where they may consciously or unconsciously associate the interview questions with the environment and ultimately health professionals. Given that the interview topics centred on treatment satisfaction, this may have affected the results. For example, patients may have tried to provide more favourable responses. On the other hand, some patients may feel that interviews performed at home are less private especially if family or friends are about, which may in turn also affect the results. Further research could explore patients' subjective experiences and the notion of treatment satisfaction in CLBP using more open-ended questions and in different environments.

4.5.2 Reflexivity

Reflexivity refers to the self awareness researchers have in terms of how they may influence the research conducted (Willig, 2001). Generally, all the interviews went very well. Patients were keen to talk about their experiences with CLBP. However, on reflection, during the first interview, as an enthusiastic researcher, I wrote many notes to help later to support the interpretation of the data that would emerge from the transcripts. Gradually I became aware of the fact that as an interviewer, the process of writing notes reinforced the patient to talk more and taking notes was distracting them as they were more focused on giving the answer they thought they should give or checking what I had written was correct. Consequently, I modified my approach for all other interviews and wrote notes only in cases where it was absolutely necessary.

Also, I was surprised to find that expectations as a concept had not emerged as a theme during the data driven process. I revisited the data at a later date to check and found one instance when a patient had talked about how satisfaction was related to their expectations. However, revisiting the audio-tapes of the interview and closer examination of the transcripts indicated that the patient was actually responding to being probed by me as the interviewer. Since the theme had not emerged during the original analysis, it was not included but this incident made me aware of how researcher's pre-conceptions can affect interpretation.

These experiences and reflexivity made me more aware, and as a consequence the research process was an even richer experience.

4.6 Conclusion

The main purpose of the interviews was to explore CLBP patients' subjective experiences with treatment including their satisfaction and/or dissatisfaction with various aspects of their treatment. A conceptual model of CLBP was developed to show how widely CLBP impacts on patients' daily lives. The impact ranged from physical functioning and social functioning to influences on appearance, emotions, mood, self-esteem, confidence, sleep, relationships, and sex.

A thematic map of satisfaction and dissatisfaction was also developed. Satisfaction was related to being ‘happy’ or ‘pleased’, maintaining general health and normal functioning. If the treatment was not working, causing discomfort, or negatively affecting their health-related quality of life then this was related to dissatisfaction. The inconvenience of taking medication, lack of information, not feeling involved in treatment decisions, lack of trust and confidence in healthcare professionals, being misdiagnosed or undiagnosed, and feeling healthcare professionals were not listening were key factors.

Findings suggest satisfaction and dissatisfaction with treatments is a multidimensional concept. Further research should consider all key components.

Chapter 5 - Development and Cognitive Debriefing of the CLBP Treatment Satisfaction and Dissatisfaction Questionnaire

This Chapter documents the development and cognitive testing of the CLBP Treatment Satisfaction Questionnaire. There are two parts to this Chapter. The first describes the development process and includes details of how the items (questions) and response options of the questionnaire were generated. The second part covers cognitive debriefing to generate evidence to support the face and content validity of the questionnaire.

Part I: Development

5.1 Introduction

Results from the systematic review described in Chapter 3 revealed a need to develop a valid and reliable measure of treatment satisfaction and dissatisfaction that is based on rich qualitative data from in-depth interviews with patients with CLBP. Chapter 4 presents results of a qualitative study exploring subjective experiences in patients with CLBP receiving treatment, based on face-to-face semi-structured interviews. This is part I of Chapter 5 and documents the development of the CLBP Treatment Satisfaction Questionnaire, including a description of the outcome of the item generation process.

The content of a questionnaire is highly dependent on the item generation method, which can include a review of the literature and interviews or focus groups with HCPs and/or patients. There is some evidence to suggest that methods such as focus groups using clinicians do not generate as many items as those with patients. Further, as a method of item generation, clinician focus groups or interviews do not usually identify any new items compared to patient focus groups or interviews (Rat et al., 2007). This is perhaps not surprising since clinicians may be best observers of behaviours whereas patients are able to describe their subjective experiences (Streiner & Norman, 1999).

Since capturing important and relevant concepts from patients' perspectives will increase the sensitivity of the instrument, data saturation is important at this stage. Further, ensuring item generation is performed accurately is critical since no statistics can compensate for poorly worded items, ambiguous or irrelevant concepts, or missing relevant concepts (Streiner & Norman, 1999). Ideally, items should be generated by avoiding double-barrelled questions, jargon, and value-laden words (Streiner & Norman, 1999).

5.2 Objectives

The objective of this part of the study was to use information from in-depth patient interviews to develop items for a questionnaire to measure treatment satisfaction and dissatisfaction with treatments in patients with CLBP.

5.3 Methods

Details of participants, interview agenda, procedure, saturation, and data analysis are presented in section 4.3. For each theme and sub-theme associated with treatment satisfaction or dissatisfaction in patients with CLBP that emerged from the data driven thematic analysis (see Chapter 4), patient quotes were examined and items (questions) formulated. The open-ended questions asked during the patient interviews ensured all relevant concepts were covered. The first draft of the instrument was developed. The items of the questionnaire and the hypothesized domains were created following thematic analyses, and a close examination of how patients conceptually understood their experience of CLBP, symptoms and impact, as well as satisfaction and dissatisfaction with treatment (medication and/or physiotherapy). During the item generation process, researchers avoided leading questions, double-barrelled questions, jargon, and value-laden words that may prejudice the patients and lead them to answer inaccurately (Streiner & Norman, 1999). In addition, items were kept short as possible (Oppenheim, 1992). Also, some terms used in the questionnaire were defined to ensure that all patients understood the term in the same way.

A simplified measure of gobbledygook (SMOG) formula that gives a readability level for written material was used to test for readability (McLaughlin, 1969). Readability is an attempt to match the reading level of written material to the "reading with understanding" level of the reader (McLaughlin, 1969).

5.4 Results

5.4.1 Item Generation

The emergent themes of the interviews (see section 4.4) were organized into a manageable format of six broad categories. These were: ‘Information Provided to You About Back Pain and Treatment’, ‘About Your Medical Care’, ‘Your Health‘, ‘Beliefs About Your Back Pain Medication’, ‘Side Effects from Back Pain Medication’, ‘Satisfaction with Treatments for Back Pain’. The items that were developed related to these six broad categories, but there were also some items which did not easily fit within the categories but were related to how much pain the patient experienced, or their preferences for mode of administration.

The purpose of the section ‘Information Provided to You About Back Pain and Treatment’ was to gain insight into how much information patients would have liked to receive about their condition or injury, the causes of their back pain, and their back pain medications, including potential side effects of back pain medications. This section also assesses how much information patients would have liked about the treatment options available (other than medications), as well as posture and positioning, goal setting (setting tasks to do), pacing (taking things gradually), and exercise.

The section ‘About Your Medical Care’ was developed to find out about patients beliefs regarding whether they thoughts doctors knew what was wrong with them, as well as their beliefs regarding whether they felt involved in treatment decisions, and whether they had been misdiagnosed.

The purpose of the section ‘Your Health and Well-Being’ was to ascertain to what extent patients felt their back pain interfered with regular activities, physical functioning, confidence, appearance, mood, relationships, and sleep. For example, questions relating to regular daily activities explored the extent to which patients felt they spent less time on tasks than they would have liked to, how much they were limited in the tasks that they could do, whether they stopped everyday tasks (including work), and whether they went out of the home.

The section related to ‘Beliefs About Your Back Pain Treatments’ explored the extent to which patients agreed or disagreed that their back pain medication was helpful, prevented future problems, enabled them to be independent (carry out everyday activities), and made them feel out of control. This section also explored whether patients altered the amount of medication they took, whether they set realistic goals, remembered to do their exercises, and paced their activities.

The purpose of the ‘Side Effects from Back Pain Medication’ section was to establish whether patients experienced side effects from their back pain medication, and if so, to what extent each side effect was a problem. Side effects included loss of appetite, weight gain, inability to concentrate, drowsiness, nausea, constipation, diarrhoea, stomach aches, heartburn, and inability to sleep.

The ‘Satisfaction with Treatments for Back Pain’ section explored the extent to which patients were satisfied or dissatisfied with the communication with their doctor regarding back pain medication, the information provided about the possible side effects from back pain medication, the form of administration of back pain medication (e.g. tablet, injection, patch), the amount of medication prescribed, as well as the way doctors had dealt with the side effects of back pain medication.

Space was also provided at the end of the questionnaire so that patients could express any opinions or additional comments, which would bring to attention important concepts not captured by existing items or response options. Findings by Williams and Calnan (1991) indicated that specific questions and those of a qualitative nature are more likely to elicit responses reflecting dissatisfaction and therefore reduce response bias.

It should be noted that as indicated above, the questionnaire covered a variety of concepts (e.g. quality of life, mood, physical functioning, and adherence). The rationale to include all these in a satisfaction questionnaire (rather than using different instruments to assess these) was driven in part by results from the patient interviews but also, from a practical perspective, it allowed a more standardised assessment across the concepts with regard to, for example, the instructions and response format. This was expected to help minimise the burden to patients and increase the likelihood of obtaining a complete meaningful dataset to measure treatment satisfaction in CLBP. Given that the various concepts were measured in a consistent manner, the data collected was then considered suitable for exploratory factor analyses to consider a total score of treatment satisfaction or various principal components.

The items of the questionnaire varied in terms of direction and were usually developed using the same language that patients had used. Consequently, since CLBP was generally described by patients negatively, for example, in terms of limiting their physical abilities, the direction of the items of the questionnaire was generally more negatively than positively worded. All items were written in the first person. The draft of the questionnaire contained 113 initial items. The questionnaire had a SMOG grade of 11, suggesting patients do not need college education to understand the questionnaire.

5.4.2 Recall Period

The majority of items referred to patients' experiences (such as those that relate to the impact of back pain and its treatment on patients' lives or the experience of side effects from treatments) and usually stared with the stem, 'During the last 7 days…' The rationale for using a 7-day recall period was to avoid the problem of being influenced by a good day or a bad day; a longer than 7-day recall period has the potential to increase measurement error via recall bias. In addition, a 7-day recall period was deemed appropriate given the nature of CLBP, as well as its treatment and management, as patients with CLBP often visit a HCP such as a physiotherapist once a week. This rationale is in line with a recent published article that suggests that recall can be influenced by characteristics of the recalled concept (e.g. attributes and complexity), as well as by the context or meaning of the recalled concept (e.g. patient experience and mood) (Stull, Leidy, Parasuraman, & Chassany, 2009).

However, there were some questions where a 7-day recall period did not apply including questions related to the amount of information that a patient would have liked to have received about the causes of their back pain, their back pain medication, and potential side effects. In addition, items related to initial diagnosis and involvement in treatment decisions did not specify a recall period since the timeframe for each patient may have varied significantly from around 12 weeks (or 3 months) to several years. Further, all attitudinal or belief related items such as satisfaction and dissatisfaction items or how helpful they perceive medication to be were developed to assess patients' current opinions, since retrospective assessment of satisfaction and/or dissatisfaction was considered too complex for patients and likely to generate inaccurate responses.

5.4.3 Response Options

The majority of items were measured on a 5-point Likert scale, which is the most widely used standard response option for survey research (Likert, 1932). For example, response options to items in to the ‘Health and Well-Being’ section ranged from 1 (‘all of the time’) to 5 (‘none of the time’). Response options to satisfaction items ranged from 1 (‘very satisfied’) to 5 (‘very dissatisfied’). A Likert-type scale allows for non forced-choice answers so that respondents can answer neutrally (Guy & Norvell, 1977). Furthermore, Likert-type scales are more valid than forced-choice scales because they reduce consenting response bias, and are therefore considered more reliable (Ray, 1990).

5.4.4 Instructions

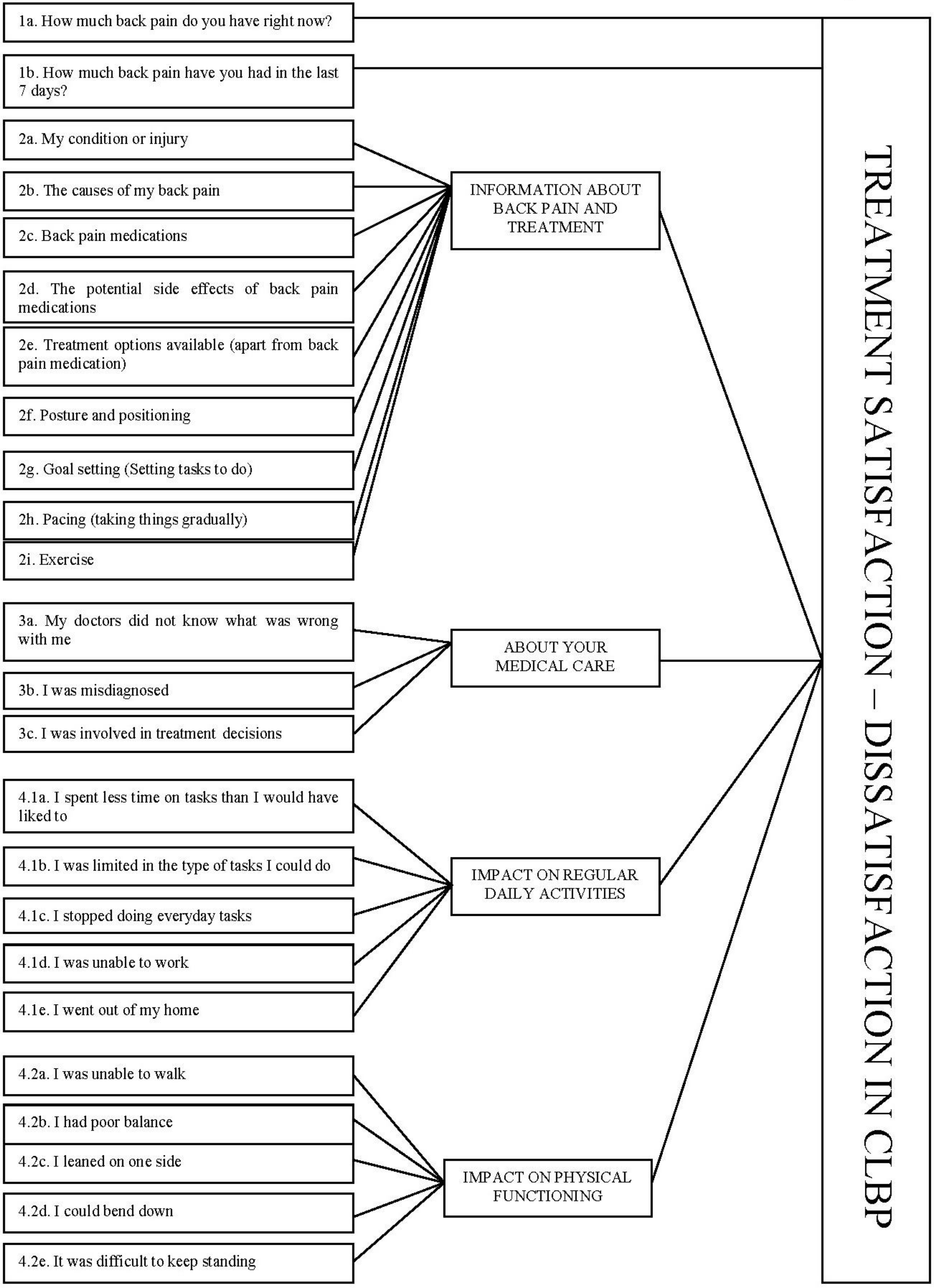
Because this is a self-administered questionnaire, there was an introductory section included to set the scene and explain to patients how they should read and answer the questionnaire. Specifically, the instructions stated “This questionnaire asks for your views about your back pain and your treatment. Please read the following statements carefully and then place a circle around the most appropriate number that applies to you.”

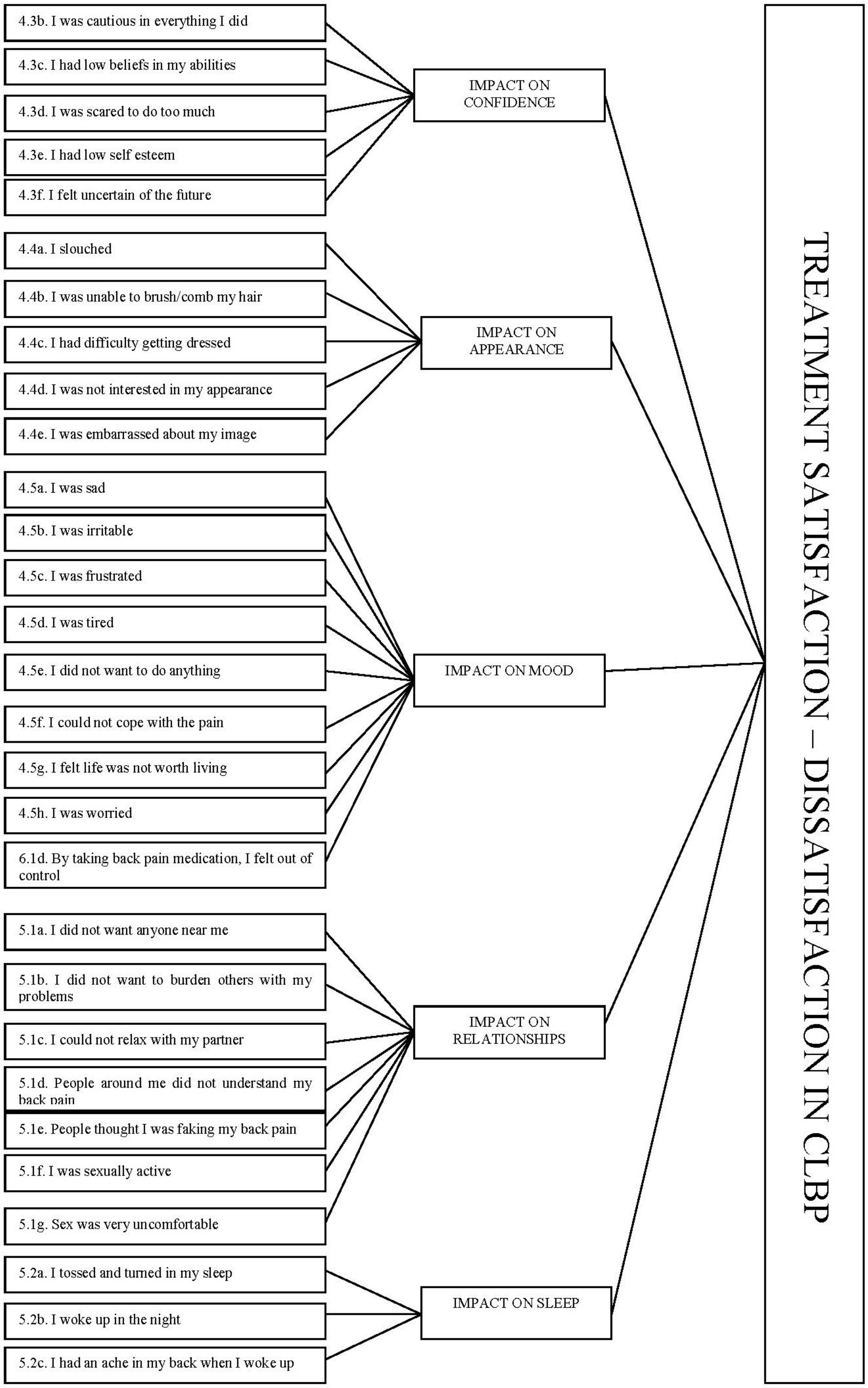
5.4.5 Draft Conceptual Framework

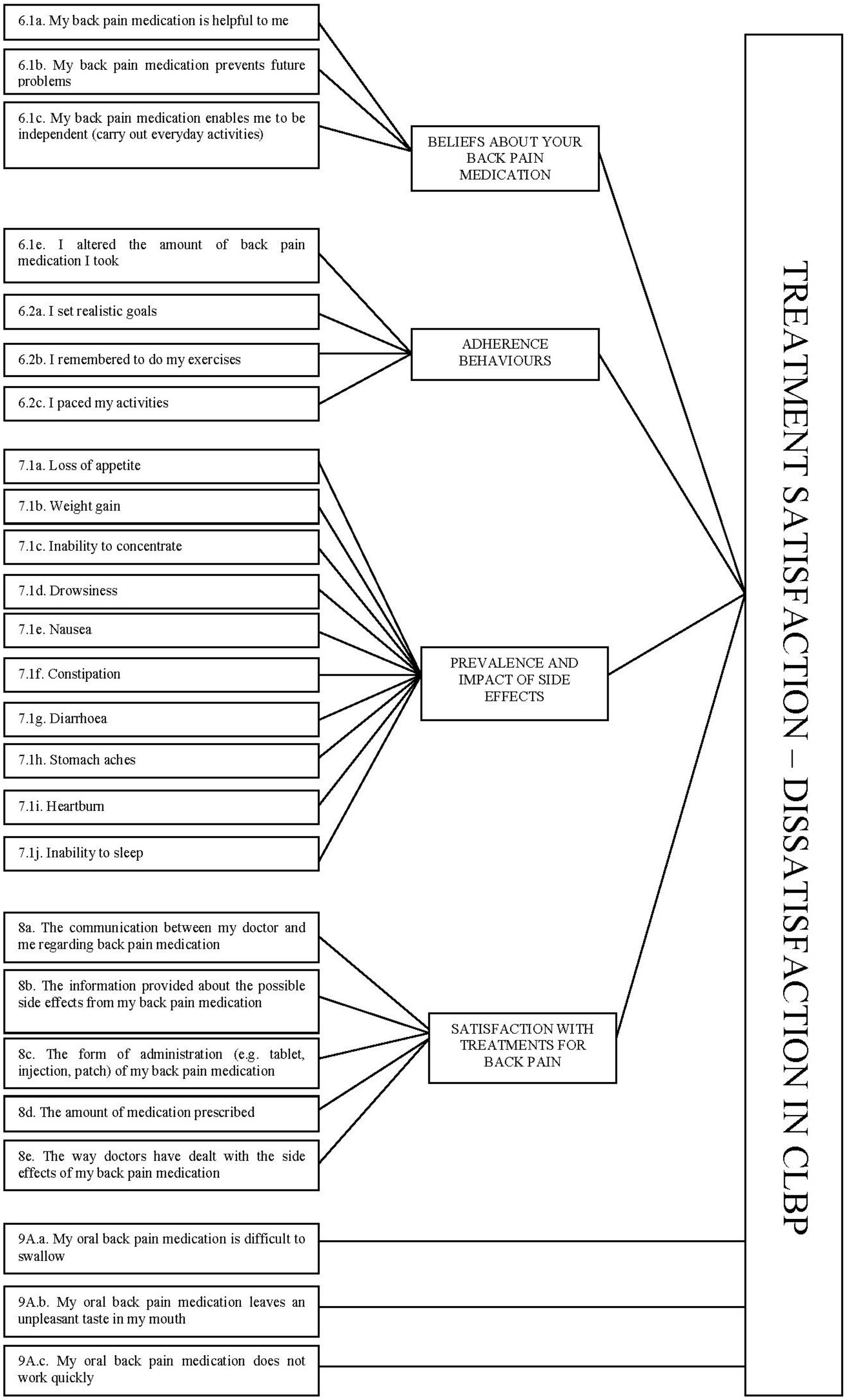
A conceptual framework outlines the relationships between the various aspects of the concepts being measured in a questionnaire and demonstrates hypothesised domains (factors) (Food and Drug Association, 2009). In the case of the satisfaction questionnaire, the conceptual framework shows how the items that were generated from patient interviews relate to each other and whether they can be summarized by factors or sub-concepts. It also demonstrates how the sub-concepts are linked to the overall concept of ‘satisfaction’. The draft conceptual framework that was used to group items in draft versions of the satisfaction questionnaire is illustrated below Figure 9.

This conceptual framework categorised items according to Information Provided about Back Pain and Treatment, About Medical Care, About Health, Beliefs About Back Pain Treatment, Side Effects from Back Pain Medication, and Satisfaction with Treatments for Back Pain. However, it is important to note that items could be grouped in other ways or can be studied as individual items, as in the case of the side effects related to CLBP medications. Further, please note that patients were encouraged to talk about their experiences regardless of the proposed categorisation.

Figure 9: Draft Conceptual Framework of the Treatment Satisfaction and Dissatisfaction Questionnaire




4.3b. I was cautious in everything I did
4.3c. I had low beliefs in my abilities
4.3d. I was scared to do too much
4.3e. I had low self esteem
4.3f. I felt uncertain of the future
IMPACT ON CONFIDENCE
4.4a. I slouched
4.4b. I was unable to brush/comb my hair
4.4c. I had difficulty getting dressed
4.4d. I was not interested in my appearance
4.4e. I was embarrassed about my image
IMPACT ON APPEARANCE
4.5a. I was sad
4.5b. I was irritable
4.5c. I was frustrated
4.5d. I was tired
4.5e. I did not want to do anything
4.5f. I could not cope with the pain
4.5g. I felt life was not worth living
4.5h. I was worried
6.1d. By taking back pain medication, I felt out of control
IMPACT ON MOOD
5.1a. I did not want anyone near me
5.1b. I did not want to burden others with my problems
5.1c. I could not relax with my partner
5.1d. People around me did not understand my back pain
5.1e. People thought I was faking my back pain
5.1f. I was sexually active
5.1g. Sex was very uncomfortable
IMPACT ON RELATIONSHIPS
5.2a. I tossed and turned in my sleep
5.2b. I woke up in the night
5.2c. I had an ache in my back when I woke up
IMPACT ON SLEEP
TREATMENT SATISFACTION – DISSATISFACTION IN CLBP


6.1a. My back pain medication is helpful to me
6.1b. My back pain medication prevents future problems
6.1c. My back pain medication enables me to be independent (carry out everyday activities)
BELIEFS ABOUT YOUR BACK PAIN MEDICATION
6.1e. I altered the amount of back pain medication I took
6.2a. I set realistic goals
6.2b. I remembered to do my exercises
6.2c. I paced my activities
ADHERENCE BEHAVIOURS
7.1a. Loss of appetite
7.1b. Weight gain
7.1c. Inability to concentrate
7.1d. Drowsiness
7.1e. Nausea
7.1f. Constipation
7.1g. Diarrhoea
7.1h. Stomach aches
7.1i. Heartburn
7.1j. Inability to sleep
PREVALENCE AND IMPACT OF SIDE EFFECTS
8a. The communication between my doctor and me regarding back pain medication
8b. The information provided about the possible side effects from my back pain medication
8c. The form of administration (e.g. tablet, injection, patch) of my back pain medication
8d. The amount of medication prescribed
8e. The way doctors have dealt with the side effects of my back pain medication
SATISFACTION WITH TREATMENTS FOR BACK PAIN
9A.a. My oral back pain medication is difficult to swallow
9A.b. My oral back pain medication leaves an unpleasant taste in my mouth
9A.c. My oral back pain medication does not work quickly
TREATMENT SATISFACTION – DISSATISFACTION IN CLBP

5.5 Discussion

The aim of this part of the study was to develop a draft questionnaire to measure satisfaction or dissatisfaction with treatments (medication and/or physiotherapy) for CLBP relief from patients' perspective. Items were generated from in-depth patient interviews based on data driven thematic analysis (see Chapter 4). The draft questionnaire had six broad categories: 'Information Provided to You About Back Pain and Treatment', 'About Your Medical Care', 'Your Health', 'Beliefs About Your Back Pain Medication', 'Side Effects from Back Pain Medication', and 'Satisfaction with Treatments for Back Pain'. In addition to questions in these six broad categories, there were some items which seemed independent but were related to how much pain the patient experienced or their preferences for a particular mode of administration (e.g. tablet, injection etc.).

Whilst a SMOG grade 11 was obtained, suggesting patients do not need college education to understand the questionnaire, cognitive debriefing interviews are required to establish with greater certainty the face and content validity of the draft questionnaire, and to ensure that patients truly understand the questions.

Further, it should be noted that the draft questionnaire is long and contains 113 items. This means that it is subject to fatigue and burden to patients during completion, which may affect the responses they provide to questions. Despite this limitation, item reduction was not implemented at this stage since all the concepts included were deemed important from the patients' perspective and derived as a consequence of data driven thematic analysis. This is in line with recent papers that suggest that patient-reported questionnaires should be developed in this way (Turner et al., 2007). Section 5.7 of this Chapter discusses the cognitive debriefing interviews that were performed and in Chapter 6 factor analysis and reliability and validity testing are described. Following the latter, items could be removed from the total scoring algorithm or deleted from the entire questionnaire if statistically they do not perform adequately and if closer reflections of the qualitative analyses support such decisions.

The majority of items that referred to patients experiences had a 7-day recall period (‘During the last 7 days…’). Some items related to concepts like ‘initial diagnosis’ where the recall period may vary significantly between patients (from around 12 weeks to several years) or ‘involvement in treatment decisions’ where the aim of data collection was to understand the extent to which patients felt involved in treatment decisions, did not have specific recall periods. Further, all attitudinal or belief related items, such as satisfaction and dissatisfaction items, were developed to assess patients’ current opinions since retrospective assessment of satisfaction and/or dissatisfaction was considered too complex for patients and likely to generate inaccurate responses.

It should be noted that a mixed recall period is not ideal and could be confusing to patients. The decision to retain this approach was based on the principle that patients’ evaluations of their experience during the reference period is what matters most, rather than the accuracy of recall of every single experience leading to that judgment. Also, any response process relies on cognitive processing and to some extent on memory, and even ‘current state’ is open to interpretation. In any case, the draft questionnaire will be further tested during cognitive debriefing interviews with particular attention to the recall period of items.

Also, based on the item generation process, a proposed conceptual framework was developed to present a graphical representation of the hypothesized associations between the items of the questionnaire and the potential domains (factors). This warrants further testing.

5.6 Conclusion

The CLBP Treatment Satisfaction Questionnaire captures concepts relevant to patients. Its face and content validity requires testing using a cognitive debriefing exercise (see Part II).

Part II: Cognitive Debriefing

5.7 Introduction

During patient-reported questionnaire development, it is important to ensure that the items are based on rich qualitative data that ideally emerged from in-depth patient interviews or focus groups (Turner et al., 2007). Further, achieving saturation during this first step provides evidence that the concept one purports to measure is comprehensive and captures all the relevant aspects from patients who describe their subjective experiences with the condition and treatment of interest. The outcome of part I of this Chapter was a draft questionnaire to measure satisfaction and dissatisfaction with treatments (medication and/or physiotherapy) for CLBP relief (Appendix H).

The next step was to ensure that the items and response options that comprise the draft questionnaire are truly understood by patients with CLBP receiving treatment, and that the questionnaire is relevant to them. It should be emphasised that the focus is ensuring that patients understand the concepts and items rather than saturation. Cognitive debriefing interviews allow us to test for relevance and comprehension, including whether the questionnaire has face and content validity (Turner et al., 2007). Face validity is whether the questionnaire appears to measure what it purports to measure, and content validity is whether the questionnaire contains all the relevant items and concepts related to the phenomenon of interest, in this case satisfaction or dissatisfaction with treatment (Oppenheim, 1992).

5.8 Objectives

The main objective of this part of the study was to perform face and content validation of the items developed to measure satisfaction and dissatisfaction with treatments for CLBP relief. The ultimate aim was to produce a version of the questionnaire that was clear, comprehensive, and relevant.

5.9 Method

The questionnaire was scrutinised by colleagues and potential users of the information generated by the questionnaire (for example, 2 psychologists and 2 physiotherapists and a nurse working with patients with CLBP). Additionally, before carrying out the main study, a cross-section of patients who met the inclusion criteria and none of the exclusion criteria participated in a cognitive debriefing exercise to establish the face and content validity of the questionnaire (see section 5.9.1). These patients were different to those who participated in part I.

5.9.1 Participants

Ten patients with CLBP participated and varied in age from 32 to 58 years (mean age 46 years). There were six women and four men. Patients were recruited from one NHS Trust in the North of England (Stepping Hill Hospital) via physiotherapists.

Purposive sampling was performed where patients attending a pain clinic and/or receiving physiotherapy were screened. They were considered eligible if they met all of the inclusion criteria and none of the exclusion criteria which were pre-specified on a screening script (Appendix C). Please note these were criteria as the initial interviews. The inclusion criteria were:

- Patient diagnosed with CLBP (pain lasting longer than 12 weeks, affecting the lower back, between the bottom of the ribs and top of the legs);

- Patient was receiving treatment for CLBP, or advised by their doctor to do so;
- Patient was 18 years or older;
- Patient was able to understand and communicate in English.

The exclusion criteria were:

- Patient had known cognitive impairment;
- Patient had a case-note diagnosis of co-morbid learning disabilities;
- Patient was currently using alcohol or illegal drugs;
- Patient had brain injury or any other organic disorder.

5.9.2 Interview Agenda

A cognitive debriefing interview agenda was developed for patients with CLBP receiving treatment and was partly informed by knowledge from the in-depth semi-structured patient interviews (see Chapter 4), as well as the draft questionnaire. The content of the interview agenda was decided upon based on two independent researchers' opinions according to the research question, and was designed as much as possible move from general questions to more specific questions when rapport had been established.

The first step involved asking patients an open-ended question, 'what does satisfaction with treatment mean to you?', followed by another open question, 'what does dissatisfaction mean to you?' Patients then completed the draft questionnaire to familiarise themselves with the instructions, items, and response options. Next, the interview explored patients' general impressions of the questionnaire, including general feelings about ease or difficulty understanding the questionnaire, opinions about the instructions and length of the instructions, what they thought of the length of the questionnaire, and whether anything needed to be added or deleted. Outpatients were also asked whether there were any questions that were unclear and what they thought of the layout. This section also enquired about the appropriateness of the response options to the questions and the relevance of the recall period in terms of how far back patients were thinking when answering the questions.

Following the general impressions section, more specific questions were asked regarding each aspect of the questionnaire, including the title, instructions, the statement before the items, and each item. These specific questions were ‘Did you have difficulty understanding the question?’, ‘What does it mean to you?’, ‘Is it relevant to your situation?’, ‘How would you have worded the question?’, and ‘Are the response choices clear and consistent with the question?’ At the end of the cognitive debriefing agenda, patients were asked whether there were any questions or areas missing from the questionnaire.

5.9.3 Procedure

The Head of the Physiotherapy Department at Stepping Hill Hospital agreed to identify physiotherapists in their team who could help to recruit patients into the study according to the screening script. The physiotherapists who agreed to help were briefed regarding the purpose of the study and the inclusion/exclusion criteria for recruitment of patients (see Appendix C). If patients met all of the inclusion criteria and none of the exclusion criteria, they were informed by the physiotherapist that a study was taking place to explore their experiences with CLBP and their opinions about a questionnaire. Patients who were interested were provided with an information sheet and completed a consent form (see Appendix D and E). An interview date and time was then arranged.

At the start of the interview, patients were briefed and consent forms were obtained from patients. They were assured anonymity and were informed that they had the right to withdraw at any time. They were also informed that any decision to withdraw would not affect the treatment and care that they receive in any way. Once the patient was comfortable, the tape recorder was switched on and they were asked to repeat their consent to participate for recording purposes. Patients then responded to some questions before being asked to complete the draft questionnaire so that they were familiar with it. Any problems or questions incurred during completion or observed by the interviewer were recorded. Then the cognitive debriefing interview continued according to the interview agenda (see section 5.9.2).

The interviews lasted between 35 and 60 minutes, depending on how much each patient wanted to say. The interviewer was female and all interviews were conducted in an enclosed office at Stepping Hill Hospital to ensure confidentiality. All patients were asked identical questions in the same sequence, but the interviewer probed inductively on key responses, and probes were asked only if a patient's response to the initial question did not cover certain topics of interest.

All interviews were audio-taped and transcribed verbatim by the researcher to allow greater familiarity with the data prior to analyses. A tracking form was used to ensure the data generated from a specific interview was identifiable via patient identification numbers thus ensuring anonymity. The tracking form was stored on a password protected laptop computer.

5.9.4 Analysis of Cognitive Debriefing Interviews

Transcripts were analysed in-depth and quotes were arranged using an Excel spreadsheet into appropriate sections relating to satisfaction or dissatisfaction with treatment, general impressions of the draft questionnaire (overall opinion, length of questionnaire, instructions, items, recall period, and response options), as well as details relating to cognitive debriefing of each aspect of the questionnaire (for example, the title, instructions, and items).

5.10 Results

5.10.1 Demographic Characteristics

Ages ranged from 32 to 58 years. The overall mean age was 46 years. There were six women and four men. The majority of patients had no qualifications (n=8), and two had O-levels. Eight patients were unemployed, and two worked part time. All patients reported that their work was limited by their CLBP.

Symptoms recorded on patients’ case notes included pain in lower back; numbness in back; constant ache and intense pain; lack of strength in back; and unable to walk long distances. Duration since first diagnosis varied from four months to 34 years.

Patients were receiving a number of different medications for CLBP relief, including non-opioid analgesics (such as paracetamol or cocodamol) (n=8), NSAIDs (ibuprofen, diclofenic, or naproxen) (n=9), opioid analgesics (codeine or dihydrocodeine) (n=3), benzodiazepines (diazepam) (n=3), and tricyclic antidepressants (amitriptiline) (n=1). Most were taking these medications as required. Side effects reported in patients’ case notes included loss of appetite, nausea, and constipation. In addition to taking medications for CLBP relief, all patients were seeing a physiotherapist regularly.

5.10.2 Satisfaction and Dissatisfaction with Treatments for CLBP Relief

When asked ‘what does satisfaction with treatment mean to you?’ patients with CLBP described positive opinions of treatment such as being ‘pleased’ and ‘content’ with the treatment. Patients described getting rid of the pain. They also mentioned that for them to be satisfied, the medication needs to work quickly, and they need to be able to continue with their everyday activities such as going to work or doing housework. Satisfaction with treatment was also associated with good communication with HCPs such as doctors and physiotherapists, and being provided with information regarding treatment options and the potential consequences of medication such as side effects. It was important to patients that their HCP or a family member such as a partner was taking their complaints about back pain seriously. Experiencing side effects influenced the level of satisfaction with treatment.

When asked ‘what does dissatisfaction with treatment mean to you?’ all patients said that it was the opposite of satisfaction with treatment and referred to negative aspects of treatment. Patients talked about their medication not working, experiencing constant pain, and this impacting their lives in terms of what they could do every day. Some patients mentioned that they had become extremely cautious about everything that they did, and had lost self confidence. Others talked of how it had affected their self esteem, appearance, and their relationship with their partners. Being misdiagnosed or undiagnosed for a significant time contributed to dissatisfaction with treatment. Experiencing side effects and the extent to which those side effects were a problem to patients were also associated with dissatisfaction.

5.10.3 General Impressions of the Draft Questionnaire

To help establish the usability of the draft questionnaire, patients with CLBP were asked their opinions about its coverage and format. Patients were asked to complete the draft version of the questionnaire first.

Overall, the majority of patients were positive about the questionnaire and reported that it was “helpful” and “relevant”. One patient (ID09) stated, “These questions are good. I have never been asked these questions in 20 years!” Another patient (ID06) mentioned that although it was quite long, they didn’t mind it because it was related to their problems. When asked if there was anything missing from the questionnaire, patients did not contribute any additional suggestions.

In terms of the length of the questionnaire, one patient (ID03) suggested making the questionnaire shorter, and another two patients stated it was too long (ID04; ID07). However, another patient (ID05) stated the length of the questionnaire was “just right”. Therefore, the questionnaire was reviewed for overlapping items. For example, ‘I felt I gained weight’ was deleted from the ‘Health’ section of the questionnaire because ‘weight gain’ was already an item in the ‘Side Effects from Back Pain Medication’ section, and based on informal discussions with HCPs it was felt that weight gain was more a consequence of the medication than of the back pain.

Generally, the instructions of the draft questionnaire were well understood. However, one patient (ID03) stated it would be helpful to explain in the instructions why the questionnaire focuses on ‘7 days’ rather than ‘since your diagnosis’ or ‘since the start of treatment’. Another patient (ID02) stated that they thought the questionnaire was in relation to their physiotherapy class. Consequently, treatment was operationally defined in the instructions to specify ‘medication and/or physiotherapy’.

With regard to the recall period of 7 days, one patient (ID02) mentioned that they felt the recall period was too short and that they wanted to review all the time that had passed since their CLBP diagnosis. However, this change was not implemented since there is some evidence to suggest recall bias and measurement error are associated with longer recall periods (Stull et al., 2009).

Further, all the patients reported that the response options were relevant to the questions. However, one patient (ID01) stated that it may be useful to include ‘not applicable’ responses for some items, such as those relating to oral, injection or patch treatments. With this in mind, ‘not applicable’ options were added to the draft questionnaire for items such as whether the back pain interfered with relationships, since not all patients may have a partner or family. However, the ‘not applicable’ option was not added to items associated with mode of administration because those items were preceded by answering questions regarding how back pain medication is administered (oral, injections, patch) and then requiring patients to complete only the sections that apply to them.

5.10.4 Cognitive Debriefing Items

A total of 26 items were deleted since they overlapped with other items in the questionnaire, and one item was modified following face and content validation (Table 10). For example, the item 'How much back pain have you had in the last 24 hours?' was deleted to minimise the number of questions and duplication, and also because patients' responses did not vary compared to the question 'How much back pain do you have right now?' which was retained.

One patient (ID01) suggested changing '1 week' to '7 days' to make the questionnaire more consistent. Thus, the item 'How much back pain have you had in the last week?' was modified to 'How much back pain have you had in the last 7 days?'

Another patient (ID03) recommended that the section 'Symptoms of Back Pain' with items such as 'Pain in back', 'Pain in legs', 'Pins and needles', 'Numbness' and 'Stiffness' were too similar to the section 'About Your Back Pain'. Consequently, these items were deleted since closer examination of the qualitative data that emerged from Chapter 5 indicated that patients described pain as the main symptom, and the location or description of pain was not mentioned as important in terms of the concept of satisfaction or dissatisfaction with treatment.

Discussing the item 'I stopped doing sports', two patients (ID04; ID07) stated that they never did any sports in the first place. Thus this item was deleted because it was not necessarily relevant to everyone and the concept of not being able to do sports could be captured by other items, such as ‘I stopped doing my everyday tasks’.

Another patient (ID05) mentioned that the item ‘I felt depressed’ was too similar to ‘I felt life was not worth living’. Consequently, ‘I felt depressed’ was deleted, as this could still be captured by ‘I felt life was not worth living’.

In addition, the items ‘I did not sleep well’ and ‘It was difficult to get comfortable to get to sleep’ were both deleted since three patients (ID04; ID08; ID10) indicated that these were too similar to the item ‘Inability to sleep’ in the Side Effects from Back Pain Medication section.

One patient (ID10) mentioned that all items relating to relationships were only relevant if you have a partner; another patient (ID01) similarly critiqued the item ‘I could not relax with my partner’. These statements reinforced the decision to include ‘not applicable’ to the response options for items relating to relationships.

Further, the items ‘My partner was frustrated’, ‘My partner felt guilty’, and ‘My partner treated me as fragile’ were deleted because three patients (ID01; ID03; ID10) stated that their partner’s feelings had nothing to do with CLBP. These items were also deleted because the draft questionnaire was intended to capture patients’ subjective experiences, and on reflection these items were proxies (the patient was reporting on behalf of their partner) and thus results may not have been accurate. Also, the item ‘I tried not to worry my family’ was deleted because one patient stated that this was the same as ‘I did not want to burden others with my problems’.

The section ‘About Your Current Medication’ was reworded to ‘Beliefs About Your Back Pain Medication’, as one patient (ID06) said that this section was more about beliefs and therefore should say so.

Also, in relation to the section ‘How satisfied or dissatisfied are you with the following...’ and the item ‘the care provided for my back pain’, one patient (ID07) stated that the term care was too generic and could relate to hospital care, GP, physiotherapy, help at home, or other types of care. In line with the patient’s suggestion, this item was deleted because it was too broad.

Table 10: Summary of Deletions and Modifications to Draft Questionnaire Following Face and Content Validation

Original Item	Modified /Deleted	Rationale for Change
1c. How much back pain have you had in the last 24 hours?	Deleted	Overlapped with 1b. How much back pain do you have right now?
2a. Pain in back	Deleted	Pain is the main symptom and the location or description is not important in relation to satisfaction or dissatisfaction with treatment.
2b. Pain in legs	Deleted	
2c. Pins and needles	Deleted	
2d. Numbness	Deleted	
2e. Stiffness	Deleted	
4j. Injections	Deleted	Item was considered not essential and not relevant to many patients.
5.1d. I stopped doing tasks I wanted to do	Deleted	Overlapped with 4.1c. I stopped doing my everyday tasks.
5.1e. I stopped doing sports	Deleted	Not relevant to all patients and overlaps with 4.1c. I stopped doing my everyday tasks.
5.2a. I went to work	Deleted	Not relevant to all patients and overlaps with 4.1c. I stopped doing my everyday tasks.
5.2b. I was unable to work due to my physical limitations	Deleted	
5.2c. It was difficult to be positive at work	Deleted	Also, physical limitations can refer to walking or bending and this overlaps with other items e.g. 5.3a. I was able to do physical activities.
5.6a. I felt I gained weight	Deleted	Overlapped with 7b. Weight gain.
5.7.e I was annoyed	Deleted	Overlapped with 5.7c. I was frustrated.
5.7i. I felt depressed	Deleted	Overlapped with 5.7h. I felt life was not worth living.
5.8a. I did not sleep well	Deleted	Overlapped with 7j. Inability to sleep.
5.8b. It was difficult to get comfortable to get to sleep	Deleted	
5.9b.I was interested in relationships	Deleted	Overlapped with 5.9a. I did not want anyone near me.
5.9d.I tried not to worry my family	Deleted	Overlapped with 5.9c. I did not want to burden others with my problems.
5.9f. I did not have sex	Modified	Reworded positively: ‘I was sexually active’
5.9h. My partner was frustrated	Deleted	Feelings about partners are not necessarily linked to CLBP. Also, draft questionnaire intended to measure patients’ subjective experiences rather than a proxy for partners.
5.9i. My partner felt guilty	Deleted	
5.9j. My partner treated me as fragile	Deleted	

Original Item	Modified /Deleted	Rationale for Change
5.9k. People around me were sympathetic	Deleted	Overlapped with 5.9m. People around me did not understand.
8a. The care provided for my back pain.	Deleted	Care was considered too broad and covers for example, hospital, GP, physiotherapy, help at home.
8b.The communication between myself and health professionals regarding my back pain medication	Modified	'Healthcare professional' replaced with 'doctor' because they prescribe the medication.
8c. The information provided about the treatment options	Deleted	Overlapped with 4c. Treatment options available (apart from back pain medication).
8g. The amount of time taken to take my back pain medication	Deleted	Not meaningful since the time taken for most medications are minimal.

5.10.5 Revised Questionnaire and Conceptual Framework

Following the modifications outlined in Table 10, the questionnaire and conceptual frameworks were revised (Appendix J and K).

5.11 Discussion

The cognitive debriefing interviews demonstrated that patients liked this questionnaire because it was relevant to them. The majority of items were well understood and appropriate to patients with CLBP receiving treatment. Twenty-six items were deleted, the main reason being that they overlapped with other items in the questionnaire that were more appropriate. When asked if there was anything missing from the questionnaire, all of the patients stated that there was nothing missing, and none contributed anything additional beyond what was already in the questionnaire. However, there were a few minor modifications to either operationally define treatment, clarify the recall period, or to be more specific in the section titles. The deletion of items and minor modifications were implemented to form a revised draft questionnaire (see Appendix J).

However, it should be emphasised that although the items of the questionnaire were reviewed for overlap and some minor modifications implemented, further changes to shorten the draft questionnaire were not implemented since item reduction should follow factor analysis as well as reliability and validity testing.

Further, one patient thought the recall period should extend beyond 7 days, but this was not implemented because there is some evidence to suggest that long recall periods are subject to recall bias and are more likely to incur measurement error (Stull et al., 2009). It should be noted that Chapter 6 presents the main study where the revised questionnaire is implemented over time. For patients recruited from a physiotherapy clinic, data was collected during the first week of treatment (day 1 to 7), second week of treatment (day 8 to 14), and six weeks from the start of treatment (day 33 to 42).

Also, a 7-day recall period was not used for some items in the questionnaire since it was not considered appropriate. For example, retrospective assessment of satisfaction or dissatisfaction items was considered too complex for patients. Indeed, this was in line with a comment from a patient with CLBP who stated that 7 days was not long enough for them to report their satisfaction with treatment. One point for consideration is that whilst the 7-day recall period was included for some sections but not others, it’s possible that some patients may miss this subtlety and this could have some impact on results.

5.12 Conclusion

The CLBP Treatment Satisfaction Questionnaire has good face and content validity. Patients find the items very relevant, and understand the questions and associated response options. The recall period is also relevant to patients in the context of CLBP. Psychometric validation is necessary to establish the factor structure and scoring method, as well as explore whether the questionnaire has discriminative validity and reliability (see Chapter 6).

Chapter 6 - Study III: Psychometric Testing of the Treatment Satisfaction and Dissatisfaction Questionnaire

6.1 Introduction

Chapter 5 documents the development and face and content validity of the CLBP Treatment Satisfaction Questionnaire. This Chapter explores the psychometric properties of the questionnaire in terms of validity and reliability.

Instrument validity is concerned with the extent to which the questionnaire is measuring what it purports to measure (British Psychological Society Steering Committee on Test Standards, 1999). When testing the validity of an instrument, it is important to know the content of the questionnaire, the purpose the questionnaire is intended for and the type of validity being applied (Oppenheim, 1992). If a test is not reliable, it is unlikely to be valid. There are different types of validity, including but not limited to face and content validity (which is demonstrated in part II of Chapter 5), construct validity, concurrent validity, clinical validity, and discriminant validity. It's not necessary to assess all types of validity, but the methods chosen should be based on the project objectives, resources, and needs. The statistical methods for testing validity and the reasons for using these methods in the present study are outlined below (section 6.3.8).

Reliability is often referred to in terms of consistency or repeatability (Kline, 2000). The British Psychological Society (BPS) Steering Committee on Test Standards refers to reliability as "the extent to which the outcome of a test remains unaffected by irrelevant variations in the conditions and procedures of testing" (British Psychological Society Steering Committee on Test Standards, 1992). The BPS Steering Committee also state that reliability reflects accuracy and precision (British Psychological Society Steering Committee on Test Standards, 1999). There are various types of reliability, including but not limited to internal consistency and test-retest reliability. The statistical methods for measuring reliability and rationale for these methods in this study are provided in section 6.3.8.

6.2 Objectives

The main objective of this part of the study was to explore the psychometric properties of the CLBP Treatment Satisfaction Questionnaire. The ultimate aim was to produce a reliable and valid version of the questionnaire. The second objective was to construct a framework to make sense of factors associated with treatment satisfaction in CLBP.

6.3 Methods

6.3.1 Study Design

This study was a longitudinal study that involved collected data from the same sample at three timepoints (Table 11). The rationale for a longitudinal design was that it enabled a large number of patients to be compared at the same time, provided data that was sufficient to enable an exploration of the factor structure(s) of the questionnaire (The CLBP Treatment Satisfaction Questionnaire), as well as allowing exploration of test-retest reliability, and responsiveness to change over time.

For patients recruited from physiotherapy clinics, the week 1 assessment was prior to the first consultation, week 2 was the first follow-up (varied between day 8 and day 14), and week 6 was the last, end of study (EOS) assessment (varied between day 33 and 42). For patients recruited from the Back Show in London, there were no follow-ups and of those patients who were receiving physiotherapy in this group, patients may have had more than one consultation at baseline.

Table 11: Schedule of Assessments

Questionnaires	**Week 1 – Baseline [prior to 1st consultation]**	**Week 2 – 1st Follow-up [Day 8 – 14]**	**Week 6 – EOS [Day 33 - 42]**
Demographic & clinical details	x		
Satisfaction	x	x	x
Change question		x	x
Adherence	x	x	x
SF-36	x	x	x
PETS	x	x	x
McGill PAIN	x	x	x
Roland & Morris	x	x	x

6.3.2 Participants

Two-hundred and fifty participants took part in the study and presented with CLBP as their primary complaint. All participants were above 21 years of age, ranging from 21 to 77 years, with a mean of 47.86 years. 173 (70%) participants were female. Participants were recruited by a researcher (DR) at the Back Show in London in October 2008, or were consecutive referrals from an Extended Scope Practitioner (ESP) to a physiotherapist or a pain clinic. Participants were included in the study if they fulfilled all of the following criteria:

- Had a diagnosis of CLBP (defined as pain lasting longer than 12 weeks, affecting the lower back, between the bottom of the ribs and tops of the legs);
- Were receiving treatment for CLBP (medication and/or physiotherapy), or had been advised by their doctor to do so;
- Were able to understand and communicate in English;

Participants were excluded if they had any one of the following:

- Known cognitive impairment;

- Case note diagnosis of co-morbid learning disabilities;
- Were abusing alcohol or taking illegal drugs;
- Had brain injury or any other organic disorder.

6.3.3 Sample Size

As there is no formal method to estimate sample size, in order to conduct an exploratory factor analysis, the generally accepted rule of 3 participants for every item was employed (Mundform, Shaw, & Ke, 2005).

There were 77 items to be included in the exploratory factor analysis, and therefore it was estimated that 231 (77x3) patients was an acceptable sample size. This figure was in line with Comrey and Lee (1992) who stated that a sample size of 200 was "fair", 300 "good" and 500 "very good".

6.3.4 The CLBP Treatment Satisfaction Questionnaire

All participants completed the revised CLBP Treatment Satisfaction questionnaire which had been developed specifically for this study and consists of 87 items. Seventy-seven items were included in the validation study. The remaining items provided additional qualitative information and were therefore not included in the PCA.

6.3.5 Other Patient-Reported Outcome Instruments

The following other patient-reported instruments were completed by participants: The Adherence Questionnaire (Horne, 1997); The Short Form 36 Item Health Survey (Ware & Sherbourne, 1992); The Problematic Experiences of Therapy Scale (Yardley & Kirby, 2006); The McGill Pain Questionnaire (Melzack, 1987); and the Roland and Morris Disability Questionnaire (Roland & Morris, 1983) (see Appendix M to Q). The main reason these questionnaires were included were because together they covered the main topics of interest that emerged from the patient interviews in Chapter 5, and which would allow various psychometric testing of the CLBP Treatment Satisfaction Questionnaire to be performed.

The Adherence Questionnaire (Horne, 1997)

The adherence questionnaire contains the following five items which were analysed independently because there was little evidence of reliability and validity: 1) I forget to take my medicines; 2) I alter the dose of my medicines; 3) I stop taking my medicines for a while; 4) I decided to miss a dose; and 5) I take less than instructed. All items are rated on the following scale: always, often, sometimes, rarely, and never.

The Short Form 36-Item Health Survey (Ware & Sherbourne, 1992)

The Short Form 36 Item Health Survey (SF-36) version is a self-administered questionnaire that contains 36 items comprising eight domains: Physical Functioning (10 items); Role Limitation due to Physical Health Problems (4 items); Bodily Pain (2 items); General Health Perceptions (5 items); Vitality (4 items); Social Functioning (2 items); Role Limitations due to Emotional Problems (3 items); and General Mental Health (5 items). There are also Physical and Mental Component Summary scores. There is an additional single item giving information on health change over the past year. The response options for items vary between items. For example, some items have a dichotomous response option (yes or no), some have three response options (yes limited a lot, yes limited a little, and no not limited at all), and others are on a 5-point Likert scale (all of the time, most of the time, a good bit of the time, some of the time, and a little of the time). Item scores for each domain are coded, summed and transformed to a scale from 0 (worst possible health state measured by the questionnaire) to 100 (best possible health state). The higher values indicate a better evaluation of health. The SF-36 is well-documented in terms of reliability and validity (see for example, Ware & Sherbourne, 1992).

Problematic Experiences of Therapy Scale (Yardley & Kirby, 2006)

The Problematic Experiences of Therapy Scale (PETS) is a self-administered questionnaire composed of 12 items forming four domains: Symptoms too severe or aggravated by therapy (3 items); Uncertainty about how to carry out the treatment (2 items); Doubts about treatment efficacy (3 items); and Practical problems (such as lack of time or opportunity, forgetting) (4 items). All items are scored on a scale of 1-5, with 1 = disagree strongly and 5 = agree strongly. The subscales are calculated by adding the relevant items together and dividing by the number of items in that subscale. High scores indicate problematic experiences with therapy. There is evidence to support good reliability and validity of the PETS (Yardley & Kirby, 2006).

The Short-Form McGill Pain Questionnaire (Melzack, 1987)

The Short-Form McGill Pain Questionnaire (SF-MPQ) comprises three sections. The first section contains a list of 15 words used to describe pain. Eleven of the 15 words are sensory descriptors and the other four are affective descriptors. Patients rate their pain on each descriptor as ‘none’, ‘mild’, ‘moderate’, or ‘severe’. The second section is a 10cm visual analogue scale (VAS) with the term ‘no pain’ and ‘worst possible pain’ as anchors at either end. The third section consists of a Present Pain Intensity Scale (PPI). The PPI contains six terms to describe the level of pain. The Short-Form McGill Pain Questionnaire yields five scores: a sensory score, an affective score, a total score (sensory and affective), a VAS score, and a PPI score. The good psychometric properties of the SF-MPQ are presented in Melzack (1987).

The Roland and Morris Disability Questionnaire (Roland & Morris, 1983)

The Roland and Morris Disability Questionnaire (RMDQ) contains 24 statements that people with back pain could use to describe themselves. Patients are required to mark 0 for false or 1 for true to indicate statements that best describe them on the day of completion. The RMDQ is scored by adding the number of items checked. Scores range from 0 to 24, with higher scores indicating greater disability. There are several papers providing evidence to support the reliability and validity of the RMDQ (see for example, Kuijer, Dijkstra, Goeken, Groothoff, & Geertzen, 2004; Stratford, Binkley, & Riddle, 2000).

The Change Item

At follow-up, patients were asked the following question to establish the degree of change in their health that could then be used to define patients as improved, stable, or worsened: ‘Compared to the way you felt at the start of this study, please rate the degree of change in your health on the following scale: very much worse, moderately worse, a little worse, about the same, a little better, moderately better, very much better.’

Demographic and Clinical Details

Patients answered questions on demographic characteristics and clinical history including gender, age, work status, number of working days lost due to CLBP in the last 4 weeks, date of first diagnosis, present medication details and other treatments they were currently taking to help them with their CLBP. These questions were developed so that the data obtained could be compared to UK national statistics to the greatest extent possible.

6.3.6 Data Collection Procedure

Ethical approval was granted for the protocol by North Manchester Research Ethics Committee (REC reference number 07/Q1406/50). Although random sampling was preferential, this approach was impracticable because a list of all the patients could not be obtained. Therefore, the method of selection employed was purposive sampling because patients were identified from specific locations according to pre-specified inclusion/exclusion criteria and for the intention of collecting data on patients with CLBP.

Specifically, the patient sample was recruited from ESPs and physiotherapists at Stepping Hill Hospital, Tameside Hospital, Kingsgate Medical Centre, and Hyde Physiotherapy Clinic. The researcher (DR) informed the ESPs and physiotherapists in each hospital or clinic about the survey and gained their support. An email was sent to ESPs and physiotherapists informing them of the aims and procedure of the survey, together with contact details of the researcher involved, so that any queries could be dealt with directly.

Information and consent forms (Appendix L), a demographic and clinical details form, and the battery of questionnaires (Appendix M to Q) were prepared as survey packs for each hospital and pain clinic. A tracking form was developed to maintain anonymity by assigning each participating site an ID number and listing the ID numbers allocated for each participating patient. The census for each participating site was arranged so that immediately after the researcher visited (to provide survey packs) the physiotherapists would issue the packs and then ensure that every patient who attended was given the opportunity to participate. The researcher explained the procedure at the time of the visit and clarified any concerns raised by the teams.

Physiotherapists were asked to distribute a survey pack to every patient on their caseload who met the inclusion criteria and none of the exclusion criteria (See section 6.3.2). If a patient refused to participate, physiotherapists were asked to offer the survey pack to the next patient on their caseload until they had no more survey packs. Written informed consent was obtained from all patients and confirmed by physiotherapists.

Patients attending a consultation with an ESP who were subsequently referred to visit a physiotherapist or attend a pain clinic were screened using the pre-specified inclusion/exclusion criteria prior to their first appointment with a physiotherapist or attendance at a pain clinic. Those meeting all of the inclusion criteria and none of the exclusion criteria were invited to participate in the study. After one week, follow up calls were made to each head of physiotherapy departments or pain clinics to ensure everything was in place and address any questions that may have emerged. Additionally, a thank you letter was sent to all those who had assisted in the facilitation of the survey.

For patients attending physiotherapy or pain clinics in the North West of England, those who agreed completed the survey during their second visit, one week later, and again at week six (see Figure 10)

Patients with CLBP were also recruited from the Back Show in London (October 2008), as well as support groups run by charities. For those attending the Back Show, announcements were made throughout each day inviting people who have back pain to visit the Brunel University stand to help with ongoing research. At the stand, patients were screened by trained researchers (DR and a researcher trained by DR) according to the pre-specified screening script (Appendix C), and people who met all of the inclusion criteria and none of the exclusion criteria were invited to participate. Each person with CLBP who met the criteria were provided with an information sheet (Appendix L) informing them of the purpose of the study, and those who wished to take part were asked to sign the consent form (Appendix E).

Patients were then individually asked to complete a battery of questionnaires that were presented as a survey pack (see sections 6.3.4 and 6.3.5). Patients recruited from the Back Show did not participate in follow-up assessments.

As the completed survey sheets and clinical details forms were received, the information was entered on a Statistical Package for Social Scientists database (SPSS, version 13) and the consent forms were filed. The requirements of the Data Protection Act were considered at all times. Descriptive and inferential statistics were conducted. Interpretation of results preceded writing up and disseminating the findings, including to all patients who wished to receive feedback and to all physiotherapists and team leaders.

6.3.7 Analysis Methods

Description of Variables, Normality, and Outliers

Nominal and ordinal variables (such as ‘In general, how do you rate your health?’) were described by the number of patients and the percentage for each response category. Continuous variables (such as the VAS) were described by presenting the frequency, mean, standard deviation, standard error, median, minimum, maximum, and number of missing data.

Normality refers to the extent to which the distribution of scores appears ‘normal’, i.e., the degree to which the data represents a symmetrical, bell-shaped curve, with the greatest frequency of scores in the middle, and smaller frequencies towards the extremes (Pallant, 2001). It should be noted that patient-reported outcomes data is frequently non-normal, and despite this parametric tests are often used because they are robust to non-normality and are more powerful than non-parametric tests. For this reason parametric tests were employed, but the normality of the data was explored using the Kolmogorov-Smirnov statistic to understand the data. A non-significant result (significance value of >0.05) is indicative of ‘normal’ distribution of scores. The actual shapes of the distribution were also observed using histograms, as well as the inspection of Normal-Q-Q Plots, Detrended

Normal Q-Q Plots, and box plots. This information was considered in parallel to descriptive statistics such as the mean, 5% trimmed mean, skeweness, and kurtosis.

Software, Statistical Tests, and Level of Significance

All data were analysed using the Statistical Package for Social Scientists (SPSS) version 13. Scoring of all questionnaires except the Satisfaction questionnaire were performed as per the instructions of the developers of those questionnaires. For the Satisfaction questionnaire, scoring was determined during the factor-analyses. Principal Components Analysis (PCA) with varimax rotation was performed in order to explore the construct of the instrument (ordinal items) (see section 6.4.4).

For all statistical tests, a threshold of 0.05 was used for statistical significance unless otherwise specified, and all hypotheses were two-tailed. No adjustment on threshold p-values for multiplicity was performed as the analyses were exploratory in nature. Therefore, the p-values were presented as an indication of trend.

6.3.8 Statistical Analysis Plan

Study Populations

In order to analyse the psychometric properties of the CLBP Treatment Satisfaction Questionnaire, three population groups were defined. The ‘validation’ population included patients with exploitable satisfaction questionnaires at week 1 - baseline. All cross sectional analyses were performed on the ‘validation’ population. The ‘test-retest’ population included patients with both baseline and week 2 CLBP Treatment Satisfaction Questionnaires. Test-retest analyses were performed on this population. The ‘responsiveness’ population included patients with both baseline and week 6 CLBP Treatment Satisfaction Questionnaires. Responsiveness to change over time was performed on this population.

Summary Report

The response rate was reported and the following were described for the overall sample:

- Number of CLBP Treatment Satisfaction questionnaires, the Adherence Questionnaire, the Problems with Therapy questionnaire, The McGill Pain Questionnaire; and the Roland and Morris Functional Disability Questionnaire, for each time point (baseline, week 2, and week 6)
- Number of patients selected when analysing the construct of the scale (‘validation’ population)
- Number of patients selected for the test-retest analyses
- Number of patients selected for the responsiveness analyses

Description of Responses to CLBP Treatment Satisfaction Questionnaire

A description of patients’ responses on each of the items of the CLBP Treatment Satisfaction Questionnaire was performed for the total sample at baseline.

Item Recoding

Not applicable responses were relevant to items on relationships and problems with side effects. For the relationship items, participants were asked ‘during the last 7 days, to what extent has your back pain interfered with your relationships?’ This section comprised seven items such as ‘I did not want anyone near me’, with the following response options and raw scores:

1 = all of the time

2 = most of the time

3 = some of the time

4 = a little of the time

5 = none of the time

6 = not applicable

The PCA ultimately is based on the correlation between items and requires that items be coded on a continuous scale. ‘Not applicable’ options are not suitable as part of a continuous scale. Further, the PCA can be performed on complete cases, i.e. only for those participants who answered all of the items. Therefore, in order to retain sufficient sample size for the purpose of the PCA, those answering ‘not applicable’ were re-assigned to the ‘none of the time’ category. The rationale being that relationship items would not be relevant to those who answered ‘not applicable’, presumably because they did not have a partner or were not sexually active etc. Consequently, a raw score of 6 for ‘not applicable’ was re-assigned a score of 5 representing ‘none of the time’.

Similarly, for the problems with side effects items, participants were asked ‘Because of your back pain medication, in the last 7 days how much of a problem were the following’. This section comprised 7 items such as ‘loss of appetite’, or ‘weight gain’ with the following response options and raw scores:

1 = not a problem

2= a little bit of a problem

3 = a problem

4 = a big problem

5 = a severe problem

6 = not applicable

For the same reasons as those outlined above, those answering ‘not applicable’ were re-assigned to the ‘not a problem’ category. The rationale for this being, those who answered ‘not applicable’ either did not experience the side effect or did not notice it sufficient to report it was a problem to them and therefore there is no impact to patients. In this case, a raw score of 6 was reassigned a score of 1.

It should be emphasised that only ‘not applicable’ responses related to relationships and problems with side effects items were re-assigned another code because there was a clear rationale to do so (as outlined above), and this method is sometimes referred to as ‘smart imputation’. For the remaining items, no such imputation was performed because there was no clear rationale to do so.

For the purpose of calculating domain scores, items that were negatively worded were rescored in a positive direction in order to match the other items in a scale, and to ensure that all items provided consistent information (i.e. a higher score indicating a higher level of satisfaction or related concept). The reverse scored items were 3c, 4.1e, 4.2d, 4.3a, 5.1f, 6.2a – 6.2c, 7a – 7j, and 8a – 8e. Items that represented non-scaled values (for example, missing or not applicable) were not included in the reverse scoring or the computation of subscale scores.

Exploratory Analysis of the Construct Validity of the CLBP Treatment Satisfaction Questionnaire and Item Reduction

The construct validity of a questionnaire refers to the underlying theoretical concepts that correspond to a set of related items (variables) (Kline, 2000). There are various analytical methods that can be used to assess the construct validity of a questionnaire, the most common of which is broadly referred to as factor analysis (FA) (Tabachnick & Fidell, 2001). Although FA and PCA often produce similar results (Pallant, 2001), in this study PCA was used as a type of exploratory factor analysis using orthogonal (varimax) rotation to make sense of the complex factors associated with satisfaction, and to observe relationships between the items of the instrument. The rationale for this analytic method included that the ultimate aim was to obtain an empirical summary of the dataset rather than a theoretical solution that is not confounded by unique and error variability (Tabachnick & Fidell, 2001). Also, PCA is often the preferred method and is documented as ‘psychometrically sound’. It is a simpler mathematical solution than FA, and often limits potential problems related to ambiguous factors (Stevens, 1996; Abbott et al., 2005).

For PCA, there are two issues to consider when determining whether a dataset is suitable. The first relates to sample size. As there is no formal method to estimate sample size, in order to conduct an exploratory factor analysis, the generally accepted rule of 3 to 10 participants for every item was employed (see for example, Tabachnick & Fidell, 2001; Mundform et al., 2005) (see section 6.3.3). The other main issue relates to the strength of the correlations between the items (variables). If there are few correlations above 0.3, then factor analysis may not be suitable. In addition, Bartlett’s test of sphericity (Bartlett, 1954) and Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy (Kaiser, 1970; Kaiser, 1974) are tests to help assess the factorability of the data (Pallant, 2001). Both were used in this study; the Bartlett’s test should be significant ($p<0.05$), and the KMO (which ranges from 0 to 1) should be at least 0.6 for good factor analysis (Tabachnick & Fidell, 2001).

Also, as mentioned earlier, there are a number of factor extraction techniques (methods used to establish a small number of factors to represent related variables) including PCA, principal factors, image factoring, maximum likelihood factoring, alpha factoring, unweighted least squares, and generalized least squares. PCA is the most common of these (Pallant, 2001). An exploratory approach is recommended whereby the number of factors extracted that best describes the underlying relationships among variables is determined by the researcher, and involves compromising in terms of finding as few factors as possible as well as explaining as much of the variance as possible (Tabachnick & Fidell, 2001). Kaiser's criterion (also known as the eigenvalue rule) and observation of Catell's scree test (Cattell, 1966) were used to facilitate decision making regarding the number of factors to retain.

Following factor extraction, factors are 'rotated' to aid interpretation either via 'orthogonal' (uncorrelated) or 'oblique' (correlated) rotation. Often both provide similar factor solutions when correlations between the variables are clearly defined; however, it has been reported that orthogonal rotation provides outputs that are easier to interpret but assumes that the factors are independent and unrelated (Tabachnick & Fidell, 2001). Also, it should be noted that there are various types of orthogonal and oblique rotation. The most commonly used orthogonal technique is varimax (reduces the number of variables with high loadings on each factor) and the most used oblique technique is direct oblimin. In this study, varimax rotation was used as it is the most common approach. Further, item reduction was performed according to poor item-factor loadings (correlation).

Psychometric Testing of the CLBP Treatment Satisfaction Questionnaire

The following analyses were performed for the validation sample: internal consistency, concurrent validity, and discriminant validity. In addition, test-retest reliability was performed on the test-retest sample (all those who completed the CLBP Treatment Satisfaction Questionnaire at baseline and week 2), and responsiveness to change over time was performed on the responsiveness sample. Analyses are detailed below.

1) *Internal Consistency*

Internal consistency reliability refers to the degree to which a group of items (for example, in a factor) are measuring the same underlying concept (Hays & Hayashi, 1990). There are various statistical methods that can be used to calculate the internal consistency of a scale; the most common is the Cronbach's alpha coefficient (Cronbach, 1951), which was used in this study. Cronbach's alpha scores provide an average correlation amongst the items within a scale. Scores range from 0 to 1 and the alpha should be at least 0.7 to be acceptable (British Psychological Society Steering Committee on Test Standards, 1995). It should be noted that Cronbach's alpha scores are sensitive to the number of items in a scale, with fewer items associated with lower Cronbach's alpha scores (Kline, 2000). Therefore, in scales with a small number of items, a slightly lower criterion of acceptability of about 0.6 can be adopted (Kline, 2000).

2) *Concurrent Validity*

Concurrent validity is defined as the extent to which a questionnaire concurs with other measures that quantify the same concept (Kline, 2000). To explore concurrent validity, correlations are often calculated between the scales which measure the same concepts, often with scores of ≥ 0.40 considered acceptable (see for example, Rofail et al., 2008).

In this study, concurrent validity was assessed by examining correlations between the relevant domains of the SF-36 that measure health concepts, as well as relevant domains of the PETS that are similar to the domains of the CLBP Treatment Satisfaction Questionnaire. Since HRQoL may be associated with Satisfaction (see for example, Innocenti et al., 2005), it is expected that there will be correlations between all of the SF-36 domains with all of the domains of the CLBP Treatment Satisfaction Questionnaire. But in particular, moderate correlations are expected between the SF-36 and the Burden of Back Pain domain. In addition, moderate correlations are expected between the Symptoms too severe or aggravated by therapy domain of the PETS and the Problems with Side Effects domain of the CLBP Treatment Satisfaction Questionnaire, as well as between the Problems due to uncertainty or doubts about the therapy and practical problems domains of the PETS with the Adherence to Physiotherapy domain of the CLBP Treatment Satisfaction Questionnaire. Further moderate correlations are also expected between the PETS domains and both the Information about Back Pain and Treatment domain as well as the Satisfaction with the Treatment Process domain of the CLBP Treatment Satisfaction Questionnaire. When interpreting results, correlations were considered negligible if <0.20, small if ≥ 0.20 and <0.40, moderate if ≥ 0.40 and < 0.70, and large if ≥ 0.70.

3) *Discriminant Validity*

Discriminant validity refers to the ability of a questionnaire to discriminate between groups known to differ, for example, in their clinical severity or some other parameter. There are various statistical methods that can be used to demonstrate discriminant validity including correlating the questionnaire scores with clinical parameters, or describing mean scores according to such parameters and using statistical tests to test for differences between groups.

In this study, discriminant validity was assessed by exploring the mean domain scores of the CLBP Treatment Satisfaction Questionnaire according to how patients rated their health (e.g. excellent, very good, etc.), how much pain they had right now, and how much pain patients had had in the last 7 days (See sections 6.3.4 and 6.3.5).

4) *Test-Retest Reliability*

Test-retest reliability refers to the extent to which the two administrations of the same questionnaire to the same group of participants provide consistent results (Guyatt, Deyo, & Charlson, 1989). It is often assessed in stable patients, usually defined as those who report ‘no change’ in their condition based on a response to clinicians’ assessments or the patient global impression (PGI) of improvement on a six or seven-point ordinal scale at the second assessment (see for example, Deyo, Diehr, & Patrick, 1991).

To explore test-retest reliability, a visual description of a correlation can be developed as a scatter plot where scores for two variables from the same participants are plotted with one variable on the X-axis and the other variable on the Y-axis. In addition, the Pearson’s correlation coefficient is usually used for continuous measures in test-retest reliability and captures the degree of linearity between two variables (i.e. the perfect relationship between two variables) (Schuck, 2004). However, some researchers have critiqued the Pearson’s correlation for not providing an accurate measure of reliability because it does not detect systematic error. That is, it does not measure “identity of measurement pairs” (Schuck, 2004). This is one of the common reasons why the Intraclass Correlation Coefficient (ICC) is often used as an alternative assessment of reproducibility (Deyo et al., 1991). It should be noted that there is much discussion in the literature regarding computing and interpreting ICC (for details see for example, Schuck, 2004; Deyo et al., 1991; Shrout & Fleiss, 1979).

Scores range from -1 to +1 with higher scores (for Pearson’s r and ICC) indicating greater agreement between the two assessments and therefore greater reliability. As a general rule of thumb, correlation coefficients surpassing the criterion of 0.70 indicate a high level of consistency between the scores at the two time points. The correlations can also be squared to provide a percentage of agreement between the two scores (Kline, 2000). Further, if the correlation reliably differs from zero, the r-value will be statistically significant (i.e., does not result from a chance occurrence). Such findings imply that if the same variables were measured on another set of similar subjects, a similar correlation would result (Kline, 2000).

In this study, test-retest reliability was explored by performing scatter plots, Pearson's correlation coefficients and ICC. For ICC, two-way mixed effects models were performed where people effects were random and measures effects fixed, with single measures of absolute agreement because systematic differences among levels of ratings were considered relevant.

5) *Responsiveness to Change over Time*

Responsiveness refers to how sensitive the questionnaire is over time (Kline, 2000) and is the ability of a measure to reflect underlying change (Guyatt et al., 1989). It is often assessed in patients who have improved or worsened, as defined by clinician assessments of improvement or the PGI (see test-retest reliability above). For responsiveness, mean domain questionnaire scores are usually considered according to patients in the 'improved' group or the 'worsened' group, and then differences between groups are compared to zero using appropriate statistical tests (e.g. ANOVAs) (see for example, Rofail et al., 2008). ES is often calculated to determine the magnitude of the differences and categorised as small (0.2), moderate (0.5), or large (0.8) (Cohen, 1977).

In this study, responsiveness of the CLBP Treatment Satisfaction Questionnaire was assessed using the responsiveness sample. Specifically, the change scores between baseline and week 6 were calculated for three subgroups of patients (worsened, stable, and improved as defined by the PGI of health) but only improved and worsened patients were used for responsiveness analysis.

6) *Exploring Factors Associated with the CLBP Treatment Satisfaction Questionnaire*

Since this study collected data on a number of different variables, this provided an opportunity to further explore how well demographic, treatment, and pain variables predict the various components of treatment satisfaction in CLBP, how much variance can be explained by the predictors, and to establish which variables are the best predictors. Therefore, Standard Multiple Linear Regressions were used whereby the domains of the CLBP Treatment Satisfaction Questionnaire were the dependent variables and the following independent variables were entered into each model: gender, age, ethnicity, academic qualifications, whether patients had time off work in the last four weeks, whether patients were taking opioid analgesics, whether patients were taking non-opioid analgesics, whether patients experience side effects, pain severity in the last seven days, and the McGill Total Score.

6.4 Results

6.4.1 Response Rate and Summary Report

Of the 485 questionnaires distributed, 249 questionnaires were returned (124 from individuals from the Back Show, 59 from physiotherapists in hospitals, 51 from pain clinics, 7 from charities, and 8 unknown). This is a 51.3% response rate.

The number of documents received at baseline, week 2, and week 6 are presented in Table 12. Among the 249 patients included in the study, all patients returned the CLBP Treatment Satisfaction Questionnaire, and of those one was not evaluable. Therefore, 248 patients were included in the 'validation' population. The 'test-retest' population had 35 patients, and the 'responsiveness' population contained 31 patients.

Figure 10: Flow Diagram of Participants Included in the Study at Baseline and Follow-up

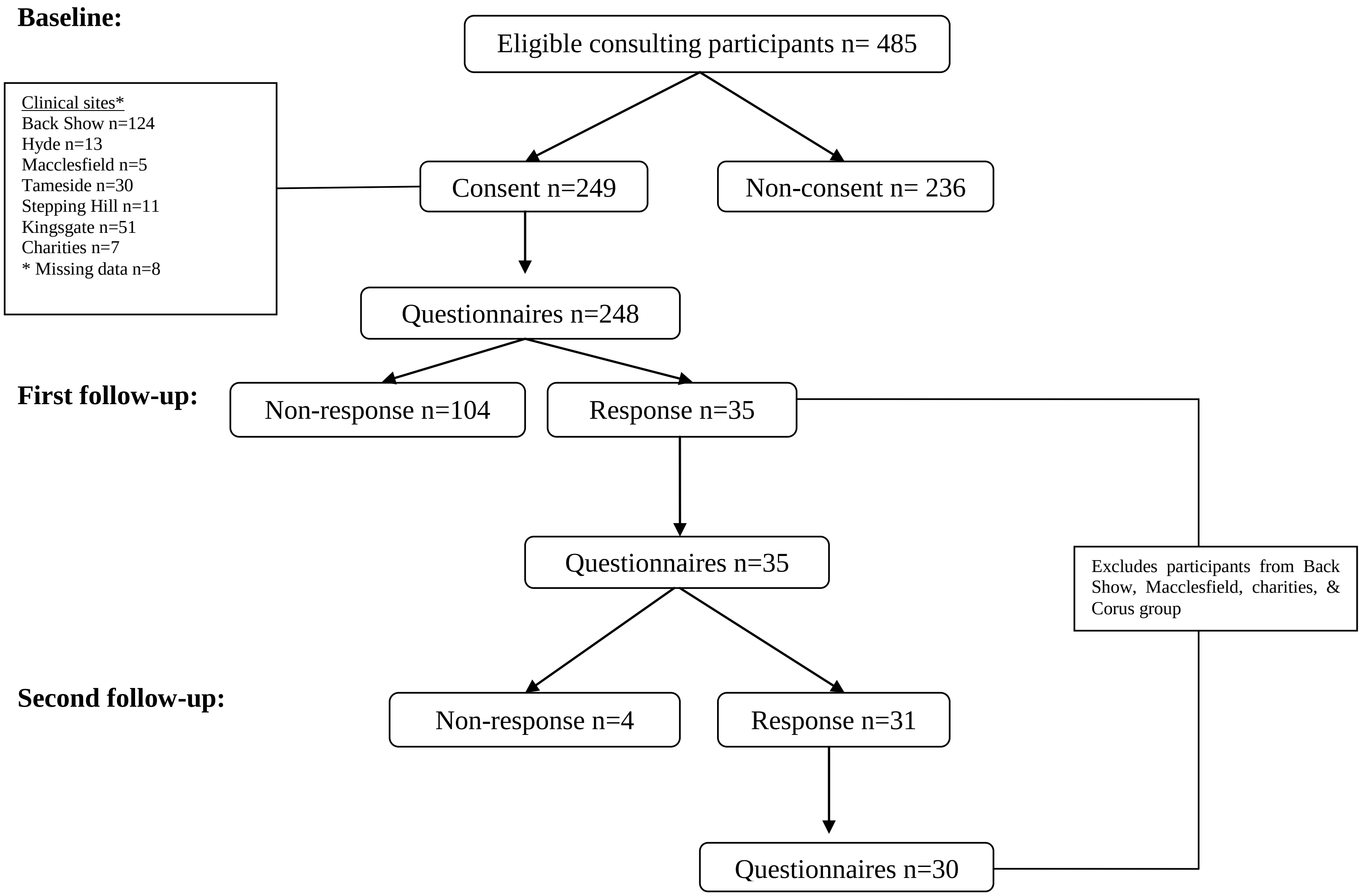


Table 12: Number of Documents Received at Baseline, Week 2, and Week 6

	Baseline						Week 2						Week 6					
	Physio	**Pain Clinics**	**Charities**	**Back Show**	**NC**	**Total**	**Physio**	**Pain Clinics**	**Charities**	**Back Show**	**NC**	**Total**	**Physio**	**Pain Clinics**	**Charities**	**Back Show**	**NC**	**Total**
Demographic form	59	44	7	119	8	237	Not applicable						Not applicable					
CLBP Treatment Satisfaction	59	51	7	124	8	249	18	17	0	0	0	35	12	19	0	0	0	31
Adherence	54	39	7	91	6	197	15	15	0	0	0	30	8	17	0	0	0	25
SF-36	55	28	7	101	7	198	18	17	0	0	0	35	12	17	0	0	0	29
PETS	26	9	6	51	4	96	17	16	0	0	0	33	12	17	0	0	0	29
McGill PAIN	51	23	7	98	6	185	17	16	0	0	0	33	12	17	0	0	0	29
RMDQ	52	25	7	98	5	187	18	16	0	0	0	34	12	17	0	0	0	29

NC - Not classified

6.4.2 Description of Sample at Baseline

Socio-demographic Characteristics

Socio-demographic characteristics are presented in Table 13 by subgroups for the overall sample, and compared to data obtained from the Office of Population Censuses and Survey (OPCS) regarding the prevalence of back pain in Great Britain (The Department of Health Statistics Division, 1999). The overall sample included a greater proportion of women to men (73.0% and 27.0%, respectively). The mean age of the overall sample was 47.9 years (21-77 years). Two hundred and eight (88.5%) participants were Caucasian or white. With regard to academic qualifications, 108 (49.3%) completed 'other' to indicate having for example a diploma. A further 73 (33.3%) had GCSE or O levels, and another 27 (12.3%) had A levels. Only 11 (5.0%) reported having no qualifications. One hundred and seven (45.1%) were working full-time, 61 (25.7%) were working part-time, and 64 (27.0%) were unemployed. Five participants (2.1%) were economically inactive (e.g., retired or student). Of the overall sample, 168 (70.9%) participants aged 16 to 64 years were employed in the 4 weeks prior to the first assessment. In this age group, 70 (41.9%) had taken time off work during that period due to back pain. Further, 69 (29.1%) participants aged 16 – 64 years who were not in employment in the preceding four weeks were asked why they were not employed. Seventy-three (37.3%) reported back pain as a reason; 11 (5.6%) reported other health problems; 104 (53.3%) stated other problems not related to their health; and 7 (3.6%) didn't want a job. The mean duration of time off work was 5.02 days (SD=9.52) and range from no days to 31 days.

The mean duration since being diagnosed with CLBP was 138.3 months (SD=154.3 months) and ranged from 3 to 552 months. This translates into a mean duration of 11.5 years (SD=12.9 years) ranging from 3 months to 46 years.

Although there were similarities observed in socio-demographic characteristics between subgroups (e.g. participants recruited from physiotherapy departments compared to those from pain clinics or charities) there were also differences. For example, the age of participants appeared to be higher in the charities and pain clinics than the physiotherapy and Back Show groups. Specifically, there were 5 out of 7 patients (71.4%) in the 55-64 age group for charities, 24 patients in the 45-54 age group (54.6%) from the pain clinic group, and 22 (37.9%) and 44 (38.9%) patients in the 25-44 age group from the physiotherapy and Back Show groups respectively. Also, whilst the majority of patients were Caucasian or white in all groups, there was a slightly higher proportion of patients from the Back Show who were non-white; twenty-one (17%) compared to 3 in the physiotherapy group (5.1%), 2 from the pain clinic group (4.8%), and none from the charities. Similarly, whilst the majority of patient's highest qualifications were GCSE or O-levels in the physiotherapy and Pain Clinic groups (41.5% and 53.8%, respectively), the majority of patients from the Back Show had 'other' qualifications (63.7%) and those from the charity group had a range of qualifications (e.g. 33.3% had GCSE/O-levels, another 33.3% had A Levels, and another 33.3% had other qualifications). With regard to work status, the majority of patients from the physiotherapy, Pain Clinic and Back Show groups were in full-time employment (39.0%, 50.0%, and 47.9%, respectively) compared to those in the charity group, where the majority were unemployed (85.7%). Comparisons between subgroups according to categorical socio-demographic characteristics reached statistical significance ($p<0.05$ level) using Chi^2 and Fisher's Exact Tests.

Further, the total sample was broadly comparable to the national average provided by the OPCS (The Department of Health Statistics Division, 1999). However, notable differences between the data sets were apparent in gender (more women than men in this study compared to OPCS study), age (more patients in the 16-24 age group in the OPCS study compared to this study), and reasons why patients were not employed (more patients in this study reported back problems or other problems getting a job as reasons for not being employed compared to the OPCS study) (Table 13).

Table 13: Socio-demographic Characteristics of Patients who completed the Satisfaction Questionnaire in Comparison with Data Presented from the OPCS (1998) Regarding the Prevalence of Back Pain in Great Britain

	Recruitment Sites[*] for This Study										**OPCS Study[**]**
	Physiotherapy		**Pain Clinics**		**Charities**		**Back Show**		**Total**		Completed questionnaires (n=5,549)
	Completed questionnaires (n=59)		Completed questionnaires (n=51)		Completed questionnaires (n=7)		Completed questionnaires (n=124)		Completed questionnaires (n=248)		
	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Percent (%)
Gender *(MD[†]=11)*											
Chi^2 p = 0.11											
Male	14	23.7	18	40.9	0	0	31	26.1	64	27.0	40
Female	45	76.3	26	59.1	7	100	88	74.0	173	73.0	41
Age *(MD[§]=18)*											
Fisher's p not available[††]											
16-24	4	6.9	0	0	0	0	2	1.8	6	2.6	31
25-44	22	37.9	13	29.6	0	0	44	38.9	86	37.4	39
45-54	12	20.7	24	54.6	2	28.6	28	24.8	66	28.7	39
55-64	11	19.0	5	11.4	5	71.4	28	24.8	49	21.3	31
65 and over	9	15.5	2	4.5	0	0	11	9.7	23	10.0	39

	Recruitment Sites* for This Study										OPCS Study**
	Physiotherapy Completed questionnaires (n=59)		**Pain Clinics** Completed questionnaires (n=51)		**Charities** Completed questionnaires (n=7)		**Back Show** Completed questionnaires (n=124)		**Total** Completed questionnaires (n=248)		Completed questionnaires (n=5,549)
	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Percent (%)
Ethnicity *(MD§=13)*											
Fisher's p < 0.05											
White	56	94.9	40	95.2	7	100	98	82.4	208	88.5	Data not available
Non-white	3	5.1	2	4.8	0	0	21	17.7	27	11.5	
Qualifications *(MD§=29)*											
Fisher's p < 0.0005											
GCSE/ O levels	22	41.5	21	53.8	2	33.3	24	21.2	73	33.3	Data not available
A level or higher	7	13.2	4	10.3	2	33.3	14	12.4	27	12.3	
Other	18	34.0	12	30.8	2	33.3	72	63.7	108	49.3	
None	6	11.3	2	5.1	0	0	3	2.7	11	5.0	
Employment *(MD§=11)*											
Fisher's p = 0.06											
Working part time	11	18.6	13	29.5	0	0	36	30.3	61	25.7	Data not Available
Working full time	23	39.0	22	50.0	1	14.3	57	47.9	107	45.1	
Unemployed	21	35.6	8	18.1	6	85.7	26	21.8	64	27.0	
Economically inactive	4	6.8	1	2.3	0	0	0	0	5	2.1	

	Recruitment Sites[*] for This Study										OPCS Study[**]
	Physiotherapy Completed questionnaires (n=59)		**Pain Clinics** Completed questionnaires (n=51)		**Charities** Completed questionnaires (n=7)		**Back Show** Completed questionnaires (n=124)		**Total** Completed questionnaires (n=248)		Completed questionnaires (n=5,549)
	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Percent (%)
Whether patients 16-64 years who were employed had time off due to CLBP *(MD[§]=21)*											
Fisher's p < 0.005											
Employed in preceding 4 weeks	34	57.6	35	79.5	1	14.3	93	78.2	168	70.9	63
Days off due to back pain	14	41.2	15	42.9	1	100	38	41.3	70	41.9	5
No days off	20	58.8	20	57.1	0	0	54	58.7	97	58.1	60
Not employed	25	42.4	9	20.5	6	85.7	26	22.8	69	29.1	34
Reasons not employed *(MD=53)*											
Fisher's p = 0.08											
Back pain	14	35.9	16	44.4	1	33.3	37	33.9	73	37.3	13
Other health problems	4	10.3	0	0	2	66.7	5	4.6	11	5.6	24
Other problems getting a job	20	51.3	19	52.8	0	0	62	56.9	104	53.3	24
Didn't want a job	1	2.6	1	2.8	0	0	5	4.6	7	3.6	46

[*] Some cases were not classified by recruitment site; [**] Percentage of general population with back pain for at least one day in the last 12 months
[†] MD: Missing data indicated for total sample; [††] Fishers Exact Test could not be calculated due to computational resources

Short Form McGill Pain Scores

At baseline, the mean sensory score was 12.01 (SD = 7.64, n=182), the mean affective score was 3.06 (SD = 3.28, n = 185), the mean total score was 15.02 (SD = 10.04, n=182), and the mean VAS score was 58.87 (SD = 23.85, n=110). Six (3.3%) patients reported ‘no pain’, 31 (16.9%) described their present pain as ‘mild’, 90 (49.2%) as ‘discomforting’, 31 (16.9%) as ‘distressing’, 21 (11.5%) as ‘horrible, and 4 (2.2%) as ‘excruciating’. The present pain index mean score was 2.23 (SD = 1.04, n = 183).

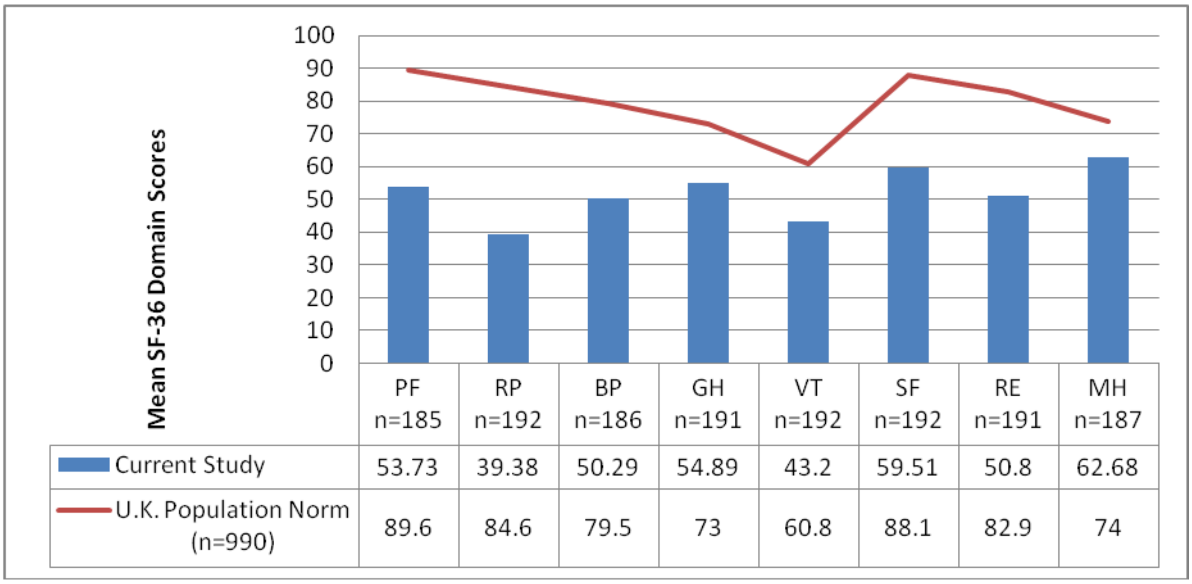
Roland and Morris Disability Questionnaire Scores

At baseline, the mean RMDQ score was 11.47 (SD = 5.92) and ranged from 0 – 23 (n=179).

SF-36 Scores

At baseline, CLBP patients had significantly lower HRQoL scores than U.K. age-matched norms particularly for Role Functioning due to Physical Limitations, and Vitality (Figure 11). Mean point differences between study scores and age-matched norms ranged from 11.32 for Mental Health to 45.30 for Role Functioning due to Physical Limitations. Since 3 to 5 point differences are considered clinically meaningful (Kosinski, Zhao, & Dedhiya, 2000; Samsa, Edelman, & Rothman, 1999), these results indicate that patients with CLBP in this study had clinically significant HRQoL impairment.

Figure 11: Study Participants’ SF-36 Domain Scores (Mean Age = 47.8 years) Compared with U.K. Age-Matched Norms



	PF n=185	RP n=192	BP n=186	GH n=191	VT n=192	SF n=192	RE n=191	MH n=187
Current Study	53.73	39.38	50.29	54.89	43.2	59.51	50.8	62.68
U.K. Population Norm (n=990)	89.6	84.6	79.5	73	60.8	88.1	82.9	74

PF=Physical Functioning; RP=Role Functioning due to Physical Limitations; BP=Bodily Pain; GH=General Health; VT=Vitality; SF=Social Functioning; RE=Role Functioning due to Emotional Limitations; MH=Mental Health.

Treatment Characteristics

Participants in this study were on a range of medications to help them with their CLBP (Table 14). The majority were taking non-opioid analgesics (n=174, 87.9%) or NSAIDs (n=123, 62.1%), followed by paracetamol (n=63, 31.8%).

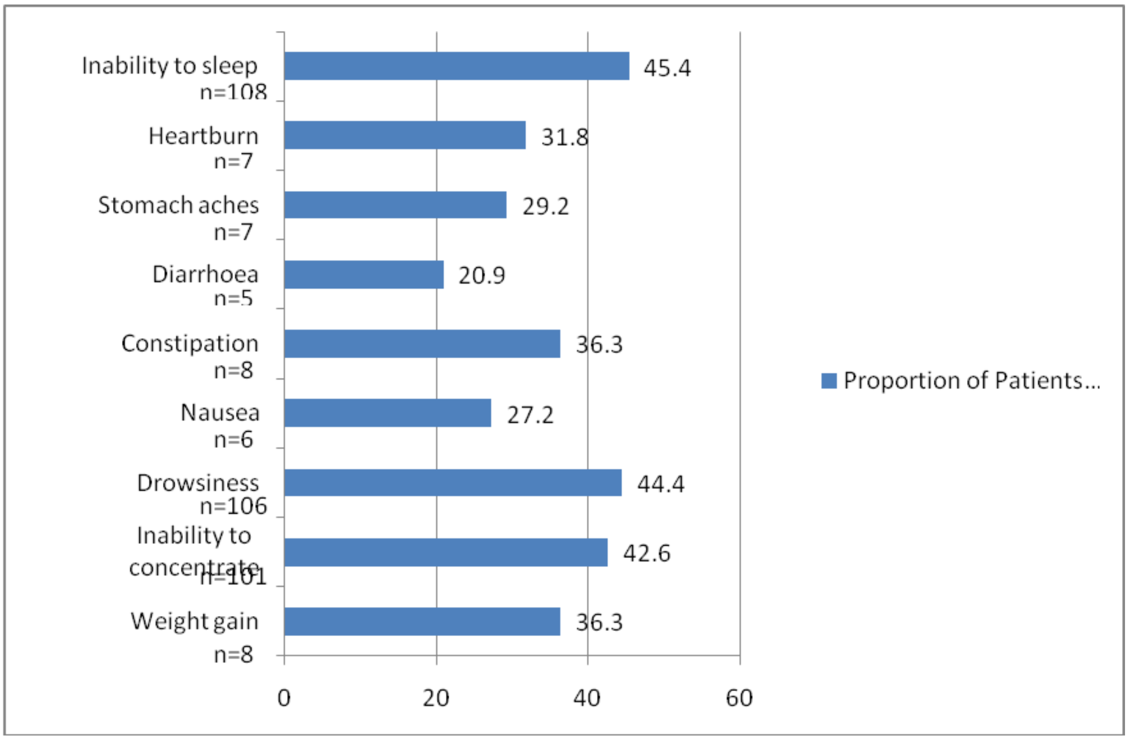
Table 14: Type of Medications Taken by Patients with CLBP Included in this Study

Type of Medication*	**Number (n)**	**Percent (%)**
Non-opioid analgesics	174	87.9
Paracetamol	63	31.8
Compound analgesics	55	27.8
NSAIDs	123	62.1
Opioid analgesics	43	21.7
Skeletal muscle relaxants	22	11.1
Benzodiazapines	10	4.0
Corticosteroids	16	8.1
Anti-epileptic	18	13.3
Antidepressants	20	10.1

*Patients with CLBP may have reported more than one medication for CLBP relief.

In addition, the majority of patients (n=156, 65%) reported that they experience side effects from their back pain medication. Figure 12 below, illustrates the prevalence of side effects amongst patients; the most common reported were ‘inability to sleep’, affecting 108 (45.4%) patients, followed by ‘drowsiness’ with 106 patients (44.4%), and then ‘inability to concentrate’, experienced by 101 patients (42.6%). The least common type of side effect experienced was ‘diarrhoea’, affecting 50 patients (20.9%). Note that many patients on CLBP medication experience more than one side effect.

Figure 12: The Prevalence of Side Effects from CLBP Medication*



*Patients with CLBP may have reported more than one side effect

Adherence to Medications

In response to the statement 'I forget to take my medicines', 8 (4.0%) stated 'always', 8 (4.0%) stated 'often', 56 (28.1%) reported 'sometimes', 51 (26.7%) answered 'rarely', and 68 (35.6%) reported 'never'. Further, although 58 (29.1%) answered 'never' to the statement 'I alter the dose of my medicines' and 29 (14.6%) reported 'rarely', 69 (34.7%) reported 'sometimes', 25 (12.6%) stated 'often', and 10 (5%) said 'always'. Also, whilst 73 (36.9%) stated 'sometimes' they stopped taking medicines for a while, 21 (10.6%) reported 'often' 8 (4.0%) stated 'always', 19 (8.6%) reported 'rarely' and a further 69 (34.8%) answered 'never'. Moreover, although the majority (n=63, 32.6%) responded 'sometimes' they decided to miss a dose, 33 (17.1%) said 'often', 7 (3.6%) reported 'always', 23 (11.9%) stated 'rarely' and 59 (30.6%) answered 'never'. In addition, in response to 'I take less than instructed', whilst 55 (27.8%) reported 'never' and a further

28 (14.1%) mentioned ‘rarely’, the majority 70 (35.4%) reported ‘sometimes’, 24 (12.1%) stated ‘often’, and 14 (7.1%) answered ‘always’.

Other Types of Monotherapies

Many participants included in this study were also taking other types of treatment to help them with their CLBP. For example, 79 (40.3%) were using physiotherapy, 40 (20.2%) were attending a pain management programme, and 17 (8.6%) were receiving osteopathy. Other types of treatment that patients were taking included acupuncture (n=10, 5.1%), massage (n=2, 1%), and TENS (n=1, 0.5%).

6.4.3 Description of Responses on the CLBP Treatment Satisfaction Items

Detailed results concerning the description of responses to the CLBP treatment satisfaction items are presented in Appendix R. Results are provided by recruitment site (physiotherapy, pain clinic, charities, and the Back Show) and for the total sample. The distribution of responses to each of the items did not seem to vary according to recruitment site.

General (Items 1a to 1c)

Many participants reported their health was ‘good’ (n=96, 40.3%). Participants rated the level of pain right now, and in the last 7 days, from 1 (no pain) to 10 (worst pain possible). The majority indicated a level of pain of between 4 and 8 (n=175, 73.6%; and n=176, 73.6%, respectively).

Information about Back Pain and Its Treatment (Items 2a to 2i)

The majority of participants reported that they would like ‘more’ or ‘a bit more’ information about their condition or injury (n=150, 61.9%), the causes of their back pain (n=151, 62.9%), back pain medications (n=142, 59%), and the potential side effects of back pain medications (n=140, 58.1%). The majority also reported they would like ‘more’ or ‘a bit more’ information about the treatment options available (apart from back pain medication) (n=164, 68.9%), goal setting (setting tasks to do) (n=140, 58.6%), posture and positioning (n=154, 64.2%), pacing (taking things gradually) (n=129, 53.5%), and exercise (n=139, 57.7%). Very few participants (between 3 and 8) reported that they would have liked to have ‘a little less’ information or ‘none’.

About Your Medical Care (Items 3a to 3c)

Although many of participants reported that they ‘disagree’ or ‘strongly disagree’ with the statement ‘my doctors did not know what was wrong with me (n=91, 38%), one third reported that they ‘agree’ or ‘strongly agree’ (n=83, 34.8%). Similarly, whilst the majority stated they ‘disagree’ or strongly disagree’ with the statement ‘I was misdiagnosed’ (n=121, 50.9%), nearly a quarter agreed or strongly agreed (n=55, 23.1%). Further, over half responded ‘disagree’ or ‘strongly disagree’ to the statement, ‘I was involved in treatment decisions’. Details are provided in Table 32 in Appendix R.

Impact of Back Pain on Regular Activities (Items 4.1a-4.1e)

The majority of participants responded ‘most of the time’ or ‘some of the time’ to the statements ‘I spent less time on tasks than I would have liked to’ (n=145, 60.7%), and ‘I was limited in the type of tasks that I could do’ (n=135, 56.7%). Similarly, many responded ‘some of the time’ or ‘most of the time’ to the item ‘I stopped doing everyday tasks’ (n=107, 45.5%), although a third reported ‘none of the time’ (n=73, 31.1%). Whilst a small proportion of participants answered ‘all of the time’ to the item ‘I was unable to work’ (n=31, 13.5%), and many answered ‘most of the time’, ‘some of the time’ or ‘a bit of the time’ (n=89, 38.9%), the majority stated ‘none of the time’ (n=109, 47.6%). Further, although nearly one fifth of participants answered ‘none of the time’ to ‘I went out of the home' (n=41, 17.4%), many reported 'a little of the time' or 'some of the time' (n=103, 43.8%). Details are provided in Table 33 in Appendix R).

Impact of Back Pain on Physical Functioning (Items 4.2a-4.2e)

Whilst the majority of participants responded 'none of the time' to 'I was unable to walk' (n=116, 50.7%), 'I had poor balance' (n=98, 41.2%), and 'I leaned on one side' (n=82, 35.0%), there were many who reported that at least 'a little of the time' back pain interfered with walking ability, balance, and posture. Back pain also interfered with participants' ability to bend down, with a few responding 'none of the time' to 'I could bend down' (n=26, 11%), and over a quarter answering 'all of the time' or 'most of the time' to 'It was difficult to keep standing' (n=66, 27.5%). Details are provided in Table 34 in Appendix R.

Impact of Back Pain on Confidence (Items 4.3a-4.3f)

Whilst a few participants responded 'none of the time' to 'I planned before I did things' (n=47, 19.7%) and 'I was cautious in everything I did' (n=32, 13.6%), the majority responded at least 'a little of the time'. Similarly, whilst many answered 'none of the time' to 'I had low beliefs in my abilities' (n=85, 35.9%), 'I was scared to do too much' (n=58, 24.4%), and 'I had low self esteem (n=97, 40.8%), the majority answered at least 'a little of the time'. Moreover, in response to 'I felt uncertain of the future', although a third reported 'none of the time', approximately a third said 'most of the time' or 'all of the time' (n=69, 28.7%), and the remaining reported 'a little of the time' or 'some of the time' (n=91, 37.9%). Details are provided in Table 35 in Appendix R.

Impact of Back Pain on Appearance (Items 4.4a to 4.4e)

The majority of participants reported 'none of the time' to 'I was unable to brush/comb my hair (n=179, 75.8%), 'I had difficulty getting dressed (n=115, 48.1%), 'I slouched' (n=70, 29.2%), 'I was not interested in my appearance' (n=134, 56.3%), and 'I was embarrassed about my image' (n=132, 56.2%). However, the remaining reported at least 'a little of the time'. Details are provided in Table 36 in Appendix R.

Impact of Back Pain on Mood (Items 4.5a to 4.5h)

The majority of participants answered 'some of the time' to 'I was irritable' (n=79, 33.3%), 'I was frustrated' (n=74, 31.1%), 'I was tired' (n=77, 32.2%), and 'I did not want to do anything' (n=65, 27.2%). Further, whilst the majority answered 'none of the time' to 'I was sad' (n=78, 33.5%), 'I was worried' (n=74, 34%), 'I could not cope with the pain' (n=84, 35.1%), and 'I felt life was not worth living' (n=164, 69.2%), the remaining responded at least 'a little of the time'. Details are provided in Table 37 in Appendix R.

Impact of Back Pain on Relationships (Items 5.1a to 5.1g)

Overall, the majority of participants answered 'some of the time' or 'most of the time' in response to 'I did not want to burden others with my problems' (n=101, 50.3%). Although, many responded 'none of the time' to 'I did not want anyone near me' (n=72, 39.6%), 'I could not relax with my partner' (n=61, 35.5%), and 'People thought I was faking my back pain' (n=100, 52.4%), the remaining reported at least 'a little of the time'. Further, whilst the majority responded 'all of the time' or 'most of the time' to 'I was sexually active' (n=92, 59.0%), a smaller proportion reported 'some of the time' (n=49, 31.4%), and nearly 10% answered 'a little of the time' or 'none of the time' (n=15, 9.6%). In addition, although the majorityanswered 'none of the time' to 'sex was very uncomfortable' (n=47, 34.6%), one fifth stated 'most of the time' or 'all of the time' (n=30, 22%), and the remaining stated 'some of the time' or 'most of the time' (n=59, 43.4%). Details are provided in Table 38 in Appendix R.

Impact of Back Pain on Sleep (Items 5.2a to 5.2c)

The majority of participants indicated that back pain had interfered with their sleep, with most reporting ‘some of the time’ or ‘most of the time’ to ‘I tossed and turned in my sleep’ (n=135, 56.5%), and ‘I woke up in the night’ (n=124, 51.9%). Further, in response to ‘I had an ache in my back when I woke’, many answered ‘all of the time’ (n=95, 39.7%), and the majority reported ‘some of the time’ or ‘most of the time’ (n=105, 44%). Details are provided in Table 39 in Appendix R.

Beliefs about Back Pain Medications (Items 6.1a to 6.1e)

Although a large number of participants responded ‘disagree’ or ‘strongly disagree’ to ‘my back pain medication is helpful to me (n=125, 54.8%), the majority agreed or strongly agreed in response to ‘my back pain medication prevents future problems’ (n=113, 49.6%). However, the majority also answered ‘disagree’ or ‘strongly disagree’ to ‘my back pain medication helps me to be independent’ (n=95, 42%). Further, only a small proportion of patients answered ‘agree’ to ‘by taking back pain medication, I felt out of control’ (n=32, 13.9%); one fifth were ‘not sure’ (n=50, 21.7%), and the remaining answered ‘disagree’ or ‘strongly disagree’ (n=136, 59.1%). In addition, the majority agreed that they altered the amount of back pain medication they took (n=89, 39.6%). Details are provided in Table 40 in Appendix R.

Adherence to Physiotherapy (Items 6.2a to 6.2c)

The majority of participants reported ‘disagree’ in response to ‘I set realistic goals’ n=121, 51.5%), ‘I remembered to do my exercises’ (n=100, 42.9%), and ‘I paced my activities’ (n=138, 58.7%). Details are provided in Table 41 in Appendix R.

Problems with Side Effects (Items 7a to 7j)

Of those who reported experiencing side effects, the majority stated they were 'a big problem' or 'a severe problem' for 'loss of appetite' (n=57, 82.6%), 'weight gain' (n=38, 43.6%), 'inability to concentrate' (n=53, 75.5%), 'drowsiness' (n=62, 59.6%), 'nausea' (n=43, 63.2%), 'constipation' (n=53, 59.6%), 'diarrhoea' (n=35, 68.6%), 'stomach aches' (n=40, 58.8%), 'heartburn' (n=50, 63.3%), and 'inability to sleep' (n=42, 38.5%). Details are provided in Table 42 in Appendix R.

Satisfaction with Treatment for Back Pain (Items 8a to 8e)

Most participants reported being 'dissatisfied' or 'very dissatisfied' for the following items: 'the communication between my doctor and I regarding my back pain medication' (n=117, 50.9%), 'the information provided about the possible side effects from my back pain medication' (n=84, 37%), 'the form of administration (e.g. tablet, injection, patch) of my back pain medication' (n=119, 54.1%), 'the amount of medication prescribed' (n=114, 51.1%), and 'the way doctors have dealt with the side effects of my back pain medication' (n=77, 34.8%). Details are provided in Table 43 in Appendix R.

Oral Medication Characteristics (Items 9.Aa to 9.Ac)

Whilst the majority of participants disagreed or strongly disagreed in response to 'my oral medication is difficult to swallow' (n=151, 70.9%), and 'my oral medication leaves an unpleasant taste in my mouth' (n=137, 65.6%), the majority reported 'agree' or 'strongly agree' to 'my oral medication doesn't work quickly' (n=66, 32.2%).

6.4.4 Construct Validity of the CLBP Treatment Satisfaction Instrument

The suitability of data was assessed before performing a PCA. After recoding 'not applicable' scores for items related to relationships and problems with side effects (see section 6.3.8), and deleting cases of missing data (n=39), a PCA was performed on the resulting sample (n=209). A review of the correlation matrix indicated the presence of many coefficients of 0.3 and above. The KMO value was 0.76, exceeding the recommended value of 0.60 (Kaiser, 1970; Kaiser, 1974). Also, the Bartlett's Test of Sphericity (Bartlett, 1954) reached statistical significance (p <0.0001). Consequently, the data were considered appropriate for PCA analysis.

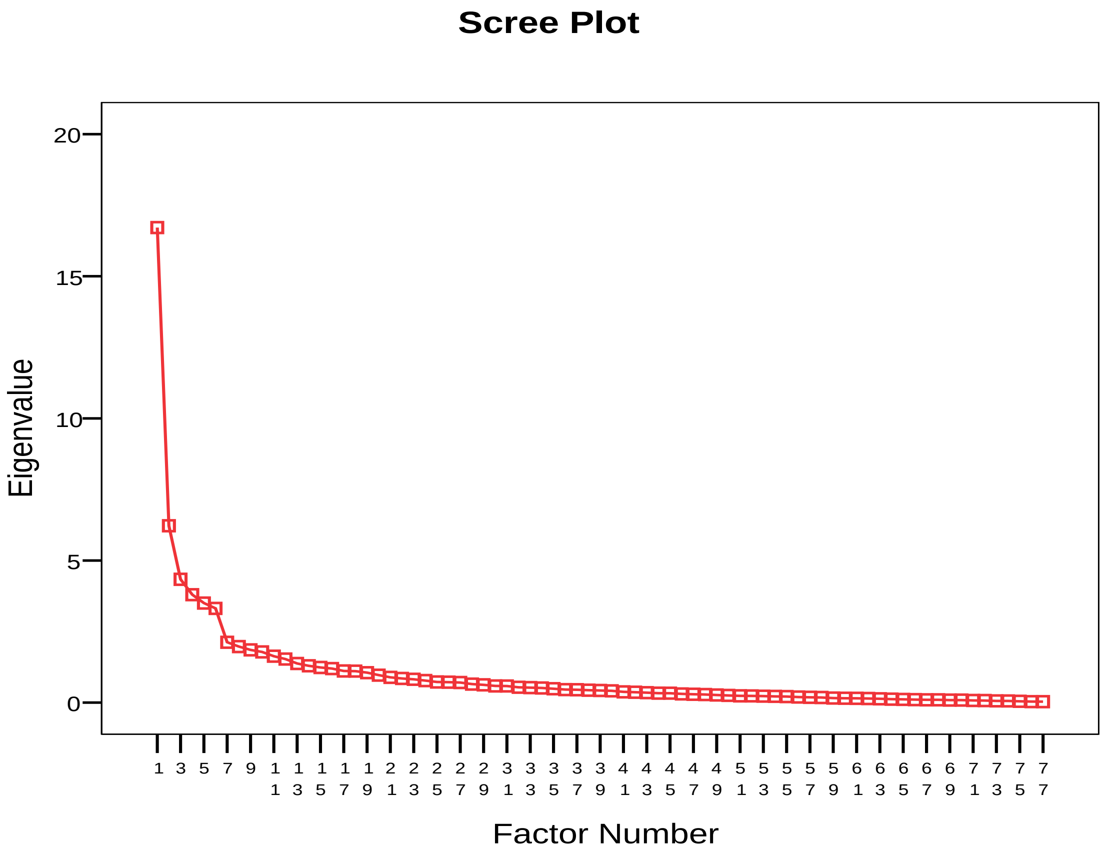
This was conducted on the collected data and 19 principal axis factors were initially extracted with eigenvalues greater than one. Table 15 shows the eigenvalues, percentage of variance, and cumulative variance for the 19 factors. Closer observation of Table 15 showed a major difference in the size of the eigenvalue after the seventh factor suggesting that only seven factors should be orthogonally rotated. These explain 52.0% of the systematic covariance between the 77 items. Although this leaves 48.0% of the variance remaining, Cattell's Scree Test (Cattell, 1966), as shown in Figure 13, confirms that seven factors are powerful enough to explain any of the covariance among the 77 items that form the questionnaire.

Table 15: Initial Statistics for a Principle Components Analysis of the 77-item Satisfaction Questionnaire: Eigenvalue, Variances and Cumulative Variance for the first 19 factors

Factor	**Eigenvalue**	**Pct of. Var.**	**Cum. Pct.**
1	16.71	21.71	21.71
2	6.22	8.08	29.79
3	4.34	5.63	35.42
4	3.80	4.93	40.35
5	3.50	4.55	44.90
6	3.31	4.30	49.20
7	2.12	2.76	51.96
8	1.97	2.56	54.52
9	1.86	2.41	56.92
10	1.78	2.32	59.24
11	1.63	2.12	61.36
12	1.53	1.99	63.35
13	1.38	1.79	65.14
14	1.30	1.68	66.82
15	1.24	1.61	68.43

Factor	Eigenvalue	Pct of. Var.	Cum. Pct.
16	1.20	1.55	69.98
17	1.11	1.45	71.43
18	1.11	1.44	72.87
19	1.05	1.37	74.24

Figure 13: Factor Scree Plot of Eigenvalue for the 77-item Satisfaction Questionnaire



The seven-factor solution was further investigated to determine the actual item loadings for each factor. A Varimax-Rotation Principle Components Analysis with 25 iterations was carried out as the factors were considered independent (unrelated). The findings of this analysis are presented in Table 16 with the factor loadings matrix for the seven factors. Varimax rotation was chosen because it selects the factors that do not correlate strongly (orthogonal rotation). The internal correlation of the seven factors was .60. However, eight item of the 77 item questionnaire did not load onto any of the factors.

These were ‘I could bend down’, ‘I went out of my home’, ‘I was involved in treatment decisions’, ‘I was misdiagnosed’, ‘My back pain medication is helpful to me’, ‘My back pain medication enables me to be independent’, ‘I had an ache in my back when I woke’ and ‘I altered the amount of back pain medication I took’.

Table 16: A Factor Loading Matrix Using Varimax-Rotated PCA for the 77-item Questionnaire

		Factors						
Satisfaction Items		**1**	**2**	**3**	**4**	**5**	**6**	**7**
4.5a	I was sad	.82						
4.3d	I was scared to do too much	.81						
4.3c	I had low beliefs in everything I did	.80						
4.3f	I felt uncertain of the future	.79						
4.5h	I was worried	.76						
4.5c	I was frustrated	.75						
4.3e	I had low self esteem	.74						
4.5f	I could not cope with the pain	.69						
4.3b	I was cautious in everything I did	.69						
4.5b	I was irritable	.69						
4.1c	I stopped everyday tasks	.67						
4.5e	I did not want to do anything	.66						
4.3a	I planned before I did things	.66						
4.5g	I felt life was not worth living	.65						
4.4d	I was not interested in my appearance	.64						
4.1b	I was limited in the type of tasks I can do	.62						
4.4c	I had difficulty getting dressed	.61						
4.4a	I slouched	.61						
4.1a	I spent less time on tasks than I would have liked to	.61						
4.4e	I was embarrassed about my image	.60						
4.2e	It was difficult to keep standing	.60						
4.5d	I was tired	.59						
4.2b	I had poor balance	.55						
4.2c	I leaned on one side	.54						
4.4b	I was unable to brush/comb my hair	.51						
4.2a	I was unable to walk	.50						
4.1d	I was unable to work	.47						

		Factors						
Satisfaction Items		**1**	**2**	**3**	**4**	**5**	**6**	**7**
7f	Constipation		.76					
7c	Inability to concentrate		.75					
7j	Inability to sleep		.75					
7e	Nausea		.74					
7d	Drowsiness		.73					
7h	Stomach aches		.72					
7b	Weight gain		.64					
7g	Diarrhoea		.60					
7i	Heartburn		.57					
7a	Loss of appetite		.57					
5.2a	I tossed and turned in my sleep		.50					
5.2b	I woke up in the night		.46					
2f	Information about posture and positioning			.81				
2e	Information about treatment options available (apart from back pain medication)			.79				
2b	Information about the cause of my back pain			.77				
2a	Information about my condition or injury			.75				
2i	Information about exercise			.75				
2h	Information about pacing (taking things gradually)			.72				
2g	Information about goal setting (setting tasks to do)			.71				
2d	Information about the potential side effects of back pain medications			.68				
2c	Information about back pain medications			.67				
3a	My doctors did not know what was wrong with me			.53				
8b	Satisfaction with the information provided about the possible side effects from my back pain medication				.79			
8e	Satisfaction with the way doctors have dealt with the side effects of back pain medication				.76			

Satisfaction Items		1	2	3	4	5	6	7
					Factors			
8c	Satisfaction with the form of administration of back pain medication				.75			
8d	Satisfaction with the amount of medication prescribed				.72			
8a	Satisfaction with the communication between my doctor and I regarding back pain medication				.61			
5.1d	People around me did not understand my back pain					.75		
5.1e	People thought I was faking my back pain					.73		
5.1c	I could not relax with my partner					.72		
5.1g	Sex was very uncomfortable					.71		
5.1a	I did not want anyone near me					.66		
5.1f	I was sexually active					.64		
5.1b	I did not want to burden others with my problems					.58		
9Ab	My oral back pain medication leaves an unpleasant taste in my mouth						.72	
9Aa	My oral medication is difficult to swallow						.69	
6.1b	My back pain medication prevents future problems						.63	
9Ac	My oral back pain medication does not work quickly						.55	
6.1d	By taking medication, I felt out of control						.55	
6.2b	I remembered to do my exercises							.75
6.2c	I paced my activities							.74
6.2a	I set realistic goals							.72

Labelling the Extracted Factors

After a careful review of the content of the original variables, each of the seven factors was given a label to reflect the items related to that factor. By referring to the questionnaire (see Appendix J) inference was made from the relevant items to determine the nature of the seven factors for measuring treatment satisfaction. For each of the factors, examples of items are provided and the interpretations made stated.

Factor one with an eigenvalue of 16.71 accounted for 21.7% of the variance and consisted of 27 items with loadings ranging from .43 to .82. Generally, it has been accepted that the first factor usually has moderate loadings, ranging from approximately .3 to .7 (Kline, 2000). The items in this factor, such as 4.5a ‘I was sad’; 4.3b ‘I was cautious in everything I did’; 4.3a ‘I planned before I did things’; 4.4.e ‘I was embarrassed about my image’; 4.2e ‘It was difficult to keep standing’; and 4.1d ‘I was unable to work’, all reflect the burden of back pain, and are thus labelled ‘Burden of Back Pain’.

Factor two with eigenvalue of 6.22 accounted for 8.1% of the variance and consisted of 12 items with loadings ranging from .46 to .76. The items in this factor, such as 7f ‘constipation’; 7e ‘nausea’; 7h ‘stomach aches’; 7g ‘diarrhoea’; 7a ‘loss of appetite’; and 7j ‘inability to sleep’ all reflect problems encountered with side effects, and are thus labelled ‘Problems with Side Effects of Back Pain Medication’.

Factor three with an eigenvalue of 4.34 accounted for 5.6% of the variance and consisted of 10 items with loadings ranging from .53 to .81. The items in this factor, 2f ‘Information about posture and positioning’; 2e ‘Information about treatment options available (apart from back pain medication)’; 2b ‘Information about the cause of my back pain’; 2c ‘Information about back pain medication’; 2d ‘Information about the potential side effects of back pain medication’; and 3a ‘My doctors did not know what was wrong with me', all reflect information and knowledge about back pain and treatment, and are thus labelled 'Information About Back Pain and Treatment'.

The fourth factor with an eigenvalue of 3.80 accounted for 4.9% of the variance and consisted of 5 items with loadings ranging from .61 to .79. The items in this factor, 8b 'Satisfaction with the information provided about the possible side effects from back pain medication'; 8e 'Satisfaction with the way doctors have dealt with the side effects of back pain medication'; 8d 'Satisfaction with the amount of medication prescribed'; and 8a 'Satisfaction with the communication between my doctor and I regarding back pain medication' all reflect satisfaction with medical processes such as the information provided, the amount of medication prescribed, the way doctors have dealt with side effects as well as communication between the doctor and patient, and are thus labelled 'Satisfaction with the Back Pain Treatment Process'.

Factor five with an eigenvalue of 3.50 accounted for 4.6% of the variance and consisted of 7 items, with loadings ranging from .58 to .75. The items in this factor, 5.1d 'People around me did not understand my back pain'; 5.1e 'People thought I was faking my back pain'; 5.1c 'I could not relax with my partner'; 5.1a 'I did not want anyone near me'; 5.1b 'I did not want to burden others with my problems', all reflect aspects of relationships with others, and are thus labelled 'Impact of Back Pain on Relationships'.

The sixth factor with an eigenvalue of 3.31 accounted for 4.3% of the variance and consisted of 5 items with loadings ranging from .55 to .72. The items in this factor, 9Ab 'My back pain medication leaves an unpleasant taste in my mouth'; 9Aa 'My back pain medication is difficult to swallow'; 6.1b 'My back pain medication prevents future problems'; and 9Ac 'My back pain medication does not work quickly', all reflect patients' acceptability of back pain medication in terms of convenience and the ease of administration, preference in terms of the taste of medication, and how quickly the medication works, and are thus labelled ‘Back Pain Medication Acceptability’.

The seventh factor with an eigenvalue of 2.12 accounted for 2.8% of the variance. It consisted of 3 items with loadings ranging from .72 to .75. The items in this factor, 6.2b ‘I remembered to do my exercises’; 6.2c ‘I paced my activities’; and 6.2a ‘I set realistic goals’, all reflect adherence behaviours related to physiotherapy regimens, and are thus labelled ‘Adherence to Physiotherapy’.

6.4.5 Internal Consistency

To investigate the internal consistency of the re-formulated questionnaire (69 items remained after PCA), Cronbach’s alpha was calculated for each of the seven factors. The results of the final Chronbach’s alpha solutions are summarised in Table 17.

Table 17: Cronbach’s Alpha for the CLBP Treatment Satisfaction Questionnaire Domains: Internal Consistency

CLBP Treatment Satisfaction Questionnaire Domains	Number of Items	Cronbach’s alpha
Burden of Back Pain	27	0.94
Problems with Side Effects	10	0.89
Information Provided About Back Pain and Treatment	10	0.91
Satisfaction with the Treatment Process	5	0.85
Impact of Back Pain and Treatment on Relationships	7	0.84
Back Pain Medication Acceptability	3	0.75
Adherence to Physiotherapy	3	0.79

6.4.6 Tests for Normality and Outliers

The Kolmogorov-Smirnov statistic was significant for all domains, indicating that the data were non-normal. Inspection of the shape of the distribution revealed bimodal or occasional multi-modal distributions (e.g. the Burden of Back Pain) and skewness and kurtosis were observed. However, closer observation of the descriptive statistics indicated that the skewness and kurtosis values were well below the threshold of 4.0 considered generally acceptable, and therefore the data does not deviate from the mean significantly enough to warrant transformation of scores. Further, all scores fell within the expected ranges and whilst there were some outliers, attention to the 5% trimmed mean compared to the mean indicated small differences. See Appendix S for normality and outlier tests. Given the above, and because parametric tests are more powerful than non-parametric tests and are generally robust to non-normality, parametric tests were performed for the remaining analyses.

6.4.7 Concurrent Validity

Table 18 provides evidence to support the concurrent validity of the CLBP Treatment Satisfaction Questionnaire. In general, there were low to moderate correlations with both the SF-36 ($r=0.003$ to 0.76) and the PETS ($r= -0.11$ to -0.61).

As expected, the Burden of Back Pain and the Impact of Back Pain on Relationships domain of the CLBP Treatment Satisfaction Questionnaire indicated statistically significant moderate correlations with the HRQoL domains of the SF-36: $r=0.49$ to 0.66, $p<0.0001$, $r=0.42$ to 0.64, $p<0.0001$, respectively. There were also low to moderate correlations between the Problems with Side Effects domain of the CLBP Treatment Satisfaction Questionnaire and the SF-36: $r=0.30$ to 0.76, some of which reached statistical significance at the $p<0.0001$ or $p<0.05$ levels.

Further, there were low to moderate statistically significant correlations between the Adherence to Physiotherapy domain of the CLBP Treatment Satisfaction Questionnaire and all domains of the PETS: r= -0.37 to -0.51, p<0.0001. Closer examination of Table 18 also indicates similar findings between the PETS and the following domains of the CLBP Treatment Satisfaction Questionnaire: Information about Back Pain and its Treatment (r= -.38 to -0.54, p<0.0001), and the Satisfaction with Treatment Process (r= -0.30 to -0.48, p<0.0001). The Impact of Back Pain on Relationships domain of the CLBP Treatment Satisfaction Questionnaire was also statistically significantly (p<0.0001) correlated with the PETS domains (with the exception of the Practical Problems): r= 0.44 to 0.45.

Table 18: Pearson’s Correlations between the Domains of the CLBP Treatment Satisfaction Questionnaire with the SF-36 and PETS Domains: Concurrent Validity

	Burden of Back Pain	**Problems with Side Effects**	**Information about Back Pain and Treatment**	**Satisfaction with the Treatment Process**	**Impact of Back Pain on Relationships**	**Back Pain Medication Acceptability**	**Adherence to Physiotherapy**
SF-36							
Physical Functioning	**0.57**** n=162	0.36 n=29	0.09 n=174	**-0.24*** n=170	**0.42**** n=71	0.01 n=157	0.08 n=177
Role-Physical	**0.55**** n=167	0.31 n=28	**0.19*** n=181	-0.10 n=175	**0.49**** n=73	0.11 n=162	-0.11 n=183
Bodily Pain	**0.63**** n=163	0.37 n=28	0.08 n=175	-0.05 n=169	**0.52**** n=71	0.00 n=157	0.02 n=178
General Health	**0.49**** n=170	**0.76****n=29	0.04 n=180	-0.01 n=174	**0.37**** n=73	0.13 n=161	**0.17*** n=183
Vitality	**0.58**** n=168	**0.51****n=29	**0.17*** n=181	-0.01 n=175	**0.59**** n=73	**0.16*** n=164	**0.16*** n=184
Social Functioning	**0.66**** n=168	**0.58****n=29	**0.15*** n-181	0.04 n=175	**0.55**** n=73	0.09 n=162	0.04 n=184
Mental Health	**0.58**** n=168	**0.37** n=29	0.08 n=180	-0.10 n=174	**0.62**** n=73	**0.18*** n=161	0.06 n=183
Role Emotional	**0.63**** n=164	0.30 n=28	0.12 n=176	-0.01 n=170	**0.64**** n=71	0.07 n=159	0.10 n=179
PETS							
Symptoms too severe or aggravated by therapy	**-0.37****n=83	-0.48 n=14	**-0.38**** n=90	**-0.30****n=87	**-0.44**n**=41	-0.12 n=80	**-0.48**** n=93
Uncertainty about how to carry out the treatment	**-0.24*** n=80	-0.13 n=14	**-0.43**** n=86	**-0.38****n=83	**-0.44**** n=40	-0.11 n=76	**-0.37**** n=89
Doubts about treatment efficacy	-0.21 n=81	-0.47 n=14	**-0.54**** n=88	**-0.46**** n=85	**-0.45**** n=41	-0.02 n=78	**-0.41**** n=91
Practical Problems	-0.16 n=80	**-0.61***n=14	**-0.40**** n=88	**-0.48**** n=85	-0.29 n=41	-0.12 n=78	**-0.51**** n=91

*p<0.05; ** p<0.0001

6.4.8 Description of Baseline CLBP Treatment Satisfaction Domain Scores

Table 19 provides summary statistics for baseline scores of the CLBP Treatment Satisfaction Questionnaire domains.

Table 19: Summary Statistics of the CLBP Treatment Satisfaction Questionnaire

	n	**Mean**	**SD**
Burden of Back Pain	227	96.8	20.9
Problems with Side Effects	32	38.8	8.2
Information About Back Pain and Its Treatment	223	21.4	7.2
Satisfaction with Treatment Process	217	16.3	4.1
Impact of Back Pain on Relationships	99	23.8	6.1
Adherence to Physiotherapy	232	10.9	2.6
Back Pain Medication Acceptability	205	10.4	2.6

6.4.9 Discriminant Validity

Table 20 and Table 21 provide evidence to support the discriminative validity of the CLBP Treatment Satisfaction Questionnaire. One-way between-groups ANOVAs were performed to describe and compare the distribution of scores according to the following variables related to clinical severity:

- Patients' rating of health
- Level of pain in the last 7 days
- Level of pain right now

'How do you rate your health' had five response options: excellent, very good, good, fair, and poor. There were statistically significant differences at the $p<0.05$ level in CLBP Treatment Satisfaction Scores for the following domains: Burden of Back Pain [$F(4, 198)=10.60$, $p<0.0001$]; Problems with Side Effects [$F(3, 28)=8.49$, $p<0.0001$]; and

Impact of Back Pain on Relationships [F(4, 91)=8.00, p<0.0001]. The effect sizes, calculated using eta squared, were 0.18, 0.48, and 0.26, respectively. There was also a trend towards significance for the Back Pain Medication Acceptability domain [F(4, 197)=2.24, p=0.07] with an effect size of 0.04. However, mean differences for the following domains did not reach statistical significance: Information about Back Pain and Its Treatment, Satisfaction with the Treatment Process, and Adherence to Physiotherapy.

Table 20: Comparison of CLBP Treatment Satisfaction Domain Scores at Baseline According to How Patients Rate Their Health: Discriminative Validity

		How do you rate your health?		
		n	**Mean**	**SD**
Burden of Back Pain	Excellent	5	87.40	26.11
	Very good	56	105.43	19.29
	Good	83	100.00	19.18
	Fair	51	85.45	18.81
	Poor	8	75.50	17.01
Problems with Side Effects	Excellent	0	-	-
	Very good	5	48.00	2.00
	Good	13	39.92	5.75
	Fair	11	37.00	6.97
	Poor	3	25.67	9.81
Information about Back Pain and Its Treatment	Excellent	5	19.80	7.01
	Very good	58	21.14	7.73
	Good	91	22.31	7.24
	Fair	56	21.23	6.68
	Poor	9	15.56	7.04
Satisfaction with the Treatment Process	Excellent	3	13.67	3.21
	Very good	59	16.15	4.41
	Good	86	16.77	3.51
	Fair	56	16.25	4.42
	Poor	10	14.10	4.09
Impact of Back Pain on Relationships	Excellent	5	21.80	4.09
	Very good	20	27.45	5.39
	Good	42	25.57	5.61
	Fair	23	20.09	4.94
	Poor	6	18.17	5.91

		How do you rate your health?		
		n	**Mean**	**SD**
Back Pain Medication Acceptability	Excellent	3	10.33	1.53
	Very good	52	11.17	2.87
	Good	83	10.41	2.27
	Fair	54	9.94	2.77
	Poor	10	9.10	2.28
Adherence to Physiotherapy	Excellent	5	12.00	1.41
	Very good	60	11.27	3.21
	Good	90	10.81	2.26
	Fair	62	10.79	2.33
	Poor	10	9.40	3.60

- No data available

Level of pain in the last 7 days and level of pain right now were originally scored on a scale of 1 to 10. However, to obtain sufficient sample size and minimise the number of groups for comparison, patients' responses were grouped to create five categories: 1-2, 3-4, 5-6, 7-8, and 9-10.

For both level of pain in the last 7 days, and level of pain right now, there were statistically significant differences at the $p<0.05$ level in the following CLBP Treatment Satisfaction domains: Burden of Back Pain ([$F(4,199)=12.39$, $p<0.0001$] and [$F(4,198)=11.89$, $p<0.0001$], respectively); Impact of Back Pain on Relationships ([$F(4,90)=2.93$, $p<0.05$] and [$F(4,89)=3.35$, $p<0.01$]). Back Pain Medication Acceptability was also statistically significant for level of pain in the last 7 days, and there was a trend towards significance for level of pain right now [$F(4,198)=2.87$, $p<0.02$] and [$F(4,197)=2.16$, $p=0.07$). Effect sizes using eta squared ranged from 0.01 to 0.30.

For pain in the last 7 days, there were also statistically significant differences for Problems with Side Effects [$F(4,27)=2.96$, $p<0.05$] and Satisfaction with the Treatment Process [$F(4,209)=2.98$, $p=0.20$], with effect sizes ranging from 0.05 to 0.30. However, mean differences did not reach statistical significance for level of pain right now, and mean differences for Adherence to Physiotherapy did not reach statistical significance for either clinical severity variable.

Table 21: Comparison of CLBP Treatment Satisfaction Questionnaire Scores at Baseline According to Pain in the Last 7 days, and Pain Right Now: Discriminative Validity

		Pain in the Last 7 days			Pain Right Now		
		n	**Mean**	**SD**	**n**	**Mean**	**SD**
Burden of Back Pain	1-2	15	121.13	15.38	26	111.38	20.84
	3-4	46	104.52	18.51	53	101.11	19.32
	5-6	55	96.82	20.70	61	99.38	19.87
	7-8	66	89.62	18.43	57	84.04	17.40
	9-10	22	85.36	19.47	6	83.67	12.96
Problems with Side Effects	1-2	1	37.00	-	1	37.00	-
	3-4	2	37.00	2.83	9	36.44	11.98
	5-6	7	45.86	4.49	8	41.75	6.14
	7-8	19	35.68	8.54	13	38.62	6.70
	9-10	3	44.33	2.08	1	42.00	-
Information about Back Pain and Its Treatment	1-2	16	22.94	8.83	29	22.28	7.61
	3-4	44	20.41	6.28	54	20.06	6.72
	5-6	61	20.97	7.49	66	23.18	7.80
	7-8	74	21.99	7.50	63	20.21	6.85
	9-10	25	22.16	6.55	7	22.57	7.02

		Pain in the Last 7 days			Pain Right Now		
		n	Mean	SD	n	Mean	SD
Satisfaction with Treatment Process	1-2	14	17.64	5.08	27	17.67	4.44
	3-4	41	15.61	3.08	51	15.96	3.26
	5-6	58	15.83	3.66	62	15.74	4.07
	7-8	77	16.18	4.52	67	16.33	4.44
	9-10	25	18.60	3.64	7	18.57	3.51
Impact of Back Pain on Relationships	1-2	10	28.60	5.30	16	26.94	6.55
	3-4	23	25.48	5.62	27	24.59	6.00
	5-6	25	23.24	6.42	27	24.19	6.95
	7-8	27	21.82	6.07	21	20.19	3.09
	9-10	10	23.50	5.15	3	25.67	4.51
Adherence to Physiotherapy	1-2	15	12.07	3.81	30	11.03	3.59
	3-4	47	10.89	2.27	55	11.04	2.33
	5-6	64	10.89	2.56	67	10.54	2.74
	7-8	80	10.81	2.59	69	10.97	2.33
	9-10	22	10.54	2.69	6	11.80	1.60

		Pain in the Last 7 days			Pain Right Now		
		n	**Mean**	**SD**	**n**	**Mean**	**SD**
Back Pain Medication Acceptability	1-2	12	10.42	3.18	23	11.35	2.93
	3-4	37	10.05	2.91	49	10.12	2.84
	5-6	55	10.93	2.80	58	10.86	2.56
	7-8	74	9.84	2.36	64	9.84	2.31
	9-10	25	11.52	1.71	8	10.63	1.19

- Not applicable

6.4.10 Test-Retest Reliability

Thirty-four participants completed the satisfaction questionnaire at baseline and week 2. Of these, 17 (50%) were considered stable because they responded ‘about the same’ to the Patient Global Impression (PGI) question ‘Compared to the way you felt at the start of the study, please rate the degree of change in your health?’ The other 17 indicated their health had improved with 8 (23.5%) answering ‘a little better’, 5 (14.7%) ‘moderately better’, and 4 (11.8%) ‘very much better’. Since test-retest assumes no change in health status, the analyses focused on the 17 patients who were defined as stable. Reliability data for the 17 stable patients are shown in Table 22 and Table 23.

Table 22: CLBP Treatment Satisfaction Questionnaire Test-Retest Reliability in Stable Patients who Responded ‘no change’ on the Patient Global Impression (PGI) of Health: Paired t-tests Between Baseline and Week 2

		Baseline		**Week 2**		**t-test**	**p-value**
CLBP Treatment Satisfaction Domain	**n**	**Mean**	**SD**	**Mean**	**SD**		
Burden of Back Pain	14	102.64	16.68	105.71	13.61	-0.97	p=0.35
Problems with Side Effects				Not relevant			
Information About Back Pain and Treatment	13	22.15	7.12	33.31	13.09	-3.75	**p≤0.005****
Satisfaction with Treatment Process	15	16.20	3.19	16.53	2.92	-0.54	p=0.60
Impact of Back Pain on Relationships	-	-	-	-	-	-	-
Back Pain Medication Acceptability	15	10.40	2.29	11.06	3.43	-0.89	p=0.39
Adherence to Physiotherapy	15	11.46	1.96	12.60	1.18	-2.24	**p≤0.05***

- Sample size too small to calculate *p≤0.05; ** p≤0.005

Table 23: Test-Retest Reliability between Baseline and Week 2 as Assessed Using Pearson's and Intraclass Correlation Coefficients for Stable Patients who Responded 'about the same' on the Patient Global Impression (PGI) of Health

CLBP Treatment Satisfaction Domain	**Stable Patients who responded 'about the same' on the PGI between baseline and week 2**						
	n	**Pearson's r**	**p-value**	**% of agreement§**	**ICC$^{\neq}$**	**p -value**	**% of agreement§**
Burden of Back Pain	14	0.71	0.004	50.4	0.70	**$p \leq 0.01$****	49.0
Problems with Side Effects	-	-	-	-	-	-	-
Information About Back Pain and its Treatment	13	0.58	0.04	33.6	0.32	**$p \leq 0.05$***	10.2
Satisfaction with Treatment Process	15	0.70	0.004	0.49	0.71	**$p \leq 0.001$*****	50.4
Impact of Back Pain on Relationships	-	-	-	-	-	-	-
Back Pain Medication Acceptability	15	0.55	0.03	30.3	0.51	**$p \leq 0.05$***	26.0
Adherence to Physiotherapy	15	0.30	0.274	0.09	0.22	$p=0.16$	4.8

$^{\neq}$Two way mixed effects model were people are random and measures are fixed
§Correlation coefficient squared
*$p \leq 0.05$; **$p \leq 0.01$; *** $p \leq 0.001$

Table 22 indicates that mean differences between baseline and week 2 were small and all domains of the CLBP Treatment Satisfaction questionnaire did not reach statistical significance with the exception of Information Provided about Back Pain and its Treatment, and Adherence to Physiotherapy.

Table 23 shows that ICC correlations between baseline and week 2 were 0.70 and above for the Burden of Back Pain domain and the Satisfaction with Treatment Process domain ($p<0.05$). With the exception of the Adherence to Physiotherapy domain (ICC = 0.22), all other ICC correlations reached statistical significance and ranged from 0.32 to 0.51. Pearson's correlation coefficients ranged from 0.30 to 0.71 and were also statistically significant for all domains except the Adherence to Physiotherapy domain.

6.4.11 Responsiveness to Change over Time

Responsiveness for all domains of the CLBP Treatment Satisfaction questionnaire was calculated except the Problems with Side Effects and the Impact of Back Pain and Treatment on Relationships domains, where sample sizes were too small. Results presented in Table 24 show responsiveness data for the remaining domains. Mean change scores were positive for the improved group for all domains, and statistical significance was achieved for all domains except the Satisfaction with Treatment Process and the Medication Acceptability domains (p values for t-test $p \leq 0.05$). Effect sizes were calculated for all significant results and findings showed that the magnitude of the differences were often moderate to large, ranging from -0.36 to -0.73.

Table 24: Description and Comparison of the Changes in CLBP Treatment Satisfaction Questionnaire between Baseline and Week 6: Responsiveness

			Baseline		**Week 6**		**t-test**	**p-value**	**ES†**
CLBP Treatment Satisfaction Domain	**Status of Patients**	**n**	**Mean**	**SD**	**Mean**	**SD**			
Burden of Back Pain	MD	2	109.50	10.61	118.00	2.83	-0.97	p=0.54	
	Worsened	-	-	-	-	-	-	-	-
	Stable	4	101.25	21.93	97.25	6.34		p=0.69	
	Improved	13	102.15	23.97	118.62	17.54		**p≤0.05***	-0.36
Problems with Side Effects	MD								
	Worsened		Not calculated due to small sample sizes between groups						
	Stable								
	Improved								
Information	MD	2	20.50	3.54	36.00	4.24	-3.75	p=0.22	

			Baseline		Week 6		t-test	p-value	ES†
CLBP Treatment Satisfaction Domain	**Status of Patients**	**n**	**Mean**	**SD**	**Mean**	**SD**			
About Back Pain and Treatment	Worsened	-	-	-	-	-	-	-	-
	Stable	5	23.40	3.65	35.40	13.57		p=0.12	
	Improved	16	24.50	6.44	42.50	10.09		**p≤0.0001*** **	-0.73
Satisfaction with Treatment Process	MD	2	18.50	0.71	13.00	4.24	-0.54	p=0.27	
	Worsened	-	-	-	-	-	-	-	-
	Stable	5	17.20	2.82	17.21	2.20		p=1.00	
	Improved	11	17.60	4.22	18.50	3.71		p=0.15	
Impact of Back Pain on Relationships	MD								
	Worsened	Not calculated due to small sample sizes between groups							
	Stable								
	Improved								
Back Pain Medication Acceptability	MD	2	11.00	1.41	9.00	4.24	-0.89	p=0.71	
	Worsened	-	-	-	-	-	-	-	-
	Stable	6	10.83	3.06	11.67	2.16		p=0.22	
	Improved	11	11.45	2.62	12.09	1.79		p=0.40	
Adherence to Physio-therapy	MD	2	11.00	1.41	12.50	3.54	-2.24	p=0.74	
	Worsened	-	-	-	-	-	-	-	-
	Stable	6	11.50	2.26	11.17	1.33		p=0.80	
	Improved	16	11.25	2.52	13.19	1.38		**p≤0.01*** *	-0.41

*p≤0.05; ** p≤0.01; ***p<0.0001 †ES Effect size only calculated where statistical significance observed

6.4.12 Exploring Factors Associated with the CLBP Treatment Satisfaction Questionnaire

Standard Multiple Linear Regression was used. The assumptions of multiple linear regression were tested for and results indicate that they were met (see Appendix T). Specifically, examination of the collinearity diagnostic values for the predictor variables was quite respectable (ranging from .54 to .92). Inspection of the Normal Probability Plot of the standardised residuals show the points generally lie in a reasonably straight diagonal line from bottom left to top right, suggesting no major deviations from normality. The scatterplot of the standardised residuals shows that residuals are roughly rectangularly distributed with most of the scores concentrated in the centre, again suggesting no major deviations from normality.

Each multiple regression model included the following variables: gender, age, ethnicity, academic qualifications, whether patients had time off work in the last four weeks, whether patients were taking opioid analgesics, whether patients were taking non-opioid analgesics, whether patients experience side effects, pain severity in the last seven days, and the McGill Total Score. The models reached statistical significance for all domains except the Problems with Side Effects and Medication Acceptability domain.

Multiple Linear Regressions of Variables on Burden of Back Pain

Adjusted R^2 indicated that the model explained 53% of the variance in Burden of Back Pain. Of the variables, the McGill Total score made the largest unique contribution (beta = -.36) although time off work (beta = .29), pain severity in the last seven days (beta = -.27), duration since diagnosis (beta = -.22), and ethnicity (beta = -.20) also make significant contributions (see Table 25 for summary of Beta coefficients, significance levels, partial correlations and unique variance).

Table 25: Standard Multiple Regression of Gender, Age, Ethnicity, Academic Qualifications, Time off Work in the Last 4 weeks, Duration since Diagnosis, Opioid Analgesics, Side Effects, and Pain Severity in the Last 7 days on Burden of Back Pain

Predictor variable	**Beta coefficients**	**Partial correlation**	**Unique variance**	**t-value**	**p-value**
Gender	.05	.06	.04	.50	0.62
Age	.09	.12	.08	.99	0.33
Ethnicity	-.20	-.28	-.18	-2.31	**0.02**
Academic qualifications	.13	.19	.12	1.50	0.14
Time off work in the last 4 weeks	.29	.38	.26	3.28	**0.002**
Duration since diagnosis	-.22	-.28	-.18	-2.27	**0.03**

Predictor variable	Beta coefficients	Partial correlation	Unique variance	t-value	p-value
Opioid analgesics	-.16	-.21	-.13	-1.69	0.10
Non-opioid analgesics	-.04	-.06	-.04	-.49	0.63
Side Effects	.03	.04	.03	.32	0.75
Pain Severity in last 7 days	-.27	-.32	-.21	-2.65	**0.01**
Involvement in treatment decisions	.08	.12	.08	.99	0.33
McGill Total Score	-.36	-.36	-.25	-3.11	**0.003**

$R^2 = .61$, Adjusted $R^2 = .53$, $p \leq 0.0001$

Multiple Linear Regression of Variables on Information About Back Pain and Treatments

Adjusted R^2 indicated that the model explained 26% of the variance of Information about Back Pain and Treatments. Of the variables, involvement in treatment decisions made the largest unique contribution (beta = .56) although academic qualifications also makes significant contributions (beta = -.27) (see Table 26 for summary of Beta coefficients, significance levels, partial correlations and unique variance).

Table 26: Standard Multiple Regression of Gender, Age, Ethnicity, Academic Qualifications, Time off Work in the Last 4 weeks, Duration since Diagnosis, Opioid Analgesics, Side Effects, and Pain Severity in the Last 7 days on Information Provided About Back Pain and Treatment

Predictor variable	Beta coefficients	Partial correlation	Unique variance	t-value	p-value
Gender	.09	.09	.074	.75	0.45
Age	-.10	-.10	.08	-.81	0.42
Ethnicity	-.02	-.02	-0.16	-.16	0.87
Academic qualifications	-.27	-.31	-.26	-2.65	**0.01**
Time off work in the last 4 weeks	.11	.13	.10	1.04	0.30
Duration since diagnosis	.14	.15	.12	1.22	0.23
Opioid analgesics	.02	.03	.02	.21	0.84

Predictor variable	Beta coefficients	Partial correlation	Unique variance	t-value	p-value
Non-opioid analgesics	.03	.04	.03	.28	0.78
Side Effects	-.07	-.07	-.06	-.58	0.57
Pain Severity in last 7 days	-.04	-.04	-.03	-.31	0.75
Involvement in treatment decisions	.56	.56	.53	5.39	**0.0001**
McGill Total Score	.16	.15	.12	1.25	0.22

R^2 = .38, Adjusted R^2 =.26, $p \leq 0.001$

Multiple Linear Regression of Variables on Satisfaction with the Treatment Process

Adjusted R^2 indicated that the model explained 16% of the variance in Satisfaction with the Treatment Process. Of the variables, involvement in treatment decisions made the largest significant unique contribution (beta = .38). There was a trend towards significance for the variable whether patients were taking opioid analgesics (beta = -.23) (see Table 27 for summary of Beta coefficients, significance levels, partial correlations and unique variance).

Table 27: Standard Multiple Regression of Gender, Age, Ethnicity, Academic Qualifications, Time off Work in the Last 4 weeks, Duration since Diagnosis, Opioid Analgesics, Side Effects, and Pain Severity in the Last 7 days on Satisfaction with Treatment Process

Predictor variable	Beta coefficients	Partial correlation	Unique variance	t-value	p-value
Gender	.09	.10	.08	.76	0.45
Age	.14	.14	.12	1.11	0.27
Ethnicity	-.15	-.16	-.14	-1.30	0.20
Academic qualifications	-.02	-.03	-.02	-.22	0.83
Time off work in the last 4 weeks	-.02	-.02	-.02	-.16	0.87
Duration since diagnosis	.20	.20	.17	1.60	0.11
Opioid analgesics	-.23	-.21	-.18	-1.74	0.09
Non-opioid analgesics	-.07	-.08	-.06	-.60	0.55
Side Effects	.21	.21	.18	1.70	0.09

Predictor variable	**Beta coefficients**	**Partial correlation**	**Unique variance**	**t-value**	**p-value**
Pain Severity in last 7 days	.12	.11	.09	.89	0.38
Involvement in treatment decisions	.38	.39	.36	3.39	**0.001**
McGill Total Score	-.02	-.02	-.02	-.14	0.89

R^2= .29, Adjusted R^2 =.16, $p \leq 0.05$

Multiple Linear Regressions of Variables on Adherence to Physiotherapy

Adjusted R^2 indicated that the model explained 14% of the variance in Adherence to Physiotherapy. Of the variables, ethnicity makes the largest significant unique contribution (beta = -.23). There were trends towards significance for the variables duration since diagnosis (beta = -.24), whether patients were taking opioid analgesics (beta = -.22), and whether patients are taking non-opioid analgesics (beta = -.21) (see Table 28 for summary of Beta coefficients, significance levels, partial correlations and unique variance).

Table 28: Standard Multiple Regression of Gender, Age, Ethnicity, Academic Qualifications, Time off Work in the Last 4 weeks, Duration since Diagnosis, Opioid Analgesics, Side Effects, and Pain Severity in the Last 7 days on Adherence to Physiotherapy

Predictor variable	**Beta coefficients**	**Partial correlation**	**Unique variance**	**t-value**	**p-value**
Gender	-.04	-.04	-.03	-.30	0.76
Age	.11	.11	.09	.89	0.38
Ethnicity	-.23	-.24	-.21	-1.97	**0.05**
Academic qualifications	-.03	-.04	-.03	-.31	0.76
Time off work in the last 4 weeks	.17	.18	.15	1.45	0.15
Duration since diagnosis	.24	.23	.21	1.93	0.06
Opioid analgesics	-.22	-.21	-.18	-1.74	0.09
Non-opioid analgesics	-.21	-.21	-.19	-1.77	0.08
Side Effects	.12	.12	.10	.98	0.33
Pain Severity in last 7 days	-.21	-.19	-.16	-1.55	0.13
Involvement in treatment decisions	-.01	-.01	-.10	-.09	0.93
McGill Total Score	.22	.19	.17	1.60	0.12

R^2 = .27, Adjusted R^2 =.14, $p \leq 0.05$

Multiple Linear Regressions of Variables on Impact of Back Pain and Treatment on Relationships

Adjusted R^2 indicated that the model explained 39% of the variance in Impact of Back Pain and Treatment on Relationships. Of the variables, whether patients are taking opioid analgesics (beta = -.75) made the largest unique contribution (beta = -.36) although age (beta =.58), whether patients are taking non-opioid analgesics (beta = -.47), duration since diagnosis (beta = -.47), and academic qualifications (beta = .34) also make statistically significant contributions (see Table 25 for summary of Beta coefficients, significance levels, partial correlations and unique variance).

Table 29: Standard Multiple Regression of Gender, Age, Ethnicity, Academic Qualifications, Time off Work in the Last 4 weeks, Duration since Diagnosis, Opioid Analgesics, Side Effects, and Pain Severity in the Last 7 days on Impact of Back Pain on Relationships

Predictor variable	**Beta coefficients**	**Partial correlation**	**Unique variance**	**t-value**	**p-value**
Gender	.01	.01	.10	.06	0.95
Age	.58	.52	.38	2.79	**0.01**
Ethnicity	-.24	-.30	-.19	-1.43	0.17
Academic qualifications	.34	.42	.23	2.13	**0.05**
Time off work in the last 4 weeks	.15	.19	.12	.87	0.40
Duration since diagnosis	-.47	-.46	-.32	-2.38	**0.03**
Opioid analgesics	-.75	-.55	-.41	-3.02	**0.01**
Non-opioid analgesics	-.47	-.47	-.33	-2.45	**0.02**
Side Effects	.11	.10	.06	.47	0.64
Pain Severity in last 7 days	-.25	-.27	-.17	-1.27	0.22
Involvement in treatment decisions	-.12	-.15	-.10	-.71	0.49
McGill Total Score	-.14	-.16	-.10	-.75	0.46

R^2 = .61, Adjusted R^2 =.39, $p \leq 0.05$

6.4.13 Summary of Results

The main objective of this part of the study was to explore the psychometric properties of the CLBP Treatment Satisfaction Questionnaire. The results provide some evidence to support the reliability and validity of the instrument, and are summarised briefly below:

- A PCA analysis resulted in seven main factors that explained 52% of the total variance. The factors were labelled
    - ‘Burden of Back Pain’
    - ‘Problems with Side Effects of Back Pain Medication’
    - ‘Information About Back Pain and Treatment’
    - ‘Satisfaction with the Back Pain Treatment Process’
    - ‘Impact of Back Pain on Relationships’
    - ‘Back Pain Medication Acceptability’
    - ‘Adherence to Physiotherapy’
- Internal consistency for each domain was good; Cronbach’s alpha ranged from 0.79 for ‘Adherence to Physiotherapy’ to 0.94 for ‘Burden of Back Pain’.
- There was evidence of concurrent validity, with low to moderate correlations between the CLBP Satisfaction Question and both the SF-36 (r=0.003 to 0.76) and the PETS (r= -0.11 to -0.61).
- There was evidence of discriminative validity of the CLBP Treatment Satisfaction Questionnaire with distribution of scores according to the following variables related to clinical severity:

    - Patients’ rating of health
    - Level of pain in the last 7 days
    - Level of pain right now
- Test-retest reliability requires further testing.
    - Whilst the sample size was very small (n=17), mean differences between baseline and week 2 were small and all domains of the CLBP Treatment Satisfaction questionnaire did not reach statistical significance with the exception of Information Provided about Back Pain and its Treatment, and Adherence to Physiotherapy.
    - ICC correlations between baseline and week 2 were 0.70 and above for the ‘Burden of Back Pain’ domain and the ‘Satisfaction with Treatment Process’ domain. However, ICCs could not be calculated due to insufficient sample sizes for Problems with Side Effects and Impact of Back Pain on Relationships. Further, ICCs were poor for the remaining domains: Information about Back Pain and its Treatment, Medication Acceptability, Adherence to Physiotherapy.
- Responsiveness was demonstrated for all domains except the ‘Problems with Side Effects’ and the ‘Impact of Back Pain and Treatment on Relationships’ domains where sample sizes were too small to perform tests.
- Multiple linear regressions showed various clinical and demographic factors associated with the principal components of the CLBP Treatment Satisfaction Questionnaire. Specifically:

- 53% of the variance of ‘Burden of Back Pain’ was explained by the McGill Total Score, Time off work in the last 4 weeks, pain severity, duration since diagnosis and ethnicity.
- 26% of the variance of ‘Information About Back Pain and Treatment’ was explained by involvement in treatment decisions and academic qualifications.
- 16% of the variance of ‘Satisfaction with the Treatment Process’ was explained by involvement in treatment decisions.
- 14% of the variance of ‘Adherence to Physiotherapy’ was explained by ethnicity.
- 39% of the variance of ‘Impact of Back Pain and Treatment on Relationships’ was explained by whether patients take opioids, whether patients take non-opioids to help them with their problems, duration since diagnosis, and academic qualifications.

6.5 Discussion

6.5.1 Overview of Study Objectives

The purpose of this part of the study was two-fold. The first aim was to test the psychometric properties of the CLBP Treatment Satisfaction Instrument. In particular, the aims were to explore the construct validity, internal consistency, concurrent validity, discriminative validity, test-retest reliability, and responsiveness.

The second aim was to construct a framework to make sense of the complex set of factors associated with treatment satisfaction in CLBP. In particular, the aim was to explore the predictors of the principal components of the CLBP Treatment Satisfaction Questionnaire to understand how well demographic, treatment, and pain variables predict the various components of treatment satisfaction in CLBP, how much variance can be explained by the predictors, and to establish which variables are the best predictors.

6.5.2 Summary of Main Findings

With regard to the first aim of this study, the study found some evidence to support the reliability and validity of the CLBP Treatment Satisfaction Questionnaire. A PCA analysis resulted in seven main factors that explained 52% of the total variance. The factors were labelled 'Burden of Back Pain', 'Problems with Side Effects of Back Pain Medication', 'Information About Back Pain and Treatment', 'Satisfaction with the Back Pain Treatment Process', 'Impact of Back Pain on Relationships', 'Back Pain Medication Acceptability', and 'Adherence to Physiotherapy'. Internal consistency for each domain was good, supporting that items within each domain are measuring the same concept.

Following construct validity and internal consistency analyses, the final CLBP Treatment Satisfaction Questionnaire was scored so that high scores on each of the domains indicated positive outcomes associated with treatment satisfaction. Scores were generally non-normal, with some bimodal and multimodal distributions observed.

Statistical tests in this study supported the discriminative validity of the domains of the CLBP Treatment Satisfaction Questionnaire. For example, with the exception of 'Information Provided about Back Pain and Treatment' and 'Adherence to Physiotherapy', all domains of the CLBP Treatment Satisfaction Questionnaire were able to discriminate between levels of pain in the last 7 days, with lower pain scores associated with more positive outcomes. For example, with higher levels of pain, lower scores were observed for 'Burden of Back Pain', indicating significant negative impact on patients' regular activities. Similarly, the higher the pain, the lower the scores were for 'Impact of Back Pain and Treatment on Relationships', indicating that back pain interferes with patients' relationships. In addition, all domains except 'Information Provided about Back Pain' were able to discriminate according to levels of pain in the last 7 days.

In terms of test-retest reliability, although the sample size was well below the recommended 100 (Kline, 2000) for stable patients who completed the questionnaire at baseline and week 2, results provide some evidence to support the reproducibility of some of the CLBP Treatment Satisfaction Questionnaire. Specifically, mean differences between baseline and week 2 were small for all domains of the CLBP Treatment Satisfaction Questionnaire and did not reach statistical significance. The exceptions were for the 'Information about Back Pain and Treatment' and 'Adherence to Physiotherapy' domains.

Further, test-retest reliability refers to the extent to which the two administrations of the same questionnaire to the same group of patients provide consistent results (Guyatt et al., 1989). Pearson's correlation coefficients provided some evidence to support agreement between the two assessments for some domains (i.e. 'Burden of Back Pain', and 'Satisfaction with the Treatment Process'). Since Pearson's correlation coefficients cannot detect systematic error (Deyo et al., 1991; Schuck, 2004), ICCs were also calculated using a two-way mixed effects model where people were random and measures were fixed, with an absolute agreement definition and single measures reported between baseline and week 2. ICCs were 0.70 and above for 'Burden of Back Pain' and the 'Satisfaction with Treatment Process' domains, indicating some confidence in test-retest reliability (Kline, 2000). With the exception of 'Adherence to Physiotherapy' domain (ICC=0.22), all other ICC correlations that were tested reached statistical significance and ranged from 0.32 to 0.71. However, it should be noted that ICCs were poor for 'Information about Back Pain and Treatment', 'Medication Acceptability', and

‘Adherence to Physiotherapy’. Given these findings and the small sample sizes, further testing is required in a larger sample size of stable patients to ascertain with greater certainty the test-retest reliability of the CLBP Treatment Satisfaction Questionnaire, and particularly for the ‘Problems with Side Effects’ and the ‘Impact of Back Pain on Relationships’ domains which could not be explored due to the small sample sizes.

Scores were sensitive to change over time between baseline and week 6, providing some evidence of responsiveness. Mean scores between baseline and week 6 were positive for the improved group for all domains and statistical significance was achieved for all domains except the ‘Satisfaction with Treatment Process’ and the ‘Medication Acceptability’ domains. Effect sizes were moderate to large, ranging from -0.36 to -0.73. It should be noted that responsiveness could not be explored for ‘Problems with Side Effects’ and ‘Impact on Relationships’ where sample sizes were too small.

With regard to the second aim, standard MLRs were performed on the principal components of the CLBP Treatment Satisfaction Questionnaire. The assumptions of MLR were tested and met. All models were significant except for ‘Problems with Side Effects’ and ‘Medication Acceptability’. The following variables explained 53% of the variance of the ‘Burden of Back Pain’ domain: McGill Total pain score, time off in the last four weeks, pain severity in the last 7 days, duration of CLBP since diagnosis, and ethnicity. These findings are not surprising since the burden of back pain and whether patients can go about their regular activities will be related to how much pain they are experiencing. Interestingly, ethnicity was associated with Burden of Back Pain.

A different set of variables also explained 39% of the variance of the ‘Impact of Back Pain and Treatment on Relationships’ domain: whether patients take opioid analgesics, age, whether patients take non-opioid analgesics, duration of CLBP since diagnosis, and academic qualifications. Again, these finding are not unexpected and these associations seem relatively intuitive. For example, the Relationships domain contains items associated with whether patients are sexually active and whether they find sex uncomfortable, and one would expect that if individuals experience CLBP then these aspects may be affected. On reflection, during the in-depth patient interviews (see Chapter 4), one patient stated: *"I don't know but my wife has noticed that probably my sex life has been affected because I hardly do it anymore because of the pain and all the surroundings that goes with it" (ID04).* Also, age may be associated with whether patients have a partner and the desire for sex. Indeed, during in-depth patient interviews, another patient stated *"You can forget sex with my back. When you get to my age there's no one nice anyway" (ID02).*

A total of 26% of the variance of 'Information about Back Pain and Treatment' was explained by the factors involvement in treatment decisions and academic qualifications. Again, these findings seem to be logical in that if patients feel involved in treatment decisions, then they are likely to be informed about their condition and (for example) the treatment options available to them. Also, it seems intuitive that the degree of academic qualifications is associated with how much information patients would have liked about various aspects of their condition and treatment.

Involvement in treatment decisions was also a significant predictor of 'Satisfaction with Treatment Process' domain, which, together with whether patients take opioids, explained 16% of the total variance. Further, there were four factors that predicted Adherence to Physiotherapy: ethnicity, duration of CLBP since diagnosis, whether patients take opioids, and whether patients take non-opioids. Together, these explained 14% of the total variance of Adherence to Physiotherapy.

6.5.3 Baseline Sample Characteristics

The mean age of the overall sample at baseline was 47.9 years and included a greater proportion of women to men. Unfortunately, national UK statistics were not available for patients with CLBP, and OPCS data suggests that the prevalence of back pain (defined as pain for at least one day in the last year, i.e. acute or sub-acute) is similar between males and females (The Department of Health Statistics Division, 1999). It is possible that the transition from acute or sub-acute back pain to CLBP is more prevalent in women than men; this hypothesis requires further testing using empirical data. Another possibility is that women are perhaps more likely to participate than men. Again, future research is warranted to explore this further, since establishing the proportion of males and female non-responders could be useful.

Although there were similarities observed in socio-demographic characteristics between subgroups (e.g. participants recruited from physiotherapy departments compared to those from pain clinics or charities) there were also some differences. For example, the age of participants from charities and pain clinics was higher than the physiotherapy and Back Show groups. This result is not surprising, since people attending pain clinics are often referred by an ESP and have already tried physiotherapy and/or other treatment methods, or have psychological barriers concerning pain; therefore, there is a tendency for them to be older. Patients from the Back Show were generally more mobile and therefore may be younger.

Also, whilst the majority of patients were Caucasian or white in all groups, there was a slightly higher proportion of patients from the Back Show who were non-white. Since the Back Show was held in London where there is a higher proportion of ethnic minority groups compared to the Northern England recruitment sites, this is unsurprising.

Comparisons between subgroups according to socio-demographic characteristics reached statistical significance for ethnicity, academic qualifications, employment, and whether patients 16-64 years who were employed had time off work due to CLBP. These findings suggest that the characteristics of the subgroups are not homogenous. Whilst it could be inferred that the data from the subgroups should not be pooled, nevertheless samples were pooled in order to obtain sufficient sample for psychometric testing. Further, pooling samples allowed an increase in the variability of the level of pain reported by patients, which was particularly important for the purpose of this study.

The sample used in this study was broadly comparable to the national average as reported by the OPCS (The Department of Health Statistics Division, 1999); therefore, it can be inferred that findings from this study are representative of patients with CLBP and can be generalised to the wider population. However, some differences between the data sets are apparent in gender (more women than men in this study compared to OPCS study), age (more patients in the 16-24 age group in the OPCS study compared to this study), whether patients who were employed had time off due to back pain (more patients in this study who had time off due to their back pain than in the OPCS study), and reasons why patients were not employed (more patients in this study reported back problems or other problems getting a job as reasons for not being employed compared to the OPCS study). These differences may be explained by the fact that the OPCS study (which was the only national average data available at the time) was primarily calculated based on the percentage of general population with back pain at least one day in the last 12 months, whereas this study was focused on patients with CLBP defined as pain lasting for at least three months.

6.5.4 Baseline Scores of Validated Instruments

Results using the SF-36 suggest that at baseline patients with CLBP in this study had significantly lower HRQoL scores than U.K. age-matched norms (see section 6.4.2). These findings were particularly prominent across HRQoL domains, and mean point differences between study scores and age-matched norms ranged from 11.32 for Mental Health to 45.3 for Role Functioning due to Physical Limitations. Since 3 to 5 point differences are considered clinically meaningful (see for example, Kosinski et al., 2000; Samsa et al., 1999), these results indicate that patients with CLBP in this study had clinically significant impairment in HRQoL domains compared to U.K. age-matched norms. This is supported by RMDQ scores, which indicated that patients experienced moderate disability due to their CLBP.

These findings point towards a need for continued support and care for patients with CLBP, with particular attention to how CLBP impacts patients' HRQoL in terms of Role Functioning, Social Functioning, Physical Functioning, Vitality, and General Health.

Further, results from this quantitative study suggested that patients do not adhere to the medication regimens recommended by their doctors (see section 6.4.2). These findings are in line with (Myers & Midence, 1998). Non-adherence may be a result of lack of awareness, knowledge, understanding by patients regarding how medication can help with everyday activities, and misunderstanding about the potential for dependence or other side effects (Myers & Midence, 1998).

Regarding pain scores, results indicated inconsistencies in scores between measures of pain, which may in part be explained by the fact that the sensory and affective scores of the SF MPQ are calculated by summing various items that belong to each subscale, whereas the VAS establishes patients' experience of pain in a single item.

Whilst there is evidence to support the validity and reliability of both methods, there is no clear consensus in the literature regarding which pain score is the best indicator, and further research is warranted to establish this.

6.5.5 Overview of Responses to CLBP Treatment Satisfaction Items

The description of scores for the CLBP Treatment Satisfaction items showed the significant and diverse impact of CLBP and its treatment on patients' lives (see section 6.4.3). For example, of those patients who experienced side effects, the majority reported that they were a big problem or a severe problem. In addition, most patients stated that they disagreed or strongly disagreed that their medication was helpful. When asked questions about satisfaction or dissatisfaction with the treatment process, overall most patients reported that they were 'dissatisfied' or 'very dissatisfied', specifically with the communication with their doctor regarding back pain medication, as well as with the information provided about the possible side effects incurred from back pain medication, the form of administration (e.g. tablet, patch, etc.), the amount of medication prescribed, and the way side effects were dealt with by their doctor. With regard to medication acceptability, although the majority disagreed that their back pain medication was difficult to swallow or left an unpleasant taste in their mouth, the majority 'agreed' that their back medication does not work quickly. Furthermore, the majority 'disagreed' that they set realistic goals, they paced their activities, and remembered to do their exercises.

These findings suggest that medication management and physiotherapy regimens need to be more patient focused. Actively listening and empathising with patients may help contribute towards more positive satisfaction ratings, as well as asking patients whether they experience side effects and how much of a problem they are to them, to help make them feel more involved in the treatment process and ultimately facilitate doctor-patient communication.

6.5.6 Construct Validity of the CLBP Treatment Satisfaction Questionnaire

The PCA produced seven factors (Burden of Back Pain, Problems with Side Effects of Back Pain Medication, Information Provided about Back Pain and Treatment, Satisfaction with the Back Pain Treatment Process, Impact of Back Pain and Treatment on Relationships, Adherence to Physiotherapy, and Back Pain Medication Acceptability) which accounted for 52% of the systematic covariance of the items. Eight-items did not load on any of the seven factors: ‘I was misdiagnosed’, ‘I was not involved in treatment decisions’, ‘I went out of the home’, ‘I could bend down’, ‘I had an ache in my back when I woke’, ‘My back pain medication is helpful to me’, ‘my back pain medication enables me to be independent’, and ‘I altered the amount of back pain medication I took’. Closer examination of the qualitative data and themes that emerged from in-depth interviews with patients (see section 4.4.2) suggests that these items are important to patients. Therefore, they were not deleted but do not form part of the seven domain scores of the questionnaire, and thus are analysed separately. Whilst data from this study showed a clear factor structure, further research is warranted to confirm with greater certainty the construct validity of the CLBP Treatment Satisfaction Instrument, and also whether the eight items that did not load on to any of the domains of the instrument should be retained.

Whilst a very clear factor structure was observed, additional testing using another sample of patients with CLBP is warranted to confirm these findings.

Further, as noted earlier, the PCA is ultimately based on the correlation between items and requires that items be coded on a continuous scale. Because ‘not applicable’ options are not suitable as part of a continuous scale and the PCA can be performed on complete cases, i.e. only for those participants who answered all of the items, in order to retain sufficient sample size for the purpose of the PCA, those answering ‘not applicable' to relationship items were re-assigned to the 'none of the time' category. The rationale being that relationship items would not be relevant to those who answered 'not applicable', presumably because they did not have a partner or were not sexually active etc. Consequently, a raw score of 6 for 'not applicable' was re-assigned a score of 5 representing 'none of the time'.

Similarly, for the problems with side effects items, participants were asked 'Because of your back pain medication, in the last 7 days how much of a problem were the following'. This section comprised 7 items such as 'loss of appetite', or 'weight gain' and how much of a problem the side effect was, was rated from 1 not a problem, to 5 a severe problem. Those answering 'not applicable' because they did not have the side effect were re-assigned to the 'not a problem' category.

In practical terms, including and re-assigning the 'not applicable' group means for example, those participants who did not have the symptom and those who had the symptom but it was not a problem, were grouped together. One implication is that this will have affected the distribution of scores by inflating the number of participant at one end of the scale ('not a problem'/'none of the time). This may have led to a more skewed distribution of the answers.

Whilst this is not ideal for psychometric testing such as discriminant analyses where one needs sufficient distribution of scores to help establish whether there are differences between groups, such scoring is not expected to impact significantly on the PCA results where sample size and the strength of relationship among the items are the main issues for consideration (Pallant, 2001) – and this is why this scoring was specific to the PCA analyses.

Having scored the questionnaire in this way, the overall sample that the PCA was performed on was 209 participants. According to Comrey and Lee (1992) this overall sample size is considered ‘fair’ for PCA. However, it should be noted that with 77 items included in the PCA and using a ratio of 3 participants per item, the overall sample size of 209 falls slightly short of the required 231 estimated sample size (see section 6.4.4). The possible implication of this outcome is that factors obtained from small datasets do not generalise as well as those derived from larger samples (Pallant, 2001)and therefore further PCA could be performed using a larger sample size and with particular attention to meaningful missing data such as ‘not applicable’.

Another possible implication is that by re-assigning raw scores from ‘not applicable’ category to either ‘none of the time’ or ‘not a problem’ according to the item, it’s possible that the outcome may have been to underestimate the actual impact which may have been greater if they had had a partner or experienced the side effect. But as mentioned previously, if this ‘smart imputation’ had not been performed then the sample would have been very small and not appropriate for PCA.

Further, if PCA had been performed for all participants who had a partner or experienced a side effect, then there may be a question of generalisability since then the results of the PCA would be only valid for people with a partner and who experienced side effects. This would be a very restrictive population as people with CLBP have a range of experiences some with or without partners and some with or without side effects from medication. Consequently, the rationale for ‘smart imputation’ on items related to relationships or problems with side effects was considered appropriate.

With regard to the consequences of ‘smart imputation’ for PCA, it is likely to have had limited impact on the results. However, one possibility is that the imputation may have, in part, caused the creation of the grouping of items into a single factor but as the imputation was only performed on one end of the scale, this alone, is not likely to explain that all these items loaded on a single factor. Nevertheless, in light of this possibility, future research could try to confirm the factor structure of the CLBP Treatment Satisfaction questionnaire, especially for these domains (i.e. Impact on Relationships and Problems with Side Effects) using methods such as exploratory and confirmatory factor analyses.

Further, whilst there is justification for performing ‘smart imputation’ for items related to relationships and problems with side effects, and such a method is considered meaningful and appropriate, an alternative approach for future research could be to perform the PCA on all participants by deleting the two domain’s items entirely, and to later do additional analysis on the subgroup to examine how the domains fit into the structure in that subgroup. In this way, the applicable domain results generalize to the entire population, and the additional domain results apply to the applicable subset of the population.

Nevertheless, the methods used in this study are considered appropriate and meaningful, and results from patient interviews as well as informal discussions with clinicians suggested that treatment satisfaction in CLBP was in part related to the impact on relationships and the problems with side effects encountered by patients, thus providing further support for the approach taken.

6.5.7 Internal Consistency

All seven domains of the questionnaire had satisfactory internal consistency, exceeding Nunnally’s threshold of 0.70 (Nunnally, 1978). These findings suggest that the items which comprise each domain are related to each other and point towards the conclusion that the items within each domain are indeed measuring the same concepts.

6.5.8 Tests for Normality and Outliers

The data were generally non-normal and there were some bimodal and multimodal distributions observed. This is not surprising since the data in this study emerged from patient reports, and the majority of data that come from behavioural sciences are frequently non-normally distributed (see for example, Micceri, 1989). Another possible explanation for non-normality is that patients were recruited from diverse types of sites. Therefore, it’s feasible that if these groups were considered separately, then scores may appear normally distributed. However, the data were pooled so that sufficient sample size was obtained to explore the main purpose of the study: establishing the factor structure of the CLBP Treatment Satisfaction questionnaire. Future research could stratify the data by sub-groups (e.g. considering scores by recruitment site or treatment, etc.). In addition, some of the questions may have been too easy or too difficult for patients with CLBP to respond to, resulting in some floor or ceiling effects. (Examples include some of the physical functioning related items such as ‘I was unable to work’, ‘I leaned on one side’ and ‘I had poor balance’ and all the appearance items: ‘I was unable to brush/comb my hair’, ‘I had difficulty getting dressed’, ‘I slouched’, ‘I was not interested in my appearance’, and ‘I was embarrassed about my image’.) The skeweness, indicative of floor and ceiling effects, suggests patients performed extremely well or very badly on items. Implications include the systematic under estimation or over estimation of scores, which may lead to an inability to distinguish between groups or even the incorrect classification of individuals into groups. With this in mind, whilst all items underwent a rigorous development and cognitive debriefing process (see Chapter 5), further research research with patients regarding the content and appropriateness is necessary to establish whether these items should be retained in the CLBP Treatment Satisfaction Questionnaire or whether the wording of these items needs to be revised.

Despite observations of non-normality, generally the deviations from the means were minimal and skewness and kurtosis scores were well below an acceptable 4.0, indicating that transformation of scores is not required. In addition, the scores were all within the expected ranges, and any outliers did not significantly impact the mean because comparisons to the 5% trimmed mean showed that there were only small differences.

However, it should be noted that the use of parametric tests on non-normal data can cause problems with the interpretation of results. Namely, there is a chance of incurring a type I error (rejecting the null hypothesis when it is true) or type II error (accepting the null hypothesis when it is false). Thus, observed differences between groups should be considered exploratory and further testing is warranted to establish the reliability of the results.

6.5.9 Concurrent Validity

Low to moderate correlations were observed between the domains of the CLBP Treatment Satisfaction Instrument and both the SF-36 HRQoL measure and the PETS, indicating concurrent validity, i.e., that the instruments are measuring similar but different concepts. These findings are partly supportive of what was expected in that the Burden of Back Pain domain shows significant and moderate correlations with the SF-36. Unexpectedly, the Impact on Relationships domain and the Problems with Side Effects domains also showed significant moderate correlations with the SF-36. This may in part be explained by the fact that although the domains are not measuring exactly the same concepts they are probably related, for example, it is clinically intuitive that Problems with Side Effects would be related to HRQoL.

In addition, as expected the following domains of the CLBP Treatment Satisfaction Questionnaire were significantly and moderately correlated with the PETS domains: Information about Back Pain and Treatment, Satisfaction with the Treatment Process domain, and Adherence to Physiotherapy domains.

However, it should be noted that the sample sizes for the Problems with Side Effects domain were small. The reason for this is because patients may not have experienced a side effect at baseline and therefore a score could not be calculated for that domain. Similarly, the sample sizes for the relationships domain were also small and the reason for this is that some patients answered ‘not applicable’ to these questions presumably because they did not have a partner. The small sample sizes for these domains suggest less confidence in the results obtained for concurrent validity and therefore require further testing. Further, given the small sample sizes for these domains, alternative scoring algorithms should be considered in the future. For example, with regard to the Problems with Side Effects domain, it may be more meaningful to analyse each item individually in terms of frequency (whether the patient experienced the side effect) and then how much of a problem it was to them. However, there are other analytical methods that could be considered such as cluster analysis (which would organise the data according to common observations or homogenous cases) or multiple regression analyses to consider whether experiencing a particular side effect predicts the likelihood of adhering to for example medication regimens.

6.5.10 Description of Baseline CLBP Treatment Satisfaction Domain Scores

Based on the validation of the CLBP Treatment Satisfaction Questionnaire, descriptive statistics of domain scores were calculated and summarised. To aid interpretation, the mean score for each domain was divided by the total number of items for that domain, and since a score of 5 represents satisfaction/positive outcomes for all items in a domain, a mean of 3.5 or more suggests most patients were satisfied/had positive outcomes with most or all items in the domain.

Results suggest that patients were experiencing burden from their back pain some of the time and also that back pain impacted on their relationships some of the time. For those who experienced side effects, these presented as a problem. Overall, patients in this study wanted a bit more information about their back pain and its treatment, and results suggested that they were neither satisfied nor dissatisfied with the treatment process. Further, patients were not sure about adherence to physiotherapy such as whether they set realistic goals and paced their activities.

These results are consistent with recent literature which demonstrates similar findings (see for example, Cherkin et al., 1991; McPhillips-Tangum et al., 1998) (see section 2.6.5). The implications of these findings suggest potential unmet needs for patients with CLBP in the UK. Therefore, HCPs can actively target the various components to help alleviate symptoms and the burden incurred to patients. This is expected to improve associated outcomes such as satisfaction and adherence.

6.5.11 Discriminative Validity

Whilst there was evidence to support the discriminant validity of the CLBP Treatment Satisfaction Questionnaire, the domains Information about Back Pain and Treatment and Adherence to Physiotherapy did not reach statistical significance in discriminating between levels of pain. One possible explanation for this is that these items and the overall Information about Back Pain score may not necessarily be associated with how much pain patients have had in the last 7 days. Similarly, the Adherence to Physiotherapy domain assesses the degree to which patients agree or disagree that they set realistic goals, remember to do exercises, and pace activities; these may also not necessarily be associated with pain in the last 7 days.

Burden of Back Pain, and Impact of Back Pain and Treatment on Relationships were able to significantly discriminate according to levels of pain right now, and how patients rate their health. Whilst these results provide further evidence for the discriminative validity of the CLBP Treatment Satisfaction Questionnaire, some domains did not significantly discriminate according to levels of pain right now and how patients rate their health. One possible reason for this is that patients rating of health and pain right now may not have captured sufficient spread of scores (e.g. patients may not have been experiencing pain at the time they completed the questionnaires). Further research could explore other variables that may better reflect the discriminative validity of the CLBP Treatment Satisfaction Questionnaire, for example. pain in the last 24-hours.

Moreover, it should be noted that the Levene's test of homogeneity of variance for Impact of Back Pain and Treatment on Relationships with level of pain right now reached statistical significance, suggesting that the variances between the groups were not the same. Similarly, the Levene's test reached statistical significance for Problems with Side Effects of Back Pain Medication with pain in the last seven days, as well as with how patients rate their health. These results indicate violation of one of the assumptions of the ANOVA test used in this study to assess differences between groups for discriminative validity. Future research could explore the discriminative validity of these domains using modified procedures that do not assume equality of variance if necessary.

6.5.12 Test-Retest Reliability

Change between baseline and week 2 scores for all domains tested of the CLBP Relief Treatment Satisfaction Questionnaire did not reach statistical significance for all domains except Information About Back Pain and Treatment, and Adherence to Physiotherapy. These results are not surprising, since the test-retest sample was composed of patients who had been referred by an ESP to physiotherapy or a pain clinic.

Such patients would have completed the baseline assessment prior to their first consultation with the physiotherapist, and then their second assessment approximately 1 week later. During this time, the physiotherapist or pain specialist would have educated them about good back care and provided information about their condition, treatment options, posture and positioning, and the importance of remembering to do their exercises, setting realistic goals, and pacing activities. Therefore, given this patient group, change in scores on the Information about Back Pain and Treatment and Adherence to Physiotherapy domains are expected.

Note that test-retest reliability could not be calculated for the Problems with Side Effects of Medication domain since sample sizes were far too small, with only two patients reporting problems with the same side effects at baseline and at week 2. Again, this is not surprising since the experience of symptoms and side effects is highly variable and can change within hours or days (Stull et al., 2009).

Whilst some evidence for test-retest reliability was demonstrated for some domains, it is important to acknowledge that inconsistencies may be due to the person, the instrument, or the context, and there are various factors that may contribute to distorting results. One such factor is the sample size. Samples should be representative of the target population and comprise at least 100 participants (Kline, 2000). Unfortunately, such a sample size was not feasible in this study where the majority of patients were recruited from the Back Show in London and follow-up was not possible. Further, the test-retest sample was originally 35, of which only 17 were classified stable based on the fact they reported their health was ‘about the same’ since the start of the study.

In addition, timing between the two assessments is often debated, with some recommending a three-month period of test-retest reliability (Kline, 2000), and others suggesting a much shorter time difference between the experience and the rating of an experience in order to minimise the difficulty as well as increase precision and accuracy of recall (Stull et al., 2009). The concern with shorter recall periods relates to exposure to recall bias in which patients may remember their responses on the first assessment and learning effects may be observed. This may have been the case for statistically significant mean differences that were observed between baseline and Week 2 for Information about Back Pain and Adherence to Physiotherapy; the effect observed may be a result of real differences between the two assessments or to error such as learning or fatigue effects.

In this study, the rationales for assessing test-retest reliability between baseline and week 2 were two-fold. First, since follow-up patients were recruited from physiotherapy and pain clinics, assessments had to be scheduled around appointments with minimal interruption to the daily treatment and care of patients. Thus, having patients complete the first assessment at the clinic prior to their first consultation and again whilst they waited for their second consultation seemed most appropriate. Second, test-retest reliability scores assume that patients' health status remains unchanged and ideally that patients are not receiving treatment (Kline, 2000). Thus, a one-week time difference at the very start of physiotherapy or attendance to a pain clinic was considered appropriate because it was anticipated that patients' CLBP would not have changed over this time. However, even with assessment of patients at baseline and week 2 based on clearly defined rationale, variability between the time points for assessments per individual was incurred, with some having the second assessment at day 8 since start of study and some as late as day 12 or 13. Furthermore, although CLBP is defined as pain lasting 3 months or longer, the intensity of the pain may vary by day or even by hour. In addition, it was recognised that patients would be taking medication to help with their pain on an as required basis and naturally would have started physiotherapy consultations or attendance to the pain clinic, so these factors may have confounded results.

One other possible reason for distortion of test-retest reliability is that there is a problem with the scales or in accurately recording the results. Alternatively, patients' psychological states may have contributed to variability in the percentage of agreements between baseline and week 2, especially since depression and anxiety are associated risk factors of CLBP (see section 1.4). Further, as with administering any type of questionnaire, environmental factors may also have influenced individual responses and contributed to inconsistencies. For example, noise and interruptions during assessments, personal factors the individual may have encountered such as problems at work or stress, as well as possible life changes that may have occurred for individuals between baseline and week 2.

Nevertheless, despite all these potential confounding variables, this study provides some evidence of test-retest reliability for Burden of Back Pain and Satisfaction with the Treatment Process domains based on a small sample size. However, future studies should explore test-retest reliability for all domains using a larger sample size (ideally 100 or more) and especially for those domains not tested in this study such as Problems with Side Effects and Impact of Back Pain on Relationships, or where ICCs were poor such as for Adherence to Physiotherapy.

6.5.13 Responsiveness

The findings from this study suggest that some of the CLBP Treatment Satisfaction domains are sensitive to change over time. Specifically, mean changes between baseline and week 6 were positive for the improved group for all domains tested (note sample sizes were too small to test Problems with Side Effects of Back Pain Medication and Impact of Back Pain and Treatment on Relationships domains).

Statistical significance was reached for all domains except the Satisfaction with Back Pain Treatment Process and the Medication Acceptability domains. Lack of statistical significance may in part be explained by the small sample sizes. Although there were 31 patients who completed satisfaction data at baseline and at week 6, the number of those classified as ‘improved’ ranged from 11 to 16. These small sample sizes occurred because exploring sensitivity to change over time was not the main purpose of this study and follow-up was only implemented in a small subgroup of patients (those recruited from physiotherapy and pain clinics or hospitals). Further research could explore responsiveness of the CLBP Treatment Satisfaction Questionnaire with larger sample sizes to determine whether these differences are statistically significant.

Where statistical significance was obtained, effect sizes were calculated to establish the magnitude of the difference. Effect sizes ranged from -0.36 for the Burden of Back Pain domain to -0.73 for the Information Provided About Back Pain and Treatment domain. According to Cohen (1977), these effect sizes generally show moderate to large change, suggesting that the differences that occurred between baseline and end of study for these patients were clinically meaningful.

6.5.14 Factors Associated with Treatment Satisfaction in Patients with CLBP

Significance was reached for all MLR models except the Problems with Side Effects of Back Pain Medication and the Medication Acceptability domain. One possible reason for non-significance was the sample size, which was only 32 for the Problems with Side Effects of Back Pain Medication domain. Further research should explore predictors of these variables using larger sample sizes.

In addition, the exploratory analyses using the CLBP Treatment Satisfaction Questionnaire, which is based on patient’s subjective experiences, have shown that there are several related factors. Whilst these factors can be considered by HCPs to tailor medication management and physiotherapy programmes, further research is warranted to confirm with greater certainty, associations between pain, demographic/treatment variables and treatment satisfaction in CLBP. For example, in this study, patients were asked to describe which category best describes their ethnic origin from the following options: White, Black, Asian or Other. On reflection, ethnicity was measured in a rather crude way and this is a weakness of the study. A more acceptable way for future studies is to use a commonly used classification such as the 17 categories of ethnic origin based on the UK census (Office for national statistics, 2001).

Further, for the purpose of standard MLR and due to the low numbers for some categories, the results were then collapsed. For example, with regard to ethnicity, categories were collapsed into white and non-white. This approach is often used in cases where there are insufficient numbers in each cell (Amponsah-Afuwape, Myers, & Newman, 2002). Consequently, the sample size was 208 for white and 27 for the non-white group. It is important to acknowledge that the sample size can have an effect on tests of statistical significance. For example, Allison (Allison, 1999) states: “With a sample of 60 people, a correlation has to be at least .25 (in magnitude) to be significantly different from zero (at the 0.5 level). With a sample of 10,000 people, any correlation larger than 0.2 will be statistically significant.” However, what constitutes a large or small sample is ambiguous. Whilst the overall larger sample size is considered adequate for standard MLR (Tabachnick & Fidell, 2001), it may in part be contributing to the significance of the mean differences.

Closer examination of the data reveals that the mean differences and SDs between the white and non-white group are small, and this is confirmed by small ES. In line with Allison’s recommendations, whilst such statistical significant coefficients and ES should be taken seriously, the non-significant outputs in other standard MLRs performed in this study are weak evidence for the absence of an effect (Allison, 1999). Thus further research is recommended to explore the role of ethnicity on treatment satisfaction in CLBP, with greater consideration regarding the measurement of ethnic origin.

Further, the MLRs performed should be considered exploratory in that there was no attempt to adjust for multiple testing. Therefore, further research is needed to replicate these findings using a different dataset. Other studies could also consider stratifying the data according to these key predictor variables to establish the direction of the associations or explore mediating and moderating factors.

6.5.15 Response Rate

Of the 485 questionnaires despatched, 249 were returned, representing a 51.3% response rate. There is little in the literature as a bench mark of what constitutes an ‘acceptable’ response rate for treatment satisfaction studies, based on good rationale and empirical evidence (Sitzia & Wood, 1998). However, a systematic review of 210 studies from 1994 that explored response rates in patient satisfaction research indicated that response rates range between 25% to 98% (Sitzia & Wood, 1998). These findings suggest that the response rate for this study is satisfactory. Further, the response rate can be deemed acceptable given that the main aims of this study were to test the psychometric properties of the newly developed questionnaire and explore factors associated with treatment satisfaction in CLBP, where the issue is more a case of whether sufficient sample size has been obtained and whether associations between various factors would be different in larger populations, rather than describing satisfaction levels and establishing whether the satisfaction level is dissimilar to larger populations (Sitzia & Wood, 1998).

Also, whilst the response rate shows that 48.7% did not respond, the 51.3% response rate can be considered reasonable given the diverse recruitment sites employed. For example, examination of response rates by recruitment sites reveals that there was a higher response rate for individuals from the Back Show compared to those recruited from physiotherapy departments or attending pain clinics. This is unsurprising since people attending the Back Show are inclined to be interested in understanding their back pain and therefore more willing to participate in CLBP research. Further, pain clinics are designed to tackle psychological barriers associated with CLBP (e.g. managing stress from work, dealing with relationship problems, unemployment etc.), so it may be that patients from pain clinics were less motivated to participate in research. Further, recruitment at the Back Show involved two full-time dedicated researchers (DR and a trained researcher) whose primary role and purpose was to invite individuals who met all of the inclusion and none of the exclusion criteria to take part; therefore, personal contact with researchers may help explain the higher response rate obtained from Back Show participants (Sitzia & Wood, 1998; see for example, Sitzia & Wood, 1997 for details regarding social desirability effects).

The non-response rate may partially be accounted for by the fact that this was an unfunded study. In most cases, HCPs agreed to support the study as a ‘gesture of good will’, but may not have prioritised recruitment due to the competing factors of busy clinics, other commitments, etc.

Another possible explanation for non-response is that even though the patient information sheet emphasised that patients’ participation would in no way affect the treatment and care they receive, patients may have been reluctant to take part, especially since this study focuses on treatment satisfaction. Alternatively, it may be that only satisfied patients took part, or perhaps those with ‘worse’ health states did not want to take part, or even that responders and non-responders differed according to demographic or clinical characteristics. Further research could attempt to explore such differences in patients with CLBP participating in treatment satisfaction research.

6.5.16 Study Strengths and Limitations

Study III has several strengths. It uses an instrument that was developed based on extensive qualitative research from in-depth interviews with patients who have CLBP. Therefore, the instrument captures sensitive issues relevant to these patients as they pertain to treatment satisfaction. The items and response options underwent rigorous cognitive debriefing to ensure that patients understood what was being asked of them and to rectify any ambiguity in format or wording. It then follows that the instrument demonstrates some evidence of reliability, validity and responsiveness. Using this instrument to quantify treatment satisfaction according to seven domains (Burden of Back Pain, Information Provided about Back Pain and Treatment, Impact of Back Pain and Treatment on Relationships, Problems with Side Effects of Back Pain Medication, Satisfaction with the Back Pain Treatment Process, Adherence to Physiotherapy, and Medication Acceptability), it was then possible to explore potential factors that may predict treatment satisfaction with CLBP, and results were insightful. However, it is essential that they be interpreted with an understanding of the current limitations of the data and methodological considerations.

Firstly, the sample is representative of people with CLBP who are in receipt of services or who attended the Back Show in London in 2008. That is, people were invited and agreed to participate and therefore the data obtained is based on those who are receiving treatment, who are more likely to adhere to their medication regimes and have a level of satisfaction with their back pain medication. There is insufficient understanding of CLBP treatment and satisfaction issues in the general population.

Future research should investigate satisfaction and subjective experiences with back pain medications and physiotherapy between patients who adhere and those who do not adhere to their medication regimes.

Also, as with surveys in general, it is difficult to ensure consistency amongst the sample. Whilst every attempt was made to operationally define terms used in the CLBP Treatment Satisfaction Questionnaire, not everyone will have understood or responded to the items in a way that is consistent with everyone else.

Some of the questions required that the responses be categorised for meaningful use (for example, the response options to the item 'Compared to the way you felt at the start of the study, please rate the degree of change in your health on the following scale: very much worse, moderately worse, a little worse, about the same, a little better, moderately better, very much better, were collapsed' to 'worse', 'stable' and 'improved'). Because of this, it is inevitable that some of the responses were lost.

Also, there was no control for the Hawthorne effect (obtaining positive outcomes from patients as a result of being made to feel important as part of the research). Consequently, HCPs' involvement and interest in the distribution of survey packs that contain a measure of patients' satisfaction with their back pain medication and/or physiotherapy may have led patients to give more positive ratings. However, a number of HCPs were involved in the distribution of this survey, and this bias would have been minimised.

The response rate was 51.3%, as discussed in section 6.5.2. It should be noted that the follow-up groups are significantly smaller than the cross-sectional groups. Part of this can be explained by the fact that follow-up was only pursued in physiotherapy, pain clinic and hospital settings. Much of the sample was recruited from the Back Show, where follow-up was not feasible. Nevertheless, there were 35 patients at week 2 and 31 patients at week 6. Such sample sizes mean that the results should be interpreted with caution and should be considered exploratory; there is a need to further explore test-retest reliability and responsiveness of the CLBP Treatment Satisfaction Questionnaire.

As the study was based on patients' self reports, there were issues such as recall bias and respondent honesty. Some items referred to previous experiences with treatment and retrospective items are open to bias through distortions of memory, which might have affected the accuracy of the reporting (Stull et al., 2009). However, attempts were made to standardise responses and ensure that, for example, people with a case-note diagnosis of learning disabilities were excluded from the study.

This study has reported on the influence of one factor such as ethnic origin and its effect on patients' satisfaction. However, isolation of factors is pragmatically impossible due to their inter-relation. Therefore, there are always potential confounders and it becomes difficult to differentiate between whether factors are moderators or mediators.

Further, ethnic origin was measured rather crudely and this is a weakness of the study. Patients were asked to describe which category best describes their ethnic origin from the following options: White, Black, Asian or other. Future studies should consider use of a commonly used classification such as the 17 categories of ethnic origin based on the UK census (Office for national statistics, 2001) (see section 6.5.14 for further discussion).

6.6 Conclusions

This study provides some evidence to support the reliability and validity of the CLBP Relief Treatment Satisfaction Questionnaire that provides insight into patients' experiences of back pain and treatment. It is a useful instrument for future longitudinal studies and may be helpful in clinical practice to facilitate treatment decision making.

Further testing is warranted to confirm the psychometric properties of the instrument. In particular, further research should consider the test-retest reliability of the instrument in a larger sample size.

Chapter 7- Discussion

7.1 Overview of Research

The aim of the research presented in this thesis was to develop an instrument to measure treatment satisfaction and dissatisfaction in patients with CLBP that is supported by evidence of reliability and validity. In pursuing this aim, the thesis had three objectives:

1. To establish the research performed to date in the field of treatment satisfaction in CLBP.
2. To explore patients' subjective experiences with CLBP and its treatments, as well as satisfaction and dissatisfaction with treatments.
3. To develop a new instrument to measure treatment satisfaction in CLBP, and to explore its psychometric properties.

This Chapter summarises for each of these objectives the main findings, strengths and limitations of the studies, and possible future directions. Findings suggest treatment satisfaction and dissatisfaction in CLBP can be viewed on a continuum, which as a dependent variable involves a multi-dimensional appraisal process of the following domains: 'Information Provided about Back Pain and Treatment; 'Burden of Back Pain'; 'Impact of Back Pain and Treatment on Relationships'; 'Satisfaction with the Back PainTreatment Process'; 'Problems with Side Effects of Back Pain Medication'; 'Adherence to Physiotherapy'; and 'Medication Acceptability'. Furthermore, there was some evidence to suggest that these factors were significantly associated with various patient and clinical characteristics. 'Information about Back Pain and Treatment' was significantly associated with involvement in treatment decisions and academic qualifications. 'Burden of Back Pain' was related to pain as measured by the total score of the McGill Pain Questionnaire, pain severity in the last seven days, whether patients took time off from work in the last four weeks due to back problems, duration since CLBP diagnosis, and ethnicity. ‘Impact of Back Pain and Treatment on Relationships’ was significantly associated with whether patients took non-opioid and opioids, duration since CLBP diagnosis, and academic qualifications. ‘Satisfaction with the Back Pain Treatment Process’ was significantly related to involvement in treatment decisions and whether patients took opioids. ‘Adherence to Physiotherapy’ was significantly linked to ethnicity, duration since CLBP diagnosis, and whether patients took opioids.

More studies are required to confirm these findings using the validated instrument. However, the CLBP treatment satisfaction questionnaire can be used to help identify aspects of treatment that may require change, as well as to help with the planning of new medications or physiotherapy programmes.

In addition, more theoretical and empirical research is needed to develop a shorter instrument for use in clinical practice that can help identify aspects of treatment in CLBP that may require change. The shorter version of the instrument might also be used to establish the association with adherence, and could be used to screen for patients who may not be adherent, thereby facilitating treatment decision making and medication management.

7.2 Objective 1

To establish research performed to date in the field of treatment satisfaction in CLBP

Systematic Review: Satisfaction and Dissatisfaction with Treatments for CLBP

Main Findings

- Twenty-six studies were included in the review that investigated treatment satisfaction and dissatisfaction in CLBP.
    - Of these, none of the studies operationally defined the term treatment satisfaction or dissatisfaction in CLBP, or proposed a conceptual framework or model to help visually represent and theoretically understand what comprises the concepts of interest.
    - None of the studies specified whether treatment satisfaction and dissatisfaction was considered an independent or dependent variable, or whether it was uni-dimensional or multi-dimensional.
- All but one of the 26 studies reported satisfaction data from the patient's perspective. The one study that didn't used a telephone interview method.
- The satisfaction outcome measures of PRO studies were diverse and differed in the number of items included and the rating scale.
    - For example, two studies by the same author used the Cherkin and MacCornack satisfaction questionnaire, which has a 5-point Likert response scale (Nyiendo et al., 2000; Nyiendo et al., 2001) and others

    used a global satisfaction item (See for example, Buchner et al., 2006; Licciardone et al., 2003).

    - Even the global satisfaction items had diverse foci; for example, one study used a global satisfaction rating that focused on pain relief (Katz et al., 2005), while another measured back satisfaction (Holm et al., 2003).
    - Response scales also varied from 5-point Likert-type scales (See for example, Buchner et al., 2006; Buchner et al., 2007; Buchner et al., 2007), visual analogue scales that ranged from 0 to 10 or 0 to 100 (See for example, Groessl et al., 2008; Haas et al., 2005), or scales with four options (extremely satisfied, satisfied, neutral, and extremely dissatisfied) (See for example, Shirado et al., 2005).
    - The Cherkin and MacCornack questionnaire was the only multi-item questionnaire used. However, the items of the questionnaire were developed retrospectively in 1991, based on focus groups with patients who mainly had CLBP but also based on clinical judgement. The questionnaire could not be obtained for closer examination of the content, and there were few data regarding the validation of the instrument.
- There were also various methodological limitations within the 26 studies which may have led to bias and therefore restricted the generalisation of results.
    - For example, the criteria for patients with CLBP varied between studies. Sometimes CLBP was referred to as pain lasting ≥ three months or ≥ 3 months constant/intermittent LBP (See for example,

Licciardone et al., 2003; Barker et al., 2008; Buchner et al., 2006) or in some instances ≥ 3 months continual/recurrent LBP (See for example, Mannion et al., 1999). However, one study defined CLBP as having had pain for ≥ 6 weeks (Nyiendo et al., 2000).

Strengths

The main strength of the systematic review was that it synthesised evidence from the literature specific to treatment satisfaction and CLBP.

Limitations

The main limitation of the review was that the findings were based predominantly on published literature identified via electronic databases and some hand searches.

Future research

- More studies are needed to establish what treatment satisfaction and dissatisfaction means to patients with CLBP.
- A new instrument is required to measure treatment satisfaction and dissatisfaction in patients with CLBP. This instrument should be based on patients' opinions and subjective experiences, and should be validated psychometrically in the population of interest.

7.3 Objective 2

To explore patients subjective experiences with CLBP and its treatments, as well as satisfaction and dissatisfaction with treatments.

Qualitative Study: Satisfaction and Dissatisfaction with Treatments in Patients with CLBP

Main Findings

- Thematic analysis of in-depth interviews with CLBP patients about their subjective experiences with treatment (medications and physiotherapy) found the following main themes and sub-themes:
    - Pain (duration, severity, and tolerability)
    - Symptoms (slicing, twinge, pins and needles, stabbing, numbness, swelling, and burning)
    - Physical (functioning and activities of daily living)
    - Social functioning
    - Emotional (anxiety, fear of movement, worry, uncertainty about the future, depression, motivation, embarrassment, annoyment, frustration, irritability, misery)
    - Confidence (lack of confidence, cautious)
    - Sleep (quality, difficulty, awake)
    - Tiredness
    - Relationships
    - Sex life
    - Self esteem

- For patients with CLBP receiving physiotherapy and taking medications on an as required basis, satisfaction and dissatisfaction with treatments is a multidimensional concept.
    - Treatment satisfaction was described by patients positively in terms of receiving the correct diagnosis, being ‘happy’ or ‘pleased’ with treatment, maintaining general health, and returning to normal functioning such as carrying out everyday activities or going to work.
    - Treatment dissatisfaction is associated with negative aspects of treatment such as being misdiagnosed or undiagnosed, having lack of trust and confidence in clinicians, and lack of information about back pain and its treatments. Communication with healthcare professionals is important and treatment dissatisfaction is also related to lack of empathy and lack of active listening from HCPs. Ineffective treatment that did not remove or minimise the back pain, and consequently did not enable patients to return to normal functioning (thus impacting HRQoL) was also associated with treatment dissatisfaction. Other key factors of treatment dissatisfaction included experiencing side effects and how much of a problem they were, inconvenience of treatment regimens, lack of regard for patients’ preferences in terms of treatment characteristics.

Strengths

The main strengths of this qualitative study were:

- It provides an understanding of subjective experiences of treatment (medication and physiotherapy) in CLBP, and opinions' regarding what constitutes treatment satisfaction and dissatisfaction from patients' perspective, using non-leading questions and probes during the interview and a rigorous inductive and data driven process of thematic analysis.
- Saturation and an exhaustive dataset was achieved with ten interviews allowing the development of:
    - A conceptual model to make sense of the various components of CLBP and associations between concepts.
    - A proposed operational definition of treatment satisfaction and dissatisfaction of treatments (medication and physiotherapy) in CLBP based on a thematic map that forms a visual representation of the key themes and sub-themes – neither of which have been documented in the literature to date.
- A homogenous sample was obtained where patients shared common criteria: having CLBP (pain lasting ≥3 months), taking medication, and receiving physiotherapy.

Limitations

The limitations of this study were:

- The use of a purposive homogenous sampling strategy may in part explain a sample comprised of mainly females, of narrow age range and occupational background.

Future Research

Future research would be strengthened by the following:

- An instrument of treatment satisfaction and dissatisfaction with CLBP is needed to quantify the concepts in cross-sectional and longitudinal studies. The development of the instrument should be based on:
    - An operational definition of the concept formed from patients' opinions.
    - A conceptual framework that allows the pre-specification of hypothesised associations between items and domains (factors) a priori.
    - Good psychometric properties demonstrated within cross-sectional and longitudinal samples.
- A wider range of concepts linked to CLBP need to be assessed quantitatively. Treatment satisfaction and dissatisfaction should also be assessesd to establish factors associated with the concept.
- Additional qualitative studies could explore subgroups and identify thematic variability within a sample to establish the cohesiveness of themes/subthemes and its association to sample heterogeneity.
- Studies using other purposive sampling strategies could be considered and may provide alternative insights into patients' subjective experiences. For example, maximum variation sampling could help to establish central themes across patient variations such as patients with CLBP of different ages, or those with different occupational backgrounds. Alternatively, extreme case

sampling could help consider patients' subjective experiences or the concept of treatment satisfaction in cases which are unusual or special in some way. For example, one might expect that patients with CLBP who were misdiagnosed or undiagnosed on several occasions are likely to have different experiences.

7.4 Objective 3

To develop a new instrument to measure treatment satisfaction in CLBP, and to explore its psychometric properties.

Development and Psychometric Validation of the CLBP Treatment Satisfaction Questionnaire

Main Findings

- Based on qualitative analyses, the initial questionnaire had six broad categories:
    - 'Information Provided to You About Back Pain and Treatment'
    - 'About Your Medical Care'
    - 'Your Health'
    - 'Beliefs About Your Back Pain Medication'
    - 'Side Effects from Back Pain Medications'
    - 'Satisfaction with Treatments for Back Pain'
- Cognitive debriefing interviews of the 113-item questionnaire provided evidence of face and content validity.
    - Patients with CLBP liked the questionnaire and felt it was relevant to them, and all items were well understood.

    - Twenty-six items were deleted because they overlapped with other items in the questionnaire.
- The PCA found seven factors that explained 52% of the total variance. The factors were labelled following close examination of the items:
    - ‘Information Provided About Back Pain and Treatment’
    - ‘Burden of Back Pain’
    - ‘Impact of Back Pain and Treatment on Relationships’
    - ‘Problems with Side Effects of Back PainTreatment’
    - ‘Satisfaction with the Back PainTreatment Process’
    - ‘Adherence to Physiotherapy’
    - ‘Medication Acceptability’
- There were eight items that did not load on any factor and were therefore not included as part of the domain scores:
    - ‘I was misdiagnosed’
    - ‘I was not involved in treatment decisions’
    - ‘I went out of the home’
    - ‘I could bend down’
    - ‘I had an ache in my back when I woke’
    - ‘My back pain medication is helpful to me’
    - My back pain medication enables me to be independent (carry out everyday activities)’
    - ‘I altered the amount of medication I took’

- Additional psychometric testing provided evidence to support the reliability and validity of the questionnaire:
    - All seven domains of the questionnaire had satisfactory internal consistency, exceeding Nunnally's threshold of 0.70 (Nunnally, 1978).
    - All seven domains showed low to moderate correlations with both the SF-36 and the PETS, providing evidence to support concurrent validity.
    - All seven domains were able to discriminate between levels of pain in the last seven days with statistical significance being reached for all domains except 'Information about Back Pain and Treatment', and 'Adherence to Physiotherapy'. Higher levels of pain were associated with less overall satisfaction.
    - In terms of test-retest reliability, although the sample size for stable patients was small, there was some evidence to support the reproducibility of some domains (Burden of Back Pain and Satisfaction with the Treatment Process). As expected, mean differences between baseline and week 2 were small and did not reach statistical significance for all domains except 'Information Provided about Back Pain and Treatment'. Pearson's correlation coefficients ranged from 0.30 for 'Adherence to Physiotherapy' to 0.71 for 'Burden of Back Pain', and ICCs exceeded 0.70, indicating adequate confidence in test-retest reliability (Kline, 2000) for 'Burden of Back Pain', and 'Satisfaction with the Treatment Process' domains. However, ICCs were poor for Information About Back Pain and its

    Treatment, Medication Acceptability, and Adherence to Physiotherapy. Further, test-retest reliability could not be calculated for Problems with Side Effects and Impact of Back Pain on Relationships domains.

  - Responsiveness analyses provided some evidence that the following domains of the questionnaire were sensitive to change over time: ‘Burden of Back Pain’, ‘Information about Back Pain and Treatment’, and Adherence to Physiotherapy’. As expected, mean changes between baseline and week 6 were positive for the improved group, and effect sizes were generally moderate, ranging from -0.36 to -0.71.

- Standard multiple linear regressions showed that different patient and clinical factors were associated with the domains of the CLBP Treatment Satisfaction Questionnaire. The variances explained for each domain ranged from 14% for ‘Adherence to Physiotherapy’ to 53% for ‘Burden of Back Pain’, and ‘Impact of Back Pain and Relationships on Treatment’).

Strengths

The main strengths of this study were:

- It used an instrument developed based on extensive qualitative research from in-depth patient interviews with patients with CLBP, and therefore captures important and sensitive issues relevant to these patients pertaining to treatment satisfaction.
- The items and response options of the questionnaire were tested by rigorous cognitive debriefing to ensure patients understood what was being asked of them, and to rectify any problems with item wording or responses.

- The instrument demonstrates some evidence of reliability and validity based on a homogoneous sample of patients with CLBP and clearly defined and pre-specified inclusion and exclusion criteria.
- Using the well developed and validiated instrument, potential factors associated with each domain of treatment satisfaction were identified.

Limitations

The following limitations should be considered:

- The sample is representative of patients with CLBP who are in receipt of services or who attended the Back Show in London in 2008.
- The sampling was purposive and the sample size was quite small for the number of items included in the PCA.
- Although there was some evidence of test-retest reliability, the sample size of stable patients was well below 100 (n=17), and test-retest reliability could not be calculated for Problems with Side Effects or Impact of Back Pain on Relationships due to insufficient sample sizes. Further, ICCs were poor for some domains e.g. Medication Acceptability.
- The sample size of improved patients was also small at follow-up and well below an acceptable sample size for responsiveness analyses.
- Ethnic origin was measured rather crudely in this study (White, Black, Asian and other) and is a weakness of this study. Therefore, MLR analyses related to this should be considered with caution.
- The response options for some questions were collapsed to allow for analysis, and it was inevitable that responses to some questions were lost.

- There was no control for the Hawthorne effect, so HCPs' involvement in the the study may have contributed to some bias in scores.
- As a PRO study, the results are subject to recall bias and respondent honesty.

7.5 Implications of Research

The results of these studies point towards a need for the continued treatment and care, and a need for a holistic approach that can support patients not only with the pain experienced, but also with regard to all other related aspects such as physical functioning, and relationships. Further, it is apparent that patients require more information about their CLBP, the possible side effects incurred from medication, and the various treatment options available. Thus HCPs could try to incorporate an educational component to patients' treatment and care. In addition, since patients find side effects of medication problematic, HCPs could help facilitate discussions with patients in order to establish whether patients are taking medication as recommended and to consider whether other medications may be more suitable given the side effects and impact incurred. A similar approach can be implemented as it relates to aspects of physiotherapy such as pacing and goal setting. Such discussions may also facilitate the HCP-patient relationship and increase treatment acceptability.

Further, whilst there are various services available to patients (e.g. medications, physiotherapy, pain management programmes etc.), how patients access them needs to be further considered. For example, during qualitative interviews (see section 4.4.2), some patients reported that they had been misdiagnosed by the doctor, or that the doctor did not know what was wrong with them. These findings were supported by quantitative responses to items from the CLBP Treatment Satisfaction Questionnaire, where nearly a quarter of patients reported they were misdiagnosed (see section 6.4.3). Therefore, there is a need to re-assess and standardise the screening process at each stage within the NHS to ensure everyone with CLBP symptoms receives appropriate support and care as efficiently as possible.

HCPs must also be educated regarding issues associated with patients’ subjective experiences and the patient burden of CLBP and its treatment, so that patients are indeed offered the most appropriate treatment and care as efficiently as possible. The results of these studies should be communicated to HCPs at key target audiences at conferences and published in peer-reviewed academic journals. This would get important messages to key stakeholders at local and national levels within the UK (e.g. decision makers at the Department of Health / National Institute of Clinical Excellence, as well as HCPs, GPs and hospitals), which in turn may help support and/or influence decision making.

7.6 Future Research

Future research could move forward in two main ways. The first is with regard to the development of the CLBP Treatment Satisfaction Questionnaire. Additional studies could be performed to confirm the factor structure of the CLBP Treatment Satisfaction Questionnaire and further explore its psychometric properties in a larger study using the same inclusion and exclusion criterias for patients as in studies II and III. Studies could also be implemented to linguistically validate the instrument for use internationally. These studies should ideally involve the same kind of approach as in this thesis, i.e. in-depth interviews with patients in each language to confirm the content validity, followed by cognitive debriefing interviews to establish face and content validity, and then assessment of the measurement properties.

The instrument could then be used to help demonstrate burden of illness and problems with existing treatments (medications and/or physiotherapy) to key target audiences and help them consider what aspects of treatment may require change in patients with CLBP. This information may also be useful for planning new medical products for patients with CLBP, as well as helping to improve the healthcare delivery system for patients with CLBP.

In addition, a shorter version of the CLBP Treatment Satisfaction Questionnaire could be devised for use in clinical trials or alternatively to be used in clinical practice to facilitate treatment decision making and help with medication management programmes such as physiotherapy regimens. In particular, what is the minimal important difference in treatment satisfaction scores that would necessitate a change in treatment or would constitute a success?

The second way to move forward is with a large interventional study. This study could focus on treatment satisfaction as one of the main outcomes. It would be particularly interesting to explore how treatment satisfaction scores change over time, whether they are associated with behaviours such as adherence to treatment regimens, and the interplay with HRQoL.

The interventional studies could also explore treatment satisfaction and subjective experiences between sub-groups of CLBP patients. For example, whether scores vary between patients receiving physiotherapy versus those attending pain management programmes. In addition, in this study, patients' ethnicity was defined in terms of 'white' versus 'non-white' so additional studies could define ethnicity and further explore the association with treatment satisfaction.

Other studies could also be designed to further explore how demographic, clinical and treatment factors are associated with CLBP treatment satisfaction, as well as how psychological factors such as coping, fear-avoidance behaviour, anxiety, depression etc. may be related to CLBP treatment satisfaction. For example, exploring treatment satisfaction in CLBP according to patients' beliefs, with regard to whether their pain is of organic or psychological nature. The measure of pain beliefs would need to be sensitive to discern the possible stigma associated with unexplained pain.

It would also be interesting to consider whether factors were mediating or moderating factors. All of these studies would need to be sufficiently powered to detect differences, and adjustments would need to be made for multiple testing.

7.7 A Personal Reflection

This section provides an overview of the PhD process with particular attention to what I have learned through carrying out this research, some personal reflection regarding the limitations, how this may have affected the knowledge produced, and further thoughts on how it could be improved in the future.

To set the scene, I feel I should first explain that I have always found the topic of treatment satisfaction intrinsically interesting, and since my B.Sc. days wondered what does the concept mean to patients and how can we capture this to adequately assess it in studies. At that time, my work was focused on patients with schizophrenia and gradually expanded to patients with Alzheimer’s disease, and those with iron overload such as beta thalassemia, sickle cell disease and mylodysplastic syndromes. During these years of research, I realised based on talking to patients and reviewing published literature that there were some common traits but clearly the topic of treatment satisfaction was also different according to the patient’s disease and the type of treatment. With this in mind, and given that a great proportion of individuals experience CLBP, I pursued my interests in this population and this formed the basis of my PhD.

To proceed, during discussions with my PhD supervisor, it became apparent that it would be important not only to read around the concept of treatment satisfaction but also to gain insight into CLBP and patients’ subjective experiences. This was extremely challenging given the wealth of knowledge available for both treatment satisfaction and CLBP. Also, understanding patients experiences was complicated given the many factors that seem to be interlinked, as well as that diagnosis is often difficult given the nature of the condition (whereby sometimes no physical cause can be located), and also there are diverse treatment options available. Nevertheless, the information obtained from electronic databases was collected and summarised appropriately to form Chapter 1 of this thesis. Whilst, it provides a good overview of the various issues related to CLBP, it is important to emphasise that it is in no way comprehensive. For example, as my knowledge in this area has developed, it has become apparent that there are differences in healthcare systems between countries and therefore patients may be diagnosed and treated differently. Future research could consider how these differences are related to treatment satisfaction in CLBP.

Chapter 2 was written to provide an overview of treatment satisfaction and dissatisfaction. Like the topic of CLBP and as mentioned above, this was particularly challenging given the wealth of information available in the literature. However, I think it was an essential part of the process in trying to establish what were the general definitions and theories regarding the concept, where they originated, and what empirical evidence there was to support these. Nevertheless, on reflection, when I embarked on this journey, I expected that I would have all the answers. But the reality was that whilst I gained significant insight into the various issues to help me set the scene for my thesis, I became aware that the concept is very broad and that it simply wasn't practical to expect to capture everything. For example, the field of expectations seem just as broad a concept confounded by similar issues to satisfaction e.g. what constitutes expectations, how can we operationally define the concept and then adequately measure it, and even if we can achieve this, some patients may not feel comfortable to comment on expectations and aspects such as locus of control may also contribute to the picture or patients previous experiences. As I continued to read and learn, it became more apparent that there are many broad concepts such as convenience, preferences, and doctor-patient communication to name but a few, and each of which could form a theses in themselves but also seem to be associated with treatment satisfaction. In order to ensure that this thesis remained manageable, I considered these aspects but tried as much as possible to remain close to the concept of treatment satisfaction.

This approach transitioned into the systematic review, Chapter 3 and influenced the search terms I used to identify papers associated with treatment satisfaction or dissatisfaction in CLBP. My goal was to understand what was treatment satisfaction and how was it measured in studies of CLBP, so I used the terms treatment satisfaction or treatment dissatisfaction with other keywords such as CLBP (see section 3.3.2). I was aware that I could use alternative terms to satisfaction such as attitudes, expectations, preferences, and convenience, but not only would this explode the search to what would be considered not feasible and unmanageable but it also induced other issues. For example, if I used the term attitudes and looked at studies that described positive experiences of treatment, then I felt that I was imposing my subjective thoughts regarding whether that indeed truly constitutes treatment satisfaction. Further, I felt the keywords I used focusing on treatment satisfaction and treatment dissatisfaction were appropriate given my understanding of the literature which suggested that satisfaction was more than a positive feeling or experience but involved an appraisal process or a comparison to a subjective standard (see section 2.2). Despite this, on reflection, whilst I still feel that my approach is acceptable I acknowledge that if I had used alternative terms then other studies that measure treatment satisfaction or treatment dissatisfaction may have been identified. Nevertheless, despite this, I am confident that I captured the main studies from the literature and sufficient to inform how to proceed with the other PhD studies. With this in mind, future studies could consider using alternative terms to consider whether there are other studies not captured within the scope of this PhD but which may provide further insights into definitions and measurement of treatment satisfaction or dissatisfaction in CLBP.

Using the information and knowledge acquired from the literature, the next study documented in Chapter 4 was to explore patients' subjective experiences of CLBP and its treatment, as well as what does treatment satisfaction or dissatisfaction mean to patients. This was a very valuable and insightful exercise on several accounts. For example, it provided me with rich in-depth details from the patient perspective ultimately helping to inform the content and structure of the newly developed questionnaire. But I also learned from the methods employed. One example of this is that whilst the interview guide was intended to be as open-ended as possible by asking questions such as 'What does pain mean to you?' or 'What does the term chronic mean to you?', on reflection, some of the questions were still rather closed such as 'Do you experience symptoms from CLBP?' and then 'If yes, what are they?' Such questions were developed in such a way as to try not to lead patients by not assuming that they do experience symptoms. However, I recognise that by asking questions in this manner, the control of the interview remains predominantly with the interviewer rather than with the patient, and this may have affected the information generated. So, future studies could try to address this matter by using more open-ended questions. Also, the interviews were performed in the hospital for the convenience of the patient. However, I appreciate that the setting in which the interviews are performed could also influence the information that patients provide. Consequently, future studies could consider performing interviews under different environments such as at home or in a neutral area. However, it's important to realise that whatever context the interviews are performed, may have some bearing on the information provided. For example, a home setting may be more familiar to the patient but means less control with regard to potential interruptions during the interview (e.g. door bell ringing or phone call), and also that there may be others at home resulting in less likelihood of disclosing sensitive matters such as how back pain impacts on relationships.

Perhaps another thing I feel I have learned during the PhD is the meaning of purposive sampling within different contexts. I feel I have always recognised the importance of qualitative and quantitative research, and I'm a strong believer that good statistics are not really meaningful if from a qualitative perspective we have not captured all the important concepts and ensured content validity. But despite this strong personal belief, my training in my B.Sc. years was very heavily weighted from a statistical perspective. Consequently, when it came to the sampling strategy for the qualitative study (see section 4.3.1), I adopted a rather restricted style in which I recruited patients who had similar common characteristics such as for example that they had been diagnosed with CLBP and were currently receiving treatment for CLBP or advised to do so. Thus the sampling strategy I adopted was homogenous and I was focused on obtaining theoretical saturation, which resulted in mainly female patients, with narrow age range and similar occupational backgrounds. At this time, I should emphasise that whilst I was always aware that the purpose of qualitative research is not to draw statistical conclusions, I was not aware of the various types of purposive sampling strategies such as maximum variation sampling which would establish central themes across patient variations e.g. patients of different ages and occupational backgrounds. Another alternative is extreme case sampling strategy which would allow exploration of unusual cases or ones that are special in some way e.g. exploring patients experiences of CLBP in those who had been misdiagnosed or undiagnosed, or those who had been advised to take medication every day but did not do so. Employing such sampling strategies in qualitative research would provide even greater insights and future qualitative studies should consider this.

Chapter 5 documents the development and cognitive debriefing process of the newly developed CLBP Treatment Satisfaction Questionnaire. It was really great to develop a questionnaire that patients thought was relevant and which tapped into the key issues related to treatment satisfaction in CLBP. Nevertheless, one challenge I faced was that there were so many relevant aspects that the questionnaire was quite lengthy and covered many topics such as level of pain, the burden of CLBP and impact on relationships, problems with side effects from medications, level of information provided, satisfaction with the treatment process, medication acceptability, and adherence to physiotherapy. In talking to patients and through informal discussions with clinicians it was apparent that there was a need for an instrument that covered all these topics and whereby the instructions, questions and response options were asked in a consistent manner. However, on reflection, I realise that using such an instrument for example within a clinical trial context could be problematic given that pain and functioning are likely to be primary and secondary endpoints and thus by including the CLBP Treatment Satisfaction Questionnaire in its entirety there would be overlap and consequently unnecessary burden to the patient resulting in potential fatigue/responder burden. To overcome this, careful consideration is warranted regarding the endpoints of CLBP clinical trials. Indeed, this instrument has been developed and validated for use in its entirety. However, future research could consider developing a shorter version for the purpose described above.

Also, at this time, I learned just how important cognitive debriefing and pilot testing is prior to using a newly developed questionnaire in any study. Whilst I think the way that the cognitive debriefing was performed is acceptable, I discovered other methods that could be very insightful such as using a think aloud process. This would involve the patient reading out the instructions of the questionnaire, as well as each question followed by its response option whilst completing it. The process of ‘thinking aloud' would indicate where patients were experiencing difficulties, for example, indications of potential problems are if the patient has to re-read a question or the response options, or if they pause for a long time. The think aloud technique could be used in parallel with other methods such as the ones employed in this thesis and future studies could consider this.

During the main study in Chapter 6, I learned many things that I think have positioned me as a knowledgeable researcher and which will no doubt come in good use in future studies. An example of one of these relates to the issue of how best to develop a scoring algorithm for a questionnaire that measures side effects. In this study, PCA was used because the focus was on 'problems' with side effects. However, if it were frequency or incidence of side effects then I would be reluctant to consider PCA because for example there is no clear rationale for why experiencing one side effect may be related to others. I thoroughly enjoyed reading about this topic and realised that alternative scoring algorithms may be more appropriate such as cluster analyses or regressions where the experience of a side effect and/or how much of a problem it is to a patient may help predict for example long-term adherence and in-turn, may help with the efficacy of a medication given that if patients take it as recommended then the medication is likely to work and help reduce pain. Whilst future studies could consider such approaches there will be other potential challenges such as adequately quantifying adherence. Something I learned through reading the literature and also when talking to patients is that adherence appears to be strongly associated with information, and that even if information is provided to the patient, at what point can we be sure that knowledge has been acquired or that knowledge will transition into behaviour? Even if these aspects can be overcome, many patients are fearful of taking medications given the issues of dependency and so either only take medication when they are in excruciating pain or sometimes take medication holidays.

In addition, during the main study, I discovered how difficult it is to assess test-retest reliability and I learned a lot about how to define patients in terms of, for example, stable. I was very proud to capture relevant data to enable test-retest reliability but the data was limited not only in terms of a small sample size, but also in hindsight, there were many factors that could not be controlled for and which may have influenced the ICCs. For example, the second assessment was scheduled one week after the baseline assessment. However, there was diversity in terms of when these patients were seen. For example, some may have been seen on day 8 and others on day 10 or 12. Also, what constitutes chronicity added complexity to the issue because whilst all the patients included in the study had a diagnosis of CLBP defined by pre-specified inclusion/exclusion criteria, pain is a very fluctuating concept. Some patients may have had a constant pain all day everyday which on a scale of 0 for no pain to 10 for worst imaginable pain, was rated as for example 4. Sometimes the pain for these patients may have got worse so their rating would go to for example 8 or 9. Alternatively, some patients may have had excruciating pain all the time (around 9 or 10), every day and for others the pain intensity may have fluctuated from hour to hour within the same day. Also, for patients who have had CLBP for 12 weeks, their experience and perception of pain may be very different to someone who has lived with the pain for say 40 years. All of this would have added to variability in test-retest scores. It should also be emphasised that whilst test-retest reliability was not the primary focus of this study, future research could consider such aspects to further establish test-retest reliability of the CLBP Treatment Satisfaction Questionnaire.

This reflection is in no way a comprehensive account of all the things I have learned during the PhD journey. However, I hope it provides a flavour of some of the challenges I've faced, the rationales behind certain decisions and additional considerations for future research.

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APPENDIX A: List of Reviewed Articles

Barker, K. L., Elliott, C. J., Sackley, C. M., & Fairbank, J. C. (2008). Treatment of chronic back pain by sensory discrimination training. A Phase I RCT of a novel device (FairMed) vs. TENS. *BMC Musculoskelet.Disord., 9,* 97.

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APPENDIX B: Ethical Approval Letter (Study II)

Stockport Research Ethics Committee
Room 181, 1st Floor
Gateway House
Piccadilly South
Manchester
M60 7LP

Telephone: 0161 237 2166
Facsimile: 0161 237 2383
Email: niall.bowcock@gmsha.nhs.uk

07 August 2006

Miss Diana Rofail
Health Psychologist Researcher, Project Manager
Mapi Values Limited
Adelphi Mill
Grimshaw Lane
Bollington
SK10 5JB

Dear Miss Rofail

Full title of study:	Patients' Satisfaction and Dissatisfaction with Treatment(s) for Chronic Low Back Pain: A Qualitative Study
REC reference number:	06/Q1401/41

Thank you for your letter of 21 July 2006, responding to the Committee’s request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

6) Ethical review of research sites

The Committee has designated this study as exempt from site-specific assessment (SSA). There is no requirement for Local Research Ethics Committees to be informed or for site-specific assessment to be carried out at each site.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Application	5.1	24 April 2006
Investigator CV (Dr Lynn B Myers)		24 April 2006
Investigator CV (Miss Diana Rofail)		24 April 2006
Covering Letter	1.0	24 April 2006
Protocol (Appendix A)	1.0	24 April 2006
Patient Screening Script (Appendix B)	1.0	24 April 2006
Participant Information Sheet (Appendix C)	1.0	24 April 2006
Participant Consent Form (Appendix D)	2.0	21 July 2006
Interview Schedules/Topic Guides (Appendix E)	2.0	21 July 2006
GP/Consultant Information Sheets (Appendix F)	1.0	24 April 2006
Participant Information Sheet (Appendix G) (Clinician Information Sheet)	1.0	24 April 2006
Participant Consent Form (Appendix H) (Clinician)	2.0	21 July 2006
Interview Schedules/Topic Guides (Appendix I) (Clinical Interview Guide)	1.0	24 April 2006
Response to Request for Further Information	1.04	21 July 2006
Indemnity Arrangements (UCL) (Sharon George, AON Ltd)		01 August 2005

Research governance approval

You should arrange for the R&D department at all relevant NHS care organisations to be notified that the research will be taking place, and provide a copy of the REC application, the protocol and this letter.

All researchers and research collaborators who will be participating in the research must obtain final research governance approval before commencing any research procedures. Where a substantive contract is not held with the care organisation, it may be necessary for an honorary contract to be issued before approval for the research can be given.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

06/Q1401/41 Please quote this number on all correspondence

With the Committee’s best wishes for the success of this project

Yours sincerely

Dr Effi Eyong
Chair

Email: niall.bowcock@gmsha.nhs.uk

Enclosures:	*Standard approval conditions*
Copy to:	*[Sponsor]* Dr Lynn Myers, University College London
	[R&D Department] Ms Louise Fletcher, Stepping Hill Hospital

APPENDIX C: Patient Screening Script (Inclusion/Exclusion Criteria)

Study Number:

Clinician Identification Number for this study:

Title of Project: Patient Satisfaction and Dissatisfaction With Treatments in Chronic Low Back Pain (CLBP)

The purpose of the screening script is to ensure that patients are eligible to be recruited in the study, based on a set of pre-specified inclusion and exclusion criteria. The following questions should be completed by the clinician prior to information the potential participant about the study and inviting them to participate.

Questions	**Yes**	**No**
1) Has the patient been diagnosed with **Chronic** Low Back Pain (Pain lasting longer than 12 weeks, affecting the lower back, between the bottom of the ribs and top of the legs)?	☐	☐
2) Is the patient currently receiving treatment for CLBP, or have they been advised by their doctor to do so?	☐	☐
3) Is the patient 18 years or older?	☐	☐
4) Is the patient able to understand and communicate in English?	☐	☐
5) Does the patient have known cognitive impairment?	☐	☐
6) Does the patient have any case note diagnosis of co-morbid learning disabilities?	☐	☐
7) Is the patient currently abusing alcohol or illegal drugs?	☐	☐
8) Does the patient have brain injury or any other organic disorder?	☐	☐

For the patient to be considered eligible for recruitment, the ‘Yes’ box must be checked for the first 4 questions (numbers 1 to 4) **AND** the ‘No’ box checked for the following 4 questions (numbers 5 to 8).

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APPENDIX D: Patient Information Sheet (Study II)

March 2006 version 1

Study Title: Patient Satisfaction and Dissatisfaction With Treatments in Chronic Low Back Pain (CLBP)

You are being invited to participate in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. 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 the conduct of the study.

PART 1

1. What is this study about?

The purpose of this research is to investigate patients' experiences with treatments in chronic low back pain (CLBP). To do this, we need to learn more about how people with Chronic Low Back Pain (CLBP) feel about the effects of their condition. This study will collect information on the importance to you of Chronic Low Back Pain (CLBP) symptoms and their effects on you. Also, on whether you are satisfied or dissatisfied with the treatment you are receiving, and what aspects if any could be improved.

This study is in part fulfilment of a PhD at University College London.

2. Why have I been chosen?

You have been invited because you have a diagnosis of Chronic Low Back Pain (CLBP). There will be a total of 10 participants.

3. Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and you will be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

4. What will happen to me if I take part?

If you agree to participate, you will be asked to complete a face-to-face interview with a trained interviewer. The interviewer will ask you about your experience of having Chronic Low Back Pain (CLBP), and your opinion about your treatments. This usually takes no longer than one hour. The researcher will audio tape the interview to minimise the need to take extensive notes, and your doctor will be informed that you had taken part in this study.

5. Will I experience any risks or discomforts if I participate in the study?

There are no risks to participating in this study. You are free to share your questions and concerns during the interview, or to speak to the interviewer following the interview.

6. What if there is a problem?

Any complaint about the way you have been dealt with during this study or any possible harm you might suffer will be addressed. The detailed information on this is given in part 2.

For complaints please contact Diana Rofail on 01625 508897 or email at d.rofail@ucl.ac.uk, or Dr Lynn Myers on 020 7679 9478.

7. Will my taking part in a study be kept confidential?

Yes. All the information about your participation will be kept confidential. The details are included in Part 2.

8. What will happen if don’t want to carry on with the study?

You can withdraw from the study at any time, and the information you provided can be destroyed immediately.

9. What do I do if I have any questions?

If you have any questions about the study, you may call or write to Diana Rofail, Research Psychologist on 01625 578897 or Susan Wagstaff Physiotherapy Services Manager on 0161 419 4065.

Part 1 of this information sheet is complete.

If the information in Part 1 has interested you and you are considering taking part, please continue to read the additional information in Part 2 before making a decision.

PART 2

10. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions (Diana Rofail on 01625 578897). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

11. Will my taking part in this study be kept confidential?

If you join the study, the data collected for this study will be looked at by authorised persons from University College London. The researcher would have your name and contact number but these details will immediately be destroyed following the interview. Thus confidentiality is agreed.

12. What will happen to the results of the research study?

The researchers will look at the results from the interviews for themes and ideas that are important to people who have taken part in the study and this will form the basis of an intervention study to assess satisfaction with treatments in Chronic Low Back Pain (CLBP). The results will be documented as part of a PhD thesis, and may be published in a peer reviewed academic journal, and disseminated at key conferences to health professionals.

13. Who is organising and funding the research?

This study is self-funded and is being conducted in part fulfilment of a PhD at University College London.

If you agree to take part, your doctor will be informed that you are participating in this study but s/he will not be paid for your participation.

14. Who has reviewed this study?

This study has been reviewed and approved by Stockport Ethics Committee.

Thank you for taking time to read this information sheet. You will be given an information sheet and signed consent form to keep.

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APPENDIX E: Patient Consent Form (Study II and III)

Study Number:

Patient Identification Number for this study:

Title of Project: Patient Satisfaction and Dissatisfaction With Treatments in Chronic Low Back Pain (CLBP)

Name of researcher: Diana Rofail

1. I confirm that I have read and understand the information sheet dates March 2006 for the above study. I have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that relevant sections of any of my medical notes and data collected during the study, may be looked at by responsible individuals from the University College London, or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
5. I agree to take part in the above study. ☐

Name of patient	Date	Signature
Name of person taking consent (if different from researcher)	Date	Signature

When completed, 1 for patient, 1 for researcher site file, 1 (original) to be kept in medical records

Patient # ________ (1-10) Date of interview ____________

Gender ________ (M/F)

APPENDIX F: Patient Interview Agenda

Patient Satisfaction and Dissatisfaction with Treatments in Chronic Low Back Pain (CLBP)

1 Introduction

Section length approx. 5 minutes

Introduce yourself by name and Institute of Affiliation. [Tell the service user that the interview usually lasts approximately one hour and ensure that he/she has enough time to participate]

Please read the following to the patient:

“The purpose of this interview is to find out about your experiences with treatment for Chronic Low Back Pain (CLBP) and the impact that it has on your daily life. The information provided by people who take part will allow us to identify themes and ideas that are important to people with CLBP and this will form the basis of an intervention study to assess satisfaction with treatments in CLBP”.

“This conversation will be held in total confidence. None of the information you provide will be associated with your name, and in no way will the information you provide affect you and/or the treatment you receive.”

"Do you have any questions at this point?" *[If yes, please answer the service user's questions]*

"If at any time you do not wish to continue with this interview we can stop at any time. Are you still willing to take part in this interview?" [Obtain oral consent].

Before we begin, I would like to ask you a few questions about you:

1. When were you born?

2. Are you employed?

   Yes ☐ No ☐

   If yes, do you feel your ability at work is affected by your CLBP?

   If no, did you give up work because of your CLBP?

3. Do you have any qualifications?

   Yes ☐ No ☐

4. Do you ever experience CLBP?

   Yes ☐ No ☐

   If yes, how long have you experienced CLBP?

5. Are you currently taking any medications for your CLBP?

Yes ☐ No ☐

If yes, what are they?

Probes:

Oral drugs:

- Analgesics (drugs that reduce pain e.g. aspirin, acetaminophen, and ibuprofen)
- Antidepressants (drugs used for the treatment of depression e.g. Imipramine (Tofranil), amitriptyline (Elavil), and fluoxetine (Prozac))
- Non-steroidal anti-inflammatory drugs (NSAIDS: drugs used to reduce inflammation and pain but not steroids e.g. paracetamol)
- Muscle relaxants (drugs which relieve muscle spasms e.g. Diazepam (Valium) and carisoprodol (such as Soma)

Injection Therapy

- Epidural steroid injections (an injection that delivers steroids directly into the spine)
- Local injections (an injection of local anaesthetics, steroids, or narcotics into affected local tissue)
- Facet joint injections (an injection into the facet joints)

6. Are you currently receiving any other treatments for your CLBP?

Yes ☐ No ☐

If yes, what are they?

Probes:

- Physiotherapy or physical therapy (therapeutic use of massage, exercise, heat, or electricity to relieve pain)
- Cognitive behavioural therapy (talking therapy)
- Osteopathy (manipulation of the skeleton/muscles)
- Chiropractic therapy (spinal manipulation therapy)
- Relaxation therapy
- Intensive multidisciplinary treatment programmes/Combination therapy (please specify)
- Other (please specify)

7. Do you use any substances (e.g. alcohol/cannabis) to help you with your CLBP problems?

Yes ☐ No ☐ If yes, what are they?

2 Chronic Low Back Pain

Section length approx. 5-10 minutes

Ask the patient:

1. What does ‘pain’ mean to you?

2. What does ‘CLBP’ mean to you?

3. What does the term ‘Chronic’ mean to you?

4. What is the cause of your CLBP?

5. Do you experience symptoms from CLBP?

   Yes ☐ No ☐

   If yes, what are they?

6. Do the symptoms of your CLBP impact on your life?

   Yes ☐ No ☐

   If yes, how does CLBP impact on your life?

Probes:

- *Pain/discomfort (how?)*
- *Sleep (how?)*
- *Appearance (how?)*
- *Self-esteem (how?)*
- *Self-confidence (how?)*
- *How you feel about yourself (how?)*
- Daytime activities (what?)
- *Night-time activities (what?)*
- *Social activities (what?)*
- *Sex life (how?)*
- *Relationships (how?)*
- *Dependence (how?)*
- *Mental health – anxiety/depression (how?)*
- *Trust and confidence in the clinician (how?)*

3 Treatments in CLBP

Section length approx. 20-30 minutes

Ask the patient:

1. Why do you take treatment for CLBP?
2. Do you feel involved in treatment decisions?

   Yes ☐ No ☐

   If yes, why? If no, why not?

Medications

Note to the interviewer: If the patient takes medication for CLBP, please ask the following:

1. Please describe what taking medication for CLBP involves on a daily basis from your perspective

Probe** each of the following**:

- Mode of administration (pill/injection)
- Frequency of administration (e.g. once a day/week/month…)
- Time to take medication
- Convenience of taking medication
- Location of administration (e.g. home, hospital, anywhere)

2. Are there any benefits of taking medication for CLBP?

   Yes ☐ No ☐

   If yes, what are they? If no, why not?

3. Does your CLBP medication(s) meet your expectations?

   Yes ☐ No ☐

   If yes, why? If no, why not?

4. Do you feel motivated to take your CLBP medication(s)?

   Yes ☐ No ☐

   If yes, why? If no, why not?

5. Are there any disadvantages to taking CLBP medication(s)?

   Yes ☐ No ☐

   If yes, what are they?

6. Do you experience side effects from your CLBP medication?

   Yes ☐ No ☐

   If yes, what are they?

7. Do you take your CLBP medication(s) exactly as prescribed by your doctor?

   Yes ☐ No ☐

If yes or no, please **probe**:

- Dose
- Frequency
- Time taken

8. Do you sometimes forget to take your CLBP medication(s)?

   Yes ☐ No ☐

9. Do you alter the amount of CLBP medication(s) you get?

   Yes ☐ No ☐

10. Do medication(s) for CLBP impact on your life?

    Yes ☐ No ☐

    If yes, please ***probe*** each of the following:

    - *Pain/discomfort (how?)*
    - *Sleep (how?)*
    - *Appearance (how?)*
    - *Self-esteem (how?)*
    - *Self-confidence (how?)*
    - *How you feel about yourself (how?)*
    - Daytime activities (what?)
    - *Night-time activities (what?)*
    - *Social activities (what?)*
    - *Sex life (how?)*
    - *Relationships (how?)*
    - *Dependence (how?)*
    - *Mental health – anxiety/depression (how?)*
    - *Trust and confidence in the clinician (how?)*

11. Are you able to tell the difference between the symptoms of CLBP and the side effects of your medication?

    Yes ☐ No ☐

    If yes, what is the difference?

<u>Physiotherapy or Physical Therapy</u>

Note to the interviewer: If the patient receives physiotherapy for their CLBP, please ask the following:

1. Please describe what physiotherapy for CLBP involves on a daily basis from your perspective

Probe *each of the following:*

- Community – based supervised exercise or hospital
- Frequency of routine (daily/weekly/monthly)
- Involvement in the planning of the programme
- Involvement in the evaluation of the programme

2. Do you have any expectations of physiotherapy for CLBP?

    Yes ☐ No ☐

    If yes, what are they?

3. Have your expectations of physiotherapy for CLBP been met?

    Yes ☐ No ☐

    If yes, why? If no, why not?

4. Do you continue to exercise after attendance as recommended by your physiotherapist?

   Yes ☐ No ☐

   If no, why not?

5. Do you continue to use the advice given after attendance with your physiotherapist?

   Yes ☐ No ☐

   If no, why not?

6. Have your physiotherapy activity levels been limited?

   Yes ☐ No ☐

   If yes, how?

   ***Probe** each of the following:*

- Pain
- Type
- Family constraints

7. Have the type of activities you participate been affected?

   Yes ☐ No ☐

   If yes, please explain

Cognitive Behavioural Therapy (Talking therapies)

Note to the interviewer: If the patient receives talking therapies for their CLBP, please ask the following:

1. Please describe what cognitive behavioural therapy (cognitive behavioural therapy) involves on a daily basis from your perspective

***Probe** each of the following:*

- Understanding
- Usefulness of CBT materials
- assigned homework exercises

2. Do you have any expectations of CBT for CLBP?

   Yes ☐ No ☐

   If yes, what are they?

3. Have your expectations of CBT for CLBP been met?

   Yes ☐ No ☐

   If yes, why? If no, why not?

4. Do you feel motivated to take part in your CBT programme?

   Yes ☐ No ☐

   If yes, why? If no, why not?

5. Are there any disadvantages to CBT for CLBP?

   Yes ☐ No ☐

   If yes, what are they?

6. Do you perceive your CBT materials as helpful?

   Yes ☐ No ☐

7. Do you do your assigned CBT homework exercises as recommended by your doctor?

   Yes ☐ No ☐

4 Satisfaction with Treatments in CLBP

Section length approx. 10-15 minutes

1. What does 'satisfaction with treatment' mean to you?

2. What does 'dissatisfaction with treatment' mean to you?

3. Are you satisfied with your treatment for CLBP?

   Yes ☐ No ☐

   If yes/no, why?

5 Other Points for Discussion

Section length approx. 5 minutes

Are there any other points that you would like to mention in relation to our discussions on treatment for chronic low back pain (CLBP), its impact on your life, satisfaction, or adherence?

Thank you very much for participating in this interview.

APPENDIX G: Examples of Transcripts of Patient Interviews

Patient Transcript 001
Interviewer: When were you born?
Patient: 1945
Interviewer: Are you employed?
Patient: Yes
Interviewer: Do you feel your ability at work was affected by your CLBP?
Patient: Yes I gave up work because of the pain in my back.
Interviewer: Do you have any qualifications?
Patient: No
Interviewer: Do you ever experience CLBP?
Patient: Yes for ages. Probably 20 years. It doesn't allow you to have a normal life. It happened very slowly and gradually at work.
Interviewer: Are you currently taking any medications for your CLBP?
Patient: Yes. My back really went around Mid September. I got a twist and a lump. It swelled and got worse. It happened very quickly and I got in to bed. After that I couldn't stand, get dressed from down below, so I took really strong pain killers.
Interviewer: When did you experience CLBP?
Patient: The severe part of CLBP was August to September this year. Since then I am on the recovery.
Interviewer: Are you currently taking any medications?
Patient: No, no medications at the moment. I find the side effects are worse than the pain. The pain is in my back, and the pain stops you carrying on. The tiredness and numbness from my CLBP are really bad. But I felt the side effects made me feel as though I was on another planet. The medicines definitely stop the pain, but I was losing days. It went in a blur. You didn't feel you were in control of what was going on. I didn't like the feeling but it did stop the pain.
Interviewer: Do you know what medicines you were taking?
Patient: Yes. Trimladin, Diflopheric, Diazapam, and Cocodomol. It was the Diflopheric which made me spaced. You lay there while things are going on but you cant take things in.
Interviewer: Did you take any injections?
Patient: I had morphine as an injection. It's wonderful. It was the first time I was out of pain for weeks.
Interviewer: Did you experience any side effects from the morphine?
Patient: Not its not a painful process at all.
Interviewer: Are you currently taking any other treatments for your CLBP?
Patient: I'm coming to Physio twice a week and attending the classes. I have also been to the chiropractor. I went for two weeks before coming to Physio. I find physio wonderful.
Interviewer: Have you received any talking therapies?
Patient: Well I go to a talk after the physio classes. It's really good to talk to the staff. They push you through the excercises even though I was crying.
Interviewer: Do you use substances such as alcohol or cannabis to help you with your problems?
Patient: No, not at all.
Interviewer: Moving on to some questions about CLBP. What does 'pain' mean to you?
Patient: Pain is where you can't put up with a feeling your experiencing.
Interviewer: What does CLBP mean to you?

Patient: CLBP means devastation. I can't describe the pain. I would never believe you could experience such agony as what happened. It was worse than having kids. The pain sometimes extends to my legs. You're going through such an experience that I don't remember. All I know is I was experiencing the pain that was unbelievable. Nothing goes in. The pain is just there. Just trying to deal with it and staying calm was all I focused on. I was sweating, my blood pressure went through the roof, and I thought I was going to die. The most horrible experience I've ever had. If anyone saw me in that state I'd curl up and die.

Interviewer: What does Chronic mean to you?

Patient: I can put up with the pain, when it first started and function. I'm not mad but I couldn't deal with it when it was chronic.

Interviewer: What is the cause of your CLBP?

Patient: I haven't got a clue what started it. I can put theories but I can't be sure. The main thing was at work. We had an office and clinic room decorated and there was only the three of us doing moving files, taking things off the walls, and then we had to put everything back. But I don't think I was fit enough to do it. It all started with moving and doing manual stuff. But I never felt anything move out of place.

Interviewer: Do you experience symptoms from you CLBP?

Patient: I get a twinge as symptoms in my back. I get a lot of problems with my leg. If I start doing something I can't continue and that's why I haven't got back to work. They've said I need to get the pain from the leg back into my back.

I'm getting lots of nerve twitches in legs after the excercises they've given me. But I can't carry anything. As I walk I end up dragging my leg. I can't stand either. I get physical problems but associated with leg.

Interveiwer: Do the symptoms of your CLBP impact on your life?

Patient: The symptoms of CLBP stop me from carrying as I would. You don't realise how important it is until something happens. For example, I can't get through my work because I physically can't keep going. I won't give into it though. But as the day goes on, I can't go on socialising in the evening. I used to do ballroom dancing and play bowls but I don't have the stamina to carry on. If I was at work I wouldn't be able to open the drawers and the carrying. It's very frustrating because you can't do what you want. Its just gets you annoyed because you have to stop and rest. But I feel better after the excercises.

Interviewer: Does CLBP affect your sleep?

Patient: No it doesn't affect my sleep as much now but the pain used to keep me awake. Now if I wake p its because its very very stiff but not as bad as before.

Interviewer: Does CLBP affect your appearance?

Patient: It knocks your confidence so much and I don't feel the same about yourself and you can't look after yourself because you don't have the same interest. When you're in the office you feel really self conscious.

Interviewer: How about your mood?

Patient: I felt very low in my mood and associate that with my CLBP.

Interviewer: Did your CLBP affect your daytime activities?

Patient: Standing during the day is very difficult especially after five minutes. Then you start to feel your leg going. I can't do indoor bowling and ball room dancing. If I go out I just sit. For example I go to watch the dancing. I still go where I would normally go but I don't do it. Even when I felt better I didn't go out because I didn't feel right, so just stayed in.

Interviewer: Does CLBP affect your relationships with people or your sex life?

Patient: The sexy part, it's difficult anyway. Sex wasn't a be all and end all anyway. I didn't feel different because I was not so active with my husband before then. But my husband used to get frustrated because he couldn't understand the pain I was in.
Interviewer: Did your CLBP make you anxious or depression?
Patient: It made me very anxious but I didn't get very depressed because I started getting better very quickly once I started coming to physio so I could be positive.
Interviewer: How about your trust and confidence in clinicians?
Patient: I saw two locums at open clinics and they haven't a clue and no I dident trust the clinicians. That's why I went to the chiropractor. I was taken to A&E and they got me into physio, well to the first one, and then just got referred to back clinics. So the hospital has done something good getting me the treatment. After the second time at A&E when my back and leg got really bad, doctors don't do emergency calls after 10pm so I ended up in A&E.
I don't know if that's in the right order because that period was very fuzzy. I was in agony and nearly on the floor. But I couldn't take a seat. I got discharged and asked to sit in the canteen. If anyone had slit my throat I would have been glad. My sister was crying because she couldn't do anything. I got morphine when I got back in. The doctor wasn't pleased with it all but I got referred to the back clinic and now I do the exercises.
But I had a lot of sympathy from everybody because they haven't had it and they don't know. The physio part has just been marvellous.
Interviewer: Moving on to treatments of CLBP. Why do you take treatment for CLBP?
Patient: I take treatment to make me feel better and get right again.
Interviewer: Do you feel involved in treatment decisions?
Patient: I've just gone along with all the decisions. But I feel involved by doing my exercises at home and I know it's important to keep my back strong so that it doesn't happen again.
Interviewer: Are you actually taking medication at the moment?
Patient: No, just physio.
Interviewer: Okay we can move to the physio part then. Can you please describe what physiotherapy for their CLBP involves on a daily basis from your perspective?
Patient: Physio makes everything easier and keeps you relaxed. Its making me stronger especially my muscles and I realise its important. I have exercises everyday and I fid the talks after each session very useful as it makes me understand whats happening.
Interviewer: Do you have any expectations of physiotherapy for CLBP?
Patient: My expectations of physiotherapy is to get back to work and back to normal again. Carrying on with my daily life without having to stop.
Interviewer: Have your expectations of physiotherapy for CLBP been met?
Patient: My expectations have been met but I am not back to work and my daily activities are not the same but mentally much happier that way.
Interviewer: Do you continue to exercises after attendance as recommended by your doctor?
Patient: Yes I try to.
Interviewer: Do you continue to use the advice given after attendance with your physiotherapist?
Patient: Yes the advice is very helpful. I've never been pushed. They've always said to pace yourself and go as far as can but don't over do it.
Interviewer: Do you do any talking therapies?
Patient: Just the talks after the physio sessions.
Interviewer: Okay, I have some questions now which relate to satisfaction with treatments. What does satisfaction mean to you?

Patient: Satisfaction with treatment means everything to me because it gets better. They are treating me to get back to fitness and everything done so far has really helped towards that. There haven't been any backward steps. Satisfaction is feeling happy with treatment.
Interviewer: Are you satisfied with your treatment?
Patient: I'm satisfied with treatment. There is nothing I am not satisfied with.
Interviewer: What does dissatisfaction mean to you?
Patient: Dissatisfaction would mean if you didn't get the time or if the treatment wasn't appropriate, if their attitude wasn't good. If your left waiting too ling or if they weren't interested and just going through the motions.
Interviewer: Are there any other points that you would like to mention in relation to our discussions on treatment for CLBP, its impact on your life, satisfaction, or adherence?
Patient: I cant think of anything. The doctors don't have a clue. Because they didn't have it they don't know. The doctor said we need to get you back to work. That made me feel as if he thought I was faking it. He had no understanding of what I've been through. So does he even understand whats wrong with me?
Mentally I could go back but physically this isn't right. He said I didn't have a problem. I didn't say anything to him but he didn't give me that sick note.
He asked me if my headaches were better but I haven't had headaches so I don't think they have understanding or sympathy.
The side effects would affect my satisfaction. Everybody in my class come off the medications because you don't feel right. I don't like the tables because I am not as ill without them.
Interviewer: Thank you for your time and for coming in especially to see me. If you have any questions or concerns regarding our discussions then I can be reached on the number on the information sheet.

Patient Transcript 002
Interviewer: When were you born?
Patient: 26th June 1953
Interviewer: Are you employed?
Patient: Yes
Interviewer: Do you feel your work is affected by your CLBP?
Patient: Yes my work is impacted by CLBP. I'm struggling to bend down. It's an effort to stand up, bend my knees, lean over. I need to then think about how I'm going to get up before doing it.
Interviewer: Do you have any qualifications?
Patient: No
Interviewer: Do you experience CLBP?
Patient: I have back pain. Rehab makes it difficult and stiff. Sitting still can be a bit of a problem.
Interviewer: How long have you experienced CLBP?
Patient: About 30 years ago now playing squash was when it first started. I had no problem until about 5 years ago. I had a scan and then an injection in my back. It started again at the end of June and carried on again.
Interviewer: Are you currently taking any medications for your CLBP?
Patient: No I'm not taking medications. I made a decision not to take them unless I was absolutely desperate. No one explained to me how drugs make you feel. I couldn't eat breakfast, and I was unable to sleep anytime after 2pm.

Diazapam is habit forming and I was afraid of that. But when I started physio I decided to come off them. The medicines made me not know if it was Xmas or Easter and I was told to go and see a counsellor and I was not happy.
Interviewer: So, do you know what medicines you took?
Patient: Diazapam, codeine, paracetamol and ibuprofen. Not sure what does what. I just wanted to remove the pain.
Interviewer: Are you currently receiving any other treatments for your CLBP?
Patient: Yes I had a n injection and that was fantastic. The most unpleasanbnt thing was having something cold and I didn't like the recovery room. There were no nasty side effects. I have nothing but praise for injection therapy. Shame it didn't last more than a few years though.
Interviewer: Are there any other treatments you took?
Patient: Just the rehabilitation class. I've stopped driving and do lots of walking now. When I stopped taking the diazepam then I felt a lot better. I tried all sorts of things though. Osteopathy, Chiropractic therapy, and physio. Chiro is nice but I'm not sure it was doing anything good.
Interviewer: Do you use any substances such as alcohol or cannabis to help you with your problems?
Patient: No I don't but I thought about it especially with the pain I had.
Interviewer: Okay, I'm going to ask you a few questions about CLBP now. What does pain mean to you?
Patient: Pain means to me that it makes you feel miserable, not able to cope, and gets things out of perspective. Pain is stabbing, burning, pins and needles in toes etc…Something hurts and you think flip pin heck. But if you go to bed with it, and wake up with it, and it's like that all day, it's just intolerable.
Interviewer: What does CLBP mean to you?
Patient: I get the pain in my back and hip and an ache sometimes in the front of my leg. But I can usually walk that off.
Interviewer: What does chronic mean to you?
Patient: A nuisance pain with no value.
Interviewer: What is the cause of your CLBP?
Patient: I don't know, I have no idea.
Interviewer: Do you experience any symptoms from CLBP?
Patient: Nothing apart from the pain. I get an ache, tingling, and pins and needles in my toes. But it's not as bad as it was.
Interviewer: How does CLBP impact on your life?
Patient: I feel fed up and miserable. It makes me not want to do anything. I know I should. I'm scared to do too much to set the pain of. I never do anything without thinking about how I'm going to do it, even the ironing.
I have to get up and get ready for work. I just get on with it. Say I just get on with the ironing. I was a doer and not a thinker but now I think before I do.
Interviewer: How does CLBP affect your sleep?
Patient: I had to buy a new bed mattress but that's not a bad thing. I get cramp in my left foot and then it takes ages to get back to sleep. Generally not sleeping well and something always aches in my back in the morning. But it doesn't last all day.
Interviewer: Does CLBP affect our appearance?
Patient: Well just look at my hair! I cant do my hair because it hurts my back trying to do it. Every time I try it catches right in the middle of my back.
Interviewer: Does CLBP affect your self confidence?

Patient: My self confidence has taken a knock because I don't think I was treated well. I had 8 weeks off work and when I got back they change my job. I didn't want them to change my job. It was all arranged previously, I had sponsorship, training…I had plans and they all got changed.

I also had to cancel my holiday. The holiday involved going round wildlife and nature and I couldn't do that. Eveeryone else went but when they came back and said they had a great time, and that they saw dolphins etc…my family and sister made me feel awful.

I don't want to go too far away from comfort zones such as home. I don't want to go far away from where I can get help if something goes wrong. I just need to get home. I dint go far for shopping etc…certainly not further then 2 hours away. I tried it once and I just wanted to go home.

Interviewer: Does CLBP affect your daytime activities?

Patient: It doesn't affect daytime activities. I still have to go to work. But I've been to the cinema once and out for a meal one night but chairs were uncomfortable.

Interviewer: Does CLBP affect your relationships or sex life?

Patient: There's nobody in my life. You can forget sex with my back. When you get to my age there's no one nice anyway. I rely on my mum and dad even though I have my own home simply because there were no alternatives. I keep getting stuck when I'm on my own. So they're taking care of me and helping me.

Interviewer: Does your CLBP make you anxious or depressed?

Patient: I've been fed up, frustrated and cross. Miserable but not desperate.

Interveiwer: Do you have trust and confidence in the clinicians who manage your CLBP?

Patient: Well just with regard to pain killers. I had to wait in A&E for 2 hours. The doctors showed me in a room and moved my leg up and down. They sent me to the back pain clinic. There was nothing they would do. They won't admit you. The CLBP clinic was on Thursdays. She, the physio, asked me what drugs I was taking. The whole process annoyed me. People with brain injury etc…could have shown more interest. I didn't know what was going on. I didn't know if it was something serious or something temporary.

Interviewer: Why do you take treatment for CLBP?

Patient: Just the back class, exercises including those from the physio class.

Interviewer: Do you feel involved in treatment decisions?

Patient: I never felt involved. I trust them now they know. But I choose to do the exercises and attend the classes, but they know whats best for me. I'm ignorant.

Interviewer: Please describe what physiotherapy involves on a daily basis from your perspective.

Patient: Exercises each day for half an hour a day. But I do some in the morning, some at lunch time and some in the evening. It makes it more pleasant and helps me.

Interviewer: Do you have any help from the community, any supervision, or is it all hospital based?

Patient: No I don't have any community support.

Interviewer: Are you involved in the planning and evaluation of your exercise programme?

Patient: No not at all. The physio makes all the decisions.

Interviewer: Do you have any expectations of physiotherapy for CLBP?

Patient: My expectation is a plan for how to manage my CLBP in the future. When I finish I want to be able to do the plan myself and implement the plan so long as it works.

Interviewer: Have your expectations been met?

Patient: The rehab class is fantastic. Its like a life line. Everyone in the class feels the same so it's a great support. Its not me whose crazy. When they suggested counselling it made me feel really awkward an I though flippin heck!
Interviewer: Do you continue the exercises after attendance as recommended by your physiotherapist?
Patient: I do exactly what they tell me. I sometimes cheat for one or two of them but I don't really like doing that and then I try and make up for it. My conscience always gets the better of me.
Interviewer: Do you continue to use the advice given after attendance with your physiotherapist?
Patient: I'm getting better with the activities and exercises. It takes a while.
Interviewer: Have the type of activities you participate in been affected?
Patient: There no impact on my family. Everyone just carries on as normal and ignores me.
Interviewer: What does satisfaction with treatment mean to you?
Patient: Satisfaction with treatment means you are satisfied with the treatment you receive and you're happy with it.
Interviewer: What does dissatisfaction mean to you?
Patient: I'm not satisfied with treatment. I'm miffed with A&E because they weren't interested. I know there are more important things. But they gave me a prescription and shoved me out the door.
Medicines make me feel awful. I didn't know if it was Xmas or Easter. My head was all over the place. And I was muddled up. I needed to walk for miles to clear my head. My back was important to me and A&E ignored me.
And the medicines stopped me eating…I guess every cloud has a silver lining because I lost weight!
Interviewer: Are you satisfied with your treatment?
Patient: Satisfaction is being pleased. But I didn't know about the side effects. If I'd known I wouldn't have taken the medication for as long. I'm satisfied but I had to go through a lot to get to where I am now.

Patient Transcript 003
Interviewer: When were you born?
Patient: 9th March 1956
Interviewer: Are you employed?
Patient: Yes
Interviewer: Is your employment affected by your CLBP?
Patient: It is yes.
Interviewer: Could you tell me how?
Patient: Since the accident I was off for 8 months, and I've been back at work as a nurse since August 14th and I've been on restricted hours and restricted duties. So, I haven't been doing manual handling up until a month ago and I'm just gradually returning to full time employment and full time strength really.
Interviewer: Okay and do you have any qualifications?
Patient: I have yes. I am a parish nurse.
Interviewer: Do you experience CLBP?
Patient: Yes
Interviewer: And, how long have you had it?
Patient: Since January.
Interviewer: Are you currently taking any medications for your back pain?

Patient: I am yes. It wasn't chronic at first its become chronic. It was acute at first. Yes I take ibuprofen and paracetamol. I also take renitedin which is for the stomach for the effects of the ibuprofen.

Interviewer: Okay so let's go back a little bit. So, you said it was acute first and then it became chronic. So, did it become chronic around January?

Patient: No I fell in Jan and had an undiagnosed fracture T11 till June. So I was being treated for muscular CLBP until they found there was a fracture. For them the physio has changed and it's left me with rib pain and LBP. The fracture has healed and I am still waiting for investigations to see if there is anything mechanical with the rib.

Interviewer: Okay and you've told me what medications you're on.

Patient: I also take HRT.

Interviewer: And are you taking any injection therapies at all?

Patient: No.

Interviewer: Okay and are you taking any other treatments?

Patient: At the moment no.

Interviewer: And what about cognitive therapies, talking therapy, relaxation therapy, anything like that?

Patient: I've had to go to staff counselling because they've actually told me that I have post traumatic stress syndrome which I didn't realise I had. But just coming to terms with the accident, and how it's affected my life. So I have had one session for counselling and another 5 booked.

Interviewer: Okay have you gone for any chiropractic therapies or anything else?

Patient: I went to an osteopath. That was about April because the physio wasn't happy doing anything on my back because any time he touched my wrist it became really painful. So, he wasn't happy doing my back so I went to an osteopath who I had seen in the past for joint problems and he again wasn't happy touching my back and said he wasn't going to touch my back unless I see an x-ray because theres something not right. So that pushed me to go and see someone privately and I had to have an MRI scan which proved I had a fracture. So I went to the osteopath but he wouldn't do anything, luckily! Good osteopath really.

Interviewer: And just to check, do you use any substances such as alcohol and cannabis to help you with your problems?

Patient: No.

Interviewer: What does pain mean to you?

Patient: To me the pain is something that either irritates me or stops me doing my normal functions. Sort of limiting me.

Interviewer: And, how severe would you describe your pain?

Patient: If I'm having a good day then I forget, which is lovely, but I forget to take my Ibuprofen. The next day without treatment its about 60, and with the Ibuprofen I get pain of 30 to 40.

Interviewer: So what is CLBP?

Patient: My idea of CLBP is something that tires me, brings me down, and stops me from what I want to do. But it tires me, and I find I don't sleep well. I find it tires me. It's a tiring type of pain.

Interviewer: What does chronic mean to you?

Patient: Its something long term. Something over 6 months. Its something long term that you just get used to, or either put up with it or find a way of coping with it.

Interviewer: And do you know the cause of your back pain?

Patient: Yes I got a fracture in my wrist.

Interviewer: And do you experience symptoms of CLBP?

Patient: Pain on inhaling deeply. It's a slicing pain. I get a sort of a rib pain on inhaling deeply. The rib feels tender but if I take a deep breath it feels like its slicing.
Interviewer: Are there any other symptoms from you CLBP?
Patient: My posture, I tend to lean to one side. My balance was quite poor but I feel the back class has helped with that. Irritability, and frustration because I was quite fit before. Also I can't do what I used to do. And it's left me with a lack of confidence. I don't know if it's CLBP or the accident itself but its left me with a lack of confidence in physical things like go ice skating if it's on at Piccadily. The thought of going on the ice and falling just knocks me stomach. I'm really cautious. I'm cautious driving, I'm cautious going down steps, and I'm just cautious doing everything really.
Interviewer: Okay so how does the CLBP impact on your sleep?
Patient: I've got to about twice a night where I would wake up. In the early days I would wake up when I couldn't move and I'd wake up where I feel num. I probably wake up a couple of times in the night but its getting easier. Im not comfortable lying on my left side but my right side is comfortable. So its still impacting on my sleep but not as badly.
Interviewer: And has CLBP affected your appearance at all?
Patient: I have been told that I walk with my head down more when I'm walking but whether its the accident or the pain I don't know. I do feel that I walk with my head down. Its more of an effort to stand up right. Slouching is a lot more comfortable. I don't think anything else about my appearance apart from feeling miserable all the time.
Interviewer: Do you feel your mood is affected?
Patient: I don't feel I'm as bright as I was and I think that's down to the chronic pain that hasn't been sorted yet. So yeah I'm not as happy and cheerful. Its more of an effort at times, you know at work, to be positive, just because its impacted on my job so much and its still impacting a bit.
Interviewer: How about your self esteem?
Patient: It's difficult because it goes back to the accident rather than the CLBP. Because I was undiagnosed for so long, I was having physio, and every time I was having physio it was getting worse. The frustrations of not being able to get it sorted, when I finally had the MRI scan privately which cost me thousands of pounds that I couldn't afford. That was a relief but at least, because I was beginning to think that everybody was thinking I was just playing on it, including my husband. You know 'get back to work; you've got a bad back, so what?' And I was struggling to get acknowledged so that didn't do anything for my self esteem anymore.
Interviewer: And what about your self confidence?
Patient: No Im not as confident on my feet anymore as I was. Im not happy like going ice skating. I've not run anywhere. My driving is more slower. People have noticed that you know I'm just more cautious in everything I do because it's such a freak accident.
Interviewer: How about the way you feel about yourself?
Patient: Yeah I am different. I'm different because Im frustrated, and I'm trying to work on my self confidence. I'm very self aware of what I am because I do know that I need to deal with a few issues with my accident and CLBP. I was under no-bodies no care. So I went to BUPA, and he said he would see me as an outpatient as I needed. So I wasn't under anyone's care. And I went to one doctor who said there is no point referring you because there's nothing else they can do. So I went to another GP and I insisted on seeing a consultant, so that I am certain that yes we've done as much as we can.
Interviewer: What about your day and night time activities?
Patient: Well with work yes. I don't walk as usual as I used to do at work. And I am just being re-introduced to manual handling with patients. So I've started doing it but I'm quite wary. So I can do it at my own pace. As for outside activities, I wasn't sporty but

I’ve put a stone one weight nearly, so I need to exercise. But its just because of irritability.

Interviewer: Okay, anything like going to the pub or restaurants?

Patient: I don’t drink. I’ve been involved in the church and that has helped me a lot, and I walk a dog with a friend. And I go to a choir still.

Interviewer: What about relationships and sex life and things like that?

Patient: Because in the early days of doing it, once I’d got over the acute stage and it had gone in to a couple of months, my husband was obviously, right come on get back on with it. So when he found there was something seriously wrong, he treated me like glass. So, since then hes totally backed of and its not like it used to be before the back pain.

Interviewer: And how do you feel about that?

Patient: Frustrated I suppose but then I just get on with it. But we have been married for 31 years so you go through phases anyway where your sex life suffers with things and then you pick things up again. I think we just got out of habit now because of his fear factor. I think he feels guilty about everything.

Interviewer: What about other relationships, children, friends?

Patient: My children live away from home, and my friend, she has CLBP so she’s very helpful.

Interviewer: Okay, what about your mental health, anxiety or depression?

Patient: I don’t think Ive been depressed. Yes, anxious because I wanted to go back to work and I couldn’t because I knew I wasn’t fit enough. Luckily they were quite supportive here. How long that will go on for? But I am decreasing all the time.

Interviewer: And what about the trust and confidence in the clinicians?

Patient: No. The only people I trust are the physio’s.

Interviewer: Could you tell me a bit more about that?

Patient: When I fell on the ward here, I was in absolute agony, I was put in a wheelchair, taken to A&E which is what A&E said. I was shoved in awaiting room in A&E there for 4 and half hours, in a nurses uniform, in agony, I was triaged, I had 14 x-rays, they couldn’t find anything, they thought I’d fractured my wrist, and they thought I must just have some back pain. They sent me home with a prescription for me to take. I couldn’t even walk let alone go to the pharmacist to get it. No regard that I was in uniform. Just not nice. Had to go back to the clinic, and they were just not interested. They were just interested in my wrist. They put me on a splint rather than plaster. After 2 weeks they arranged for an [inaudible] which too ages. They had the splint on and off for about 7 weeks, and then they decided that I had had a minimally displaced fractured bone. Which was actually on the other side of where the pain was. The physio wasn’t convinced himself. I kept telling them about my back, and they said don’t worry its getting better all the time. So then they decided to send me to physio for my wrist and I said what about my back? And as an after thought he wrote and back on the notes. So the clinic I have no confidence whatsoever. And I couldn’t get myself out of all this. Its only as occupational health got involved, and then I went to the osteopath and then I went to see someone privately. Its just that they didn’t listen and they didn’t document. And its only the physio that have taken that pain seriously. I couldn’t get past the GPs either so its poor confidence with them as well.

Interviewer: So, did you say you’ve had physio?

Patient: I had physio on my back for a good few months before I was diagnosed. I had hydrotherapy, then acupuncture, and the physio class.

Interviewer: Okay, so why do you take treatments for CLBP?

Patient: So that I can mobilise better and I stop getting so irritable when the pain gets so bad.

Interviewer: Do you feel involved in treatment decisions?
Patient: Yes no one else is involved.
Interviewer: Can you describe what taking treatment involves on a daily basis from your perspective?
Patient: I don't like take medication. I have a sensitive stomach anyway. So, when I don't take something like a non-steroidal anti-inflammatory, it gives me loose stools, horrendous heart burn, so then I have to take another medication, Renitidine, to counter the effects of that. I stopped taking co-codamol because it doesn't suit me, and I take paracetamol.
Interviewer: And when you say it doesn't suit you, what do you mean?
Patient: The cocodamol – it makes me very light headed, and where the steroids make me loose, the co-codamol make me so constipated that I have to take laxatives. So Ive found sort of if Im just taking two lots of Ibuprofen a day, I can supplement that with a Paractamol and the Renitidine. But as Ive said, I've tried to cut it down to as little as possible.
Interviewer: Did you say they are pills?
Patient: Yes. I have used the gel but I don't know if it works or not.
Interviewer: And what about frequency of administration?
Patient: I take the Ibuprofen twice a day, and sometimes, the paracetamol as well. But generally, twice a day with or without the paracetamol.
Interviewer: Does it take long to take the medication?
Patient: No.
Interviewer: And, is it convenient?
Patient: Yes but I have to take it with food and I don't like to take it in front of people.
Interviewer: Can you tell me more about that?
Patient: I don't know, I've no idea, never thought about it. But I definitely wait until everyones gone. It's a very private thing and I don't want to disclose it to anyone.
Interviewer: Are there any benefits of taking medication for CLBP?
Patient: Personally I think the benefit is that I can be more mobile. And I know that that's important, you know that you don't stop. And if it stops me being irritable because the pain is getting to me then yeah.
Interviewer: And does CLBP medication meet your expectations?
Patient: No. I'd like to have no pain at all. I know if I up the doses a lot, it probably would be. But I don't feel as though I want to take high doses of medication, I feel like I've got to try and work through it.
Interviewer: And do you feel motivated to take the CLBP medications?
Patient: The pain motivates me because when I haven't taken it, I know about it, so then I have to take it.
Interviewer: And are there any disadvantages to taking it?
Patient: Yeah, the stomach lining, and the bowl movements, and the cost. Yeah and just the psychology thing of you don't want to take the tablets. The tablets are cheaper than on prescription.
Interviewer: And do you experience side effects?
Patient: Yes as I said earlier.
Interviewer: Okay, and do you take your medication as prescribed by your doctor?
Patient: I am taking them as prescribed but I play about with them so I might take more if I need more. If I forget at tea time its good cause it means I am not having discomfort through the night so then I take it later.
Interviewer: Do medications impact on your life?

Patient: They do when they upset my stomach. I get a lot of heart burn, a lot of horendouus hear burn. You get a cough from it and it impacts on what I'm doing like singing the choir.
Interviewer: Does medication for CLBP affect your self esteem, self-confidence?
Patient: I think its more related to the pain but the ones I'm on don't.
Interviewer: Are you able to tell the difference between the symptom of CLBP and the side effects of your treatment?
Patient: Yes. Yes. Yeah. The CLBP is pain, the side effects are gastric.
Interviewer: Can you describe what physiotherapy involves on daily basis from your perspective?
Patient: Its remembering the exercises you've been given. And your posture, and more aware of your lifting techniques.
Interviewer: Do you feel you get support from the community for physio?
Patient: No I just come into the hospital. It started off once a day, then twice a week, and now once a week.
Interviewer: Were you involved in the physio programme?
Patient: I was consulted all the way. And you work with the physio.
Interviewer: Do you have any expectations of physio?
Patient: Yes, I didn't have before but I do now. Its to help so that you don't stiffen up. I didn't realise how Id been holding myself so stiffly because I've been stiffening up. My idea of physio now are to help keep the muscles moving in the same way.
Interviewer: And have your expectations of physio been met so far?
Patient: I think the physio has been excellent once I received the correct diagosis. When the got the diagnosis wrong then that was quite stressful as well as the physio, knowing what they'd been doing. So, yes my expectations have been met now. I'd say 90%. I'd like to be more mobile and more confident but I think its just more time.
Interviewer: Do you continue to exercise as recommended after attendance for physio?
Patient: No not really cause none of us do, do we? I do do a lot of the things that they did. Things like step ups and all that, cause I had arthritis in the knee that made if worse so I'm not doing that. I'm doing the balance ones and the twisting and stretching. So I'm doing 70% of what they've recommended.
Interviewer: Have your physiotherapy activity levels been affected?
Patient: I was limited in what I could do as some of them weren't easy in what I could do. I was embarresed by the pain because of my body's response to the pain. It was just so painful.
Interviewer: So, can you tell me what does dissatisfaction with treatment mean to you?
Patient: Not being listened to. Long waiting lists to get seen to things. Long referral processes. Treatment not working, not helping, hindering. Causing more discomfort. Like the physio would make me feel worse for 4 days that I was in pain afterwards. So at the time it wasn't helping. It was causing me more pain than I arrived with.
Interviewer: Are you satisfied with your treatment for CLBP?
Patient: Since getting the correct diagnosis yes. Apart from the medical side of it, but from the physio part yes. Paying privately was excellent but the NHS no. And I don't believe in private health care so I had to go against my beliefs. So that's hard.
Interviewer: And is there any of the treatments and or satisfaction that you felt we havent covered?
Patient: The hydrotherapy was extremely beneficial.
Interviewer: Anything else you'd like to share.
Patient: I think we've covered everything.
Interviewer: Okay thank you very much for your time and participation.

Patient Transcript 004

Interviewer: When were you born?

Patient: Specifically? 16th of September 1966.

Interviewer: And, are you employed?

Patient: Yes.

Interviewer: Do you feel your ability to work has been affected by your CLBP?

Patient: I think my ability to do certain jobs is affected. I only work part-time. And, I actually don't think I could work full-time, because I get too tired and then it all kicks in. So, I suppose that's a yes.

Interviewer: Do you have any qualifications?

Patient: GCSEs or O-levels.

Interviewer: Okay and you've already told me that you experience CLBP. Can you tell me how long for?

Patient: About 11 years, and related to a car accident.

Interviewer: Okay, and are you currently taking any medications for your CLBP?

Patient: I try not to. If I do take them, it tends to be paracetamol or codeine. I mean at one time I was on stronger prescriptions of other types of medicines.

Interviewer: When you say stronger, can you give me an idea of what stronger types of medication you've taken in the past? If anything.

Patient: I don't remember because it was that long ago. But I decided not to take them because I was dopey all the time and I didn't have any quality of life or anything. That's what I want you know. My back pain relates to two car accidents, neither of which were my fault but that's where it all stemmed from. I didn't have any pain before then. I don't want the medication living my life for me. I want to take it over. I mean I am probably in pain all the time but I just deal with it.

Interviewer: So, you said you take paracetamol and codeine. Do you take any antidepressants at all, do you know?

Patient: I was actually on antidepressants because I was misdiagnosed with a Thyroid a problem, and they put me on that, and I was like zombie.

Interviewer: Right so you didn't like antidepressants?

Patient: No, that's why I stopped taking them.

Interviewer: And, how about any muscle relaxants like diazepam?

Patient: No.

Interviewer: Have you tried any injections?

Patient: No.

Interviewer: Are you currently receiving any other treatments?

Patient: Physiotherapy and that's it. I've got the one session left to go to.

Interviewer: Have you tried any relaxation therapies?

Patient: Only self relaxation therapy. I do use it and can use it. I'm so tense that I don't need to tense up in order to relax. Maybe some weeks I do it a lot and sometimes I don't. Mainly when I get too stressed and I need to relax. But its not that I have been on a course, or had treatment from the doctors.

Interviewer: Okay. Do you use any substances such as alcohol or cannabis to help you with your problems?

Patient: Not really no. Sometimes I've had the odd glass of wine and I've though "oh that helped" but I don't think I've done it deliberately. Or, I've gone to the pub to have a drink and I may have, you know had a drink, and then thought I feel quite good now. But never knowingly.

Interviewer: And, how about cannabis?

Patient: No never. The only thing I do use, is I have a tans machine. I use that more than I use pain killers. But, you haven't mentioned that.
Interviewer: Well, you can tell me about it if you want.
Patient: No no, I was just thinking I use the tans machine which I find invaluable. Its really good and sometimes it's the only way of getting through the day. I bought one about six years ago, maybe not even that. And, if I had to get one every year I would get one. It's very helpful. And, a hot water bottle. Every night I go to bed with a hot water bottle.
Interviewer: Right, and does that help?
Patient: Yes, it just eases it.
Interviewer: Would you use it where the pain is?
Patient: I actually lie on me back and put it between my back and the bed.
Interviewer: Okay so I am going to ask you a few questions about CLBP now. There are no right or wrong answers. We are just interested in your experiences and opinions. So, if we start with, what does pain mean to you?
Patient: Well it's a physical thing and I know myself that if I get a pain anywhere, I tend to be aware of it and then I do things differently. And, then I end up getting pain somewhere else. But it is quite debilitating and does stop me doing quite a lot of things. It's a way of life really. You want it the same way of life as if you were pain free. It can be that, if my back is very bad, then I am up for a few days and I'm very cautious. I don't know if it's a psychological thing. Because it's a general and physical pain but you do get "oh don't do that because it will end up hurting, or don't do that because it will come back again", it does affect your whole way of life. I mean some days I think to hell with it, I'm just gonna get on and do it, or I rely on the tens machine which does help and I don't know if it's the right thing to do but I don't want to have to rely on drugs or something like that. Because ultimately long term, relying on things like that, if you get any ailments of pain, then it doesn't even touch it. You know its like if you get tooth ache, your average Joe would just take a paracetamol, not just dull it and keep on going. I felt I got to a stage where I was taking strong pain killers and you know it wasn't even touching it.
Interviewer: So, what does chronic mean to you?
Patient: Well, what I think it is is that it's more or less always there. Its almost like a tooth ache. But, there's always an element of consistency. It's always there.
Interviewer: So, what does CLBP mean to you?
Patient: Its just pain in your lower back really. I do have problems with my shoulder and my neck. I had a whip lash injury but it's my lower back, and I find hard to sit down.
Interviewer: On a scale of zero which is no pain, and 100 which is worst imaginable pain, where is your pain today?
Patient: It wasn't too bad this morning, but I've been out and about all day, sitting at work this morning and sitting now, so I would say about 25. Its there but a 25 is probably about where it is because I am used to it.
Interviewer: Throughout the course of the 11 years that you have had CLBP, how bad has your pain been on that scale?
Patient: It sounds really bad but I would have to say 100 cause I mean I used think I had no pain threshold until I gave birth and they gave me gas and air. And that was about 16 years ago. So, I thought I could get through that if I could get some air, but this is just horrendous.
Interviewer: So, does your pain ever go to a zero?
Patient: I don't think it ever goes to a zero. As I say today at 20 to 25 that's probably as low as it would go. There is never a day when the pain is never there.

Interviewer: Do you know what the cause of your CLBP is?
Patient: Well I think I get muscle spasms that's when it gets worse and it tightens. But it all came from the car accident, that's when the tissue injury occurred.
Interviewer: Okay so you had the car accindent and then you started to have pain, and sometime your muscles tense and then it triggers right?
Patient: Yes. Or it may be that something triggers it and then I tense and it triggers it. I don't know.
Interviewer: Okay, so do you experience any symptoms from CLBP?
Patient: Just pain. Pain is the thing.
Interviewer: Is there anything else, or is it just the pain?
Patient: Just pain although I do feel as though I am quite num in that area even though I've got pain, it feels numb on the outside.
Interviewer: So, is that you almost don't feel from the outside but you hurt from inside.
Patient: Yes.
Interviewer: Is there anything else?
Patient: I have had pain in the shoulder but I don't think its related to the back pain.
Interviewer: Did your CLBP impact on your life?
Patient: Yes.
Interviewer: Can you tell me more about that?
Patient: As I said before, the fact that as I said before, it does affect your day to day life because you are aware that its there. Even though its mild, its still there. But particularly when you get flare-ups, that stops you doing lots of things.
Interviewer: So, in what way does it stop your life? When you say it stops your activities?
Patient: It stops your activities, it stops your social life, it can affect your work. I've had it when its really bad and I can even get out of bed. But there are times when you think I cant be bothered.
Interviewer: So, it impacts on your life in quite a way really. Does it affect your sleep at all?
Patient: Yes.
Interviewer: How?
Patient: It just, its very difficult to get comfortable to go to sleep in the first place. It can wake you up in the night and then you have the same scenario all over again of trying to get back to sleep.
Interviewer: Why do you wake up?
Patient: Because the pain is so bad. And, then you can be stiff in the morning.
Interviewer: What about self-esteem, self-confidence, and self-appearance? Does it affect any of those in any way?
Patient: Yes again because your whole life has changed and it affects your life so much. Cause you cant do certain things that you could do before, or your worried about things so you stop doing those things, and then you stop doing whatever it is socially that you do.
Interviewer: And how's your self esteem, or self confidence?
Patient: Well I am lucky in that I am extremely outgoing and confident and I talk to anybody. But, I know that when it was really bad I didn't go anywhere and I didn't do anything and then there is that having to get back into it which I didn't find easy but for some people I imagine, some people find it extremely difficult depending their nature anyway.
Interviewer: Right, so it's like your motivation, and once you stop going out that motivation is gone.

Patient: Yes.
Interviewer: And you've mentioned day time activities in terms of work and just doing your day to day things. What sort of things do you mean?
Patient: Yes all sorts of things, shopping, housework.
Interviewer: And night time activities, and going out are affected?
Patient: Yes.
Interviewer: Could you give me an idea of how often you go out?
Patient: Well I used to be involved in a lot more things than I am now. But that's not necessarily related to my back as much as to my personal situation I think. But I do, I try and go out and see my friends one evening a week. But I would have gone out more than that and doing social things.
Interviewer: Okay, and how about relationships, and sex life, your family life, does it affect any of that?
Patient: Well I just recently got divorced but that wasn't necessarily anything to do with my back pain.
Interviewer: Did it have anything to do with it though?
Patient: No. I think there were times when it does affect you so much that you don't want any one near you, you don't want to know, and you're in a bad mood, and you'd bite the head off the person who was nearest to you. So, I mean yes, it does affect relationships.
Interviewer: And do you get anxious or depressed at all?
Patient: It would get me down. It would get me down and I can get frustrated because I cant do what I want to do.
Interviewer: So, you get quite a bit of frustration. How about anger?
Patient: No not really. You get a bit snappy but I don't get angry. Snappy is the word.
Interviewer: How about trust and confidence in any of the clinicians? It could be nurses, doctors, physiotherapists, any health professional.
Patient: I actually do feel quite let down from the point of view of the long standing problem that I've got. I mean I paid privately to get treatment purely because you know the waiting list was so long that I would have ended ten times as worse before I would have got some treatment. But then I went to my GPs and I said I need some treatment and I can't afford to pay privately, and they were very good. But originally from that point of view, I maybe didn't try enough, but maybe not.
Interviewer: So, when you say maybe not, was it that you weren't happy with the treatments, or?
Patient: It was just that really long wait. I just couldn't have waited. But as I say I went and I thought no its bothering me more and I can see going on a slippery slope. Cause physio really does help me. I mean what we have done in the classes thing has helped as well. But its keeping it up. And I know we have a bit in our folder where we can ring up and find out about classes in your area and that's a thing I need to do. Because doing it in the group and what we did helped me. It gives you that, we are all in the same boat, you don't particularly want to go to the gym on your own and everybody is like super fit and your there with a bad back. You know.
Interviewer: Okay so I am just going to talk to you about the treatments that you're taking.
Patient: Well I take a physio class, pain killers, and the tens machine.
Interviewer: Okay so if we start with medication first. Why do you take medication?
Patient: Because it helps to num the pain really. It's as simple as that. Just to get rid of the pain.
Interviewer: Do you feel involved in the treatment decisions of your medications?

Patient: Yes because I am doing it myself. You know its paracetamol and codeine and that’s it.
Interviewer: So it’s over the counter?
Patient: Yes.
Interviewer: So, can you describe what taking medication involves from your perspective on a daily basis?
Patient: On a daily basis I don’t. I only use it when it gets particularly bad. And as I said I take some pain killers and hope for the best really. Bacuse I don’t want to rely on tablets all my life. I am probably living with more pain than other people because I don’t want to take the tablets. But I can deal with it if the pain is 20 or 25, its when it gets to 60, that’s when its bad.
Interviewer: What about taking the pills, I presume their tablets? Is it easy to take?
Patient: Yes but theyre not easy to take. I buy the capsules, as I find the tablets hard to swallow. I mean I would quite like some sort of patches you just stick on you know, stick it on you’re your lower back and you’d go ooh because it would get to the spot quicker.
Interviewer: So, its not ideal but its okay.
Patient: No, its not ideal.
Interviewer: And how do you feel about taking them in front of people? Are you okay with that?
Patient: It doesn’t really bother me. If anyone really wanted to ask me, I’d just say period pains as its so embarresing really. It’s like whats it to you. Know one’s ever asked.
Interviewer: Okay and what about the time you take the medication? Do you just take it when you need it?
Patient: Yes I just take it as I need it. I have a box in my drawer at work so they are always dotted about, and I always know that there are some.
Interviewer: And what about the convenience of taking them? Do you experience any problems?
Patient: Well if you’re travelling somewhere you know of a train or vehicle then that might be a bit inconvenient. But I always make sure that if Im going anywhere I’ve got them with me.
Interviewer: And are there any benefits of taking medication for CLBP?
Patient: Well it does help a bit. I mean that’s why I won’t take strong ones. I mean in one of the classes they talked about taking your medication, and taking it and taking it and taking it and then not needing to top it up. But the thought of taking, you know, if we are talking paracetamols, 8 paracetamols a day for the rest of your life, its not really good.
Interviewer: Right, so you’d rather not take tablets at all?
Patient: Yes I’d rather not take tablets at all. And that’s why I don’t and I always live with the level of pain that I live with. And then its only when it gets above a manageable, or tolerable level I should say, that I take them.
Interviewer: Do your CLBP medications meet your expectations?
Patient: No. They need to be stronger probably but I don’t want to go there.
Interviewer: Will you tell me a bit more?
Patient: Well my expectations were to remove pain but I know the tablets wont do it.
Interviewer: Right so the over the counter medications don’t do it? Have you tried the other medications, the stronger things?
Patient: Well yes, but as I say I don’t want to take them.
Interviewer: Is that because of dependency?
Patient: I think dependency and tolerance really. You know you get to a point where it isn’t going to do anything.

Interviewer: Right, cause you get so used to it.
Patient: Yes and cause I got to that and that's why I stopped taking them. You know this is zombified you know. It's taking pain killers to live. You know I need tablets to live because I have thyroid problems but taking pain killers to live, its not.
Interviewer: And when you say zombified, can you expand on that?
Patient: Just to the point where you feel spaced out and not really fully aware and I don't feel like I feel in control of my life frankly and you get to the point where your just living from one tablet to the next.
Interviewer: Do you feel motivated to take the CLBP medication?
Patient: I'm only motivated by the pain.
Interviewer: And are there any disadvantages of taking CLBP medications?
Patient: Well yes, getting zombified if you take them all the time. You don't feel in control.
Interviewer: Is there anything else?
Patient: Well it makes you lethargic, it's all part and parcel of not really being with it when you're taking strong pain killers and taking a lot of them because you need them. I would rather live as I'm living with a certain amount of pain, than to have no pain and really no quality of life, that's how I look at it.
Interviewer: Do you take the medication as recommended by the doctor?
Patient: I just take them when I need them.
Interviewer: Does the doctor tell you to take your medication more than that?
Patient: Yes originally when I was on prescribed pain killers, I was taking substantially more. You know I don't take pain killers everyday.
Interviewer: Right, was it recommended to take the medications everyday and then you decided this isn't working for me. So, do you alter the amount of medication for your CLBP?
Patient: Yes I do. Because of the side effects and because of the tolerability. They used to make me feel zombified. If I took the prescribed medication that the GP had prescribed, I'd just have been spaced out really. You felt okay but you don't feel much else.
Interviewer: And if you felt that way how did it affect other things?
Patient: Well it stopped me from doing anything. Relationships, friends, family, going out, basically all the things we talked about.
Interviewer: Are you able to tell the difference between the symptoms of your CLBP, from the side effects of your treatment?
Patient: Yes. I get pain from my lower back, and I feel spaced out or zombified from my treatment.
Interviewer: Okay, I am going to speak to you a bit about physiotherapy now.
Patient: Okay.
Interviewer: Can you please describe what physiotherapy involves on a daily basis for CLBP from your perspective?
Patient: When I first came to physio, I mean they go through lots of movement etc…that's why the classes really benefited me. Because its doing exercises to strengthen areas there which I can feel benefits from. I was one of the unfortunate ones who pulled a muscle on the last day. I just moved funny. But we did a lot of, if you move that way then you need to move that way. That really, I use that now. Not necessarily my lower back, but you know any kind of movement that you do is good. So I found that really. I mean to me, it was never obvious and I thought, oh that might work and yeah that's good.
Interviewer: Were you recommended to do any exercises?

Patient: Yeah.
Interviewer: Do you do them?
Patient: Yeah.
Interviewer: Do you do them as recommended by your physiotherapist?
Patient: Some of them are not particularly easy to do in your daily life so some of them you need to improvise. I mean its like when we had to do exercises with a medicine ball. I know I'm doing that because I'm getting things out of my cupboard and putting things in my fridge. So, I'm doing that without really knowing I'm doing it. Some of them you wouldn't do and you have to consciously do. But I do find it helpful and its really benefited.
Interviewer: Do you have any expectations of physiotherapy for CLBP?
Patient: I don't think I have any expectations now, but I think I've already seen benefits from what I've done from the physio. I mean as I say I can see why we do that and I can see the benefit from it and I can see that I need to do this more and I wont have to you know, have the pain.
Interviewer: Did you have expectations before you started the physiotherapy?
Patient: I sort of had. Well I'd give everything a go. But if I can keep this up I thought, you know I can see that it strengthens these muscles. Therefore I wont get this problem, and you know what to if you get a problem. So, I didn't particularly have expectations, and I didn't particularly think it was going to be a miracle cure, but really appreciate doing it. I mean obviously at this time, I'm still not pain free. I don't know but it certainly helped me.
Interviewer: So, have your expectations then, been met now?
Patient: Well because I didn't really have any expectations that much, then I think its over exceeded. I mean because I didn't go in thinking "oh, this is a miracle cure" so it exceeded. I mean you have got to be realistic, I mean I've had pain for 11 years, its not going to cure itself over night and its not going to go away. But I certainly know that its improved.
Interviewer: And so when you say you don't have any expecations, did you go in with the view of, 'I'll give this a go?'
Patient: Yes.
Interviewer: And you said you continue the exercises as recommended although sometimes you improvise.
Patient: Yes.
Interviewer: And, do you continue to use the advise given after attendance?
Patient: Yes. Yes. Things like that. I mean there are some things that we were advised about, you know, like shopping. Strangely enough when I started on this course, I met someone whose just finished the course. And she's a single mum. And she said that they said "don't do big shops, do little shops". But the reality is, you cant. The advise is great but the reality is, no body, unless they don't have anything better to do, can go shopping all their life.
Interviewer: Why did they ask you to do shopping to do everyday?
Patient: Well they didn't ask me, and I didn't took it like that. But that's how she did. Its so that your not doing lots of you know picking up. But I said that at the end of the day you can come in and just take the things that you need into the house, and wait till the kids get them to empty your boot. You know at the end of the day there are ways round things and its sort of how you interpret what you're told.
Interviewer: Okay, did you say you've had any talking therapies like cognitive behavioural therapy, or counselling?
Patient: We've had lots of lectures and talks and things.

Interviewer: Okay but have you been seeing a psychologist or counsellor?
Patient: No.
Interviewer: Okay weve nearly finished now. Can you tell me what satisfaction with treatment means to you?
Patient: No I think that…well going back to what you were saying 'do I think my expectations were met?' I don't really think that's what it means because everyone's different and every bodies way of being satisfied is different. I actually have really benefited from, particularly this class. And maybe more than, well as I say I didn't really go in with any expectations so my expectations were more than met in that respects.
Interviewer: So, what is satisfaction to you? Is there any way that you could describe it?
Patient: Well satisfaction is having everything that you want and being happy, healthy and something like that.
Interviewer: So, when you say happy with everything? So, do you mean happy with the aspects of treatment?
Patient: Yes. I actually thought it was good. There were a lot of things that I took on board and thought, you know just certain things like, wow that makes sense, you know, I'd never thought it before. But what I particularly thought at the time is wow that really makes sense that. Cause we have this talk about your pain can never be shut down and so its always there. Some people took great offense at that, you know that its your brain telling you that your in great pain, so your in pain and don't shut this down because pain is not as bad as your thinking. I though yeah I can understand that in a certain aspect. So there were a lot of things that I really gained from it like personally, and not just you know I gained not just that I gained from learning that, but I also gained from thinking "ah that's how people perceive you". So, its not just about what your saying but its also about how people perceive you. And you know you've got this pain but it may not be as bad as you think because of this.
Interviewer: So, could you elaborate a bit more on the perception side of things?
Patient: Well, I could sit here and say to you "My back's killing me" and there's only my word for it. There is no physical proof. I think there is a big element of that. So its just your opinion.
Interviewer: Okay, so do you feel people judge you on that?
Patient: I think there are. I think there are. Bacaeuse you can have good days and bad days whereby today I could do this, and tomorrow I couldn't do it. And theres an element of "oh well you were alright last week and now you can hardly do anything for all you know". And I do believe that there is an element of I've overdone it and then I'm suffering after that. And then people say oh well you were well enough to do that and now you're not well enough to do this. And I think, no but I am genuinely not. And it's my own fault for saying anything because I did too much because I felt alright. I mean its not like I have a severe case of acne, and people say oh yeah, of course we can see that, or whatever. So there is an element of that.
Interviewer: So can you tell me what dissatisfaction means to you?
Patient: Well not meeting your expectations really because I came into it with not expecting anything.
Interviewer: So, when you say your not expecting anything, is that because of something that has happened before?
Patient: Possibly there is an element of yeah I don't think this is going to be the cure. But I don't think that that's necessarily related to my back as I suppose other things in life.
Interviewer: And are you satisfied with your treatment at the moment?
Patient: Yeah. But I guess if I can carry it on then I know I haven't been satisfied.

Interviewer: Is there anything else that you feel we have perhaps haven't covered that you think I should know about in relation to everything that we have talked about?
Patient: No not really. Just that you know that every bodies life outside of CLBP are different. Like we were saying, your expectations and satisfaction are different. Because I was misdiagnosed with a thyroid problem, I was treated for being depressed for quite a while actually; I mean that's always bothered me. I mean at the end of the day I was on these tablets, I was playing scrabble and the rest of the world was playing monopoly when I was on the antidpressants. Because quite clearly I didn't need them because that wasn't what was wrong. And it was brilliant when I got diagnosed with my thyroid problem and you know, most people wouldn't say that but you know. So there is always that element and obviously it relates to the medical industry as such. Because I have had, after I had my sons, I had problems and I had to have a couple of operations to make it right and that was again well I could put it down to medical problems, and that could be wrong but technically it would be. So, I got those two issues, well not issues to me but there there and it happened. I mean its gone, its dealt with, and theres nothing else, but ultimately there is that here we go again possibly. All I want is to be right and because of those other things. And then there are personal life things where you get to a point where it is really worth it.
Interviewer: So there personal things that are not related to CLBP?
Patient: They're not related to CLBP what so ever but they could be related to how I think about, maybe that why I think I won't go into it with any expectations because then it will go…possibly there is an element there that it could be. I'm not saying that that's the case but there is an element there that it could be. Because I've had a couple of medical things in the past that haven't been dealt with appropriately and there could be an element of "oh I'm not expecting anything because I'll get let down." But if anything happens which improves it then it's a bonus. But there is and that could be related to my personal life as well. So I may just be the sort of person who doesn't want to try anything because then you won't get disappointed. I don't know if I am that sort of person but I think its fair to say that there is an element of it. If I don't have big expectations then it can only go one way. And because maybe you should have expectations and you get something out of it, then you're satisfied. So, it's where your line is really, or your marker is on that line as to what your expectations are because yes I think your expectations and your satisfaction are related. I don't know if all that helps.
Interviewer: It does indeed. Thank you very much.

Patient Transcript 005
Interviewer: When were you born?
Patient: 1958
Interviewer: Are you employed?
Patient: Yes, full-time. I sit at a desk. I work as a PC administrator. So most of my work involves dealing with fault computer parts. So I gather them, I put them in like sheets, sort them all them, then I have to pack them in the box, and then send them back to the manufacturer. So my job basically involves sitting down, standing up, and most of the time lifting heavy boxes. It just depends what part of the computer I am handling. If its hard drives they can be quite heavy. Because I don't just do one, I do twenty. Or mother boards, or anything.
Interviewer: Did you give up work because of your CLBP?
Patient: As soon as my back gives me trouble again I have to take time off of course. And I haven't been back since. Until recently I had been given disability status. So I have not been back to work since last year, last January.

Interviewer: Do you have any qualifications?
Patient: No.
Interviewer: Do you ever experience CLBP?
Patient: Yes, all the time.
Interviewer: How long have you experienced CLBP?
Patient: Since 1997. In 1997 I had back pain and I was basically in the bed for about 3 months. And I was referred by my doctor to see my consultant, and they diagnosed that I have a bad back. And it was about after 3 months and after then it was about normal. And then I was okay until the year 2000. In the year 2000 my back flared up again. I couldn't do any thing. I was off work for about a month. After physiotherapy it went back to what you call near normal. Since then it was okay until November last year. November last year I was working, and I was helping to move departments at work and that's when it started again. From then up to now it's just been really painful experience. I went to see the consultant again about six months ago. They looked at my history and they recommended I take physiotherapy sessions again. They looked at my past X-rays and everything again. They said they think it's the same problems. They said go have the physiotherapy. If that doesn't work then you probably need an operation. Since I started the physiotherapy about 6 months ago, the pain moved from my calf to my back, and I am still suffering from it all on a daily basis. Because of attending the physiotherapy, I have learned a great deal about managing my pain. Basically, its there all the time. And I am trying to live with it. In the last two months I started suffering from neck pain, and I have pain inside my head. So, Cathy Riley referred me to Mandy Evans who was dealing with my neck pain. Just after X-mas, in fact on the 2nd of January this year I attended the last session and she asked me if there was any improvement or pain in my head and unfortunately not. So she decided to refer me to my doctor and see if he wants to investigate it more. That's in brief, yeah?
Interviewer: Okay, well thank you. We will be touching more on some of the things you have mentioned on a bit. Are you currently receiving treatment?
Patient: Yes I take pain killers and anti-inflammatory tablets. The pain killer is called anti-tirex and a tablet called retrinol. For the last I would say 3 weeks, I stopped taking them. It was with the advise of Mandy Evans to see if my head pain is a side effect of my treatment or not. And apparently on the 2nd of January again this year, she decided that it was not the effect of the drugs. So I am taking them again.
Interviewer: Do you experience any side effects of those treatments?
Patient: Not what I could say, but definitely I get stomach ache sometimes, when I go to the loo. I don't know if its side effects of the drugs or just the condition itself.
Interviewer: Do you use substances to help you with your problems?
Patient: No. Prior to last January I was working and I was doing normal things. I always had up until 1997, I always had a sort of a back pain. But I always put it in the back of mind and just carry on with life as normal. Thinking it's probably my age, you know as you get older, I'm not doing the things I used to, I'm not clubbing any more, you know I'm not doing sport anymore. There is a fact there, that I have problems with my knees as well, so I think that's a big factor relating to my knees. Because I have a long time knee injury. I've had a couple of operations but it really didn't solve the problems. And that's affected the way I walk, I can't run, I cant do any physical sport. Because of that, so if I play football now, which I doubt it now because I know that my knees give way.
Interviewer: What does pain mean to you?
Patient: Pain means when I feel pain. It's very hard for me to explain. It's just painful if I cant bend, If I cant sort of stand up, I sleep on the floor for the last several weeks. It helps a bit. Every time I sleep on the bed it makes my back worse. So, what's the

definition of pain? There's a lot of things I can say about pain. I cant sleep sometimes. I am sorting of turning all the time. Pain to me is sort of discomfort, its so painful sometimes it just cause discomfort. I don't know if you understand what I mean?
Interviewer: Well I understand what you're saying but I never had chronic.
Patient: Well what's chronic? Is it just relates to back pain or is it pain just all the time?
Interviewer: Well, that's actually my next question to you.
Patient: I would say my back is just. I mean it gets from bad to worse sometimes, and it improves as well. I mean when I started physiotherapy my sciatic nerve was a problem. As soon as I got the pain it related to my leg. Where it is now in the back, it's not as bad. Its still bad, but not as bad. So it just depends what you call chronic.
Interviewer: So, if you had to rate your pain today from 0 which is no pain to 100 which is worst imaginable pain, where would you say your pain would be?
Patient: I would say it's at 50. In the middle. At its worst I would say it's about 97, 95 to 97. It's never no pain at all. The lowest when I am just ignoring it is that it's about 30. But like I said sometimes you don't want to moan about it and you don't want to go on about it. And like I said, my wife she has low back problems sometimes. So like I said I don't want to go on about it. And my wife has just recently been diagnosed with breast cancer recently so compared to her sort of illness, mines nothing. So it's always there, it's always been there. But on a scale of 0-100, I would say its 30, when it gets worse it's around 97, 90, obviously after the physiotherapy I do the exercises every day. I've learned to manage my back pain.
Interviewer: What is the cause of your CLBP?
Patient: My back pain goes back to 1997. At that time I wasn't playing any sports or anything. At that time I just played snooker, and I don't even do that now. Whether its something to do with my knees, you know my back pain relates to my knees, I'm really not sure.
Interviewer: Do you experience symptoms of CLBP?
Patient: Yes. Its always there. The pain of course, and the pain then stops you doing things. Like again, it makes you walk wobbly etc…I am self conscious all the time, trying to sort of balance things. You know not to hurt my back and not to give way. If that happens it will be disaster really. So it's just a matter of being self conscious all the time. I don't walk as I used to like a lot of people. If you see me walking I don't walk as I used to. I try to rush it. Not because I'm a fast walker or anything, but just because it gives me a better balance. If I walk slowly, you know I am not confident walking in a straight line. You know if the police see me, they probably think I am drunk. So, that's what I experience all the time.
Interviewer: How does CLBP impact on your life?
Patient: I don't know but my wife has noticed that probably my sex life has been affected because I hardly do it anymore because of the pain and all the surroundings that goes with it. So I would say that activity wise I don't do much of sport, or social life. Like I said I don't go out. I go to snooker club to watch my friends play and if I feel well enough then I take part. You know I don't go to pubs, so I use it as a social place. So I go there every Saturday four o'clock to half seven. But I don't go to pubs. I don't go to clubs.
Interviewer: Is that because of your pain?
Patient: Yes it's because of my pain of course. There are a lot of other things that go with that. I can't afford it. That's the main thing. You know I'm not working but even when I was working I couldn't afford it because of other things in life. You know I've got a baby which is 3 years old, you know, I've got family, so its very hard when you earn £800. You know by the time you pay all your bills there's nothing left. But as far as

activities are concerned, I don't do any sport. I walk whenever I can, that's the only thing I can do, or try to do. That's the advice is to keep moving. I discovered that sitting down doesn't help at all. You know by the time you get your blood circulation going again, you're tired anyway. So I would rather keep moving until I drop.

Interviewer: Right, and how about the impact on your family?

Patient: Well my family is in Libya. We only socialise with my wife's family or my friends. My family know about my back problem from a long time ago, about years ago. My mum and my dad are nearly 90 years, and they have their own problems. So whenever they ask me I just say I am fine. Because they have their own problems. When I ask them my mum say, she's got bad back, bad knees. I understand it you know because of the age. So I tend not to really worry them with more worries. I mean now they know I have been suffering with a bad back, and I've been off work. Cause you know, I had to tell them in the end because I couldn't just pretend. And they knew about my wife's condition but whenever they ask, I say yes I'm fine. Have you been back to work? Yes, yes, I would say. To give them less worries and I wouldn't say it affects my families, because it affects me.

Interviewer: How about your self esteem?

Patient: Well when you're not working, your not mixing, the brain tends to get less active. So I don't know I always think that my self esteem is not affected by this. You know I have highs and lows. Some days you feel great, the next thing you feel down. Back pain give you an uncertainty for the future – you don't know if you're gonna get fit again or whether you will be doing this and that. And everybody has an ambition, you know, try to do better, try to improve their lives you know. In that respects yeah, it probably affects my self esteem, and my confidence. On the other hand I would say no. Maybe I am being stubborn but that's probably something, you know it keeps me thinking no no, it shouldn't affect me, why should it? So, I try to think, I don't want to be affected by this or by anything.

Interviewer: How about trust and confidence in the clinicians?

Patient: I just leave it to them. My problem is in their hands and I leave it up to them to come up with a solution. So far, I've been told that this is it, you know, you do this you do that. Like with the physiotherapy, I've been advised to do my exercises with the view to it improving my quality of life. Its true, its been improving. Like I said when my back pain started it was a big pain down to my leg but now its moving back to the low part of my back. So, yeah I do trust them. But it's a slow process of course. It's frustrating sometimes. By the time I see my GP and by the time he referred me, I was doing nothing for about 3 months, until I got an appointment with the consultant. I was hoping that they would take up to date x-rays and MRI scans, but they went on the past MRI which was done 10 years ago. So, my life is in their hands basically. I can't condemn them because they know what they're doing. But I can't say its great because I'm not well yet. But I can't blame them, because it's my problem and I understand that. It's my problem. I would like, or I would hope that things can be done faster and quicker, for my sake.

Interviewer: What treatments are you taking again?

Patient: Pain killers

Interviewer: How often do you take them?

Patient: Its one tablet each. I was on two for pain killers at one stage and my doctor said two of each is okay. But I hate taking medication. Just from being young, whenever I had headaches, whatever, even in my teen times, even if I had hangover from drinking or something I try to sleep it off. You know, try and avoid chemicals really. You know try and sleep it off. So, being on tablets for the last 11 months, it's not something that I like

to do but if it helps taking them. I take them but now and again if I feel okay I don’t take them just to get it out of my system. I don’t want to rely on medication basically.
Interviewer: Do you take your medication as recommended by your doctors?
Patient: Yes. But I told my GP if I feel okay I don’t want to take them, and he said yeah, just take them when you need them. I am worried about dependency. I don’t want to rely on them. I mean just before Xmas I saw the physiotherapist who though my headaches were from my medication. So we left them out for a couple of weeks. Unfortunately, the pain I am experiencing in my head were not from my medication. During that time, I had to put up with a lot of pain in my back. I had the pain in my back but I tend not take anything. I smoke, so I just go out and whenever I feel really, you know have a cigarette just to give it a chance to help the problem. So, I would like to find out why this has all occurred and I will see my GP, and hopefully he will investigate the pain more.
Interviewer: Are there any benefits of taking medication?
Patient: Yes I have less pain.
Interviewer: Does CLBP medications meet your expectations?
Patient: Well, I was expecting to be pain free. But what I’ve learned from the past 6-7 months is that once your there, you can never be free from the pain so you might as well just learn to manage it. So that’s what I’m doing on a daily basis. If I’m feeling bad I tend to just do less.
Interviewer: Have your expectations been met?
Patient: Not yet. Because you move from one thing to another. You start with my back, then my neck, then I have a headache. It’s a very weird headache, its not like I can take a tablet and it will go away. When I shake my head I get a very painful sensation, and in the last 2 weeks I’ve started experiencing pain around the back of my eye. So I don’t know whats that. Whether its to do with my back or something completely different. So I am still hoping to get back to normal. You know at some stage I will be fully functioning, and go back to work, and just do normal things like every body else. I will never be 20 again, I’m nearly 48. But I expect to be a good healthy 48, you know at some stage I expect to be healthy and able to go back to work again.
Interviewer: Do you experience any side effects from your CLBP medication?
Patient: Like I said sometimes it makes me go to the bathroom, sometimes I have light diarrhoea, or the other one, constipation. I think it’s the body getting used to the tablet but apart from that nothing abnormal.
Interviewer: Are there any disadvantages to taking the medication?
Patient: I just close my eyes and swallow them. Basically, try and do it as quickly as possible. Because of the pain you know I just want to get it over with.
Interviewer: What does satisfaction with treatment mean to you?
Patient: Satisfaction with treatment means when I am 100% satisfied with my body. Like I said because the pain has been there a long time, and its probably going to be there for the rest of my life. So, I don’t expect satisfaction to me is just, going back to work, feeling fit, I can do daily things, you know daily activities, it doesn’t have to be something extreme. You know I’m not going to do a bungee jump, or something like that, I don’t expect to do something like that. My satisfaction is just going about doing my daily life as normal as possible.
Interviewer: Okay, and what does dissatisfaction with treatment mean to you?
Patient: If my back collapses totally, then I would go back to square one. Like last January then that would be really disappointing. I don’t want to go back to that stage, because that was severe pain because that would be my worse nightmare. I would be very dissatisfied if I get to that stage. That’s something I don’t even want to think about it.

Interviewer: Okay and are you satisfied or dissatisfied with your treatment?
Patient: I cant say otherwise. They do their best. They can only go so far with the treatment with any illness. You know they're doing there best. I totally understand that. I would have liked to do more physiotherapy because it gives me the motivation to do more or try harder. So I would like to carry on with that but I will need to ask my GP. You know I can understand that they have probably had enough of my face being around for a couple of months. So, yes I am satisfied.
Interviewer: Okay, and is there anything else you would like to share with me?
Patient: I think we covered a lot. But I would say that everyone has different opinions about how to express their pain and their condition. I would say that probably my condition is worse than a lot of people. But when I seen some people, I thought, still I could move about. So, seeing other people helps you to have a wider knowledge of the problem and it shows you it's not the end, there is always a light at the end of the tunnel. You know there is always room for improvement there.
Interviewer: Right well thank you for that.

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APPENDIX H: Draft CLBP Treatment Satisfaction Questionnaire

This questionnaire asks for your views about **your back pain** and **your treatment**. Please read the following statements carefully and then place a circle around the most appropriate number that applies to you. If there are any statements you do not feel comfortable responding to, please feel free to miss them out.

1. ABOUT YOUR BACK PAIN

a.	In general, how do you rate your health?									
	1	2	3	4	5					
	Excellent	Very Good	Good	Fair	poor					
b.	How much back pain do you have right now?									
	No pain									**Severe Pain**
	1	2	3	4	5	6	7	8	9	10
c.	How much back pain have you had in the last 24 hours?									
	No pain									**Severe Pain**
	1	2	3	4	5	6	7	8	9	10
d.	How much back pain have you had in the last week?									
	No pain									**Severe Pain**
	1	2	3	4	5	6	7	8	9	10

2. SYMPTOMS OF BACK PAIN

In the last 7 days how much of a problem were the following symptoms:		**Please circle one number only for each side effect**					
		NO	**YES I had this side effect and it was….**				
		I did not have this symptom	**Not a problem**	**A little bit of a problem**	**A problem**	**A big problem**	**A severe problem**
a.	Pain in back	0	1	2	3	4	5
b.	Pain in legs	0	1	2	3	4	5
c.	Pins and needles	0	1	2	3	4	5
d.	Numbness	0	1	2	3	4	5
e.	Stiffness	0	1	2	3	4	5

3. ABOUT YOUR MEDICAL CARE

During the last 7 days, how do you rate the following statements?		**Strongly agree**	**Agree**	**Not sure**	**Disagree**	**Strongly disagree**
a.	My doctors did not know what was wrong with me	1	2	3	4	5
b.	I was misdiagnosed	1	2	3	4	5
c.	I was involved in treatment decisions	1	2	3	4	5

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4. INFORMATION PROVIDED TO YOU ABOUT BACK PAIN AND TREATMENT

How much information would you have liked to have received about the following:		**More**	**A little more**	**I was happy with the level of information provided**	**A little less**	**None**
a.	My condition or injury	1	2	3	4	5
b.	The causes of my back pain	1	2	3	4	5
c.	Treatment options available (apart from back pain medication)	1	2	3	4	5
d.	Back pain medications	1	2	3	4	5
e.	The potential side effects of back pain medications	1	2	3	4	5
f.	Posture and positioning	1	2	3	4	5
g.	Goal setting	1	2	3	4	5
h.	Pacing (taking things gradually)	1	2	3	4	5
i.	Exercise	1	2	3	4	5
j.	Injections	1	2	3	4	5

5. YOUR HEALTH AND WELL-BEING

During the last 7 days, to what extent has your back pain interfered with your regular daily activities?		**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a.	I cut down on the amount of time I spent on tasks	1	2	3	4	5
b.	I was limited in the type of tasks I could do	1	2	3	4	5
c.	I stopped doing my everyday tasks	1	2	3	4	5
d.	I stopped doing tasks I wanted to do	1	2	3	4	5
e.	I stopped doing sports	1	2	3	4	5

During the last 7 days, to what extent has your back pain interfered with your regular work?		**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a.	I went to work	1	2	3	4	5
b.	I was unable to work due to my physical limitations	1	2	3	4	5
c.	It was difficult to be positive at work	1	2	3	4	5

During the last 7 days, to what extent has your back pain interfered with your physical functioning?		**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a.	I was able to do physical activities	1	2	3	4	5
b.	I was unable to walk	1	2	3	4	5
c.	I had poor balance	1	2	3	4	5
d.	I leaned on one side	1	2	3	4	5
e.	I could bend down	1	2	3	4	5
f.	It was difficult to keep standing	1	2	3	4	5

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During the last 7 days, to what extent has your back pain interfered with your social activities?		**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a.	I went out	1	2	3	4	5
b.	I socialised	1	2	3	4	5

During the last 7 days, to what extent has your back pain interfered with your self-confidence?		**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a.	I planned before I did things	1	2	3	4	5
b.	I was cautious in everything I did	1	2	3	4	5
c.	I had low belief in my abilities	1	2	3	4	5
d.	I was scared to do too much	1	2	3	4	5
e.	I had low self esteem	1	2	3	4	5

During the last 7 days, to what extent has your back pain interfered with your appearance?		**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a.	I felt I gained weight	1	2	3	4	5
b.	Slouching was more comfortable	1	2	3	4	5
c.	I was unable to brush/comb my hair	1	2	3	4	5
d.	I had difficulty getting dressed	1	2	3	4	5
e.	I was not interested in my appearance	1	2	3	4	5
f.	I was embarrassed about my image	1	2	3	4	5

During the last 7 days, to what extent has your back pain interfered with your mood?		**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a.	I was sad	1	2	3	4	5
b.	I was irritable	1	2	3	4	5
c.	I was frustrated	1	2	3	4	5
d.	I felt tired	1	2	3	4	5
e.	I was annoyed	1	2	3	4	5
f.	I did not want to do anything	1	2	3	4	5
g.	I could not cope with the pain	1	2	3	4	5
h.	I felt life was not worth living	1	2	3	4	5
i.	I felt depressed	1	2	3	4	5
k.	I was anxious	1	2	3	4	5
l.	I felt uncertain of the future	1	2	3	4	5

During the last 7 days, to what extent has your back pain interfered with your sleep?		**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a.	I did not sleep well	1	2	3	4	5
b.	It was difficult to get comfortable to get to sleep	1	2	3	4	5
c.	I tossed and turned in my sleep	1	2	3	4	5
d.	I woke up in the night	1	2	3	4	5
e.	I had an ache in my back when I woke up	1	2	3	4	5

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During the last 7 days, to what extent has your back pain interfered with your relationships?		**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a.	I did not want anyone near me	1	2	3	4	5
b.	I was interested in relationships	1	2	3	4	5
c.	I did not want to burden others with my problems	1	2	3	4	5
d.	I tried not to worry my family	1	2	3	4	5
e.	Sex was very uncomfortable	1	2	3	4	5
f.	I did not have sex	1	2	3	4	5
g.	I could not relax with my partner	1	2	3	4	5
h.	My partner was frustrated	1	2	3	4	5
i.	My partner felt guilty	1	2	3	4	5
j.	My partner treated me as fragile	1	2	3	4	5
k.	People around me were sympathetic	1	2	3	4	5
l.	People thought I was faking it	1	2	3	4	5
m.	People around me did not understand	1	2	3	4	5

6. ABOUT YOUR CURRENT TREATMENT

During the last 7 days, how do you rate the following statements?		**Strongly agree**	**Agree**	**Not sure**	**Disagree**	**Strongly disagree**
a.	My back pain medication is helpful to me	1	2	3	4	5
b.	My back pain medication prevents future problems	1	2	3	4	5
c.	My back pain medication enables me to be independent (carry out everyday activities)	1	2	3	4	5
d.	By taking back medication, I felt out of control	1	2	3	4	5
e.	I altered the amount of back pain medication I took	1	2	3	4	5

During the last 7 days, how do you rate the following statements?		**Strongly agree**	**Agree**	**Not sure**	**Disagree**	**Strongly disagree**
a.	I set realistic goals	1	2	3	4	5
b.	I remembered to do my exercises	1	2	3	4	5
c.	I paced my activities	1	2	3	4	5

7. SIDE EFFECTS FROM MEDICATION

Because of your back pain medication, in the last 7 days how much of a problem were the following:		**Please circle one number only for each side effect**					
		NO	**YES I had this side effect and it was….**				
		I did not have this side effect	**Not a problem**	**A little bit of a problem**	**A problem**	**A big problem**	**A severe problem**
a.	Loss of appetite	0	1	2	3	4	5
b.	Weight gain	0	1	2	3	4	5
c.	Inability to concentrate	0	1	2	3	4	5
d.	Drowsiness	0	1	2	3	4	5
e.	Nausea	0	1	2	3	4	5
f.	Constipation	0	1	2	3	4	5

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Because of your back pain medication, in the last 7 days how much of a problem were the following:		**Please circle one number only for each side effect**					
		NO	**YES I had this side effect and it was….**				
		I did not have this side effect	**Not a problem**	**A little bit of a problem**	**A problem**	**A big problem**	**A severe problem**
g.	Diarrhoea	0	1	2	3	4	5
h.	Stomach aches	0	1	2	3	4	5
i.	Heartburn	0	1	2	3	4	5
j.	Inability to sleep	0	1	2	3	4	5

8. SATISFACTION WITH CURRENT MEDICATION AND CARE

In the last 7 days, how satisfied or dissatisfied were you with the following:		**Very satisfied**	**Satisfied**	**Neither**	**Dissatisfied**	**Very Dissatisfied**
a.	The care provided for my back pain	1	2	3	4	5
b.	The communication between myself and health professionals regarding my back pain medication	1	2	3	4	5
c.	The information provided about the treatment options	1	2	3	4	5
d.	The information provided about the possible side effects from my back pain medication	1	2	3	4	5
e.	The form of administration (e.g. tablet, injection, patch) of my back pain medication	1	2	3	4	5
f.	The amount of medication prescribed	1	2	3	4	5
g.	The amount of time taken to take my back pain medication	1	2	3	4	5
h.	The way health professionals have dealt with the side effects of my back pain medication	1	2	3	4	5

9. MODE OF ADMINISTRATION

How is your back pain medication administered? Please check (✓) all that apply and complete the relevant sections.			
a.	Orally (e.g. tablet or syrup)	☐	If yes, go to section A
b.	Injections	☐	If yes, go to section 10
c.	Patch	☐	If yes, go to section 10

SECTION A: ORAL BACK PAIN MEDICATIONS

During the last 7 days, how do you rate the following statements?		**Strongly agree**	**Agree**	**Not sure**	**Disagree**	**Strongly disagree**
a.	My oral back pain medication is difficult to swallow	1	2	3	4	5
b.	My oral back pain medication leaves an unpleasant taste in mouth	1	2	3	4	5

☐☐☐☐☐

10. ADDITIONAL COMMENTS you would like to add about your experiences of treatment:

Thank you for taking time to fill in this questionnaire

Patient # ________ (1-10) Date of interview ____________

Gender ________ (M/F)

APPENDIX I: Cognitive Debriefing Guide

Patient Satisfaction and Dissatisfaction with Treatments in Chronic Low Back Pain (CLBP)

COGNITIVE DEBRIEFING

Chronic Low Back Pain (CLBP) Treatment Satisfaction Questionnaire

In order to assess the clarity, comprehension and appropriateness of wording in the questionnaire it will be tested on patients.

The aim of this cognitive debriefing is to:

1) Identify questions which are problematic
2) Determine reason(s) why
3) Record the solutions proposed
4) Determine the relevance of each question to the patient.

The interview should be conducted as follows:

General impression

Enquire about the participant's general feeling about the questionnaire

1. What is your overall opinion about the questionnaire?
    - Easy/ difficult to understand?
    - Clear/ not clear?
    - Easy/ difficult to answer?
    - Length?

2. What is your opinion about the instructions?

3. What is your opinion about the length of the instructions?
    - PROBE: Are they long enough? Are they too detailed?

4. What is your opinion about the length of the questionnaire?

5. Would you add anything? What? Why?

6. Would you delete anything? What? Why?

7. Are there any questions that are unclear? Which ones? Why?

8. When you completed the questionnaire, how far back were you thinking?

9. What do you think of the way the questionnaire is laid out?
    - Too long?
    - Too repetitive?
    - Is it clear how you answer the questions?
    - Did you find it confusing at all?
    - Would you lay out the questionnaire differently at all?
        - How?

10. Do you think the answer choices are appropriate?
    - Would you prefer there to be more or less answer choices, or is the number about right?
    - Did you think the length of the description for each answer choice is appropriate?
    - Did you think the descriptions for each answer choice are appropriate and relevant?

3 - Specific questions

Read each question to the participant one at a time.
(remind the participant that we are not interested in his/her responses but in the formulation of the questions)

Check whether:

- Each question was difficult to understand or to answer. If so, why?

- The underlying concept is interpreted correctly i.e. there are no ambiguous wordings that would make more than one interpretation possible; the wording used is easily understandable and colloquial.

- The participant would ask the question another way.

- The response choices are clear and consistent with the question.

The aim of the cognitive debriefing is to produce a version of the questionnaire that is clear, comprehensive and relevant to all participants receiving treatment for CLBP.

COGNITIVE DEBRIEFING FORM

Age: ___________

Sex: _____________

Time to complete the questionnaire: ___________________________

General Impression

____
____
____
____
____
____
____
____
____
____
____

	Did you have difficulty understanding the title?	**Are there words that you find difficult to understand?**	**How would you have worded the title?**	**Is there anything missing in the title?**
Title:				

	Are the instructions clear & comprehensive?	**Are there any words/ terms that patients may find difficult to understand?**	**How would you have worded the instructions?**	**Is there anything missing in the Instructions?**
Instructions – front page: * The following pages ask some questions about your treatment. Within this questionnaire ‘treatment’ refers to your current treatment for CLBP. * Please read each one and answer as honestly as				

	Are the instructions clear & comprehensive?	**Are there any words/ terms that patients may find difficult to understand?**	**How would you have worded the instructions?**	**Is there anything missing in the Instructions?**
you can without the help of anyone. * There are no right or wrong answers. * All of your answers will remain confidential. * This questionnaire will take about 10 minutes to complete.				

Your thoughts about treatment for CLBP					
	Did you have difficulty understanding these instructions?	**Are there words that you find difficult to understand?**	**How would you have worded the instructions?**	**Is there anything missing in the Instructions?**	**–**
Instructions at top of page 1:					
Statement before questions x-x: **In general,**					

	Did you have difficulty understanding this question?	What does it mean to you?	Is it relevant to your situation?	How would you have worded the question?	Are the response choices clear and consistent with the question?
Question 1:					
Question 2:					
Question 3:					
Question 4:					
Question 5:					
Question 6:					
Question 7:					
Question 8:					
Question 9:					
Question 10:					
Question 11:					
Question 12:					
Question 13:					

	Did you have difficulty understanding the response choices?	What do they mean to you?	Are they relevant to your situation?	How would you have worded the response choices?	-
Response choices					

Impact of treatment on your daily life					
	Did you have difficulty understanding these instructions?	**Are there words that you find difficult to understand?**	**How would you have worded the instructions?**	**Is there anything missing in the Instructions?**	**_**
Statement before questions x-x:					

	Did you have difficulty understanding this question?	What does it mean to you?	Is it relevant to your situation?	How would you have worded the question?	Are the response choices clear and consistent with the question?
Question 14:					
Question 15:					
Question 16:					
Question 17:					

	Did you have difficulty understanding this question?	What does it mean to you?	Is it relevant to your situation?	How would you have worded the question?	Are the response choices clear and consistent with the question?
Question 18:					
Question 19:					
Question 20:					
Question 21:					
Question 22:					
Question 23:					
Question 24:					

Remembering to take treatment for CLBP					
	Did you have difficulty understanding these instructions?	Are there words that you find difficult to understand?	How would you have worded the instructions?	Is there anything missing in the Instructions?	_
Statement:					
Statement before Question x-x					

	Did you have difficulty understanding this question?	What does it mean to you?	Is it relevant to your situation?	How would you have worded the question?	Are the response choices clear and consistent with the question?
Question 25:					
Question 26:					
Question 27:					
Question 28:					
Out of pocket costs for taking treatment for CLBP					
	Did you have difficulty understanding these instructions?	**Are there words that you find difficult to understand?**	**How would you have worded the instructions?**	**Is there anything missing in the Instructions?**	**–**
Statement before Questions x-x:					
	Did you have difficulty understanding this question?	**What does it mean to you?**	**Is it relevant to your situation?**	**How would you have worded the question?**	**Are the response choices clear and consistent with the question?**
Question 29:					
Question 30:					

Satisfaction with current treatment for CLBP					
	Did you have difficulty understanding these instructions?	**Are there words that you find difficult to understand?**	**How would you have worded the instructions?**	**Is there anything missing in the Instructions?**	**_**
Statement before Questions x-x:					
	Did you have difficulty understanding this question?	**What does it mean to you?**	**Is it relevant to your situation?**	**How would you have worded the question?**	**Are the response choices clear and consistent with the question?**
Question 31:					
Question 32:					
Question 33:					
Question 34:					
Question 35:					
Question 36:					
Question 37:					
Question 38:					
Question 39:					
Question 40:					

Treatment preferences/ trade-offs					
	Did you have difficulty understanding these instructions?	**Are there words that you find difficult to understand?**	**How would you have worded the instructions?**	**Is there anything missing in the Instructions?**	**–**
Statement before Question 41:					

	Did you have difficulty understanding this question?	**What does it mean to you?**	**Is it relevant to your situation?**	**How would you have worded the question?**	**Are the response choices clear and consistent with the question?**
Question 41:					

Are there any questions/ areas missing from the questionnaire in your opinion?	List here: .. ..

End of interview.

☐☐☐☐☐

APPENDIX J: Revised CLBP Treatment Satisfaction Questionnaire

This questionnaire asks for your views about **<u>your back pain</u>** and **<u>your treatment</u>** (medication and/or physiotherapy). Please read the following statements carefully and then place a circle around the most appropriate number that applies to you. If there are any statements you do not feel comfortable responding to, please feel free to miss them out.

1. ABOUT YOUR HEALTH

a.	In general, how do you rate your health?									
	1 Excellent		2 Very Good		3 Good		4 Fair		5 poor	
b.	How much back pain do you have right now?									
	No pain									**Severe Pain**
	1	2	3	4	5	6	7	8	9	10
c.	How much back pain have you had in the last 7 days?									
	No pain									**Severe Pain**
	1	2	3	4	5	6	7	8	9	10

2. INFORMATION PROVIDED TO YOU ABOUT BACK PAIN AND TREATMENT

How much information would you have liked to have received about the following:		**More**	**A little more**	**I was happy with the level of information provided**	**A little less**	**None**
a.	My condition or injury	1	2	3	4	5
b.	The causes of my back pain	1	2	3	4	5
c.	Back pain medications	1	2	3	4	5
d.	The potential side effects of back pain medications	1	2	3	4	5
e.	Treatment options available (apart from back pain medication)	1	2	3	4	5
f.	Posture and positioning	1	2	3	4	5
g.	Goal setting (Setting tasks to do)	1	2	3	4	5
h.	Pacing (taking things gradually)	1	2	3	4	5
i.	Exercise	1	2	3	4	5

3. ABOUT YOUR MEDICAL CARE

How do you rate the following statements?		**Strongly agree**	**Agree**	**Not sure**	**Disagree**	**Strongly disagree**
a.	My doctors did not know what was wrong with me	1	2	3	4	5
b.	I was misdiagnosed	1	2	3	4	5
c.	I was involved in treatment decisions	1	2	3	4	5

☐☐☐☐☐

4. YOUR HEALTH

During the last 7 days, to what extent has your back pain interfered with your regular daily activities?		**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
1a.	I spent less time on tasks than I would have liked to	1	2	3	4	5
1b.	I was limited in the type of tasks I could do	1	2	3	4	5
1c.	I stopped doing everyday tasks	1	2	3	4	5
1d.	I was unable to work	1	2	3	4	5
1e.	I went out of my home	1	2	3	4	5

During the last 7 days, to what extent has your back pain interfered with your physical functioning?		**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
2a.	I was unable to walk	1	2	3	4	5
2b.	I had poor balance	1	2	3	4	5
2c.	I leaned on one side	1	2	3	4	5
2d.	I could bend down	1	2	3	4	5
2e.	It was difficult to keep standing	1	2	3	4	5

During the last 7 days, to what extent has your back pain interfered with your confidence?		**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
3a.	I planned before I did things	1	2	3	4	5
3b.	I was cautious in everything I did	1	2	3	4	5
3c.	I had low beliefs in my abilities	1	2	3	4	5
3d.	I was scared to do too much	1	2	3	4	5
3e.	I had low self esteem	1	2	3	4	5
3f.	I felt uncertain of the future	1	2	3	4	5

During the last 7 days, to what extent has your back pain interfered with your appearance?		**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
4a.	I slouched	1	2	3	4	5
4b.	I was unable to brush/comb my hair	1	2	3	4	5
4c.	I had difficulty getting dressed	1	2	3	4	5
4d.	I was not interested in my appearance	1	2	3	4	5
4e.	I was embarrassed about my image	1	2	3	4	5

During the last 7 days, to what extent has your back pain interfered with your mood?		**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
5a.	I was sad	1	2	3	4	5
5b.	I was irritable	1	2	3	4	5
5c.	I was frustrated	1	2	3	4	5
5d.	I was tired	1	2	3	4	5
5e.	I did not want to do anything	1	2	3	4	5
5f.	I could not cope with the pain	1	2	3	4	5
5g.	I felt life was not worth living	1	2	3	4	5
5h.	I was worried	1	2	3	4	5

5. RELATIONSHIPS & SLEEP

During the last 7 days, to what extent has your back pain interfered with your relationships?		**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**	**Not applicable**
1a.	I did not want anyone near me	1	2	3	4	5	6
1b.	I did not want to burden others with my problems	1	2	3	4	5	6
1c.	I could not relax with my partner	1	2	3	4	5	6
1d.	People around me did not understand my back pain	1	2	3	4	5	6
1e.	People thought I was faking my back pain	1	2	3	4	5	6
1f.	I was sexually active	1	2	3	4	5	6
1g.	Sex was very uncomfortable	1	2	3	4	5	6

During the last 7 days, to what extent has your back pain interfered with your sleep?		**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
2a.	I tossed and turned in my sleep	1	2	3	4	5
2b.	I woke up in the night	1	2	3	4	5
2c.	I had an ache in my back when I woke up	1	2	3	4	5

6. BELIEFS ABOUT YOUR BACK PAIN MEDICATION

How do you rate the following statements?		**Strongly agree**	**Agree**	**Not sure**	**Disagree**	**Strongly disagree**
1a.	My back pain medication is helpful to me	1	2	3	4	5
1b.	My back pain medication prevents future problems	1	2	3	4	5
1c.	My back pain medication enables me to be independent (carry out everyday activities)	1	2	3	4	5
1d.	By taking back medication, I felt out of control	1	2	3	4	5
1e.	I altered the amount of back pain medication I took	1	2	3	4	5

During the last 7 days, how do you rate the following statements?		**Strongly agree**	**Agree**	**Not sure**	**Disagree**	**Strongly disagree**
2a.	I set realistic goals	1	2	3	4	5
2b.	I remembered to do my exercises	1	2	3	4	5
2c.	I paced my activities	1	2	3	4	5

☐☐☐☐☐

7. SIDE EFFECTS FROM BACK PAIN MEDICATION

Because of your back pain medication, in the last 7 days how much of a problem were the following:		**Did Side Effect Occur?**	**Please circle one number only for each side effect**				
			YES I had this side effect and it was….				
			Not a problem	**A little bit of a problem**	**A problem**	**A big problem**	**A severe problem**
a.	Loss of appetite	☐ No					
		☐ Yes →	1	2	3	4	5
b.	Weight gain	☐ No					
		☐ Yes →	1	2	3	4	5
c.	Inability to concentrate	☐ No					
		☐ Yes →	1	2	3	4	5
d.	Drowsiness	☐ No					
		☐ Yes →	1	2	3	4	5
e.	Nausea	☐ No					
		☐ Yes →	1	2	3	4	5
f.	Constipation	☐ No					
		☐ Yes →	1	2	3	4	5
g.	Diarrhoea	☐ No					
		☐ Yes →	1	2	3	4	5
h.	Stomach aches	☐ No					
		☐ Yes →	1	2	3	4	5
i.	Heartburn	☐ No					
		☐ Yes →	1	2	3	4	5
j.	Inability to sleep	☐ No					
		☐ Yes →	1	2	3	4	5

8. SATISFACTION WITH TREATMENTS FOR BACK PAIN RELIEF

How satisfied or dissatisfied are you with the following:		**Very satisfied**	**Satisfied**	**Neither**	**Dissatisfied**	**Very Dissatisfied**
a.	The communication between my doctor and I regarding my back pain medication	1	2	3	4	5
b.	The information provided about the possible side effects from my back pain medication	1	2	3	4	5
c.	The form of administration (e.g. tablet, injection, patch) of my back pain medication	1	2	3	4	5
d.	The amount of medication prescribed	1	2	3	4	5
e.	The way doctors have dealt with the side effects of my back pain medication	1	2	3	4	5

9. MODE OF ADMINISTRATION

How is your back pain medication administered? Please check (✓) all that apply and complete the relevant sections.			
a.	Orally (e.g. tablet or syrup)	☐	If yes, go to section A
b.	Injections	☐	Go to section 10
c.	Patch	☐	Go to section 10

☐☐☐☐☐

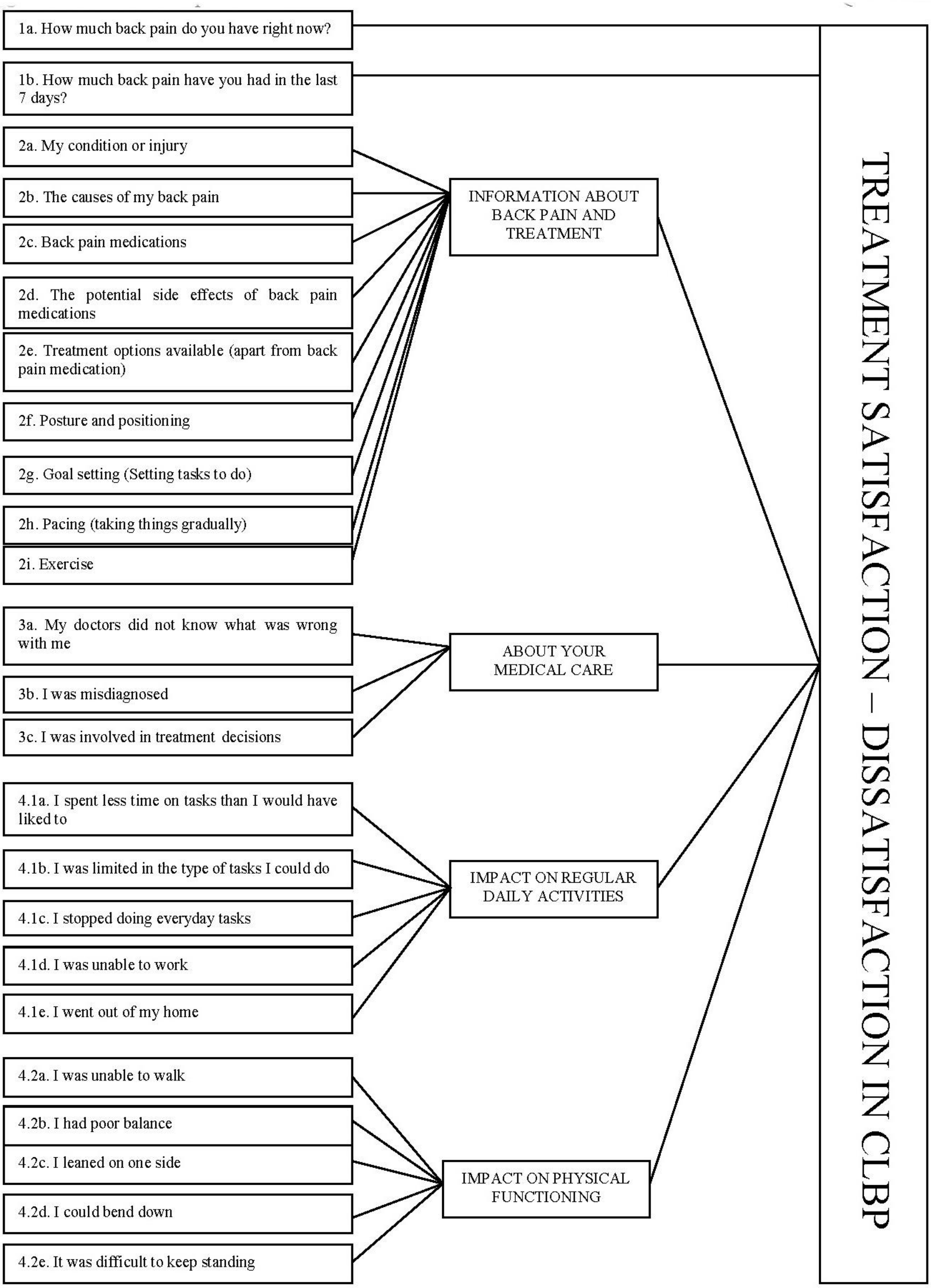
SECTION A: ORAL BACK PAIN MEDICATIONS

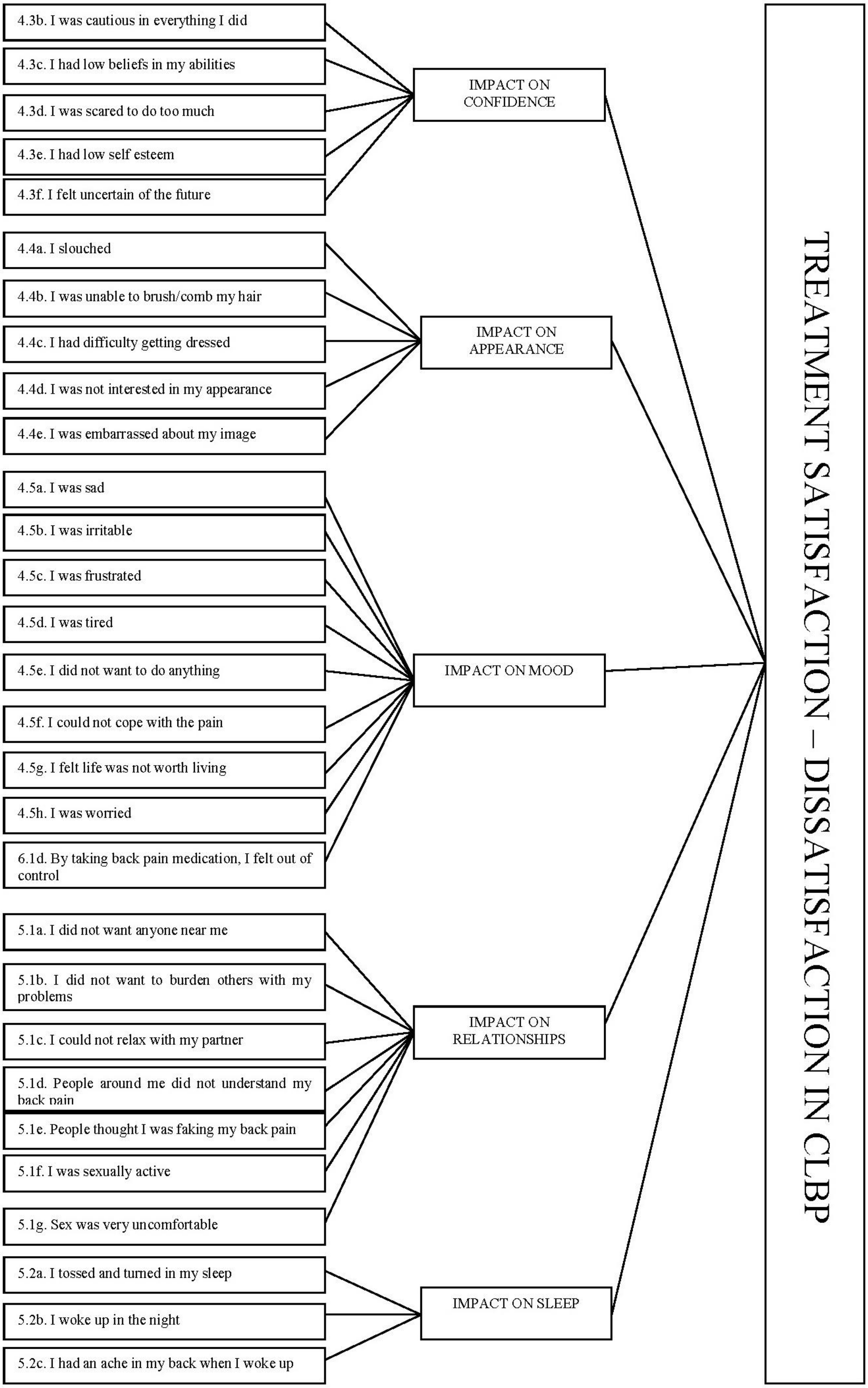
During the last 7 days, how do you rate the following statements?		Strongly agree	Agree	Not sure	Disagree	Strongly disagree
a.	My oral back pain medication is difficult to swallow	1	2	3	4	5
b.	My oral back pain medication leaves an unpleasant taste in mouth	1	2	3	4	5
c.	My oral back pain medication does not work quickly	1	2	3	4	5

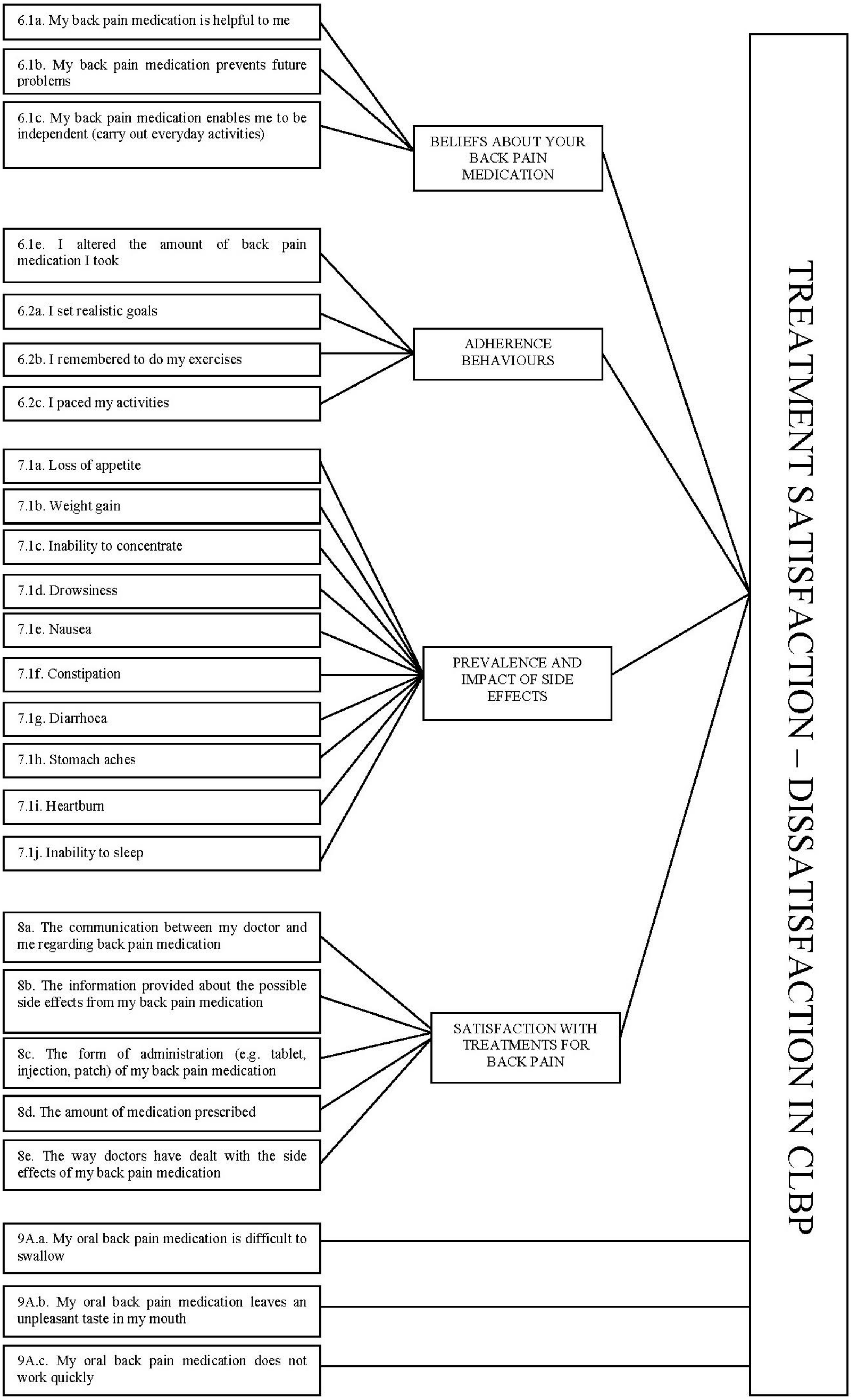
10. ADDITIONAL COMMENTS you would like to add about your experiences of treatment:

Thank you for taking time to fill in this questionnaire

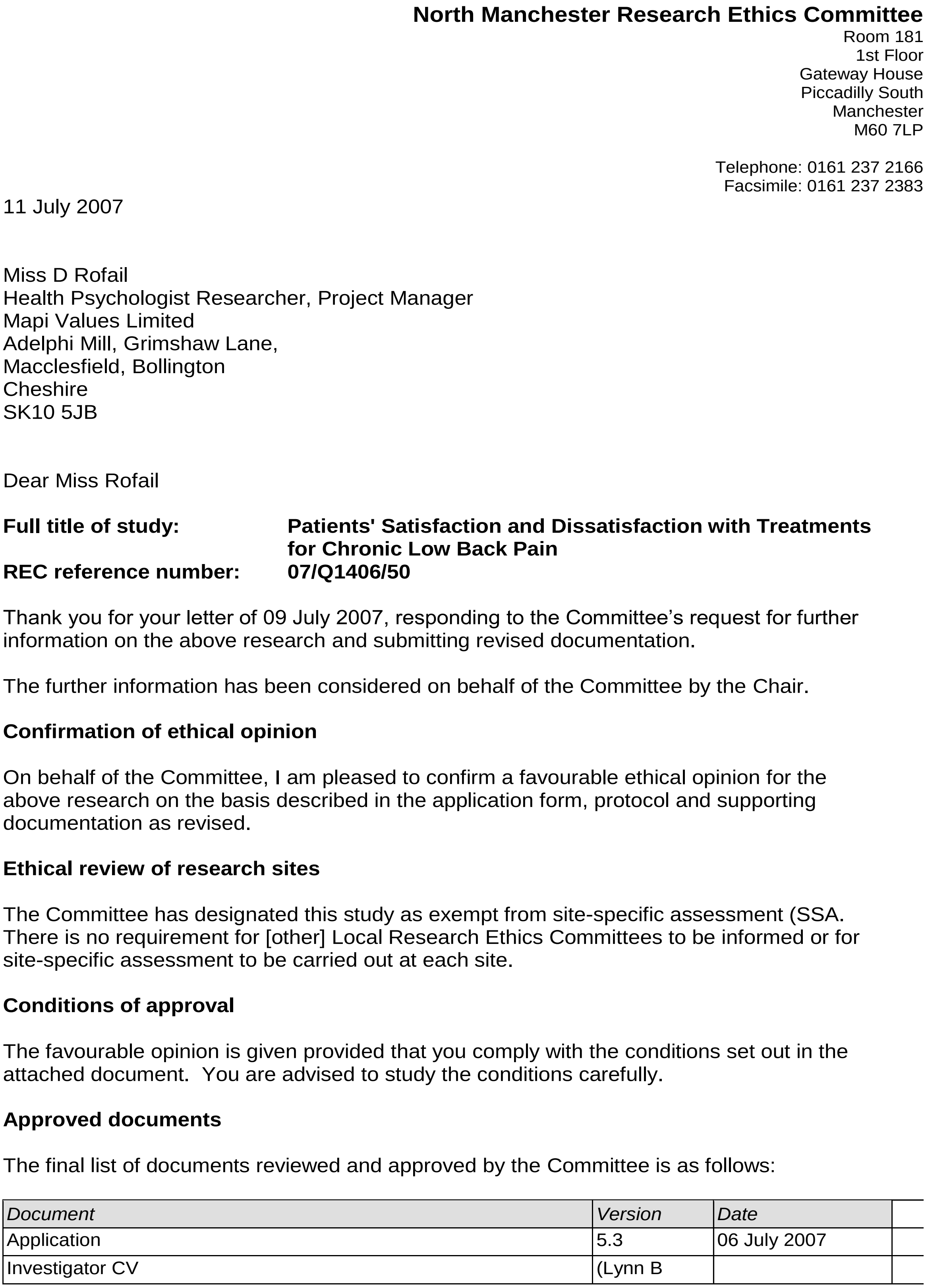
APPENDIX K: Revised Conceptual Framework of the CLBP Treatment Satisfaction Questionnaire




4.3b. I was cautious in everything I did
4.3c. I had low beliefs in my abilities
4.3d. I was scared to do too much
4.3e. I had low self esteem
4.3f. I felt uncertain of the future
IMPACT ON CONFIDENCE
4.4a. I slouched
4.4b. I was unable to brush/comb my hair
4.4c. I had difficulty getting dressed
4.4d. I was not interested in my appearance
4.4e. I was embarrassed about my image
IMPACT ON APPEARANCE
4.5a. I was sad
4.5b. I was irritable
4.5c. I was frustrated
4.5d. I was tired
4.5e. I did not want to do anything
4.5f. I could not cope with the pain
4.5g. I felt life was not worth living
4.5h. I was worried
6.1d. By taking back pain medication, I felt out of control
IMPACT ON MOOD
5.1a. I did not want anyone near me
5.1b. I did not want to burden others with my problems
5.1c. I could not relax with my partner
5.1d. People around me did not understand my back pain
5.1e. People thought I was faking my back pain
5.1f. I was sexually active
5.1g. Sex was very uncomfortable
IMPACT ON RELATIONSHIPS
5.2a. I tossed and turned in my sleep
5.2b. I woke up in the night
5.2c. I had an ache in my back when I woke up
IMPACT ON SLEEP
TREATMENT SATISFACTION – DISSATISFACTION IN CLBP


6.1a. My back pain medication is helpful to me
6.1b. My back pain medication prevents future problems
6.1c. My back pain medication enables me to be independent (carry out everyday activities)
BELIEFS ABOUT YOUR BACK PAIN MEDICATION
6.1e. I altered the amount of back pain medication I took
6.2a. I set realistic goals
6.2b. I remembered to do my exercises
6.2c. I paced my activities
ADHERENCE BEHAVIOURS
7.1a. Loss of appetite
7.1b. Weight gain
7.1c. Inability to concentrate
7.1d. Drowsiness
7.1e. Nausea
7.1f. Constipation
7.1g. Diarrhoea
7.1h. Stomach aches
7.1i. Heartburn
7.1j. Inability to sleep
PREVALENCE AND IMPACT OF SIDE EFFECTS
8a. The communication between my doctor and me regarding back pain medication
8b. The information provided about the possible side effects from my back pain medication
8c. The form of administration (e.g. tablet, injection, patch) of my back pain medication
8d. The amount of medication prescribed
8e. The way doctors have dealt with the side effects of my back pain medication
SATISFACTION WITH TREATMENTS FOR BACK PAIN
9A.a. My oral back pain medication is difficult to swallow
9A.b. My oral back pain medication leaves an unpleasant taste in my mouth
9A.c. My oral back pain medication does not work quickly
TREATMENT SATISFACTION – DISSATISFACTION IN CLBP

APPENDIX K: Ethics Approval (Study III)



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11 July 2007

Miss D Rofail
Health Psychologist Researcher, Project Manager
Mapi Values Limited
Adelphi Mill, Grimshaw Lane,
Macclesfield, Bollington
Cheshire
SK10 5JB

Dear Miss Rofail

Full title of study: **Patients' Satisfaction and Dissatisfaction with Treatments for Chronic Low Back Pain**
REC reference number: **07/Q1406/50**

Thank you for your letter of 09 July 2007, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Ethical review of research sites

The Committee has designated this study as exempt from site-specific assessment (SSA. There is no requirement for [other] Local Research Ethics Committees to be informed or for site-specific assessment to be carried out at each site.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*	
Application	5.3	06 July 2007	
Investigator CV	(Lynn B		

Investigator CV	(Miss Diana Rofail)		
Protocol	1.0 (Appendix A)		
Covering Letter		06 June 2007	
Statistician Comments	(Appendix M)	01 May 2007	
Questionnaire: (Problematic Experiences of Therapy Scale (PETS) - Appendix I)			
Questionnaire: (SF-36 Health Survey - Appendix H)	1.0		
Questionnaire: (Satisfaction and Dissatisfaction with treatments for Chronic Low Back Pain - Appendix G)			
Questionnaire: (Roland and Morris - Appendix F)			
Questionnaire: (Short-Form McGill Pain Questionnaire- Appendix E)			
Questionnaire: (Appendix K)			
GP/Consultant Information Sheets	1 (Appendix L)		
Participant Information Sheet	2	11 July 2007	
Participant Consent Form: (Appendix D)	1	06 June 2007	
Response to Request for Further Information	Diana Rofail	09 July 2007	
(Statement of Indemnity arrangements - Appendix N)			

Research governance approval

All researchers and research collaborators who will be participating in the research at NHS sites should apply for Research governance approval from the relevant care organisation, if they have not yet done so. Research governance approval is required, whether or not the study is exempt from SSA. You should advise researchers and local collaborators accordingly.

Further guidance is available from http://www.rdforum.nhs.uk/rdform.htm.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

Feedback on the application process

Now that you have completed the application process you are invited to give your view of the service you received from the National Research Ethics Service. If you wish to make your views known please use the feedback form available on the NRES website at:

https://www.nresform.org.uk/AppForm/Modules/Feedback/EthicalReview.aspx

We value your views and comments and will use them to inform the operational process and further improve our service.

07/Q1406/50	**Please quote this number on all correspondence**

With the Committee’s best wishes for the success of this project

Yours sincerely

Mrs Gillian Rimington
Chair

Email: stephen.tebbutt@northwest.nhs.uk

Enclosures:	Standard approval conditions

Copy to:

Professor T Wydell
Head of Psychology
School of Social Sciences
Brunel University
Uxbridge
Middlesex UB8 3PH

APPENDIX L: Patient Information Sheet (Study 3)

Professor Lynn B. Myers
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JULY 2007

Study Title: Patient Satisfaction and Dissatisfaction With Treatments in Chronic Low Back Pain (CLBP)

You are being invited to participate in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. 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 the conduct of the study.

PART 1

1. What is this study about?

The purpose of this research is to investigate patients' experiences with treatments in chronic low back pain (CLBP). To do this, we need to learn more about how people with Chronic Low Back Pain (CLBP) feel about the effects of their condition. This study will collect information on the importance to you of Chronic Low Back Pain (CLBP) symptoms and their effects on you. Also, on whether you are satisfied or dissatisfied with the treatment you are receiving, and what aspects if any could be improved.

This study is in part fulfilment of a PhD at Brunel University.

2. Why have I been chosen?

You have been invited because you have a diagnosis of Chronic Low Back Pain (CLBP) and are receiving treatment. There will be approximately 380 participants.

3. Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and you will be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

4. What will happen to me if I take part?

If you agree to participate, you will be asked to complete seven questionnaires at three different time points (start of study, two weeks later, and at week 6 which is the end of the study). The questionnaires ask you about your experience of having Chronic Low Back Pain (CLBP), and your opinion about your treatments for back pain. This usually takes no longer than thirty minutes each time you complete the questionnaires. Your doctor will be informed that you had taken part in this study.

5. Will I experience any risks or discomforts if I participate in the study?

There are no risks to participating in this study. You are free to share your questions and concerns during the interview, or to speak to the interviewer following the interview.

6. What if there is a problem?

Any complaint about the way you have been dealt with during this study or any possible harm you might suffer will be addressed. The detailed information on this is given in part 2.

For complaints please contact ***Diana Rofail on 01625 578897*** or email at ***diana@rofail.freeserve.co.uk***, or ***Professor Lynn Myers on 01895 265879***.

7. Will my taking part in a study be kept confidential?

Yes. All the information about your participation will be kept confidential. The details are included in Part 2.

8. What will happen if don't want to carry on with the study?

You can withdraw from the study at any time, and the information you provided can be destroyed immediately.

9. What do I do if I have any questions?

If you have any questions about the study, you may call or write to Diana Rofail, Research Psychologist on 01625 578897.

Part 1 of this information sheet is complete.

If the information in Part 1 has interested you and you are considering taking part, please continue to read the additional information in Part 2 before making a decision.

PART 2

10. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions (Diana Rofail on 01625 578897). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

11. Will my taking part in this study be kept confidential?

If you join the study, the data collected for this study will be looked at by authorised persons from Brunel University. The researcher would have your name and contact number but these details will immediately be destroyed following the interview. Thus confidentiality is agreed.

12. What will happen to the results of the research study?

The researchers will look at the results from the interviews for themes and ideas that are important to people who have taken part in the study and this will form the basis of an intervention study to assess satisfaction with treatments in Chronic Low Back Pain (CLBP). The results will be documented as part of a PhD thesis, and may be published in a peer reviewed academic journal, and disseminated at key conferences to health professionals.

12. Who is organising and funding the research?

This study is self-funded and is being conducted in part fulfilment of a PhD at Brunel University.

If you agree to take part, your doctor will be informed that you are participating in this study but s/he will not be paid for your participation.

13. Who has reviewed this study?

This study has been reviewed and approved by Manchester Research Ethics Committee.

Thank you for taking time to read this information sheet. You will be given an information sheet and signed consent form to keep.

APPENDIX M: The Adherence Questionnaire

Please read each statement clearly and mark a cross (x) for each statement in the appropriate box

	Always	Often	Sometimes	Rarely	Never
I forget to take my medicines					
I alter the dose of my medicines					
I stop taking my medicines for a while					
I decided to miss a dose					
I take less than instructed					

APPENDIX N: The SF-36 Health Survey

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is:

(circle one)

Excellent	1
Very good	2
Good	3
Fair	4
Poor	5

2. <u>Compared to one year ago</u>, how would you rate your health in general <u>now</u>?

(circle one)

Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same as one year ago	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

☐☐☐☐☐

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

(circle one number on each line)

ACTIVITIES	**Yes, Limited A Lot**	**Yes, Limited A Little**	**No, Not Limited At All**
a. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
c. Lifting or carrying groceries	1	2	3
d. Climbing **several** flights of stairs	1	2	3
e. Climbing **one** flight of stairs	1	2	3
f. Bending, kneeling, or stooping	1	2	3
g. Walking **more than a mile**	1	2	3
h. Walking **half a mile**	1	2	3
i. Walking **one hundred yards**	1	2	3
j. Bathing or dressing yourself	1	2	3

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

(circle one number on each line)

	YES	**NO**
a. Cut down on the **amount of time** you spent on work or other activities	1	2
b. **Accomplished less** than you would like	1	2
c. Were limited in the **kind** of work or other activities	1	2
d. Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2

☐☐☐☐☐

5. During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

(circle one number on each line)

	YES	NO
a. Cut down on the **amount of time** you spent on work or other activities	1	2
b. **Accomplished less** than you would like	1	2
c. Didn't do work or other activities as **carefully** as usual	1	2

6. During the <u>past 4 weeks</u>, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

(circle one)

Not at all	1
Slightly	2
Moderately	3
Quite a bit	4
Extremely	5

7. How much <u>bodily</u> pain have you had during the <u>past 4 weeks</u>?

(circle one)

None	1
Very mild	2
Mild	3
Moderate	4
Severe	5
Very severe	6

☐☐☐☐☐

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

(circle one)

Not at all	1
A little bit	2
Moderately	3
Quite a bit	4
Extremely	5

9. 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 -

(circle one number on each line)

	All of the Time	**Most of the Time**	**A Good Bit of the Time**	**Some of the Time**	**A Little of the Time**	**None of the Time**
a. Did you feel full of life?	1	2	3	4	5	6
b. Have you been a very nervous person?	1	2	3	4	5	6
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d. Have you felt calm and peaceful?	1	2	3	4	5	6
e. Did you have a lot of energy?	1	2	3	4	5	6
f. Have you felt downhearted and low?	1	2	3	4	5	6
g. Did you feel worn out?	1	2	3	4	5	6
h. Have you been a happy person?	1	2	3	4	5	6
i. Did you feel tired?	1	2	3	4	5	6

☐☐☐☐☐

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

(circle one)

All of the time	1
Most of the time	2
Some of the time	3
A little of the time	4
None of the time	5

11. How TRUE or FALSE is each of the following statements for you?

(circle one number on each line)

	Definitely True	**Mostly True**	**Don't Know**	**Mostly False**	**Definitely False**
a. I seem to get ill more easily than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

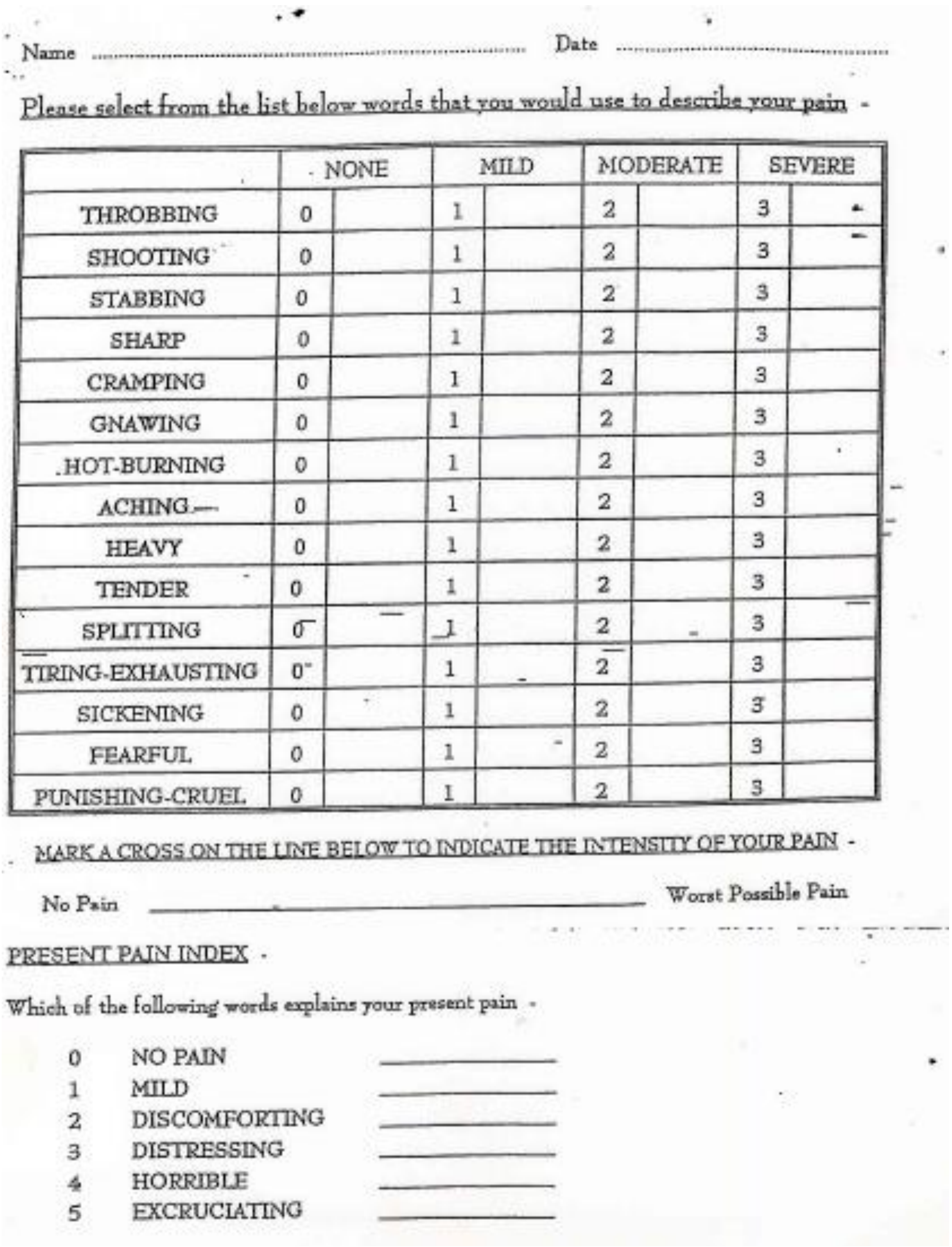
☐☐☐☐☐

APPENDIX O: Problematic Experiences with Therapy Scale (PETS)

We would like to know how easy or difficult it was for you to carry out the therapy. We want to find out if it was difficult in any way for you to carry out at home, and if so, what difficulties were and how often they prevented you from practicing the techniques you have learnt. Please circle the most appropriate response.

Problems due to symptoms					
I had to skip the therapy because it made my symptoms worse.	Agree Strongly	Agree Slightly	Not Sure	Disagree Slightly	Disagree Strongly
I was prevented from carrying out the therapy by severe symptoms.	Agree Strongly	Agree Slightly	Not Sure	Disagree Slightly	Disagree Strongly
I could not carry out the therapy because it caused more symptoms.	Agree Strongly	Agree Slightly	Not Sure	Disagree Slightly	Disagree Strongly
Problems due to uncertainty or doubts about the therapy					
I could not carry out the therapy because I was unsure how to do it properly.	Agree Strongly	Agree Slightly	Not Sure	Disagree Slightly	Disagree Strongly
I was unable to carry out the therapy because it was difficult to know what to do.	Agree Strongly	Agree Slightly	Not Sure	Disagree Slightly	Disagree Strongly
I skipped the therapy because I was not sure if it was helping.	Agree Strongly	Agree Slightly	Not Sure	Disagree Slightly	Disagree Strongly
I skipped the therapy because it did not seem relevant to my symptoms and problems.	Agree Strongly	Agree Slightly	Not Sure	Disagree Slightly	Disagree Strongly
I did not carry out the therapy because I was not convinced it was right for me.	Agree Strongly	Agree Slightly	Not Sure	Disagree Slightly	Disagree Strongly
Practical Problems					
Lack of time prevented me from carrying out the therapy.	Agree Strongly	Agree Slightly	Not Sure	Disagree Slightly	Disagree Strongly
It was not possible to find suitable opportunities to carry out the therapy.	Agree Strongly	Agree Slightly	Not Sure	Disagree Slightly	Disagree Strongly
I was too busy or tired to carry out the therapy.	Agree Strongly	Agree Slightly	Not Sure	Disagree Slightly	Disagree Strongly
I found it difficult to remember to carry out the therapy.	Agree Strongly	Agree Slightly	Not Sure	Disagree Slightly	Disagree Strongly

APPENDIX P: The Short Form McGill Questionnaire



Name .... Date ....

Please select from the list below words that you would use to describe your pain -

	NONE		MILD		MODERATE		SEVERE	
THROBBING	0		1		2		3	
SHOOTING	0		1		2		3	
STABBING	0		1		2		3	
SHARP	0		1		2		3	
CRAMPING	0		1		2		3	
GNAWING	0		1		2		3	
HOT-BURNING	0		1		2		3	
ACHING	0		1		2		3	
HEAVY	0		1		2		3	
TENDER	0		1		2		3	
SPLITTING	0		1		2		3	
TIRING-EXHAUSTING	0		1		2		3	
SICKENING	0		1		2		3	
FEARFUL	0		1		2		3	
PUNISHING-CRUEL	0		1		2		3	

MARK A CROSS ON THE LINE BELOW TO INDICATE THE INTENSITY OF YOUR PAIN -

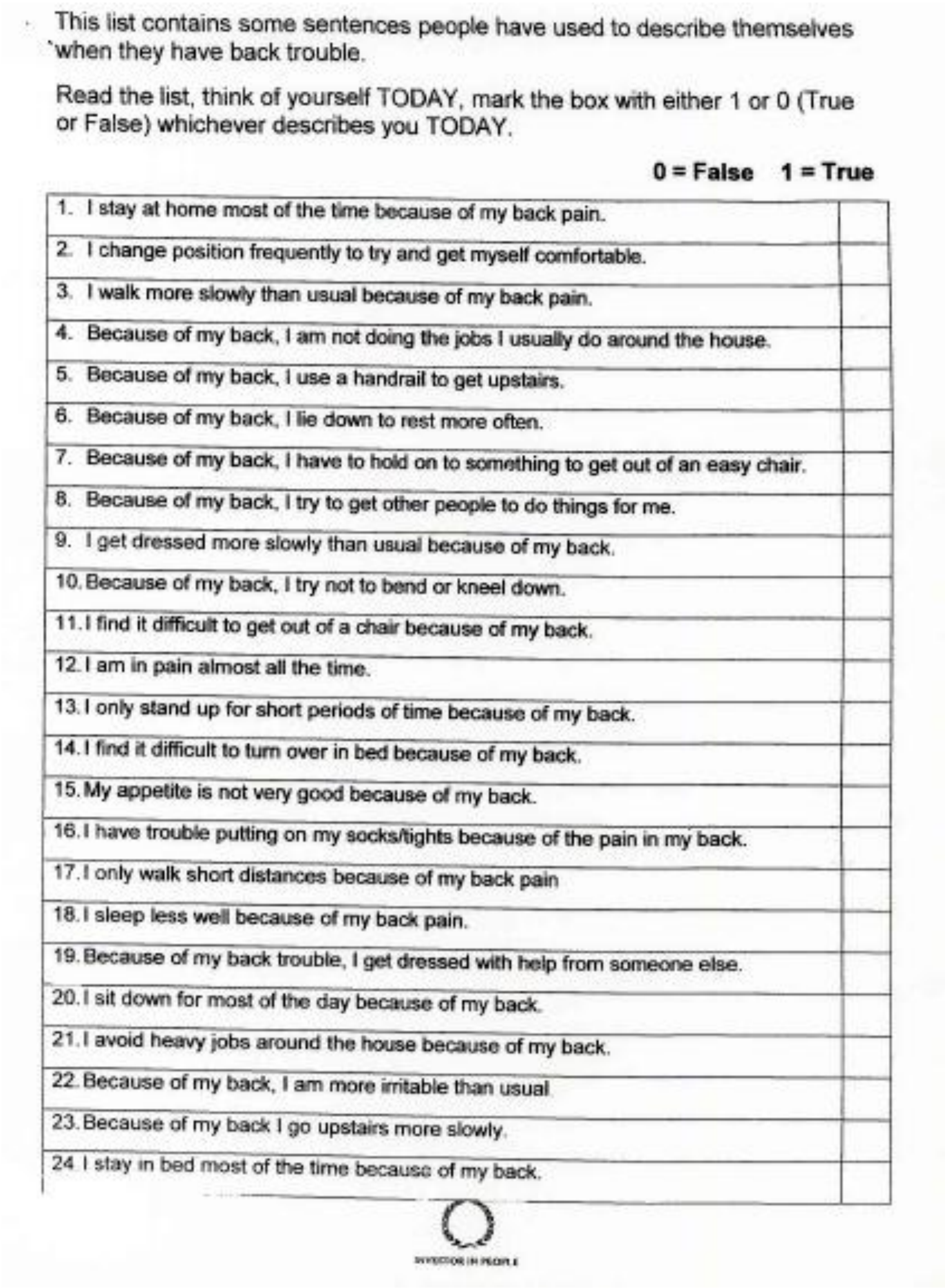
No Pain ______________________________ Worst Possible Pain

PRESENT PAIN INDEX -

Which of the following words explains your present pain -

0	NO PAIN	________
1	MILD	________
2	DISCOMFORTING	________
3	DISTRESSING	________
4	HORRIBLE	________
5	EXCRUCIATING	________

APPENDIX Q: The Roland and Morris Disability Questionnaire



This list contains some sentences people have used to describe themselves when they have back trouble.

Read the list, think of yourself TODAY, mark the box with either 1 or 0 (True or False) whichever describes you TODAY.

0 = False 1 = True

1. I stay at home most of the time because of my back pain.	
2. I change position frequently to try and get myself comfortable.	
3. I walk more slowly than usual because of my back pain.	
4. Because of my back, I am not doing the jobs I usually do around the house.	
5. Because of my back, I use a handrail to get upstairs.	
6. Because of my back, I lie down to rest more often.	
7. Because of my back, I have to hold on to something to get out of an easy chair.	
8. Because of my back, I try to get other people to do things for me.	
9. I get dressed more slowly than usual because of my back.	
10. Because of my back, I try not to bend or kneel down.	
11. I find it difficult to get out of a chair because of my back.	
12. I am in pain almost all the time.	
13. I only stand up for short periods of time because of my back.	
14. I find it difficult to turn over in bed because of my back.	
15. My appetite is not very good because of my back.	
16. I have trouble putting on my socks/tights because of the pain in my back.	
17. I only walk short distances because of my back pain	
18. I sleep less well because of my back pain.	
19. Because of my back trouble, I get dressed with help from someone else.	
20. I sit down for most of the day because of my back.	
21. I avoid heavy jobs around the house because of my back.	
22. Because of my back, I am more irritable than usual	
23. Because of my back I go upstairs more slowly.	
24. I stay in bed most of the time because of my back.	

INVESTOR IN PEOPLE

APPENDIX R: Proportion of patient responding to CLBP Treatment Satisfaction Items

Table 30: Proportion of Participants Responding to Items on Health and Pain

		Recruitment Site*									
		Physiotherapy		**Pain Clinic**		**Charities**		**Back Show**		**Total**	
Item	**Response options**	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)
1a. In general, how do you rate your health?	Excellent	1	1.7	0	0	0	0	4	3.3	5	2.1
	Very good	14	23.7	7	15.6	0	0	39	32.0	62	26.1
	Good	26	44.1	23	51.1	1	14.3	43	35.2	96	40.3
	Fair	13	22.0	14	31.1	5	71.4	30	24.6	64	26.9
	Poor	2	3.4	1	2.2	1	14.3	6	4.9	11	4.6
	MD	3	-	5	-	0	-	2	-	10	-
1b. How much back pain do you have right now?	1	1	1.8	2	4.7	0	0	6	4.8	10	4.2
	2	1	1.8	7	16.3	0	0	14	11.3	22	9.2
	3	5	8.9	4	9.3	0	0	13	10.5	23	9.7
	4	12	21.4	2	4.7	0	0	19	15.3	33	13.9
	5	8	14.3	5	11.6	0	0	14	11.3	29	12.2
	6	9	16.1	6	14.0	4	57.1	21	16.9	40	16.8
	7	11	19.6	14	32.6	3	42.9	19	15.3	49	20.6
	8	6	10.7	1	2.3	0	0	15	12.1	24	10.1
	9	0	0	1	2.3	0	0	1	0.8	2	0.8
	10	3	5.4	1	2.3	0	0	2	1.6	6	2.5
	MD	3	-	7	-	0	-	0	-	10	-
1c. How much back pain have you had in the last 7 days?	1	1	1.8	2	4.4	0	0	3	2.4	6	2.5
	2	1	1.8	2	4.4	0	0	6	4.9	10	4.2
	3	6	10.7	4	8.9	0	0	10	8.1	21	8.8
	4	4	7.1	7	15.6	0	0	18	14.6	29	12.1
	5	9	16.1	1	2.2	0	0	16	13.0	26	10.9
	6	9	16.1	8	17.8	1	14.3	15	12.2	34	14.2
	7	10	17.9	11	24.4	3	42.9	26	21.1	52	21.8
	8	5	8.9	6	13.3	2	28.6	20	16.3	35	14.6
	9	6	10.7	2	4.4	1	14.3	7	5.7	17	7.1
	10	5	8.9	2	4.4	0	0	2	1.6	9	3.8
	MD	3	-	5	-	0	-	1	-	9	-

*Please note some cases were not classified by recruitment site

Table 31: Proportion of Participants Responding to Items on Information About Back Pain and Its Treatments

		Recruitment Site*									
		Physiotherapy		**Pain Clinic**		**Charities**		**Back Show**		**Total**	
Item	**Response options**	n	%	n	%	n	%	n	%	n	%
2a. My condition or injury	More	28	50	15	31.9	1	14.3	50	40.3	101	41.7
	A little more	11	19.6	9	19.1	3	42.9	25	20.2	49	20.2
	I was happy with the level of information	17	30.4	22	46.8	3	42.9	40	32.3	82	33.9
	A little less	0	0	1	2.1	0	0	2	1.6	7	2.9
	None	0	0	0	0	0	0	7	5.6	3	1.2
	MD	3	-	3	-	0	-	0	-	6	-
2b. The causes of my back pain	More	29	51.8	9	19.1	1	14.3	52	42.6	96	40
	A little more	11	19.6	17	36.2	3	42.9	24	19.7	55	22.9
	I was happy with the level of information	16	28.6	19	40.4	3	42.9	38	31.1	78	32.5
	A little less	0	0	2	4.3	0	0	2	1.6	4	1.7
	None	0	0	0	0	0	0	6	4.9	7	2.9
	MD	3	-	3	-	0	-	2	-	8	-
2c. Back pain medications	More	21	37.5	11	23.4	0	0	42	34.1	78	32.4
	A little more	14	25.0	17	36.2	3	42.9	28	22.8	64	26.6
	I was happy with the level of information	19	33.9	16	34.0	3	42.9	47	38.2	87	36.1
	A little less	1	1.8	1	2.1	0	0	2	1.6	4	1.7
	None	1	1.8	2	4.3	1	14.3	4	3.3	8	3.3
	MD	3	-	3	-	0	-	1	-	7	-
2d. The potential side effects of back pain medications	More	18	32.1	11	23.4	0	0	42	34.1	76	31.5
	A little more	18	32.1	19	40.4	3	42.9	22	17.9	64	26.6
	I was happy with the level of information	16	28.6	15	31.9	3	42.9	54	43.9	89	36.9
	A little less	2	3.6	0	0	0	0	2	1.6	4	1.7
	None	2	3.6	2	4.3	1	14.3	3	2.4	8	3.3
	MD	3	-	3	-	0	-	1	-	7	-
2e. Treatment options available (apart from back pain medication)	More	31	55.4	15	31.9	3	42.9	59	49.2	113	47.5
	A little more	11	19.6	13	27.7	3	42.9	22	18.3	51	21.4
	I was happy with the level of information	13	23.2	19	40.4	1	14.3	31	25.8	64	26.9
	A little less	1	1.8	0	0	0	0	4	3.3	6	2.5
	None	0	0	0	0	0	0	4	3.3	4	1.7

		Recruitment Site*									
		Physiotherapy		Pain Clinic		Charities		Back Show		Total	
Item	**Response options**	n	%	n	%	n	%	n	%	n	%
	MD	3	-	3	-	0	-	4	-	10	-
2f. Goal setting (Setting tasks to do)	More	19	34.5	8	17.8	1	14.3	48	38.7	79	33.1
	A little more	12	21.8	17	37.8	1	14.3	27	21.8	61	25.5
	I was happy with the level of information	21	38.2	16	35.6	5	71.4	46	37.1	89	37.2
	A little less	0	0	3	6.7	0	0	0	0	3	1.3
	None	3	5.5	1	2.2	0	0	3	2.4	7	2.9
	MD	4	-	5	-	0	-	0	-	9	-
2g. Posture and positioning	More	27	48.2	12	25.5	1	14.3	50	41.0	95	39.6
	A little more	14	25.0	15	31.9	3	42.9	25	20.5	59	24.6
	I was happy with the level of information	15	26.8	19	40.4	3	42.9	40	32.8	78	32.5
	A little less	0	0	1	2.1	0	0	0	0	1	0.4
	None	0	0	0	0	0	0	7	5.7	7	2.9
	MD	3	-	3	-	0	-	2	-	8	-
2h. Pacing (taking things gradually)	More	16	29.1	10	21.3	2	28.6	39	31.5	69	28.6
	A little more	16	29.1	18	38.3	0	0	23	18.5	60	24.9
	I was happy with the level of info	21	38.2	15	31.9	5	71.4	58	46.8	102	42.3
	A little less	0	0	3	6.4	0	0	0	0	3	1.2
	None	2	3.6	1	2.1	0	0	4	3.2	7	2.9
	MD	4	-	3	-	0	-	0	-	7	-
2i. Exercise	More	26	47.3	13	27.7	2	28.6	34	27.4	79	32.8
	A little more	12	21.8	18	38.3	0	0	27	21.8	60	24.9
	I was happy with the level of information	16	29.1	13	27.7	5	71.4	55	44.4	89	36.9
	A little less	0	0	2	4.3	0	0	4	3.2	6	2.5
	None	1	1.8	1	2.1	0	0	4	3.2	7	2.9
	MD	4	-	3	-	0	-	0	-	7	-

*Please note some cases were not classified by recruitment site; - Not applicable

Table 32: Proportion of Participants Responding to Items About Your Medical Care

Item	Response options	Physiotherapy		Pain Clinic		Charities		Back Show		Total	
		No. (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)
3a. My doctors did not know what was wrong with me	Strongly agree	10	17.9	1	2.1	0	0	29	23.8	41	17.2
	Agree	10	17.9	5	10.6	0	0	23	18.9	42	17.6
	Not sure	15	26.8	22	46.8	3	50.0	25	20.5	65	27.2
	Disagree	17	30.4	14	29.8	3	50.0	31	25.4	67	28.0
	Strongly disagree	4	7.1	5	10.6	0	0	14	11.5	24	10.0
	MD	3	-	3	-	1	-	2	-	9	-
3b. I was misdiagnosed	Strongly agree	5	9.1	1	2.1	0	0	19	15.6	26	10.9
	Agree	6	10.9	7	14.9	0	0	16	13.1	29	12.2
	Not sure	13	23.6	16	34.0	2	33.3	28	23.0	62	26.1
	Disagree	21	38.2	15	31.9	4	66.7	40	32.8	82	34.5
	Strongly disagree	10	18.2	8	17.0	0	0	19	15.6	39	16.4
	MD	4	-	3	-	1`	-	2	-	10	-
3c. I was involved in treatment decisions	Strongly agree	5	9.1	2	4.3	0	0	8	6.6	17	7.1
	Agree	12	21.8	10	21.3	3	50.0	29	23.8	54	22.7
	Not sure	12	21.8	11	23.4	0	0	18	14.8	42	17.6
	Disagree	23	41.8	24	51.1	3	50.0	42	34.4	95	39.9
	Strongly disagree	3	5.5	0	0	0	0	25	20.5	30	12.6
	MD	4	-	3	-	1	-	2	-	10	-

Table 33: Proportion of Participants Responding to Items on the Impact of Back Pain on Regular Activities

Item	Response options	Physiotherapy		Pain Clinic		Charities		Back Show		Total	
		Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)
4.1a. I spent less time on tasks than I would have liked to	All of the time	12	21.1	6	12.8	1	14.3	14	11.7	36	15.1
	Most of the time	17	29.8	12	25.5	3	42.9	32	26.7	65	27.2
	Some of the time	19	33.3	18	38.3	3	42.9	37	30.8	80	33.5
	A little of the time	4	7.0	8	17.0	0	0	25	20.8	37	15.5
	None of the time	5	8.8	3	6.4	0	0	12	10.8	21	8.8
	MD	2	-	3	-	0	-	4	-	9	-
4.1b. I was limited in the type of tasks I could do	All of the time	15	26.8	6	13.3	1	14.3	17	13.9	43	18.1
	Most of the time	13	23.2	14	31.1	3	42.9	36	29.5	66	27.7
	Some of the time	13	23.2	15	33.3	3	42.9	36	29.5	69	29.0
	A little of the time	12	21.4	3	6.7	0	0	18	14.8	34	14.3
	None of the time	3	5.4	7	15.6	0	0	15	12.3	26	10.9
	MD	3	-	5	-	0	-	2	-	10	-

Item	**Response options**	**Physiotherapy**		**Pain Clinic**		**Charities**		**Back Show**		**Total**	
		Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)
4.1c. I stopped doing everyday tasks	All of the time	3	5.5	1	2.2	1	14.3	4	3.3	10	4.3
	Most of the time	6	10.9	5	11.1	0	0	18	15.0	29	12.3
	Some of the time	18	32.7	15	33.3	3	42.9	38	31.7	78	33.2
	A little of the time	12	21.8	8	17.8	3	42.9	21	17.5	45	19.1
	None of the time	16	29.1	16	35.6	0	0	39	32.5	73	31.1
	MD	4	-	5	-	0	-	4	-	13	-
4.1d. I was unable to work	All of the time	5	9.3	5	11.4	3	60.0	16	13.6	31	13.5
	Most of the time	3	5.6	2	4.5	0	0	11	9.3	16	7.0
	Some of the time	11	20.4	14	31.8	0	0	19	16.1	45	19.7
	A little of the time	7	13.0	5	11.4	2	40.0	13	11.0	28	12.2
	None of the time	28	51.9	18	40.9	0	0	59	50.0	109	47.6
	MD	5	-	6	-	2	-	6	-	19	
4.1e. I went out of my home	All of the time	10	17.9	10	22.2	1	16.7	43	35.8	67	28.5
	Most of the time	9	16.1	8	17.8	4	66.7	6	5.0	24	10.2
	Some of the time	20	35.7	9	20.0	1	16.7	39	32.5	75	31.9
	A little of the time	5	8.9	8	17.8	0	0	15	12.5	28	11.9
	None of the time	12	21.4	10	22.2	0	0	17	14.2	41	17.4
	MD	3	-	5	-	1	-	4	-	13	-

Table 34: Proportion of Participants Responding to Items on the Impact of Back Pain on Physical Functioning

		Physiotherapy		**Pain Clinic**		**Charities**		**Back Show**		**Total**	
Item	**Response options**	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)
4.2a. I was unable to walk	All of the time	2	3.6	0	0	0	0	7	6.0	9	3.9
	Most of the time	4	7.1	0	0	0	0	6	5.2	10	4.4
	Some of the time	14	25.0	6	14.0	3	50.0	27	23.3	53	23.1
	A little of the time	12	21.4	8	18.6	2	33.3	17	14.7	41	17.9
	None of the time	24	42.9	29	67.4	1	16.7	59	50.9	116	50.7
	MD	3	-	7	-	1	-	8	-	19	-
4.2b. I had poor balance	All of the time	2	3.5	0	0	0	0	0	0	4	1.7
	Most of the time	4	7.0	0	0	1	14.3	11	9.0	18	7.6
	Some of the time	15	26.3	11	25.0	3	42.9	32	26.2	62	26.1
	A little of the time	13	22.8	11	25.0	2	28.6	28	23.0	56	23.5
	None of the time	23	40.4	22	50.0	1	14.3	51	41.8	98	41.2
	MD	2	-	6	-	0	-	2	-	10	-
4.2c. I leaned on one side	All of the time	3	5.4	1	2.2	1	14.3	10	8.5	19	8.1
	Most of the time	6	10.7	4	8.9	0	0	20	16.9	31	13.2
	Some of the time	12	21.4	11	24.4	2	28.6	27	22.9	54	23.1
	A little of the time	13	23.2	10	22.2	3	42.9	22	18.6	48	20.5
	None of the time	22	39.3	19	42.4	1	14.3	39	33.1	82	35.0
	MD	3	-	5	-	0	-	6	-	14	-
4.2d. I could bend down	All of the time	14	24.6	5	11.1	3	42.9	33	27.5	55	23.2
	Most of the time	10	17.5	10	22.2	0	0	25	20.8	45	19.0
	Some of the time	15	26.3	12	26.7	4	57.1	32	26.7	68	28.7
	A little of the time	13	22.8	12	26.7	0	0	17	14.2	43	18.1
	None of the time	5	8.8	6	13.3	0	0	13	10.8	26	11.0
	MD	2	-	5	-	0	-	4	-	11	-
4.2e. It was difficult to keep standing	All of the time	4	7.1	3	6.4	0	0	12	9.8	20	8.3
	Most of the time	14	25.0	9	19.1	2	28.6	20	16.4	46	19.2
	Some of the time	14	25.0	13	27.7	2	28.6	32	26.2	65	27.1
	A little of the time	10	17.9	9	19.1	3	42.9	22	18.0	44	18.3
	None of the time	14	25.0	13	27.7	0	0	36	29.5	65	27.1
	MD	3	-	3	-	0	-	2	-	8	-

Table 35: Proportion of Participants Responding to Items on the Impact of Back Pain on Confidence

		Physiotherapy		**Pain Clinic**		**Charities**		**Back Show**		**Total**	
Item	**Response options**	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)
4.3a. I planned before I did things	All of the time	11	19.6	13	27.7	0	0	27	22.5	54	22.7
	Most of the time	11	19.6	8	17.0	1	14.3	10	8.3	30	12.6
	Some of the time	12	21.4	5	10.6	2	28.6	26	21.7	47	19.7
	A little of the time	12	21.4	16	34.0	1	14.3	30	25.0	60	25.2
	None of the time	10	17.9	5	10.6	3	42.9	27	22.5	47	19.7
	MD	3	-	3	-	0	-	4	-	10	-
4.3b. I was cautious in everything I did	All of the time	11	20.0	3	6.7	1	14.3	23	19.2	42	17.9
	Most of the time	11	20.0	12	26.7	2	28.6	32	26.7	58	24.7
	Some of the time	14	25.5	15	33.3	0	0	31	25.8	60	25.5
	A little of the time	11	20.0	8	17.8	4	57.1	18	15.0	43	18.3
	None of the time	8	14.5	7	15.6	0	0	16	13.3	32	13.6
	MD	4	-	5	-	0	-	4	-	13	-
4.3c. I had low beliefs in my abilities	All of the time	5	8.9	3	6.5	0	0	4	3.3	14	5.9
	Most of the time	11	19.6	3	6.5	1	14.3	20	16.7	36	15.2
	Some of the time	11	19.6	17	37.0	0	0	34	28.3	63	26.6
	A little of the time	7	12.5	9	19.6	2	28.6	21	17.5	39	16.5
	None of the time	22	39.3	14	30.4	4	57.1	41	34.2	85	35.9
	MD	3	-	4	-	0	-	4	-	11	-
4.3d. I was scared to do too much	All of the time	7	12.5	3	6.4	0	0	15	12.5	27	11.3
	Most of the time	9	16.1	9	19.1	1	14.3	18	15.0	38	16.0
	Some of the time	14	25.0	10	21.3	0	0	34	28.3	61	25.6
	A little of the time	14	25.0	10	21.3	4	57.1	26	21.7	54	22.7
	None of the time	12	21.4	15	31.9	2	28.6	27	22.5	58	24.4
	MD	3	-	3	-	0	-	4	-	10	-
4.3e. I had low self esteem	All of the time	7	12.5	4	8.5	0	0	10	8.3	22	9.2
	Most of the time	7	12.5	6	12.8	0	0	9	7.5	22	9.2
	Some of the time	13	23.2	11	23.4	3	42.9	26	21.7	56	23.5
	A little of the time	8	14.3	10	21.3	2	28.6	20	16.7	41	17.2
	None of the time	21	37.5	16	34.0	2	28.6	55	45.8	97	40.8
	MD	3	-	3	-	0	-	4	-	10	-
4.3f. I felt uncertain of the future	All of the time	9	16.1	7	14.9	0	0	14	11.5	32	13.3
	Most of the time	8	14.3	9	19.1	0	0	19	15.6	37	15.4
	Some of the time	15	26.8	6	12.8	1	14.3	33	27.0	56	23.3
	A little of the time	7	12.5	8	17.0	3	42.9	17	13.9	35	14.6
	None of the time	17	30.4	17	36.2	3	42.9	39	32.0	80	33.3
	MD	3	-	3	-	0	-	2	-	8	-

Table 36: Proportion of Participants Responding to Items on the Impact of Back Pain on Appearance

		Physiotherapy		**Pain Clinic**		**Charities**		**Back Show**		**Total**	
Item	**Response options**	No. (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)
4.4a. I slouched	All of the time	7	12.5	2	4.3	0	0	17	13.9	30	12.5
	Most of the time	8	14.3	9	19.1	2	28.6	17	13.9	37	15.4
	Some of the time	16	28.6	12	25.5	1	14.3	30	24.6	61	25.4
	A little of the time	10	17.9	7	14.9	3	42.9	21	17.2	42	17.5
	None of the time	15	26.8	17	36.2	1	14.3	37	30.3	70	29.2
	MD	3	-	3	-	0	-	2	-	8	-
4.4b. I was unable to brush/comb my hair	All of the time	0	0	0	0	0	0	0	0	0	0
	Most of the time	3	5.5	2	4.3	0	0	6	5.0	11	4.7
	Some of the time	3	5.5	4	8.5	0	0	13	10.8	20	8.5
	A little of the time	4	7.3	7	14.9	4	66.7	10	8.3	26	11.0
	None of the time	45	81.8	34	72.3	2	33.3	91	75.8	179	75.8
	MD	4	-	3	-	1	-	4	-	12	-
4.4c. I had difficulty getting dressed	All of the time	2	3.5	2	4.3	1	14.3	1	0.8	6	2.5
	Most of the time	4	7.0	1	2.1	0	0	11	9.2	17	7.1
	Some of the time	9	15.8	10	21.3	2	28.6	16	13.3	38	15.9
	A little of the time	14	24.6	15	31.9	4	57.1	30	25.0	63	26.4
	None of the time	28	49.1	19	40.4	0	0	62	51.7	115	48.1
	MD	2	-	3	-	0	-	4	-	9	-
4.4d. I was not interested in my appearance	All of the time	1	1.8	4	8.5	0	0	6	5.0	12	5.0
	Most of the time	3	5.4	1	2.1	0	0	6	5.0	10	4.2
	Some of the time	9	16.1	4	8.5	1	14.3	19	15.8	34	14.3
	A little of the time	11	19.6	13	27.7	4	57.1	19	15.8	48	20.2
	None of the time	32	57.1	25	53.2	2	28.6	70	58.3	134	56.3
	MD	3	-	3	-	0	-	4	-	10	-
4.4e. I was embarrassed about my image	All of the time	3	5.4	0	0	0	0	6	5.0	9	3.8
	Most of the time	2	3.6	2	4.4	0	0	5	4.2	10	4.3
	Some of the time	8	14.3	6	13.3	1	14.3	19	16.0	35	14.9
	A little of the time	9	16.1	16	35.6	2	28.6	21	17.6	49	20.9
	None of the time	34	60.7	21	46.7	4	57.1	68	57.1	132	56.2
	MD	3	-	5	-	0	-	5	-	13	-

Table 37: Proportion of Participants Responding to Items on the Impact of Back Pain on Mood

Item	**Response options**	**Physiotherapy**		**Pain Clinic**		**Charities**		**Back Show**		**Total**	
		Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)
4.5a. I was sad	All of the time	4	7.1	2	4.5	0	0	16	13.6	24	10.3
	Most of the time	6	10.7	5	11.4	0	0	7	5.9	19	8.2
	Some of the time	14	25.0	15	34.1	1	14.3	29	24.6	61	26.2
	A little of the time	16	28.6	6	13.6	5	71.4	23	19.5	51	21.9
	None of the time	16	28.6	16	36.4	1	14.3	43	36.4	78	33.5
	MD	3	-	6	-	0	-	6	-	15	-
4.5b. I was irritable	All of the time	6	10.7	4	8.5	0	0	9	7.6	20	8.4
	Most of the time	9	16.1	8	17.0	0	0	30	25.2	50	21.1
	Some of the time	20	35.7	18	38.3	5	71.4	33	27.7	79	33.3
	A little of the time	10	17.9	8	17.0	2	28.6	23	19.3	44	18.6
	None of the time	11	19.6	9	19.1	0	0	24	20.2	44	18.6
	MD	3	-	3	-	0	-	5	-	11	-
4.5c. I was frustrated	All of the time	8	14.3	0	0	0	0	11	9.1	20	8.4
	Most of the time	15	26.8	17	37.0	0	0	33	27.3	67	28.2
	Some of the time	13	23.2	16	34.8	4	57.1	38	31.4	74	31.1
	A little of the time	13	23.2	7	15.2	3	42.9	19	15.7	42	17.6
	None of the time	7	12.5	6	13.0	0	0	20	16.5	35	14.7
	MD	3	-	4	-	0	-	3	-	10	-
4.5d. I was tired	All of the time	11	19.3	6	13.0	2	28.6	15	12.4	36	15.1
	Most of the time	12	21.1	16	34.8	0	0	39	32.2	70	29.3
	Some of the time	22	38.6	14	30.4	4	57.1	34	28.1	77	32.2
	A little of the time	5	8.8	4	8.7	1	14.3	15	12.4	24	10.0
	None of the time	7	12.3	6	13.0	0	0	18	14.9	32	13.4
	MD	2	-	4	-	0	-	3	-	9	-
4.5e. I did not want to do anything	All of the time	1	1.8	2	4.3	0	0	8	6.7	12	5.0
	Most of the time	11	19.3	7	14.9	0	0	17	14.2	37	15.5
	Some of the time	15	26.3	15	31.9	0	0	34	28.3	65	27.2
	A little of the time	11	19.3	11	23.4	6	85.7	32	26.7	62	25.9
	None of the time	19	33.3	12	25.5	1	14.3	29	24.2	63	26.4
	MD	2	-	3	-	0	-	4	-	9	-
4.5f. I could not cope with the pain	All of the time	3	5.3	0	0	0	0	8	6.7	14	5.9
	Most of the time	7	12.3	1	2.1	0	0	11	9.2	19	7.9
	Some of the time	13	22.8	16	34.0	1	14.3	34	28.3	66	27.6
	A little of the time	16	28.1	15	31.9	3	42.9	22	18.3	56	23.4
	None of the time	18	31.6	15	31.9	3	42.9	45	37.5	84	35.1
	MD	2	-	3	-	0	-	4	-	9	-

Item	Response options	Physiotherapy Number (n)	Percent (%)	Pain Clinic Number (n)	Percent (%)	Charities Number (n)	Percent (%)	Back Show Number (n)	Percent (%)	Total Number (n)	Percent (%)
4.5g. I felt life was not worth living	All of the time	1	1.8	2	4.3	0	0	4	3.3	9	3.8
	Most of the time	4	7.1	0	0	0	0	9	7.5	14	5.9
	Some of the time	7	12.5	5	10.9	0	0	16	13.3	28	11.8
	A little of the time	4	7.1	10	21.7	0	0	8	6.7	22	9.3
	None of the time	40	71.4	29	63.0	7	100	83	69.2	164	69.2
	MD	3	-	4	-	0	-	4	-	11	-
4.5h. I was worried	All of the time	7	12.3	2	4.3	5	71.4	11	9.2	23	9.6
	Most of the time	3	5.3	5	10.6	0	0	11	9.2	20	8.4
	Some of the time	15	26.3	8	17.0	0	0	36	30.0	59	24.7
	A little of the time	15	26.3	15	31.9	0	0	27	22.5	63	26.4
	None of the time	17	29.8	17	36.2	2	28.6	35	29.2	74	31.0
	MD	2	-	3	-	0	-	4	-	9	-

Table 38: Proportion of Participants Responding to Items on the Impact of Back Pain on Relationships

		Physiotherapy		**Pain Clinic**		**Charities**		**Back Show**		**Total**	
Item	**Response options**	No. (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)
4.6a. I did not want anyone near me	All of the time	3	7.3	0	0	1	20.0	5	5.4	10	5.5
	Most of the time	5	12.2	6	14.6	0	0	7	7.6	18	9.9
	Some of the time	9	22.0	7	17.1	0	0	28	30.4	46	25.3
	A little of the time	4	9.8	11	26.8	1	20.0	20	21.7	36	19.8
	None of the time	20	48.8	17	41.5	3	60.0	32	34.8	72	39.6
	MD	18	-	9	-	2	-	32	-	66	-
4.6b. I did not want to burden others with my problems	All of the time	7	14.6	8	19.5	0	0	8	7.9	24	11.9
	Most of the time	11	22.9	10	24.4	5	71.4	28	27.7	56	27.9
	Some of the time	9	18.8	8	19.5	1	14.3	26	25.7	45	22.4
	A little of the time	11	22.9	10	24.4	1	14.3	16	15.8	38	18.9
	None of the time	10	20.8	5	12.2	0	0	23	22.8	38	18.9
	MD	11	-	9	-	0	-	23	-	47	-
4.6c. I could not relax with my partner	All of the time	6	15.0	2	5.3	0	0	3	3.4	12	7.0
	Most of the time	8	20.0	5	13.2	1	25.0	8	9.2	22	12.8
	Some of the time	6	15.0	13	34.2	0	0	22	25.3	41	23.8
	A little of the time	8	20.0	5	13.2	2	50.0	19	21.8	36	20.9
	None of the time	12	30.0	13	34.2	1	25.0	35	40.2	61	35.5
	MD	19	-	38	-	3	-	37	-	76	-
4.6d. People around me did not understand my back pain	All of the time	0	0	3	7.3	0	0	13	12.7	18	8.7
	Most of the time	10	20	11	26.8	0	0	17	16.7	38	18.4
	Some of the time	17	34.0	7	17.1	2	28.6	9	28.4	57	27.7
	A little of the time	9	18.0	13	31.7	2	28.6	20	19.6	44	21.4
	None of the time	14	28.0	7	17.1	3	42.9	23	22.5	49	23.8
	MD	9	-	9	-	0	-	22	-	42	-
4.6e. People thought I was faking my back pain	All of the time	2	4.4	2	4.9	0	0	6	6.5	11	5.8
	Most of the time	2	4.4	3	7.3	0	0	14	15.2	19	9.9
	Some of the time	9	20.0	9	22.0	2	28.6	19	20.7	39	20.4
	A little of the time	4	8.9	8	19.5	5	71.4	8	8.7	22	11.5
	None of the time	28	62.0	19	46.3	0	0	45	48.9	100	52.4
	MD	14	-	9	-	0	-	32	-	57	-
4.6f. I was sexually active	All of the time	17	40.5	10	35.7	3	50.0	28	36.4	59	37.8
	Most of the time	12	28.6	5	17.9	2	33.3	14	18.2	33	21.2
	Some of the time	11	26.2	6	21.4	1	16.7	29	37.7	49	31.4
	A little of the time	2	4.8	3	10.7	0	0	4	5.2	9	5.8
	None of the time	0	0	4	14.3	0	0	2	2.6	6	3.8
	MD	17	-	22	-	1	-	47	-	92	-

		Physiotherapy		Pain Clinic		Charities		Back Show		Total	
Item	**Response options**	No. (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)
4.6g. Sex was very uncomfortable	All of the time	3	8.6	1	3.1	0	0	4	6.3	9	6.6
	Most of the time	5	14.3	5	15.6	1	25.0	10	15.9	21	15.4
	Some of the time	11	31.4	5	15.6	1	25.0	8	12.7	26	19.1
	A little of the time	7	20.0	11	34.4	2	50.0	13	20.6	33	24.3
	None of the time	9	25.7	10	31.3	0	0	28	44.4	47	34.6
	MD	24	-	18	-	3	-	61	-	112	-

Table 39: Proportion of Participants Responding to Items on the Impact on Sleep

		Physiotherapy		Pain Clinic		Charities		Back Show		Total	
Item	**Response options**	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)
4.7a. I tossed and turned in my sleep	All of the time	10	17.5	8	17.8	2	28.6	26	21.3	47	19.7
	Most of the time	16	28.1	15	33.3	3	42.9	37	30.3	74	31.0
	Some of the time	17	29.8	12	26.7	2	28.6	26	21.3	61	25.5
	A little of the time	3	5.3	7	15.6	0	0	13	10.7	23	9.6
	None of the time	11	19.3	3	6.7	0	0	20	16.4	34	14.2
	MD	2	-	5	-	0	-	2	-	9	-
4.7b. I woke up in the night	All of the time	12	21.1	9	19.1	2	28.6	27	22.5	52	21.8
	Most of the time	12	21.1	15	31.9	4	57.1	33	27.5	66	27.6
	Some of the time	18	31.6	9	19.1	1	14.3	28	23.3	58	24.3
	A little of the time	7	12.3	9	19.1	0	0	18	15.0	36	15.1
	None of the time	8	14.0	5	10.6	0	0	14	11.7	27	11.3
	MD	2	-	3	-	0	-	4	-	9	-
4.7c. I had an ache in my back when I woke up	All of the time	26	46.4	14	30.4	4	57.1	48	39.3	95	39.7
	Most of the time	10	17.9	12	26.1	1	14.3	28	23.0	53	22.2
	Some of the time	12	21.4	10	21.7	2	28.6	27	22.1	52	21.8
	A little of the time	4	7.1	8	17.4	0	0	9	7.4	22	9.2
	None of the time	4	7.1	2	4.3	0	0	10	8.2	17	7.1
	MD	3	-	4	-	0	-	2	-	9	-

Table 40: Proportion of Participants Responding to Items on Beliefs About Back Pain Medication

		Physiotherapy		Pain Clinic		Charities		Back Show		Total	
Item	**Response options**	No.r (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)
6.1a. My back pain medication is helpful to me	Strongly agree	3	5.7	2	4.8	0	0	3	2.5	3	3.9
	Agree	7	13.2	5	11.9	1	14.3	10	8.5	25	11.0
	Not sure	19	35.8	9	21.4	1	14.3	38	32.2	69	30.3
	Disagree	19	35.8	24	57.1	4	57.1	46	39.0	96	42.1
	Strongly disagree	5	9.4	2	4.8	1	14.3	21	17.8	29	12.7
	MD	6	-	8	-	0	-	6	-	20	-
6.1b. My back pain medication prevents future problems	Strongly agree	9	17.0	6	15.0	2	28.6	27	22.5	46	20.2
	Agree	17	32.1	10	25.0	4	57.1	34	28.3	67	29.4
	Not sure	23	43.4	19	47.5	1	14.3	39	32.5	85	37.3
	Disagree	3	5.7	3	7.5	0	0	18	15.0	24	10.5
	Strongly disagree	1	1.9	2	5.0	0	0	2	1.7	6	2.6
	MD	6	-	10	-	0	-	4	-	20	-
6.1c. My back pain medication enables me to be independent (carry out everyday activities)	Strongly agree	3	5.7	1	2.4	0	0	5	4.2	9	4.0
	Agree	17	32.1	4	9.8	0	0	35	29.7	58	25.7
	Not sure	18	34.0	12	29.3	1	16.7	31	26.3	64	37.6
	Disagree	13	24.5	22	53.7	5	83.3	42	35.6	85	37.6
	Strongly disagree	2	3.8	2	4.9	0	0	5	4.2	10	4.4
	MD	6	-	9	-	1	-	6	-	22	-
6.1d. By taking back medication, I felt out of control	Strongly agree	2	3.8	1	2.3	1	14.3	8	6.7	12	5.2
	Agree	7	13.5	4	9.3	1	14.3	18	15.0	32	13.9
	Not sure	10	19.2	13	30.2	0	0	25	20.8	50	21.7
	Disagree	20	38.5	13	30.2	2	28.6	43	35.8	81	35.2
	Strongly disagree	13	25.0	12	27.9	3	42.9	26	21.7	55	23.9
	MD	7	-	7	-	0	-	4	-	18	-
6.1e. I altered the amount of back pain medication I took	Strongly agree	2	3.9	4	9.8	0	0	17	14.2	24	10.7
	Agree	21	41.2	16	39.0	4	57.1	46	38.3	89	39.6
	Not sure	7	13.7	6	14.6	0	0	13	10.8	27	12.0
	Disagree	12	23.5	11	26.8	3	42.9	30	25.0	58	25.8
	Strongly disagree	9	17.6	4	9.8	0	0	14	11.7	27	12.0
	MD	8	-	9	-	0	-	4	-	23	-

Table 41: Proportion of Participants Responding to Items on Adherence

Item	Response options	Physiotherapy		Pain Clinic		Charities		Back Show		Total	
		No. (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)
I set realistic goals	Strongly agree	0	0	2	4.3	1	14.3	3	2.5	6	2.6
	Agree	11	20.8	6	13.0	2	28.6	9	7.4	30	12.8
	Not sure	11	20.8	16	34.8	0	0	20	16.4	47	20.0
	Disagree	27	50.9	18	39.1	1	14.3	73	59.8	121	51.5
	Strongly disagree	4	7.5	4	8.7	3	42.9	17	13.9	31	13.2
	MD	6	-	4	-	0	-	2	-	13	-
I remembered to do my exercises	Strongly agree	4	7.8	0	0	1	14.3	5	4.1	11	4.7
	Agree	9	17.6	9	19.6	0	0	22	18.0	42	18.0
	Not sure	9	17.6	10	21.7	0	0	11	9.0	30	12.9
	Disagree	19	37.3	21	45.7	4	57.1	53	43.4	100	42.9
	Strongly disagree	10	19.6	6	13.0	2	28.6	31	25.4	50	21.5
	MD	8	-	4	-	0	-	2	-	15	-
I paced my activities	Strongly agree	0	0	1	2.1	1	14.3	5	4.1	7	3.0
	Agree	8	15.4	4	8.5	0	0	15	12.3	31	13.2
	Not sure	7	13.5	3	6.4	0	0	10	8.2	20	8.5
	Disagree	32	61.5	29	61.7	3	42.9	71	58.2	138	58.7
	Strongly disagree	5	9.6	10	21.3	3	42.9	21	17.2	39	16.6
	MD	7	-	3	-	0	-	2	-	13	-

Table 42: Proportion of Participants Responding to Items on Problems with Side Effects

Item	Response options	Physiotherapy		Pain Clinic		Charities		Back Show		Total	
		No. (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)
Loss of appetite	Not a problem	0	0	0	0	0	0	0	0	0	0
	A bit of a problem	1	5.6	0	0	0	0	5	13.9	7	10.1
	A problem	1	5.6	2	18.2	0	0	2	5.6	5	7.2
	A big problem	9	50.0	5	45.5	0	0	15	41.7	30	43.5
	A severe problem	7	38.9	4	36.4	2	100	14	38.9	27	39.1
	MD	41	-	39	-	5	-	88	-	179	-
Weight gain	Not a problem	1	4.5	0	0	0	0	5	10.9	6	6.9
	A bit of a problem	2	9.1	1	9.1	0	0	17	37.0	21	24.1
	A problem	7	31.8	2	18.2	4	66.7	9	19.6	22	25.3
	A big problem	5	22.7	4	36.4	0	0	8	17.4	17	19.5
	A severe problem	7	31.8	4	36.4	2	33.3	7	15.2	21	24.1
	MD	37	-	39	-	1	-	78	-	161	-
Inability to concentrate	Not a problem	0	0	0	0	1	14.3	2	4.1	2	1.9
	A bit of a problem	2	7.4	0	0	0	0	12	24.5	15	14.2
	A problem	6	22.2	8	44.4	4	57.1	16	32.7	36	34.0
	A big problem	16	59.3	8	44.4	1	14.3	16	32.7	44	41.5
	A severe problem	3	11.1	2	11.1	1	14.3	3	6.1	9	8.5
	MD	32	-	32	-	0	-	75	-	142	-

Item	Response options	Physiotherapy		Pain Clinic		Charities		Back Show		Total	
		No. (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)
Drowsiness	Not a problem	0	0	1	6.3	1	16.7	0	0	2	1.9
	A bit of a problem	1	3.2	0	0	0	0	16	33.3	18	17.3
	A problem	3	9.7	7	43.8	0	0	10	20.8	22	21.2
	A big problem	21	67.7	6	37.5	5	83.3	19	39.6	51	49.0
	A severe problem	6	19.4	2	12.5	0	0	3	6.3	11	10.6
	MD	28	-	34	-	1	-	76	-	144	-
Nausea	Not a problem	0	0	0	0	0	0	0	0	0	0
	A bit of a problem	0	0	2	20.0	0	0	5	16.1	8	11.8
	A problem	5	26.3	2	20.0	3	50.0	6	19.4	17	25.0
	A big problem	6	31.6	0	0	3	50.0	11	35.5	20	29.4
	A severe problem	8	42.1	6	60.0	0	0	9	29.0	23	33.8
	MD	40	-	40	-	1	-	93	-	180	-
Constipation	Not a problem	1	4.0	0	0	3	50.0	2	4.9	6	6.7
	A bit of a problem	4	16.0	0	0	0	0	9	22.0	14	15.7
	A problem	6	24.0	2	14.3	0	0	7	17.1	16	18.0
	A big problem	4	16.0	10	71.4	2	33.3	13	31.7	29	32.6
	A severe problem	10	40.0	2	14.3	1	16.7	10	24.4	24	27.0
	MD	34	-	36	-	1	-	83	-	159	-
Diarrhoea	Not a problem	0	0	0	0	1	33.3	0	0	1	2.0
	A bit of a problem	1	5.9	0	0	0	0	4	18.2	6	11.8
	A problem	2	11.8	0	0	2	66.7	5	22.7	9	17.6
	A big problem	4	23.5	1	14.3	0	0	3	13.6	8	15.7
	A severe problem	10	58.8	6	85.7	0	0	10	45.5	27	52.9
	MD	42	-	43	-	4	-	102	-	197	-
Stomach aches	Not a problem	0	0	1	10.0	1	20.0	0	0	2	2.9
	A bit of a problem	3	15.8	0	0	0	0	10	31.3	14	20.6
	A problem	5	26.3	1	10.0	0	0	5	15.6	12	17.6
	A big problem	4	21.1	6	60.0	4	80.0	10	31.3	24	35.3
	A severe problem	7	36.8	2	20.0	0	0	7	21.9	16	23.5
	MD	40	-	40	-	2	-	92	-	180	-

Item	Response options	Physiotherapy No. (n)	 Percent (%)	Pain Clinic Number (n)	 Percent (%)	Charities Number (n)	 Percent (%)	Back Show Number (n)	 Percent (%)	Total Number (n)	 Percent (%)
Heartburn	Not a problem	1	4.2	0	0	0	0	2	5.3	3	3.8
	A bit of a problem	3	12.5	2	15.4	0	0	8	21.1	13	16.5
	A problem	1	4.2	3	23.1	0	0	9	23.7	13	16.5
	A big problem	11	45.8	4	30.8	2	66.7	12	31.6	29	36.7
	A severe problem	8	33.3	4	30.8	1	33.3	7	18.4	21	26.6
	MD	35	-	37	-	4	-	86	-	169	-
Inability to sleep	Not a problem	4	13.3	0	0	1	14.3	6	11.1	12	11.0
	A bit of a problem	8	26.7	4	26.7	2	28.6	16	29.6	30	27.5
	A problem	6	20.0	8	53.3	1	14.3	9	16.7	25	22.9
	A big problem	8	26.7	3	20.0	2	28.6	17	31.5	31	28.4
	A severe problem	4	13.3	0	0	1	14.3	6	11.1	11	10.1
	MD	29	-	35	-	0	-	70	-	139	-

Table 43: Proportion of Participants Responding to Items on Satisfaction with the Treatment Process

Item	Response options	Physiotherapy		Pain Clinic		Charities		Back Show		Total	
		No. (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)
The communication between my doctor and I regarding my back pain medication	Very satisfied	2	3.7	2	4.5	0	0	10	8.5	14	6.1
	Satisfied	11	20.4	4	9.1	0	0	25	21.2	42	18.3
	Neither	14	25.9	8	18.2	4	57.1	28	23.7	57	24.8
	Dissatisfied	18	33.3	29	65.9	1	14.3	33	28.0	81	35.2
	Very dissatisfied	9	16.7	1	2.3	2	28.6	22	18.6	36	15.7
	MD	5	-	6	-	0	-	6	-	18	-
The information provided about the possible side effects from my back pain medication	Very satisfied	3	5.7	2	4.9	0	0	10	8.5	15	6.6
	Satisfied	12	22.6	5	12.2	2	28.6	30	25.4	53	23.3
	Neither	17	32.1	17	41.5	2	28.6	36	30.5	75	33.0
	Dissatisfied	15	28.3	17	41.5	3	42.9	31	26.3	66	29.1
	Very dissatisfied	6	11.3	0	0	0	0	11	9.3	18	7.9
	MD	6	-	9	-	0	-	6	-	21	-
The form of administration (e.g. tablet, injection, patch) of my back pain medication	Very satisfied	1	2.0	0	0	0	0	6	5.2	7	3.2
	Satisfied	7	14.0	3	7.7	0	0	15	12.9	27	12.3
	Neither	11	22.0	11	28.2	2	28.6	40	34.5	67	30.5
	Dissatisfied	25	50.0	24	61.5	5	71.4	38	32.8	94	42.7
	Very dissatisfied	6	12.0	1	2.6	0	0	17	14.7	25	11.4
	MD	9	-	11	-	0	-	8	-	28	-
The amount of medication prescribed	Very satisfied	1	2.0	1	2.4	0	0	4	3.4	6	2.7
	Satisfied	10	19.6	4	9.8	1	14.3	29	25.0	46	20.6
	Neither	13	25.5	10	24.4	1	14.3	29	25.0	57	25.6
	Dissatisfied	25	49.0	22	53.7	5	71.4	45	38.0	98	43.9
	Very dissatisfied	2	3.9	4	9.8	0	0	9	7.8	16	7.2
	MD	8	-	9	-	0	-	8	-	25	-
The way doctors have dealt with the side effects of my back pain medication	Very satisfied	2	3.8	2	5.1	0	0	10	8.7	14	6.3
	Satisfied	10	19.2	5	12.8	3	42.9	28	24.3	50	22.6
	Neither	20	38.5	21	53.8	1	14.3	35	30.4	80	36.2
	Dissatisfied	14	26.9	11	28.2	1	14.3	28	24.3	54	24.4
	Very dissatisfied	6	11.5	0	0	2	28.6	14	12.2	23	10.4
	MD	7	-	11	-	0	-	9	-	27	-

Table 44: Proportion of Participants Responding to Items on Back Pain Medication Acceptability

Item	**Response options**	**Physiotherapy**		**Pain Clinic**		**Charities**		**Back Show**		**Total**	
		No. (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)	Number (n)	Percent (%)
My oral medication is difficult to swallow	Strongly agree	0	0	0	0	0	0	4	3.6	4	1.9
	Agree	12	24.5	8	19.5	3	60.0	20	18.0	44	20.7
	Not sure	3	6.1	5	12.2	0	0	5	4.5	14	6.6
	Disagree	19	38.8	14	34.1	2	40.0	44	39.6	81	38.0
	Strongly disagree	15	30.6	14	34.1	0	0	38	34.2	70	32.9
	MD	10	-	9	-	2	-	13	-	35	-
My oral medication leaves an unpleasant taste in my mouth	Strongly agree	2	4.1	0	0	0	0	2	1.8	5	2.4
	Agree	12	24.5	7	17.9	1	20.0	19	17.4	40	19.1
	Not sure	3	6.1	8	20.5	0	0	14	12.8	27	12.9
	Disagree	17	34.7	10	25.6	2	40	44	40.4	75	35.9
	Strongly disagree	15	30.6	14	35.9	2	40	30	27.5	62	29.7
	MD	10	-	11	-	2	-	15	-	39	-
My oral medication doesn’t work quickly	Strongly agree	6	12.5	2	5.3	2	40	10	9.3	22	10.7
	Agree	16	33.3	20	52.6	2	40	33	30.8	74	36.1
	Not sure	14	29.2	5	13.2	1	20	22	20.6	43	21.0
	Disagree	8	16.7	7	18.4	0	0	29	27.1	45	22.0
	Strongly disagree	4	8.3	4	10.5	0	0	13	12.1	21	10.2
	MD	11	-	12	-	2	-	17	-	43	-

APPENDIX S: Normality and Outlier Tests for the CLBP Treatment Satisfaction Questionnaire Domains

Table 45. Descriptive Statistics of the CLBP Treatment Satisfaction Questionnaire Domains

CLBP Treatment Satisfaction Questionnaire Domains			**Statistic**	**Std. Error**
Burden of Back Pain	Mean		96.85	1.45
	95% Confidence Interval for Mean	Lower Bound	93.98	
		Upper Bound	99.71	
	5% Trimmed Mean		97.44	
	Median		100.00	
	Variance		436.32	
	Std. Deviation		20.89	
	Minimum		43.00	
	Maximum		131.00	
	Range		88.00	
	Interquartile Range		32.00	
	Skewness		-.31	.17
	Kurtosis		-.64	.34
Problems with Side Effects	Mean		38.84	1.45
	95% Confidence Interval for Mean	Lower Bound	35.89	
		Upper Bound	41.80	
	5% Trimmed Mean		39.27	
	Median		40.50	
	Variance		67.23	
	Std. Deviation		8.20	
	Minimum		20.00	
	Maximum		50.00	
	Range		30.00	
	Interquartile Range		12.75	
	Skewness		-.65	.41
	Kurtosis		-.06	.81
Information about back pain/treatment	Mean		21.40	.48
	95% Confidence Interval for Mean	Lower Bound	20.44	

CLBP Treatment Satisfaction Questionnaire Domains			Statistic	Std. Error
		Upper Bound	22.35	
	5% Trimmed Mean		21.26	
	Median		21.00	
	Variance		52.41	
	Std. Deviation		7.24	
	Minimum		10.00	
	Maximum		50.00	
	Range		40.00	
	Interquartile Range		13.00	
	Skewness		.29	.16
	Kurtosis		-.29	.32
Satisfaction with treatment process	Mean		16.31	.28
	95% Confidence Interval for Mean	Lower Bound	15.76	
		Upper Bound	16.85	
	5% Trimmed Mean		16.34	
	Median		16.00	
	Variance		16.64	
	Std. Deviation		4.08	
	Minimum		5.00	
	Maximum		25.00	
	Range		20.00	
	Interquartile Range		5.00	
	Skewness		-.19	.17
	Kurtosis		.30	.33
Adherence to physiotherapy	Mean		10.90	.17
	95% Confidence Interval for Mean	Lower Bound	10.56	
		Upper Bound	11.23	
	5% Trimmed Mean		11.01	
	Median		12.00	
	Variance		6.78	
	Std. Deviation		2.60	
	Minimum		3.00	
	Maximum		15.00	
	Range		12.00	
	Interquartile Range		3.00	
	Skewness		-.70	.16
	Kurtosis		.41	.32
Impact of back pain on relationships	Mean		23.84	.61

CLBP Treatment Satisfaction Questionnaire Domains			**Statistic**	**Std. Error**
	95% Confidence Interval for Mean	Lower Bound	22.63	
		Upper Bound	25.05	
	5% Trimmed Mean		23.98	
	Median		23.00	
	Variance		36.97	
	Std. Deviation		6.08	
	Minimum		9.00	
	Maximum		35.00	
	Range		26.00	
	Interquartile Range		9.00	
	Skewness		-.12	.24
	Kurtosis		-.79	.48
Medication Acceptability	Mean		10.41	.18
	95% Confidence Interval for Mean	Lower Bound	10.05	
		Upper Bound	10.77	
	5% Trimmed Mean		10.41	
	Median		11.00	
	Variance		6.70	
	Std. Deviation		2.59	
	Minimum		5.00	
	Maximum		15.00	
	Range		10.00	
	Interquartile Range		3.50	
	Skewness		-.11	.17
	Kurtosis		-.83	.34

Table 46. Kolmogorov-Smirnov Statistic for the CLBP Treatment Satisfaction Questionnaire Domains

CLBP Treatment Satisfaction Questionnaire Domains	**Kolmogorov-Smirnov**[†]		
	Statistic	**df**	**p-value**
Burden of Back Pain	.07	207	**p≤0.01***
Problems with Side Effects	.15	32	p=0.07
Information about back pain/treatment	.08	223	**p≤0.0001****
Satisfaction with treatment process	.11	217	**p≤0.0001****
Adherence to physiotherapy	.19	232	**p≤0.0001****
Impact of back pain on relationships	.15	99	**p≤0.0001****
Medication Acceptability	.12	205	**p≤0.0001****

[†] Lilliefors Significance Correction

*p≤0.01; **p≤0.0001

Figure 14: Histogram to Show Distribution of Scores for the Burden of Back Pain Domain

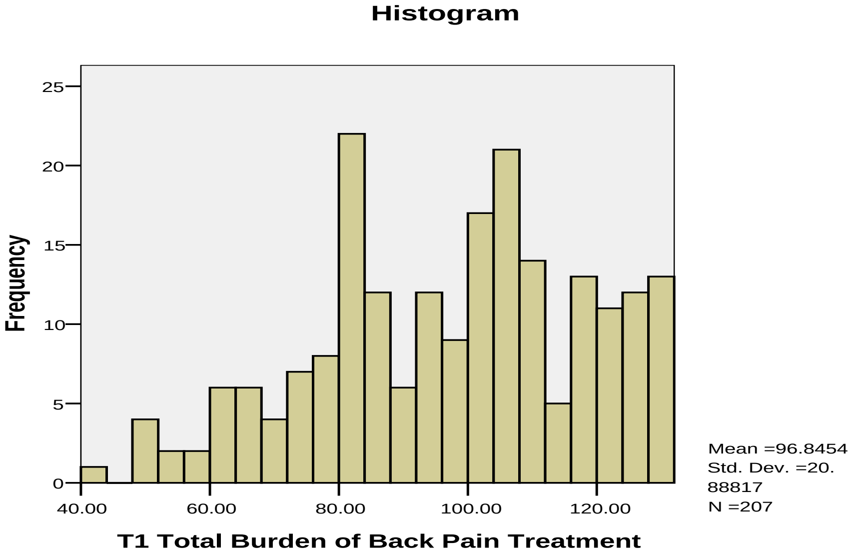


Figure 15: Normal Q-Q Plot for the Burden of Back Pain Domain

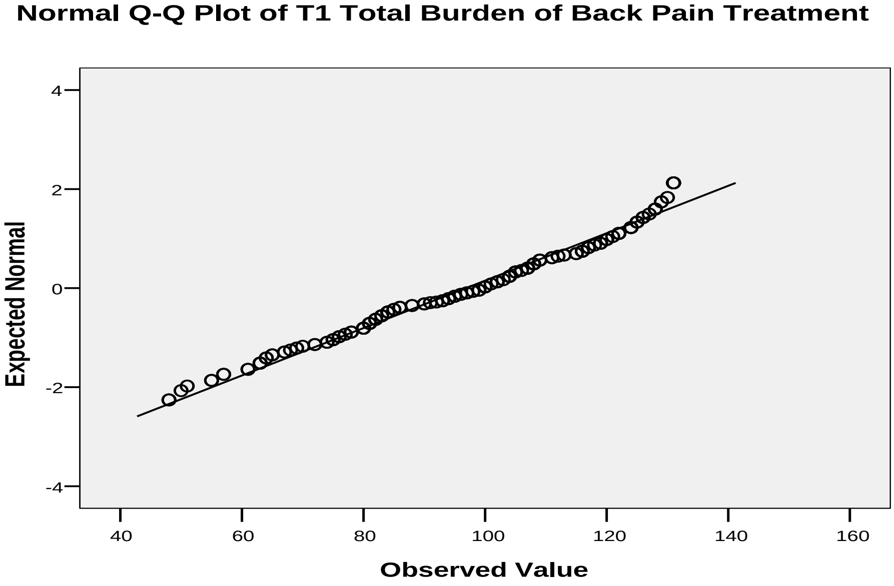


Figure 16: Detrended Normal Q-Q Plot of the Burden of Back Pain Domain

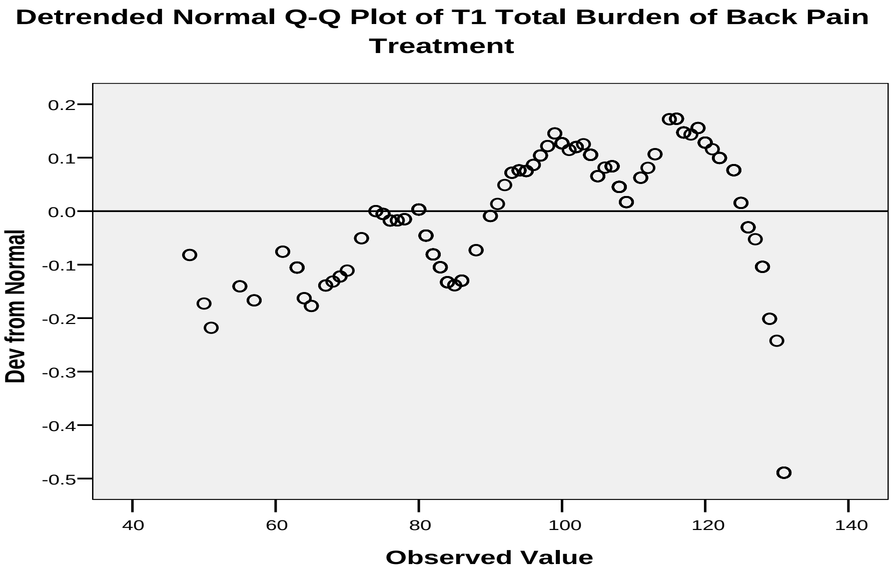


Figure 17: Boxplot of the Burden of Back Pain Domain

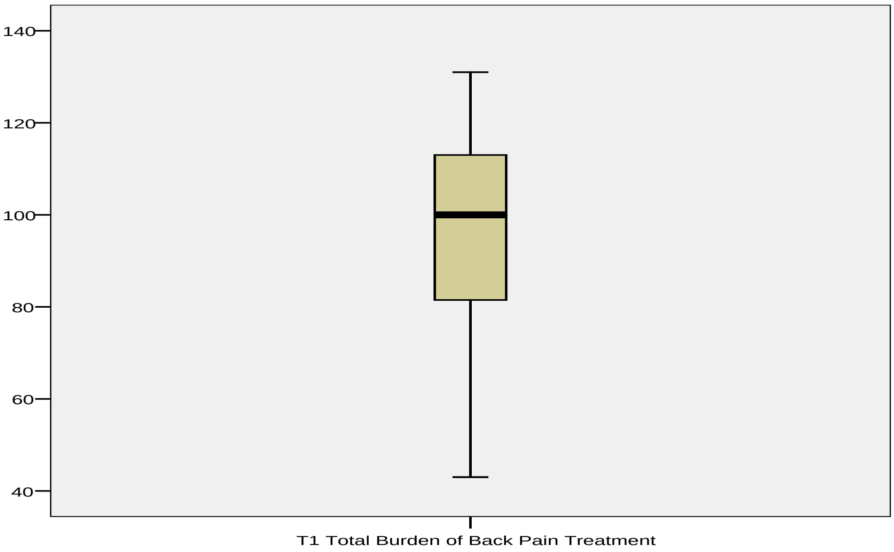


Figure 18: Histogram to Show Distribution of Scores for the Problems with Side Effects Domain

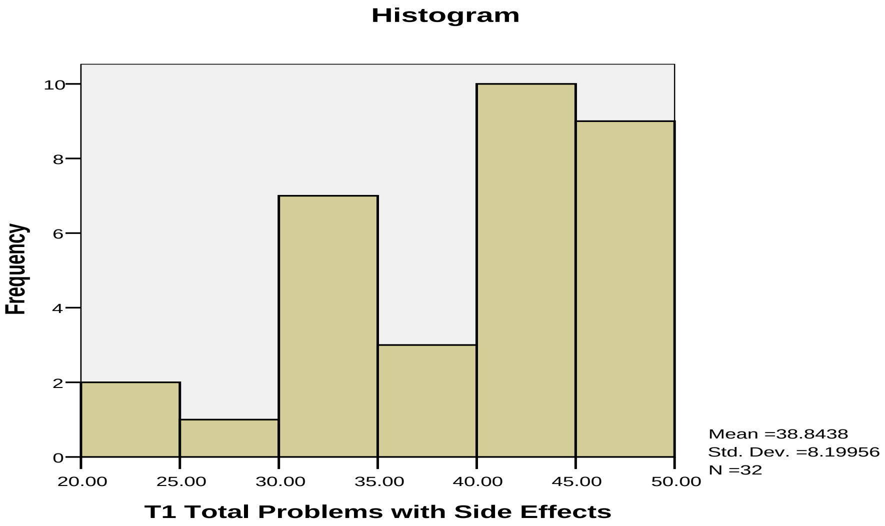


Figure 19: Normal Q-Q Plot of the Problems with Side Effects Domain

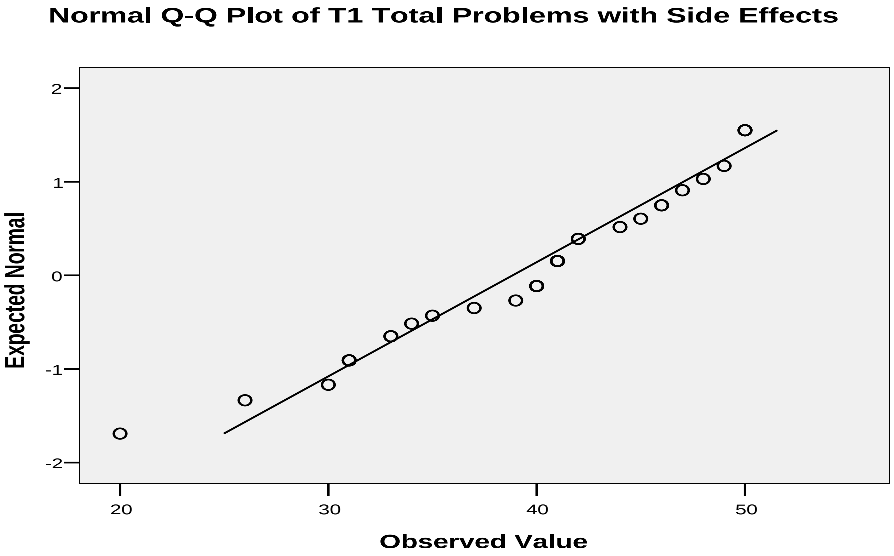


Figure 20: Detrended Normal Q-Q Plot of the Problems with Side Effects Domain

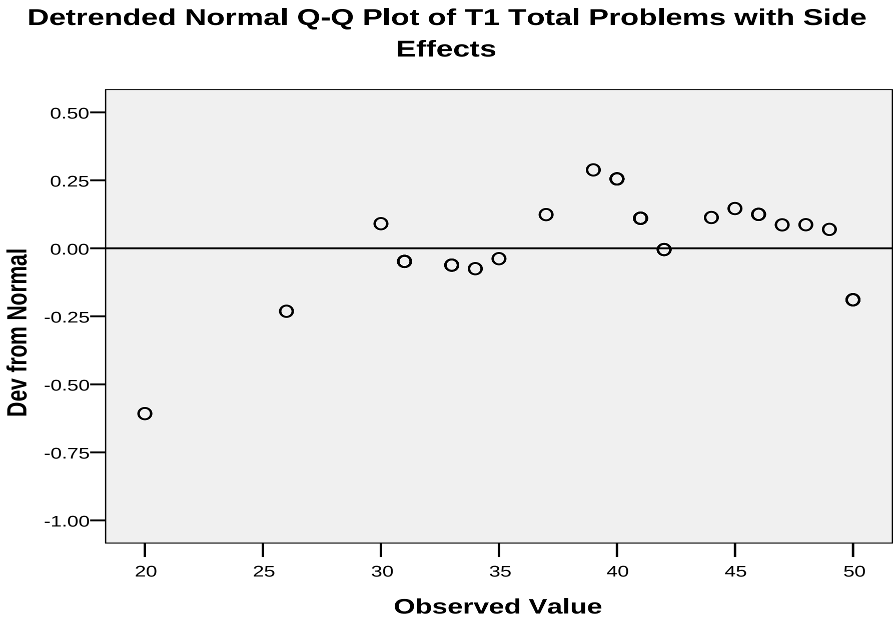


Figure 21: Boxplot for the Problems with Side Effects Domain

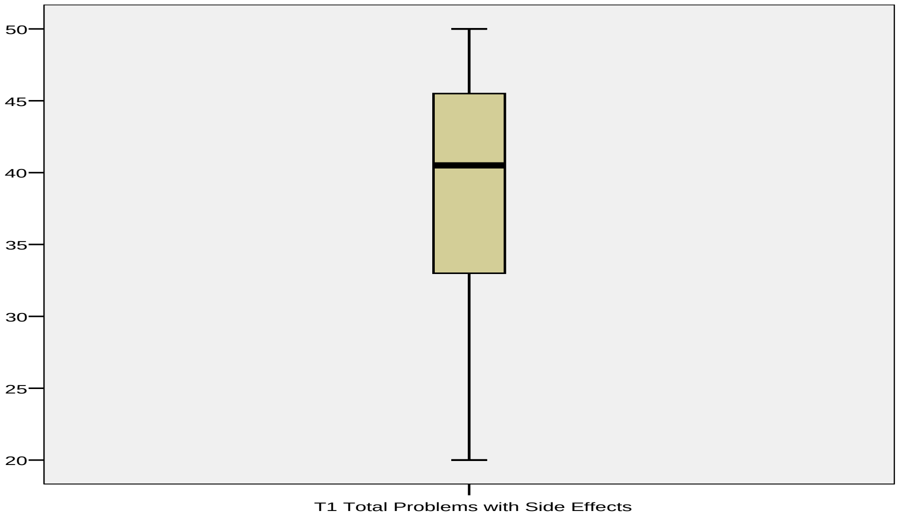


Figure 22: Histogram to Show Distribution of Scores for the Information About Back Pain and Treatment Domain

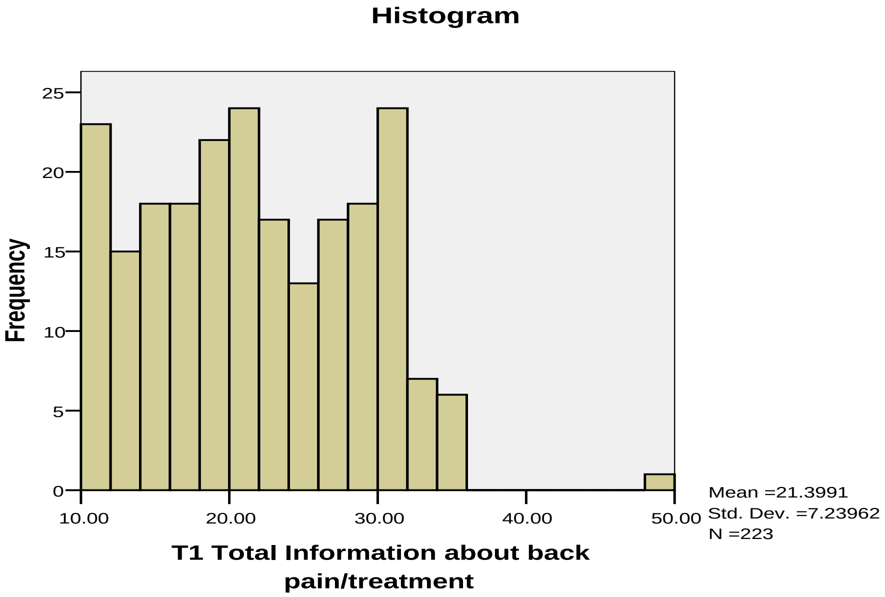


Figure 23: Normal Q-Q Plot of the Information About Back Pain and Treatment Domain

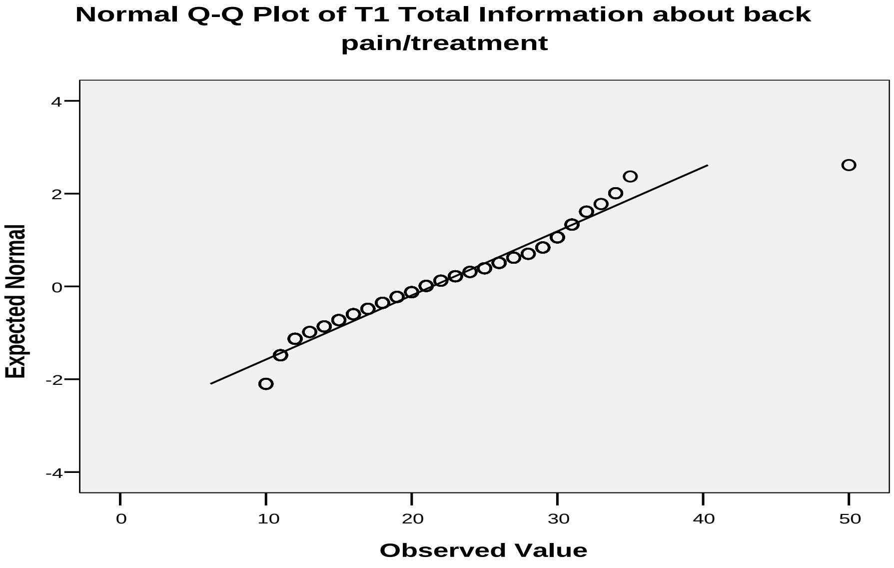


Figure 24: Detrended Normal Q-Q Plot of the Information About Back Pain and Treatment Domain

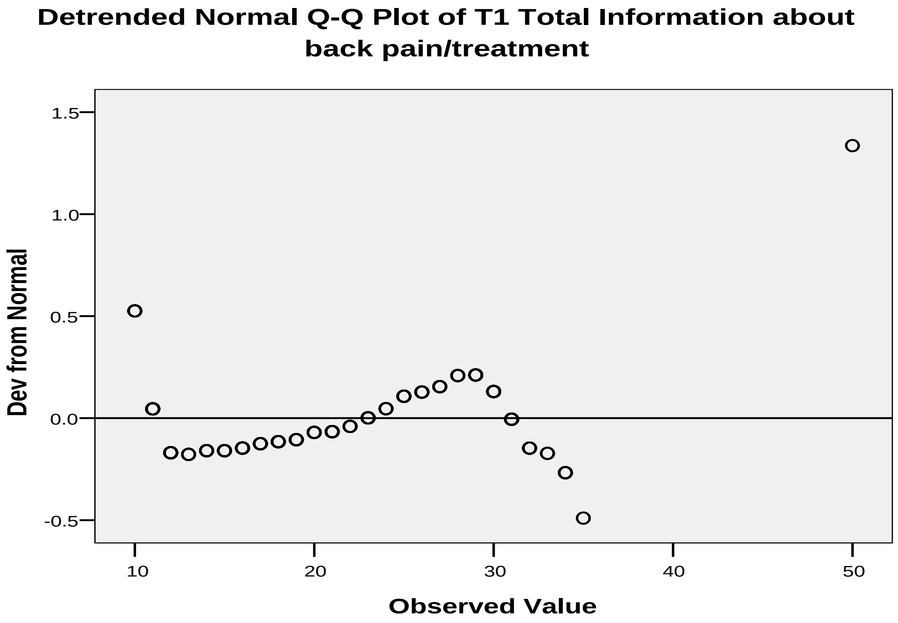


Figure 25: Boxplot for The Information About Back Pain and Treatment Domain

Figure 26: Histogram to Show Distribution of Scores for the Satisfaction with Treatment Process Domain

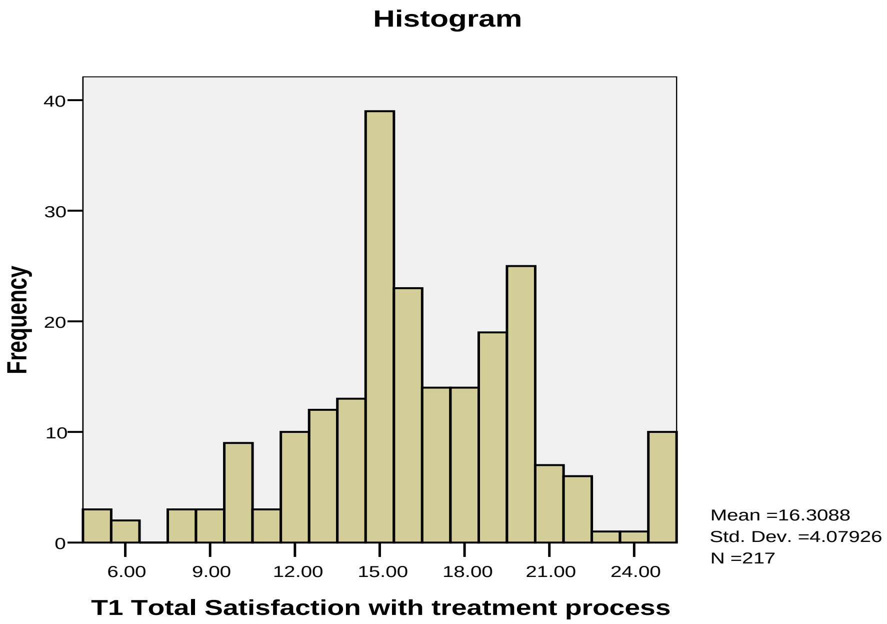


Figure 27: Normal Q-Q Plot of the Satisfaction with Treatment Process Domain

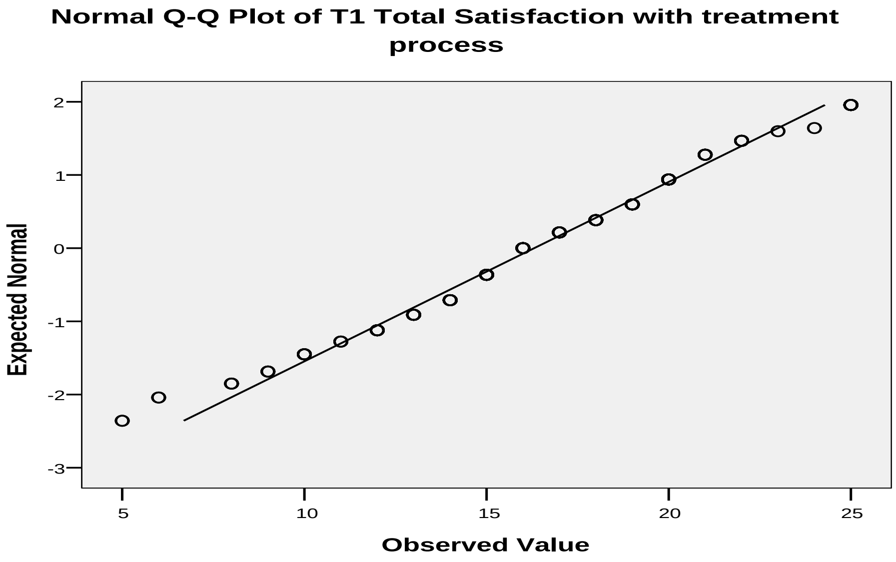


Figure 28: Detrended Normal Q-Q Plot of the Satisfaction with Treatment Process Domain

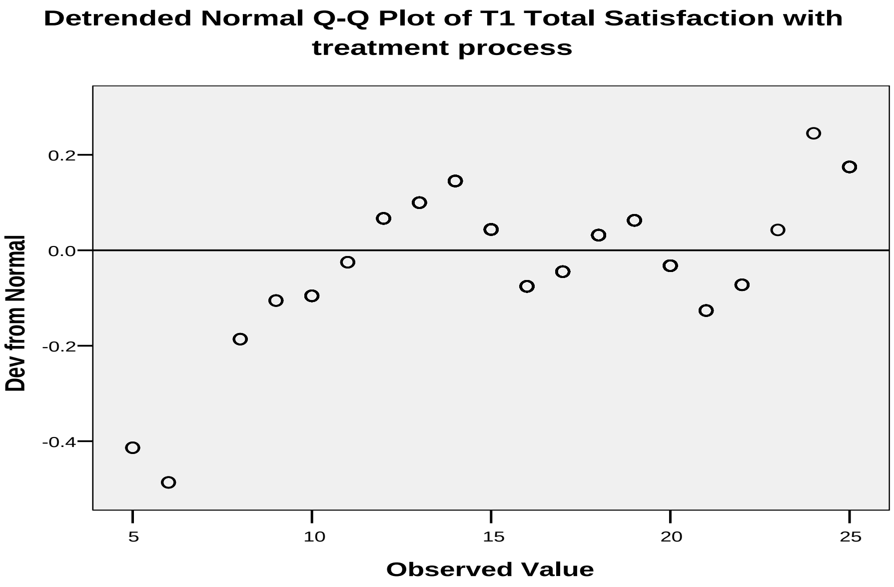


Figure 29: Boxplot of the Satisfaction with Treatment Process Domain

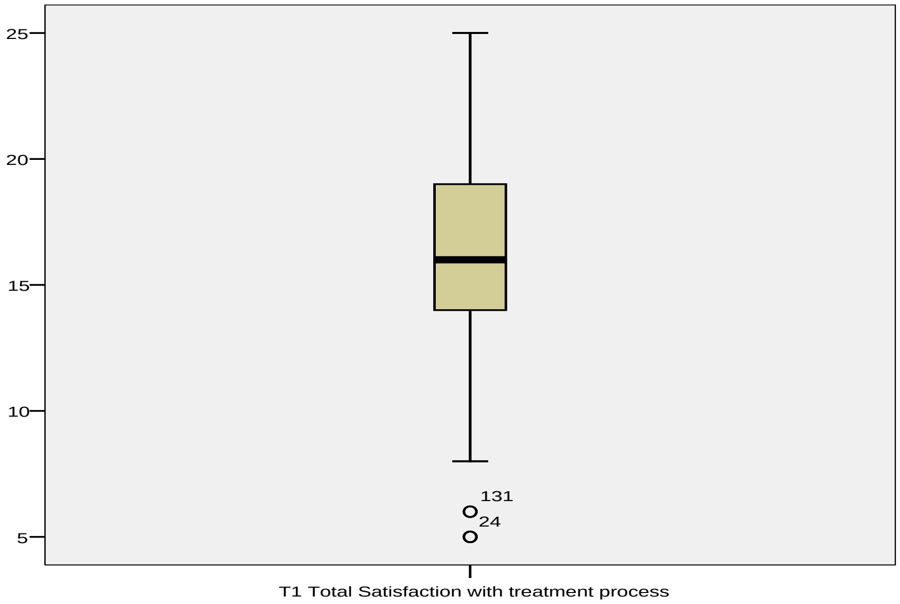


Figure 30: Histogram to Show Distribution of Scores for the Adherence to Physiotherapy Domain

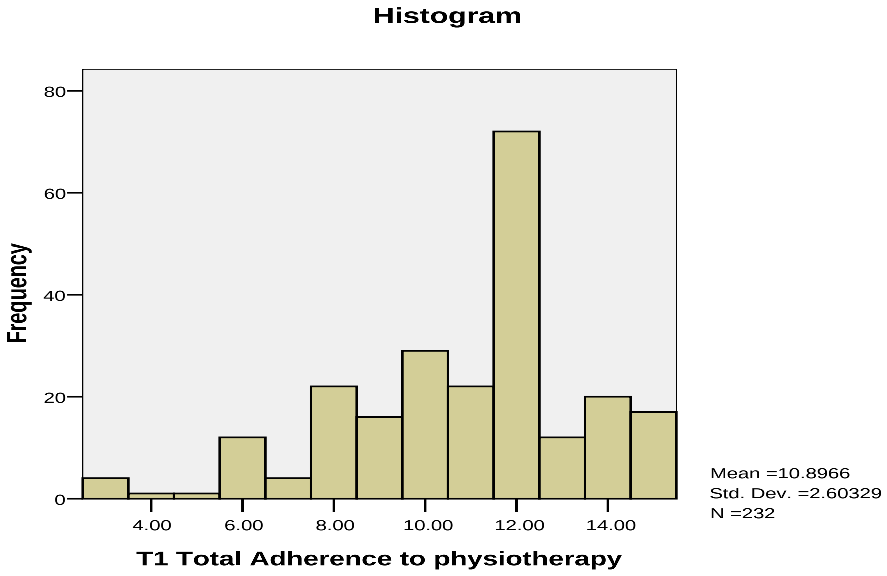


Figure 31: Normal Q-Q Plot of the Adherence to Physiotherapy Domain

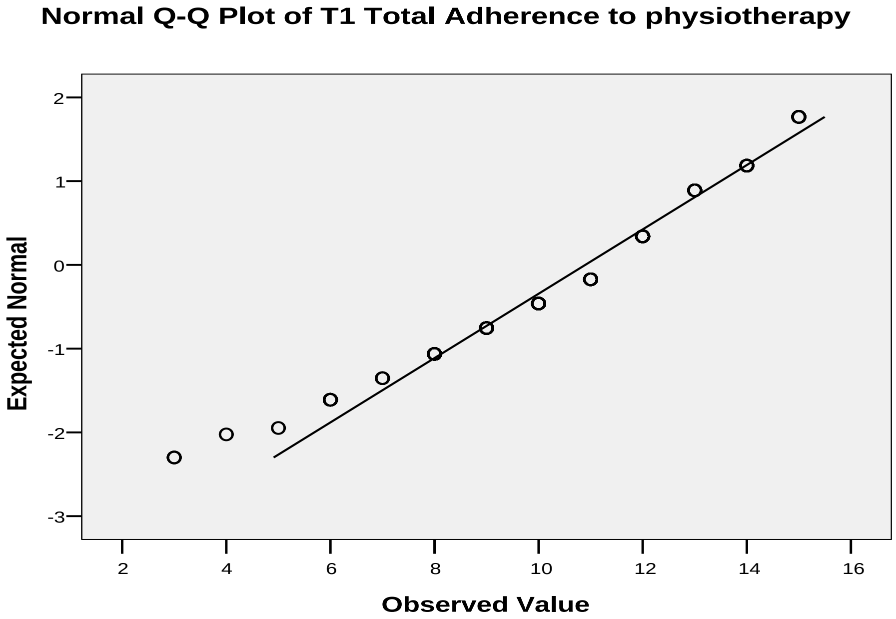


Figure 32: Detrended Normal Q-Q Plot of the Adherence to Physiotherapy Domain

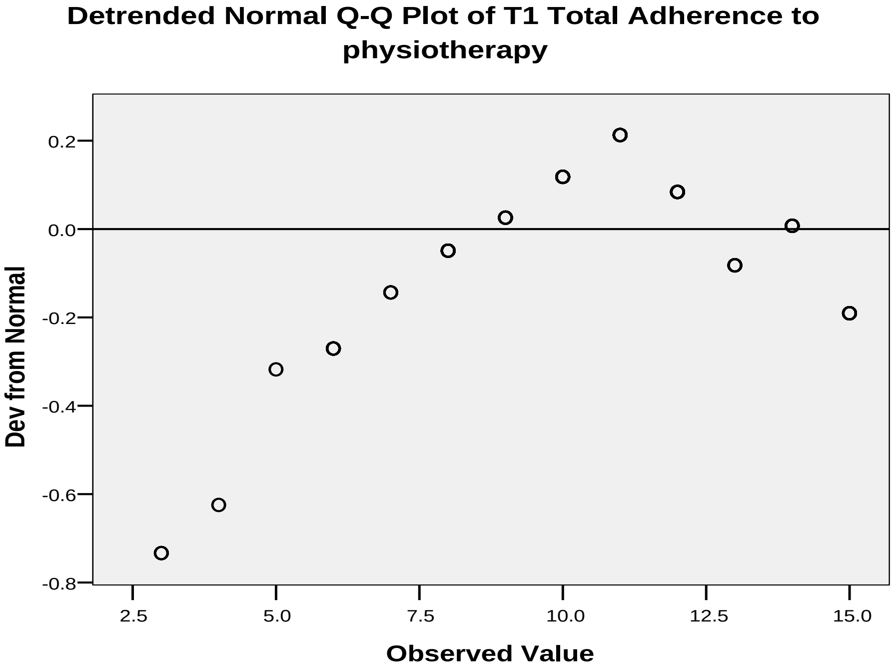


Figure 33: Boxplot of the Adherence to Physiotherapy Domain

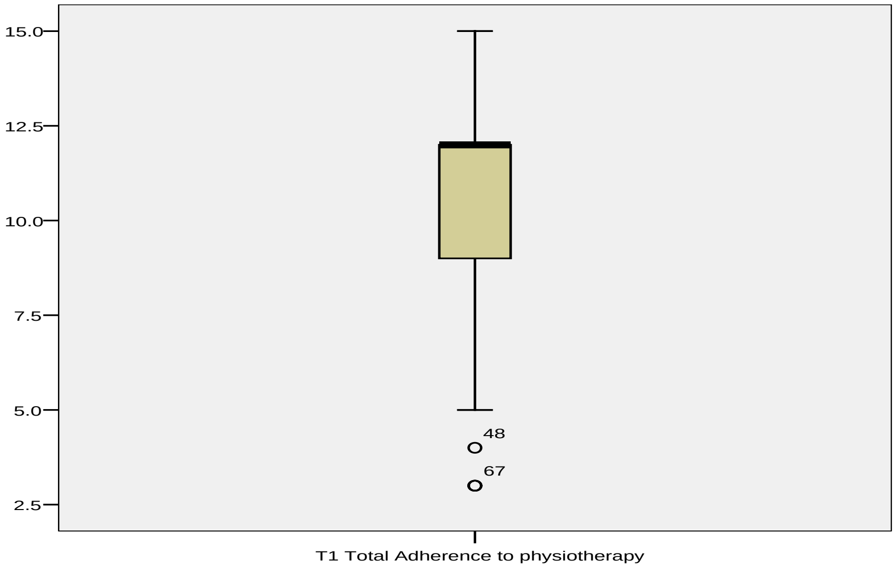


Figure 34: Histogram to Show Distribution of Scores for the Impact of Back Pain and Treatment on Relationships Domain

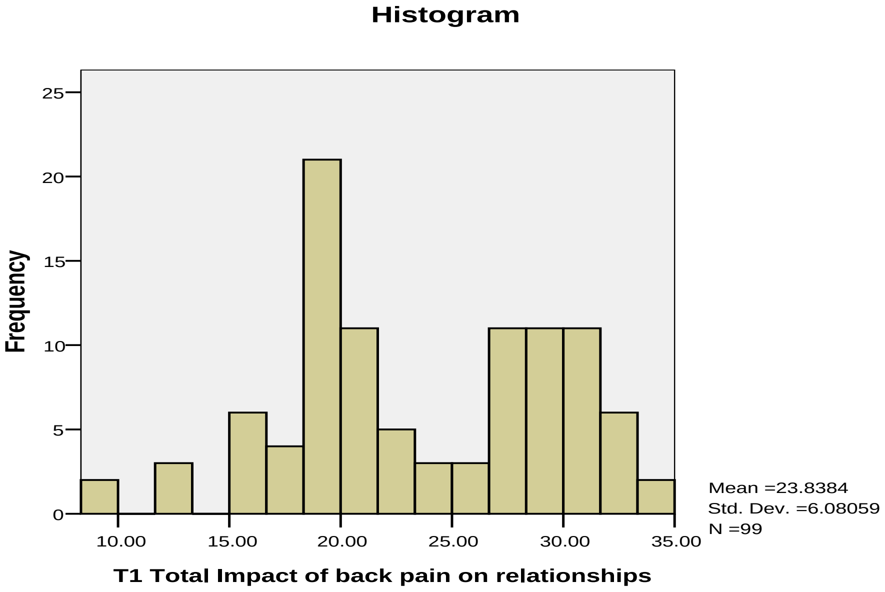


Figure 35: Normal Q-Q Plot of the Impact of Back Pain and Treatment on Relationships Domain

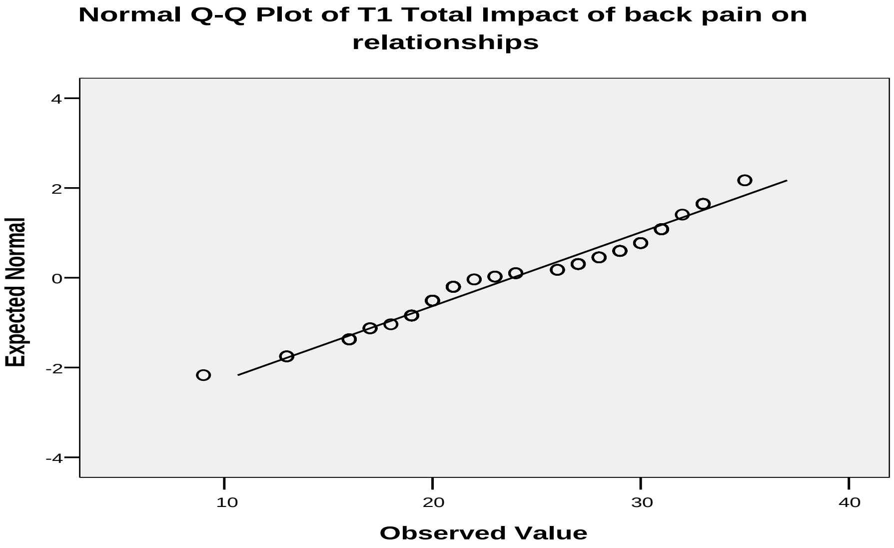


Figure 36: Detrended Normal Q-Q Plot of the Impact of Back Pain and Treatment on Relationships Domain

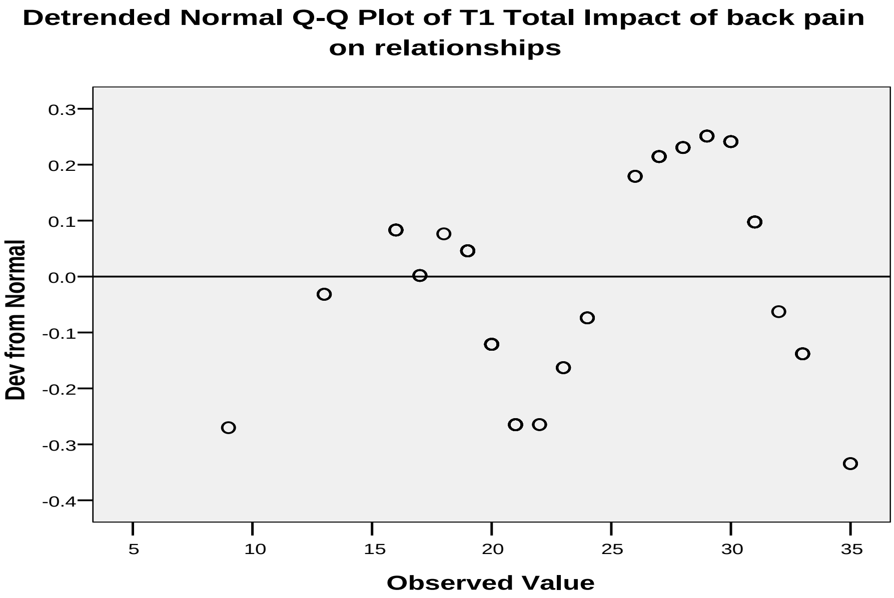


Figure 37: Boxplot of the Impact of Back Pain and Treatment on Relationships Domain

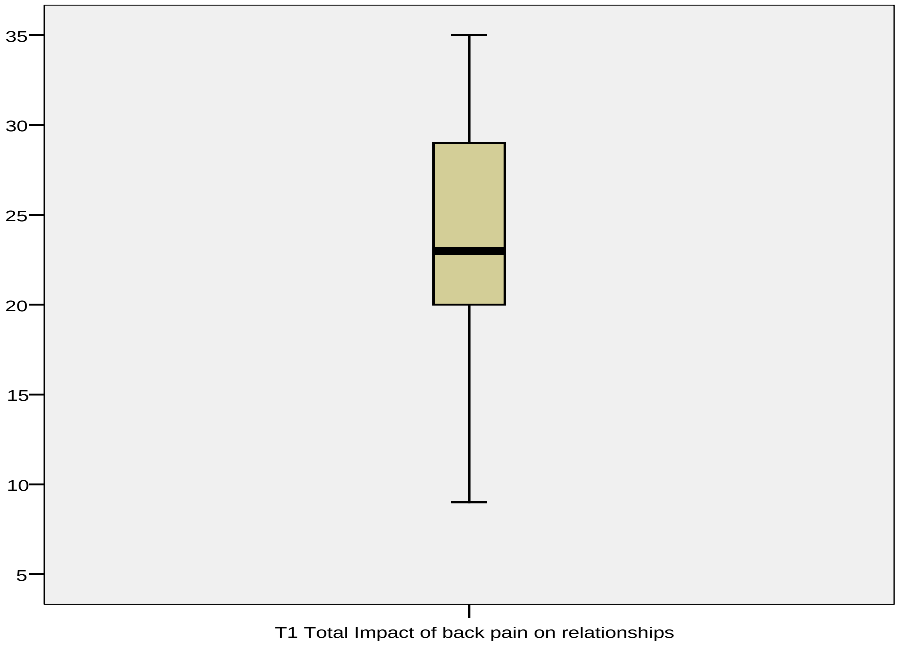


Figure 38: Histogram to Show Distribution of Scores for the Medication Acceptability Domain

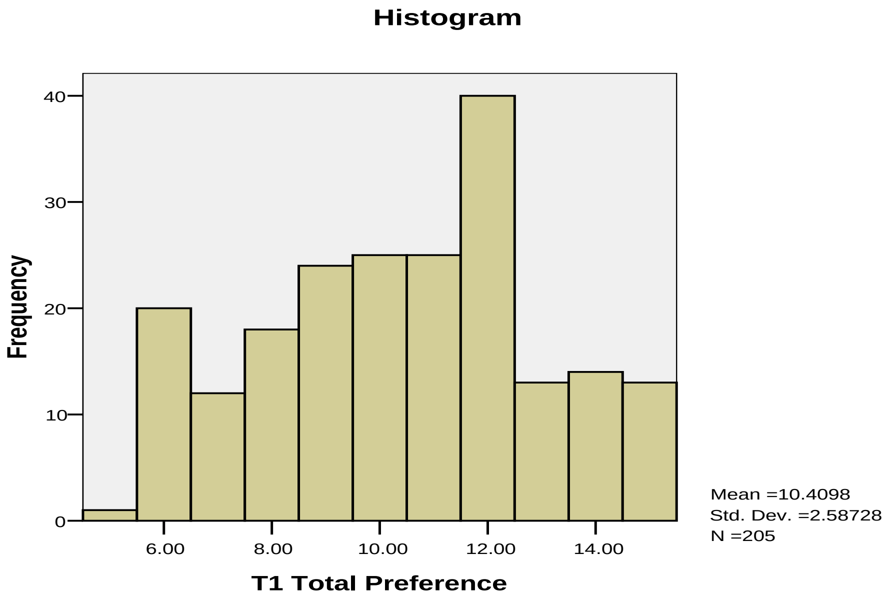


Figure 39: Normal Q-Q Plot for the Medication Acceptability Domain

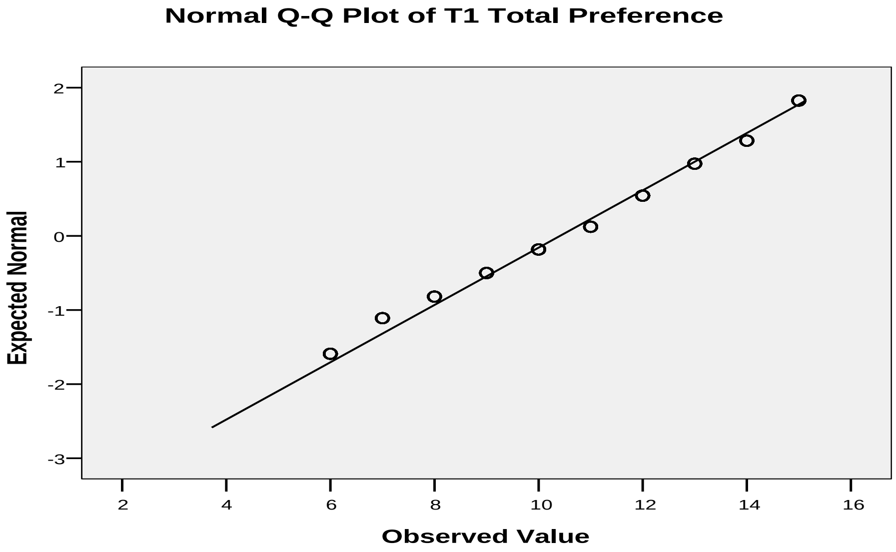


Figure 40: Detrended Normal Q-Q Plot of the Medication Acceptability Domain

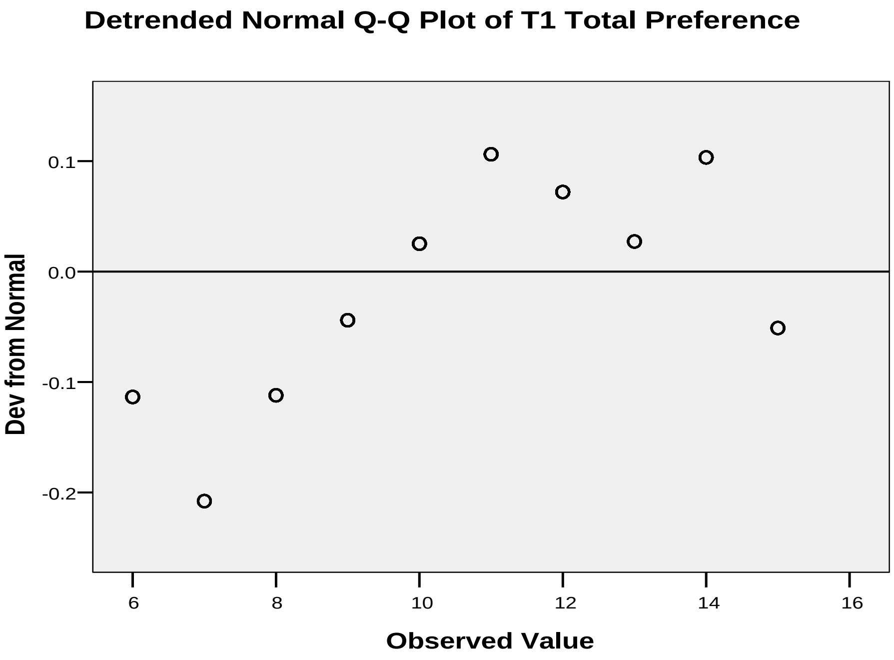
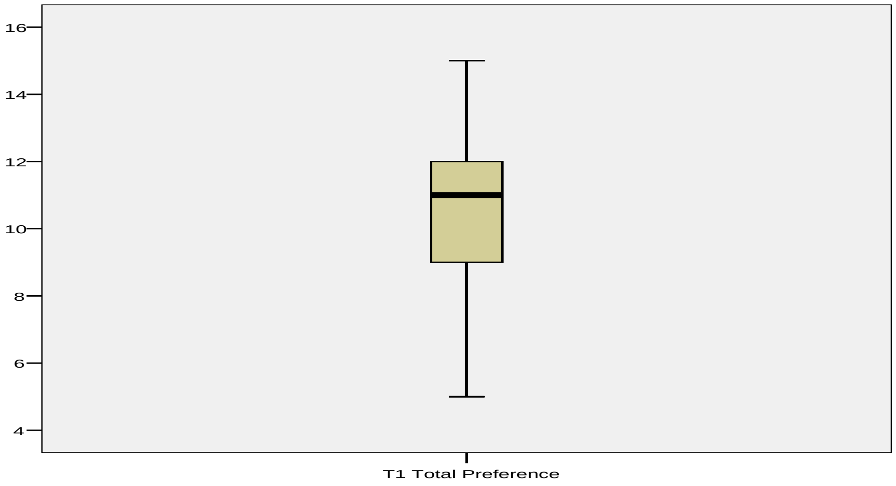


Figure 41: Boxplot of the Medication Acceptability Domain



APPENDIX T: Assumption Testing for Multiple Linear Regressions

Figure 42. Normal P-P Plot of Regression Standardized Residual for the Burden of Back Pain Domain

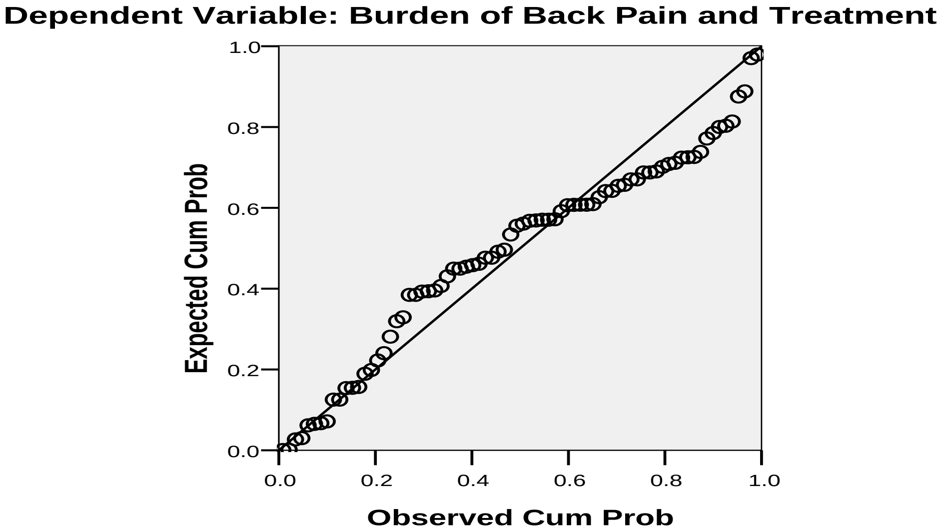


Figure 43. Scatterplot of the Burden of Back Pain Domain

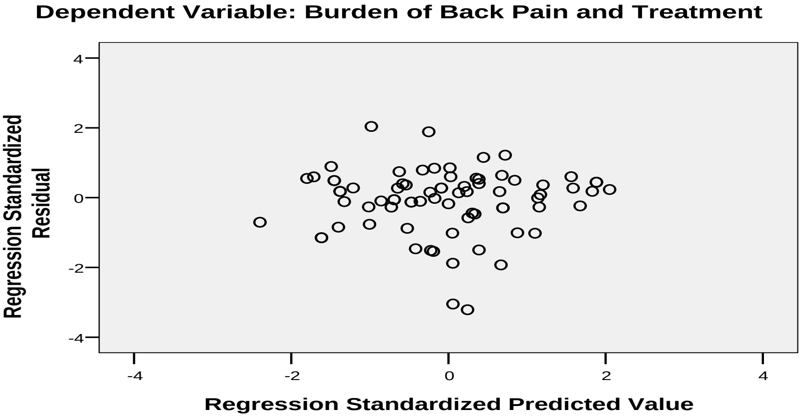


Figure 44. Normal P-P Plot of Regression Standardized Residual for the Problems with Side Effects Domain

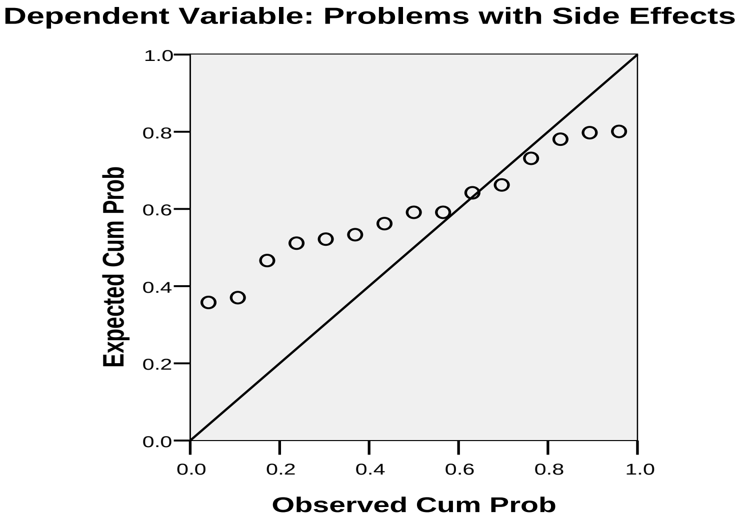


Figure 45. Scatterplot of the Problems with Side Effects Domain

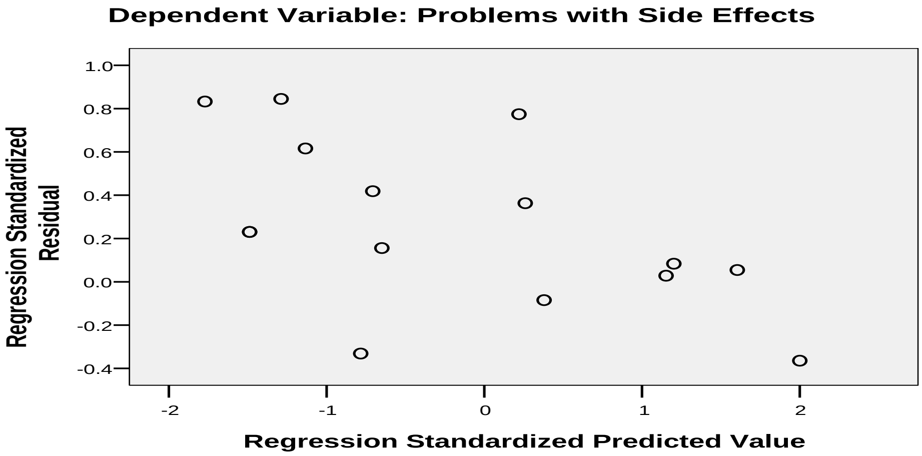


Figure 46. Normal P-P Plot of Regression Standardized Residual for the Information About Back Pain and Treatment Domain

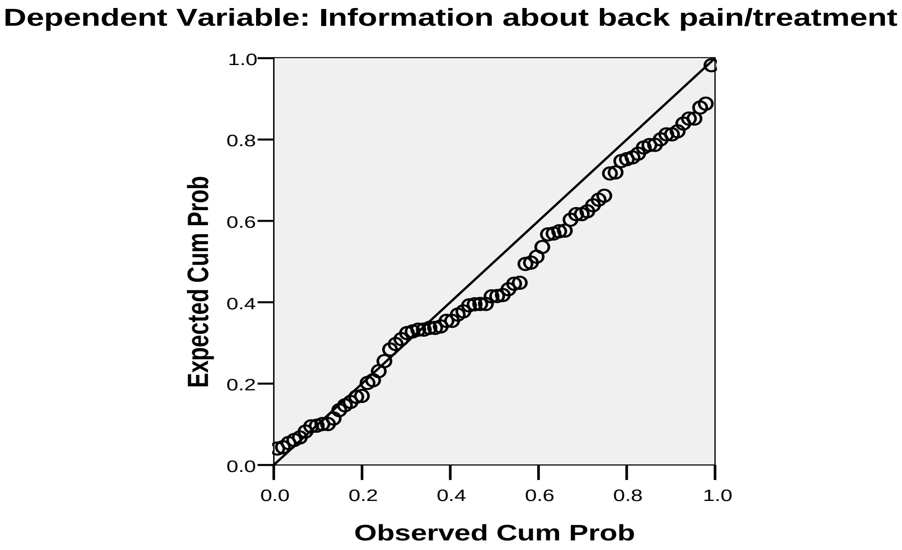


Figure 47. Scatterplot for the Information About Back Pain Treatment Domain

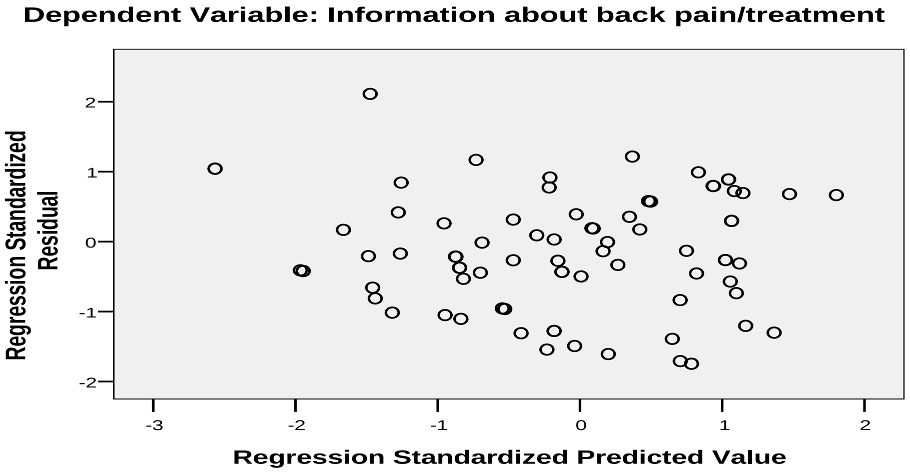


Figure 48. Normal P-P Plot of Regression Standardized Residual for the Satisfaction with Treatment Process Domain

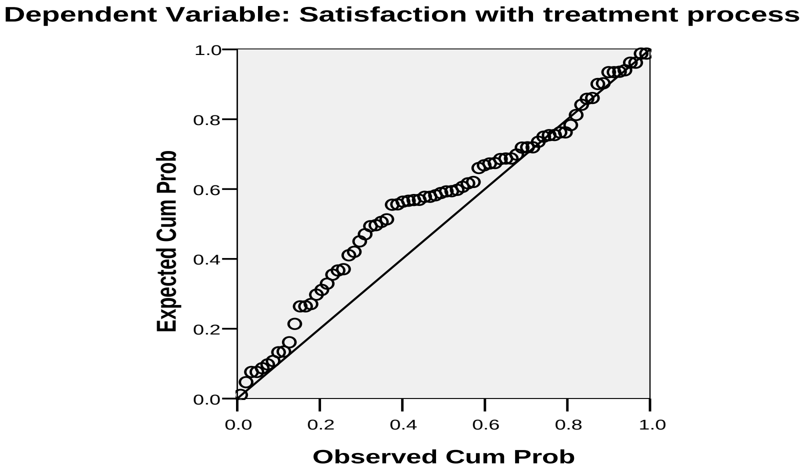


Figure 49. Scatterplot for the Satisfaction with Treatment Process Domain

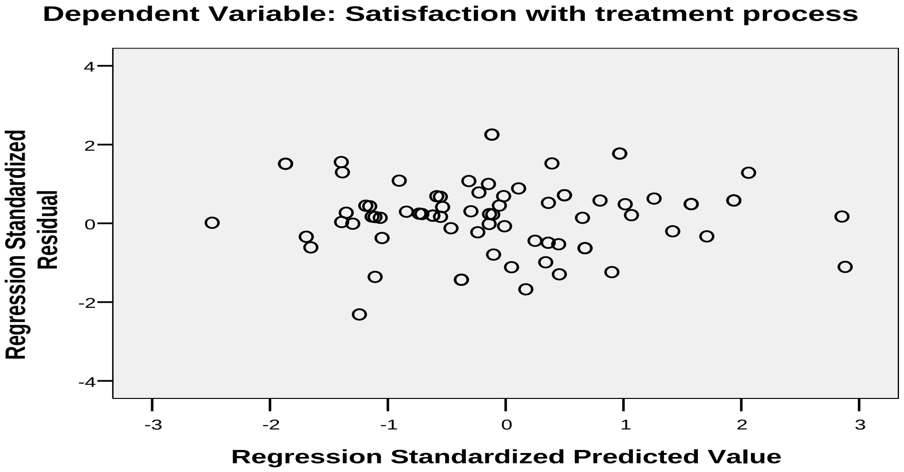


Figure 50. Normal P-P Plot of Regression Standardized Residual for the Adherence to Physiotherapy Domain

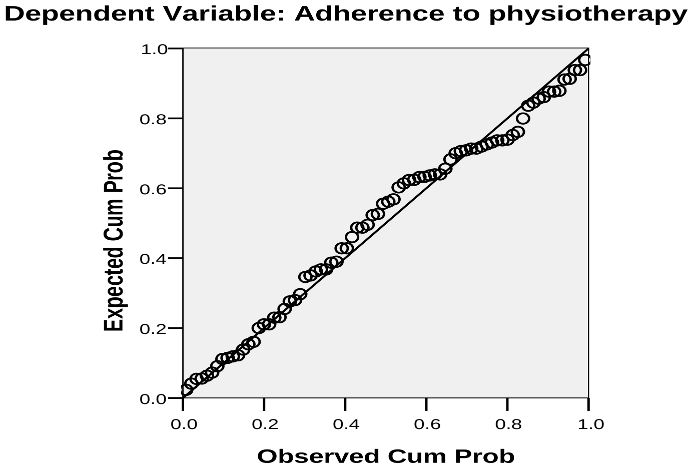


Figure 51. Scatterplot for the Adherence to Physiotherapy Domain

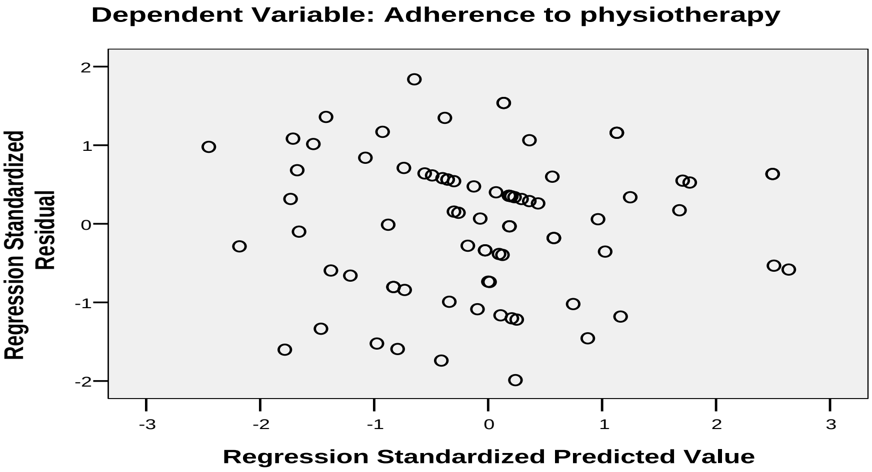


Figure 52. Normal P-P Plot of Regression Standardized Residual for the Impact of Back Pain and Treatment on Relationships Domain

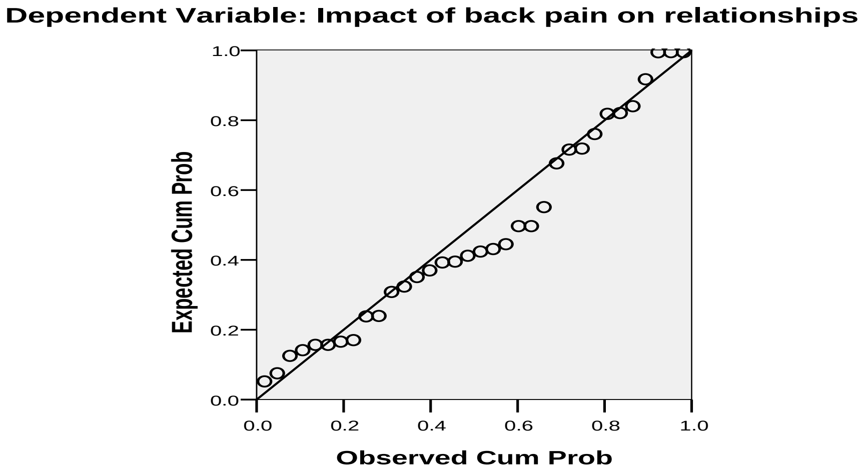


Figure 53. Scatterplot for the Impact of Back Pain and Treatment on Relationships Domain

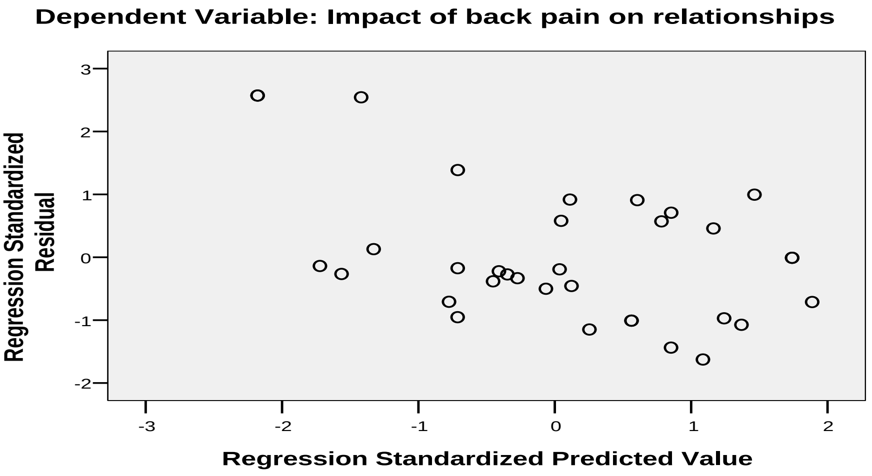


Figure 54. Normal P-P Plot of Regression Standardized Residual for the Medication Acceptability Domain

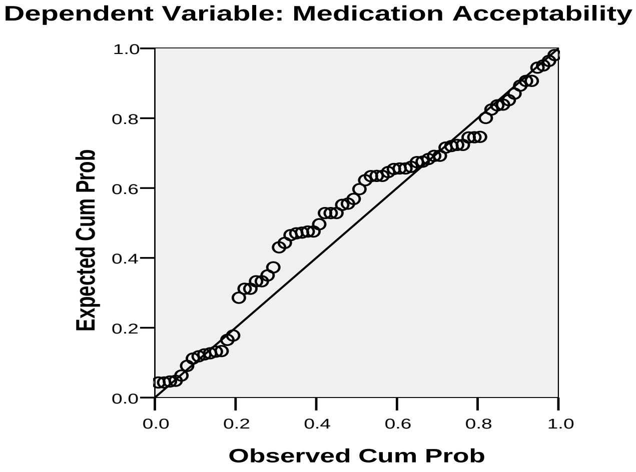


Figure 55. Scatterplot for the Medication Acceptability Domain