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The impact of chronic pain on quality of life: the development of a WHOQOL-based pain module

Mason, Victoria L.

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Submitted by Victoria L. Mason

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Victoria Mason.

ProQuest LLC
789 East Eisenhower Parkway
P.O. Box 1346
Ann Arbor, MI 48106-1346

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Frequently cited abbreviations

Activities of daily living	ADL
Chronic lower back pain	CLBP
Chronic pain	CP
Chronic Pain Acceptance Questionnaire	CPAQ
Chronic pain patients	CPP's
Cognitive Behaviour Therapy	CBT
Cognitive interviewing	CI
Fibromyalgia	FMS
Focus groups	FG's
Gate Control Theory	GCT
International Association for the Study of Pain	IASP
Low back pain	LBP
Lumbar epidural steroid	LES
McGill Pain Questionnaire	MPQ
Medical Outcomes Survey short-form 12	SF-12
Mental Health Component Score of SF-12	MCS
Non-steroidal anti-inflammatory	NSAIDs
No treatment	NT
Osteoarthritis	OA
Overall quality of life and health	G
Pain and discomfort module	PDM
Pain Management Programme	PMP
Physical Health Component Score of SF-12	PCS
Present pain level	PPL
Quality of Life	QoL
Randomised controlled trial	RCT
Rheumatoid arthritis	RA
Spirituality, religion and personal beliefs	SRPB
Transcutaneous electrical nerve stimulation	TENS
World Health Organisation Quality of Life Assessment	WHOQOL

For my mother, father and Anna
and in memory of Hannah May Reavill

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Abstract

The aim of this thesis was to develop a new module on pain and discomfort to be used in conjunction with the UK World Health Organisation Quality of Life Assessment (WHOQOL-100) that elaborates the experience of chronic pain (CP). Further aims were to elucidate its psychometric properties and assess the quality of life (QoL) of people with CP. The WHOQOL-100 is a multilingual, generic instrument for the subjective assessment of QoL in adults. It contains 100 core items represented by 25 specific facets covering six broad domains. The four items in the WHOQOL-100 that address pain and discomfort have been found to under-represent the impact of pain on QoL, hence the need to develop a pain and discomfort module (PDM). Focus groups (FG's) were conducted to generate data on how pain affects QoL. Ten new facets of QoL pertaining to CP were identified; flare-ups; pain relief; anger/ frustration; vulnerability/ fear/ worry; uncertainty; loss/ loneliness/ feeling alone; positive strategies; communication; guilt/ burdening others; relationship with health care providers. Concurrently, a web survey was conducted to provide confirmation and validation of the areas of QoL identified. A definition and items were written for each new facet of QoL. The resulting 108-item questionnaire was pre-piloted in a sample of people with CP using the technique of cognitive interviewing. Following deletion and modification of items, the 68-item PDM and 16 importance items were administered in a cross-sectional survey, where 4 facets remained in the PDM represented by 16 items. The WHOQOL and PDM were administered to low back pain patients having lumbar epidural steroid injections at baseline and 4-weeks following the intervention in a longitudinal survey to examine sensitivity to change. Patients not undergoing treatment also completed the WHOQOL and PDM at baseline and after 2 weeks to examine test-retest reliability. Pain relief, anger and frustration, vulnerability, fear and worry and uncertainty influence the QoL of people with pain. The PDM will be self-administered and must be used in conjunction with the UK WHOQOL-100 for large-scale survey work, for evaluating the effectiveness of new and existing interventions designed to reduce the impact of pain on QoL and to identify the needs of sufferers.

Chapter one

What is Chronic Pain?

1.1 Introduction

Everyone experiences pain at some point during their lives. Such experience is an inherently subjective experience and is associated with varied meanings. For some individuals, pain is perceived constantly through disease or ill health, sometimes even in the absence of pathology. Indeed, reports of pain are not highly associated with physical evidence of damage (Hunter, 2001). Given the inherent subjectivity, it is not possible to measure pain objectively by the extent of underlying pathology. Consequently, measuring or assessing a person's pain must rely on verbal report or non-verbal behaviour. A person's past experience, and the meaning and context of pain can influence such reports and lead to diverse consequences. This has led to the development of many different methods for measuring and assessing pain from simple visual analogue scales to multidimensional instruments assessing quality of life (QoL). The limitations of medical science to alleviate the suffering of persistent pain and the disability that may result from this has raised the question of how such experience may impact on the quality of people's lives. This thesis addresses the impact that persistent pain has on the life quality of sufferers by developing an instrument to assess this.

1.2 Pain

Before going on to discuss the extent of the problem of pain, definitions of pain are introduced. In 1986, the international association for the study of pain (IASP) subcommittee on taxonomy defined pain as 'an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage'. That pain could be defined in this way, and as a consequence of important historical developments, such as the explication of the Gate Control Theory (GCT) (Melzack and Wall, 1965), the conceptualisation and understanding of pain has broadened to include the psychological and social aspects of a person's experience. The application of psychology to the study of pain has become central to understanding its complexity, which is revealed in the burgeoning literature (e.g.

Sternbach, 1977; Skevington, 1995; Price, 1999; Gonzales, Martelli and Baker, 2000; Frischenschlager and Pucher, 2002, Turk and Okifuji, 2002).

1.2.1 Defining chronic pain

Defining chronic pain (CP) is conceptually necessary, useful in clinical practice and of paramount importance in empirical research. If CP is not adequately defined in studies investigating it, the reader is uncertain of which group of individuals are being referred to, or about whom the conclusions and recommendations are being made. CP has been defined as that which persists beyond the normal time of healing (Bonica, 1953). In practice, this may be less than one month, but is more likely to be more than six months, indeed six months is often preferred for research purposes (IASP Task Force on taxonomy, 1994) to sufficiently distinguish between acute and chronic pain. In general, it is suggested that three months is the most convenient point to distinguish acute and CP where pain is non-malignant, for example as 'pain that has persisted for longer than three months or past the expected time of healing', which contrasts with the definition of acute pain as 'pain associated with acute injury or disease' (The Royal College of Anaesthetists and The Pain Society, Pain Management Services Good Practice, May 2003). Despite such definitions, it is suggested that the normal healing does not always occur and that the period of time will vary depending on the circumstances (IASP Task Force on taxonomy, 1994; Macrae and Davies, 1999). Indeed, in some situations, repair may never be complete, for example, neuromata in an amputation stump represent a failure to heal and may be a site of persistent pain (Geraghty and Jones, 1996).

Advances in our understanding of CP have come about with research demonstrating the plasticity of the nervous system (Wall, 1989) where changes occur to its structure and function in response to the input it receives. Consequently, pain can be prolonged and maintained because of the response of the nervous system to injury. In view of this, it is suggested that CP may be viewed as "a persistent pain that is not amenable, as a rule, to treatments based upon specific remedies, or to the routine methods of pain control such as non-narcotic analgesics" (IASP Task Force on taxonomy, 1994). Consequently, the coding system developed by the IASP for classifying CP allows for durations of less than one month, one month to six months and more than six months (IASP Task force on Taxonomy, 1994). Although the differences between acute and

CP are discussed, the IASP does not have a specific definition for ‘chronic pain’ (personal communication, October 2000). Moreover, although having a single definition of CP is a pragmatic one, the use of 'chronic pain' as an overarching term as a scientific construct has been questioned because it has been suggested that it is meaningless to compare different groups under this heading such as those with trigeminal neuralgia and low back pain (LBP) (Chapman and Donaldson, 1995). However, Novy and colleagues (1995) respond to this by suggesting that the term 'chronic pain' has inherent clinical value. Anecdotally, this can be seen by the frequency with which health professionals refer to ‘chronic pain’ and the shared understanding of its meaning.

CP has also been defined as “pain which has continued for at least three months and is unlikely to resolve spontaneously” (Working Group of the National Medical Advisory committee, 1994). However, this may exclude some diagnostic groups, for example, recurrent headache, which may be experienced intermittently. A more inclusive definition is **“pain or discomfort, that persists continuously or intermittently for longer than three months”** (Elliott et al., 1999). For research purposes, this may be a better choice, since this allows for the inclusion of diagnostic groups characterised by intermittent pain or flare-ups, which are known to characterise some chronically painful conditions (Croft et al., 1998). In its operationalisation of CP, the series of studies reported in this thesis uses this definition as its main inclusion criterion. Furthermore, only patients with pain arising out of benign conditions such as chronic low back pain (CLBP) and rheumatoid arthritis (RA) are included, as opposed to malignant or life-threatening disease such as the persistent or breakthrough pain associated with certain types of cancer and its treatment.

1.2.2 Prevalence of chronic pain

Research reveals that estimating the prevalence of CP is problematic, given the lack of clarity in defining CP and the inherent subjectivity of the pain experience. Prevalence is defined as the number of persons with CP at a specific time divided by the total size of that population. Estimating prevalence is usually carried out through cross-sectional survey work. Researchers use different definitions, ranging from pain persisting for longer that one month (for example, Magni et al., 1993) to that persisting longer than six months (for example, Gureje et al., 1998). Despite numerous epidemiological studies on specific pain conditions or syndromes, there are few UK studies on CP across a wide range of diagnostic conditions. In order to select and recruit a representative sample for a research endeavour, it is necessary to have an accurate estimate of prevalence across the diversity of pain conditions, whilst being mindful of the fact that those presenting at primary care or beyond may represent the tip of the iceberg (Smith et al., 1996; Crombie and Davies, 1998).

In a review of 15 studies of the prevalence of benign CP, a median point prevalence of 15% in the adult population, ranging from 2% to 40% was found (Veerhak et al., 1998). People with CP tended to be women of lower socio-economic status and pain was most frequently present in the lower back, shoulder and neck and was often associated with depression or psychological distress. It is suggested that a 10% prevalence would be a very cautious estimate and that obtaining an accurate assessment of prevalence is problematic, given the inherent subjectivity of pain. Furthermore, it is suggested that it is more important to investigate the impact of pain on the lives of sufferers than to determine precisely how many people suffer (Veerhak et al., 1998). However, in order to carry out research on representative samples of people with CP, an important goal is to develop accurate ways of estimating prevalence to enable researchers to structure their samples in a way that can be said to represent people presenting with different types of CP. Large-scale epidemiological research is needed to quantify the extent of this distressing problem and to take account of the diversity of chronically painful conditions.

Three UK studies were included in the review (Veerhak et al., 1998). The first was a telephone survey of 2942 people of all ages in Great Britain (Bowsher et al., 1991). CP was defined as ‘pain which has lasted on and off for longer than the last three months’, allowing for the inclusion of recurrent pain. Taking into account location, temporal characteristics and social disability, the estimated prevalence was 7%. Pain was attributed to ‘arthritis’ (44%), ‘illness’ (8%), ‘injury’ (7%), ‘heart’ (6%) and ‘surgery’ (4%). Pain was found to be most frequent in women of lower socio-economic status and the bulk of people complained of musculoskeletal or articular disease, that is, pertaining to the joint. Although no significant differences in socio-economic class were found for the prevalence of arthritis/ rheumatism, it was found to be significantly less common in the south of England (Greater London, south-east and south-west). The most common sites of pain were neck/back/spine, followed by, lower limb, upper limb, abdomen, chest and hips, and finally the head.

The second study was a postal survey of the registered population of two general practices in England of 1340 people between 18 and 85 years-of-age (Croft et al., 1993). Pain was defined as ‘a report of any pain during the past month which has lasted for longer than 24 hours’. CP was defined as ‘pain as defined above, which started more than three months ago’. Widespread pain was defined as ‘along the axial skeleton (the skull and vertebral column) and in two contralateral quadrants of the body’. Finally, chronic widespread pain was defined as ‘widespread pain >3 months’. The prevalence of pain was 56%, widespread pain 16% and chronic widespread pain was 13%. Chronic widespread pain increased with age and was more common in women and a positive association was also found with somatic symptoms, tiredness and affective symptoms.

The third study by Potter and Jones (1992) was carried out with eight general practitioners for 10 months in England with people between the ages of 18 and 65. Pain was defined as a ‘new episode of musculoskeletal pain of 4 weeks’ duration’, CP as ‘still pain after 26 weeks’, otherwise ‘acute pain’. Taking into account the intensity and sensory/affective/evaluative aspects of pain and coping, they found 20 patients with CP, 25 with acute pain and three with pain but no follow up data. People with CP reported more intense pain than those with acute pain and more depressive symptoms were found amongst people with CP in addition to a greater use of passive coping strategies. This study is of limited value when considering the broad range of pain conditions across diagnostic groups, since only musculoskeletal conditions are investigated.

In a World Health Organisation Study in Primary Care on persistent pain and well-being, Gureje and colleagues assessed the prevalence of persistent pain across 15 different centres world-wide (Gureje et al., 1998). Pain was defined as 'pain present most of the time for a period of 6 months or more during the prior year'. They also assessed psychological illness, disability and activity limitation days in the previous month. Across the centres, persistent pain was found to be significantly more common among women than men, although in the UK sample taken from

Manchester, England, 26% of men and 18% of women complained of persistent pain, giving an overall percentage of 21%. It was also found that back pain (BP), headache and joint pain were the three most commonly reported anatomical pain sites. This was followed by arm or leg pain, chest pain, abdominal pain and elsewhere. A large number of primary care patients also reported pain in at least two anatomical sites. In the UK sample, a relationship was found between depressive or anxiety disorder and persistent pain, rating health as fair to poor, work interference and three or more activity limitation days in the previous month.

Elliott and colleagues carried out a study to quantify and describe the distribution and prevalence of CP in the community (Elliott et al., 1999). A sample of 5036 patients was selected from 29 general practices and surveyed by postal self-completion questionnaire. As described above, CP was defined as 'pain or discomfort, that persisted continuously or intermittently for longer than three months'. The estimated prevalence of CP in the general population was 46.5% (95% CI 44.8-48.2). The most common complaints were BP and arthritis, which accounted for a third of all reported causes. In a subsequent study, Elliott and colleagues (2002) examined the course of CP in the community in a 4-year follow-up study in the Grampian region of Scotland. Participants were asked questions about whether they had CP, in addition to questions about severity, site, duration, and health care use. All participants gave socio-demographic details and completed the chronic pain grade questionnaire and the SF-36. A response rate of 83.0% was achieved with 1608 returned questionnaires. The results indicate that there was no significant difference between the proportion of men and women reporting CP, in contrast to findings of previous studies (see above). The proportion reporting CP increased with age at both baseline and follow-up and the overall prevalence of pain increased over the 4-year period. The increase in prevalence was larger amongst women than men and for the youngest age group. Of those without pain at baseline, 33.3% had pain at follow up (annual incidence of 8.3%). Of those with pain at baseline, 21.5% no longer had pain (annual recovery rate 5.4%). When examining predictors of onset and recovery from CP, amongst those without CP at baseline, those with poorest physical and social functioning and more bodily pain (assessed by the SF-36) were most likely to develop CP in the next four years. Retired individuals at baseline were less likely than employed people to develop CP and individuals who had more bodily pain and poorer general health at baseline were least likely to recover. Furthermore, those aged between 45-74 at baseline were less likely to recover than the youngest people with CP. Generally, CP severity was found to be relatively static, that is, remain the same or change by one grade. Overall, health factors were better predictors of pain onset and recovery than socio-demographic factors. The authors conclude that pain is common and persistent, has high incidence, low recovery rates and its severity is relatively static over time.

In a systematic review on the prevalence of CP (Ospina and Harstall, 2003), each study was weighted according to its sample size to enable a single estimate of prevalence to be estimated. The prevalence rates varied widely according to how CP was defined, which population was being studied and the methods of data collection used. Of the 13 studies published between 1991 and 2002, 3 were carried out in the UK. The minimum criterion for defining CP was between three months and six months depending on the study. The weighted mean prevalence was 35.5%, with estimates ranging from 11.5% to 55.2% and for females it was 39.6% (range 13.4-55.5%) and for males it was 31.0% (range 9.1-54.9%). Although severity of pain was defined in quite different ways across the studies, the prevalence of severe CP in the general adult population was estimated to be 11%. Prevalence estimates ranged from 10.1% to 55.2% and high prevalence rates among females were consistently reported. Given the variations observed in the data, including the use of different definitions and methods, the need for the conduction of concurrent, prospective epidemiological studies to estimate CP prevalence using clear, standardised case definitions and reliable and well-validated data collection tools, including QoL is recommended.

These studies illustrate the considerable variation in estimates of prevalence of CP in the community and diversity of diagnostic groups that constitute it, largely due to differing definitions and inclusion criteria, range of diagnoses included and the different methods determining prevalence. Consequently, elucidating the prevalence of the different types of pain as a proportion of all those presenting with CP is problematic. For many CP conditions, the pain is of unknown aetiology, and there is no apparent organic pathophysiological basis for its existence, which raises problems with accurate classification, particularly for patients reporting LBP, when there is no evidence of radiographic findings (van Tulder et al., 1997). Overall, prevalence of CP ranged from 10-20%, although some studies reported higher estimates. In general, there is agreement that the prevalence and consequent burden of musculoskeletal conditions is amongst the highest, in particular, pain pertaining to the bones and joints, such as back and neck pain and osteoarthritis. In general, prevalence rates were highest amongst women of lower socio-demographic status and increased with age. However, Elliott and colleagues (2002) found health to be a better predictor than socio-demographic status and comparable prevalence rates for men and women, although larger increases in prevalence were found for women over time. In contrast, the WHO study found that fewer females than males complained of chronic pain in their UK sample (Gureje et al., 1998). Many studies found co-morbidity, particularly with depressive symptomatology (Veerhak et al., 1998), which concurs with the strong association between pain and depression found amongst primary care patients (VonKorff and Simon, 1996). Taken together, these studies highlight the extent of the problem of pain in society, which necessitates further understanding of this complex, variable and prevalent experience.

1.3 Theories and models of pain

Having discussed definitions and prevalence CP, theoretical approaches to understanding pain are considered, before going on to discuss the importance of assessing its impact. There has been a proliferation of theories attempting to understand pain in recent decades and they reflect different levels of understanding, from biological theories explaining nociceptive processes to theories relating to higher order processes and outcomes such as QoL. The Gate Control Theory (Melzack & Wall, 1965) has revolutionised the understanding of pain with its acknowledgment and elucidation of the role of psychological processes, including descending control mechanisms (Melzack, 1982). Numerous theories have attempted to explain the aetiology, experience of and maintenance and treatment of CP and it is widely acknowledged by contemporary theories that pain is a multidimensional experience (Melzack, 2001; Martelli et al, 2004; Nicholson and Martelli, 2004). Consequently, any attempt to dichotomise pain into 'physical' and 'psychogenic' is not possible given that pain represents the complex interplay between numerous physical, psychological, social and cultural factors (Frischenschlager and Pucher, 2002). Models and theoretical approaches can be contrasted by whether they are broad conceptualisations, for example the biopsychosocial model, or derived specifically as a framework for the treatment and management of pain, for example cognitive behavioural approaches.

1.3.1 Biomedical model

The biomedical model conceptualises pain as a physical problem that arises from underlying disease processes or pathology, which can be treated by medical intervention. It focuses on elucidating the biological factors generating and maintaining disease processes, to the exclusion of psychological, social and cultural factors influencing the response to pain, which have been shown to be important (e.g. Coste et al., 2004). It has been argued that the biomedical approach is strongly dualistic in its epistemology because if no organic pathology is identifiable, pain is assumed to be of psychogenic origin (Spiegel, 1999). A study has shown that 80% of patients had no identifiable organic basis for their BP (Deyo, 1986); conversely, many people reporting no pain have identifiable abnormalities such as herniated discs (Jensen et al., 1994). Given these issues, and despite the massive advances of biomedicine, in terms of understanding the complexity of the genetic, neurochemical and pharmacological aspects of pain and its treatment, this model is limited in its ability to adequately account for the influence of intrapersonal, interpersonal and cultural mediators of pain or the complexity of human behaviour with respect to well-being and health. The evidence for the biopsychosocial model discussed below supports such a conclusion.

1.3.2 Biopsychosocial model

The biopsychosocial model extends and broadens the narrow medicalised approach of the biomedical model and has arguably become the dominant paradigm within the field of health psychology. Engel was one of the first to propose such a model (Engel, 1959; 1977) and more recently, others have been instrumental in developing the model in the field of pain (Waddell, 1992; Waddell et al., 1993; Turk, 1996; Gonzales et al., 2000). The model accounts for the biological, psychological and social aspects of health and its appeal derives from its all encompassing nature and applicability to numerous chronic health problems. The model conceptualises the multidimensional CP experience by accounting for the biological features of pain, perceptual awareness of nociceptive sensations by the sufferer, the psychological aspects including cognitions and emotions and the social environment in which individuals operate. It has been suggested that the movement towards the biopsychosocial approach, and away from the biomedical one, reflects the importance of psychological and environmental factors in pain (Garofalo, 2000). The model can be represented diagrammatically by three concentric circles, where social features encompass the psychological and biological, which is at the core. Within the model, the role of psychological processes has been drawn on extensively to elucidate the aetiology, maintenance, treatment and prevention of pain (Linton, 1995). Although the social dimension of the model is in need of elaboration, the advantage of this model is that it contextualises the individual and helps to account for the fact that CP is not just a consequence of underlying tissue damage (e.g. Ferrari and Schrader, 2001). The next two approaches discussed, based on behavioural and cognitive-behavioural theories, incorporate the biopsychosocial model in their treatment approach by acknowledging that social, behavioural and psychological factors influencing pain and its treatment.

1.3.3 Behavioural approach

One of the central tenets of the behavioural view is that behaviours arising from the pain experience, such as limping, grimacing and rubbing are subject to the influence of conditioning (Fordyce, 1996). Consequently, if such behaviours invoke reinforcing consequences, these behaviours are likely to persist beyond the time of healing (Sanders, 1996). Although the principles of the behavioural model have been applied widely to the treatment of pain for several decades (Fordyce, 1973), the approach has been subject to much criticism, including the assumption that such pain behaviours are maladaptive (Turk, 1996). Fundamentally, the lack of any cognitive constructs in the theory and the denial that a patient's interpretation of environmental changes may be important (Sharp, 2001) limits its applicability and challenges common sense assumptions and the views of patients. Moreover, a large body of research has provided convincing evidence for the role of cognitive constructs such as catastrophising and fear avoidance in explaining, or mediating the response to pain (Main and Waddell, 1991; Vlaeyen and Linton, 2000; Swinkels-Meewisse et al., 2003). Although treatment based on modifying behaviour through environmental contingencies has been shown to successfully reduce 'pain behaviours', Sharp (2001) challenges the interpretation that this provides support for the model, since it is not possible to rule out the importance of cognitive factors. The cognitive-behavioural approach described below integrates such factors with the more traditional behavioural views.

1.3.4 Cognitive-behavioural approach

The cognitive-behavioural approach to pain is the dominant paradigm in the treatment and management of pain. It was born out of the operant behavioural approach espoused by Fordyce, and combined with the acknowledgement of the importance and contribution of cognitive constructs (Sharp, 2001). From this approach, pain is viewed as complex and multidimensional and it is influenced by the underlying tissue damage, thoughts (cognitions), feelings (emotions) and behaviour (Turk and Kerns, 1983; Bradley, 1996). Its central tenets are that it is the thoughts and feelings associated with pain and its consequent behaviour that can be modified to bring about important treatment gains. Systems theory is also integrated into this approach, as a change in one dimension of the pain experience influences other domains (Main, Keefe and Rollman, 2002). Treatment based on cognitive-behavioural principles is widely used and a comprehensive meta-analysis has demonstrated its efficacy compared to waiting list controls (Morley et al., 1999). This approach has the potential to be integrated with QoL theory given the broad aspects of a person's experience that are covered.

1.3.5 Model of the psychosocial processes and social factors implicated in the generation and maintenance of a chronically painful illness

The models outlined above are limited by giving only tacit acknowledgement to the social factors that influence the response to pain. Consequently, the model proposed by Skevington (1995) presents four levels of understanding and provides a framework within which the social aspects of CP may be better appreciated. Level 1 defines the individual processes affected by social influences, such as perceived bodily sensations. In contrast, Level 2 characterises salient interpersonal behaviours, in particular, that person's relationship with significant others. Level 3 defines group and intergroup behaviours such as group beliefs, experience and influences, while Level 4 encompasses some of the higher order factors that affect socio-psychological processing, such as health ideology and health politics. Although reductionist, this model aims to understand the processes within each level and the relationships between levels, rather than assuming that each level can be better explained by looking at the level below. Consequently the strength of the model lies within its broad conceptualisation of CP by removing the individual from their social and cultural 'black box' and through the inclusion of higher order factors such as QoL (Skevington, 1995, Skevington and Mason, 2004).

These theoretical approaches and models provide a framework to conceptualise the complex response to living with persistent pain. Given the limitations of the biomedical and behavioural approach in their narrow conceptualisation of pain and exclusion of other important factors, the biopsychosocial model and the model outlined by Skevington (1995) provide the most useful framework to understand the multidimensional experience of pain. Such models acknowledge that pain can be influenced by cognitive, social and cultural factors, in addition to the extent of underlying pathology, which is compatible with the holistic assessment of QoL. From the conceptualisation of pain, we turn to the ways in which pain has been measured and assessed.

1.4 Assessment of pain

1.4.1 Measurement of pain and disability

There has been considerable debate about the best way to measure pain, given the inherent subjectivity of the experience. Despite its apparent salience or intensity, finding words to describe the experience can be a challenge to the sufferer, although this has been aided by the seminal work of Melzack and Torgerson on verbal descriptors or adjectives describing the experience of pain (Melzack and Torgerson, 1971). The instruments summarised in table 1.1, illustrate commonly used measures of pain, its intensity, severity, quality and physical and psychological consequences. Such instruments reflect the complexity and diversity of approaches to measuring pain and its concomitants and highlight the need for multidimensional assessment.

Table 1.1 Summary of commonly used instruments used to assess pain and its consequences

Instrument	Authors	Purpose of instrument	Qualities of pain assessed	Examples or issues
The McGill Pain Questionnaire (MPQ)	Melzack, 1975	Evaluates pain qualitatively	Consists of a pain drawing, a 5-point Visual rating scale & a list of 78 pain adjectives divided into 20 subclasses that reflect four dimensions of experience. These are, sensory, affective, evaluative & miscellaneous. Patients indicate which word/s best describe their pain	The discriminant validity of the Pain Rating Index (PRI) is questioned because of high intercorrelations between the 3 components. Use of the total score of the PRI is recommended (Turk et al., 1985)
Short-form McGill Pain Questionnaire (SF-MPQ)	Melzack, 1987	Evaluates pain qualitatively	15 pain adjectives, 11 sensory & four affective	Well validated & used extensively with people with CP
The Chronic Pain Grade questionnaire (CPG)	VonKorff et al., 1992	Grades the severity of pain	Seven-item instrument grading the severity of pain in two dimensions, namely, intensity & disability. Patients are classified into five hierarchical grades: Grade 0 (pain free), Grade I (low disability- low intensity), Grade II (low disability- moderately limiting), & Grade IV (high disability- severely limiting)	Developed in the USA, but validated in the UK. Acceptable, valid & reliable for use as a postal questionnaire (Smith et al., 1997)
The West Haven-Yale Multidimensional Pain Inventory (WHYMPI)	Kerns et al., 1985	Assess clinical pain expressing psychosocial variables relevant to the pain experience	Self-report questionnaire, derived form the cognitive- behavioural model. Twelve scales make up 3 parts of the inventory that assess the impact of pain on the lives of patients, the responses of others to communications of pain & the extent to which patients engage in daily activities. Yields 3 profiles; dysfunctional, interpersonally distressed & adaptive copers	Good psychometric properties (Mikail et al., 1993) & it also contains a Pain Control Scale
Tampa Scale for Kinesiophobia (TSK)	Kori et al., 1990	Measures fear of movement, pain & injury	A 10-item scale, 4-point rating scales are used for whether patients agree or disagree with statements	Reliability & validity is well documented (Crombez et al., 1999)
The Coping Strategies Questionnaire (CSQ)	Rosensteil & Keefe, 1983	Measures the frequency with which people use six pain coping strategies	Coping self-statements, ignoring pain sensations, reinterpreting pain sensations, diverting attention, praying & hoping & increasing behavioural activities	Extensively used & well validated (Keefe et al., 1992)

Instrument	Authors	Purpose of instrument	Qualities of pain assessed	Examples or issues
Survey of Pain Attitudes (SOPA)	Jensen et al., 1994	Perceived level of disability	A 10-item disability sub-scale measuring perceived level of disability	Change in pain cognitions assessed by the SOPA is associated with change in physical performance in patients with LBP (Moseley, 2004)
Cervical Spine Outcomes Questionnaire (CSOQ)	BenDebba et al., 2002	A comprehensive, disease-specific questionnaire for the assessment & evaluation of treatments for neck pain	Six composite measures can be derived, which assess; pain severity, functional disability, psychological distress, physical symptoms, health care utilisation & satisfaction	Reliable, valid & responsive to change (BenDebba et al., 2002)
Rheumatoid Arthritis Pain Scale (RAPS)	Anderson, 2001	Measures pain in adults with Rheumatoid Arthritis (RA)	A 24-item self-report scale consisting of 4 subscales; physiological, affective, sensory-discriminative & cognitive to account for the multidimensional experience of pain	Scale has high internal consistency with a reliability coefficient of .92. Subscale α ranged from .65 to .86

1.4.2 Why assess the impact of pain on QoL?

The variety of instruments to assess pain and its consequences highlight its multidimensional nature. Given the complexity of pain, assessing the broader impact, including QoL, is becoming increasing important. Indeed, according to Niv and Kreitler (2001), two major factors have contributed to the increasing interest in the QoL of people with pain. The first is an epidemiological or socio-economic factor, that is, the high prevalence of pain amongst the community, the extensive use of health and social care by people with CP and the increasing demand for evaluating the effectiveness of interventions in a culture of evidenced based practice and clinical governance. The second factor is the emphasis on the 'whole person' brought about by an increased understanding of the mechanisms underlying the experience of pain (Niv and Kreitler, 2001). Indeed the emphasis on QoL represents a move from the biomedical to the biopsychosocial model. More generally, research has shown that pain has a significant negative impact on QoL (Skevington, 1998) and Becker and colleagues have demonstrated that QoL amongst Danish pain patients is lower than that of any other condition (Becker et al., 1997). Similarly, Sprangers and co-workers ranked QoL scores from eight data sets from over 15,000 participants and found that musculoskeletal conditions impacted most severely on QoL; within this category, osteoarthritis had the most severe impact, followed by back problems and RA (Sprangers et al., 2000). More recently, people with spinal, neuropathic and somatic pain have been shown to have a lower QoL than healthy controls (Fanciullo et al., 2003).

Such evidence supports the need for assessing QoL in addition to the other important outcomes summarised in table 1.1. Within such an assessment, instrument quality, such as the reliability, validity and sensitivity to change is important to demonstrate treatment success and to show improvements in traditional outcomes (reduction in pain, increased functioning and so on) in addition to well-being and QoL. Key outcomes incorporate different levels of functioning and include higher level factors such as QoL, health care utilisation and lifestyle behaviour; physical factors such as pain, activity restrictions, functional status, mobility and ADL; aspects of mental health such as depression, anxiety, knowledge about pain and other identified correlates of pain such as catastrophising, self-efficacy, health locus of control (HLC) and so on. One of the challenges to pain researchers and health professionals is to maximise, promote and retain positive gains following interventions, given that improvements are often not maintained at follow-up (for example, Hopman-Rock and Westhoff, 2000). This has both economic implications and consequences for individual sufferers. Consequently, identifying the important correlates of pain allows for more effective targeting of interventions. A systematic review of rehabilitation for CLBP found that few RCT's report on the effects on QoL or global assessments (Guzman et al., 2001) and given the importance of evidenced based practice, developing, validating and standardising such outcome measures greatly assists the planning, implementing and interpretation of RCT's (Cranney et al., 1999), highlighting the need for such instruments to be routinely included.

To conclude this section, it has been shown that assessing QoL in people with CP is important due to the high prevalence of pain, an increased understanding of its impact coupled with a more holistic approach to health care and evidence suggesting that the QoL of people with pain is more compromised than that found amongst other conditions. Furthermore, consideration must be given to the quality of instruments purporting to assess outcomes and the importance of incorporating QoL assessment into RCT's due to the diverse impact of CP. Table 1.2 summaries instruments that have been designed specifically to measure the impact on QoL of particular diseases or conditions where pain is a major feature, such as cancer or RA. In the section that follows, studies investigating the QoL of people with CP are discussed, although QoL is introduced and discussed in more detail in chapter two.

1.4.3 Studies assessing the QoL of people with pain

The previous section highlighted the need for assessing QoL. Numerous studies have examined the relationship between CP and aspects QoL, for example, perceived support from a social network, self-esteem, sense of internal control over health and a negative attitude towards illness were found to be correlates of QoL in a study of arthritis patients (Burkhardt, 1985). At the time of the study, each of these concepts required a different scale. Consequently, it has been suggested that in addition to assessing health status, other measures should be included to account for the influence of other important mediating variables to enable a comprehensive assessment to be obtained (Deyo, 1993). Since that time, a number of comprehensive assessments have been developed, for example, in the work of the WHOQOL Group (detailed in chapter two) in order to capture the diverse consequences of health conditions on QoL.

Burton and colleagues (1998) investigated the relationship between QoL and health locus of control orientation in 219 patients with CP and also found an association between internal locus of control and physical, emotional and social well-being, where patients categorised as internally orientated had a better psychological profile, reported less pain and less pain interference and had better coping skills than externally orientated patients. It is suggested that CBT interventions designed to change locus of control orientation could improve QoL. However, the study used a cross-sectional design and thus it is not possible to establish the direction of causation, that is, whether internal control leads to positive well-being or whether positive well-being brings about an internally orientated locus of control. Furthermore, although the authors claim to show a relationship between internal life orientation and increased QoL, they do not actually measure QoL *per se* because their instrumentation does not include an assessment of QoL.

Investigating the frequency of CP following inguinal hernia repair and its impact on QoL using the SF-36, Poobalan and colleagues found that compared to controls, those with CP had poorer social functioning and mental health and more pain (Poobalan et al., 2001). However, the SF-36 assesses health status rather than QoL *per se* and thus conclusions about the impact on QoL should be made with caution. Indeed, it has been argued that the conclusions can be misleading when a health-status measure is used to assess quality of life (Bradley, 2001). This is an important point given the large number of studies claiming to measure QoL using health status instruments such as the SF-36. Additionally, more 'precision' is needed when using the term QoL, particularly if clinicians are to be clear that health status measures assess whether a particular intervention changes perceived health, not whether or not it improves or decreases QoL (Bradley, 2001).

In a pilot study exploring the impact of stressors on the QoL of people with chronic non-malignant pain, Gerstle, All and Wallace (2001) used Neuman's Systems Model as a framework. This model is based on the concept of stress and reaction to stress.

Table 1.2 Summary of commonly used specific QoL instruments relating to pain

Instrument	Authors	Purpose of instrument	Aspects of QoL assessed	Examples
The European Organisation for Research & Treatment of Cancer core quality of life questionnaire (EORTC QLQ-C30)	Aaronson et al., 1993	Evaluates the QoL of people taking part in clinical trials for cancer	Incorporates 9 multi-item scales; 5 functional scales (physical, role, cognitive, emotional & social); 3 symptom scales (fatigue, pain, & nausea & vomiting); & a global health & QoL scale. Also contains several single-item symptom measures	Reliable, valid measure for use in clinical trial outcome measurement for cancer (Niezgoda & Pater, 1993)
The McGill Quality of Life questionnaire (MQOL)	Cohen, 1995	Measures the subjective well being of people living with a life-threatening illness	20-item scale measuring QoL at the end of life	Can distinguish between good & bad days of patients attending oncology outpatient clinics or receiving palliative care (Cohen & Mount, 2000)
The Rheumatoid Arthritis Quality of Life (RAQoL) questionnaire	Whalley et al., 1997	Assesses the QoL of people with rheumatoid arthritis	30-item questionnaire developed simultaneous in the UK & The Netherlands, derived from patient interviews. It has a yes/ no format & takes around 6 minutes to complete	High internal consistency & test-retest reliability & is sensitive to discriminating between groups with various disease severity (de Zong et al., 1997)
Migraine Specific Quality of Life Questionnaire (MSQOL)	Wagner et al., 1996	Assesses the global subjective impact of migraine on QoL	20-items with 3 hypothesized scales, Role Function-Restrictive, Role Function-Preventive, & Emotional Function	Reliable & valid, with scale α=.93 (Patrick, Hurst & Hughes, 2000)
Osteoporosis Functional Disability Questionnaire (OFDQ)	Helmes et al., 1995	Assesses functional disability in patients with osteoporosis & BP due to vertebral fractures	Five domains; quantitative indices of pain, a standard 20-item depression scale, 26 items relating to functional abilities, a scale of social activities, & confidence in the ability of prescribed osteoporosis treatment to reverse disability	Reliable, valid & sensitive to change (Helmes et al., 1995)

They compared QoL in terms of health and functioning and variables such as age, gender and so on. In a descriptive correlational research design, of 36 people with CP, QoL was assessed with the Ferrans and Powers QoL Index (Ferrans and Powers, 1985). Gerstle and colleagues found a higher QoL across broad domains amongst older, female, employed patients and those who were receiving workman's compensation. In contrast, poor QoL was associated with low income, high treatment costs and an absence of workman's compensation. They also found that, in general, QoL was low amongst this group compared to previously reported levels from other studies. It is likely that the stressors associated with living in the United States are different from those in the United Kingdom and thus caution should be used when applying these findings to UK populations who typically do not pay for health care or necessarily received compensation, which highlights the importance of accounting for contextual factors and cross-cultural issues when considering the assessment of QoL.

Other studies have also investigated the QoL of people from particular diagnostic groups with a variety of instruments purporting to measure QoL. For example, a study investigating which aspects of QoL were important to people with reflex sympathetic dystrophy (RSD) of the arm or leg used the Sickness Impact Profile (SIP), the Nottingham Health Profile (NHP) and the EuroQoL-5D (EQ-5D) (Kemler and de Vet, 2000). Although using generic instruments with highly scoring dimensions provided a responsive instrument to enable clinicians to focus on aspects of health-related QoL (HRQoL) affected by such a condition, focusing specifically on HRQoL does not account for the broader life domains affected by pain and its consequences.

In a pilot study using a non-experimental causal-comparative design to examine the perception of QoL of CP patients undergoing a multidisciplinary pain-management treatment programme in a rural community (All et al., 2000), QoL was measured using the Ferrans and Powers Quality of Life Index (Ferrans and Powers, 1985). Although it was hypothesised that those not receiving an intervention would report a lower QoL, the opposite was found to be the case, although this difference was not statistically significant. It was concluded that there were no differences between the intervention and non-intervention group in terms of perceptions of QoL. However, the study size was small (N=36) and conclusions based on such a small sample are difficult to draw. Furthermore, the instrumentation may not have been sensitive enough to detect important changes in QoL.

Although chapter two discusses QoL in more detail, this section has highlighted the diversity of instruments used to assess pain and QoL. A number of caveats have also been shown in studies purporting to measure QoL. For example, many studies use a cross-sectional design, which does not allow causal relationships be elucidated. Moreover, a considerable diversity of measures has been employed to assess QoL, which makes it difficult to draw comparisons across different cultural contexts, communities or diagnostic groups. Other studies assess the QoL of people from particular diagnostic groups where pain is a major symptom rather than examining the features that are common across groups, which was the goal of the research reported in this thesis. Furthermore, conclusions are frequently drawn about QoL when health status instruments have been used, which is problematic because such instruments do not account for the breadth of influences on QoL because they are specific to health and, relative to the holistic, multidimensional concept of QoL, are narrowly conceptualised.

1.5 Conclusion

This chapter began with an introduction to the extensive literature on CP, including how pain is defined, its prevalence in society and theoretical models and approaches to understanding pain and its consequences. Furthermore, it has argued that investigation of its impact on QoL is necessary because of its multidimensional impact and because of the lack of comprehensive instrumentation. Chapter two introduces, defines and discusses QoL in addition to outlining the rationale, aims and objectives, methodology and target population of the studies that follow. This work is set in the context of wider health psychological research and the fields of outcome measurement and psychometrics. The importance of understanding how living with persistent pain impacts on a person's life quality is the common thread tying this thesis together and the following chapters report the development of a new instrument for assessing the impact of CP on QoL.

Chapter two

Quality of Life

2.1 Defining Quality of Life

Reaching a consensus about what QoL is and how to define it is a more daunting task than the apparent ease with which people seem able to talk about their QoL. Despite recognition that QoL covers broad life domains (Rosenburg, 1995), it has been suggested that there is a lack of consensus in the meaning of QoL (Helmes, 2000) and a lack of agreement on the definition of QoL (Skevington, 1995). There is a relative dearth of literature on conceptualising QoL compared to research claiming to measure it and there appears to be some conceptual confusion between QoL and health-related QoL (HRQoL), indeed the two terms are often used interchangeably. However, QoL covers much broader life domains than HRQoL, which focuses on those areas of life pertaining to health. According to LePlege and Hunt, attempts to measure HRQoL are improbable because of the interconnectedness of health with other aspects of life; something that people cannot necessarily distinguish (LePlege and Hunt, 1997). Such lack of consensus and the consequent diversity of outcomes purporting to measure QoL present a challenge because of the difficulty of making meaningful comparisons across studies or contexts.

Table 2.1 summarises some of the definitions that have arisen over the last 25 years. Welch (1994) has pointed out that the term 'quality of life' was first used in Index Medicus in 1977. The examples shown here are not exhaustive, but have been chosen to represent the diverse ways in which QoL has been described and defined. Calman's (1984) view incorporates the notion that a person's expectations relate to their QoL, in the perceived gap between these and their actual experience. Gill and Feinstein's (1994) definition encompasses broader non-health areas such as employment, family, friends and life circumstances and the ways in which patients perceive and react to aspects of life. Shin and Johnson's (1978) definition embodies social comparison theory (discussed in chapter three), as illustrated by the last sentence where QoL results in part from the perception that one benefits from downward social comparison, that is, one perceives oneself positively compared to others. However, this definition fails to account for individuals who report a good QoL, despite not being able to fully participate in society, which presents a challenge to explaining the disability paradox, where despite considerable adversity, people are able to enjoy a relatively good QoL (Albrecht and Devlieger, 1999). Furthermore, this definition appears to reflect an ethno-centric position, with its focus on 'wants', 'desires' and 'self actualisation', which arguably reflect and embody western values. However, to its credit, it encompasses resources and participation, which can be seen as broad aspects of QoL. The definition offered by Cella and Tulsky (1990) and Lutgendorf and colleagues (1995) also includes notions of comparison with internal standards or ideal states in making judgements about QoL. Cohen's (1982) focus on achieving life ambitions also fails to account for the disability paradox, where people may have such aspirations dashed by illness or disease, yet still report a good QoL. Such counterintuitive reports have been explained by response shift, which is described below (Sprangers and Schwartz, 1999).

Other definitions, such as those offered by Le Mendola and Pellegrini's (1979), Spilker (1990) and Jacobson, de Groot and Samson (1995) are restricted to health and do not account for or encompass other domains or aspects of life that might impact on QoL because of their focus on illness and its consequences. Although more comprehensive than definitions relating to health, the definition offered by Wenger and colleagues (1984) emphasises functioning and satisfaction with role performance, which precludes a more holistic assessment. However, the strength of Spilker's definition is that it explicitly acknowledges the patient as the decider or assessor of his or her own QoL. The emphasis of these and many other definitions is the reliance on the subjective perception of the individual assessing their own QoL. Although this is a strength of such conceptualisations, there are clearly implications for measurement if an individual is unable to assess their own QoL because of cognitive or communication difficulties.

Such varied definitions reflect the challenge to develop a comprehensive definition accounting for the complexity of QoL. The World Health Organisation Quality of Life (WHOQOL) Group have addressed such a challenge by defining QoL as **'an individual's perception of their position in life, in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept, affected in a complex**

way by the person's physical health, psychological state, level of independence, social relationships and their relationship to salient features of their environment' (The WHOQOL Group, 1995). The purpose of the definition is to provide conceptual clarity and to provide a framework within which to conceptualise and measure QoL. Its strengths are its breadth, its cross-cultural applicability and the notion that QoL is subjectively defined rather than being based on any objective indicators such as wealth. Furthermore, it embodies the notion that the perception of QoL takes place within the context of one's culture and in relation to others. The WHOQOL definition and many of the definitions discussed above share a relativist position where QoL is subjectively defined in relation to one's experience. Comparative themes are also shared by a number of these conceptualisations, where perceptions of QoL arise out of comparison of oneself with others (Shin and Johnson, 1978) or with one's own standards (WHOQOL Group, 1995) or ideal states (Cella and Tulsky, 1990; Lutgendorf et al., 1995).

2.2 Models of Quality of Life

From conceptualising QoL in a definition, models have been developed as a framework to understand and assess QoL. Quality-adjusted life years (QALYs) were developed in order to include an assessment of years of life saved and QoL in making resource allocation decisions, hence their importance in the rationing of health care. There are two components; remaining life years gained from carrying out a particular procedure, treatment or intervention and an adjustment for the QoL of years gained from that procedure (Baldwin et al., 1990). Despite criticism of the use of QALYs in priority setting in health care on ethical grounds, Williams (1996) concludes that given the alternatives, it should not be discarded because of its significant role.

Lindström (1992) contrasts different approaches to QoL, such as the sociological approach of Allardt (1981) which encompasses needs and satisfaction with material and immaterial resources or 'being happy' with, for example, 'being rich' in terms of Gross National Product (GNP). However, GNP takes no account of the distribution of wealth in a population, forms of social assistance lower GNP but are nonetheless ways of improving QoL of vulnerable groups and there is evidence that an increase in wealth does not lead to a corresponding increase in QoL (for example, Mastekassa, 1988) (Lindström, 1992). In contrast to the 'being happy' and 'being rich' views is

Table 2.1 Author and corresponding definition of QoL

Author	Definition of QoL
Shin and Johnson, 1978	The possession of resources necessary to the satisfaction of individual needs, wants and desires, participation in activities enabling personal self-development and self-actualisation and satisfactory comparison between oneself and others
Le Mendola and Pellegrini, 1979	The individual's achievement of a satisfactory social situation within the limits of perceived physical capacity
Allardt, 1981	The immaterial resources and needs of people, or people's relationships to other people, society and nature (loving and being), and the subjective perceptions of the same
Cohen, 1982	Achieving their life ambitions
Calman, 1984	The extent to which our hopes and ambitions are matched by experience
Wenger et al., 1984	A multidimensional construct that includes a wide range of capabilities, limitations, symptoms, and personal psychosocial characteristics that describe an individuals ability to function and derive satisfaction from a variety of roles
Wenger et al., 1984	The individual's perceptions of his or her functioning and well-being in different domains of life
Spilker, 1990	The functional effect of an illness and its consequent therapy upon a patient, as perceived by the patient
Cella and Tulsky, 1990; Lutgendorf et al., 1995	The importance of peoples subjective perception of current ability to function as compared with their own internalised standards of what is possible or ideal
Lindström, 1992	The essential characteristics of life which, in the general public, is often interpreted as the positive values of life or the good parts of life *or* the total existence of an individual, a group or society
Gill and Fernstein, 1994	The reflection of the way that patients' perceive and react to their health status and to non-medical aspects of their lives
Jacobson, de Groot and Samson, 1995	The individual's subjective perception of well-being, as it relates to health status
Leung, 2002	A global, lasting state of being, which comprises perceived life satisfaction, presence of positive affect, and absence of negative affect

'staying normal' which is a medical view where one sits on the continuum between disease and health. In Lindström's examination of different approaches to QoL, it is shown that philosophy focuses on the 'good life' and values of life; sociology on nonmaterial welfare and well-being, human needs and wants; an economic approach focuses on economic standards and resources; behavioural science on well-being and mental well-being; and medicine on normality and medical interventions. This clearly demonstrates the inherent biases associated with approaching the problem of QoL from particular disciplines and further reveals the complexity of the concept that can be articulated and understood from numerous positions.

In contrast to the models described above a system model of QoL has been developed, which can be used to guide rehabilitation and psychosocial care (Leung, 2002). The model attempts to address the question of how QoL perceptions are formed, and is based upon the Gap model of QoL (Michalos, 1980). In this model, perceived QoL results from the appraisal of the gap between personal aspiration and reality, and is mediated by comparative frames such as the past, present and future status of the individual and by other factors such as peer group and sociocultural norms. The reality itself is seen as a result of the person-environment interaction, which generates different feelings towards various aspects of life. It is these feelings that are said to mediate the appraisal of QoL domains (Veenhoven, 1997). The advantage of this model is its dynamic nature, which accounts for changes in perception of QoL by shifting of comparative frames. Such a model also reflects the definitions discussed above that include reference to making comparisons or the gap between ones expectations and reality.

Such models offer competing approaches and conceptualisations of QoL. In contrast, the WHOQOL model of QoL embodies its multidimensional definition in conceptualising and measuring broad life domains and emphasising the subjective and relative aspects of QoL. Furthermore, given that comparative QoL research is difficult because of the lack of consensus over the definition (Lindström, 1992), the WHOQOL Group overcome this limitation by providing a way of measuring QoL cross-culturally, which it has been shown to do successfully (Bowden and Fox-Rushby, 2003). The WHOQOL model also contrasts with the disease-focused approach to QoL which has tended to leave out the positive aspects of a person's life, precluding a truly comprehensive assessment.

In general, these models illustrate that it is possible to view QoL from different conceptual frameworks. From the narrow pragmatic and economic focus of QALYs in priority setting of health care, to the competing approaches described by Lindström, where according to Allardt (1981), QoL is seen as synonymous with subjective well-being and happiness, which is contrasted with level of living or being wealthy and being healthy and free from disease. Further differences are reflected in Leung's system model based on the gap between expectation and actual experience, which can be used to guide rehabilitation and care and the multidimensional, subjective, cross-cultural approach of the WHOQOL Group. All of these approaches confer advantages depending on the purpose of measurement. In the section that follows, assessment of QoL is introduced and discussed.

2.3 Assessment of QoL

Having introduced and discussed definitions and models of QoL, this section examines the ways in which QoL is assessed. Although QoL is a concern of health professionals, it has been argued that it is rarely assessed in a systematic way (Skevington, 1995). Despite the increased use of QoL as an outcome in clinical trials, it does not necessarily influence clinical decision making or short-term changes in health status because physicians and trial designers are more likely to rely upon more objective, unidimensional measures such as observable behaviour, medication intake or work status and so on. It has been suggested that if the use of QoL information is to be increased, it must be integrated in an acceptable and useful manner (Fitzpatrick et al., 1992). Furthermore, outcomes are unhelpful if they are unnecessarily long or poorly defined or they do not allow clinicians to make sensible judgements based on known differences between scores on QoL instruments. The scoring must be easily translatable or interpretable in a clinical context if it is to be used for such situations, as opposed to those primarily designed for large-scale survey work or audit. The decision to select one instrument over another involves a trade-off between brief, clinically useful measures and multidimensional scales covering a broad comprehensive spectrum of dimensions.

There are numerous methods for assessing QoL and the last decade has seen an explosion of instruments purporting to measure this concept. However, a study of QoL measures found that very few research papers claiming to measure QoL provide a definition for the reader and they also make conceptual errors in defining QoL (Velanovich, 2001). Such issues lead to difficulty in making comparisons between studies and different patient groups because underlying concepts are not defined or made explicit. The need for international standards for conducting and reporting QoL in clinical trials has been proposed (Bottomley et al., 2002) given the failure of published trials to meet good standards of reporting (Lee and Chi, 2000). Despite the development of Consolidated Standards of Reporting Trials (CONSORT) which is a standardised evaluation of the quality of methodology reporting, to improve the reporting of randomised controlled trials (RCT's) and to enable readers to understand the way a trial has been conducted and to assess the validity of its results (Begg et al., 1996; Moher et al., 2003), it has been suggested that these guidelines fail to address the issue of QoL (Bottomley et al., 2002).

QoL instruments can measure so-called objective indicators of QoL and subjective aspects. It is generally argued that the latter give a more realistic impression of a person's QoL because it captures the perception of the individual rather than making assumptions about what should be important. This has become an increasingly important issue since the recognition that despite considerable ill health or disability, people may report a remarkably good QoL (Bury, 1991). The theory of response shift, defined as "changes to the meaning of one's self-evaluation of a target construct", describes the adaptation to illness where a re-calibration, re-prioritisation and reconceptualisation of internal standards occurs, a process that involves re-evaluating priorities, standards and values (Sprangers and Schwartz, 1999; Schwartz and Sprangers, 1999). This theory has been employed to explain the apparent paradox that QoL can be rated as good despite objectively appearing to be poor, which challenges what it means to have a good QoL, that is, one free from ill health. Three points of reference for the measurement of QoL have been proposed. That QoL should be assessed against previous or best ever QoL, against the value seen in others suffering with the same disease and with the same background characteristics, or the platonic view, where QoL is assessed against the ideal self or imagined position (Sartorius, 1987). Each of these approaches requires that individuals make comparisons. Such processes are embodied in many of the definitions described earlier

Instruments can be self-administered, that is, completed by the person the instrument is claiming to measure, or proxy assessed, where the assessment is completed by another person on behalf of the person whose QoL is being measured, usually a significant other (SO) or health professional. The view of the individual has become increasingly more central given that historically, the patient perspective was rarely taken account of (Lindström, 1992). However, proxy assessment often occurs when, for cognitive or physical reasons, a person is unable to complete an assessment for themselves. Much controversy exists around the issue of proxy assessment of QoL given the apparent disparity between observer and self assessed QoL (Coen, 1999). In a review of the role of health care providers and SO's in evaluating the QoL of people with chronic disease, Sprangers and Aaronson found a tendency to underestimate QoL, that both SO's and health care provider's evaluations were comparably (in)accurate and that health care providers underrated pain intensity. Furthermore, they found that proxy ratings are more accurate when assessing more observable or concrete aspects and that although SO's ratings can be more accurate if they live closely with the patient, the role of caregiver can bias the ratings (Sprangers and Aaronson, 1992). More recently, Andresen and colleagues looked at the reliability of proxy measurement of people with disabilities (Andresen et al., 2001). To do this, they compared the HRQoL of people with disabilities (PWD) to that judged by proxies (a total of 131 pairs). They found that the highest reliability and agreement was between PWD and relatives, followed by friends and then health care proxies. Generally, proxies tended to underestimate HRQoL and overestimate impairment. However, for pain, this pattern was reversed and it was underestimated. They conclude that caution must be applied to using proxy assessments, particularly for the more subjective domains such as pain. This has implications for the delivery of health care if health care provider assessments are inaccurate and for the distress and behaviour of carers if there is a disparity between ratings.

The content of QoL instruments and coverage of scales differs widely, and as with the lack of consensus about defining QoL discussed above, there is also little agreement about what should be included in QoL instruments. Despite claims to be based on the concerns of patients, the content of QoL instruments are not always based on the views of patients. For example, Hunt (1997) gives the example of the epilepsy scale, which contains items that do not mirror the concerns of epilepsy sufferers as suggested by qualitative interviews with patients (Scrambler and Hopkins, 1991). This further reinforces the importance of developing questionnaire items based on the real concerns of the group of people the instrument is being applied to. User involvement in the development of measures is a way of overcoming the problems inherent in developing relevant and appropriate outcome measures for use with clinical populations and the WHOQOL Group have pioneered this approach in the development of the WHOQOL instruments (WHOQOL Group, 1994; Skevington, McArthur and Somerset, 1997, see below).

Assessing QoL presents a number of challenges, for example, the inclusion of aspects of QoL in a form and format that means the same thing to everyone in the target population, developing instruments that adequately reflect each domain of QoL and establishing how important each domain is to different individuals (Kane, 2001). Such criteria can be useful in critiquing QoL instruments. Similarly, it is assumed that when measuring QoL, we know what and why certain variables are being measured, and that the assessment provides a valid indicator of an individual's QoL (Lancet editorial, 1995). Such assumptions have been challenged by Gill and Feinstein (1994), who provide evidence to suggest that out of a sample of 75 papers with 'quality of life' in their titles, only 15% included a definition of QoL, only a third provided a rationale for inclusion of particular instruments, and patient rated QoL was only obtained in 13% of cases. This implies that QoL assessment is not satisfactorily operationalised in studies claiming to measure it. Given the longer survival of those with fatal diseases, the associated side effects of therapeutic interventions and the increase in chronic diseases in society due to the aging population (van den Bos and Limburg, 1995) QoL is an increasing important outcome (Lancet editorial, 1995). Furthermore, a wish amongst breast cancer patients for a greater emphasis on QoL has been found (Goodare and Smith, 1995), demonstrating a demand from patients to include assessments of their QoL. Although QoL assessment has become integral to outcome measurement in clinical research (Muldoon et al., 1998) and is now required as a secondary outcome measure in all clinical trials by the US Food and Drugs Administration (Apolone, 2003), fewer than 5% of RCT's between 1980 and 1997 reported on QoL, and of those who did, a variety of instruments were used and the standard of method and results reporting was poor (Saunders et al., 1998).

This section has highlighted some of the important considerations in the assessment of QoL, including the appropriateness and interpretability of instruments, the need for international standards in reporting of QoL in clinical trials, the issue of subjective assessment and problems associated with proxy assessment. Furthermore, the relevance of the content of instruments to the QoL of the people being assessed, the challenges of assessing QoL and the increasing importance of including QoL as an outcome have been discussed. When selecting appropriate outcome measures, instruments must be appropriate, reliable, valid, responsive, precise, interpretable, acceptable and feasible (Fitzpatrick et al., 1998). These criteria also apply to the development of QoL instruments and are addressed throughout this thesis.

2.3.1 Generic and disease specific measures

There is ongoing debate about the relative merits of using generic or disease specific measures of QoL. Generic instruments contain broad life domains and are applicable to any population (see table 2.2). In contrast, specific instruments tend to focus on the domains or aspects of life specific to a particular condition or disease state, for example the EORTC, designed to measure the QoL of people with cancer undergoing clinical trials (Aaronson et al., 1993; Sprangers et al., 1993) (see chapter one, table 1.2). During longitudinal studies of treatment efficacy, specific instruments tend to produce bigger effect sizes compared to generic instruments. This is because specific measures are more sensitive to the nuances of any particular condition and are therefore likely to be more sensitive to change when an effective intervention is applied. This has important implications for assessing the subtle differences between individuals from relatively homogeneous groups undergoing the same intervention and for assessing change over time for particular individuals. In contrast, generic instruments assess the more global effects of a condition or intervention and this is important too, since the effects of a condition or intervention can be broad and far-reaching and are rarely specific to health (LePlege and Hunt, 1997). Furthermore, generic instruments allow people from different diagnostic groups or cultures to be compared, which provides important information about the QoL of different groups, can inform policy decision making about setting priorities and allow cross-cultural comparisons to be drawn and so on. Given the need to develop disease-specific models to assess the QoL of particular groups and to evaluate intervention efficacy (Guyatt et al., 1986) it has been suggested that combining specific and general models would increase usability (Flanagan, 1982). Consequently, appending instruments assessing condition specific aspects of QoL with generic instruments would offer distinct advantages.

2.3.2 Generic QoL instruments

Table 2.2 summarises a selection of widely used generic instruments for the assessment of QoL. Although the SF-36 assesses health status rather than QoL *per se* and dominates the literature (Bowden and Fox-Rushby, 2003), studies often report its use in assessing QoL. Similarly, the EQ-5D is a measure of health status and has been applied to a range of studies in Europe. Bradley (2001) has described the EQ-5D as a 'blunt instrument', because it was unable to detect differences between people with different diabetes complications in the UK Prospective Diabetes Study (UKPDS Group, 1998). Another study has showed that the EQ-5D was limited in its ability to detect changes in health of people with ankylosing spondylitis (Haywood et al., 2002). The Quality of Well-Being Scale (QWB) is used as part of a General Health Policy Model to estimate QALYs and is limited because it does not include a mental health component. However, the validity of the QWB in people with osteoarthritis has been shown as it has been found to correlate with the Arthritis Impact Measurement Scale over 1 year (Groessl, Kaplan and Cronan, 2003). The SEIQoL and PGI are both respondent generated measures designed to take into account individual preferences by allowing individuals to indicate which aspects of their lives are important. The PGI is advantageous because it gives an indication of how a person's current reality compares with the expectations held about the areas of life that are most important. However, the symptoms and functions rated can vary between patients (Ward, 2004) making it difficult to make comparisons. Moreover, in a recent review of patient generated instruments, it has been argued that despite the utility of such instruments in complementing traditional instruments and guiding treatment decisions, their use in clinical trials is questionable (Patel et al., 2003).

Generic instruments have been used widely in the CP literature, particularly in rheumatology (Garratt et al, 2002). However, given some of the limitations discussed above, developing condition specific modules would enhance the responsiveness and sensitivity of generic instruments, whilst still enabling comparisons to be made across diverse diagnostic groups. Moreover, the specific instruments discussed in chapter one tend to pertain to specific conditions such as rheumatoid arthritis, migraine and so on and do not allow for comparisons between patients from different diagnostic groups. An instrument with a generic core and a specific module to assess the QoL of people with pain from broad diagnostic groups would fill this gap. This would provide added value both in research and in clinical settings with heterogeneous patient groups presenting with CP.

Table 2.2 Generic health status and QoL instruments validated for use with CPP's

Instrument	Authors	Purpose of instrument	Domains assessed	Validated with CPP's?
The Medical Outcomes Survey short-form (SF-36)	Ware & Sherbourne, 1992	Generic health status measure developed in the United States. Minor modifications have been used to adapt the instrument to a UK context (Jenkinson et al., 1999)	Measurement of subjective health status across 8 domains; physical functioning (10 items), social functioning (2 items), role limitations due to physical problems (4 items), role limitations due to emotional problems (3 items), mental health (5 items), energy/vitality (4 items), pain (2 items), general health perception (5 items) & another item asking about health change over the last year	Rheumatoid arthritis (Kosinski et al., 2002)
EuroQol (EQ-5D)	Developed by an international multidisciplinary group since 1987 (Rabin & de Charro, 2001)	Health status	Five dimensions; mobility, self-care, usual activity, pain/ discomfort & anxiety depression, which are divided into three levels; no problem, some problem & extreme problem, generating a single numeric index of health status	Complex regional pain syndrome type I (Kemler & deVet, 2000; Forouzanfar et al., 2004); CLBP (Seitz et al., 2001)
The Quality of Well-Being Scale (QWB)	Kaplan et al., 1998	Used as part of a General Health policy Model to estimate QALYs	Functional components, including mobility, physical activity & social activity & a list of symptoms & problems. The QWB places the individual on a continuum of wellness from dead (0) to asymptomatic (1.0) The QWB does not include a mental health component	Osteoarthritis (Groessl, Kaplan & Cronan, 2003); Fibromyalgia (Kaplan, Schmidt & Cronan, 2000)
The Schedule for the Evaluation of Individual Quality of Life (SEIQoL)	McGee et al., 1991	Respondent generated measure of QoL	Measure patients' level of functioning in five self-nominated facets of life & the relative weight or importance attached to these areas	Patients undergoing hip replacement (O'Boyle et al., 1992)

Instrument	Authors	Purpose of instrument	Domains assessed	Validated with CPP's?
The Patient Generated Index (PGI)	Ruta et al., 1994	Respondent generated instrument designed to measure HRQoL for postal & interview administration	List the five most important areas of life affected by the condition. Mark on a VAS how badly these areas are affected, from 0 (worst) to 100 (best). Rate how much other aspects of life are affected by their condition. Imagine that they can improve these areas with a number of points, which they allocate to each area depending on their priorities. The index gives an indication of how current reality compares with the expectations held about important areas of life	Low back pain (Ruta et al., 1994); elderly people with arthritis (Tully & Cantrill, 2002)
Ferrans & Powers Quality of Life Index	Ferrans & Powers, 1985	QoL in healthy & sick populations	Satisfaction with & perceived importance of different domains of life, including, health care, relationships & family, employment, leisure, faith & life goals. There are 64 self-report items arranged with 6-point Likert scales. There are also subscales addressing health & functioning, socio-economic, psychological, spiritual & family factors	Chronic pain (Gerstle et al., 2001)

2.4 Review of development and validation of the WHOQOL-100

Having introduced and discussed definitions, models and methods of assessing QoL, this section reports the extensive literature on the development and validation of the WHOQOL instruments. Since 1991, 15 collaborating countries worldwide have taken part in the development and piloting of the WHOQOL pilot form (The WHOQOL group, 1998). The WHOQOL-100 is a generic, multilingual instrument for the assessment of QoL in adults. It contains 100 core items (and 2 additional national items) represented by 25 facets and six domains of QoL; physical, psychological, level of independence, social relationships, environment and spirituality, religion and personal beliefs (SRPB). In addition to the 102 items, there are 26 importance items relating to the facets of the WHOQOL that can be appended to the core instrument and these can be applied concurrently. To be considered important, facets must have a mean importance rating of 3.0 on a 5-point Likert scale (Skevington, MacArthur and Somerset, 1997). Subsequently, an abbreviated form, the WHOQOL-Bref has been derived from the WHOQOL-100, which contains 26 items; one per facet and one that asks about general QoL (see below) (The WHOQOL group, 1998). The WHOQOL was designed to assess subjective aspects of QoL and it was proposed to be used with four groups of individuals; those suffering with disease, health professionals and carers, those living in stressful situations and those unable to communicate their feelings (Orley and Kuyken, 1994).

At the core of the WHO project was that the instrument would be used in different cultural settings worldwide and that operational equivalence would be achieved, which refers to cross-culturally comparable reliability, validity and responsiveness (The WHOQOL Group, 1994). A position paper from the WHOQOL Group described the project to develop the WHOQOL instrument (WHOQOL Group, 1995). One major goal was to allow for the assessment of QoL cross-culturally by collaborating with different cultural centres. Another was to determine the extent to which the impact of disease on QoL is mediated by social and cultural factors. It was recognised that translating existing QoL instruments from one language to another was problematic given the lack of conceptual and semantic equivalence between language and cultures. The method involves simultaneous development in different cultures (The WHOQOL Group, 1994; Bullinger, 1994) and is known as spoke wheel methodology where the items were generated simultaneously in the collaborating centres and then fed back to the centre in Geneva. The methodology is characterised by its translation method of forward and back translation to achieve conceptual, semantic and technical equivalence in different language versions. Field centres based in cultures with different levels of industrialisation, health service availability and other relevant factors were selected. In a review of generic QoL measures, Bowden and Fox Rushby (2003) evaluated the WHOQOL and some of the other generic instruments discussed above, according to conceptual, item, semantic, operational, measurement and functional equivalence cross-culturally, with a particular focus on translating and adapting such measures. The WHOQOL was found to have evaluated equivalence most rigorously, although it is suggested that further testing is needed because of the imposed definition of health and that an index is not calculated in the scoring.

The development of the WHOQOL was based on the execution of several stages (WHOQOL Group, 1994), concept clarification, qualitative pilot, development of the pilot instrument and field-testing. Concept clarification was achieved by international expert review, which created a QoL definition and a protocol for the study. The qualitative pilot determined the domains and facets of QoL, drafted and selected items to create a global item pool and generated response scales. This was achieved through expert review, focus groups (FG's), and expert and lay item writing panels. Views of patients and health professionals are represented in the development of the WHOQOL, and FG's were conducted with sick and well people to generate the important facets of QoL and the items for the instrument (Skevington, MacArthur and Somerset, 1997). Although the items in the instrument are culturally specific, cross-cultural comparisons are possible.

The pilot test reported by the WHOQOL Group describes the international development and psychometric properties of the WHOQOL (The WHOQOL Group, 1998). The aims were to look at the construct validity of the WHOQOL domain and facet structure, select the best items to produce a version to be used in the field trials and to establish its psychometric properties. The 15 participating centres were each requested to administer the instrument to a minimum of 300 participants (250 health care users and 50 healthy respondents). The pilot instrument consisted of 236 items, covering six domains and 29 facets, approximately 8 items per facet. Other items were also included addressing overall QoL and health perceptions and there were 41 importance items. The total number of participants across the centres was 4802.

Correlations between perceived objective and self-report subjective QoL were at r>0.8 which led to the distinction between these two levels being dropped in the field trial. Five of the 29 facets were dropped; activities as provider/ supporter, sensory functions, dependence on non-medicinal substances, communication capacity and work satisfaction, leaving 24 facets. Four items per facet were selected because four is the minimum required for scale reliability analyses (Kline, 1983). At this point, the field trial became known as the WHOQOL-100 and facets were calculated by summing the item scores, therefore ranging from 4 –20. Using Cronbach's alpha (α), the internal consistency was shown to be good, ranging from 0.65 (physical environment) to 0.93 (working capacity). Higher scores represent higher QoL and consequently, where it is not possible to phrase an item in a positive way (for example, items relating to pain and discomfort, negative feelings and dependence on medication), the scoring for that item is reversed.

The results suggested that contrary to expectation, it was possible to develop an instrument with the same facet and domain structure for each of the 15 centres taking part in the field trial. A number of the centres had additional 'national items' (see below), which were found not to perform any better than the core items. Following exploratory factor analysis, a four-factor structure was yielded, consisting of the physical, environment, psychological and social relationships domains. Confirmatory factor analysis confirmed that the four-factor structure was a better fit than either a six-domain or single domain structure (The WHOQOL group, 1998).

In contrast to the international development described above, Skevington, MacArthur and Somerset (1997) investigated contemporary beliefs about QoL in Britain as part of the process of developing items for the WHOQOL. Their three aims were; to investigate whether the proposed facets were relevant to people in Britain, to see if there were any areas that were not covered by the proposed facets, that is, that were specific to people in Britain and thirdly to ascertain the importance of the core facets. To do this, 7 focus groups were conducted with 46 individuals. The groups discussed the proposed facets and definitions, which were provided in a manual. The group were then invited to generate items for each of the facets, rate the importance of each of the facets on 5-point Likert scales and add anything else that had not been covered. The groups were found largely to confirm the relevance of the proposed facets. Although happiness was found to be most important, religion and dependence on substances were neither important nor unimportant, but since these two facets were important to subsections of the population, they were retained. Omissions were identified in four areas; need for the intimacy of loving relationships, job security and fear of losing employment, fears of bereavement or the loss of loved ones and concerns about the environment.

In a paper introducing the UK WHOQOL, Skevington presents the psychometric properties of the instrument (Skevington, 1999). A total of 320 sick and well people completed the WHOQOL. The best predictor of QoL in Britain was found to be the presence or absence of positive feelings. This was improved with the addition of information about mobility and energy. The scores were found to discriminate well between sick and well people and the instrument showed excellent internal consistency reliability (α=.97). In a subsequent study, Skevington and colleagues examined the properties of the national items to be appended to the WHOQOL, using data from 3740 participants from 10 of the WHOQOL centres (Skevington, Bradshaw and Saxena, 1999). Five statistical criteria were applied to 144 national items; hierarchical multiple regression analysis, item-national facet correlations, item-facet and item-total correlations, Cronbach's α, hierarchical cluster analysis and multidimensional scaling. Multidimensional scaling and cluster analysis allowed an examination of the structural relationship of the national items within their own facet. This led to the selection of 29% or 40 of the national items, including 'How fed up do you feel?' and 'To what extent are you satisfied with your level of happiness?' in the UK.

Skevington and Tucker report on the development of response scales designed in the UK for use with the UK WHOQOL (Skevington and Tucker, 1999). To do this, they asked 20 sick and well people to assign 60 descriptions to separate 100 mm lines. There were 15 descriptions for each of 4 types of response scale and the anchor points had already been agreed as internationally meaningful by the WHOQOL. Means and standard deviations were calculated for each label at the 25%, 50% and 75% interval and those with the closest means and smallest standard deviations were selected. The study resulted in a set of 5-point interval response scales relating to how much, how completely, how satisfied, happy or good and how often a person has experienced an aspect of QoL, where 1 represents poor QoL and 5 good QoL.

Since the development of the WHOQOL instruments, extensive validation work has been conducted in diverse patient groups, confirming the broad applicability of the core generic instruments to a range of health conditions. For example, the relationship between pain and discomfort and QoL was investigated by Skevington, using the WHOQOL-100 (Skevington, 1998). A total of 320 well people and people from different diagnostic groups completed the 276 item WHOQOL (29 facets, grouped under 6 domains). Pain and discomfort was found to make a significant impact on perceptions of general QoL related to health. The presence of pain affected five domains of QoL, but did not affect SRPB. Negative feelings were most closely associated with reports of pain than any other facet of QoL. QoL relating to pain was better explained by the addition of six other facets. These were; the availability of social care, mobility, ADL, positive mood, less relevant, but nonetheless important were; sleep and dependence on medication. Other findings include; those without pain reported significantly better QoL than those with pain, pain of a longer duration is associated with poorer QoL, intense affective pain has an adverse effect on QoL. The pain and discomfort facet was found to have good internal consistency, discriminant and criterion/ concurrent validity.

In another study, Skevington, Carse and Williams (2001) examined the impact of a pain management programme (PMP) on the QoL of CP patients. The QoL of 106 CP patients was assessed before and one month after taking part in a PMP with the WHOQOL-100. The MOS SF-36, the Beck Depression Inventory and measures of pain intensity, duration, disruption and distress were also applied concurrently. Following the PMP, QoL improved generally and in the physical, psychological and independence domains and in ten facets of QoL, including pain and discomfort. Low levels of pain distress, severity and disruption were associated with good QoL, where each domain was significantly negatively correlated with pain severity, pain and distress, disrupted activities and Beck Depression Inventory (BDI) scores at <0.01, with the exception of SRPB. The WHOQOL demonstrated good psychometric properties, although the internal consistency reliability was marginal for the pain and discomfort facet (α =.67). The study shows that for chronic pain patients (CPP's) taking part in a PMP, QoL is improved on several dimensions and that the WHOQOL-100 is a valid and reliable tool for use with CPP's. However, the authors suggest that the inclusion of more items pertaining to CP would improve its sensitivity to clinical change and would also allow for the exploration of more aspects of QoL within the framework of the WHOQOL.

Given the generic nature of the core instrument, it was proposed that add-on modules would be developed for assessing the QoL of people with particular diseases (The WHOQOL Group, 1994). Of the five priority areas, persons suffering from chronic diseases are the first and CP fits this category. The protocol for developing these modules is outlined in a WHO study protocol (WHO, 1993). However, although the protocol states that modules must be developed simultaneously in at least three culturally diverse centres, at the time of commencing the present study it was not possible to obtain funding to achieve this, or to find at least two other centres world-wide with sufficient interest in CP and QoL to conduct such a study. However, this does not preclude such a study in the future. This thesis describes the development of a pain and discomfort module (PDM), in order for it to be more sensitive to the needs and issues pertinent to people with CP

2.4.1 Review of the development and validation of the WHOQOL-Bref

In 1998, the WHOQOL Group described the derivation of the WHOQOL Bref, an abbreviated version of the WHOQOL-100 (The WHOQOL Group, 1998). The Bref is scored in four domains and includes a facet on overall QoL and health. The Bref consists of 26 items that were selected from the WHOQOL-100 on the basis of those items that correlated most highly with the mean of all facets. The domain scores of the Bref were found to correlate highly with the domains scores of the WHOQOL-100. The Bref show good discriminant validity (significant differences between ill and well people in all domains), internal consistency (domain α ranged from 0.66 to 0.84) and test-retest reliability (domain correlations between time 1 and 2 ranged from 0.66 to 0.87). The Bref is advantageous when quick assessments of QoL are required, for example when evaluating the impact of treatment on QoL. In a study of the importance of WHOQOL Bref items for cross-cultural research, data from 4804 respondents from 15 centres world-wide was examined (Saxena et al., 2001). All items representing the 24 facets had a mean rating of between 3.29 and 4.29, suggesting that they were all considered to be at least moderately important. The results also suggest that no single domain was seen to be more important than any other, rather different aspects or facets of the domains were. Gender differences were observed, where women rated the majority of items as more important than men, with the exception of sexual life. Differences were also found between younger and older adults, where younger adults rated more items as more important to them than older adults. In general, the results reaffirm the importance of the 24 facets of QoL selected to be applicable cross-culturally.

2.4.2 Domain and facet structure of the core WHOQOL

Table 2.3 lists the domains and facets of QoL covered by the WHOQOL assessment. As described above, the WHOQOL inquires into six broad domains and 24 specific facets of QoL. Four items address each facet, including a facet enquiring into overall QoL and general health.

Table 2.3 Core WHOQOL facets and domains

Overall quality of life and general health
Domain I - Physical
1. Pain and discomfort
2. Energy and fatigue
3. Sleep and rest
Domain II – Psychological domain
4. Positive feelings
5. Thinking, learning, memory and concentration
6. Self-esteem
7. Bodily image and appearance
8. Negative feelings
Domain III – Level of independence
9. Mobility
10. Activities of daily living
11. Dependence on medication or treatments
12. Working capacity
Domain IV – Social relationships
13. Personal relationships
14. Social support
15. Sexual activity
Domain V - Environment
16. Physical safety and security
17. Home environment
18. Financial resources
19. Health and social care: availability and quality
20. Opportunities for acquiring new information or skills
21. Participating in and opportunities for recreation/ leisure
22. Physical environment (pollution/ noise/ traffic/ climate)
23. Transport
Domain VI – Spirituality/ religion/ personal beliefs
24. Spirituality/ religion/ personal beliefs

2.5 Rationale

The extensive literature on CP and QoL has been introduced in the first two chapters to provide a context within which to illustrate why this research was timely. The prominence of CP derives from its increasing prevalence, its consequent economic burden and the inability of traditional biomedicine to adequately manage it without the aid of psychology and related disciplines. Elucidating, understanding and measuring its impact on QoL become central because of the persistence of pain. Moreover, given the complexity of understanding pain and its management, assessing its impact goes far beyond pain severity or intensity alone, hence the need to measure the broader sequelae, within the context of a culture of evidenced based health care. Given the heterogeneous diagnostic groups that experience pain as a major symptom, the need for assessments that are reliable, valid and able to discriminate between these groups are warranted to enable comparisons to be made across time and in different contexts.

2.6 Aims and objectives

- To develop a new module (set of specific items [questions]) to be added to the WHOQOL-100 that elaborates the experience of CP.
- To develop an instrument that is acceptable and applicable to the main CP groups, regardless of clinical condition using WHOQOL methodology with the addition of innovative methods and techniques.
- To explore the relationship between the new PDM and the core facets and domains of QoL measured.
- To determine whether the new PDM is reliable, valid and sensitive to changes in clinical condition.
- To make a preliminary assessment of the QoL of people with CP.
- To propose ways of incorporating the WHOQOL and the PDM into the management of pain, as an outcome measure and as part of large scale survey work and studies designed to measure the efficacy of interventions designed to decrease pain and increase functioning and well-being.

2.7 Methodology

Following the WHOQOL procedure, there are three key methodological stages to the development of the module, which are outlined below and summarised in table 2.4.

2.7.1 Stage one - qualitative studies

The aim of the first stage is to identify facets of QoL and to develop items pertaining to these facets in the vernacular, which are most salient for all major CP groups. The FG's will consist of individuals from one of three categories, health professionals, informal carers and people with CP from different diagnostic groups. Items raised in the FG's will be pooled and assessed to derive a set of items asking about the new aspects of QoL identified by the FG participants. Concurrently, results from a web survey will provide validation for these new facets by ensuring that the results from the FG's are not idiosyncratic to the participating patients.

2.7.2 Stage two - cross-sectional quantitative development

The PDM will be administered with the WHOQOL-100 in a pre-pilot study using the technique of cognitive interviewing, a cognitive aspect of survey methodology (CASM). The WHOQOL-100 and a selection of items will then be administered to a representative sample of CP patients from a range of diagnostic groups in a cross-sectional survey to enable the relationship between the new module and core facets to be examined. During analysis, the items in the PDM will be reduced in number using traditional psychometric procedures. Following an examination of the psychometric properties of the pilot data, a small number of items will be selected from the item-pool to form the PDM, which can be used in conjunction with the WHOQOL-100.

2.7.3 Stage three - longitudinal quantitative study

The final stage will be a field test to determine how the WHOQOL and PDM behave when applied to a clinical population. This will be a longitudinal study over a period of 4 weeks, assessing the QoL of patient with chronic low back pain (CLBP) undergoing a lumbar epidural steroid injection. Other instruments will be completed concurrently, to test the validity of the PDM. Analysis of the data will elucidate the psychometric properties of the PDM and determine whether the measure is sensitive to changes in clinical condition. Concurrently, test-retest reliability will be examined in a population not undergoing treatment over a 2-week period.

2.7.4 Ethical issues

Ethical approval for the entire study was granted from the Bath Local Research Ethics Committee and from the Swindon Local Research Ethics Committee, through their reciprocal agreement with Bath.

2.7.5 Participating centres

All the work reported in this thesis was conducted from the UK Field Centre for the study of Quality of Life in Bath. Patients from the following places took part; Royal United Hospital (RUH) (Pain Clinic, orthopaedics, maxillo-facial surgery, genito-urinary medicine, physiotherapy and gynaecology); Royal National Hospital for Rheumatic Diseases (Rheumatology); Salisbury District General Hospital; Combe Down General Practice Surgery; Box General Practice Surgery; The Wiltshire Back Pain Network; Pain Concern, East Lothian (registered pain charity); Local Support Groups (Fibromyalgia and Positive Living - former patients of the Pain Management Programme at the RUH).

2.7.6 Target population

The goal of this research was to represent all CP groups to ensure that the results can be said to apply to people from across diagnostic categories. However, a clear distinction is made between chronic benign pain, such as pain deriving from the lumbar spine or from osteoarthritis and pain experienced as a result of malignant conditions such as some cancers. This distinction is made because of the different psychosocial consequences of having a life limiting versus a life threatening disease or condition. Furthermore, those working in the field of cancer have worked hard to develop generic and specific instruments to assess its impact and aid in the reduction of pain and suffering (for example, the EORTC). The main focus is adults over the age of 18 who have pain persisting continuously or intermittently for longer than three months. Participants will have a good literacy level and language ability, with English as the first language (with the exception of the web survey). The presence of other illness that might impact on QoL such as depression or another medical condition will be noted, however it is unrealistic to exclude such people since some co-morbidity is inevitable. Developing an instrument for too specific a population will limit its use and thus the aim is to focus on conditions where pain is the major symptom to ensure that the instrument will be applicable to all patient groups with CP.

Table 2.4 Summary of stages in the development of the pain and discomfort module

Stage	Method	Products	Objectives
Conceptual and methodological work	Review of the literature and history of the work of the WHOQOL Group	Development of protocol based on the work of WHOQOL Group	Establishing a need for a pain specific module to increase specificity and sensitivity
Empirical I: Qualitative pilot	Focus groups (11 groups, N=59)	10 new facets pertaining to pain and discomfort	To elucidate the impact of pain on QoL and identifying new facets of QoL through systematic qualitative analysis of focus group transcripts
Empirical II: Web survey	Technology based survey using the Internet (N=234). A combination of quantitative descriptive analysis and qualitative analysis	International data set providing confirmation of the 10 new facets identified by the FG's	To gather data on how pain effects QoL from an international, geographically dispersed sample by allowing people with pain to express their views about how pain impacts on their QoL
Consolidation: Definition and item construction	Definitions and items constructed for each of the new facets	Multidimensional definitions and items to represent the facets of QoL	To explore and conceptualise the facets relating to pain related QoL and to write items based on contextual material from the FG's
Questionnaire development	Construction of the pilot PDM	The pilot PDM consisting of 108 items attached to appropriate response scales and arranged in response scale blocks	To form the PDM by putting the items together, attaching response scales and arranging in a suitable format in preparation for preliminary pilot work.
Empirical III: Pre-pilot testing and module refinement	Cognitive interviewing (N=9) and expert reading of the PDM	Modified and reduced pilot PDM consisting of 84 items	To reduce the number of items and to ensure that items are comprehensive and meaningful
Empirical IV: Field test I	Cross sectional survey design (N=216)	Reduced number of items to 16, representing 4 facets of QoL relating to pain and discomfort	To establish the psychometric properties of the WHOQOL-100 with the addition of the PDM
Empirical V: Field test II	Longitudinal survey design (N=133), consisting of a trial of steroidal epidurals for low back pain (N=57) and test re-test reliability (N=30)	Further elucidation of the psychometric properties of the WHOQOL and new PDM	To establish whether the PDM is reliable, valid and sensitive enough to detect change in a clinical population

2.8 Conclusion

These two chapters have explored how pain has been defined, discussed studies estimating the prevalence of CP in the general population, introduced recent models of pain and reviewed the relevant literature on QoL and its assessment. The core objectives, methodology of the study, ethical issues, participating centres and the target population of the research have also been described. Lack of consensus over defining QoL has led to problems with, and different approaches to measurement. Given that relatively few attempts have been made to find a way of adequately measuring the impact of a chronically painful condition on the QoL of the sufferer, this provides the rationale for developing an instrument for the subjective assessment of QoL in people with CP. It highlights the importance of adequately defining the concepts that one purports to measure and in adopting rigorous methods for developing these instruments, by combining traditional and novel methodologies. Accurate assessments of QoL from the perspective of the patient will lead to improved design and implementation of interventions to improve the QoL of people with pain and will assist the work of health professionals who are engaged in this task.

2.9 Outline of remaining chapters

This thesis consists of two introductory chapters (one and two), five pieces of empirical work (three, four, six, seven and eight), one process and consolidatory chapter (five), a preliminary assessment of the QoL of people with CP (nine) and a final discussion (ten). Specifically, chapter three presents the first empirical data, using FG methodology to identify facets of QoL relating to pain. Chapter four describes a web survey that was set up to obtain a larger international data set about the QoL of people with CP. Chapter five outlines the process of questionnaire development, including definition construction and item writing. Chapter six reports the preliminary pilot work using cognitive interviewing. In chapter seven, the preliminary psychometric properties of the new module are explored through data derived from a cross-sectional survey of heterogeneous sample of people with CP. Chapter eight further explores the validity and reliability of the new module through a longitudinal field test and summarises its psychometric properties. Chapter nine presents a preliminary assessment of the QoL of people with CP. Finally, chapter ten discusses the findings and implications in greater depth, including a critique and future work.

Chapter three

Focus Groups:

The Quality of Life of People with Chronic Pain

3.1 Introduction

The previous two chapters reviewed the literature on chronic pain (CP) and quality of life (QoL) and presented the rationale for this research. This chapter explores the QoL of people with CP from a qualitative perspective. In doing this, it outlines the preliminary work to develop a pain and discomfort module (PDM) to be used in conjunction with the UK World Health Organisation Quality of Life Assessment (WHOQOL-100). The goal of this qualitative study was to investigate CP and its affect on QoL and to identify new facets of QoL pertaining to pain and discomfort.

3.1.1 Chronic pain and quality of life

Pain is one of the primary reasons for seeking help from a general practitioner (Schappert, 1992) and has a complex, multi-factorial aetiology, which is often unknown. Moreover, it has been argued that disability associated with CP is reaching epidemic proportions (Aronoff, 1991; Loeser, 1991). As measures of disease status alone are not sufficient to capture the wide impact of living with a chronic condition, it is therefore necessary to measure the multidimensional experience of CP by assessing QoL. This is important for two reasons, firstly because of the non-linear relationship between pain and disability (Waddell, 1987) and the erroneous assumption that improvements in pain or disability necessarily correlate with substantial improvements in QoL. Secondly, because chronic benign pain rarely causes death and cure is unlikely, alternative outcomes are necessary to measure the efficacy of treatments in meaningful and accurate way.

As discussed in chapter two, the WHOQOL-100 was designed to allow the development of specific modules addressing particular disease groups or conditions that could be appended to the core instrument (The WHOQOL Group, 1998). Focus groups (FG's) were used in the development of questionnaire items for the WHOQOL-100 and can also be used in the development of additional modules (see below). It was necessary to develop a PDM because the existing pain and discomfort facet in the WHOQOL-100 may under-represent the impact of pain on QoL (Skevington, 1998; Skevington, Carse and Williams, 2001) and pain has often been considered in isolation from other aspects of a patient's life. It has also been noted that a more holistic approach to pain is necessary (Dunn, 2000). Furthermore, previous measures of pain have tended to focus on the measurement of the severity or intensity of pain alone, for example in the widespread use of the visual analogue scale, despite the recognition that pain is a multidimensional phenomenon (Turk and Okifuji, 1999). Gaining a greater understanding about the way pain can affect a person's QoL is a necessary step to bridging the gap between the needs of patients and the way that health care is delivered to this group, who are avid users of health care resources (Maniadakis and Gray, 2000).

In addition to issues around measurement, theoretically it is useful to ask what beliefs or psychological processes affect the decisions people make about their QoL, above the immediate impact of a particular health condition or adverse situation. First elaborated by Festinger (1954), social comparison theory holds that when people are under threat from health problems, the consequent uncertainty increases the need for information and hence the desire for comparison (Taylor et al., 1990). Festinger (1954) originally assumed that upward comparison would almost always occur because it would provide information, however Brickman and Bulman (1977) recognised that this failed to account for the potential stress generated for the person doing the comparing. Consequently, the importance of downward comparisons was acknowledged (Wills, 1981). Gibbons argues that when people are faced with significant life events, social comparison increases and that the level of social comparison decreases and that these cognitive alterations impact on the success of coping (Gibbons, 1999). Evidence suggests that the importance attributed to different life domains is adjusted, for example, in a study of reactions to significant negative health events, greater emphasis was put on mental abilities (Bulman and Wortman, 1977). A number of correlational studies of people with CP have found a relationship between engaging in downward comparison and positive affect and well-being (Jensen and Karoly, 1992; Tennen and Affleck, 1997).

Skevington also found that people with arthritic diseases use social comparison when they think about and make decisions about their QoL (Skevington, 1994). In a qualitative study of 6 FG's with 31 people with rheumatological conditions, support was found for the use of three levels of analysis, intrapersonal, interpersonal and sociocultural. Intrapersonal comparison involves comparing one's current state with a past or imagined future one. Interpersonal comparison occurs when people compare themselves upwardly, downwardly or horizontally with other individuals. Sociocultural comparison occurs when people compare themselves to society's expectation of how they should be. Interpersonal comparisons were used most frequently, particularly regarding age. Downward comparisons were used more frequently than upward comparisons, although the consequences of these comparisons were mixed. Downward comparisons did not always produce a positive effect because the behaviour of others sometimes provided a model of how not to behave; similarly these comparisons could also be threatening. At the sociocultural level, the perception of a lack of understanding or caring about the person with chronic illness and a stigmatisation of the condition also impacted on QoL. Social comparison is important because it has been encapsulated in many of the definitions of QoL discussed above and provides an important theoretical contribution to the way that people make decisions about their QoL.

3.1.2 Focus groups

Numerous qualitative methods can be employed to elucidate factors pertaining to health, and FG's are one such method. FG's are a form of group interview; however, unlike interviews the important data comes from the interaction between group members, rather than the answers to individual questions from the researcher, who acts as a facilitator. Morgan suggests that the hallmark of FG's is "the explicit use of the group interaction to produce data and insights that would be less accessible without the interaction found in the group" (Morgan, 1988; 1998). In other words, the richness of data would not be found in individual interviews. Morgan has also emphasised the use of FG's as a qualitative research tool and as part of a larger research program, such as the development of questionnaires in the present study.

The WHOQOL Group has used FG's as a bottom up approach to the development of items in the development of the WHOQOL (WHOQOL Group, 1993), enabling the use of standardised protocols whilst generating rich data. The aim of using FG's is to develop items in the vernacular, capturing the ways in which people discuss issues, the idiosyncratic use of language and conversation, and the use of humour and anecdotes in particular populations during group interaction. Thus, FG's have been used to develop the international core and can also be used in the development of additional disease specific modules.

The aim of this research was to develop a module to measure subjective QoL related to CP. The work presented here details the preliminary stage of the research and the chapters that follow detail the subsequent stages. The specific aim of the FG's was to generate facets pertaining to the impact of pain on QoL. Three different groups of participants (described below) were asked about CP related QoL, and this chapter draws on the key themes discussed in the FG's and attempts to understand their views about QoL relating to pain and discomfort. Primacy was given to the views of patient participants.

3.2 Method

3.2.1 Sample

Eleven FG's were conducted with 59 voluntary participants between December 2000 and March 2001. A purposive sampling strategy (Mays and Pope, 1995) was adopted to ensure that FG's were conducted with people representing a heterogeneous cross-section of diagnostic groups to reflect the diversity of people with CP (Kuzel, 1992). FG's were also conducted with health professionals working with people in CP and informal carers of people with CP. Each FG consisted of 4 to 9 participants.

3.2.2 Patient groups

Six FG's were conducted with 32 people with CP recruited from the Pain Clinic, Rheumatology, Oral surgery and Orthopaedic services of a District General Hospital (Royal United Hospital (RUH)), a specialist centre for rheumatic diseases (Royal National Hospital for Rheumatic Diseases (RNHRD)), and from primary care through a local General Practice in Bath. One hundred and twenty four letters were sent inviting people to attend a group on a given day, accompanied by a full explanation of the purpose of the study and an assurance of confidentiality. Known reasons for refusing to take part were transport difficulties, having prior arrangements, being too tired, having other responsibilities, being unable to leave work on time, illness, being advised to rest before joint replacement surgery and receiving information too late because of being on holiday. The mean age of patient participants was 49.41, (range 28-69) and 69% were female. Participants came from a range of diagnostic categories (as described by participants) and these are shown in table 3.1. The duration of groups was between 1 hour 30 minutes and 2 hours.

Table 3.1 Pain and diagnostic characteristics of patient groups

Group	Number in group	Age range	Gender (F=female, M=male)	Mean pain duration (months) and SD*	Diagnostic composition of group
1	4	33-56	3 F, 1 M	125.5 (range 64– 264, SD 94.0)	Neck pain; rheumatoid arthritis (RA), arthritis in hip; RA; left hip soft tissue damage, sciatica
2	4	29-53	2 F, 2 M	120.0 (range 36– 240, SD 89.3)	Back pain (BP); temporomandibular joint disorder; fibromyalgia (FMS), osteoarthritis (OA); chronic pancreatitis
3	4	29-63	2 F, 2 M	195.0 (range 36– 552, SD 241.5)	Spinal injury; rib muscle and chest pain, BP; BP, arthritis; OA, neuropathic foot
4	5	39-69	2 F, 3 M	77.0 (range 5– 180, SD 84.4)	OA, ankylosing Spondylitis; BP, arthritis; frozen shoulder; BP; RA
5	6	28-69	4 F, 2 M	187.6 (range 96- 384, SD 114.3)	Pain in stomach; Neck pain; BP; BP, arm pain, lumbar canal stenosis; BP
6	9	37-69	9 F, 0 M	175.3 (range 32- 456, SD 168.6)	FMS; FMS; FMS; FMS; FMS; FMS, BP; OA, ruptured tendons, carpal tunnel; FMS, OA; FMS, viral arthritis

* Standard Deviation

3.2.3 Health professional groups

Three FG's were conducted with a total of 17 health professionals who were experienced in working with people with CP, recruited from the RUH in Bath, Frenchay Hospital in Bristol and the Gloucester Royal Hospital in Gloucester (Health professional groups from 4 hospitals were approached, 3 agreed to take part). The composition of the groups is shown in table 3.2. Group members had a range of experience of working with people with CP on an individual and group basis, in the assessment of people with CP and in the delivery of various treatments and pain management programs. The duration of groups was between 1 hour 15 minutes and 1 hour 45 minutes. The rationale for including health professionals was that this group are experienced in talking to their patients about issues pertinent to their QoL, and consequently, would understand something about the nature of its impact.

Table 3.2 Characteristics of health professional groups

Group	Number in group	Age range	Gender (F=female, M=male)	Health professions	Hospital recruited from
1	5	23-52	5 F, 0 M	Clinical Psychologist, Trainee Health Psychologist, Physiotherapist, Nurse Specialist, Occupational Therapist	Gloucester Royal Hospital Pain Management team
2	6	31-49	4 F, 2 M	Consultant Clinical Psychologist, Physiotherapist, CP nurse, Sister, Senior Occupational Therapist, Chaplain	Friends' Outpatients, Pain Clinic team, RUH
3	6	33-55	5 F, 1 M	Four Clinical Psychologists, Physiotherapist, Occupational therapist	Frenchay Hospital Pain Management team

3.2.4 Informal carer groups

Two FG's were conducted with a total of 10 informal carers who were recruited through contacting local CP support groups (of the 4 groups approached, 2 agreed to take part). The composition of the groups is shown in table 3.3. The duration of groups was between 1 hour 35 minutes and 1 hour 45 minutes. The inclusion of carers was seen as an important step to elucidate their perception of the QoL of the people with pain that they care for, and how this compares to patients' perceptions of their own QoL.

Table 3.3 Characteristics of informal carer groups

Group	Number in group	Age range	Gender (F=female, M=male)	Relationship to person with CP	Duration of caring responsibilities (range)
1	6	29-63	3 F, 3 M	3 husbands, 2 wives, 1 mother	3-18 years
2	4	38-74	2 F, 2 M	2 mothers, 2 husbands	14 months – 13 years

3.2.5 Procedure

Participants were provided with an information sheet about the WHOQOL project, a consent form, a map, confirmation of the meeting and a WHOQOL-100 with importance items to complete in advance of FG the meeting, to familiarise themselves with the content. This also provided data on demographic factors such as age, gender, educational level, marital status, occupation, patient status, nature of health problem, provision of care for others (for carers only) and professional status (for health professionals only). Supplementary information was obtained from patients and carers on the site/ nature/ diagnostic condition and the duration of pain that they/ their family member had experienced. Patient and carer FG's were conducted in a hospital setting in Bath. Health professional groups were conducted in a hospital setting in Bath, Bristol and Gloucester. Seats were arranged in a U-shape to facilitate group interaction. All FG's were audiotaped and ideas and questions elicited by participants were summarised on a flip chart.

Two moderators, a lead moderator and a co-moderator facilitated each group. The role of the lead moderator was to introduce the project and the task, emphasising that all participants' views were equally valid, that there were no correct answers, that each individual's viewpoint should be listened to and respected and that all information was strictly confidential. The role of the co-moderator was to assist the lead moderator and take detailed notes of the session to supplement the audiotapes. Both moderators ensured that all participants were focused on the task and probed participants about their experience to avoid the exchange of anecdotes.

The moderators and participants introduced themselves to the group (all members, including moderators wore a name badge). Participants were provided with a pen and paper and asked to free-list how pain had affected their QoL in the last two weeks. Participants were asked if there were any aspects of their/ their patients/ their family members' QoL specific to living with CP that were not included in the core WHOQOL. The task of the group was firstly, to consider how having CP affects QoL and whether there were any aspects that were not covered by the core WHOQOL facets. Secondly, to consider how important these new aspects were, and thirdly, to generate suitable questions in their own words that could be used to ask others in CP about these aspects of QoL.

At the end of each group, participants were thanked and provided with a telephone number for any post-session counselling (this was not taken up by anybody). After the group, the moderators conducted a debriefing session to discuss impressions of, and issues raised during the group, any unexpected findings and commented on group dynamics.

Although the FG procedure was standardised from the outset (see figure 3.1), the process of conducting groups evolved and was refined each time to ensure that data collection was maximised. For example, a list of the three goals of the group was introduced and put up after several groups, to help focus the group on the task. A list of the four core items addressing pain and discomfort was also introduced and put up after several groups to further stimulate discussion and highlight any possible gaps in these items addressing pain.

FG's were run until saturation was reached, that is, no new themes or areas of QoL were emerging from the groups and the data from each new group provided further confirmation of data derived from the previous groups.

Figure 3.1 Focus group interview schedule adapted from the WHOQOL User Manual, appendix six (WHOQOL Group, 1998)

Participants should have completed the WHOQOL prior to the session.

Welcome

- Opportunity for the participants to get to know one another.
- Moderators hand out name badges.
- Participants complete participant forms and consent forms (for patients only) to provide demographic information e.g. name, gender, age, educational level, occupation, marital status, length of time in pain/ length of time caring for somebody with pain/ professional status (for health professionals only) and diagnostic group or painful area/s.

Orientation and Instructions

The following points were covered before beginning the discussion.

- What is a FG? A type of "group interview" to generate ideas about an issue and involves doing a task i.e. thinking about generating questions that relate to the areas brought up in the discussion.
- FG's are a "different" and "new" way of collecting information.
- Outline briefly the WHOQOL project and the place of FG's within it. Describe the definition of quality of life in lay terms.
- Describe the purpose of this group. To generate additional items/ questions for a questionnaire for use with people who have CP.
- The FG is "time out" from normal cultural and social rules about what is said and what is acceptable to discuss.
- Emphasise that there are no right or wrong answers, just different points of view.

- All participants' ideas and views are equally valuable.
- Participants should try to say as honestly as they can, what they think, rather than what they think they should or are expected to say.
- The session will be recorded, but all data is confidential.
- The session will be expected to take 1.5 hours, with a break for refreshments.
- Opportunity for participants to ask questions.

Warm-up

- A warm-up exercise is given to familiarise participants with what is expected of them and facilitate subsequent discussion. Participants are asked to free-list areas of their/ the person they care for/ their patients life that are affected by having CP and to think about the ways in which pain affects quality of life.
- To help focus the group, the aims of the session are put up on the board. These are as follows;
  1. To identify and discuss how CP affects your/ the person you care for/ your patients QoL.
  2. To establish how important each of these areas are to you/ them.
  3. To think about how you would ask about these areas, i.e. try and generate questions asking about these areas of your/ the person you care for/ your patients life.

Main session

- Participants are asked to think about the WHOQOL-100 that they have completed and say if there is anything that they think might be missing, that is specific to CP.
- Participants are invited to begin discussing some of the issues that they have written down, pertaining to CP and quality of life. It is explained that if an area arises that is already covered by the WHOQOL-100, the moderators will ask the participants to move on to a new area that has not already been covered. The aim was for the group to discuss new areas that are specific to having pain.
- The co-moderator uses a flip chart to record issues raised by participants.
- As a prompt for further discussion, the moderator asks:

"Are there any issues important to your/ the person you care for/ your patients quality of life that have been missed out of this (facet) list?"

- After an opinion has been stated, the moderator should enquire of the group if this opinion is consensually held.
- The questions addressing pain and discomfort are put up and the moderator also asks:

"Do the questions for pain and discomfort fully address pain-related quality of life?"

- If an issue is consensually felt to be inadequately covered:

"How would you ask about how CP affects QoL?"

- Any new areas or questions are written up on the flipchart as they arise.
- The moderator then summarises the group discussion by going through the list of areas written up by the co-moderator. This helps to highlight if anything else has been missed by giving participants to elaborate on particular areas if necessary and insures that each of the areas is important to everyone, not just particular individuals.

Closure, Debriefing and thank you!

Debrief with co-moderator

Consider the following questions:

- What are the most important themes or ideas discussed?
- How did these differ from what we expected?
- How did these differ from what occurred in earlier FG's?
- What points need to be included in the report?
- What quotes should be remembered and possible included in the report?
- Were there any unexpected or anticipated findings?
- Should we do anything differently for the next FG?

Compare notes and check on whether there is agreement of key points.

3.3 Analysis

3.3.1 Identification of themes

All audiotaped FG's were fully transcribed and systematically coded for themes (see appendix 1 for a sample of coded transcript). First, general themes were identified and the WHOQOL domain and facet structure provided a theoretical framework for this analysis (The WHOQOL Group, 1998), although additional attention was paid to narrative supporting social comparison theory. Particular attention was paid to identifying new areas of QoL, not covered by the WHOQOL-100. Themes from each FG were first arranged under the most appropriate headings based broadly on the six-domain structure of the WHOQOL. Subsequently, a matrix was formed of themes, plotted against each FG, allowing the similarities and differences between the groups to become apparent. From this, it was clear which themes had emerged consistently across all groups and which were idiosyncratic to particular groups. Criteria for inclusion as a facet were a.) themes not already covered by the core WHOQOL, b.) themes specific to people with CP and c.) themes represented in each of the transcripts. The themes were further refined and clustered according to their conceptual and semantic attributes. During this refinement process, conceptually similar themes were merged together to allow for a more parsimonious account of the important areas identified by the FG's, to give facets of QoL.

3.3.2 Inter-rater reliability

To ensure that the themes identified were a reliable representation of the FG narrative, inter-rater reliability assessed the extent of agreement between 2 independent raters (the author and a Health Psychology Masters student). Both raters coded the data using the core WHOQOL facet and domain structure as a coding frame to aid their interpretation of the text, with the additional task of identifying themes relating to chronic pain (CP) that were not covered by this core structure. Both raters were familiar with the structure of the WHOQOL. An adequate level of agreement between raters for the identification of additional themes pertaining to CP was achieved in a 17% sample of the total patient focus group (FG) transcripts. This provided confidence that the themes identified were representative of the views of FG participants.

3.4 Results

3.4.1 Themes

Although participants were requested to discuss areas not covered by the core instrument, evidence for the 25 core WHOQOL facets was found in the FG transcripts. Table 3.4 shows the 31 themes identified in the transcripts organised as described above. The 31 themes were then reduced to 10 facets pertaining to pain and discomfort, arranged under three domain headings; physical, psychological and social relationships. Table 3.5 shows the final list of 10 facets of QoL and how these were incorporated into the domain structure of the WHOQOL. The contraction from 31 themes to 10 facets was based on an examination of their semantic proximity, taking into account the contextual material from the transcripts. To achieve this, the location of themes was changed until they were placed where the domain heading best fitted with their conceptual and semantic qualities. Reference to the contextual material from the transcripts also ensured that facets were allocated to the most appropriate domain.

The process of refining and re-working the themes was an evolving process involving the deletion of, and movement of themes between domains following discussion with the Principal Investigator. For example, 'adapting the environment' was deleted because there was not enough supporting evidence across the transcripts. 'Feeling alone' was moved from the social to the psychological domain because of its association with loss. In addition, 'guilt' was moved from the psychological to the social domain because of the contextual nature of guilt, i.e. being firmly rooted in social relations where guilt is experienced as a result of a person's increasing dependence on others.

Table 3.4 List of 31 themes arranged under headings based broadly on the six-domain structure of the WHOQOL

Physical
1. Flare ups
2. Fluctuations
3. Getting comfortable
4. Ability to do what once could
5. Ability to obtain relief
6. Side effects of treatment/ medication
Psychological
Mood changes;
7. Anger
8. Frustration
9. Vulnerability and fear
Higher order processes;
10. Guilt
11. Uncertainty
12. Future plans
13. Loss
14. Sense of humour
15. Hope
Issues around treatment
16. Side effects of treatment/ medication
17. Complimentary therapies/ medicine
18. Information
19. Worry about medication / treatment
20. Hope of cure/ relief
Social/ personal relationships
21. Pain is invisible
22. Being understood
23. Communicating feelings
24. Burdening others
25. Feeling alone
26. Identity
Relationships with health care providers
27. Relationship with doctor/s
Environment
28. Adapting the environment
Relationship with system
29. Support from system
30. Dependency
31. Societal attitude towards pain and use of health or social care

Table 3.5 Ten new facets pertaining to CP and QoL derived from the FG work

Physical domain
I Changes in pain*
II Pain relief
Psychological domain
III Anger and Frustration
IV Vulnerability, fear and worry
V Uncertainty
VI Loss, loneliness and feeling alone
VII Positive strategies
Social relationships domain
VIII Communication
IX Guilt and burdening others
X Relationship with health care providers

*Changed at a later stage to ‘flare-ups’.

3.4.2 Importance of WHOQOL facets

FG participants completed the WHOQOL importance items prior to attending the group and table 3.6 shows the mean importance ratings for each of the 25 facets. Each item is scored on a 5-point Likert scale where 1= not important, 2= a little important, 3= moderately important, 4= very important, 5= extremely important. All facets received an importance rating >3, reflecting their perceived importance to people with CP. The most important facet was activities of daily living (ADL) and the least important was body image and appearance.

Table 3.6 Mean importance ratings for the core WHOQOL facets (N=31)

Importance items	**Mean (SD)**
Overall QoL and general health Overall QoL	4.29 (.74)
Overall health	4.35 (.61)
Domain I – Physical health 1. Pain and discomfort	4.32 (.75)
2. Energy and fatigue	4.26 (.63)
3. Sleep and rest	4.42 (.72)
Domain II – Psychological 4. Positive feelings	4.03 (.71)
5. Thinking, learning, memory and concentration	4.26 (.68)
6. Self-esteem	4.10 (.75)
7. Body image and appearance	3.52** (.89)
8. Negative feelings	4.23 (.62)
Domain III – Level of independence 9. Mobility	4.42 (.62)
10. Activities of daily living	4.68* (.48)
11. Dependence on medication or treatments	4.16 (.86)
12. Work capacity	3.84 (.90)
Domain IV – Social relationships 13. Personal relationships	4.10 (.94)
14. Social support	3.94 (.89)
15. Sexual activity	3.58 (1.03)
Domain V - Environment 16. Physical safety and security	4.10 (.60)
17. Home environment	4.42 (.56)
18. Financial resources	4.10 (.75)
19. Health and social care: availability and quality	4.39 (.62)
20. Opportunities for acquiring new information or skills	3.97 (.60)
21. Participation in and opportunities for recreation and leisure	4.10 (.54)
22. Physical environment (pollution, noise, traffic, climate)	4.23 (.72)
23. Transport	4.19 (.60)
Domain VI – Spirituality/ religion/ personal beliefs 24. Spirituality, religion and personal beliefs	3.71 (.94)

* Most important facet.

** Least important facet.

The results presented here are divided into two sections, evidence of facets from the transcripts, and evidence of the use of social comparison in thinking about and describing pain related QoL.

3.4.3 Evidence of facets from the transcripts

The following quotes have been extracted from the FG transcripts to demonstrate how the discourse reveals the multidimensional nature of the new facets, their conceptual complexity and their impact on QoL. The letters at the start of each quote represent the identity of the participant making the statement.

3.4.4 DOMAIN 1: PHYSICAL DOMAIN

3.4.5 I Flare-ups are defined as the changing nature of a person's pain or condition characterised by temporary and acute worsening of pain. Flare-ups include the notion of pain increasing with activity; of the unexpectedness and unexplained nature of flare-ups and of the adaptations made to live with and try and avoid these flare-ups.

C It's little things really. The frustrations' there because you feel that you're just about coping within it, and then all of a sudden you think 'what did I do to cause that?' And you think, I should be able to sit on the floor and wrap up Christmas presents, without causing the pain to flare up (FG3).

3.4.6 II Pain relief is a facet that reflects the importance of being able to achieve pain relief through the means available to a person, and how this impacts on QoL. For example, in terms of being physically comfortable, obtaining relief and controlling pain. As the text illustrates, achieving pain relief is an important goal that brings with it a sense of control, however, this relief offers no certainty about pain relief in the future.

D ……I'm lucky that I can plan ahead because I've got some control for my pain at the moment with the medications. I'm getting lots of breaks, which is wonderful, but I'm always wary that it's there, sitting in the background, and it could get you at anytime. And so, I think it restricts me, it restricts me as a person too (FG2).

The following quote represents the use of broader sociocultural comparison where it is assumed that people in North America are using Cannabis for pain relief.

B but you don't do it because it's illegal and because it's obviously hard to get hold of, um, I don't know why we don't do it really if I'm being honest, I think we should LAUGHS.

A Well Americans are issuing it so why, can't we?

3.4.7 DOMAIN 2: PSYCHOLOGICAL DOMAIN

3.4.8 III Anger and frustration is reported as loss of patience, being irritable and short tempered and experiencing mood changes, which impact on a person's QoL. Anger and frustration has consequences for the self, for ones relationship with others and for QoL.

C I was actually suspended from my job because I did actually lose my temper, I'm afraid to say. A very stressful job anyway, and I was actually suspended from work last October because of the very fact that I was trying to cover the pain. I was suffering in silence. Pain is invisible, other people don't know. And you try and work through it and push through it, and pushing through pain is really the worse thing that you can do. Because you just become a very angry person (FG2).

The following quote is evidence of the frustration experienced by people with pain.

D I can tell you the most normal thing is sitting here in this chair, or sitting down at home, and it's so frustrating when you've got to get up, like getting up to move over there, cause it hurts and you think 'why is it all the time?' and I mean you've got to sit down at some point in your life (FG4).

The following quote represents the use of upward intrapersonal comparison and the mood changes that come about from being dependent on others.

G Can't do anything, can't do nearly as much now as I could two years ago, and it all gets on the next person which is my husband and he is over protective, he tries to do more than I want him to do, and I say 'leave it, I'll do it', and that upsets him then, because I lose my temper because he's trying to help.

The anger described in the next account is an example of the use of downward intrapersonal comparison and that living with and adapting to pain is an ongoing process.

F When I first was in pain, I used to think 'why me?', 'why me?', 'why does it have to be me?' and I was so angry with the world......you know, thinking well, I haven't hurt anybody, I don't deserve this, but you just get used to it, it's a part of your life, and you can't be angry about it all the time, you've just got to get on with your life the best you can.

3.4.9 IV Vulnerability, fear and worry were reported in terms of physical vulnerability from pain and its associated disability, fear and worry over high doses of medication, and concern from the apparent decreasing efficacy of medications over long periods of time. The following reveals how use of a walking stick helped to reduce feelings of physical vulnerability experienced because of the fear of being knocked over.

B *Before my legs were sorted out, I used to feel very vulnerable like you about falling over, and I was frightened of being bumped into, because if someone knocked me and I was on the floor, I wouldn't be able to get up. I still wouldn't be able to get up now. With a stick there, people do just give you a bit more of a wide berth or open a door or something, and it helps* (FG1).

The next extract reveals the fear associated with taking large quantities of medication.

B *When you're on that drug in your 40's, I try very hard not to up it* (medication) *and obviously I wouldn't do it without my doctors' advice, but what's going to happen? I'm going to get to that stage where it's not going to do any good, that frightens me more than anything* (FG4).

3.4.10 V Uncertainty describes situations where the outcome is not known or is outside a person's control and includes problems associated with making plans for the future, lack of a definitive diagnosis (in some cases), and general uncertainty of the future, all of which impact on a persons' QoL. Uncertainty may lead to catastrophic thoughts about a potentially more negative future. The consequences of uncertainty include having to live moment by moment, having to cancel plans and not wanting to commit to anything in case of not being able to honour that commitment. Here, an uncertain future is considered, along with the potential impact of this on others.

A *The other thing I think of is, if it is like this now, what am I going to be like in thirty years time? If I'm limited to things I can do now, am I going to be more reliant on people to help me in thirty years time?* (FG1).

The following discussion shows that even planning daily life can be problematic because of the possibility of pain or immobility.

A *You've got to try and plan your day, or whatever the things you do, but unfortunately, you're very often overtaken by pain or whatever, or immobility.*

F *Really, you've just got to plan one day at a time* (FG5).

In an example of upward interpersonal comparison use, this participant makes a comparison with people who are able to make plans for the future.

B *So you have nothing, it's not just that the future looks like a void, but also, it's very depressing, it's very negative, and then the anger kicks in again because other* *people know that in six months time they're doing this or they're doing that. We don't know if next week we can actually attend a dental appointment that we made three months ago.*

3.4.11 VI Loss, loneliness and feeling alone describe the emotional reaction to loss of function and role. Loneliness and feeling alone are related to loss in that they are concerned with feeling the absence of others or feeling alone in ones suffering. These feelings of isolation reveal a loss of identity and sense of bereavement for the person one could have been in the absence of a painful condition.

B You sometimes think, if I didn't have this I'd be a completely different person, and I would have lived a different life, and you almost sort of grieve. 'Cos mine started when I was 22, I was just starting in life, just sort of blossoming, and I feel that I have grieved for that person that I should have been really (FG1).

The following shows how becoming a member of a support group alleviated feelings of loneliness and aloneness and can, therefore, be a positive aspect of QoL. This is also evidence of lateral interpersonal comparison because comparing oneself with similar others confirms that one is not alone in ones suffering.

B The only thing we got out of it (being a member of a support group), *well the only thing I got out of it, which is wonderful, is I know I'm not alone and all of a sudden that was the one thing that came out, that you're not alone* (FG5).

3.4.12 VII Positive strategies include the ability to see the humorous side of events, and experiences, hope and optimism for the future. Humour may be an active attempt to be positive or to diffuse potentially embarrassing situations. Hope of a magic treatment or cure offers a distant, but nonetheless imaginable possibility of a pain free future.

B I don't talk to my husband about it because he knows when I am bad...and we don't treat it as a precious thing. We sort of joke a lot about it in our house. A lot of people might be quite offended but, there is nothing he can do to help, and I know how helpless he feels, so when it's my worse times, I don't talk to him about it. That is when I do find the medical profession very good. If they can increase my drugs to just get me through that phase, or often it's because my knees or something are really bad and I can only have a replacement. When you've had a replacement, then you can go on again. It's like walking along a road really, and it bashes you down, and when you *are having a bad time and it bashes you down to the floor. If someone mends you, you just get up walking again, 'cos well what else do you do, you've just got to keep going haven't you?* (FG1).

The importance of hope and optimism that there will be a treatment or a cure for pain is revealed here.

C I always hoped that the next treatment is going to be the one. Against this frustration is hope that somebody will give me this magic potion or whatever (LAUGHS) to rub on it, or make it better and it's quite upsetting when you discover that that treatment hasn't had that magical affect you've pinned all your hopes on, especially as you get further down and you've tried more things (FG3).

The following quote shows how self-esteem can be boosted and perceived severity can be minimised by comparison with others demonstrating the use of downward interpersonal comparison as a positive strategy. This also demonstrates willingness to engage in life despite the pain.

A You've just got to take a positive approach, but sometimes you can't. I mean, I know I've got other things wrong with me, but I consider myself lucky, because there are millions that are far worse than what I am. My problems are not life threatening. They disrupt your everyday activities, um, but I consider myself lucky, I could have something far, far worse.

3.4.13 DOMAIN 3: SOCIAL RELATIONSHIPS DOMAIN

3.4.14 VIII Communication concerns living with an invisible condition and its consequences. Looking well despite the pain makes it difficult for others to see that something is wrong. People living with CP question whether they are believed and understood by others, including how they are viewed and whether they are able to communicate their feelings. These questions affect QoL through their effect on ones relationships and subsequently on ones identity.

D The problem I have is that you cannot see anything wrong with me, people say 'you look absolutely fine', but the chronic pain is continuing and you're trying to look through it really. That's what I'm trying to do, although I will say to people if I'm on the telephone, 'we won't be taking long because it actually really aggravates the ear', they forget that and carry on talking, because they can't see anything wrong, so that's a problem for me. It's only when I'm holding my face or rubbing my ear that they say *'oh, your ears bad today isn't it?' so yeah, you can't physically see anything wrong* (FG2).

Another consequence of the lack of understanding from others is withdrawal and the cessation of communication.

C I walk very slowly and I've had people brush past me and nearly knock me down and I think that is outrageous. Before I had difficulty with my walking, I used to hide it, and if you were at work and a colleague might say 'oh what's wrong?' 'Oh, I've got really bad pain in my legs', 'oh well we've all got something wrong with us' and all this kind of attitude, when I know that I've got a recognised chronic illness and I'm not even discussing it with colleagues anymore...you don't want to look for the sympathy vote – that's not what I'm about, you just need a bit of understanding sometimes (FG2).

3.4.15 IX Guilt and burdening others describes feelings of blame for one's increasing dependence and reliance on others. Guilt is an important social experience associated with feelings of being a burden on others, of inadequacy, of not contributing equally to relationships, and of letting people down, all of which impact QoL. The following illustrates the perceived unequal contribution to relationships that results in feelings of guilt.

B I think you feel inadequate, don't you? In a relationship, you don't feel you're pulling your weight and you feel you're leaving them to do too much.

C Yeah, absolutely. Oh, I know I am, and my husband works hard, very hard, and I'm putting on him all the time (FG1).

B I think your partners suffer, which makes you feel very guilty, and because you feel guilty, you then get depressed and it's a vicious circle, it really, really is. (FG5).

3.4.16 X Relationship with health care providers addresses interpersonal interactions with doctors and other health professionals involving perceptions of support, being believed and listened to, perceived adequacy of available information, and the use and benefits gained from complementary therapies and new treatments. The quality of interactions with health care providers impacts QoL.

C I think communication and being felt like you've been listened to is quite important for your QoL, not just from your family but also from medical agencies (FG3).

B If there's some new drug out and it's supposed to be some miracle drug and you read about it in the paper or someone brings it up on the Internet and tells you about it. Well really, it's not very good to the specialist; they're so busy, which is only natural, so you don't like to take up their time. But it would be nice to have somebody to discuss with, whether you'd be able to have the new drug or is it available yet, or is it just for younger people - and stuff like that? (FG4).

This participant, who considers herself to be more fortunate than others because she has a good relationship with her doctor, shows evidence of downward interpersonal comparison.

F I must admit, I've got a good doctor, he does listen and he is very supportive, you know so, I suppose I'm lucky really compared to some people.

In summary, the 10 new facets supported by FG excerpts illustrate how living with pain impacts on QoL. The narrative also illustrates the use of social comparison by FG participants and provides preliminary evidence of the importance of acceptance of pain. This reveals the variety of strategies used to talk about QoL amongst individuals with CP, illuminating the comparative processes that are embodied in the WHOQOL Groups' definition of QoL discussed in chapter two.

3.5 Discussion

3.5.1 New facets of QoL

The FG data supports the notion that pain-related QoL is influenced by numerous facets from broad life domains. The data also suggest that in addition to the core facets of QoL, other facets are important to people with CP which can be used to elaborate the WHOQOL core. The emergent themes concerned the consequences of specific symptoms which characterise particular conditions such as living with a fluctuating condition, issues surrounding treatment, the difficulty with which people find communicating their feelings and the fact of their pain to others and their relationship with their health care provider, particularly the interpersonal context of these interactions. Ten new facets emerged in addition to the WHOQOL core, which were divided into the most appropriate categories (domains of QoL), based on the contextual information accompanying the themes. These were changes in pain (later changed to flare-ups) and pain relief (physical domain); anger and frustration, vulnerability/fear/worry, uncertainty, loss/loneliness/feeling alone, and positive strategies (psychological domain); and communication, guilt and burdening others, and relationships with health care providers (social relationships domain). These findings illustrate the salience of psychosocial variables. No new facets arose for the level of independence, environment or spirituality/ religion/ personal beliefs (SRPB) domains, suggesting that these are sufficiently elaborate to account for the impact of pain on QoL. However, it is possible that facets will shift following further development and testing of the instrument reported in subsequent chapters.

People with pain derived the new facets from FG discussions and although these issues are not original to the literature, this is the first time that such concepts have been brought together to specifically identify a holistic group of QoL issues, for the purpose of developing an outcome measure. The facets also reveal the multidimensional nature of the pain experience, underscore the importance of the biopsychosocial approach to pain management, and support a broader approach to outcome measurement. Furthermore, the results support the need for a theoretical base in QoL research and the discussion also illustrates how it might be possible to modify these areas of QoL with appropriate interventions since there is an ethical question about whether one should include or assess a variable or facet that is not potentially amenable to change.

In the physical domain, living with a fluctuating condition, the presence of flare-ups and the physical side effects of treatment were important in addition to issues covered by the core WHOQOL -100. These were reduced to flare-ups and pain relief. The occurrence of flare-ups are common to clinical experience (Whitney and VonKorff, 1992; Hammond and Freeman, 2001), however this research shows explicitly that people from wide diagnostic groups experience and are affected by flare-ups, and that these flares of pain impact on QoL. Although it is possible to argue that 'flare-ups' are a symptom of a condition, they are also a consequence or effect of living with a painful condition. Flare-ups are an important target for therapeutic intervention by decreasing their frequency and severity and Pain Management Programmes (PMP's) and other approaches already target these by introducing pacing and relaxation strategies to prevent their occurrence. In other conditions such as RA, a more pharmacological approach might be necessary to prevent or relieve the fluctuations that characterise the condition (Skevington, 1994).

It may be intuitively obvious that obtaining pain relief is important to a person's QoL, nonetheless, this facet has been elaborated upon. Pain relief itself may be affected by numerous physical and psychological variables and actions taken by the person with pain. Theoretically, obtaining relief from unremitting pain may be associated with a person's sense of control. Indeed we know that greater control of pain is associated with improved outcomes (Jensen, Karoly and Huger, 1987; Harkapaa, 1991). Pain relief is not a unidimensional phenomenon since often there is a trade off between effective pain relief, adverse medication side effects and beliefs about the safety of a particular drug. It is also simplistic to see pain relief in isolation as a purely physical occurrence, demonstrated by the multidisciplinary nature of pain management interventions emphasising the importance of a more holistic approach to pain relief. Although pain relief and a reduction in pain are important outcomes, where this is difficult to obtain, other outcomes such as improved management rather than pain relief *per se* tend to be more important.

In the psychological domain, a number of key themes emerged over and above the core WHOQOL content which provides evidence for an elaboration of the psychological domain, particularly for the presence of the specific range of negative feelings that accompany being in pain, for example, the presence of anger, frustration, guilt, vulnerability and fear. Furthermore, confidence, acceptance of pain, the inability to make future plans, uncertainty and worry about the future, role loss, hope and issues around control (life control, control of pain, control within relationships, control around treatment and medications) were well represented in the transcripts and seem to characterise the experience of pain. Many of these concepts are complex and are composed of different levels of meaning and specificity. For example, hope, which appears to be a remarkably robust characteristic, was expressed as a general hope for the future and a more specific hope for a cure or relief of pain. These psychological aspects were subsumed into five facets of QoL, anger and frustration, vulnerability/ fear/ worry, uncertainty, loss/ loneliness/ feeling alone and positive strategies. Although originally placed in the psychological domain, guilt was moved to the social relationships domain because of the contextual information regarding relationships, that is, participants experienced guilt because of what they could no longer do and the consequent impact of their increasing dependence on significant others (SO's).

FG participants talked extensively about how anger and frustration affected their QoL. Given that pain is associated with considerable negative affect, including depression and anxiety, it is not surprising that other negative emotions would need to be elaborated to fully grasp the impact of pain on QoL. It has been argued that anger is one of the most salient emotional correlates of pain and given that pain has affective as well as sensory qualities and is often associated with depression and negative affect, this is not surprising (Fernandez and Turk, 1995). This concurs with the IASP definition of pain describing pain as an emotional as well as a sensory experience. In a recent review, Suinn provides evidence to show how anger can exacerbate pain (Suinn, 2001). Furthermore, patient anger (assessed with the anger/hostility subscale of the Profile of Mood States) has also been shown to have a role in the depression of patient spouses, along with average pain and the spouses level of marital satisfaction (Schwartz et al., 1991), reflecting the social and personal consequences of the expression of anger and hostility. In a more recent study, Bruehl and colleagues looked at the different effects of 'anger in' and 'anger out' on pain intensity in patients with and without complex regional pain syndrome (CRPS) (Bruehl, Chung and Burns, 2003). 'Anger in' is characterised by suppression of anger and 'anger out' by a direct verbal or physical expression of anger and can be measured with the Anger Expression Inventory. Given the reported relationship between the outward expression of anger and elevated physiological response to stress, it appears that in conditions that reflect catecholamine-sensitive pain mechanisms such as CRPS, anger out has a greater negative impact on pain intensity, thus demonstrating that differential expression of anger can influence the reported pain intensity of different conditions in different ways. A reduction in, or increased control of, anger and frustration can be considered important goals of therapy considering the prevalence and consequence of these emotions on the person with pain and their relationship with other people. Indeed, given the role of anger in mediating spousal distress, Schwartz and colleagues argue that assessment of spouses should be routine in the evaluation of patients with CP, including a focus on marital issues and anger management (Schwartz et al., 1991).

The literature on vulnerability, fear and worry has burgeoned in the last decade or so, particularly around the issue of fear avoidance, where individuals avoid activity for fear of imagined or real damage. Fear avoidance is seen as a psychosocial variable involved in the development of disability (Symonds et al., 1995; Cohen and Rainville, 2002). Fear avoidance has been examined in relation to lumbar and cervical spine pain and a weaker relationship was found between fear avoidance and disability in cervical spine pain patients than lumbar spine pain patients. Differences were also found between sub groups of patients (George, Fritz and Erhard, 2001), which suggests that this represents a variable concept. Feeling physically vulnerable to damage is also tied up with this concept, in addition to psychological vulnerability. For example in a recent study, Davis and colleagues found that women with FMS were more vulnerable to stress than women with OA (Davis et al, 2001). Both of these studies reflect the heterogeneity of chronic pain patients (CPP's). Eccleston and colleagues have recently looked at pain and worry and found that worry was related to awareness of somatic sensations and that compared to non-pain worry, pain worry was more difficult to dismiss, more distracting, more attention grabbing, more intrusive, more distressing and less pleasant (Eccleston et al, 2001). Taken together, this evidence suggests that vulnerability, fear and worry are significant psychological variables and the evidence provided by the FG work highlights their importance for QoL. Furthermore, the narrative describing vulnerability fear and worry demonstrates the salience of treatment beliefs, including worry about the decreasing efficacy of pain medications and so on. The lay referral network might perpetuate such worries that are specific to living with and managing long-term pain in the absence of satisfactory medical advice. Vulnerability, fear and worry can all be targets of intervention for people with pain and discomfort, particularly by using cognitive-behavioural techniques to challenge thoughts that mediate these variables and to provide information to extinguish worry and fear about the future.

Uncertainty was expressed throughout and is another example of a complex theme and was expressed as uncertainty about the trajectory of a person's pain and disability, the uncertainty of the future in general, the daily uncertainty of not being able to make plans because of the fluctuating nature of the condition and the uncertainty of the efficacy of new treatments. It is possible to assess uncertainty with the Mishel Uncertainty in Illness Scale (MUIS) (Mishel and Epstein, 1990). The MUIS assesses difficulty in understanding the meaning of illness-related events. Four subscales address the patients' perceptions of the ambiguity, complexity, and inconsistency of information given to them and the unpredictability of their illness. It has been shown to have high internal consistency reliability ($\alpha = 0.93$) and convergent validity (Mishel and Epstein, 1990). A recent phenomenologic study sheds some light on the area of uncertainty. In describing the lived experience of people with pain, Thomas suggests that for people with chronic non-malignant pain it appeared that time stopped and the future seems unfathomable (Thomas, 2000), which echoes the uncertain future found amongst participants in the present study. A more recent qualitative study of the narrative accounts of 30 Finnish women with BP described the stigmatising consequences of medical uncertainty in the absence of a diagnosis (Lillrank, 2003). Such medical uncertainty has been shown previously with the scant evidence of a causal relationship between spinal radiographic findings and reports of back pain (van Tulder et al., 1997). Therapeutically, if may be possible to reduce uncertainty by providing people with information about a condition and its course and by providing cognitive strategies to manage uncertainty more effectively and to reduce feelings of uncontrollability associated with an uncertain future, and hence improve QoL.

The loneliness and isolation experienced by FG participants has also been shown by Thomas (2000), who found that the pain was a barrier that separated them from other people. Similarly, a study by Snelling shows that CP can cause social isolation, although from the grounded theory approach taken, it is not possible to make causal inference about the direction of this relationship (Snelling, 1994). It may be possible to reduce feelings of loneliness and isolation through educating and involving SO's and family members in pain management. Improving the social skills needed to feel part of a group and group work may also act to reduce feelings that one is alone in ones suffering, for example in PMP's or lay led support groups.

The literature on loss has been closely aligned to bereavement, loss of a limb and the subsequent changes to body image and loss of identity. Echoing this, Katz and Florian have distinguished three different types of loss, interpersonal loss, loss of a limb or function, and environmental loss or loss of peace of mind (Katz and Florian, 1986). Others have focused on the importance of addressing the grief that might be experienced following loss of function, which may be mistaken for depression

(Stewart and Shields, 1985). The accounts of FG participants demonstrated loss of function, loss of peace of mind through an uncertain future and loss of social role, and there was some evidence of grieving for the person that they could have been in the absence of chronic disease and pain. Loss represents a complex feature of the experience of living with a chronic condition and it may an important target for therapy. Depending on the nature of the loss experienced by the individual, providing information and skills about alternative roles and coping strategies might be useful in moderating its influence on QoL.

The use of humour and hope were found to be important to the QoL of participants in this study. Less is known about the positive aspects of adverse experience, despite these being important to individuals. Stevensen has looked at non-pharmacological pain management techniques for acute pain and found inconclusive evidence of the efficacy of humour therapy (Stevensen, 1995). Whether this is applicable to CP is not known, although Skevington and White (1998) found the use of humour to defuse embarrassment amongst a group of RA patients. More recently, Boyle and Joss-Reid (2004) conducted a psychometric investigation of the relationship of humour to health using the Multidimensional Sense of Humour Scale (Thorson and Powell, 1993) and found humour to be a multidimensional construct comprising humour production, attitudes towards humour, coping humour and humour to cope with life. Moreover, in the medical patients in the study, worse pain was associated with an increase in humour scores, which suggested that humour might be used as a coping mechanism to relieve pain. In the present study, humour was also used as a strategy to defuse the embarrassment of others, which is contrary to traditional notions of the function of humour. However, this concurs with the coping humour found by Boyle and Joss-Reid, which is described as the production of humour to cope with difficult situations which in the present study was found to be important to a person's interaction with others and hence their QoL and happiness.

The concept of hope receives limited attention in the literature; often it is in the context of hope for relief from pain. For example, Shannon and Baranowski discuss the use of opioids in non-malignant pain representing the only hope for relief from pain for some CP sufferers (Shannon and Baranowski, 1997). Tennen and Affleck summarise the prevalence and adaptive significance of construing benefits from adversity, for example, in CP. They utilise stress and coping theories to explain how people may find benefits from their experience and refer to particular dispositions such as hope and optimism (Affleck and Tennen, 1996). This work is of particular relevance to the current research because it highlights the importance of positive psychological strategies in adapting to, and managing CP, an area that has been given limited attention in previous research. Less is known about the positive aspects of adverse experience, and research tends to focus on the negative consequences of chronic illness or disease, although there are some notable exceptions (for example, Sodegren and Hyland, 2000; Sodergren et al., 2002; Folkman, 1997). This represents a broader approach to QoL and highlights the importance of positive psychological strategies in adapting to, and managing CP without focusing exclusively on negative affect and physical disability, which has too often been the case in outcome research. It also reflects the possibility that negative and positive affect can co-occur, despite adversity (Folkman, 1997). Promoting the use of humour, where appropriate, and realistic hope might be important strategies and coping mechanisms to manage pain and its sequalae more effectively.

Hope and optimism share some commonalities, and optimism is therefore relevant to the present study because of its semantic proximity to hope. Moreover, research on the elaboration of the SRPB facet has shown that both hope and optimism are important to QoL (O'Connell, PhD thesis, 2002). Garofalo, in a review of the role of optimism in pain, introduces optimism as a personality dimension and a mediator of stress, although it has been described and conceptualised in numerous ways (Garofalo, 2000). Due to the extensive focus on the importance of psychological variables in response to pain, optimism has been hypothesised to have health promoting effects. This is set within the context of an area that is poorly understood and elaborated because of the dominance of investigations into negative affect and pain. Indeed Turk and Holzman (1986) show how patients report despair and feelings of hopelessness for the future because of the limited success of treatments. Numerous researchers have shown a potential relationship between an optimistic disposition and successful treatment of people with pain (for example, Gruen, 1972; Haerkaepaeae and Jaervikoski, 1996; Jamison et al., 1993; Novy et al., 1998). This evidence reflects a potentially important area for intervention, in decreasing feelings of hopelessness and despair and promoting or maintaining optimistic beliefs about the future.

Initially, in the level of independence domain, specific issues around treatment emerged as being important to participants living with pain. For example, the diverse nature of medication side effects (physical, cognitive and social), the constant search and hope for a cure or relief, the importance of having adequate information regarding available treatments and the side effects of medication and a person's journey through the health care system. Participants often felt compelled to seek their own information about their condition through use of the Internet and libraries. Issues around the use of, and availability of complementary therapies and treatments were important. It appears that for this group of patients living with persistent pain, conventional medicine often did not provide adequate relief and thus complementary therapies where seen as an important way of obtaining some relief, or at least provided some hope of relief. Participants also expressed general beliefs about medication and treatment. These issues around treatment were subsumed into other facets to allow for a more parsimonious account, for example pain relief. Moreover, the core WHOQOL facets already account for some of these issues.

A number of themes arose for personal and social relationships. All groups talked about living with an invisible condition and its implications for relationships and general social interaction. Tied up with this, was the importance of being believed and understood by others and the difficulty participants had expressing their emotions and pain related information to SO's. This was often accompanied by a sense of guilt over the effect this had on the carer. Participants were also very aware and concerned about how they were perceived by others and the extent to which they made legitimate complaints reflecting the extent of their suffering. These issues have implications for the identity of CPP's and were subsumed into communication and guilt and burdening others.

Communication is a complex feature of CP and the key issues include communication of pain verbally and non-verbally and communication to SO's, health professionals and wider society. Ineffective communication with physicians is seen as a barrier to pain relief and Glajchen suggests communication should be part of patient education to reduce these barriers (Glajchen, 2001). Difficulty communicating with others, including communicating the fact of ones pain to others and communicating how one is feeling has been shown to impact on a person's QoL. It is possible that communication can be improved through specific intervention to give people the skills to communicate more effectively with the important people in their lives, including family, SO's and health care professionals. This raises the issue of empowerment given that CPP's are a vulnerable group in terms of traditional power relations with health professionals, particularly physicians.

Examining the literature on CP and guilt, two early studies are particularly relevant. Johansson and colleagues looked at the relationship between personality traits and endorphin levels in the cerebrospinal fluid, they found that CP patients were characterised by guilty feelings, need for order, low need for autonomy, and low tendency toward sensation seeking (Johansson et al., 1979). This provides early empirical support for the presence of guilt amongst pain patients. Stein and colleagues found a relationship between guilt and illness behaviour in the depression of people with intractable pain (Stein, Fruchter and Trief, 1983). More recently, Skevington (1994) found that guilt was associated with the intrapersonal comparisons that people use in making decisions about their QoL because of feelings that they had not appreciated the things that they had been able to do in the past. Perceptions of burdening others, whether real or imagined are genuine concerns of people with CP. The literature tends to focus on the economic and or societal burden of CP and the extensive health care utilisation of CP patients (Maniadakis and Gray, 2000; Loeser, 1999; Maetzel and Li, 2002). Literature on perceptions of burden by patients themselves is less common. Challenging feelings of guilt and addressing anxiety about burdening others might be important areas of clinical intervention to improve the QoL and perhaps the quality of relationships of people with pain and their SO's.

Participants also discussed their relationship with health care providers. The importance of the patient-doctor relationship and being listened to understood and supported. Trust and consistency was expressed as being important and there was some evidence of a conflict of beliefs between patient and doctor, for example in the perceived cause of the pain and the most suitable treatment options. Within this theme was a person's relationship to the system as a whole including perceived support, feeling caught up within the system in a stream of unexplained referrals and the extent to which a person receives adequate information about their health condition. Relationship with health care providers was also placed within the social relationships domain, because of its interpersonal nature. This is distinct from what is already covered in the WHOQOL because it highlights the interpersonal aspect of a person's relationship with health care providers as opposed to perceptions of the availability and quality of health and social care.

A person's relationship with their health care providers, including the quality of the patient-doctor relationship, perceptions of support and so on have been shown to be important to the QoL of people with pain, particularly because of their dependence on health care for continued management and relief from pain. There is empirical evidence of the importance of the patient-doctor relationship, for example, it has been shown that the quality of the patient-doctor relationship can affect treatment adherence in post-surgical pain (Moskowitz, 1996). Sternbach suggests that agreement on the features of the patient-doctor relationship is essential for the successful management of CP patients (Sternbach, 1977). However, it is not just this relationship, but also a patient's relationship with other health care professional such as nurses, occupational therapist and physiotherapists that may also have a bearing on their QoL and are increasingly important given the multidisciplinary management of CP. Less is known about the quality and nature of these relationships, which might prove to be important for understanding the experience of patients.

A recurring theme was the patient's relationships with their General Practitioner and their Consultant and how this affected their QoL. Past research has shown that medical encounters are largely social interactions (Vonbaeyer, 1994). Research has also shown that the judgements of physicians are influenced by the properties of the patient, the situation, and the valence of the patient-doctor interaction (Tait and Chibnall, 1997). This allows for greater sense to be made of the experience of the patient, by examining the perspective of the physician. From the perspective of the patient, this relationship may be tied up with the concept of support and the need to be listened to and believed. It became apparent that for those with troubled relationships with their doctors, this was a very salient narrative for discussion about their QoL. Although a causal relationship cannot be established between adjustment and relationship with doctor, it is certainly a factor influencing QoL.

There is an apparent paradox in the need for patients to feel supported by the medical profession and the need for the medical profession to reduce patient demands to utilise resources. CP presents a challenge to physicians and health professional groups talked about their own frustration at not being able to relieve the pain of their patients. Thus, feelings of being let down by the medical profession are wholly justified. Interventions in this area might be problematic and politically sensitive. However, increasing the knowledge of health professionals about psychosocial variables is an important goal, including listening and other communications skills. From the perspective of the patient, it is possible to improve their ability to communicate with their physician by providing them with effective skills to do so.

In the environment domain, reliance on aids and having to adapt the environment to reduce disability emerged, however there was not sufficient evidence of this to support its status as a new facet. Furthermore, there is a core facet addressing dependence on medication and treatment, which asks about reliance on medical aids, which is sufficient to capture this aspect of QoL. Other themes that emerged less consistently were anecdotes about the weather influencing pain levels (this might be quite important for people with RA) and mood. Indeed there is an existing item in the WHOQOL-100 that asks about climate, although this does not account for the fluctuating, unpredictable nature of British weather and its alleged affect on mood and health!

3.5.2 Theoretical observations

The results suggest that when talking about pain and its affect on QoL, people use a 'language of loss' and this is reflected by many of the emergent themes. The concepts of independence and dependence are also used to describe different aspects of a person's life with pain and such concepts are already a core part of the WHOQOL structure embodied in the level of independence domain. Participants talked about a loss of physical strength, control of pain, sleep, activities, abilities to carry out tasks of daily living, control over and loss of options for the future (loss of what the future might have been), mind, enjoyment of life, relationships, role, and so on. A degree of loss had been experienced with all these physical, psychological and social experiences and was shared by members of each group. Tied up with the concept of loss, was the apparent consequence of dependency that these losses engendered.

Independence was described as being very important to participants and these losses represented a threat to their independence. Physical independence was described in terms of being able to wash or bath oneself, psychological independence as freedom from medication and social independence as engaging in a social life without reliance on the carer, illustrating the complexity of independence. The level of independence domain of the existing WHOQOL-100 covers these aspects of a person's QoL, although these are specific examples relating to the QoL of people who live with pain and discomfort.

Furthermore, the transcripts provided evidence of the processes used by people to describe their QoL in a group setting. Considerable evidence from the transcripts emerged in support of social comparison theory. Each patient transcript provided a rich source of quotes demonstrating its use in talking about QoL, including the use of intrapersonal, interpersonal and sociocultural level comparisons. For example, participants often compared themselves to how they had been before the onset of their pain and associated disability. This intrapersonal comparison was described in terms of what they were no longer able to do, which may also be characterised by a sense of loss. This process acted to remind the patient of what they are unable to do because of the pain and associated disability and that fact that activities now take longer and require greater effort. An idealised past was used as a reference point to compare different aspects of experience and further highlights the changes to self and the increasing dependence on others, which have implications for ones relationships with others. Although such processes do not provide benefits to the individual, there is some evidence of an appreciation of what one was able to do in the past and an acceptance of the changes that have come about because of living with CP. Participant narrative also provided preliminary evidence of acceptance of pain, shown by such acceptance of changes and by the willingness to engage in activity despite the pain, which has been shown to be important in adjusting to CP (Geiser, 1992; McCracken, 1998, McCracken et al., 1999; McCracken, Vowles and Eccleston, 2004) and this is investigated further in chapter eight. In contrast to upward intrapersonal comparison, downward intrapersonal comparison occurs when people compare their current selves favourably with a less favourable point in the past so that an improvement is perceived, consequently, a sense of benefit is derived from the perception that they have changed for the better or have made a successful adaptation to adversity.

Interpersonal comparison, such as describing others who are perceived to be worse off, was another strategy employed by participants to boost their own self-regard. For example, downward interpersonal comparison was shown when comparisons were made with others who are worse off than oneself, including hypothetical comparisons, for example, believing that one could have a more severe condition, but does not. Consequently, this type of comparison can bring about psychological advantages for the person doing the comparing. Comparisons are also made with others perceived to be worse off, which can serve to minimise ones own problem, but also bring about shame for thinking about oneself. Downward interpersonal comparison is important because of the perceived benefits that can be construed from believing that ones situation is better, or less severe than that of other people. In contrast, upward interpersonal comparison is characterised by comparing oneself with someone who is perceived to be better off, which can have negative consequences for the individual. The acknowledgment that other people can do the activities that one is unable to do or that others appear to be complaining unjustly seem to impact on decision making about QoL.

Making comparisons with similar others, an example of lateral interpersonal comparison, allowed people to conclude that they were not alone in their suffering. Although FG participants used this type of comparison infrequently, benefit was derived from knowing that one is not the only person suffering with CP. A broader sociocultural level of comparison was also described in terms of methods of pain relief such as the perception that in the USA, cannabis is widely available and so on, which suggests that people make comparisons with other cultures when thinking about methods of relief that might be available to them. The use of sociocultural comparison is important because it locates individuals in their broader social and historical context and illustrates the complexity of QoL decision-making, including the diversity of issues that are considered by individuals when thinking about their QoL. Although this type of comparison was used, it is not clear that this impacts on individual QoL life decisions, rather more global statements about perceptions of the society that a person interacts with. The quotes demonstrating social comparison also provide narrative evidence of acceptance and of the possibility that response shift (discussed in chapter two) occurs in people living with, and adjusting to, a life with pain, for example through shifting priorities and altering internal standards and values as part of the process of adjusting to life with pain and disability.

3.5.3 A critique of the focus group method

In general, group members interacted well and despite attempts by some group members to dominate, this did not appear to create any discord. This was successfully resolved by ensuring that quieter members felt comfortable to be drawn into the discussion. Efforts were also made to obviate the contribution of idiosyncratic views, by focusing participants on the goals of the group. It is possible that a number of group processes were operating to potentially alter the comments and behaviour of individual members. A notable example is the possibility of social desirability bias, where people are influenced by the behaviour and comments of others and wish to appear in a certain way, for example, by agreeing with what another person is saying, despite their contrary opinion or belief. However, efforts were made during the groups to emphasise that all opinions were valuable and that participants were to respect the views of others and so on. Furthermore, awareness and sensitivity to the possible inhibiting influence of a wide range of age groups contributing to each group was considered. In the carer groups, care was taken to allow them to discuss the perspective of the patient rather than the effect it had on themselves. Recruitment of these two groups was challenging and the group consisted of a fairly homogenous sample, that is, carers of people from similar diagnostic groups. Consequently, results from the carer groups were not presented and primacy was given to the views of patients. Generally, the groups found the task of item generation quite difficult and FG participants were too fatigued to give their full attention to the task of generating items pertaining to the facets of QoL they had identified at the end of the FG. In retrospect, it would have been beneficial to ask them to do this after each new facet had been identified and discussed. However, it is also possible that this would have disrupted the flow and dynamics of the group.

FG's have been used in all stages of the WHOQOL development to identify facets of QoL cross-culturally and this has proved to be a successful method to do so (Skevington, MacArthur and Somerset, 1997). Despite their utility and feasibility, there are a number of drawbacks. Firstly in the present work, the number of participants was relatively small and were all taken from the southwest region, however, the goal was not to produce statistically generalisable results but to reach saturation where no further pertinent issues arise from subsequent groups. Furthermore, the UK WHOQOL was designed for native English speakers and its use has not been widely documented with members from British ethnic minority groups and the sampling reflects this. The sampling broadly represents the proportion of people presenting with particular conditions, however, it was not possible to include people from very specific groups such as sickle cell anaemia and amputees because of difficulty in gaining access to these groups. As anticipated, a large percentage of participants had musculoskeletal conditions and this is borne out in national statistics (for example, Elliott et al., 1999). The method also represents a departure from the collaborative procedure used for the development of the core WHOQOL instruments and other modules, which included at least three other centres internationally. Although FG's generate information rich data, in common with other qualitative approaches, limitations include the generalisability of results to the target population, determining validity and potential problems associated with group interaction. However, every attempt was made to overcome these potential drawbacks through the inclusion of a broad sample and through the effective moderation of groups. Furthermore, the systematic analysis ensured the identification and comprehensive coverage of facets pertaining to QoL.

Despite the cross-sectional nature of the study, the FG method provided some fruitful data, which confirms what is known about the process of adapting to, and managing pain in terms of the verbal reports of group members. In addition, it provided novel evidence of the impact of pain on QoL, including the importance of positive strategies such as hope and humour.

3.5.4 Conclusions

This preliminary qualitative study captures the essence of how QoL is affected by the pain experience. The 10 new facets represent new features of the physical, psychological and social relationships domains, which will form the basis of the PDM to be used in conjunction with the UK WHOQOL-100. For the physical domain, flare-ups and pain relief were found to be important to QoL. For the psychological domain, anger and frustration, vulnerability/ fear/ worry, uncertainty and loss/ loneliness/ feeling alone were elicited by FG members and are known to be salient emotional correlates of pain. Furthermore, the positive strategies of hope and humour were found to be central to QoL, which is important because of the tendency to focus on the negative consequences of illness. Finally, in the social relationships domain, communication of pain and the perception of burdening others were important features of QoL, contrasting with the focus on the economic or societal burden of CP. A person's relationship with their health care providers was also found to be a key aspect of QoL. Although the WHOQOL-100 is a reliable and valid generic measure of QoL, this chapter has shown that there are specific life domains influenced by living with CP that must also be taken account of when measuring QoL. Taken together, these new facets should improve the sensitivity and accuracy of the instrument to measure the physical, psychological and social aspects of QoL. Evidence was also found for the use of social comparison judgements and acceptance as processes involved in describing how pain and discomfort impacted on QoL.

3.5.5 Further work

In the next chapter, the results from a web survey are reported to complement and provide validation for the data derived from the FG's given the sampling limitations. In chapter five, definitions that elaborate on the concept represented by each facet title and items pertaining to these facets that address that aspect of a person's QoL are given, in preparation for piloting the new instrument.

Chapter four

The Web Survey:

Further Exploration of the Quality of Life of People with Chronic Pain

4.1 Introduction

Chapter three reported on the quality of life (QoL) of people with chronic pain (CP) using focus group (FG) methodology. This chapter reports data from an international web survey with English speaking respondents to further strengthen the conclusions drawn from the FG work. Data derived from these two sources provides the basis of a pain and discomfort module (PDM) to be used in conjunction with the UK World Health Organisation Quality of Life Assessment (WHOQOL-100). Given that few measures have taken account of cross-cultural diversity in assessing the QoL of people with CP, the Internet provides an opportunity to address this issue.

4.1.1 The World Wide Web

The Internet or World Wide Web (www) has grown rapidly over the last decade and its use has increased dramatically. It is estimated that 33 million people or 55% of the population have access to the Internet in the UK (Jupiter MMXI, 2001). This compares to the USA, which has 115 million or 62% of the population using the Internet (Chan et al., 2001). The numbers are substantially smaller in developing countries such as Africa, which has an estimated 6 million Internet users (NUA, 2002), although this varies considerably across different African countries. There has been a proliferation of sites dedicated to specific or particular health conditions, including online support groups for individuals to derive solace from others and to obtain advice and support from fellow sufferers. The Internet has become a widely used source of information to supplement other mediums of information delivery. For example, Taylor and colleagues found widespread use of the Internet amongst families using genetics clinics, although the accuracy and clarity of the information was questioned (Taylor et al., 2001). However, its use as a tool for research is less developed and relatively new. Robinson argues that unsolicited narratives from the Internet are a rich source of qualitative data (Robinson, 2001). He discusses sources of data and the ethical issues associated with using information from this potential data source. However, this only has implications for those who are unaware that their narrative or Internet use is the subject of research.

More recently, there has been debate in the literature on QoL about computer-assisted technology, including the comparison of traditional paper and pencil questionnaire administration and computer-assisted interfaces (CASI) such as touch screen or web-based administration (Litaker, 2003). Litaker found that different modes of administration have different effects on the reliability of instruments and highlights the need for studies to explore this issue. In a pilot study Bliven and colleagues collected health related QoL information using software operated over the www (Bliven et al., 2001). Compared to paper administration, they found a preference for computer-assisted administration and conclude that health related QoL (HRQoL) measures using software operating over the www is a reliable method for collecting data. Allenby and colleagues conducted a study of patients attending an ambulatory cancer clinic and found that the administration of the Cancer Needs Questionnaire (CNQ), European Organization for the Research and Treatment of Cancer quality of life questionnaire (EORTC QLQ-C30) and the short-form Beck Depression Inventory (BDI) using a touch-screen computer to assess self-reported psychosocial functioning to be an acceptable and efficient way to obtain such information (Allenby et al., 2002). Studies such as this underline the importance and benefits of utilising current technology to advance survey methods and to promote efficient and reliable modes of data collection.

The rationale for setting up a web survey was to gather data from an international heterogeneous sample of people with CP, to validate the data derived from the FG work. There was no pre-determined sampling strategy, since the goal was to reach a large number of English speaking people internationally. It was decided that since previous WHOQOL work had been firmly routed in cross-cultural research, obtaining data from an international sample via the www would be a useful way of providing validation for the data derived from FG work. Thus, the web survey provided additional data on how CP affects QoL, to confirm the data obtained from the FG's described in chapter three and to provide additional contextual material for the definition and item (question) writing stage of the PDM to be used in conjunction with the UK WHOQOL-100, which is detailed in chapter five.

4.2 Method

4.2.1 Procedure

The CP web survey was set up in December 2000 using a questionnaire template (see appendix 2 and http://www.bath.ac.uk/~pspvm/painqol.html). A configuration file was established to transfer directly into an EXCEL database, to be viewed and manipulated. The web site was advertised through web based CP support group message boards to obtain the widest possible interest. Potential respondents were invited to complete the short questionnaire about how CP affected their QoL. The questionnaire consisted of 19 questions requesting socio-demographic information, nature of medical condition, location of pain, duration of pain, temporal characteristics, intensity of pain, types of treatment utilised and how pain affected their QoL. The questionnaire took approximately 10 minutes to complete depending on the willingness of the respondents to write about their QoL. Although there is no way of checking the legitimacy of the web survey respondents, the questionnaire was structured in a way that would make it difficult for a 'hoax' respondent to complete it without knowing a considerable amount about pain, its treatment and its consequences for QoL.

4.3 Results

The web-based survey was available online between December 2000 until August 2003 and the data presented here derives from this period. The results largely confirm the existing WHOQOL domain and facet structure and provide evidence to support the 10 new CP specific facets derived from the FG work. The results report the quantitative statistics from the web survey describing the sample, and present the content analysis of the comments pertaining to the QoL of respondents, arranged under the domain and facet headings or the core WHOQOL facet and domain structure already described.

4.3.1 Socio-demographic composition

Between December 2000 and August 2003, 234 people with CP completed the online web survey. The mean age of respondents was 44.15 years (range 14-85, SD 11.66).

Of the respondents, 78.2% were female (n=183), 60.7% were married (n=142), 16.2% were single (n=38), 12.8% living as married (n=30), 6.8% divorced (n=16), 2.1% separated (n=5) and 0.9% widowed (n=2). A higher education level was achieved by 38.9% (n=91), followed by 29.1% with further education (n=68), 17.5% secondary education (n=41), 11.5% postgraduate (n=27) and 2.1% in primary education (n=5). Of the sample, 55.1% were working (n=129) and of these 28.6% were engaged in full-time work (n=67), followed by 14.1% part-time paid work (n=33), 13.7% looked after the home (n=32), 10.7% voluntary work (n=25), 8.5% looked after a child or children (n=20), 3.0% part-time unpaid work (n=7), 3.4% part-time study (n=8), 2.6% full-time study (n=6) and 0.4% full-time unpaid work (n=1). The majority of respondents came from the UK (50.9%, n=119), followed by the USA (29.1%, n=68), Canada (2.6%, n=6) and one from each of the following countries (4.7%, n=11); Australia, Bahamas, France, Ireland, Italy, Malta, New Zealand, Pakistan, Singapore, Sweden, Thailand; 30 (12.8%) respondents did not state which county they were from. All questions were answered in English.

4.3.2 Characteristics relating to pain

Most of the sample had current pain (96.6%, n=226) and had their diagnosis confirmed by a doctor (92.7%, n=217). The mean duration of pain was 105.4 months (range 3-564, SD 91.05). Of the sample, 42.3% (n=99) had some form of surgery for their pain, 84.2% (n=197) used prescribed medicine, 42.7% (n=100) used other medication (e.g. 'over the counter' medication) and 42.7% (n=100) used alternative treatment/ medicine for their pain.

4.3.3 Intensity and temporal characteristics of pain

Based on items derived from the McGill Pain Questionnaire (Melzack, 1975) and included in the questionnaire, pain intensity was distressing for 32.9% (n=77), horrible for 21.4% (n=50), discomforting for 20.5% (n=48), excruciating for 17.5% (n=41), mild for 5.6% (n=13), and 2.1% (n=5) had no pain. For the temporal characteristics, 74.4% (n=174) described their pain as continuous, 23.9% (n=56) as intermittent, 1.3% (n=3) as brief and 0.4% (n=1) did not reply.

4.3.4 Location of pain and diagnosis

Respondents reported pain in numerous bodily locations, often reporting a constellation of other symptoms. A total of 41 specific pain regions were identified. The most common site of pain was the back and spine (124), followed by the legs (97), neck (71), shoulders (58), head (44), hips (40), feet (37), arms (35), knees (31), hands (28), abdomen (26), ankles (16), all over (14), elbows (14), buttocks (13), wrists (12), sciatic nerve (12) and chest/breasts/pericardium (12). A total of 97 diagnoses or conditions were identified, as defined by the respondents, and substantial co-morbidity was recorded. The most common diagnoses reported were chronic back pain (n=58, 24.8%), degenerative discs and sequalae (n=54, 23.1%), arthritis (all types) (n=47, 20.1%), fibromyalgia (n=41, 17.5%), facial pain (n=26, 11.1%), endometriosis (n=25, 10.7%), headaches and migraines (n=20, 8.5%) and spondylosis or spondylolistthesis (n=15, 6.4%).

4.3.5 Medication and treatment utilisation and alternative medicine/ therapy use

Opioid-based drugs where used extensively for the relief of pain (206), followed by non-opioid analgesics (147), non-steroidal anti-inflammatory drugs (NSAIDs) (133), anticonvulsants (67), antidepressants (64), other drugs (25), sedatives (21), drugs for the treatment of arthritis (17), co-analgesics (8) and local anaesthetics (5). A variety of complementary/alternative therapies were also used to relieve pain, or as an adjuvant to pain relief. The most widely used were nutritional supplements (57), transcutaneous electrical nerve stimulation (TENS) (22), acupuncture (21), relaxation and meditation in its many forms (18), the use of hot and cold (16), massage therapy (14), chiropractic (11), external creams (11) and reflexology (11).

4.3.6 The QoL of web survey respondents

The content analysis is presented in table 4.1 and summarises aspects of QoL affected by pain from the perspective of web survey respondents and illustrates the frequency of individual aspects of QoL. The core domain and facet structure provided a way of coding the analysis. The first column of table 4.1 contains the domain and facet title with some examples, drawn from the qualitative data, of what this facet represents. The second column gives an example taken from the written narrative of the respondent to illustrate the relevance of the particular facet to their QoL. The frequencies shown in the third column give a sense of the relative salience or importance of particular aspects to a person's QoL and the percentages quantify the frequency with which facets were expressed in the narrative accounts. The length of the contributions made by each respondent varied and their comments representing each facet were only counted once. The facets highlighted in grey are the new facets of QoL derived from the FG work, but confirmed here, relating to pain.

The results validate the core WHOQOL facets and support the 10 new pain and discomfort facets derived from the FG work. Comments reflecting all core facets of QoL were elicited, with the exception of physical safety and security, home environment and physical environments. Of the core facets, the most frequently mentioned were activities of daily living (ADL) and the least frequent was opportunities for requiring new skills and information. Of the 10 new pain and discomfort facets, loss/ loneliness and feeling alone were the most frequently elicited and positive strategies were the least frequent. A small number of miscellaneous themes were elicited including eating and appetite, the accessibility of the environment and weather affecting pain, however, these were mentioned infrequently (<7, 3.0%).

Table 4.1 The PDM facets incorporated into the core WHOQOL domain and facet structure and the content analysis of the web survey results (frequency refers to the number of times elicited by web survey respondents (N=234, new facets (60-69) are highlighted in grey)

Domain, facet and examples	Supporting quotations	Frequency (%)
OVERALL QUALITY OF LIFE AND GENERAL HEALTH Affects general outlook on life/ entire QoL affected	"My pain affects my whole quality of life" "My entire life has been affected substantially" "I have no quality of life any longer" "My whole life seems to centre or be focused on this horrible pain" "This chronic pain has taken over my whole life" "Pain affects my entire quality of life. There isn't a single waking moment that I'm always aware of this insidious creature called pain. Whether I'm reading, entertaining, making love, dressing or just trying to see the humour in all this; pain is there to steal my life's moments"	43 (18.4)
DOMAIN I - PHYSICAL **1. Pain and discomfort** Sitting or standing for long periods painful, preoccupation with pain	"I cannot sit or stand for a long period of time; even minutes are painful" "Sometimes all I can think about is how much I hurt"	61 (26.1)
2. Energy and fatigue Slowed down/ loss of energy/ saps energy/ get tired/ fatigue/ draining	"Pain of this sort saps a person of all strength" "Constant pain drains me" "It seems that when I am undergoing the worst of the pain I feel completely and totally exhausted and robbed of my strength"	58 (24.8)
3. Sleep and rest Sleep problems/ unable to rest and relax	"I do not have a regular sleeping pattern because of the pain" "I have major problems with sleeping, it takes me hours to fall asleep and then the pain wakes me up continually during the night"	37 (15.8)
60. Flare-ups Overdoing it leads to flare-ups/ pain increases with activity/ activity leads to flare-ups/ pain can worsen from lack of activity/ pain varies/ fluctuates/ good days and bad days	"Constant pain is just unpleasant at the best of times. Flare-ups are beyond describing" "I can't keep up my housework because it causes my back to flare-up" "I have to plan my life around my pain (or anticipation of pain)!"	23 (9.8)

Domain, facet and examples	Supporting quotations	Frequency (%)
61. Pain relief No comfort/ getting comfortable/ obtaining relief 'a holiday away from pain'/ control of pain/ pain can control the person/ successful PMP can give more control over life/ ability to find relief/ managing pain is time consuming/ side effects of medication/ the success of treatment/ nervous about surgery (treatment)/ preoccupation with cure or feelings that it is too late to do anything	"Spend most free hours trying to relieve the pain with hot baths, heating pads, massage, exercise; you name it" "I feel very frustrated and depressed all the time at not being able to find long-term relief"	71 (30.3)
Miscellaneous new theme Eating/ appetite	"Even eating a meal can be a chore because of the pain"	6 (2.6)
DOMAIN II - PSYCHOLOGICAL **4. Positive feelings** Happiness	"I am happy at times but I should always be happy because as a human being I deserve better"	3 (1.3)
5. Thinking, learning, memory and concentration Cannot concentrate or think clearly which affects work and distracts/ affects memory	"I am unable to concentrate or to think properly" "Pain is constant which makes it very difficult to concentrate on activities, which is ironic as I feel that if I could concentrate better it may help take my mind off the pain."	29 (12.4)
6. Self esteem Self esteem/ loss of confidence/ self image/ self worth/ feeling inadequate/ self-motivation/ tired of keeping going	"For years, worry about being able to work and hold down a job was stressing and lowered self esteem"	15 (6.4)
7. Body image and appearance Weight gain due to inactivity/ body image/ appearance	"Weight gain affects self-esteem (and intimacy with spouse and do not think that because I am 70 years old this is not important or distressing)"	6 (2.6)
8. Negative feelings Depressed/ decreased enjoyment of life/ unhappy/ anxiety/ feeling downhearted and miserable/ feel low/ suicide ideation/ helplessness	"It often makes me feel miserable, downhearted even depressed sometimes" "It is depressing to wake up to pain everyday" "I have felt suicidal at times"	66 (28.2)
62. Anger and frustration Anger/ frustration/ loss of patience/ irritable/ mood changes/ mood swings/ short tempered/ annoyance	"The effects chronic pain has on my life is it makes me angry that I have to live this way" "Physical activity limitations causes frustration and anger" "I have had years of frustration over my health problems"	34 (14.5)
63. Vulnerability, fear and worry Avoidance of activities that will generate pain/ fear/ fear of activity/ wary of movement/ fear of losing job/ worry/ fear of pain/ worry and fear about the future and about treatment/ vulnerability/ preoccupation with pain/ suffering	"I'm so afraid I'm going to break and hurt myself" "By far the strongest emotion is fear...fear of it getting worse, fear of not being able to cope, fear of my husband getting fed up, fear of my daughter inheriting the condition and suffering like me" "I'm afraid to lift anything"	24 (10.3)

Domain, facet and examples	Supporting quotations	Frequency (%)
64. Uncertainty Uncertainty of diagnosis/ no diagnosis/ no explanation for cause/ changed life and course of future/ narrowed career options/ unable to make plans/ plan activities around pain/ restrictions/ uncertainty of future and day-to-day living/ never know when the pain will come	"I can't plan ahead as I can't foresee how bad the pain is going to be next day" "The NHS has taken nearly 14 years to come up with a diagnosis"	43 (18.4)
65. Loss, loneliness and feeling alone Not able to do what once could/ cannot do what want or need to do/ role loss/ life will never be what it once was/ wasting my life/ mourn for lost life/ feel lonely/ alone/ feelings of isolation/ loss of self (not the person I was)/ loss of life/ struggle to accept new self/ lonely because of the invisibility of pain/ isolation/ lonely and silent condition/ reduced social life because difficult to make new friends/ losing old ones/ withdrawn/ feel 'old'/ life is on hold/ prematurely standing still/ do not get out and do things with others/ lose friends because you are 'sick'	"I'm lonely because all my body parts are present but pain is invisible" "I feel very isolated" "I miss my old life" "Above all I have felt this is not 'ME'. I want to find the 'ME' I used to be again. Being trapped in a body that does not work properly feels like being in jail, it feels like being an alien - it does not feel 'right'. The person I have become is not the person I see myself as and trying to make peace with the 'new' person I have become, is terribly difficult because I do not WANT to be this new person at all" "I lost my job and school scholarship as well as my normal lifestyle"	102 (43.6)
66. Positive strategies Hope/ hope for a cure or relief/ coping self statements/ acceptance	"I only hope that someday I can be free from pain" "I am far too young to let this get me down" "I have learned a lot about managing my pain over the last decade, and attitude, perceptions, beliefs and acceptance is everything" "My life won't be the same ever again. I have learned to accept that and now look for ways to rebuild my life" "Though pain has hindered me in many ways, I try to balance it out with other activities that are fulfilling" "I find it very difficult to accept the way I am now although I try hard to keep a positive attitude and do as much as I can for myself as possible" "Though I suffer much, I know there are others out there who're much worse than I am"	15 (6.4)
Sense of humour/ use of humour to diffuse embarrassment	"My prayer through all of this is that I do not lose by sense of humour or who I am to this pain. I have not"	2 (0.9)

Domain, facet and examples	Supporting quotations	Frequency (%)
DOMAIN III - LEVEL OF INDEPENDENCE **9. Mobility** Reduced mobility/ having to think before engaging in activity, something once taken for granted	“It prevents me from having the level of mobility I desire”	55 (23.5)
10. Activities of daily living Reduced functioning/ problems with ADL/ no longer enjoy or engage in physical activity/ cannot do ‘normal’ things/ no longer able to take care of the home/ unable to do share of chores/ having to pace activity/ not wanting to ask others for help with basic things/ do not want partner to have to compensate for them e.g. do things they cannot/ reliance on others	“Limits normal daily activities that ‘normal’ people enjoy” “I was previously VERY active and self-sufficient and I can no longer stand in one spot long enough to even do the dishes”	89 (38.0)
11. Dependence on medication or treatments Reliance on medication/ dependence on pain management techniques/ use of narcotics for pain relief/ constantly trying different treatments/ concern about amount of medication needed/ attitudes towards medication (e.g. stigma associated with the use of opiates)/ the expense/ cost of chasing a cure or relief/ issues around the legalisation of cannabis and use of cannabis	“I have had to depend on pain medications for the last three years”	5 (2.1)
12. Working capacity The ability to work/ feels better when able to work (mentally and physically)	“I had to give up a job that I loved doing” “My pain has forced me to stop working totally outside the home” “My pain keeps me from working as well as finishing my degree”	89 (38.0)
DOMAIN IV - SOCIAL RELATIONSHIPS **13. Personal relationships** Personal relationships with family and friends/ unable to get involved in family life/ family do not understand	“My family doesn’t always understand why I am unable to be there for them in the ways I used to be” “I am irritable with my family” “Pain affects the relationships I have with other people”	51 (21.8)
14. Social support Loss of independence/ having a supportive carer/ support from family	“My husband is wonderful, we have a college freshman daughter, she is also very supportive” “It has also affected my family although they have been extremely supportive”	16 (6.8)
15. Sexual activity Sexual activity is reduced and painful/ intimacy with partner	“I have no sex life (this is too painful)”	19 (8.1)

Domain, facet and examples	Supporting quotations	Frequency (%)
67. Communication Being understood/ believed/ listened too/ talking about pain/ avoidance of telling others/ hard to explain pain to others/ pain is 'invisible'/ embarrassment because not able to do things/ perception of others, perceived as malingering/ stigma of being a 'slacker' when not functioning well/ trying to appear 'normal' in social situations/ hide feelings from others to be accepted as 'normal'/ being treated differently/ chronic pain is over looked and misunderstood/ others do not understand the inconsistency of behaviour, i.e. being able to do something one day, but not the next/ avoid groups in case they annoy/ anger one/ others acceptance of methods of pain relief	"Everyone says I look fine, and they don't seem to understand the state I am constantly in" "Sometimes feel that my pain is not believed by others" "You try to make yourself presentable to go out into public and people look at you as if to say 'what is your problem? You look just fine to me'. Chronic pain is a silent demon"	51 (21.8)
68. Guilt and burdening others Guilt/ worry about the effects on others/ worry about burdening others/ value in relationships/ affects the ability to care for/ help others/ unable to support/ be there for others/ family suffer because cannot do what I once could/ strain on family/ affect on partner/ grumpy and irritable with others/ more information needed for society to prevent them making pain patients feel they are a burden on society	"I feel I have struggled with this injury and feel very guilty toward my family for not being able to always join them"	34 (14.5)
69. Relationship with health care providers Passed around from doctor to doctor/ belief that chronic pain is not recognised by the Government (UK)/ relationship with doctor/ dealing with doctors and health professionals/ support from health professionals/ loss of confidence in doctors/ struggle to get pain relief from doctors because of their fears of addiction/ reluctance to give pain relief/ being listened too, understood and believed/ lack of knowledge about specific conditions/ incompetent health professionals/ treated poorly by doctors and health professionals/ compassionate doctor/ doctors confuse pain with depression/ the need for information about cause of pain/ doctors in the US reluctant to give a diagnosis/ the medical profession ignores chronic pain/ anxiety about health professionals thinking 'it's all in your head'/ labelled as drug addict or malingerer by health professionals/ blame e.g. medical system	"I am really strong willed but the constant battle I have with the medical profession to be given better pain control is shocking" "If I am in pain I have to go without pain killers the next day because doctors are afraid to give proper pain control to chronic pain sufferers in case they get addicted to the medication" "It saddened, then enraged me to find that so many doctors will readily label a person as anything from a malingerer to a drug addict without a second thought!"	57 (24.4)
DOMAIN V - ENVIRONMENT **16. Physical safety and security**	None	None (0)
17. Home environment	None	None (0)

Domain, facet and examples	**Supporting quotations**	**Frequency (%)**
18. Financial resources Financial problems	"I am uninsured and have no money to pursue further treatment" "I am financially destitute"	12 (5.1)
19. Health and social care: availability and quality Difficulty getting benefits/ disability pensions/ feeling 'let down' by the system/ perceived support from the health and benefits system	"I am continuing to fight for the social security disability benefits I paid into for 25 years" "The medical profession have just left me to more or less get on with it"	13 (5.6)
20. Opportunities for requiring new skills and information Lack of information available on treatment and other issues/ active information seeking/ need for information generally/ informed self about condition to improve sense of control	"I also became very well informed about the condition and educated myself on the causes, symptoms and treatment options. This helped tremendously and gave me some measure of control over the situation"	3 (1.3)
21. Participation and opportunities for recreation and leisure Life limiting	"I am unable to do the things that I once did; I cannot participate in sports any longer" "Work induced pain restricts my ability to pursue personal interests" "Can't enjoy normal leisure activities"	94 (40.2)
22. Physical environments	None	None (0)
23. Transport Driving problems	"I am no longer able to drive"	18 (7.7)
Miscellaneous new themes Physical environment not geared up to deal with disability/ accessibility of the environment	"There are very few shops I can go into, most are access un-friendly"	1 (0.4)
Weather (facial pain and rheumatic conditions)	"It is worsened in cold weather, and in damp weather I have trouble with my lower back and hands due to arthritis" "When weather is cold or stormy I have pain more often"	7 (3.0)
DOMAIN VI – SPIRITUALITY/ RELIGION/ PERSONAL BELIEFS **24. Spirituality/ religion/ personal beliefs** Personal beliefs/ faith/ inner strength/ will/ the positive side/ positive thinking, learning experience, personal growth/ prayer and coping/ spirituality/ pray that will cope that day/ prayer/ emotional and spiritual needs/ self-determination	"My faith in God kept me going and gave me the confidence that I ultimately would find a solution"	13 (5.6)

4.4 Discussion

Respondents of the web survey elaborated upon a complex set of interrelated issues for each of the facets of QoL pertaining to pain. The responses covered diverse aspects of QoL and there was a high degree of concurrence between the views of those taking part. In general, support was found for the core WHOQOL facets and the 10 new facets of QoL. Although there was evidence for a small number of additional themes including eating and appetite, the accessibility of the environment being a barrier to mobility and the weather affecting pain, these were infrequently elicited. The theme about the weather was described by those with rheumatic conditions such as RA and facial pain conditions such as trigeminal neuralgia and thus can be said to be idiosyncratic to particular diagnostic groups, rather than people with CP in general. The areas of QoL identified by respondents provided further evidence of the multidimensional nature of each of the new facets of QoL pertaining to pain and discomfort. Given that no new areas of QoL pertaining to CP emerged from subsequent respondent completions, it was decided that data saturation was reached.

Generally, the spontaneous elicitations of respondents gave the sense of the global impact of the pain on a person's life, illustrated by the quotes supporting the general quality of life and health facet. Moreover, many comments seemed to capture the essence of the experience of living with CP by reflecting its all-encompassing nature. Furthermore, the narrative often illustrated the complexity and elaborateness of the new facets of QoL identified. For example, feelings of irritability, being short-tempered, a loss of patience and mood swings provided support for the different aspects of anger and frustration and the way in which this can impact on QoL.

The web survey results provided validation for the core WHOQOL facets of QoL. For example, for domain I, issues around pain and discomfort, energy and fatigue and sleep and rest were elicited by 16-26% of respondents, where pain and discomfort was most frequently mentioned. These physical health facets were expected and confirmed to be salient for people with pain, in addition to the two extra facets identified in the physical domain, flare-ups and pain relief. Flare-ups occur with varying frequency and this is reflected by its low frequency compared to pain relief. However, the experience or threat of a flare-up or temporary worsening of pain appears to impact on QoL. Echoing the findings reported in chapter three, the ability or inability to obtain pain relief have also been shown to be important to an individual's QoL, in addition to issues around the side effects of medication and the ability to find a physically comfortable position to be in.

The evidence suggests that the psychological domain requires the most elaboration in order to explain the effect of pain and discomfort on QoL, with the addition of five new facets which are anger and frustration, vulnerability/ fear/ worry, uncertainty, loss/ loneliness/ feeling alone and positive strategies. The content analysis revealed that all of these areas were represented in the web survey results. The most frequent of these were feelings of loss, loneliness and feeling alone. Respondents described the isolation and loneliness of living with pain and the losses associated with their experience. Feelings of uncertainty were also common and respondents described the difficulty of making plans because of not knowing how they will feel. Consequently, uncertainty does not describe a cognitive deficit, but a logistical practical one reflecting an uncertain future. Anger and frustration were also commonly reported by respondents and were often described as a loss of patience, feeling annoyed and short tempered. The vulnerability, fear and worry expressed by respondents covered a wide range of fears and anxieties specific to pain such as fear avoidance, that is, the fear of movement, worry about treatment and so on. Positive strategies, which include hope and humour, were the least frequently reported of the new facets. Hope was elicited more frequently than the use of humour and on the basis of this relatively low frequency, particular attention will be paid to the items addressing this facet and how they behave during further testing. Possible explanations for the relative low frequency of positive strategies are that depressed respondents might be less likely to express positive thoughts or emotions, and that given limited time and space to describe how pain affects their QoL, individuals taking part in research over the Internet might be less likely to talk about their positive experiences.

The third domain to be elaborated was social relationships. Three new facets were identified and are supported by the web survey data. These are communication, guilt and burdening others and relationship with health care providers. Reports of the increasing dependence on others was associated with the experience of guilt and perceptions of being a burden to others and of the new facets in this domain, this was mentioned the least. Communication relates to being understood, believed and listened to, ones ability to communicate ones feelings to others and to the notion of the invisibility of pain. Communication represents a heterogeneous facet and later stages of questionnaire development will determine whether it is conceptually sound, or whether it might be possible to integrate aspects of this facet into core WHOQOL facets. Of the new facets in this domain, a person's relationship with health care providers was mentioned most frequently. For example a belief that the medical profession ignores pain because they do not like to deal with things that they do not understand or know how to treat properly was evident. Related to this was the constant struggle to be understood and believed by health professionals in order to obtain the most effective treatment. There was evidence of a perception of a reluctance to prescribe opioid-based medications for fears of addiction, which has been demonstrated to be an erroneous perception (Schug, Merry and Aclanc, 1991; Passik and Weinreb, 2000). These issues support the notion that a person's interaction with health care appears to impact considerable on their QoL.

Evidence of the importance of these additional facets to people with CP may provide a basis for interventions designed to modify and improve QoL in these domains. In the physical domain, minimising flares and providing pain relief are already central goals of pharmacological and pain management interventions. However, in the psychological domain, five new facets provide additional targets and a structure for minimising the impact of pain on QoL. Moreover, the social domain provides a forum in which to explore the role of the interaction between patients and their social environment, particularly the importance of communication with significant others and health care professionals, and how all of these issues contribute to QoL.

The web survey results also provide evidence of the psychological processes used by people with pain and these are illustrated by the quotes representing the facets. For example, the use of positive strategies included hope for relief from pain, coping self-statements, a sense of mastery or control and acceptance of pain. Evidence of acceptance of pain was found in the positive strategies facet, which highlights an important process that might influence QoL outcomes. Given that acceptance was also found in the FG work reported chapter three, which concurs with evidence for the relationship between acceptance and adjustment to CP (McCracken, 1998), the relationship between acceptance and QoL is tested further in chapter eight. Educating oneself about the condition could be seen as a form of problem focused coping which enhanced a sense of life control and control over pain and its consequences and this is evidence of the importance of opportunities for acquiring new information and skills. There was also evidence for the perception of self-determination and strength in promoting faith in finding a solution, which can be seen as an aspect of the SRPB domain.

Processes identified in the discourse of the respondents also reflected the use of social comparison (discussed in chapter three), for example upward intrapersonal comparison where comparisons were made with a previous 'able' self. This is shown clearly by quotes supporting a number of facets including loss, loneliness and feeling alone, ADL and participation in and opportunities for recreation and leisure. These reveal the extent to which respondents were unable to engage in former activity levels and also a sense of loss of self, articulated as not being the person one once was. There was very little evidence of upward interpersonal comparison although support for the ADL facets shows use of comparison with what 'normal' people are expected to be able to do. The evidence for downward interpersonal comparisons was also scant, although there was an example of comparison with worse off others, which could be seen as a positive strategy to boost self-regard and QoL and to put one's situation in perspective. Web survey respondents did not use downward intrapersonal comparison by comparing their current self with a time in the past when they were more affected by their pain. This seemed to suggest a general dissatisfaction with their current pain relief and control, because they did not express a time when it had been worse.

4.4.1 Variation amongst respondents

Although a global sense of the domination and centrality of pain and its sequalae was expressed and the resulting inability to pursue or attain life goals because of the perception that pain 'ruled' a person's existence, there was variation in the contribution made by each respondent. This ranged from minimal comments about the global impact of their pain on QoL to long narratives describing its impact. There was tentative evidence that respondents with musculoskeletal conditions such as back pain tended to express more anger and frustration than other groups such as women with endometriosis, however, this requires further exploration. Legitimacy of 'invisible' or stigmatised conditions such as endometriosis or fibromyalgia was consistently expressed which reflects the social consequences of pain and the complex interplay between a person in pain and their social world. Specifically, anxiety was expressed around being treated seriously and not being dismissed by health professionals and others. For those without a definitive diagnosis or who have a condition labelled by society as having a strong psychological component, a struggle to establish legitimacy is conveyed. Another general observation was that some respondents appeared to give psychologically literate accounts providing explanatory theories of their experience. However, this was not typical, but could perhaps be part of a coping repertoire characterised by coping self statements and information seeking, or indeed be gleaned from extensive interaction with health care resources or attendance at a Pain Management Programme and so on. In light of these observations, elucidating the important emotional correlates of pain for different diagnostic groups could be useful in targeting psychosocial interventions.

There was some suggestion of cross-cultural differences in the data. An example of this was the difference between the National Health Service in the UK and the system of health care in the USA. Specifically, the health care system in the UK is free at the point of access, which contrasts with respondents from the USA who elicited comments about the difficulty obtaining narcotics and other medications for pain relief, which was accompanied by a degree of frustration. This was not a prevalent view held by UK respondents. Although respondents from both countries described their relationship with health care providers as important, the nature of this relationship was different. Related to this issue, comments made by respondents pertaining to financial resources differed, in that the cost of obtaining satisfactory treatment was an issue for people from the USA, but not for those in the UK. Although the sample does not allow for robust conclusions about cross-cultural differences to be drawn, this highlights the importance of contextual factors when considering a persons' QoL and of developing culturally appropriate items for outcome measures.

4.4.2 Contrasting the FG and web survey

The aim of this investigation was to provide evidence to support the facets identified by the FG work, to ensure that other important facets had not been overlooked. This is a novel and innovative approach to collecting data about the QoL of people with pain and provides an international data set. Moreover, the web survey provided anonymity and individuality of response in contrast to the face-to-face dynamic interaction and consensus of the FG's. Unlike FG participants, web survey respondents were more geographically dispersed and had no prior knowledge of the core WHOQOL domains and facets, which meant that comments were elicited spontaneously. In contrasting the sample, the web survey respondents were younger (44.15) than the FG participants (49.41) and a greater proportion were female. People with musculoskeletal conditions, such as LBP comprised the largest proportion of both samples although the FG participants had pain of longer duration. The main differences to emerge in comments addressing the question about QoL were those relating to the cross-cultural issues discussed above. Additionally, the frequency with which loss, loneliness and feeling alone was elicited amongst web survey respondents was greater than the extent of its coverage by FG participants. This could be explained by the characteristics of Internet users, but is nonetheless an important difference to emerge from the use of these diverse methods. Web survey respondents and FG participants used comparative strategies when articulating aspects of their QoL, although there was less evidence of upward interpersonal comparison, downward interpersonal comparisons and no evidence of downward intrapersonal comparison in the web survey data. Both samples used upward intrapersonal comparison frequently when describing what they were longer able to do, which has emerged as an important aspect of decision making about QoL. The group context of the FG may have promoted the use of comparative strategies such as downward interpersonal comparisons to boost self-regard and to show others in the group that they were coping. The need to express such strategies may have been less important for the individualised and anonymous nature of the web survey.

4.4.3 Critique

Potential drawbacks and assumptions relating to the qualitative data derived from this methodology must be considered. Firstly, the respondents were self-selected, that is, there was no control over who accessed the web survey and which individuals completed it. There is sufficient complexity in the questionnaire structure to make it difficult for any potential hoax respondents to complete it. Furthermore, although an increase in Internet use has been observed in many countries worldwide, there may be biases associated with the types of individuals who have access to, use and explore the Internet. Respondents were asked an open-ended question about how their pain affected their QoL and the response to this question was variable and the extent to which individuals elaborated on this concept varied, highlighting the drawbacks of unstructured methods. Consequently, if an aspect of QoL was not expressed, it cannot be assumed that this was not important, or indeed affected by a person's pain. For example, positive emotions were infrequently articulated, which does not demonstrate an absence of these emotions, but that these emotions were not salient at the time of completion. Additionally, it might reflect the tendency of people to describe the consequences of health conditions in negative ways. Several respondent narratives expressed suicidal thoughts, which are likely to represent a subset of depressed respondents who were able to express these thoughts and feelings through the relatively anonymous medium of the Internet. Given the anonymity of the responses it was not possible to give responses to people expressing such thoughts. Respondent generated approaches such as this have clinical value, given that patient priorities are reflected and this is a similar approach to the respondent-generated instruments discussed in chapter two, such as the SEIQoL, which asks people to state the five most important aspects of their QoL (McGee et al., 1991).

The order of questions may also have influenced responses since respondents had been primed with questions about their pain, which may have generated negative feelings and thus produced negative responses to the question about their QoL. There are a disproportionately large number of US and UK respondents in the sample, which will have introduced bias because there are well known cross-cultural differences in the experience and expression of pain (Sanders et al., 1992; Bates et al., 1995; Nelson et al., 1996) and consequently limits the extent to which cross-cultural conclusions can be drawn. Given the size of the sample representing other countries (n=17, 7.3%), making reliable comparisons or generalising to other cultures is not possible. Exploring the potential differences in QoL cross-culturally is a central aim of the WHOQOL work and exploring differences in the impact of pain on QoL is an important goal of future studies. As with any cross-sectional study, the data was only collected at one time point and provides a snap shot of one group of individuals' QoL. In general, these issues highlight some of the methodological challenges involved in conducting research using the Internet.

4.4.4 Conclusions

This work reinforces the notion of QoL as a multidimensional concept and complements and validates the FG work outlined in chapter three, by confirming the 10 new facets of QoL. Furthermore, data saturation improved confidence that nothing of importance had been missed during the FG's. The web survey reveals the way in which people from diverse cultural contexts with a wide range of conditions describe the impact of pain on their lives. The qualitative data can be used as contextual material to elaborate the definitions of the 10 new facets pertaining to the QoL of people with pain and discomfort. Using the Internet is a novel method for collecting data from people with health conditions from countries worldwide. Future work could expand the debate about computer-assisted technology and explore further the use of the Internet as a research tool for reaching a broad sample of people cross-culturally, withstanding the inherent drawbacks of using this type of sampling and methodology. Future research might therefore focus on minimising the limitations inherent in using the Internet to collect data and further explore cross-cultural differences in QoL relating to pain both within and between cultures. Given that there are now more than 30 language versions of the WHOQOL-100, replicating this work in other languages this is an important goal. The research reported in this and the previous chapter represents the preliminary stages of developing a PDM to be used in conjunction with the WHOQOL-100. Chapter five details the process of questionnaire development, including the construction of facet definitions and items.

Chapter five

Stages of Questionnaire Development I: Definition Construction and Item Writing

5.1 Introduction

Chapters three and four provided the empirical and conceptual foundations to the development of the pain and discomfort module (PDM) and provided evidence for the clustering of issues to become new facets of quality of life (QoL). The purpose of this chapter is to build on and expand the pain and discomfort focus group (FG) work and the web survey by describing the process of developing definitions pertaining to the 10 new facets and the construction of items (questions) relating to these definitions.

5.2 Methodology

5.2.1 Writing definitions for the new pain and discomfort facets

Each of the 24 WHOQOL facets is accompanied by a definition to describe and elaborate its meaning. The process of writing definitions to address the new facets followed the same basic structure as the core facets (an example is given in figure 5.1), which were developed through meetings of WHO consultants and field centre investigators, and through the FG work previously described (WHO, 1992; WHO, 1993). The WHOQOL facets were originally conceptualised as 'a description of a behaviour, a state of being, a capacity or potential, or a subjective perception or experience' (WHOQOL Group, 1995). Each facet was given a conceptual definition, a description of various indicators or dimensions along which a rating can be made, and a list of situations or conditions, at various levels of intensity, that might affect that facet (WHOQOL Group, 1995). Figure 5.1 gives the facet definition, examples and items for the pain and discomfort facet to illustrate this. The goal was to use the core definitions as a guide to conceptualise each new facet in a narrative description, to clarify its meaning and coverage, including what the items will attempt to address, what it relates to in terms of the subjective experience of the target group and to say something about why it was conceptually distinct from the core facets. Thus, the format of the new definitions is consistent with the core definitions. The contextual material from the FG work and the web survey informed the content and nature of the definitions.

5.2.2 Writing items for the new pain and discomfort facets

Items for the core WHOQOL were derived from the suggestions of health professionals and patients who took part in the FG's held in each of the field centres (WHO, 1993). Consistent with the WHOQOL Group protocol, following analysis of the transcribed FG's and construction of a definition for each of the 10 facets, the process of item writing was undertaken. The goal of this process was to write items pertaining to pain related QoL, based on the evidence provided by the FG transcripts. The phrasing of items used by FG members was used as far as possible to ensure that items were framed in a comprehensive way and are understandable by the user population. The criteria used for the development of the original WHOQOL-100 items used by the writing panel are detailed in table 5.1 (WHO, 1993). Based on this, items pertaining to the QoL of people with chronic pain (CP) should adhere to these criteria. Consequently, each facet definition is accompanied by a set of items generated with consideration of the criteria. Four items address each facet in the core WHOQOL.

Table 5.1 Criteria for the development of WHOQOL items

Be based as far as possible on the suggestions of patients and health personnel participating in the FG's
Give rise to answers that are illuminating about the respondents' **pain and discomfort related** QoL, as defined in this project
Reflect the meaning conveyed in the facet definition
Cover, in combination with other items for a given facet, the key aspects of the facet as described in the facet definition
Use simple language, avoiding ambiguity in terms of either wording or phraseology
Be shorter rather than longer
Avoid double negatives
Be amenable to a rating scale
Enquire about a single issue
Avoid any explicit reference point either in terms of time or in terms of some comparison point (for example, the ideal or before I was ill)
Be applicable to individuals **from the main diagnostic groups who have CP** and with a range of impairment
Be phrased as questions and not as statements
Reflect the typology of questions adopted for the project
Where possible items must be framed in a positive way

5.2.3 Derivation of items

FG participants found the task of generating questions pertaining to the new areas of QoL they had identified a challenge. Consequently, the process of item writing departed from the WHOQOL procedure and instead items were generated by using the language of participants and by using the core WHOQOL items as a guide to structure, length and so on. Furthermore, a form of triangulation was used, by utilising the items pertaining to pain and chronic illness from the original international pool of items (WHOQOL, 1993). Some of these items were similar to the items derived through the work reported here and thus provided a way of validating and improving the items generated. Those items that were most relevant to pain and discomfort where selected and items were excluded if they were repetitions of other items, the response scales did not match the items, they were too general or that they asked about 'how often' a person experienced something. This latter question type makes the assumption that the frequency of something affects a person's QoL, without enquiring as to whether a person is bothered by something. This assumption can only be made with aspects that are unambiguously problematic, for example, the presence of negative feelings such as anxiety or depression. This provided a rationale for excluding certain items and retaining others from the original WHOQOL work. Each new facet included at least five items to begin with in order to identify the best items from this pool during subsequent stages of development.

5.2.4 Likert scales

Each WHOQOL item is answered on five-point Likert response scale, where each scale point has a verbal descriptor. There are five such response scales that address; how much and how completely a person has experienced something, how satisfied, happy or good they have felt about a particular aspect of their life, how often they have experienced something, how poor or good something is and how important various aspects of their life are. The response scale type and anchor points are shown in table 5.2 (Szabo, Orley and Saxena, 1997). Work in each of the WHOQOL centres established the most suitable verbal descriptors corresponding to the '2', '3' and '4' scale points, which correspond to 25mm, 50mm and 75mm between the lower anchor point (0mm) and the upper anchor point (100mm) (Skevington and Tucker, 1999). Skevington and Tucker asked a quota sample of 20 people in Britain to assign 15 verbal descriptions to 100mm lines for each of the 4 types of response scale. The anchor points representing '1' and '5' had been agreed internationally by the WHOQOL Group. After mean and standard deviations (SD) had been calculated for each label, the label with the closest mean and smallest SD were selected for each scale point, that is, those words whose average ratings were closest to the scale points. This provided a set of 5-point interval response scales where the scale points are equidistant (Skevington and Tucker, 1999). Consistent with this item-scale format, appropriate response scales were added to the items pertaining to each new facet. This was done by selecting the scale that best fitted the nature of the question being asked, for example whether they were asking about the degree or extent to which an aspect of QoL is experienced, their capacity to experience something, the frequency of something or a person's appraisal or evaluation of an aspect of their QoL.

Table 5.2 Response scales used in the WHOQOL instruments (Szabo, Orley and Saxena, 1997)

Type	Anchor points	
Intensity	Not at all	Extremely
Capacity	Not at all	Completely
Frequency	Never	Always
Evaluation	Very dissatisfied	Very satisfied
Evaluation	Very poor	Very good
Evaluation	Very unhappy	Very happy
Importance	Not important	Extremely important

5.2.5 Importance items

It has been demonstrated (Skevington, O'Connell and the WHOQOL Group, 2004) that establishing the importance of an area of QoL to a person is an invaluable way of understanding a person's QoL in terms of the observed discrepancy between how a person rates a core item of QoL and the importance that individual attributes to it. Facets, rated by their corresponding importance item, must be rated at 3.0 of above on a five-point Likert scale to be considered for inclusion in a QoL instrument of this kind (Skevington et al., 1997). Despite inevitable individual variation, all facets in a generic QoL instrument such as the WHOQOL should be important to all potential respondents and not idiosyncratic to particular groups and Saxena and colleagues (2001) have demonstrated that all of the core facets are important to sick and well people. Consequently, in addition to writing items representing the new facets, a set of importance items were also written corresponding to each new facet as a way of ensuring that each facet is important to people with CP. As with the items representing the facets, the structure of the importance items was based on the phrasing and format of the core importance items. The importance items corresponding to each facet are shown in the results below. In subsequent stages of development, these importance items will be used to assess the importance of each new facet and to explore the discrepancy between the importance of an area of QoL and the extent to which it is compromised by living with persistent pain.

5.2.6 The pain and discomfort facet, an example

The definition describing the pain and discomfort facet in the core WHOQOL is shown in figure 5.1 (WHOQOL Group, 1995). Two examples and four items follow the definition. These items are comprehensive and are applicable to all individuals regardless of whether or not they have pain, consistent with the generic nature of the core WHOQOL. They address how often a person suffers pain, how much they worry about it, whether or not they can 'handle' pain and whether their pain prevents them from doing what they need to do. The item asking about whether a person can 'handle' pain is a good example of how items reflect the vernacular, however, it also shows the potential problems involved in translating instruments into different language versions, a problem that the WHOQOL Group has overcome by the method of simultaneous development in different cultural centres (The WHOQOL Group, 1994; Bullinger, 1994).

5.2.7 Refinement of the items

Following the process of item writing described above, the list of items was further refined based on the readability and face value of the items. Consideration was given to whether an item asked about an aspect of QoL in an unambiguous way and which items best asked about that particular aspect, and this was done by assessing the face validity and clarity of the items. It was also necessary to establish whether items would require reverse scoring depending on the valance of the item, that is, whether it was phrased positively or negatively. It is not always possible to ask about pain in a positive way, and thus for negatively phrased items, scores need to be reversed. Indeed, all the items representing the pain and discomfort, negative feelings and dependence on medication or treatments facets in the core WHOQOL require reverse scoring, as do a number of other items representing other facets. Eliminating any ambiguity at this stage was essential to prevent problems with scoring at subsequent stages.

Figure 5.1 Facet definition, examples and items for the pain and discomfort facet (WHO, 1995)

Facet 1. Pain and discomfort

This facet explores unpleasant physical sensations experienced by a person and, the extent to which these sensations are distressing and interfere with life. Questions within the facet include the control the person has over the pain and the ease with which relief from pain can be achieved. The assumption is made that the easier the relief from pain, the less the fear of pain and its resulting affect on QoL. Similarly changes in levels of pain may be more distressing than pain itself. Even when a person is not actually in pain; either through taking drugs or because the pain itself is by its very nature on and off e.g. migraine, his/ her QoL may be affected by the constant threat of pain. It is acknowledged that people respond to pain differently, and differing tolerance and acceptance of pain is likely to affect its impact on QoL.

Unpleasant physical sensations such as stiffness, aches, long-term or short-term pain, or itches are included. Pain is judged to be present if a person reports it to be so, even if there is no medical reason to account for it.

Examples

- A person with intermittent severe migraine with possible threat of severe pain as the major feature
- A person with rheumatoid arthritis.

Items

How often do you suffer pain?
How much do you worry about pain and discomfort?
How difficult is it for you to handle pain or discomfort?
How much do you feel that pain prevents you from doing what you need to do?

Importance item

How important to you is it to be free of any pain?

5.3 Results

5.3.1 Definitions, examples and items

In order to ensure consistency, the definitions, examples and items presented for each of the new facets follows the format of the core WHOQOL facets shown by the example of pain and discomfort in figure 5.1. The definitions are longer and more detailed than the core WHOQOL definitions in order to provide sufficient depth and to detail their conceptual distinctiveness. For each new facet, 2 or 3 examples are given to illustrate what the facet represents and these were based on the experiences of FG participants. The items pertaining to each facet and their response scales are tabulated below each definition and set of examples (tables 5.3- 5.12). The item code is given in the column on the right. When followed by an 'i' this indicates that the item was taken from the original item pool, but did not form part of the final core instrument (WHOQOL Group, 1993). All definition, example and item blocks are arranged under their parent domain. The facets have been allocated the numbers 60-69 to distinguish them from ongoing WHOQOL work on the development of other modules.

5.3.2 Domain I – Physical domain

Facet 60. Flare-ups definition

This facet describes the temporary worsening or exacerbation in condition that characterises living with long-term pain, and the extent to which these flare-ups are distressing and interfere with life. Items ask about the extent to which a person worries about, or is bothered by these flare-ups. It is assumed, but may not always be the case, that a flare-up will have a negative affect upon QoL. Fear of a flare-up may be as distressing as the pain experienced during a flare-up. Flare-ups may follow over-activity, an increase in psychological distress or may be experienced without any obvious aetiology and be quite spontaneous in presentation. Flare-ups are also characterised by living from one day to the next without knowing how much pain one will be experiencing, what one will be feeling or what one will or will not be able to do because of the pain. These flare-ups have implications for a person's QoL directly and more broadly, for example, through uncertainty, which is dealt with in 'Uncertainty' (facet 64).

The opposite of experiencing flare-ups would be a condition that does not have the temporary or severe worsening which characterises flare-ups, for example, living with a painful condition that is relatively stable or unchanging. This facet is conceptually different from the core pain and discomfort facet because it addresses a specific consequence of living with long-term pain, not the actual pain and discomfort *per se.*

Examples

- A person with chronic lower back pain who experiences a temporary worsening or flare-up following light exertion or lack of sleep.
- A person with chronic rheumatoid arthritis who experiences a flare-up following emotional distress, illness such as a cold or flu, in response to the changing seasons or without any apparent precipitating event.

Table 5.3 Items and response scales for flare-ups

How much	**Code**
1. To what extent do flare-ups affect your QoL?	(F60.1)
2. To what extent do you worry about experiencing a flare-up?	(F60.2)
3. How much are you bothered by flare-ups?	(F60.3)
4. To what extent does your pain vary over time?	(F60.4)
5. How much do changes in pain bother you?	(F60.5)
How important	
1. How important is it to you to be free from flares in your pain?	(Imp60.1)
2. How important is it for you to be free from changes in your pain?	(Imp60.2)

Facet 61. Pain relief definition

This facet is concerned with whether a person living with long-term pain is able to experience a reduction in perceived pain through the means that are available to them. Items ask about the extent to which a person is able to obtain relief from, or control pain and discomfort and the extent to which this contributes to a person's QoL, for example, through the use of medication, treatments, psychological techniques or any other available strategy, conventional or otherwise. This also includes a person's ability to find a physically comfortable position to be in, regardless of whether they are sitting, standing, lying down or engaging in activity. It is acknowledged that finding and remaining in a comfortable position is problematic for those with pain (particularly musculoskeletal in origin), who often have to keep adjusting their position. A person may still be in considerable pain, but a comfortable position is one that reduces any further discomfort and does not exacerbate existing discomfort. This facet also covers the broad range of side effects experienced by those taking medication or having treatment to control, reduce or assist management of pain. It includes any adverse physical, cognitive or psychological consequences of taking medication or having treatment and their relationship to a person's QoL. Items ask about the extent to which these side effects are bothersome, worrying or cause physical or psychological distress.

The key issue is whether a person perceives a reduction in, or feels able to control pain, and its relationship to QoL. Whether a person is able to obtain relief from pain is not covered by the core WHOQOL since it is specific to those who are experiencing pain and it would not be appropriate to ask a person not in pain this type of question. Similarly, it is distinct the core pain and discomfort item asking about whether a person is able to 'handle' pain because this implies coping with pain rather than pain control and relief specifically. This facet does not address a person's dependence on medication as the core WHOQOL covers this aspect of QoL.

Examples

- A person who has tried a new treatment, medication or strategy for the first time and experiences a degree of relief and enhanced control, regardless of the level of relief experienced.
- A person who is able to find a comfortable position by sitting in a particular chair, resting on an orthopaedic bed or using a particular type of pillow.

Table 5.4 Items and response scales for pain relief

How much	**Code**
6. To what extent do the treatments available to you offer you relief from pain?	(F61.1)
7. How much control do you have over your pain?	(F61.4i)
8. To what extent has having treatment improved your QoL?	(F61.6i)
9. How easy is it for you to get into a comfortable position?	(F61.7)
10. How much are you bothered by taking medication?	(F61.8)
11. How much are you bothered about the side effects of medication?	(F61.9)
How completely	
57. How well do you cope with your level of pain?	(F61.3i)
How satisfied	
63. How satisfied are you with your ability to obtain relief from pain?	(F61.2)
64. How satisfied are you with the control of your pain?	(F61.5i)
How important	
3. How important is it for you to be able to obtain relief from pain?	(Imp61.1)
4. How important is it to be able to control your pain?	(Imp61.2)
5. How important is it for you to be able to find a comfortable position?	(Imp61.4)
6. How important is it for you to be free from the side effects of treatment?	(Imp61.5)

5.3.3 Domain II – Psychological domain

Facet 62. Anger and Frustration definition

This facet describes the emotional responses to living with pain. Anger is usually experienced as extreme displeasure and may be a feeling or an expression. Anger may be an emotional reaction to the pain itself or more broadly, a reaction to the consequences of pain. It may be directed or expressed inwardly to the self, or outwardly to others, and may itself generate distress. Frustration is characterised by feelings of irritation, agitation and annoyance and may be a consequence of the pain itself or the consequences of what the pain prevents one from doing, that is, the pain may prevent one from achieving a desired or necessary goal. Frustration may result from being unable to control the pain, being unable to carry out activities of daily living (ADL) or by ones relationship with other people and so on. Of central importance is the presence or experience of anger and frustration and the consequences of this for the individual.

Questions are framed so as to address the extent to which anger and frustration are bothersome and interfere with everyday life. Anger and frustration are distinct from the item asking about the presence of negative feelings since they are the specific emotional consequences of living with pain. Consequently, they are not synonymous with depression, blue mood or sadness and may be experienced transiently or intermittently.

Examples

- A person with chronic low back pain may experience or express anger and frustration because they do not have a definitive diagnosis.
- A person with pain may be frustrated by unsuccessful attempts to achieve satisfactory pain relief.

Table 5.5 Items and response scales for anger and frustration

How much	**Code**
12. How much are you bothered by feelings of anger?	(F62.1)
13. How much do feelings of anger interfere with your every day life?	(F62.2)
14. To what extent do feelings of anger affect your relationships with other people?	(F62.4)
15. How much do feelings of frustration bother you?	(F62.6)
16. How much do feelings of frustration interfere with your everyday life?	(F62.7)
How often	
74. How often does your pain make you feel angry?	(F62.3)
75. How often does your pain make you feel irritable?	(F62.5)
How important	
7. How important is it for you to be free from anger?	(Imp62.1)
8. How important is it for you to be free from frustration?	(Imp62.2)

Facet 63. Vulnerability/ fear/ worry definition

This facet describes how people living with pain may feel vulnerable, fearful and worried. This may relate to physical or psychological aspects of a persons experience. For example, people may feel physically vulnerable in particular situations because their problems with mobility generate fear of further damage or injury. Similarly, fear of further pain or exacerbations of pain from engaging in activity may be experienced. Furthermore, a perception that others might criticise or challenge them may bring about feelings of vulnerability. This facet also addresses worries associated with living with CP. Worry might be quite specific or general depending on the context. For example, a person may have worries regarding the need to take medication. This may include the worry about the potentially adverse long-term affects of taking medication, the concern that medication may lose its efficacy over time or the concern about the social stigma attached to taking medication. Treatment beliefs and the lay referral network may be an important aspect of this facet, since they may serve to perpetuate any worries a person is having in the absence of professional advice.

The worries a person has about their pain and discomfort and its consequences are distinct from the presence of negative feelings. Vulnerability and fear are distinct from physical safety and security, mobility and negative feelings since they deal specifically with the emotional consequences and experience that characterises living with long-term pain, which these core facets do not capture.

Examples

- A person with rheumatoid arthritis who goes out shopping may feel vulnerable in a crowd of people where they could be knocked or bumped.
- A person with chronic lower back pain who fears certain movement such as bending or reaching.
- A person without a definitive diagnosis who worries about having a malignancy.

Table 5.6 Items and response scales for vulnerability/ fear/ worry

How much	**Code**
17. How much are you bothered by feelings of vulnerability?	(F63.1)
18. How much do feelings of fear bother you?	(F63.2)
19. How much do feelings of vulnerability interfere with your everyday life?	(F63.3)
20. To what extent do you feel threatened by the possibility of pain?	(F63.4i)
21. How afraid are you of experiencing pain?	(F63.5i)
22. Are you distressed by the fear of pain?	(F63.6i)
23. How much are you bothered by feelings of worry?	(F63.7)
24. How much do you worry about having treatment?	(F63.8)
How important	
9. How important is it for you to be free from feelings of vulnerability?	(Imp63.1)
10. How important is it for you to be free from fear?	(Imp63.2)
11. How important is it for you to be free from worry?	(Imp63.3)

Facet 64. Uncertainty definition

This facet is a higher order or cognitive process that is affected by living with CP, describing the uncertainty associated with living with a chronically painful condition. Uncertainty is a psychological construct to describe situations where the outcome is either not known or is outside of a persons control. For example, a person may be uncertain about whether they will always be in pain, about the efficacy of treatments or about whether they will be able to carry out a particular activity from one day to the next. More specifically, the future is uncertain. To make plans for the future a person must have a certain amount of control over whether it will be possible for them to carry out the planned activity when the time comes. It is not the process of making plans *per se* that is affected, but the ability to execute the plans at the time that one had intended. This uncertainty has an affect on a person's QoL through its personal and social consequences. As part of the adjustment process, it might be possible that the ability to make future plans becomes less important since it is not possible to do this any longer, for example, as a result of re-conceptualising inner standards and priorities through a response shift (discussed in chapter two).

Items addressing this facet ask about the extent to which uncertainty interferes with everyday life and satisfaction with the ability to make plans for the future. Although uncertainty is conceptualised as a negative experience, it is distinct from negative feelings because it is concerned with the awareness of an uncertain or less certain future and the extent to which this is bothersome and interferes with life.

Examples

- A person with a recent diagnosis is uncertain of their future, how quickly their condition will deteriorate and how their pain and disability will change their lifestyle.
- A person with pain may be reluctant to make plans to meet a friend in case they are not able to honour the arrangement.

Table 5.7 Items and response scales for uncertainty

How much	Code
25. How much does uncertainty about the future interfere with your everyday life?	(F64.2)
26. To what extent do difficulties with planning affect your everyday life?	(F64.4)
27. Does pain prevent you from doing what you want to do?	(F64.6i)
28. Does pain or discomfort limit your life?	(F64.7)
How completely	
58. To what extent does your pain prevent you from making plans?	(F64.3)
How satisfied	
65. How satisfied are you with your ability to make future plans?	(F64.5)
How often	
76. How often do feelings of uncertainty bother you?	(F64.1)
How important	
12. How important is it for you to be free from uncertainty?	(Imp64.1)
13. How important is it to you to be able to make plans for the future?	(Imp64.2)

Facet 65. Loss/ loneliness/ feeling alone definition

The facet is a psychological construct used to describe the emotional reaction to the absence of something that formerly belonged to somebody, for example, the loss of function, loss of mobility, loss of role, loss of social relationships. The emotional reaction to the absence of these is loss and the consequent disadvantages associated with this loss. It is the perceived negative consequences of this that may have an effect on QoL, including associated disability and being unable to carry out the activities that one once could.

This facet also describes the feeling of being lonely rather than being alone *per se*. Being alone assumes the absence of others, whereas being lonely or isolated implies an emotional reaction toward being alone. A person living with pain may feel that they are the only one suffering from pain or their particular condition and as a consequence feel isolated and lonely regardless of whether they perceive that they have good social support. It concerns feelings about ones emotional isolation from others and that one might be alone in ones suffering.

Items include the extent to which a person is bothered by not being able to carry out the tasks they were previously able to do. This can range from simple ADL to more complex activities such as playing sport or going to the theatre. This may be a form of intrapersonal social comparison (discussed in chapter three), that is, what one was able to do in the past acts as a reference point to what one is able to do now. This is often accompanied by thoughts about the repertoire of activities that one will not be able to do in the future (including catastrophic thoughts), although this facet does not specifically address the future. Other items address the extent to which a person feels lonely.

This facet is distinct from the ability to carry out ADL, mobility and so on because it addresses the sense of loss associated with the changes brought about by living with persistent pain. Furthermore, it is distinct from personal relationships and social support because it describes the social and or emotional isolation or loneliness that might be a consequence of living with pain, as it should not be assumed that 'being alone' *per se* has a negative affect on QoL.

Examples

- A person may no longer be able to fulfil their social or occupational role and may experience loss and isolation as a result of this.
- A person with rheumatoid arthritis feels that they are alone in their suffering.

Table 5.8 Items and response scales for loss/ loneliness/ feeling alone

How much	**Code**
29. How much are you bothered by feelings of loss?	(F65.1)
30. How much do feelings of loss interfere with your everyday life?	(F65.2)
31. To what extent are you bothered by not being able to carry out the activities that you used to do?	(F65.3)
32. How much are you able to carry out the activities that you once could?	(F65.4
33. To what extent do feelings of loneliness bother you?	(F65.6)
34. How much does being alone bother you?	(F65.7)
How completely	
59. How lonely do you feel?	(F65.5)
How important	
14. How important is it for you to be free from feelings of loss?	(Imp65.1)
15. How important is it for you to be able to continue carrying out the activities that you once could?	(Imp65.2)
16. How important to you is it to feel that you are not alone?	(Imp65.3)

Facet 66. Positive strategies definition

This facet is characterised by the ability to see the humorous side of events or experiences and also describes a form of optimism or expectation for the future that a person's situation will improve. These strategies may represent dispositional tendencies or, if they are effortful, coping strategies or processes. A sense of humour may be more characteristic of those who perceive themselves to be coping well or those who are at later stages of the illness trajectory or who have had a long 'pain career'. It incorporates those people whose QoL is enhanced by the ability to see the humorous side of their adverse experience. The concept of hope addresses the belief that, at some point in the future, there will be a possible cure or possibility of pain relief and it is a form of optimism that the future may be pain free. This might take the form of a new drug, therapy or novel approach that has not yet been tried by the person with pain. For example, a person might hope that there will be a cure for their condition, a pill that will take their pain a way or that they will not continue to lose their function or mobility. In the absence of hope an individual might experience hopelessness. It is possible that this would occur in a subset of clinically or sub clinically depressed patients and people experiencing suicide ideation. The opposite of hope is resigned acceptance that the person will always be in pain.

Items address how much hope and humour helps people to deal with their problems and how hopeful and optimistic people feel about the future. Although it is not assumed that these represent adjustment or adaptation, hope and humour are conceptualised as positively valanced strategies. Positive strategies are distinct from the core positive feelings facet because they represent specific beliefs and strategies held and used be people with pain rather than the general experience of positive feelings.

Examples

- A person may be able to find humour in what they are unable to do for themselves.
- A person with rheumatoid arthritis might hope that the current advances in medical technology and research will bring about a cure for their condition.

Table 5.9 Items and response scales for positive strategies

How much	Code
35. How much does humour help you to deal with your problems?	(F66.2)
36. How much do you hope for relief from pain?	(F66.3)
37. How much does hope for relief from pain improve your QoL?	(F66.4)
38. How much do you experience feelings of hope?	(F66.5)
39. How hopeful and optimistic do you feel about the future?	(F66.6i)
40. How much does hope and optimism help you to deal with your problems?	(F66.7)
How often	
77. How often are you able to see the humorous side of things?	(F66.1)
How important	
17. How important to you are feelings of hope?	(Imp66.1)
18. How important to you is having a sense of humour?	(Imp66.2)

5.3.4 Domain IV – Personal/ social relationships domain

Facet 67. Communication definition

This facet concerns living with an invisible condition and the consequences this has for people living with pain. As pain is not visible to others, communication encompasses the extent to which a person feels that the people around them understand them, and the extent to which this affects their QoL. It includes whether a person feels that others understand the nature of their condition and the extent to which it impacts on their lives. This is also concerned with whether the person with pain feels that others listen to them in order to facilitate that understanding. Related to this is the ability of somebody to communicate their feelings and needs to other people and the extent to which any difficulties affect a person's QoL. This might include whether somebody feels able to talk about their pain to others, whether somebody is able to convey to another person how they are feeling as a consequence of having pain, whether a person feels comfortable to do so, and whether they have the psychological or cognitive resources to do so. This facet also covers whether a person is able to communicate their needs to the significant people around them. However, no assumption is made about whether or not communicating feelings is beneficial or not. Integral to this facet is the value the person with pain places on how other people see them and how this affects their QoL. The perceived views of others towards self are an integral part of identity and can have an impact on a person's QoL.

The opposite of aspects of communication and identity, would be having an illness or condition that others can see clearly and where the physical signs 'speak for themselves' or a situation where a person feels that the significant people in their life understand and respect the consequences that pain has on their lives. For example, it would be clear to people that a person with a leg in plaster, would have a broken leg, and people would react accordingly. This facet also highlights the limited public understanding of chronically painful illness, which is in conflict with the acute medical model of curing non-malignant disease or relieving pain. The distinctiveness of this facet derives from its specific focus on the invisibility and communicative aspects of pain and not just on personal relationships or perceptions of support.

Examples

- A person with Fibromyalgia does not appear to have any external physical signs of illness that communicate to others that they are in pain.
- A person may feel that a significant other (SO) or employer or work colleague is not listening to them or understanding the nature of their condition or the issues that relate to living with persistent pain.
- A person living with pain may find it difficult to communicate to their partner that they are suffering or find the right words to convey how they are feeling and what their pain is like.

Table 5.10 Items and response scales for communication

How much	**Code**
41. How much are you bothered by the fact that other people cannot see the extent of your pain and suffering?	(F67.1)
42. To what extent does your pain affect your relationships with other people?	(F67.2)
43. How much do you feel that other people recognise your condition and the consequences it has for you?	(F67.5)
44. To what extent are you bothered by any difficulties in communicating your feelings to others?	(F67.8)
45. How much are you concerned about how other people see your condition?	(F67.10)
46. How much do you feel that your health interferes with your personal relationships?	(F67.11i)
47. How much are you concerned about society's attitude toward how you use health and social care?	(F67.12)
How completely	
60. To what extent do you feel that other people appreciate the nature of your condition?	(F67.3)
61. To what extent do you think people understand and acknowledge your condition?	(F67.4)
How satisfied	
66. How satisfied are you that other people recognise your condition?	(F67.6)
67. How satisfied are you with your ability to communicate your needs to other people?	(F67.7)
68. How satisfied are you with your ability to express your feelings?	(F67.9i)

How important	
19. How important is it to you that people cannot see your pain?	(Imp67.1)
20. How important is it to you to feel that other people understand your pain?	(Imp67.2)
21. How important is how other people see your condition?	(Imp67.3)
22. How important is it to be able to communicate your feelings to others?	(Imp67.4)
23. How important are the attitudes of others to your use of health and social services?	(Imp67.5)

Facet 68. Guilt and burdening others definition

This facet describes a higher order psychological feeling or process associated with a social awareness. Generally, a person who experiences guilt may feel that they are to blame or have done something wrong. A person may experience guilt for numerous reasons because of their pain, although in this context, it is the guilt generated by having pain and the awareness of ones relationship to and with others. For example, guilty feelings may result from becoming increasingly dependent on a SO or because of the inability to fulfil the expectations of others. Guilt might be experienced because the person with pain may feel responsible for the changes to the lifestyle of the SO or because they feel that they have let somebody down. Consequently, people with pain may become concerned about their increasing dependency on SO's and perceive that they have become a burden on others. This perceived burden emerges as a consequence of no longer being able to do certain tasks for oneself or feeling that one has become emotionally dependent and so on, regardless of whether the carer actually perceives that they are a burden. This facet incorporates how a person perceives their condition or changed health status has affected the significant people in their life.

Guilt is distinct from the presence of negative feelings because for the person with pain, the guilt experienced by them is in the context of their personal relationships and an awareness of the effect their pain has on others. For this reason, guilt and burdening others is placed within the social relationships domain.

Examples

- A person with lower back pain may feel guilty that they are unable to go on holiday with their partner or spouse because they are not well enough.

- A person with rheumatoid arthritis may feel guilty about their increasing dependency on their carer because of concern that their reliance is becoming a burden.

Table 5.11 Items and response scales for guilt and burdening others

How much	Code
48. To what extent are you concerned about burdening others?	(F68.1)
49. How much do you worry about the effect your pain has on others?	(F68.2)
50. How much are you bothered by feelings of guilt?	(F68.3)
51. How concerned are you that you do not have enough resources to provide for others?	(F68.5i)
How satisfied	
69. How satisfied are you with your ability to support others?	(F68.4i)
How important	
24. How important is it to be free from feelings of guilt?	(Imp68.1)
25. How important is it to feel that you are not a burden to others?	(Imp68.2)

Facet 69. Relationship with health care providers definition

This facet deals with a person's relationship with their doctor/s, the other health care professionals that a person with pain has regular contact with and their relationship and perceived support from the health care system as a whole. This is concerned with the interpersonal relationship between a person and their health care providers, including whether a person feels supported, listened to and understood by their doctor/s and other health care professionals. Also included is whether a person has access to, or feel that they are given enough information about their specific condition and the available treatments. This need for information is distinguished from general everyday information because it asks specifically about the extent to which a person feels that they have enough information about their condition or pain. This information may be delivered from health care professionals or, if this is lacking, through self-teaching and use of libraries and new technology such as the Internet. It is the person's perception of whether or not they have enough information regardless of the fact that this might be a function of individual differences such as being a blunter or a monitor, that is, they may desire more or less information.

A persons relationship with health care providers is specific is people with pain because they are a group that utilise extensive resources through the investigation of their condition and subsequent use of different treatments, because of the nature of their ongoing condition. Related to this, people with pain may also be dependent on the health and social care systems for the continual management of their pain and may feel that they are caught up in a stream of referrals leading to continual reliance on the system, including the associated waiting involved for appointments and treatments. This facet also concerns a person's access to, and use of, complementary or alternative therapies or medicine and the extent to which this contributes to a person's QoL. This includes any thing outside of the conventional medicine remit and any non-prescribed therapy or medication, for example, Reiki, homeopathy, chiropractic, Chinese medicine and may also cover the use of alcohol or illegal substances such as cannabis to bring about relief and so on (non-medicinal substances).

Items ask about the extent to which a person feels supported by their doctor/s and other health care professionals and the extent to which they are satisfied with these relationships. This is contrary to the aim of some treatments, for example PMP's, whose aim it is to foster self-care, independence and self-management through effective health care interactions in order to prevent further dependence.

Examples

- A person with chronic musculoskeletal pain feels that they have a good, supportive and understanding relationship with their doctor.
- A person with chronic lower back pain feels that they have been dismissed by the system and that their problem has not been investigated thoroughly.
- A person feels that they are caught up in the medical system waiting for appointments and passed through a stream of referrals.

Table 5.12 Items and response scales for relationship with health care providers

How much	Code
52. To what extent do you feel supported by the health service?	(F69.3)
53. To what extent do you feel that you are dependent on health and social services?	(F69.4)
54. How much do you benefit from the use of complimentary therapies?	(F69.6)
55. To what extent does the use of complimentary therapy contribute to your QoL?	(F69.7)
56. How much access do you have to the information you require about your health?	(F69.9)
How completely	
62. To what extent do you have access to information about the range of available treatments?	(F69.8)
How satisfied	
70. To what extent are you satisfied with your relationship with your **doctor/s**?	(F69.1)
71. To what extent are you satisfied with your relationship with those health professionals that you have regular contact with?	(F69.2)
72. How satisfied are you with the support you receive from the **medical** service?	(F69.5)
73. How satisfied are you with the information that is made available to you about your health?	(F69.10)
How important	
26. How important is it to you to have a good relationship with your doctor/s?	(Imp69.1)
27. How important is it to you to have a good relationship with your health care professionals?	(Imp69.2)
28. How important is it to you to feel supported by the health service?	(Imp69.3)
29. How important is it for you to be free from dependency on the health service?	(Imp69.4)
30. How important to you is the availability of non-prescribed and complimentary therapy?	(Imp69.5)
31. How important is it to have adequate information regarding your condition and the availability of treatment for it?	(Imp69.6)

5.3.5 Pilot pain and discomfort module

The items generated during this stage formed the pilot PDM. Items were presented in response scale blocks to avoid potential confusion and appropriate instructions were added to each section, corresponding to the WHOQOL-100 instrument. Table 5.13 shows the number of items by response scale type, giving a total of 108 items.

Table 5.13 Number of items in the PDM by response scale block

Response scale	No. of items
How much	56
How completely	6
How satisfied	11
How often	4
Total	**77**
Importance	31
Overall total	**108**

5.3.6 Hypothesised relationships

Table 5.14 outlines the hypothesised relationships between the new and core WHOQOL-100 facets. These *a priori* predictions will be tested during the cross-sectional survey reported in chapter seven, where the analysis will explore the correlations between the new and core facets. It is hypothesised that each of the new facets are distinctive and sufficiently multidimensional to stand alone within the domain to which they have been allocated. However, if during subsequent analysis any of the new facets correlate highly with the core facets (>.70), they will be deleted, as this is evidence of a conceptual overlap suggesting that the core facets already account for that particular aspect of QoL.

Table 5.14 Hypothesised relationships between new and core facets

Facet	Core facet hypothesised to be highly correlated with
Flare-ups	1. Pain and discomfort, 9. Mobility, 10. ADL
Pain relief	1. Pain and discomfort, 9. Mobility, 10. ADL and 11. Dependence on medication or treatments, 19. Health and social care: availability and quality
Anger and frustration	8. Negative feelings and 13. Personal relationships
Vulnerability/ fear/ worry	8. Negative feelings, 9. Mobility, 16. Physical safety and security
Uncertainty	2. Energy and fatigue, 8. Negative feelings, 9. Mobility, 13. Personal relationships, 19. Health and social care: availability and quality, 21. Participation in and opportunities for recreation and leisure
Loss/ loneliness/ feeling alone	8. Negative feelings, 9. Mobility, 10. ADL, 13. Personal relationships, 14 Practical social support
Positive strategies	4. Positive feelings, 24. Spirituality, religion, personal beliefs (SRPB)
Communication	13. Personal relationships, 14. Practical social support
Guilt and burdening others	8. Negative feelings, 9. Mobility, 10. ADL, 12. Working capacity, 13. Personal relationships, 14. Practical social support, 18. Financial resources
Relationship with health care providers	5. Thinking, learning, memory and concentration, 11. Dependence on medication or treatments, 18. Financial resources, 19. Health and social care: availability and quality, 20. Opportunities for acquiring information and skills

5.4 Discussion

This chapter reported the process of constructing definitions and writing items for the 10 facets of QoL identified by the FG's and presented each of these facets with their corresponding definition, examples and items. Data derived from people with pain was used to inform the content of the definitions, provided specific examples illustrating the definitions and was used to construct items pertaining to the QoL of people with pain. The development work aimed to be as true to the language used by FG's participants as possible, to ensure that items adequately and appropriately addressed the underlying concepts, whilst taking account of the WHOQOL criteria for developing items. The definitions elaborate each facet concept and provide a foundation from which to further conceptualise and operationalise their meaning. The items reveal the complexity of the concepts underlying the 10 new facets by tapping into the semantic attributes of the definitions. This process derived 77 items and 31 importance items, giving a total of 108 items, which represents an item pool to be reduced in subsequent stages. This formed the pilot PDM, which was prepared for the preliminary pilot work described in chapter six.

Each new definition addressed how that facet differed from the core facets of QoL, as part of justifying its conceptual distinctiveness, although it is anticipated that some of the new and core facets will be highly associated either due to their conceptual similarity or because these variables covary to a high degree (Melzack and Katz, 1994). For example, **flare-ups** are hypothesised to correlate with pain and discomfort because of the semantic proximity of the underlying concepts and because flare-ups have been shown to be an integral part of the physical experience of pain and discomfort. In addition to pain and discomfort, this facet is likely to correlate with mobility and ADL because severe flare-ups are likely to affect these facets of 'level of independence' and vice versa. **Pain relief** is also likely to be closely associated with pain and discomfort because achieving pain relief is hypothesised to be an important component of the physical domain. The extent to which pain relief is achieved may be highly associated with mobility, ADL, dependence on medication or treatments and availability and quality of health and social care. Furthermore, pain relief is also closely related to a person's relationship with the health care system and their dependency on pain relieving drugs.

Anger and frustration may be most closely associated with negative feelings. Anger is one of the five basic emotions and both anger and frustration were negative experiences for the study participants. This facet may also correlate with personal relationships because of the interpersonal consequences of anger. Indeed one of the items addressing anger and frustration asks about the affect of anger on relationships. The **vulnerability/ fear/ worry** facet is predicted to be associated highly with negative feelings. Fear is also a basic emotion and vulnerability and worry are better conceptualised as higher order negative affectivity. Given the consequences of fear and vulnerability, including the avoidance of movement, this may also correlate with the mobility facet and physical safety and security. **Uncertainty** has been conceptualised broadly because of its diverse consequences for a person's QoL and consequently is hypothesised to be strongly associated with energy and fatigue, negative feelings, mobility, personal relationships, availability and quality of health and social care and participation in and opportunities for recreation and leisure.

Loss/ loneliness/ feeling alone have been conceptualised as negative experiences and so are predicted to be highly associated with negative feelings. Given the social aspect of loneliness, it could also be related to personal relationships and practical social support because this facet is related to the presence or absence of meaningful social interaction. Moreover, given the loss that living with CP engenders, it could also be associated with mobility and ADL because of its impact on level of independence. **Positive strategies** are predicted to be closely associated with positive feelings and may also be viewed as coping strategies by people with pain and discomfort. Hope and optimism are also likely to be related to the spiritual dimension of QoL and consequently, are predicted to correlate with SRPB.

Communication addresses a person's relationship with other people and is therefore likely to correlate with personal relationships and social support, although the items addressing communication address the invisibility of pain and the extent to which people feel able to communicate their feelings to others which is distinct from asking about the extent to which people feel supported by others. **Guilt and burdening others** is hypothesised to correlate with personal relationships because of the social context of this type of guilt. However, it may also be associated with negative feelings because both guilt and perceptions of burden can be seen as negative experiences, although they are higher order, more complex emotions than those already covered by negative feelings. This facet may correlate with facets in the level of independence domain such as mobility, ADL and working capacity because a reduction in mobility and limited working capacity may lead to an increased reliance on others. Practical social support and financial resources may also be highly associated with guilt and burdening others because of having to rely upon others.

Relationship with health care providers may be closely related to the availability and quality of health and social care because it addresses the relationship of people with CP to health care providers in greater detail. This facet may also correlate with thinking, learning, memory and concentration because of the need and receipt of health care information, dependence on medication or treatments because of the provision of these by the health service, financial resources where individuals have to pay for treatment, for example, alternative therapies and opportunities for acquiring information and skills because of the availability of information about a person's health condition.

Although relationships between the new and core facets have been hypothesised, the new facets have distinct conceptual qualities and are not synonymous with the core facets that they are predicted to correlate highly with because they represent specific consequences of living with persistent pain. This was demonstrated through the elaborate definitions which address how each facet differs from the core WHOQOL facets. Consequently, each PDM facet definition is longer than the core definitions to ensure that the facets were adequately elaborated and distinguished from core facets. Subsequent testing will elucidate the relationship between new and core facets. Each facet should correlate more highly with the domain within which it is placed and with the core facets that comprise that domain than with other domains and the facets within them.

This chapter has consolidated and defined the concepts identified and discussed in chapters three and four and the PDM facet definitions will provide a useful addition to the items that represent them to allow researchers using the PDM to have a detailed account of the way each facet has been conceptualised. Given that the definitions elaborate the impact of CP of QoL, they may also provide a useful framework for conducting interviews with people with CP, although this was not the intended purpose. In general, such methods of developing definitions and items are advantageous because they derive from the experience of patients and consequently this increases the acceptability, comprehensibility and face validity of the items representing these facets, which will be tested in the next stage. Chapter six reports the use of a relatively new technique in health care research based on cognitive aspects of survey methodology, to modify and eliminate items in preparation for the cross-sectional survey to pilot the new PDM (chapter seven) and the longitudinal survey to field-test a further refined PDM to elucidate its psychometric properties (chapter eight).

Chapter six

Stages of Questionnaire Development II: Preliminary Pilot Work using Cognitive Interviewing

6.1 Introduction

The previous chapters reported on the preliminary stages of developing facets of quality of life (QoL) for a pain and discomfort module (PDM) for the WHOQOL-100 (chapters three and four), including the construction of definitions and questions (items) addressing these facets (chapter five). This chapter reports on the preliminary pilot work to determine the initial appropriateness and feasibility of the PDM in patients with chronic pain (CP).

6.1.1 Cognitive aspects of survey methodology

There are now many questionnaires assessing QoL and one of the challenges to instrument development is that respondents bring many varied and different meanings to the questions derived from their experiences, personal history, culture and so on. For this reason, those who administer questionnaires do not always appreciate or monitor the processes and influences that contribute to the decision to choose a particular score or response. Given the need for instruments that are relevant, comprehensive and meaningful to the intended users, cognitive aspects of survey methods (CASM) (Jobe and Mingay, 1991; Tanur, 1992; Schwartz and Sudman, 1996; Greenhalgh, 2001) are a relatively new addition to the field of outcome measurement. Cognitive interviewing (CI) represents collaboration between cognitive psychology and survey researchers. It provides a way of pre-testing new survey instruments and has been used in the development of health status and QoL scales and measures (Meadows et al, 1998; Barofsky, 1996), particularly in the generation of disease or condition specific QoL scales (for example, Niero et al., 2002; Rouland et al., 2002).

Methods such as these are necessary because the data obtained from a given questionnaire is only as good as the instrument itself (Collins, 2000). Moreover, it allows us to find out how people make judgements about their QoL. QoL instruments must be reliable, valid and sensitive to changes in condition for them to have full practical or clinical value and such methods enable us to collect high quality data, which is a necessary feature of any research or clinical trial.

Cognitive interviews or verbal protocols were first used by cognitive psychologists such as Ericsson and Simon (1980) to develop tests of information processing. These methods rely heavily on the ability of respondent to be introspective and verbalise their thoughts. Loftus proposed that an examination of the verbal reports about thought processes or protocol analysis would be a way of looking at how people answer survey questions (Loftus, 1984). In such an examination, participants are asked to 'think aloud' whilst completing a survey instrument. Probes can be used to encourage participants to articulate their thoughts such as asking them to tell the researcher what is going through their mind (Ericsson and Simon, 1980) or what a question means to them (Willis, 1993; Belson, 1981). Such probes allow the researcher to test comprehension and meaning of questions.

The procedures used by CASM are underpinned by the question and answer model from cognitive psychology, which represents a four-step process that gives us greater access to how respondents answer questions (Tourangeau, 1984, 1987; Tourangeau and Rasinski, 1988). The first stage is comprehending the question, secondly retrieving the relevant information, thirdly making a judgement about the information and fourthly responding to the question (Tourangeau, 1984, 1987; Tourangeau and Rasinski, 1988). Although these stages can occur in seconds and without much conscious thought, they nonetheless help us to conceptualise the process of responding to questionnaire items.

CI allows respondents to talk through how they answer questions, thus offering a distinct advantage over traditional methods, which only allow us to quantify any changes to the instrument. This qualitative method also provides a rigorous way to pre-test instruments before they are subject to traditional methods espoused by survey researchers and provides greater detail on the strengths and weaknesses of individual questions (Collins, 2003). As Bjorner and colleagues point out, cognitive assessments and traditional psychometric techniques are compatible with, and can offer benefits to, each other (Bjorner, Ware and Kosinski, 2003), as this method compliments traditional psychometric techniques to ensure that questions are measuring what they intend to measure.

There are numerous methods and techniques for applying CASM's (Jobe and Mingay, 1989). The research reported here adopts concurrent 'think alouds', which allow respondents to verbalise their thoughts whilst answering questions, and paraphrasing, which allows respondents to restate the question in their own words. Concurrent 'think alouds' benefit from being a more complete report of cognitive processes, although this simultaneous process itself may influence cognitive processes. Conversely, retrospective 'think alouds' or cognitive debriefing asks participants to recall what they were thinking after the task and do not have the problem of influencing the process itself, but the report itself is more subject to memory biases and so on.

CI has been used extensively to develop health or QoL measures (Shaw et al, 2001; Jacoby et al, 2000), for example in the development of a symptom and impact diary for people with multiple sclerosis, which allowed problematic questions to be identified and modified (Greenhalgh et al., 2000). Respondent quotes also supported the notion that individuals reconceptualise their inner standards when thinking about their current health in a response shift (Sprangers and Schwartz, 1999) and provided insight into how this occurred 'through reframing or reordering ones expectations of what one wanted to do to be consistent with what one was capable of doing'. Given that validity can be compromised if respondents are unable to comprehend the meaning of questions and because people change their inner standards during treatment, complimenting CI with traditional psychometric evaluation can enhance the validity of measures (Greenhalgh et al., 2000).

Despite the utility of CASM's, such methods have been criticised because there are not shared standards for carrying out cognitive interviews (Willis, DeMaio and Harris-Kojetin, 1999). Consequently, if different protocols and techniques are being used, researchers may be deriving different results. However, there are clear advantages of selecting the techniques that are most appropriate for the type of instrument being developed. The issue of standardisation is also relevant to how data from cognitive interviews is coded. Numerous coding procedures and frames have been developed to allow researchers to make sense of the types of problems emerging and to quantify the data, although there is little consensus about how best to code the information derived from these methods (Tourangeau, Rips and Rasinski, 2000). Where verbatim transcription can be laborious and unproductive, one approach has been to summarise the information in a 'gist' transcript and then to provide a summary of problems for each question, although this may generate a potentially non-quantitative, impressionist analysis of the results (Tourangeau, Rips and Rasinski, 2000). Conrad and Blair (1996) defend the approach by developing coding frames that allow for rigorous analysis of results. Coding frames tend to distinguish between problems with different components of the response process, for example, comprehending the question, memory, judgment and response formulation. Different methods may also identify different problems (Presser and Blair, 1994), whilst not necessarily providing solutions (Tourangeau, Rips and Rasinski, 2000). A further criticism is the low reliability based on a small number of interviews (Tourangeau, Rips and Rasinski, 2000), however it has been suggested that CI is usually carried out with small samples, selected not for representativeness, but to account for the ways in which different characteristics can influence cognitive processes (Campanelli, 1995).

It is also possible that the process of measuring the cognitive strategies of respondents changes them, known as the Heisenberg effect, and caution should be applied in the use of probes facilitating the verbal responses of respondents, to avoid putting words into their mouths (Sudman et al, 1996). Avoiding such probes may reduce any possible artefacts although this may prove to be difficult when respondents are less educated or less verbally articulate. However, inclusion of such individuals in the process is essential if the instrument is to be used by a wide range of people. Other possible sources of measurement error include prestige bias, where respondents are keen to show them selves in a positive light or where they are reluctant to give answers they believe are socially undesirable. Questions may also be seen as threatening (Bradburn et al, 1979, Sudman et al, 1996). These possible sources of measurement error and bias remind us that the process of completing a questionnaire takes place and is affected by contextual factors. In general, the use of CASM's improves the face validity of instruments and gives access to otherwise inaccessible information.

The WHOQOL was designed to allow the development of modules pertaining to specific conditions such as CP, to increase the instruments' specificity and sensitivity. To date, the technique of CI has not been used in its fullest sense in the development of the WHOQOL, although during the process of item design, the WHOQOL Group used expert panels, including lay people, to select items (The WHOQOL Group, 1995), and therefore carried out this process in a limited way. Such methods have not yet been widely applied to the development of instruments assessing the impact of pain, highlighting the importance of applying such methods to new patient populations. However, these methods are being used more frequently in the development of instruments purporting to assess QoL, providing an important justification for applying such methodology to the WHOQOL, given the value of utilising and integrating the most current approaches into its protocol. Having introduced and discussed CASM's, this chapter describes the preliminary pilot work using CI, where patients are asked to 'think aloud' whilst completing the PDM to enable items to be selected for further piloting using more traditional psychometric methods.

6.2 Aims of cognitive interviewing

- To establish whether people with CP are able to complete the PDM without guidance.
- To carry out concurrent 'think alouds' allowing participants to verbalise their thoughts whilst they answer items.
- To highlight if there are particular items that are difficult to comprehend or answer and the reasons why this is the case.
- To examine how items are interpreted to check for consistency between participants by asking them to paraphrase, that is, restate the question in their own words, allowing us to determine if an item has a shared meaning.
- To determine whether items address the underlying concepts (facets of QoL).
- To select items for further pilot testing.

6.3 Method

6.3.1 The pilot PDM

As described in chapter five, the pilot PDM consisted of 108 items, which were presented in response scale blocks with appropriate instructions, corresponding to the layout and structure of the core WHOQOL-100. The items pertaining to pain-related QoL were based on the evidence provided by the FG transcripts reported in chapter three. The phrasing of items was based on the accounts of FG members and the criteria used for the development of the original WHOQOL-100 items was utilised to ensure that items were framed in a comprehensive way (WHOQOL Group, 1993). Items should also be applicable to the main diagnostic groups who have CP and with a range of impairment, such as people with chronic low back pain (CLBP) or rheumatoid arthritis (RA) and so on. As described in detail in chapter five, appropriate five-point Likert response scales were added to the items pertaining to each facet, corresponding to intensity, capacity, frequency, evaluation and importance (Szabo, Orley and Saxena, 1997). Each new facet was represented by a minimum of five items to begin with, in order to identify and select the best items from this pool (detailed in chapter five). In addition to the items representing the new facets, importance items were also written corresponding to each facet.

6.3.2 Sample

Nine people with chronic musculoskeletal pain were recruited from two hospitals in southwest England (7 people from the Pain Clinic at the Royal United Hospital (RUH) and 2 from the Royal National Hospital for Rheumatic Diseases (RNHRD)). Such sample sizes are sufficient for this methodology providing that saturation is reached, that is, a degree of confidence that no new issues are emerging from subsequent participants. Five males and four females between the ages of 29 and 53 with a range of pain conditions and locations with mean pain duration of 5.3 years (range 2 years to 14 years, SD 4.39). Of the 11 patients that were approached, two were unable to take part because they lived too far away or they declined to be involved due to caring responsibilities. Table 6.1 summarises characteristics of the participants taking part in the CI.

Table 6.1 Gender, age, condition/ diagnosis, location and pain duration (years and months) of participants (N=9)

Gender	Age	Condition/ diagnosis	Location of pain	Pain duration
Female	29	CP	Back, neck, hips, ribs and legs	3.6
Female	46	Soft tissue and nerve damage	Back, legs and feet	2.7
Female	46	RA	Hands	14.0
Female	49	Chronic obstructive pulmonary disease and chronic back pain (CBP)	Back and leg	3.0
Male	36	CBP due to torn disc	Lower back	2.3
Male	39	CP	Back, legs and shoulders	7.0
Male	51	Back problem L3 irritated nerve	Back, groin, lower stomach, legs and right foot	2.0
Male	53	Ankylosing Spondylitis	Right ankle, knee, thigh, elbow and ribs and neck	11.0
Male	53	Disc problem	Back and legs	2.4

6.3.3 Setting

Seven participants were interviewed in a quiet consulting room and two participants were interviewed in their own homes because they were unable to visit the research centre. Interviews lasted for between 1 hour and 1 hour 45 minutes.

6.3.4 Procedure

Patients were given a letter and information sheet inviting them to complete the new PDM. The task of the participant was to complete the 108 items of the PDM whilst simultaneously 'thinking aloud', to enable the poor items to be identified and discarded and the meaningful and comprehensive items to be selected for further testing. Specifically, participants were asked to say what they thought of the items they were responding to, and to try to say everything that ‘came to mind’. Participants were encouraged to talk about their thoughts and were asked questions about the meaning of items, and the degree of certainty about their response. A protocol was established to ensure that each interview was standardised (see figure 6.1). Interviews were audiotaped and detailed notes of respondent comments were recorded. The recorded interviews were not fully transcribed but were used to support and add to the detailed notes taken by the researcher during the interview.

If participants asked questions during the task, the researcher reflected the question back to the participant to avoid influencing their response, for example, by saying 'what does 'x' mean to you? or 'how did you go about answering that question? Appropriate prompts were used where participants were less forthcoming with speaking their thoughts. Where possible, attempts were made to ask participants to offer a solution to the problem that they identified unless it was irreconcilable, for example, when a participant did not understand the meaning of a word. Following completion of the task, participants were asked to comment on their overall impressions of the questionnaire in order to determine overall acceptability. Questions included; 'tell me what you thought about the new questionnaire in general?', 'was there anything you did not understand?', 'what did you think about the layout?' and 'what did you think about the instructions?'.

Figure 6.1 Cognitive interviewing protocol

Introduction

- Thank you for giving up your time today and taking part in the study.
- We have developed a questionnaire to measure the QoL of people with CP to be added to a general QoL questionnaire developed by the WHO. To do this we conducted FG's and asked people to tell us how pain affected their QoL. The purpose of the study is to find out which are the best questions for our final questionnaire. To do this we would like you to complete our new questionnaire and to 'think aloud' whilst you are doing this so that we know which are the best questions.
- We would like you to tell us what you think of the questions you are responding to and to try to say everything that comes to mind.
- This session will be recorded to enable us to capture all your comments to ensure that we select the best questions for the final questionnaire.
- You may stop or withdraw from the study at any time without having to give a reason.
- Everything you say or complete today is strictly confidential.

Task (record the start time)

- Please remember that there are no right or wrong answers and that it is the questionnaire that is being tested, not you.
- I am here to answer questions if you need me to, but I may not answer them until the end if I believe that it will affect your responses.
- Are there any questions before we begin?
- We are interested in your answers, but also how you reach your decisions. I'd like to ask you to 'think aloud' as you answer each question and tell me everything that comes to your mind in answering the question. The more you can tell us, the more useful it will be to us as we try to develop better questions. Okay?
- Please begin completing the new module, as you do so, try and tell me everything that comes to mind.
- Try and talk about your thoughts as you answer the questions. I may ask you questions about what you are doing and thinking during this task and I will be taking notes.

Ask the participant the following questions about each of the questions:

- What does this mean to you?
- How sure are you about your answer (say in %)?
- How do you feel about answering this question?

Also think about asking these questions if the participant does not say very much

- What time period were you thinking about when you answered that question?
- How did you calculate your answer?
- What information did you draw upon to answer this question?

Useful prompts

- Keep talking.
- Tell me what you are thinking?
- I am not interested in your secret thoughts, only what you are thinking about the task.
- The questionnaire is being tested, not you.
- Tell me about any questions that arise while you are working? This will help us understand your answers.
- You may not get an answer because these unanswered questions may help us to see where there are problems with the way a question is being asked and highlight any difficulty people are having with the format of the questions.

If participants ask a question about, for example, the meaning of a question, apply the following:

- How did you go about answering that question?
- What does 'x' mean to you?
- How did you feel about answering this/ that question?
- Questions sometimes have different kinds of effects on people. We'd like your opinion about that question. Perhaps tell me whether you think that question would make most people very uneasy, moderately uneasy, slightly uneasy, or not at all uneasy?

Overall impressions of the questionnaire

- Tell me what you thought about the new questionnaire in general?
- Would you like to expand on that more?
- Was there anything you didn't understand?
- What did you think about the layout?
- What did you think about the instructions?

Record the end time

6.4 Analysis and results

6.4.1 Coding of participant responses

The coding frame, based on the four-stage question and answer model (Tourangeau, 1984, 1987; Tourangeau and Rasinski, 1988), provided a structure for the response to items and the codes and their corresponding meaning are illustrated in Table 6.2. The qualitative response to each item was coded according to the type of problem or issue encountered and broad difficulties were identified. Items to be included were those with fewer than three identifiable problems, low hesitation, high certainty of response and high importance (assessed by the importance items corresponding to each facet). Excluded items were those with low importance, substantial difficulty with comprehending the meaning of the question and those that did not appear to be measuring a component of QoL. Question wording was altered when the meaning was misinterpreted or when changes would give greater clarity and readability.

In general, good items were those that adequately address the underlying concept and that are easy to comprehend, retrieve information on, judge and respond to without difficulty. In addition, they are items that might prove to be sensitive to change or that might distinguish between people with different conditions or with different pain severities. Problematic items are those whose meaning is not clear or are ambiguous, where retrieval of appropriate information is inaccessible, where there is difficulty making a judgement with that information and where a response is either absent or uncertain. Table 6.2 also summarises the frequency of difficulties and issues encountered by participants completing the PDM.

The least frequent problem was semantic difficulties, which gives a degree of confidence that the participants were able to comprehend the meaning of the words used in the items. Hesitation prior to responding to the question was the most frequent issue, followed by missed items. Hesitation (a pause before answering) is not in itself a problem, since participants are asked to think about and respond to questions that they have not been asked before and therefore hesitation to a novel task is not unexpected or surprising. Missing a question may seem problematic, and some of these items have been deleted or modified. However, this was also due to the perceived repetition of a previous question in the item pool, and thus helps in the selection of the 'best' items relating to particular facets, as participants were asked to express a preference for one item over another.

6.4.2 Specific problems with items

Having identified the frequency of problems or issues corresponding to each stage of the model, table 6.3 outlines the nature of the problem, the number of items where that problem occurred, examples of such items and a possible solution to the problem. Attention is paid to the problems or difficulties rather than those items that were considered to be 'good' because the goal was to use this information to exclude or modify problematic items and to retain the 'good' items. Low frequency issues included semantic difficulties, misinterpretation, poorly worded, time frame, response scale confusion, omission, preference and items not addressing QoL. Issues that were moderately problematic included incomprehension, multiple interpretations, repetition, relevance and good questions. High frequency issues were need for clarification, difficult questions, hesitation in comprehension and retrieval, missed question, response hesitation and responsive to change.

Table 6.2 Coding frame for the analysis of the CI and the overall frequency of problem types (total number of items =108)

Code	Meaning	No. of items
Comprehension		
Semantic difficulties	The meaning of a word is not understood	2
Incomprehension	The meaning of a question is not understood	17
Need for clarification	Clarification of the questions' meaning is sought	42
Misinterpretation	The question is not interpreted as it was intended	11
Multiple interpretations	There are two or more possible interpretations	19
Poorly worded	It is suggested that the question be reworded	11
Difficult items	Delay in comprehending question meaning and difficultly answering	36
Hesitation	Excessive pausing or hesitation whilst comprehending the question meaning	34
Judgement		
Time frame	The 2-week time frame is disregarded due to difficulty generalising over a 2-week period because of the variability of the issue in question	7
Repetition	A question has the same meaning as a previous one	25
Relevance	The extent to which the question is relevant to their experience	25
Responding		
Response certainty	The extent to which a participant is sure about their response to a question, classified as high, moderate or low certainty	N/A
Response scale confusion	Difficulty with the response scale	4
Missed question	Refusal to answer or missed question	44
Hesitation	Any excessive pausing or hesitation	84
Positive attributes of items		
Responsive to change	Items that participants have suggested are responsive to change	27
Preference	A preference is expressed for one question over another (where items have a similar content)	7
Good question	The participant believes that the question is a good one	23

Table 6.3 Problem type, frequency of problem, examples and possible solutions

Problem type	Items	Frequency	Examples	Solution
Comprehension difficulties				
Semantic difficulties	17, 19	Low (2)	17. How much are you bothered by feelings of vulnerability? 19. How much do feelings of vulnerability interfere with your everyday life?	Modification of question by shortening 'vulnerability' to 'vulnerable'
Incomprehension	4, 17, 19, 26, 47, 51, 54, 56, 68, 69, 72, 76. Importance; 2, 9, 23, 27, 30	Moderate (17)	47. How concerned are you about society's attitude toward how you use health and social care? 54. How much do you benefit from the use of complimentary therapies?	Deletion of 4, 47 and importance 2, 23 because of frequency of problems. Modification of 17, 19, 54, 72 and importance 9, 27 and 30 to ensure that the meanings of the items are clear
Need for clarification	6, 8, 10, 18, 20, 22, 23-25, 32, 37, 42-44, 47, 52-55, 57, 61, 64, 66-69, 71, 72, 75, 76. Importance; 2, 3, 6, 10, 15, 19-22, 25, 27, 30	High (42)	25. How much do feelings of uncertainty interfere with your everyday life? 54. How much do you benefit from the use of complementary therapies?	Deletion of 32, 37, 47, 55, 71 and importance 2 because of frequency of problems or difficulty scoring. Modification of 18, 20, 22, 24, 25, 53, 54, 72 and importance 27, 30 to ensure that items are clearer. Participant responses showed that it was possible to interpret the question in numerous ways. This is deliberate to ensure that the question is not too specific
Misinterpretation	25, 47, 49, 54, 56, 67, 69, 71. Importance 19, 30, 31	Low (11)	54. How much do you benefit from the use of complementary therapies? 71. To what extent are you satisfied with your relationship with those health care professionals that you have regular contact with? Imp 19. How important is it to you that other people cannot see your pain?	Deletion of 47, 71. Modification of 25, 54 and importance 30. Such responses are not necessarily problematic, but reflect the broad inclusiveness of the items. Those that were particularly problematic were deleted or made clearer to avoid misinterpretation

Problem type	**Items**	**Frequency**	**Examples**	**Solution**
Multiple interpretations	3, 17, 18, 23, 25, 35, 43, 46, 47, 50, 53, 56, 57, 64. Importance 6, 11, 14, 19, 31	Moderate (19)	17. How much are you bothered by feelings of vulnerability? 53. To what extent do you feel that you are dependent on health and social services?	Deletion of 47. Modification of 17, 18, 25, 35, 53. Reflects the broad coverage of items with a deliberate degree of ambiguity, allowing for the full range of interpretations and responses, which may confer advantages
Poorly worded	17, 18, 21-23, 25, 28, 47, 54. Importance 15, 29	Low (11)	22. Are you distressed by the fear of pain? 25. How much do feelings of uncertainty interfere with your everyday life?	Deletion of 47. Modification of 17, 18, 21, 22, 25, 54. The majority of items were modified or removed
Difficult items	2, 4, 5, 8, 9, 13, 16, 17, 19, 21, 22, 25, 33, 35, 37, 39, 41-45, 47, 54, 56, 65, 67, 71, 72. Importance 1, 5, 14, 19, 21, 23, 27, 29	High (36)	4. To what extent does your pain vary over time? 5. How much do changes in pain bother you? 17. How much are you bothered by feelings of vulnerability? 22. Are you distressed by the fear of pain?	Deletion of 4, 5, 37, 47, 71 and importance 23, 27. Modification of 9, 17, 19, 21, 22, 25, 35, 54, 72. A question could be difficult for numerous reasons and was only deleted or modified if there was consensus about this
Hesitation in comprehension and retrieval	2-5, 8, 9, 16-20, 22, 25, 26, 28, 32-34, 37, 40, 47, 51-53, 55, 56, 64, 72, 73. Importance 2, 19, 21, 23, 30	High (34)	47. How much are you concerned about society's attitude toward how you use health and social care? 72. How satisfied are you with the support you receive from the medical service?	Deletion of 4, 5, 32, 37, 47, 55 and importance 2, 23. Modification of 9, 17-20, 22, 25, 53, 72 and importance 30. Hesitation itself is not sufficient grounds for exclusion given that participants were responding to novel questions and the consequent delay in retrieving appropriate information
Judgement difficulties				
Time frame	4, 8, 15, 37, 57, 63, 73	Low (7)	4. To what extent does your pain vary over time? 37. How much does hope for relief from pain improve your quality of life?	Deletion of 4, 37. Reiterating the 2-week time frame and asking participants to give the nearest approximation to their experience in the last 2 weeks
Repetition	15, 20, 21, 25, 26, 28, 30, 32, 37-40, 42, 46-48, 55, 58, 62, 65, 66. Importance 3, 4, 28, 29	Moderate (25)	32. How much are you able to carry out the activities that you once could? 37. How much does hope for relief from pain improve your quality of life?	Deletion of 32, 37, 47, 55. Modification of 20, 21, 25. These items were considered to be repetitions of previous items, however this not a problem since the goal was to use this process to select the best items asking about similar aspects of QoL. Preferences for one question over another were considered

Problem type	Items	Frequency	Examples	Solution
Relevance	9, 17, 18, 20, 21, 24, 33, 34, 37, 44, 49, 53-55, 66, 73, 77. Importance 2, 3, 9, 10, 13, 14, 23, 25	Moderate (25)	55. To what extent does the use of complimentary therapy contribute to your quality of life? 77. How often are you able to see the humorous side of things?	Deletion of 37, 55, 77 and importance 2, 23. Modification of 9, 17, 18, 20, 21, 24, 53, 54 and importance 9. Despite questioning the relevance, the option to circle 'not at all' is still available. Such questions might be important in discriminating between people known to differ on certain characteristics
Responding				
Response certainty	-	-	-	All items were answered with low, moderate or high certainty and this varied across items and depended on the previous three stages of the model occurring
Response scale confusion	5, 9, 58. Importance 29	Low (4)	5. How much do changes in pain bother you? 9. How easy is if for you to get into a comfortable position?	Deletion of 5. Modification of 9
Missed question	4, 5, 8, 10, 17-21, 23, 25, 26, 28, 30, 32, 33, 37-40, 42-44, 47, 49, 51, 55-57, 62, 66, 70-73, 76. Importance 2, 4, 6, 9, 10, 12, 23, 30	High (44)	4. To what extent does your pain vary over time? Importance 23. How important are the attitudes of others to your use of health and social services?	Deletion of 4, 5, 32, 37, 47, 55, 71 and importance 2, 23. Modification of 17-21, 25, 70, 72 and importance 9 and 30.
Hesitation	1, 2, 4-6, 8, 9, 12-14, 16, 18-26, 28, 30, 32-35, 38-46, 49-52, 54, 56-64, 66-69, 71, 74-76. Importance 1-16, 18-23, 25-27, 29, 30	High (84)	5. How much do changes in pain bother you? Importance 27. How important is it to you to have good relationships with your health care professionals (excluding doctor/s)	Deletion of 4, 5, 32, 71 and importance 2, 23, 26. Modification of 9, 18, 19-22, 24, 25, 35, 54 and importance 9, 27, 30. Hesitation in responding is only a problem if there are other difficulties
Miscellaneous				

Problem type	Items	Frequency	Examples	Solution
Omission	Not relating to specific items but whether there was a question on exercise and another on depression or sadness (already covered by the core WHOQOL-100)	Low (2)	N/A	Already addressed in the WHOQOL-100
Positive attributes of items				
Responsive to change	3, 6-8, 12, 14, 20, 26, 32-34, 36, 42, 44, 46, 56, 62, 65, 67-69, 73. Importance 4, 16, 20, 22, 29	High (27)	8. To what extent has treatment improved your quality of life? 56. How much access do you have to the information you require about your health?	Due to other problems with the above items, 32 was deleted and 20 was modified
Preference	3, 13, 16, 19, 31, 37, 46	Low (7)	3. How much are you bothered by flare-ups? 31. To what extent are you bothered by not being able to carry out the activities that you used to do?	Deletion of 37. Modification of 19. Preferred items were retained
Good question	1-3, 5, 12, 14, 16, 17, 27, 31, 33, 34, 36, 41, 44, 48, 49, 51, 52, 61, 68, 69, 71	Moderate (23)	1. To what extent do flare-ups affect your quality of life? 12. How much are you bothered by feelings of anger?	Deletion of 71. Modification of 17
Additional category – deletion because question does not tell us about a persons QoL (e.g. difficult to score with out making an assumption).	4, 5, 32, 47, 53, 77. Importance 23	Low (7)	4. To what extent does your pain vary over time? 32. How much are you able to carry out the activities that you once could?	Deletion of 4, 5, 32, 47, 77 and importance 23

Following this analysis of the response to the 108 items, approximately 57 items were considered to be good questions and 28 items were found to be eligible for exclusion or modification. Table 6.4 summarises problems encountered by the participants during the cognitive interviews, which stage of the model these occurred at and possible solutions to these.

Table 6.4 Summary of problems encountered during CI and corresponding model stage and solutions

Problem or issue	Model stage	Possible solution or action taken
The term 'other people' was considered to be ambiguous and the response would vary according to whom that referred	Comprehension	This deliberate ambiguity is necessary to prevent the most appropriate significant others of each individual being excluded. Respondents may be more likely to consider SO's when answering questions of this nature
Participants report that the question is ambiguous in some way	Comprehension	Deliberate to ensure that all potential respondents are able to fill each question in. The more specific the items are, the less scope for responding to them. A balance has to be struck between openness and ambiguity
Thinking generally rather than about the last 2 weeks	Judgment	Emphasise or repeat that respondents should think only about the last 2 weeks given that memory for longer than two weeks is less accurate
Difficulty generalising experience to give a definite response if something is variable (e.g. a mood state such as frustration)	Judgement	Participants could be encouraged to give the first answer that they think of
The relevance of some items was thrown into doubt	Judgement	This type of response may be idiosyncratic to a particular individual and is not strong enough evidence for exclusion. There is an opportunity to respond with 'not much' or 'not at all'
Items regarding use of health service and perceptions of support etc are more likely to be susceptible to various social biases, for example, social desirability, and the need not to be seen as criticising the system and people within it	Judgement and response	Careful attention at later stages of testing for ceiling or floor effects. Not sufficient grounds for exclusion if the item is important
Some participants appear to be generally hesitant in responding to items. This could be due to the fact that the task is novel and extra retrieval and subsequent judgement	All stages	This type of individual difference will inevitably arise when in large-scale survey work and should not necessarily be seen as a problem with the instrument but

Problem or issue	Model stage	Possible solution or action taken
time is needed. Equally, it could be a side effect of medications and the fatigue associated with CP		rather the participant's interaction with, or response to it
A small number of participants picked up on every issue and potential problem	All stages	Although account should be taken of there comments, this is not particularly useful
An item is assessed as having low importance	N/A	This may be attributable to idiosyncratic aspects of individuals, for example, in terms of relevance or salience and may even distinguish between people with different conditions or with different severity
A question may not actually tell us much about a person's QoL	N/A	Careful attention needs to be paid to this both for theoretical and scoring purposes. The question must have a clear scoring direction
A facet addressed by a particular question or set of items may not be amenable to change through intervention.	N/A	This is only a problem for measures designed specifically to pick up changes over time and not necessarily for those comparing or distinguishing between different individuals

6.4.3 Importance ratings

Importance items were also included in the CI to make a preliminary assessment of the importance of the new facets. However, given that it is not possible to make any definitive conclusions because of the sample size (n=9), the importance ratings for each of the 31 importance items corresponding to the PDM facets are not shown. Each facet should be represented by one importance item, however, at this preliminary stage, facets had between 2 and 6 importance items corresponding to them. These addressed different aspects of each multidimensional definition to enable the most appropriate importance item to be selected to represent it during subsequent stages. Of these importance items, 'How important is it to be able to control your pain?', which represents the pain relief facet, obtained the highest importance rating of 5.0 across the nine participants. 'How important are the attitudes of others to your use of health and social services?', representing communication, received the lowest importance rating of 2.8 and was therefore considered to be the least important. All other importance items were rated above 3.4. Overall, the facet 'pain relief' was considered most important (4.5) and 'communication' the least (3.5). This information provides a useful indication of the relative importance attributed to the new facets of QoL to be further tested in chapter seven.

6.4.4 Performance of items

Each item was categorised following coding of responses and identification of problems based on the qualitative responses to items during CI and the importance attributed to assessed aspects of QoL into items to be retained in the PDM, removed from the PDM, or modified to be more comprehensive and coherent. Retained items those with less than 3 identified problems, low hesitation in both comprehension and judgement stages, high certainty of response and high importance (>3.0). Removed items were those with low importance (<3.0), substantial difficulty with comprehending the meaning of the question, the same difficulty raised by at least three participants, items that were not likely to be sensitive to change or amenable to intervention and items that were difficult to score or did not tell us about a persons QoL. With modified items, there had to be consensus that the question would be clearer with a change in wording or with the addition of a small number of examples in brackets and were those items that were not interpreted as intended by at least three participants.

6.4.5 Expert reading of the PDM

Following the CI with people with CP, the PDM was given to three independent experts in outcome measurement and questionnaire design with expertise in pain and one layperson. The aim was to identify any potential problems and thus consolidate the findings from the CI. As shown in table 6.5, comments related to the identification of and wording of problematic questions and offered potential solutions to these. Any identified issues were taken into account in the light of evidence from the patient participants and modifications made where necessary. Including an expert reading highlights the importance of the instrument being acceptable to both the users and the people that administer it.

Table 6.5 Summary of expert and lay comments (organised by facet)

Item	Comment	Solution
To what extent has having treatment improved your QoL?	The applicability of this item to all people with pain was questioned including the possibility of those not having treatment	Retained for further testing due to its potential for being sensitive to change
How much are you bothered by feelings of vulnerability?	Ambiguous, could be interpreted in a number of ways	Some ambiguity is intentional to avoid narrow concepts
To what extent do you feel threatened by the possibility of pain?	Not an easy concept to grasp	This item was modified from the original international pool following CI
Does pain or discomfort limit your life?	The words ‘restrict’ or ‘inhibit’ were suggested as possible alternatives to ‘limit’	There was no evidence that people use the word ‘inhibit’
How frequently do feelings of uncertainty bother you?	Simplify to ‘how often’	‘How frequently replaced with ‘how often’
To what extent do difficulties with planning affect your quality of life?	It might be easier for participants to evaluate the effect this has on their everyday life than on their overall QoL	Replace with ‘everyday life’
How much are you bothered by feelings of loss?	Ambiguous, could be interpreted in a number of ways	Some ambiguity is intentional to avoid narrow concepts
How much does humour help you to deal with your problems?	The question cannot be scored without making the assumption that there is a unidirectional relationship between having a sense of humour and QoL	Changed to ‘how much does the use of humour improve your quality of life’
How much does hope and optimism help you to deal with your problems	Although hope and optimism may help a person to cope with adversity, they do not eliminate a problem. It might be that there is a value judgment in this question as it is currently worded because one has to make the assumption that if they do not help at all we would have to assume that this was negative, whereas it might be that they adopt a different strategy to deal with their problems	Retained for further testing
How satisfied are you that other people recognise your condition?	‘Acknowledge’ could replace ‘recognise’, potential problem with scoring	Item deleted
To what extent are you bothered by any difficulties communicating your feelings to others?	Considered to be a long question	Retained for further testing

Item	Comment	Solution
How important is it to you that people cannot see your pain?	Suggested change to 'How important is the fact that people cannot see your pain?'	Item deleted
How important is it to you to feel that other people understand your pain?	It was suggested that this could be modified to 'how important is it for you to feel that other people understand your pain?' i.e. replacing 'to' with 'for'	Item deleted
How important are other people's views about your condition?	Suggested change to 'How important to you are other people's views about your condition?'	Item deleted
How concerned are you that you do not have enough resources to provide for others?	Ambiguous i.e. what kind of resources	Some ambiguity is intentional to avoid narrow concepts
How important is it for you to be free from worry about burdening others?	Suggested change to 'how important is it for you not to feel that you are a burden to others?'	Changed to 'How important is it to feel that you are not a burden to others?'
How important is it to be free from feelings of guilt?	The addition of 'to you' was suggested	Retained for further testing
To what extent are you satisfied with your relationship with those health professionals that you have regular contact with?	Too cumbersome	Replaced with 'how satisfied are you'
How important to you is being able to use alternative therapies (for example, acupuncture and osteopathy etc.)?	Examples of acupuncture and osteopathy might exclude people thinking about herbal medicines for example	Item deleted
How important is it to have adequate information regarding your condition and the availability of treatment for it?	Asks two questions; about information regarding a persons condition and about the availability of treatment for it	Item deleted
How satisfied are you with the information that is made available to you about your health?	The word 'made' might be superfluous and could be excluded	Retained for further testing
How important to you is being able to use alternative therapies (for example, acupuncture and osteopathy etc.)?	Modifications to the wording was suggested with replacing 'is being able to use' with 'are'. For example, 'how important to you are alternative therapies…..?' etc.	Item deleted
How important is it to have adequate information regarding your condition and the availability of treatment for it?	Suggested change to 'how important is it to have adequate information regarding the availability of treatment for your condition? However, this changes the meaning of the question and reduces its breadth.	Item deleted

Following the process of CI and expert reading, 11 items were eliminated and 17 were modified. Question numbers 4, 5, 32, 37, 47, 55, 71, 77 and importance items 2, 23 and 27 were deleted from the pilot PDM. Question numbers 9, 17, 18, 19, 20, 21, 22, 24, 25, 35, 54, 70, 72 and importance items 9, 21, 26 and 30 were modified based on the suggestions of patients and health professionals, to ensure that they were comprehensive to potential respondents. Appendix 3 details the item and code for the PDM facets and whether they were retained, deleted or whether the wording had changed to improve its clarity or if a more appropriate response scale had been attached.

6.4.6 Format and content of PDM

Following the processes reported here, the pilot instrument consisted of the 102 core items of the WHOQOL-100, the 68 pain and discomfort items, the 26 WHOQOL importance items and the 16 pain and discomfort importance items. Of the 68 items, 25 items were phrased positively and the remaining 43 items required reverse scoring because of the difficulty of asking about pain and its consequences in a positive way. The facet title 'changes in pain' was changed to 'flare-ups' because the items addressing changes in pain were removed from the PDM following the CI described in this chapter and there was a tendency for people to describe exacerbations or flares in their pain rather than decreases. Four new items have been inserted into the socio-demographic question page asking respondents about the duration and location of pain, perceived cause, the temporal characteristics (adapted from the McGill Pain Questionnaire, MPQ, Melzack, 1975) and the severity of pain (adapted from the MPQ). This will enable a greater understanding of the context of a persons pain related QoL. Table 6.6 shows the number of items by response scale type and per facet in the PDM before and following CI and expert reading.

Table 6.6 Number of items before and after CI and expert reading (ER) by response scale type and per facet (number of importance items corresponding to each facet are shown in brackets)

Response scale type	**Before CI and ER**	**After CI**	**After ER**	**Total change**
How much	56	49	49	-7
How completely	6	7	7	+1
How satisfied	11	10	9	-2
How often	4	3	3	-1
Importance	31	28	16	-15
Facet				
Flare-ups	5 (2)	3 (1)	3 (1)	-2 (-1)
Pain relief	9 (4)	9 (4)	9 (2)	0 (-2)
Anger and frustration	7 (2)	7 (2)	7 (2)	0 (0)
Vulnerability/ fear/ worry	8 (3)	8 (3)	8 (2)	0 (-1)
Uncertainty	7 (2)	7 (2)	7 (1)	0 (-1)
Loss/ loneliness/ feeling alone	7 (3)	6 (3)	6 (2)	-1 (-1)
Positive strategies	7 (2)	5 (2)	5 (2)	-2 (0)
Communication	12 (5)	11 (4)	10 (1)	-2 (-4)
Guilt and burdening others	5 (2)	5 (2)	5 (2)	0 (0)
Relationship with health care providers	10 (6)	8 (5)	8 (1)	-2 (-5)
Total	**77**	**69**	**68**	**-9**
Overall total	**108**	**97**	**84**	**-24**

6.5 Discussion

This chapter described the use of CI to reduce and modify the items of the PDM to assess the impact of CP on QoL. This preliminary pilot work was conducted with the 108-item pilot PDM, which represented 10 new facets of QoL derived from FG's and a web survey. During completion of the items forming a PDM, CI with 9 participants revealed which items were comprehensive enough to retain and subsequently, health professional views were elicited, to further determine the comprehensibility of the items. Items were included, excluded or modified on the basis of participant comments. Of 77 items and 31 importance items (total 108), 24 were eliminated during this process, leaving 68 items and 16 importance items in the pilot PDM. This method provided a way of ensuring that items were relevant, comprehensive and acceptable to the users, and that the items tapped concepts that they purported to measure. This preliminary work demonstrates that it is possible to ask people about their QoL and to use this information to develop items that are relevant and comprehensive. The very notion of including patient preferences ensures a high content validity since participants were asked what was important to them.

In general, there was a moderate to high degree of consensus between participants on which items were 'good' and which where 'problematic'. Saturation was reached by the ninth interview, where no new issues or problems were arising that had not been identified from a previous interview. The results show that there were very few problems with misinterpreting or understanding the meaning of items, which offers further support for the method of questionnaire development where primacy is given to using the words and phrases that people with pain use when talking about their QoL, ensuring that items adequately and appropriately address the underlying concepts. The CI provided a systematic method for weeding out problematic items and identifying possible alterations to these, in addition to providing a verbal reinforcement of the relevance of the items.

During the CI itself, the speed with which participants answer items might be an important indicator of whether or not items are 'good' or not. An item answered relatively rapidly reflects ease of comprehension and that the four stages of the question and answer model occur in rapid succession. For other items, hesitation or excessive pausing might be due to poor wording or the fluency of the item (i.e. a problem with the item), or difficulties with how to respond to an item (i.e. the response). Hesitation can therefore occur at the comprehension, retrieval, judgement or response stage of the model. It might be that there is a higher degree of certainty about which response to give for items regarding feelings because the question content is familiar, however, other items regarding more practical matters may require a greater degree of thought. In general, hesitation in itself is not grounds for excluding a question as participants may hesitate at different stages of the process for numerous reasons. For example, hesitation may be due to speed of retrieval if a person has not been asked that type of question before and consequently, more time may be needed to consider the information and make a judgement based on that information. Hesitation may also be due to a type of prestige bias whereby more time is needed to respond to a question because a person is concerned to appear in a good light. These provide plausible explanations accounting for hesitancy that do not warrant excluding the question.

Where participants asked a question regarding the meaning of an item, careful attention was paid to changing, clarifying or excluding those items. For example, questions were asked when there were two or more possible interpretations of the intended meaning of an item. A noticeable problem was that participants indicated that their answer depends on the day or time that they are completing the instrument due to the fluctuations that characterise living with CP. This has implications for the two-week time frame since participants found it hard to generalise their experience. This might be a particularly salient issue for people with CP since it is associated with frequent changes and fluctuations, which impacts on the ability to make a general statement about a two-week period. The presence and consequences of such flare-ups have been shown in previous chapters and have been reported by Mason, Skevington and Osborn (2004). However, as the timeframe of the WHOQOL instruments is two weeks, it is important that this model is adopted for the PDM.

Developing items in the vernacular has been central to the WHOQOL project (WHOQOL Group, 1995) and this illustrates the importance of developing items from the perspective of individuals with pain. The bottom up approach was confirmed by the CI, which reinforced the relevance of the 10 new facets of QoL. Patient involvement in the development of outcome measures is seen as a way of highlighting the subjective perspective of the patient and putting their views in a more prominent position than has traditionally been the case and researchers are placing greater value on this approach (Greene, 1995). Obtaining 'user views' is a key objective of outcome measurement and, more broadly, clinical governance. This underpins the importance of creating relevant and appropriate instruments for measuring theoretical, empirical or experiential constructs such as QoL. CI strengthens the quality of items and eliminates multiple meanings, which can compromise the validity of an instrument. Moreover, given the fundamental assumptions underpinning the reliability of self-report instruments, for example, that they accurately reflect a person's view of their experience, this method provides a way of improving these self-report measures (Jobe, 2003) by ensuring that the perceived meaning of items corresponds to the intended meaning.

The process of development also facilitates the process of conceptualising QoL, relating to pain and discomfort. A relative absence of conceptual clarity in research to date has been problematic to understanding the rational for inclusion of particular items in QoL instruments. Indeed, subjective assessment is emphasised here rather than health status, which although is an important outcome, has erroneously become synonymous with the measurement of QoL, which is reflected in the large number of studies claiming to assess QoL using health status measures such as the SF-36. Consolidation of the concept of QoL is a laudable and necessary aim given the increasing importance of measuring QoL in assessing outcome.

6.5.1 Critique

An advantage of using CI was that it allowed the interviewer to ask the participants for possible solutions to the problems that were identified. This overcomes the criticism that although the method of CI highlights problems, it does not offer neat solutions. Allowing participants to contribute to this is an essential part of the process of developing a good measure. Whilst it is acknowledged that the number of participants who completed the CI task was relatively small, it is generally thought to be acceptable providing saturation has been reached, where no new problems or issues are being identified with each new participant. Moreover, the goal is not to derive statistically generalisable results, but to reflect the cognitive processes that might be influenced by a range of respondent characteristics (Campanelli, 1995). It is argued that CI should become a necessary and integral way of pre-testing survey instruments, echoing the view of Collins (2003) who proposes that cognitive testing should be a standard part of the development process.

This study has shown how cognitive methods can be applied to the development of a PDM to be used in conjunction with the core WHOQOL instrument to ensure that items are relevant, comprehensive and acceptable to the potential users. Furthermore, the methodology provides evidence that the meaning of items is shared between users so that ambiguity or misinterpretation of meaning is reduced or eliminated, increasing certainty that items are measuring what they purport to measure and consequently, that the instrument fulfils its purpose (Collins, 2003). Following subsequent testing of the PDM using the complementary traditional psychometric approach, its psychometric properties will be elucidated and the number of items will be further reduced during this process to create an instrument that is psychometrically sound and that can be applied across a range of research and clinical contexts to assess subjective QoL relating to CP. The new items will increase the specificity of the core instrument to account for the impact of pain on QoL. This work is important because although CASM are now being used in QoL research (for example, Niero et al., 2002; Rouland et al., 2002), to date, such methods have not been applied to CP populations. More generally, further work should focus on deepening the understanding of the cognitive processes involved in responding to self-report instruments, whilst developing systematic protocols for implementing cognitive methods in the creation of QoL, pain and other health related questionnaires to provide rigorous and meaningful outcome measures in a world of evidenced based health care.

6.5.2 Further work

This chapter has reported the use of CI to modify and eliminate items to derive the pilot PDM to be used in conjunction with the WHOQOL-100. This methodology ensures that the items included in the pilot PDM have face and content validity, that is, are acceptable to the users and that items adequately and appropriately address the underlying concepts, to be further tested in the cross-sectional pilot survey described in chapter seven. This and the subsequent longitudinal field-test reported in chapter eight aim to elucidate the psychometric properties of the new PDM.

Chapter seven

The Cross-sectional Pilot Study: Validation of the Pain and Discomfort Module

7.1 Introduction

In chapter six, the preliminary pilot work using cognitive interviewing was described, providing confidence in the face validity, meaningfulness and relevance of the items selected to represent the 10 new facets of QoL identified by the focus group (FG) and web survey participants in chapters three and four. Consequently, it is argued that the content of the items being tested in the pilot instrument represent aspects of QoL that are important to people with chronic pain (CP), which is evidence of the content validity (Streiner and Norman, 1995) or content relevance (Messick, 1980) of items. This chapter reports a cross-sectional survey to test the preliminary psychometric properties of the new pain and discomfort module (PDM) to be used in conjunction with the UK WHOQOL-100, and to reduce the number of items in the PDM in order to make a preliminary assessment of the Quality of life (QoL) of people with CP.

Depending on the goals of measurement, instruments may be designed for different purposes; for example, Juniper and colleagues describe discriminative, predictive or evaluative instruments (Juniper, Guyatt and Jaeschke 1996). Discriminative instruments should be sensitive to distinguish between different patient groups, such as those with differing diagnoses. Predictive measures should be able to predict outcomes to a criterion standard, that is, to a predefined outcome or gold standard. Evaluative instruments must be able to detect within-patient change over time by containing items that are responsive to change with response options that have sufficient gradations to register such change (Juniper, Guyatt and Jaeschke 1996). Any new instrument purporting to measure a specified outcome must be tested in the field by applying it to the populations in which its use was intended. Subsequent analysis should involve the application of numerous psychometric tests to the data derived from its use, in order to ensure that the instrument is reliable, valid and sensitive to changes in clinical condition. This traditional approach, incorporating classical test theory, has more recently been complemented by new methodologies, such as the cognitive interviewing described in chapter six. Substantial validation work has been conducted on the core WHOQOL-100 in numerous populations, such as people with CP (Skevington, Carse, Williams, 2001), HIV (O'Connell, Skevington and Saxena, 2003) and depression (Skevington and Wright, 2001) and so on. As described in detail in chapter two, its general psychometric properties have been well documented (The WHOQOL Group, 1998).

The purpose of this investigation was to conduct a cross-sectional postal survey in order to elucidate the psychometric properties of the PDM by seeing how it behaves when applied to a clinical population. Specifically, to examine its validity in order reduce the 10 new facets and 68 items representing the PDM, to allow for a parsimonious, yet elaborate conceptualisation of the impact of pain on QoL. This chapter also explores the relationship between core WHOQOL-100 facets and domains of QoL and the 10 new facets of QoL pertaining to pain and discomfort.

7.1.1 Item pool

One of the principle ideas behind this approach is that a small number of items will be derived from an item pool (Juniper, Guyatt and Jaeschke 1996). This enables the 'best' items, based on their psychometric properties, to be selected. A number of broad criteria are applied to the performance of individual items within the context of the instrument as a whole, and these are used to decide whether or not an item should be retained or rejected. An item can be rejected based on its performance alone. For example, it might produce skewed data, which could lead to ceiling or floor effects. It may also perform badly within the instrument by not correlating very highly with its parent facet, suggesting that the item does not have a strong conceptual relationship with that facet or that the item does not tap into the concept in an adequate way. Furthermore, it might have an unacceptably low item-total correlation (Pearson's r) of less than 0.20 (Kline, 1986) and so on. The following section discusses each of the psychometric tests required in order to carry out the item reduction process.

7.1.2 Psychometric tests

7.1.3 Internal consistency

Individual items should correlate highly with other items in the same facet, and with the summed score of the total of items in the same facet, as this ensures that each item is representing a different aspect of the same concept. Very high internal consistency is not necessarily desirable because the resulting scale would contain items of a very similar nature and content. This can be measured using Cronbach's alpha, which is a model of internal consistency, which assesses the average inter-item correlation (Cronbach, 1951). High correlations represent high internal consistency and a perfect correlation of 1.0 would mean that items are measuring the same concept and consequently, such items would be redundant. Given the importance of capturing the multidimensional nature of QoL, facets addressing a narrow or unidimensional aspect of QoL are undesirable. It has been suggested that 0.70 is an acceptable reliability co-efficient (Nunnaly, 1978) and Streiner and Norman (1995) suggest that Cronbach's alpha should be between 0.70 and 0.90 to demonstrate acceptable internal consistency reliability. The correlation between individual items and the scale as a whole must also be examined, excluding the contribution of that item. Kline suggests that items should correlate a minimum of 0.20 with the scale (Kline, 1986). It is also important to examine the effect of each item on the overall scale, by systematically removing and replacing each item in order to assess its contribution to the overall scale. Consequently, if an item makes less contribution than other items representing that facet, it should be considered for deletion.

7.1.4 Validity

Validity is the extent to which an instrument measures what it claims to measure. More specifically, the important issue is whether the measure is validated with the particular population it claims to assess. Assessing the validity of an instrument is an ongoing process, beginning with the data derived from the cross-sectional survey, and followed by a longitudinal survey to examine test-retest reliability and sensitivity to change. Different types of validity must be assessed during testing of a new instrument; these are outlined below.

7.1.5 Face validity

High face validity is when an instrument appears to measure the concepts identified and Ware defines this as 'what an item appears to measure based on its manifest content' (Ware et al., 1981). This is not a test *per se*, but can be carried out by examining the items in a non-statistical way, that is, based on the match between the facet concept and the semantic attributes of the question at face value. This was confirmed through the cognitive interviewing in the previous chapter, to ascertain if the PDM is applicable, appropriate and relevant to the group under study.

7.1.6 Content validity

Ware defines content validity as 'how well a measurement battery covers important parts of the health components to be measured (Ware et al., 1981). That is, how well items cover the aspects being measured and whether these aspects are covered adequately. Guyatt and Cook (1994) ask about the involvement of people with relevant health status in developing the content. The FG work in chapter three addresses this qualitatively and confirms that this was done. Lomas and colleagues (1987) ask about the role of patients in generating and confirming the content of the instrument. Again, in the present study, patients were asked to think about ways of asking about how a particular aspect of pain impacted in their QoL and patients were also asked to confirm the content of the PDM through the process of cognitive interviewing. Despite the non-statistical nature of face and content validity tests, they are nonetheless essential to the process of developing a new measure and complement other more rigorous statistical testing. Quantitative tests provide further empirical demonstration.

7.1.7 Criterion validity

Criterion validity is concerned with whether a new measure correlates with an existing instrument known to measure the same or similar concepts, for example, the PDM should correlate with a well-validated or gold standard instrument known to assess QoL (Streiner and Norman, 1995; Juniper, Guyatt and Jaeschke 1996). Such validity can also be conducted by examining the correlations between the core WHOQOL items and the PDM items, as there is strong evidence that the core UK WHOQOL instrument assesses QoL (Skevington, 1998; Skevington, Carse and Williams, 2001), and therefore the new items should also be able to distinguish between poor and good QoL in a similar, but more sensitive way. Validity can be strengthened by making *a priori* predictions about which items are most likely to correlate, for example that new psychological or physical facets will correlate more highly with core facets housed under these domains, than with facets housed under different domains.

7.1.8 Construct validity

Construct validity looks at the relationship between a particular construct and a set of other variables in the absence of a gold standard measure (Juniper, Guyatt and Jaeschke 1996). Convergent and discriminant validity are types of construct validity (Campbell and Frisk, 1959), where predictions are made about the strength of the relationship between different variables. Related constructs will be stronger and unrelated or less related will be weaker. Patterns of items that are hypothesised to assess single underlying constructs are analysed and it is possible to check whether items correlate more with the scale in which they belong than with other scales, to ensure that items from different facets are not overlapping conceptually. Furthermore, it is important to check that items addressing one facet are measuring different aspects of the same aspect of QoL. Items in a facet should therefore correlate more highly with other items in that facet than with items in other facets. McDowell and Newell (1996) propose that a correlation coefficient of 0.60 may provide evidence of construct validity. It has been suggested that an *a priori* prediction should be made before this test is done, to ensure that it is possible to falsify validity, for example by making a prediction about the strength of the relationship between two items. Given that the PDM is multidimensional, covering facets from different QoL domains, a relationship is assumed between the different facets. For example, psychological facets should correlate more highly with each other than with physical facets.

7.1.9 Discriminant validity

Discriminant validity is whether an instrument is able to distinguish between groups known to vary on a particular characteristic, such as diagnostic group, condition, severity of symptoms, age, and gender and so on. Another way to test discriminant validity is to divide the sample into groups based on different pain severities or pain duration. This can be examined by conducting an *a priori* paired comparison analysis of variance (ANOVA) to see if there are significant differences in QoL between people who rate their pain at different intensities. Discriminant validity will be tested and reported in chapter eight on the longitudinal data and in chapter nine where further analysis will be conducted on the reduced set of PDM items from the cross-sectional data reported here. Analysis will explore the ability of the PDM to distinguish between patients who are known to differ on certain variables, for example, those defining themselves as ill or well, or those with different pain intensities or qualities.

7.1.10 Score distribution and floor and ceiling effects

Examining the score distribution of a scale allows us to see if all points on a scale are utilised by participants and whether scores tend to cluster around one or two points on the scale. It is important that all scale points are used or this will decrease the instruments ability to distinguish between different types of patients, or between the same patients at different time points. Floor and ceiling effects are related to score distribution because if the questions cannot distinguish between a good or excellent QoL in a particular aspect of life, it is not sufficiently sensitive and therefore is unable to detect varying magnitudes of change. Ceiling and floor effects occur when the questions and the response scales are presented in such a way that does not allow for further improvement of deterioration to be picked up and is a consequence of skew (Streiner and Norman, 1995). For example, if a person reports the poorest QoL, and then is asked 3 months later the same set of questions with the addition of a question asking about their health status relative to the baseline assessment, if they report a decline, the QoL assessment will not detect this deterioration, because the baseline reflected the poorest QoL. Decisions need to be taken about items that show floor or ceiling effects, once this has been established, and once their individual contribution has been elucidated. This can be done by tabulating the percentage of participants who responded with each of the points on the 5-point Likert scale (i.e. 1-5). There must be 10% in each category (each item should add up to 100%) or this might suggest floor or ceiling effects.

7.1.11 Item redundancy

An item is said to be redundant if it does not add anything to the instruments ability to assess QoL. Specifically, if an item is tapping into the same construct as another item and is essentially asking the same question, that item would be removed. An important goal is to achieve parsimony by avoiding the inclusion of superfluous items, which would add to patient burden, which can be tested by looking at the correlations between items. For example, if inter-item correlations or Cronbach's alpha is unacceptably high (> 0.9), this suggests that those items are conceptually similar or too homogeneous where items may be asking the same question in different ways (Boyle, 1991; Hattie, 1985). Consequently, one of the items should be discarded based on its performance on other tests. Careful judgment is required when selecting one item over another and the performance of each item on others tests informs the decision about which one should be discarded.

The psychometric tests for conducting item reduction have been introduced and described. It is common practice to conduct cross-sectional postal survey as part of the process of validating a new instrument to measure a specified outcome and this chapter describes such a study.

7.2 Method

7.2.1 Construction of the quota sample

The quota sample for this study was structured using data from a community prevalence study of CP using broad categories based on epidemiological data (Elliott et al, 1999). The rationale for using this, as opposed to a sample based on the prevalence of CP types amongst pain clinic populations, was to ensure that the population represented a realistic cross-section of those seeking help for their pain, since only 1% of those with CP in the UK reach speciality clinics (Smith et al., 1996). Further estimates of the prevalence of conditions not defined by Elliot and colleagues were based on data from studies of the epidemiology of pain (Crombie et al., 1999; Scher, Stewart and Lipton, 1999; Macrae and Oakley Davies, 1999; MacFarlane, 1999; Zakrzewska and Hamlyn, 1999). The known and estimated percentage prevalence of different CP types was multiplied by 2, to give the approximate number within each category to approach to achieve a sample approximating the prevalence of each pain type. Table 7.1 shows how the sample was divided into diagnostic groups by age and gender.

Table 7.1 Diagnostic group, prevalence and target number (prevalence doubled) of participants by age and gender

Diagnostic group	Prevalence %	Target no.	Male		Female	
			16-44	45+	16-44	45+
Musculoskeletal (back pain (BP) and sciatica)	23.5*	47	14	15	14	18
Rheumatology (arthritis)	23.2*	46	3	18	3	25
Spinal chord/ injury	8.7*	17	9	7	4	5
Cardiology (angina)	6.6*	13	0	7	0	6
Gynaecology	5.7*	11	-	-	7	3
Oncology	0.7*	1	0	1	0	1
Other, composed of	31.7†	64	8	13	8	11
Migraine	10†	20	-	-	-	-
Post-surgical	9†	18	-	-	-	-
Neuropathic	6†	12	-	-	-	-
Fibromyalgia (FMS)	4†	8	-	-	-	-
Facial	3†	6	-	-	-	-
Total	**100.4**	**200**	**34**	**61**	**36**	**69**

* Estimates based on data from Elliott et al., 1999

† Estimates based on data from Crombie et al., 1999; Scher, Stewart and Lipton, 1999; Macrae and Oakley Davies, 1999; MacFarlane, 1999; Zakrzewska and Hamlyn, 1999.

7.2.2 Inclusion and exclusion criteria

Male and female patients over the age of 16 (no upper limit), with pain persisting continuously or intermittently for longer than 3 months (Elliot et al., 1999) were included in the sample. Exclusion criteria were patients with a known psychological diagnosis with a referral to a Clinical Psychologist or Psychiatrist, those involved in any of the previous stages of research reported in this thesis or known to be involved in a concurrent study.

7.2.3 Procedure

Regional and national contacts were established and invited to assist in data collection by distributing the WHOQOL-100 and PDM to their patients. A total of 469 questionnaires were sent out to patients from the pain clinic, departments of orthopaedics, physiotherapy, maxillo-facial surgery, genito-urinary medicine (GUM) and gynaecology at the Royal United Hospital (RUH); the Wiltshire Back Pain Network (BPN); Royal National Hospital for Rheumatic Diseases (RNHRD) and Box Surgery General Practice in Bath and Pain Concern East Lothian (registered charity, Scotland) and a local FMS support group.

Table 7.2 details the number of patients recruited from each centre or department, the patient type, mode of administration of the questionnaire and response rate. Potential participants were either sent a questionnaire pack in the mail or were given their questionnaire pack by hand. Packs consisted of a cover letter inviting them to complete the new assessment of QoL, an information sheet giving further details about the study and explaining the ethical considerations and the questionnaire consisting of the UK WHOQOL-100 (102 items), the additional pain and discomfort items (68 items), importance items for both the international core (26 items) and the PDM (16 items). Socio-demographic and health status details were obtained from the extended 'About you' page at the back of the WHOQOL-100, which asks questions about gender, date of birth, educational level, marital status, current health problems and whether the respondent is in paid work and for their occupation. Additional questions, selected from the McGill Pain questionnaire asked about duration, location, severity and intensity of pain (Melzack, 1975). Respondents completed the questionnaire and returned it in the stamped addressed envelope provided. Based on the approximate length of time taken to complete the WHOQOL-100 (30 minutes, The WHOQOL Group, 1998), this was estimated to take around 45-50 minutes, depending on level of disability, concentration and tiredness.

7.2.4 Reminders

Reminder letters were sent to 76 of the sample, that is, those that were traceable through records, in order to boost the response rate of the survey. This was done by sending letters inviting people to complete the questionnaire if they wished to and emphasising that they still had time to do so. Those who could not be traced were from specific clinics or organisations that did not keep precise records of study participants and were not able to divulge the names and addresses of patients to respect confidentiality. As packs were sent out in batches, reminders were not sent when there was a considerable interval between first receiving the questionnaire.

Table 7.2 Centre or department, mode of administration, patient type, number of patients and response rate

Centre or department	Mode of administration	Patient type	No. of patients	Response
Pain Clinic, RUH	Mail	Musculoskeletal conditions	199	91
Orthopaedics, RUH	Mail	Hip and knee replacement waiting list	44	19
Physiotherapy, RUH	Hand and mail	Mixed diagnoses	15	9
Maxillo-facial surgery, RUH	Hand	Facial pain	11	5
GUM, RUH	Hand and mail	Mixed diagnoses	5	4
Gynaecology, RUH	Mail	Pelvic pain	3	2
BPN	Mail	BP	33	12
RNHRD	Hand	Rheumatoid arthritis (RA), osteoarthritis (OA) and Ankylosing spondylitis (AS)	50	17
General Practitioner Surgery	Mail	Mixed diagnoses	56	30
Pain Concern Lothian, registered charity	Mail	Mixed diagnoses	50	25
FMS support group	Mail	FMS	3	2
Total	-	-	**469**	**216**

7.3 Analysis

7.3.1 Data cleaning

Data cleaning involved checking that data had been entered correctly and that all item data was a numerical value between 1 and 5. Each variable was systematically examined to ensure that no incorrect entries had been made. Box plots were examined to view the spread of data for each item and check for any outliers (Tabachnick and Fidell, 1996). Means, frequencies and distributions were inspected to ensure that errors have not been made. A missing value analysis was also conducted because it is recommended that an assessment should be discarded if 20% of an assessment is missing (The WHOQOL Group, 1998). All data was retained for analysis.

7.3.2 Item reversal and scoring of domains

On receipt of the returned and completed questionnaires the data was entered into a SPSS data editor. Of the WHOQOL-100 core items, 18 required reverse scoring and 43 items from the PDM, due to the essentially negative valence of pain and its consequences. The WHOQOL-100 syntax file was adapted to include the PDM items and the necessary items were reversed and facet and domain scores were calculated. Facet scores are calculated by summing the items within each facet and domain scores are calculated by computing the mean of the facet scores (domain scores excluded the new items) (WHOQOL Group, 1998).

7.3.3 Psychometric analysis

Consistent with the development of the international core (The WHOQOL Group, 1998), the specific aims of the analysis were to examine the construct validity of the PDM facets, to select the best items to represent each new facet of QoL and to determine reliability (internal consistency) and validity. Table 7.3 summarises the criteria that apply to the selection of items, which is based on the application of the tests detailed in the introduction above.

Table 7.3 Summary of criteria that apply to the selection of items

Test	Criteria
Missing value analysis	No more than 10% missing data for each item
Normality – skew and kurtosis	Response to each item should be normally distributed (see below)
Distribution of scores	Minimum of 10% of responses at each point in scale
Item-facet correlation	Pearson's r above +.4.0. Should be higher for parent facet than other facets
Item-facet-domain correlations	Pearson's r should be higher for parent domain than other domains
Cronbach's alpha	Inclusion of each item should increase the Cronbach's alpha of the total scale reflecting its contribution
Stepwise multiple regression by facet	Items, as independent variables (IV's), should contribute to explaining the variance in overall QoL and health (G) as the dependent variable (DV)
Importance ratings	Mean rating of >3.0, ensuring that the facet is important to people with CP

7.4 Results

7.4.1 Response rate

Of the 469 questionnaires sent out, 216 (46%) completed questionnaires were returned. The highest response rates were achieved from the community samples, that is the General Practitioner (54%) and the Pain Concern charity (50%) samples, possibly explained by a higher perceived obligation or older age. Known reasons for non-response included not suffering from CP, emigration, not known at address, questionnaire undelivered and deceased. Reasons for refusal included being unhappy about inclusion in the study because of being on the waiting list, being too ill to complete, caring for ill spouse and being unhappy with the way treated by health service.

7.4.2 Socio-demographic composition

The sample consisted of 132 (61.1%) females and 84 (38.9%) males. Of the male participants, 27 were aged 16-44, 48 were 45-65 and 8 were over 66. Of the females, 41 were aged 16-44, 73 were 45-65 and 18 were over 66. The mean age was 51.32 (SD 13.63, range 20-90). Of the sample, most were married (n=133, 61.6%), followed by divorced (n=29, 13.4%), single (n=26, 12.0%), living as married (n=14, 6.5%), widowed (n=11, 5.1%) and separated (n=3, 1.4%). Participants were mostly educated to secondary level (n=106, 49.1%), followed by further education such as technical/ clerical (n=71, 32.9%), university education (n=27, 12.5%), primary school education (n=6, 2.8%) and no education (n=4, 1.9%). One participant stated that their education had been 'private', without indicating level. Of the sample, 83 (38.4%) were currently employed.

7.4.3 Health characteristics

Of the sample, most described their health as neither poor nor good (n=77, 35.6%), followed by poor (n=67, 31.0%), good (n=43, 19.9%), very poor (n=19, 8.8%) and very good (n=6, 2.8%). One hundred and twenty three (56.9%) described themselves as currently ill, 79 (36.6%) as not currently ill and 14 (6.5%) did not state.

7.4.4 Characteristics relating to pain

Mean duration of pain in months was 108.50 (SD 124.70, range 1-660 months) (10 participants did not report their pain duration). Most patients described their pain as continuous (n=143, 66.2%), followed by intermittent (n=68, 31.5%) and brief (n=4, 1.9%). Most patients described their pain as discomforting (n=77, 35.6%), followed by distressing (n=59, 27.3%), horrible (n=48, 22.2%), excruciating (n=18, 8.3%), mild (n=9, 4.2%) and no current pain (n=4, 1.9%). In general, substantial co-morbidity was apparent. The most common condition was BP and sciatica (n=67, 31.0%), followed by, arthritis (n=45, 20.8%), injury (n=19, 8.8%), gynaecological in origin (n=6, 2.8%), angina (n=4, 1.9%), cancer (n=2, 0.9%), other (n=53, 24.5%) and no condition specified (n=20, 9.3%). The most common site of pain was the legs (n=146, 67.6%), followed by the lower back and spine (n=140, 64.8%), upper shoulders and arms (n=96, 44.4%), pelvis (n=61, 28.2%), middle back and chest (n=54, 25.0%), upper back (n=51, 23.6%), head, face and mouth (46, 21.3%), abdomen (n=38, 17.6%) and other body regions (n=84, 38.9%). Respondents identified 14 more specific pain locations; ankles, elbows, feet, fingers, genitals/groin, hands, hips, knees, lungs, neck, rib cage/ chest, thigh, toes and wrists.

7.4.5 Missing value analysis for the PDM items

A missing data analysis was conducted to examine whether there are consistent patterns of items not being completed. None of the PDM items were systematically missed as items had fewer than 4 (1.9%) missing responses, which is well below the 10% maximum criteria allowed for each item and provides further support for the comprehensibility, acceptability and face validity of the items representing the PDM. The 9 items with 4 missing responses came from the vulnerability/ fear/ worry, loss/ loneliness/ feeling alone, positive strategies and relationship with HCP facets. For the importance items, 9 of the 216 participants failed to complete any of the items. There were fewer than 10% missing responses for the 16 PDM importance items, although the most frequently missed was the importance of feeling that you are not alone (n=6) (due to an initial error in printing the item), followed by the importance of sense of humour and loss (n=2). Although the small number of missing responses supports the comprehensibility and face validity of the PDM and corresponding importance items, most missing responses occurred for the loss/ loneliness/ feeling alone, positive strategies and relationship with health care provider facets.

7.4.6 Psychometric properties of the pain and discomfort items

Each of the 68 items was systematically tested in order to select the best items and discard the poorly performing items, based on the criteria discussed above. The penultimate table of the results section (table 7.13) summarises the results from each test, the aim being to derive a reduced number of 4-item facets. Each section that follows describes the performance of the items on each test.

7.4.7 Normality – skew and kurtosis

Table 7.4 shows the mean, SD, skew, standard error and kurtosis of the PDM items. Of the 68 items, 18 had problems with skewness, because a skewness value of more than twice its standard error is taken to indicate a departure from symmetry (Howell, 1997). Each of these cases will be examined in conjunction with other statistical tests to see if the item should be retained or removed.

7.4.8 Distribution of scores

At least 10% of participants must have used each of the 5 scale points corresponding to each item (WHOQOL Group, 1997). This demonstrates that the whole range of scores are being used, ensuring that ceiling or floor effects are not occurring. Table 7.5 shows the distribution of responses for each item, illustrating the way in which questionnaire respondents use the scales. Where there is a low percentage for 5 (<10%) (good QoL), this suggests a floor effect, that is, respondents are treating the scale as a 4-point scale where the verbal label for the 5-anchor point may be perceived to be too extreme. Consequently, the scale will not be sensitive to a perceived improvement. The reverse is true for items where 1 (poor QoL) has not been used (<10%) and the scale will not be sensitive enough to detect a perceived deterioration. Given that substantial work has gone into the layout and format of the core response scales (Szabo, Orley and Saxena, 1997), changing the verbal label given to the 1 or 5 anchor points to have a less extreme meaning is not a suitable solution. Consequently, items with skewed distributions can either be removed or item wording can be modified.

Table 7.4 Frequencies for the 68 PDM items (Standard error of skewness .17 for all items)

Item no.	Item	Mean	SD	Skew	Kurtosis
F60.1	Flare-ups	2.17	.92	.55*	.04
F60.2	Worry about flare-ups	2.67	1.07	.25	-.53
F60.3	Bothered by flare-ups	2.33	1.01	.45*	-.20
F61.1	Treatments offer relief	2.61	.96	-.02	-.40
F61.4i	Control over pain	2.48	.81	.35*	.37
F61.6i	Treatment imp QoL	2.64	1.03	-.012	-.79
F61.8	Bothered by medication	3.08	1.23	.09	1.0
F61.9	Side effects of medication	2.56	1.08	.45*	-.62
F62.1	Bothered by anger	3.20	1.13	-.09	-.83
F62.2	Anger interfere	3.68	1.04	-.55*	-.41
F62.4	Anger affect relationships	3.67	1.06	-.50*	-.46
F62.6	Bothered by frustration	2.53	1.06	.42*	-.35
F62.7	Frustration interferes	2.96	1.07	.01	-.68
F63.1	Bothered by vulnerable	3.31	1.05	-.17	-.61
F63.2	Fear bother	3.45	1.02	-.28	-.54
F63.3	Vulnerable interfere	3.69	.93	-.47*	.02
F63.4i	Pain a threat	2.84	1.11	.36*	-.65
F63.5i	Concerned about pain	2.53	.91	.30	.04
F63.6i	Distressed by pain	2.40	.92	.32	-.38
F63.7	Feelings of worry	2.86	1.06	.08	-.71
F63.8	Treatment worry	3.25	1.08	-.03	-.91
F64.2	Uncertainty interfere	2.86	1.09	.11	-.64
F64.4	Difficulty planning	2.94	1.11	-.01	-.80
F64.6i	Pain prevent	2.15	1.09	.79*	-.11
F64.7	Pain limit life	2.18	1.03	.77*	.08
F65.1	Bothered by loss	2.69	1.16	.34	-.71
F65.2	Loss interfere	3.16	1.15	-.07	-.83
F65.3	Carry out activities	2.14	1.04	.83*	.23
F65.6	Bothered by loneliness	3.42	1.15	-.32	-.72
F65.7	Alone bother	3.49	1.16	-.34	-.68
F66.2	Humour	3.70	.84	-.21	-.51
F66.3	Hope for relief	4.08	.91	-.84*	.31
F66.5	Feelings of hope	2.99	.98	.12	-.37
F66.6i	Hopeful optimistic	2.87	.96	.30	-.12
F66.7	Hope and problems	3.02	.93	-.04	-.28
F67.1	Others cannot see pain	2.78	1.15	.24	-.72
F67.2	Pain affect relationships	2.99	.99	-.07	-.50
F67.5	Pain invisible	2.92	1.22	.08	-.98
F67.8	Communicate feelings to others	3.19	1.12	-.17	-.56
F67.10	How others see condition	3.19	1.16	-.24	-.76
F67.11i	Health interferes with relationships	2.97	1.16	-.03	-.77
F68.1	Burden others	2.25	1.01	.69*	.16
F68.2	Worry about effect on others	2.57	1.01	.22	-.36
F68.3	Guilt	3.09	1.27	-.01	-1.00
F68.5i	Resources for others	2.91	1.28	.20	-.97

Item no.	Item	Mean	SD	Skew	Kurtosis
F69.3	Supported by health service	2.87	.94	.01	-.40
F69.4	Dependent on health service	3.13	1.17	-.00	-.90
F69.6	Benefit from cm	2.06	1.21	.84*	-.50
F69.9	Access to information	2.84	.97	.15	-.27
F61.3i	Cope with pain level	3.07	.82	-.04	.48
F61.7	Comfortable	2.50	.99	.38*	-.03
F64.3	Prevent plans	2.67	1.02	.70*	.14
F65.5	Lonely	3.57	1.15	-.31	-.83
F67.3	Others appreciate condition	2.73	.89	.01	-.39
F67.4	Others understand	2.69	.87	.09	-.10
F69.8	Access to treatment information	2.65	.96	.10	-.40
F61.2	Satisfied with relief	2.69	1.02	.19	-.64
F61.5i	Satisfied with control	2.61	.98	.20	-.62
F64.5	Satisfied with future plans	2.69	1.04	.06	-.84
F67.7	Satisfied with communication	3.26	.95	-.34	-.52
F67.9i	Satisfied with express feelings	3.23	1.06	-.23	-.73
F68.4i	Satisfied with support others	3.00	1.13	-.15	-.97
F69.1	Satisfied with relationship with HCP	3.43	.98	-.40*	-.25
F69.5	Satisfied with supp from HCP	3.17	1.07	-.12	-.66
F69.10	Satisfied with information	3.07	1.04	-.16	-.64
F62.3	Pain angry	2.98	1.11	.14	-.75
F62.5	Pain irritable	2.56	.93	.11	-.42
F64.1	Uncertainty	2.86	1.01	-.07	-.59

* Indicates where skew of item is a problem

In only 4 of the 68 items have at least 10% of respondents used each of the scale points. These 4 items come from the communication and guilt and burdening other facets and relate to how much a person is bothered that their pain is invisible to others, how much a person feels that their health interferes with their personal relationships, how much a person is bothered by feelings of guilt and how concerned a person is that they do not have enough resources to provide for others. On inspection of the distributions, this suggests that for the majority of items, respondents are not using the anchor points representing either a very poor (1) or very good QoL (5). Although this will be taken into account in the selection of items, such items might prove to be sensitive to change following further testing.

Table 7.5 Frequency distribution for the PDM items (% scores for scale point)

Item	**Scale points†**				
	1	**2**	**3**	**4**	**5**
Flare-ups					
Flare-ups	25.0	41.7	25.9	6.0	1.4
Worry about flare-ups	13.9	31.9	32.4	16.7	5.1
Bothered by flare-ups	22.7	35.2	31.0	8.3	2.8
Pain relief					
Treatments offer relief	14.4	27.4	42.8	13.5	1.9
Control over pain	8.8	43.7	39.1	7.0	1.4
Treatment improve QoL	15.8	27.9	34.4	20.0	1.9
Bothered by medication	9.3	27.0	27.0	20.0	16.7
Side effects of medication	14.5	42.1	20.6	18.7	4.2
Cope with pain level	3.2	16.2	54.6	21.8	4.2
Comfortable	15.8	34.9	36.7	8.8	3.7
Satisfied with relief	11.6	34.7	30.6	19.9	3.2
Satisfied with control	12.0	37.0	31.0	18.1	1.9
Anger & frustration					
Bothered by anger	6.0	23.3	28.4	28.8	13.5
Anger interfere	2.3	13.5	20.9	40.5	22.8
Anger affect relationships	2.8	12.6	24.2	36.3	24.2
Bothered by frustration	16.3	36.3	29.8	13.0	4.7
Frustration interferes	8.4	26.5	32.6	25.6	7.0
Pain angry	7.9	28.8	30.7	22.3	10.2
Pain irritable	13.0	34.4	37.7	13.5	1.4
Vulnerability/ fear/ worry					
Bothered by vulnerable	4.2	18.6	32.6	31.2	13.5
Fear bother	2.8	15.9	29.9	36.0	15.4
Vulnerable interfere	1.9	7.4	29.8	41.4	19.5
Pain a threat	8.4	35.8	28.4	18.1	9.3
Concerned about pain	11.6	37.7	38.6	9.8	2.3
Distressed by pain	15.3	42.3	29.8	11.6	0.9
Feelings of worry	9.8	29.8	31.2	23.7	5.6
Treatment worry	3.3	25.5	27.4	30.7	13.2
Uncertainty					
Uncertainty interfere	10.8	27.7	33.3	21.1	7.0
Difficulty planning	10.3	26.3	29.6	26.3	7.5
Pain prevent	32.9	36.2	17.4	10.3	3.3
Pain limit life	27.7	41.3	18.8	9.4	2.8
Prevent plans	7.9	42.1	33.2	8.9	7.9
Satisfied with future plans	13.4	31.9	29.6	22.7	2.3
Uncertainty	9.8	26.0	36.3	24.2	3.7
Loss/ loneliness/ feeling alone					
Bothered by loss	15.6	33.0	26.4	17.0	8.0
Loss interfere	7.5	23.0	29.1	26.8	13.6
Carry out activities	30.5	39.0	19.7	7.5	3.3
Bothered by loneliness	5.7	16.5	27.4	30.7	19.8
Alone bother	5.7	13.7	30.2	26.9	23.6
Lonely	3.7	14.8	29.2	25.0	27.3
Positive strategies					
Humour	0	8.0	30.7	44.8	16.5
Hope for relief	0.9	4.7	17.9	38.2	38.2

Item	**Scale points†**				
	1	**2**	**3**	**4**	**5**
Feelings of hope	5.2	26.3	39.9	22.1	6.6
Hopeful optimistic	5.7	29.7	42.5	16.0	6.1
Hope and problems	4.7	23.3	42.3	25.1	4.7
Communication					
Others cannot see pain	13.4	30.6	29.2	18.5	8.3
Pain affect relationships	6.5	24.7	37.2	26.5	5.1
*Pain invisible	13.6	27.1	24.8	23.4	11.2
Communicate feelings to others	8.3	16.7	36.1	25.9	13.0
How others see condition	8.9	19.2	28.2	31.0	12.7
*Health interferes with relationships	12.2	22.1	32.4	23.5	9.9
Others appreciate condition	7.9	31.9	41.2	17.6	1.4
Others understand	7.9	32.4	44.0	13.9	1.9
Satisfied with communication	3.3	20.0	30.7	40.0	6.0
Satisfied with express feelings	5.1	22.3	27.0	35.8	9.8
Satisfied with support others	9.8	27.0	22.8	34.0	6.5
Guilt & burdening others					
Burden others	24.2	40.5	24.7	7.4	3.3
Worry about effect on others	15.3	31.6	36.7	13.0	3.3
*Guilt	12.1	22.0	28.0	20.6	17.3
*Resources for others	15.0	26.2	28.0	15.0	15.9
Relationship with HCP					
Supported by health service	7.0	27.9	40.0	21.9	3.3
Dependent on health service	7.9	24.8	28.5	24.3	14.5
Benefit from cm	46.7	21.2	15.6	12.7	3.8
Access to information	7.5	29.0	40.7	18.2	4.7
Access to treatment information	11.6	31.9	38.4	15.7	2.3
Satisfied with relationship with HCP	3.3	14.0	31.2	40.0	11.6
Satisfied with support from HCP	5.6	22.1	31.9	30.0	10.3
Satisfied with information	7.1	23.1	32.5	30.7	6.6

† 1 is poorest QoL and 5 is good QoL (see appendix 3 for response scales corresponding to items)

* Indicates where each point of the scale has been used by at least 10% of the sample.

7.4.9 Reliability analyses for the 68 PDM items

Table 7.6 illustrates the reliability analyses for the 68 items in the PDM. Correlations between each item and their facet mean with that items contribution excluded are shown (range -.01- .80). The item-facet correlation must be > +0.4 to ensure that it has been placed in the most appropriate facet and the higher the correlation, the more the item contributes to the facet. For internally consistent facets, Cronbach's alpha should be between 0.7 and 0.9. For 9 of the 10 facets, standardised Cronbach's alphas ranged .75-.91, demonstrating good internal reliability. The lowest, for positive strategies (α .67) suggests that this facet is not internally consistent, reflecting that items address two different underlying constructs; humour and hope. This is further supported by the low inter-item correlation between two items addressing these different concepts. The highest Cronbach's alpha was found for anger and frustration (α .91) and uncertainty (α .91) suggesting that the items addressing these facets are highly homogenous, that is they appear to be addressing relatively unidimensional concepts. The remaining facets ranged between .73 and .89, reflecting more acceptable alpha levels. The lowest of these was relationship with HCP, and the highest was vulnerability/ fear/ worry. These results are not definitive given that alpha levels will change following item reduction. Consequently the next section further explores the performance of individual items within each facet.

Table 7.6 Reliability analyses for the 68 PDM items and 10 facets

Item	Item-facet correlation	α if item deleted	Item-total correlation
Flare-ups - facet α .85, facet-total correlation .60, α if facet deleted .90			
Flare-ups	.68	.82	.50
Worry about flare-ups	.68	.83	.59
Bothered by flare-ups	.80	.71	.54
Pain relief - facet α .81, facet-total correlation .64, α if facet deleted .89			
Treatments offer relief	.57	.77	.32
Control over pain	.53	.77	.41
Treatment improve QoL	.58	.76	.37
Bothered by medication	.15*	.83	.28
Side effects of medication	.35*	.80	.36
Cope with pain level	.46	.78	.51
Comfortable	.52	.77	.53
Satisfied with relief	.68	.75	.56
Satisfied with control	.70	.75	.57
Anger & frustration - facet α .91*, facet-total correlation .82, α if facet deleted .88			
Bothered by anger	.76	.89	.72
Anger interfere	.80	.89	.70
Anger affect relationships	.77	.89	.66
Bothered by frustration	.70	.90	.69
Frustration interferes	.73	.90	.70
Pain angry	.69	.90	.67
Pain irritable	.68	.90	.59
Vulnerability/ fear/ worry - facet α .90, facet-total correlation .76, α if facet deleted .89			
Bothered by vulnerable	.73	.87	.64
Fear bother	.72	.88	.56
Vulnerable interfere	.73	.88	.66
Pain a threat	.64	.88	.58
Concerned about pain	.70	.88	.56
Distressed by pain	.63	.88	.62
Feelings of worry	.66	.88	.66
Treatment worry	.59	.89	.61
Uncertainty - facet α .91*, facet-total correlation .80, α if facet deleted .88			
Uncertainty interfere	.66	.90	.70
Difficulty planning	.78	.89	.71
Pain prevent	.76	.89	.64
Pain limit life	.77	.89	.65
Prevent plans	.75	.89	.60
Satisfied with future plans	.74	.89	.69
Uncertainty	.64	.90	.69
Loss/ loneliness/ feeling alone - facet α .88, facet-total correlation .75, α if facet deleted .89			
Bothered by loss	.69	.86	.64
Loss interfere	.70	.86	.71
Carry out activities	.54	.88	.67
Bothered by loneliness	.78	.84	.57
Alone bother	.66	.86	.52
Lonely	.75	.85	.63
Positive strategies - facet α .67*, facet-total correlation .30, α if facet deleted .91			
Humour	.38*	.65	.26
Hope for relief	.06*	.77	-.27
Feelings of hope	.58	.55	.23

Item	Item-facet correlation	α if item deleted	Item-total correlation
Hopeful optimistic	.56	.57	.44
Hope and problems	.64	.53	.47
Communication - facet α .88, facet-total correlation .74, α if facet deleted .89			
Others cannot see pain	.69	.87	.58
Pain affect relationships	.64	.87	.69
Pain invisible	.71	.87	.53
Communicate feelings to others	.76	.87	.62
How others see condition	.68	.87	.59
Health interferes with relationships	.59	.88	.73
Others appreciate condition	.48	.88	.35
Others understand	.42	.89	.27
Satisfied with communication	.66	.87	.55
Satisfied with express feelings	.56	.88	.56
Guilt & burdening others - facet α .81, facet-total correlation .73, α if facet deleted .89			
Burden others	.68	.74	.55
Worry about effect on others	.65	.75	.50
Guilt	.65	.74	.65
Satisfied with support others	.35*	.83	.51
Resources for others	.64	.75	.58
Relationship with HCP - facet α .75, facet-total correlation .52, α if facet deleted .90			
Supported by health service	.44	.69	.26
Dependent on health service	-.10*	.80	.27
Benefit from complementary medicine	.10*	.77	.05
Access to information	.62	.66	.42
Access to treatment information	.56	.67	.36
Satisfied with relationship with HCP	.60	.66	.42
Sat with support from HCP	.66	.64	.42
Satisfied with information	.75	.63	.54

* Unacceptable (< .40)

7.4.10 Item-facet correlations

To ensure that an item is placed in the correct facet and to check for redundancy with the core WHOQOL-facets, each item must correlate more highly with its own facet (excluding that items contribution) than with other core or PDM facets. Eighteen items were problematic due to higher correlations with other facets than the parent facet. If the correlation with core facets is higher than with the parent facet, this suggests redundancy and conceptual overlap. Moreover, if the correlation with other new facets is higher than with its own facet, this might result in that item being moved to another facet, or deleted as a consequence of redundancy. Due to the large number of items, only the problematic items are shown in table 7.7. This has implications for the conceptual integrity of facets.

Table 7.7 Item-facet correlations for items correlating more highly with other facets

Item and no.	Item-facet correlation	Facet item correlates more highly with
618 Bothered by medication	.15	19 other facets, most with vulnerability, .32
619 Side effects of medication	.35	Vulnerability, .43
613 Cope with pain level	.46	Uncertainty, .47, pain, .47, vulnerability, .50
617 Comfortable	.52	Uncertainty, .54
636 Distressed by pain	.64	Pain, .68
637 Feelings of worry	.66	Loss, .68, negative feelings, .76
642 Uncertainty interfere	.66	Negative feelings, .66, vulnerability, .67, loss, .68
641 Uncertainty	.65	Loss, .66, negative feelings, .69
653 Carry out activities	.54	7 other facets, most with pain, .63, ADL, .65, uncertainty, .71
663 Hope for relief	.06	Social support, .07, body, .08
666 Hopeful optimistic	.56	Positive feelings, .67
672 Pain affect relationships	.64	Anger, .66
6711 Health interferes with relationships	.59	Vulnerability, .60, uncertainty, .61, loss, .65, anger, .66
684 Satisfied with support others	.35	17 other facets, most with uncertainty, .55, ADL, .57, work capacity, .59
693 Supported by health service	.44	Health and social care, .57
694 Dependent on health service	-.10	34 other facets, most with guilt, .33, pain, .32
696 Benefit from complementary medicine	.10	Safety, .11, information, .13, relief, .13
695 Satisfied with support from HCP	.63	Health and social care, .68

Each item should also correlate at an acceptable level with the G facet, which is considered to be the bench mark for which the other facets can be correlated against and is regarded as a form of criterion validity as the WHOQOL G facet is known to assess QoL. As shown in table 7.8, correlations with the general facet ranged from -.25 (F66.3, hope for relief) and .01 (F69.6, benefit from cm) to .67 (F64.4, diff planning). Eighteen items were strongly correlated (r>0.5), 28 were moderately correlated (r=0.35-0.5) and 22 were poorly correlated (r=0.20- 0.35). G was least related to benefit from CM, access to treatment information, access to information, bothered by medication, humour, side effects of medication, others understand condition and dependence of health service. With the exception of these items, all item- G correlations were >0.24 at p>0.001. The negative correlation between hope for relief and QoL suggests that this is inversely related to QoL, that is, the more a person hopes for relief from their pain, the poorer their QoL. Consequently, this item is problematic.

Table 7.8 Item-G Pearson's correlations

Item	Pearson r	Sig. (2-tailed)
Flare-ups		
Flare-ups	.456	.001
Worry about flare-ups	.472	.001
Bothered by flare-ups	.456	.001
Pain relief		
Treatments offer relief	.246	.001
Control over pain	.331	.001
Treatment improve QoL	.348	.001
Bothered by medication	.160	.020
Side effects of medication	.212	.002
Cope with pain level	.397	.001
Comfortable	.431	.001
Satisfied with relief	.442	.001
Satisfied with control	.517	.001
Anger and frustration		
Bothered by anger	.444	.001
Anger interfere	.505	.001
Anger affect relationships	.486	.001
Bothered by frustration	.540	.001
Frustration interferes	.576	.001
Pain angry	.442	.001
Pain irritable	.411	.001
Vulnerability/ fear/ worry		
Bothered by vulnerable	.424	.001
Fear bother	.366	.001
Vulnerable interfere	.470	.001
Pain a threat	.409	.001
Concerned about pain	.398	.001
Distressed by pain	.532	.001
Feelings of worry	.478	.001
Treatment worry	.449	.001

Item	Pearson r	Sig. (2-tailed)
Uncertainty		
Uncertainty interfere	.618	.001
Difficulty planning	.665	.001
Pain prevent	.579	.001
Pain limit life	.592	.001
Prevent plans	.574	.001
Satisfied with future plans	.641	.001
Uncertainty	.561	.001
Loss/ loneliness/ feeling alone		
Bothered by loss	.517	.001
Loss interfere	.590	.001
Carry out activities	.572	.001
Bothered by loneliness	.431	.001
Alone bother	.327	.001
Lonely	.447	.001
Positive strategies		
Humour	.177	.010
Hope for relief	-.252	.001
Feelings of hope	.301	.001
Hopeful optimistic	.525	.001
Hope and problems	.404	.001
Communication		
Others cannot see pain	.353	.001
Pain affect relationships	.469	.001
Pain invisible	.305	.001
Communicate feelings to others	.368	.001
How others see condition	.332	.001
Health interferes with relationships	.572	.001
Others appreciate condition	.236	.001
Others understand	.217	.001
Satisfied with communication	.323	.001
Satisfied with express feelings	.364	.001
Satisfied with support others	.548	.001
Guilt & burdening others		
Burden others	.327	.001
Worry about effect on others	.261	.001
Guilt	.444	.001
Resources for others	.326	.001
Relationship with HCP		
Supported by health service	.237	.001
Dependent on health service	.199	.004
Benefit from cm	.013	.849
Access to information	.202	.003
Access to treatment information	.148	.031
Satisfied with relationships with HCP	.336	.001
Satisfied with supp from HCP	.421	.001
Satisfied with info	.360	.001

7.4.11 Item-domain correlations

Each PDM item should correlate more highly with its own domain than with any other domain (domain means were calculated without the inclusion of the new items), to ensure that it has been placed in the most appropriate domain. The item-domain correlations are shown in table 7.9 and ranged from -0.06- 0.68. Where items failed to correlate more highly with the parent domain, the domain that items correlated more highly with is shown. Of the 68 items, 40 correlated more highly with other domains than with the domain in which they had been placed. Where item-domain correlations are unacceptably low, these items are problematic, for example, bothered by medication is poorly correlated with domain I and with the other domains that it correlates more highly with (<0.23). Other items, for example bothered by frustration are strongly related to the parent domain and the other domains that it correlates more with (>0.50). Where correlations are unacceptably low items will be considered for deletion and where items correlate more highly with other domains, consideration will be given to the placing of that item within the most appropriate facet and domain.

Table 7.9 Item-domain correlations

Item	Item-domain correlation	Domain that item correlates most highly with
Domain I		
Flare-ups	.506	
Worry about flare-ups	.537	
Bothered by flare-ups	.494	
Treatments offer relief	.214	
Control over pain	.341	
Treatment imp QoL	.235	V, .266
Bothered by medication	.182	II, .195, III, .205, V, .226
Side effects of medication	.277	
Cope with pain level	.451	
Comfortable	.569	
Satisfied with relief	.456	
Satisfied with control	.516	
Domain II		
Bothered by anger	.492	I, .522
Anger interfere	.531	
Anger affect relationships	.500	
Bothered by frustration	.499	III, .510, I, .621
Frustration interferes	.559	I, .605
Pain angry	.415	I, .550
Pain irritable	.405	I, .511
Bothered by vulnerable	.611	
Fear bother	.586	
Vulnerable interfere	.652	
Pain a threat	.404	I, .466

Item	Item-domain correlation	Domain that item correlates most highly with
Concerned about pain	.426	I, .479
Distressed by pain	.499	I, .627
Feelings of worry	.675	
Treatment worry	.478	Domain V, .501
Uncertainty interfere	.629	
Difficulty planning	.573	III, .630
Pain prevent	.367	V, .431, I, .643, III, .695
Pain limit life	.364	V, .419, I, .662, III, .715
Prevent plans	.365	IV, .366, V, .434, I, .526, III, .678
Satisfied with future plans	.542	I, .588, III, .606
Uncertainty	.635	
Bothered by loss	.572	
Loss interfere	.599	
Carry out activities	.437	III, .619, I, .637
Bothered by loneliness	.563	
Alone bother	.485	
Lonely	.582	IV, .634
Humour	.238	
Hope for relief	-.055	IV, -.042, VI, .013
Feelings of hope	.326	
Hopeful optimistic	.549	
Hope and problems	.493	VI, .501
Domain IV		
Others cannot see pain	.395	I, .478
Pain affect relationships	.455	I, .469, V, .477, II, .482
Pain invisible	.307	II, .321, V, .355, I, .437
Communicate feelings to others	.446	II, .455
How others see condition	.319	V, .379, II, .409, I, .437
Health interferes with relationships	.562	V, .566, II, .568
Others appreciate condition	.358	
Others understand	.365	
Satisfied with communication	.470	II, .473
Satisfied with express feelings	.493	II, .574
Burden others	.279	V, .356, II, .361, I, .419, III, .429
Worry about effect on others	.180	V, .231, II, .236, I, .332, III, .351
Guilt	.373	III, .374, V, .428, I, .478, II, 528
Resources for others	.366	I, .445, V, .470
Satisfied with support others	.389	II, .460, I, .475, III, .578
Supported by health service	.144	I, .151, V, .226
Dependent on health service	.179	V, .225, II, .294, I, .312, III, .364
Benefit from cm	.008	I, .016, III, .026, V, .039
Access to information	.283	V, .352
Access to treatment information	.234	V, .307
Satisfied with relationship with HCP	.323	V, .388
Satisfied with support from HCP	.357	V, .414
Satisfied with information	.377	V, .466

7.4.12 Facet-domain correlations

Each facet should correlate more highly with its own allocated domain than with any other domain, to ensure that it has been placed in the most appropriate domain. Table 7.10 show the facet-domain correlations. Overall, facet-domain correlations ranged from 0.10- 0.74. Facet-parent domain correlations ranged from 0.40- 0.71. Of the 10 PDM facets, 6 correlated more highly with other domains than with their parent domain. Anger and frustration with domain I, uncertainty with domain III, positive strategies with domain VI, communication with domain II (although the correlation between communication and the psychological domain was only marginally higher than with its parent social relationships domain), guilt and burdening others with domain I, II, III and V and relationship with HCP with domain V. However, given that these correlations include the full set of items representing each facet before item reduction, these results should be interpreted with caution as certain items might artificially inflate or reduce the strength of the relationship between the facets and domains.

7.4.13 Scale reliability analysis

Appendix 4 shows the item-total reliability analysis for the 68 items, illustrating the contribution of each item to the overall scale. If the scale alpha, with the contribution of each item excluded, is higher than or equal to the overall 68 item scale alpha of .96, this indicates that the item is not contributing anything to the scale and should be deleted. Conversely, items that contribute most to the scale would give the lowest scale alpha when that item is excluded and should be retained. A total of 9 items had alphas higher or equal to the overall scale alpha, suggesting that they do not contribute to the scale. Those below .96 contribute most and should be considered for retention.

Table 7.10 PDM facet-domain correlations

Facet	**D I**		**D II**		**D III**		**D IV**		**D V**		**D VI**	
	Pearson r	***P* (2-t)**	**Pearson r**	***P* (2-t)**	**Pearson r**	***P* (2-t)**	**Pearson r**	***P* (2-t)**	**Pearson r**	***P* (2-t)**	**Pearson r**	***P* (2-t)**
Flare-ups	.585*	.001	.430	.001	.490	.001	.348	.001	.398	.001	.161	.018
Pain relief	.575*	.001	.407	.001	.435	.001	.356	.001	.458	.001	.111	.107
Anger and frustration	.666†	.001	.602*	.001	.482	.001	.500	.001	.562	.001	.272	.001
Vulnerability/ fear/ worry	.621	.001	.710*	.001	.519	.001	.507	.001	.613	.001	.228	.001
Uncertainty	.732	.001	.617*	.001	.742†	.001	.533	.001	.591	.001	.192	.005
Loss/ loneliness/ feeling alone	.590	.001	.685*	.001	.513	.001	.635	.001	.632	.001	.323	.001
Positive strategies	.242	.001	.477*	.001	.197	.004	.332	.001	.331	.001	.515†	.001
Communication	.564	.001	.588†	.001	.402	.001	.587*	.001	.561	.001	.291	.001
Guilt and burdening others	.576†	.001	.516†	.001	.536†	.001	.430*	.001	.503†	.001	.107	.119
Relationship with HCP	.362	.001	.280	.001	.321	.001	.397*	.001	.505†	.001	.118	.084

* Parent domain

† Domain facet correlates more highly with this facet

7.4.14 Stepwise multiple regression – the contribution of each PDM facet item to explaining overall QoL and health

The data was analysed by stepwise multiple regression to examine the contribution of each item to explaining overall QoL and health. Consideration was given to the assumptions underlying regression, including that the relationship between the DV and IV is a linear and stable one, that the spread of data around the full length of the regression line is relatively constant (known as the homoscedasticity assumption) and finally the multicollinearity assumption, that is that the IV's are independent of each other (Argyrous, 2000). In preparation for analysis, due to the skewed responses to items reported previously, items were log transformed to achieve a normal distribution.

All items from each facet were regressed against the log transformed G facet. Thus, in each case, the facet items were the IV's and G was the DV. Table 7.11 summarises the results from the multiple regression and includes the standardised beta coefficients and r square change statistic (shown as %), which can to used to identify items that contribute most to explaining G. For the physical domain, for flare-ups, only 2 of the 3 items were retained in the model explaining the variance observed in G (items 602, 601). The regression fit for flare-ups was ($R^2_{adj} = 27.5\%$) and the overall relationship was significant ($F2,213 = 41.48$, $p < 0.05$). For pain relief, 4 of the 9 items were retained in the regression model (items 615, 617, 613, 618). The regression fit for pain relief was ($R^2_{adj} = 32.3\%$) and the overall relationship was significant ($F4,209 = 25.92$, $p < 0.05$).

In the psychological domain, for anger and frustration, 3 of the 7 items were retained (items 627, 623, 622). The regression fit for anger and frustration was ($R^2_{adj} = 37.5\%$) and the overall relationship was significant ($F3,211 = 43.15$, $p < 0.05$). For Vulnerability/ fear/ worry, 3 of the 8 items were retained (items 636, 633, 638). The regression fit for Vulnerability/ fear/ worry was ($R^2_{adj} = 39.0\%$) and the overall relationship was significant ($F3,207 = 45.21$, $p < 0.05$). For uncertainty, 4 of the 7 items were retained (items 644, 645, 642, 647). The regression fit for uncertainty was ($R^2_{adj} = 56.7\%$) and the overall relationship was significant ($F4,207 = 68.73$, $p < 0.05$). For loss/ loneliness/ feeling alone, 3 of the 6 items were retained (items 652, 653, 655). The regression fit for loss/ loneliness/ feeling alone was ($R^2_{adj} = 44.0\%$)

and the overall relationship was significant (F3,207 = 55.23, $p < 0.05$). For positive strategies, 2 of the 5 items were retained (items 666, 663). The regression fit for positive strategies was (R^2_{adj} = 31.3%) and the overall relationship was significant (F2,207 = 48.08, $p < 0.05$).

In the social relationships domain, for communication, 3 of the 10 items were retained (items 6711, 679, 672). The regression fit for communication was (R^2_{adj} = 32.5%) and the overall relationship was significant (F3,207 = 34.20, $p < 0.05$). For guilt and burdening others, 3 of the 5 items were retained (items 684, 683, 682). The regression fit for guilt and burdening others was (R^2_{adj} = 40.7%) and the overall relationship was significant (F3,208 = 48.64, $p < 0.05$). For relationship with HCP, 3 of the 8 items were retained (items 695, 694, 691). The regression fit for relationship with HCP was (R^2_{adj} = 19.7%) and the overall relationship was significant (F3,201 = 17.42, $p < 0.05$).

On examination of the r square change statistic, shown as % contribution to G, the uncertainty item 644 (To what extent do difficulties with planning affect your everyday life?) and 652 (How much do feelings of loss interfere with your everyday life?) contributed most to explaining G.

Having shown the contribution that each PDM items makes to explaining G in a stepwise multiple regression, the following section reports the importance attributed to the PDM facets.

Table 7.11 Facet items, standardised coefficient beta, t, significance levels and contribution (r square change statistic shown as %) of the PDM items (log transformed) to G from the stepwise multiple regression

Facet items	Standardised Coefficients Beta	t	Sig.	Contribution %*
Flare-ups				
602	.316	4.493	.001	22.6
601	.286	4.071	.001	5.6
Pain relief				
615	.308	4.553	.001	23.2
617	.194	2.806	.005	5.5
613	.186	2.768	.006	2.6
618	.152	2.660	.008	2.3
Anger and frustration				
627	.400	5.745	.001	32.6
623	.188	2.897	.004	4.5
622	.147	1.996	.047	1.2
Vulnerability/ fear/ worry				
636	.312	5.119	.001	25.4
633	.266	4.221	.001	1.06
638	.233	3.647	.001	3.9
Uncertainty				
644	.215	2.951	.004	43.4
645	.303	4.960	.001	9.3
642	.213	3.356	.001	2.5
647	.193	3.317	.001	2.3
Loss/ loneliness/ feeling alone				
652	.333	5.045	.001	34.3
653	.316	4.992	.001	8.3
655	.169	2.852	.005	2.2
Positive strategies				
666	.537	9.317	.001	29.2
663	-.165	-2.864	.005	2.7
Communication				
6711	.371	4.626	.001	29.9
679	.152	2.400	.017	1.9
672	.171	2.261	.025	1.7
Guilt and burdening others				
684	.476	8.547	.001	30.3
683	.404	6.118	.001	10.0
682	-.139	-2.124	.035	1.3
Relationship with HCP				
695	.302	3.605	.001	15.2
694	.207	3.259	.001	4.1
691	.166	1.990	.048	1.6

* r square change shown as %

7.4.15 PDM importance items

Table 7.12 shows the mean and SD of the items ranked in order of importance. All the new facets had a mean rating of >3.0 confirming their importance to people with pain. The most important was the importance of obtaining relief (4.43) and of controlling pain (4.43) from the physical domain and the least important was being free from guilt (3.63) from the social relationships domain and feeling that you are not alone (3.69) from the psychological domain.

Table 7.12 Frequencies for the PDM importance items

Item No.	Item	Mean importance	SD
28	Obtain relief	4.43	0.66
29	Control pain	4.43	0.66
27	Free from flares	4.30	0.79
38	Sense of humour	4.23	0.77
41	Not a burden to others	4.22	0.85
42	Relationship with HCP	4.07	0.75
33	Free from worry	4.02	0.86
31	Free from frustration	4.01	0.91
30	Free from anger	3.95	0.94
37	Feelings of hope	3.89	0.90
39	Communicate feelings	3.88	0.74
32	Free from fear	3.86	0.98
34	Free from uncertainty	3.85	0.92
35	Free from feelings of loss	3.76	1.00
36	Feel that not alone	3.69	1.03
40	Free from feelings of guilt	3.63	1.02

7.4.16 Summary of the tests to determine which items are retained and which are excluded

Table 7.13 summarises the performance of each item on the tests reported above. In the selection of items, priority was given to significant variables in a multiple regression. However, if these items failed other tests, such as correlating highly with core WHOQOL facets implying redundancy, they were excluded. The far right column gives an explanation for excluding an item or facet. On the basis of this analysis, six of the ten facets have been excluded. These were flare-ups, loss/ loneliness/ feeling alone, positive strategies, communication, guilt and burdening others and relationship with HCP. Flare-ups was deleted because it only contained 3 items, the concept was too unidimensional and it reflected a symptom rather than an outcome *per se*. Loss, loneliness/ feeling alone was also deleted because it was not conceptually robust, redundant items did not leave anything left to form a good multidimensional facet and the internal consistency reliability was low because the facet represented two concepts rather than one coherent one. As with loss/ loneliness/ feeling alone, positive strategies represented an unsuccessful attempt to put 2 concepts together with low internal consistency reliability. Consequently, there was not enough for multidimensional facet. Furthermore, the SRPB facet already accounts for hope. For communication, only one of the significant variables in the multiple regression can be retained, therefore its contribution to explaining overall QoL and health is limited. For guilt and burdening others, the items correlated more highly with other domains than their own, but not consistently showing that items comprising this facet related to different concepts. Relationship with health care providers was strongly associated with core facets; in particular the availability and quality of health & social care facet and the remaining items did not form a cohesive facet. Uncertainty was retained, but was found to be more highly associated with level of independence than with the psychological domain and consequently has been moved.

Table 7.13 Summary of the performance of each item on the psychometric tests detailed above (facets and items in bold are retained)

No. & item	Skew	Scale points with >10% responses	Item-facet correlation (acceptable >.4)	Facet that item correlates most highly with	Item-domain correlation	α with whole scale if item deleted (scale α .96)	Multiple regression by facet against G (r square change statistic shown as %)	Retain (Y) or eliminate (✂)	Reason for deletion of individual items or facet
FLARE-UPS α .85									
601 Flare-ups	.55*	1-3	.68	Flare-ups	.506	.96	5.6	✂	Only 3 items, unidimensional, symptom rather than outcome
602 Worry about flare-ups	.25	1-4	.68	Flare-ups	.537	.96	22.6	✂	Only 3 items, unidimensional, symptom rather than outcome
603 Bothered by flare-ups	.45*	1-3	.80	Flare-ups	.494	.96	-	✂	Only 3 items, unidimensional, symptom rather than outcome
PAIN RELIEF α .81									
611 Treatments offer relief	-.02	1-4	.57	Pain relief	.214	.96†	-	✂	Low inter-item correlation (613 - .20 & 617 - .32)
614 Control over pain	.35*	2-3	.53	Pain relief	.341	.96	-	✂	Low inter-item correlation (613 - .27)
616 Treatment imp QoL	**-.012**	**1-4**	**.58**	**Pain relief**	**.235***	**.96**	**-**	**Y**	**More strongly associated with domain V**
618 Bothered by med	.09	2-5	.15*	Numerous facets*	.182*	.97†	2.3	✂	Low correlation with own facet, scale α improves if item deleted, correlates more highly with other facets
619 Side effects of med	.45*	1-4	.35*	Vulnerability*	.277	.96	-	✂	Low correlation with own facet, correlates more highly with other facets
613 Cope with pain level	**-.04**	**2-4**	**.46**	**Pain & discomfort, vulnerability, uncertainty ***	**.451**	**.96**	**2.6**	**Y**	**Correlates more highly with other facets**
617 Comfortable	**.38***	**1-3**	**.52**	**Uncertainty**	**.569**	**.96**	**5.5**	**Y**	**Correlates more highly with other facets**
612 Satisfied with relief	.19	1-4	.68	Pain relief	.456	.96	-	✂	Redundant because high correlation with 615 - .80
615 Satisfied with control	**.20**	**1-4**	**.70**	**Pain relief**	**.516**	**.96**	**23.2**	**Y**	**Retain because significant regressor**
ANGER & FRUSTRATION α .91 correlates more highly with domain I									
621 Bothered by anger	-.09	2-5	.76	Anger & frustration	.492*	.96††	-	✂	Redundant because high correlation with 622 - .79
622 Anger interfere	**-.55***	**2-5**	**.80**	**Anger & frustration**	**.531**	**.96††**	**1.2**	**Y**	**High correlation with 621 - .79 & 624 - .80**
624 Anger affect relationships	-.50*	2-5	.77	Anger & frustration	.500	.96††	-	✂	Redundant because high correlation with 622 - .80

No. & item	Skew	Scale points with >10% responses	Item-facet correlation (acceptable >.4)	Facet that item correlates most highly with	Item-domain correlation	α with whole scale if item deleted (scale α .96)	Multiple regression by facet against G (r square change statistic shown as %)	Retain (Y) or eliminate (✂)	Reason for deletion of individual items or facet
626 Bothered by frustration	.42*	1-4	.70	Anger & frustration	.499*	.96††	-	✂	Redundant because high correlation with 627 - .76
627 Frustration interferes	**.01**	**2-4**	**.73**	**Anger & frustration**	**.559***	**.96††**	**32.6**	**Y**	**High correlation with 626 - .76, retain b/c regressor.**
623 Pain angry	**.14**	**2-5**	**.69**	**Anger & frustration**	**.415***	**.96††**	**4.5**	**Y**	**High correlation with 625 - .76**
625 Pain irritable	**.11**	**1-4**	**.68**	**Anger & frustration**	**.405***	**.96**	**-**	**Y**	**High correlation with 623 - .76.**
VULNERABILITY/ FEAR/ WORRY α .90									
631 Bothered by vulnerable	-.17	2-5	.73	Vulnerability	.611	.96††	-	✂	High correlation with 632 - .72 & 633 - .78
632 Fear bother	**-.28**	**2-5**	**.72**	**Vulnerability**	**.586**	**.96**	**-**	**Y**	**Highly correlated with 631 - .72 & 633- .75**
633 Vulnerable interfere	**-.47***	**2-5**	**.73**	**Vulnerability**	**.652**	**.96††**	**10.6**	**Y**	**High correlation with 631 - .78 & 632 - .75**
634 Pain a threat	.36*	2-4	.64	Vulnerability	.404*	.96	-	✂	High correlation with 635 - .70, correlates more with other domain
635 Concerned about pain	**.30**	**1-3**	**.70**	**Vulnerability**	**.426***	**.96**	**-**	**Y**	**High correlation with 634 - .70 & 636 - .72, correlates more with other domain**
636 Distressed by pain	.32	1-4	.63	Pain & discomfort*	.499*	.96	25.4	✂	Redundant because highly correlated with 635 - .72, correlates more with other facet & domain
637 Feelings of worry	.08	2-4	.66	Loss & negative feelings*	.675	.96††	-	✂	Correlates more with other facet
638 Treatment worry	**-.03**	**2-5**	**.59**	**Vulnerability**	**.478***	**.96††**	**3.9**	**Y**	**Correlates more with other domain**
UNCERTAINTY α .91 Move to domain III									
642 Uncertainty interfere	**.11**	**1-4**	**.66**	**Negative feelings, vulnerability, loss***	**.629**	**.96††**	**2.5**	**Y**	**Regressor, high correlation with 644 - .70, correlates more with other facets & domain**
644 Diff planning	**-.01**	**1-4**	**.78**	**Uncertainty**	**.573***	**.96††**	**43.4**	**Y**	**Regressor, high correlation with 642 - .70, correlates more with other domain**
646 Pain prevent	.79*	1-4	.76	Uncertainty	.367*	.96††	-	✂	Redundant because highly correlated with 647 - .87 & 643 - .72, correlates more with other domain
647 Pain limit life	**.77***	**1-3**	**.77**	**Uncertainty**	**.364***	**.96††**	**2.3**	**Y**	**Regressor, highly correlated with 646 - .87, correlates more with other domain**

No. & item	**Skew**	**Scale points with >10% responses**	**Item-facet correlation (acceptable >.4)**	**Facet that item correlates most highly with**	**Item-domain correlation**	**α with whole scale if item deleted (scale α .96)**	**Multiple regression by facet against G (r square change statistic shown as %)**	**Retain (Y) or eliminate (✂)**	**Reason for deletion of individual items or facet**
643 Prevent plans	.70*	2-3	.75	Uncertainty	.365*	.96	-	✂	Redundant because highly correlated with 646 - .72, 647 - .71 & 645 - .70, correlates more with other domain
645 Satisfied with future plans	**.06**	**1-4**	**.74**	**Uncertainty**	**.542***	**.96††**	**9.3**	**Y**	**Regressor, highly correlated with 643 - .70, correlates more with other domain**
641 Uncertainty	-.07	2-4	.64	Negative feelings & loss*	.635	96††	-	✂	Correlates more with other facets & domain
LOSS/ LONELINESS/ FEELING ALONE α .88									
651 Bothered by loss	.34	1-4	.69	Loss	.572	.96††	-	✂	Highly correlated with 652 - .83
652 Loss interfere	-.07	2-5	.70	Loss	.599	.96††	34.3	✂	Highly correlated with 651 - .83
653 Carry out activities	.83*	1-3	.54	Pain & discomfort, mobility, ADL, anger, vulnerability, uncertainty, guilt*	.437*	.96††	8.3	✂	Redundant because correlated more highly with other facets, correlated more with other domain
656 Bothered by loneliness	-.32	2-5	.78	Loss	.563	.96	-	✂	Highly correlated with 657 - .80, & 655 - .80
657 Alone bother	-.34	2-5	.66	Loss	.485	.96	-	✂	Highly correlated with 656- .80 & 655 - .72
655 Lonely	-.31	2-5	.75	Loss	.582*	.96††	2.2	✂	Highly correlated with 656 - .80 & 657 - .72, correlates more with other domain
POSITIVE STRATEGIES α .67 correlates more highly with domain VI									
662 Humour	-.21	3-5	.38*	Positive strategies	.238	.96†	-	✂	Low correlation with own facet, scale α improves if item deleted, poor facet α, correlates more with other domain
663 Hope for relief	-.84*	3-5	.06*	Body image & social support *	-.055*	.97†	2.7	✂	Low correlation with own facet, scale α improves if item deleted, poor facet α, correlates more with other facets & domain
665 Feelings of hope	.12	2-4	.58	Positive strategies	.326	.97†	-	✂	Scale α improves if item deleted, poor facet α, correlates more with other domain
666 Hopeful optimistic	.30	2-4	.56	Positive feelings*	.549	.96	29.2	✂	Poor facet α, correlates more with other domain
667 Hope & problems	-.04	2-4	.64	Positive strategies	.493*	.96	-	✂	Poor facet α, correlates more with other domain

No. & item	Skew	Scale points with >10% responses	Item-facet correlation (acceptable >.4)	Facet that item correlates most highly with	Item-domain correlation	α with whole scale if item deleted (scale α .96)	Multiple regression by facet against G (r square change statistic shown as %)	Retain (Y) or eliminate (✂)	Reason for deletion of individual items or facet
COMMUNICATION α .88 correlates more highly with domain II									
671 Others cannot see	.24	1-4	.69	Communication	.395*	.96	-	✂	Redundant because highly correlated with 675 - .82, low correlation with 674 - .29
672 Pain affect relationships	-.07	2-4	.64	Anger & frustration*	.455*	.96††	1.7	✂	Regressor, correlates more with anger, therefore redundant, item too general at face value
675Pain invisible	.08	1-5	.71	Communication	.307*	.96	-	✂	Highly correlated with 671 - .82
678 Communicate feelings to others	-.17	2-5	.76	Communication	.446*	.96††	-	✂	
6710 How others see condition	-.24	2-5	.68	Communication	.319*	.96	-	✂	Low importance in cognitive interviewing
6711 Health interferes with relationships	-.03	1-4	.59	Anger, vulnerability, uncertainty, loss*	.562*	.96††	29.9	✂	Regressor, but correlates more with other facets, item too general at face value
673 Others appreciate condition	.01	2-4	.48	Communication	.358	.96	-	✂	Low correlation with other items (.20 - .38)
674 Others understand	.09	2-4	.42	Communication	.365	.96†	-	✂	Low correlation with other items (.19 - .34), scale α improves if item deleted
677 Satisfied with comm.	-.34	2-4	.66	Communication	.470*	.96	-	✂	Redundant because highly correlated with 679 - .76
679 Satisfied with express feelings	-.23	2-4	.56	Communication	.493*	.96	1.9	✂	Regressor, highly correlated with 677 - .76, low correlation with 674 - .24
GUILT & BURDENING OTHERS α.81 correlates with 4 other domains									
681 Burden others	.69*	1-3	.68	Guilt & burdening others	.279*	.96	-	✂	Correlates most with domain III
682 Worry about effect on others	.22	1-4	.65	Guilt & burdening others	.180*	.96	1.3	✂	Correlates most with domain III
683 Guilt	-.01	1-5	.65	Guilt & burdening others	.373*	.96††	10.0	✂	Correlates more with domain II
685 Resources for others	.20	1-5	.35*	Guilt & burdening others	.366*	.96	-	✂	Correlates more with domain V
684 Satisfied with support others	-.15	2-4	.64	Numerous facets*	.389*	.96	30.3	✂	Low correlation with other items (.23- .35), low correlation with own facet, correlates more with other facets
RELATIONSHIP WITH HCP α .75 correlates more with domain V									
693 Supported by health service	.01	2-4	.44	Availability & quality of health & social care*	.144*	.96†	-	✂	Scale α improves if item deleted, correlates more with other facets

No. & item	**Skew**	**Scale points with >10% responses**	**Item-facet correlation (acceptable >.4)**	**Facet that item correlates most highly with**	**Item-domain correlation**	**α with whole scale if item deleted (scale α .96)**	**Multiple regression by facet against G (r square change statistic shown as %)**	**Retain (Y) or eliminate (✂)**	**Reason for deletion of individual items or facet**
694 Dependence on health service	-.00	2-5	-.10*	Numerous facets*	.179*	.97†	4.1	✂	Scale α improves if item deleted, low correlation with own facet, ambiguous scoring, correlates more with other facets
696 Benefit from cm	.84*	1-4	.10*	Physical safety & security, information & pain relief*	.008*	.97†	-	✂	Low correlation with own facet, scale α improves if item deleted, correlates more with other facets
699 Access to information	.15	2-4	.62	Relationship with HCP	.283*	.96	-	✂	Highly correlated with other items
698 Access to treatment info	.10	1-4	.56	Relationship with HCP	.234*	.96	-	✂	Highly correlated with other items
691 Satisfied with relationships with HCP	-.40*	2-5	.60	Relationship with HCP	.323*	.96	1.6	✂	
695 Satisfied with support from HCP	-.12	2-5	.66	Availability & quality of health & social care*	.357*	.96	15.2	✂	Highly correlated with other items, correlates more with other facets
6910 Satisfied with information	-.16	2-4	.75	Relationship with HCP	.377*	.96	-	✂	Highly correlated with other items

* Indicates problem with item

† Contributes least to overall scale alpha

†† Contributes most to overall scale alpha

- Indicates no contribution to G in the stepwise multiple regression

Table 7.14 summarises the 16-item, 4-facet PDM to be used in conjunction with the core WHOQOL-100, which are represented by pain relief, anger and frustration, vulnerability/ fear/ worry and uncertainty. Facet inter-item correlations ranged from .33- .76 and Cronbach's alphas ranged from .77 (pain relief) to .85 (uncertainty), demonstrating acceptable internal reliability.

Table 7.14 Summary of retained facets with domain, inter-item correlation range and facet Cronbach's α

Facet	Domain	Final items	Correlation range	Facet α
61. Pain relief	I	616, 613, 617, 615	.33- .56	.77
62. Anger & frustration	II	622, 627, 623, 625	.47- .76	.84
63. Vulnerability/ fear/ worry	II	632, 633, 635, 638	.43- .75	.81
64. Uncertainty	Move from Domain II to Domain III	642, 644, 647, 645	.44- .70	.85

7.5 Discussion

7.5.1 A discursive account of the item reduction

In a cross-sectional survey of people with CP, 216 completed WHOQOL-100 and PDM were returned, achieving a response rate of 46%. The aim was to test the instrument and reduce the number of items based on its psychometric properties. The highest response rate was gained from the community; that is the general practitioner (GP) and charity samples. This could reflect a higher perceived obligation of being invited to take part by their GP and a willingness to take part in research amongst people registered with a charity. Reminders were sent to 76 of the sample, however, others were not traceable due to the stipulations of the clinics or departments who distributed the questionnaires that patients would not be identified, to honour their anonymity and confidentiality. Given the sensitive nature of some of the items contained in the instrument and its length, this response rate is considered to be acceptable.

The heterogeneous sample consisted of fewer males than females and approximately 40% of the sample was currently employed. In general, the health of participants was neither poor nor good or poor and just over a half of participants described themselves as currently ill, which is an important feature of the data, since despite the fact that all respondents had a condition characterised by pain, they did not consider themselves to be ill. Amongst those describing themselves as ill, it was common for co-morbid conditions to be described rather than the perceived cause of their pain. This has implications for the perceptual labels that patients attribute to their health state and for the wording of questions relating to people with pain, as illness is not an appropriate label for many conditions (for example, back pain). Consequently, an additional question asking about the perceived cause of pain was added in order for participants to describe what they perceived was causing their pain. Without this, respondents were not inclined to include a description of their condition under the question asking about illness. Most of the sample described their pain as continuous and discomforting. BP, sciatica and arthritis were the most frequently reported conditions, mirroring the high prevalence of these in the population.

Analysis of the results from the completed questionnaires allowed the relationship of the items in the PDM to be explored systematically to each other and to the core WHOQOL items, facets and domains. The results from the psychometric and statistical tests conducted were entered into an overall summary table to enable the psychometric properties of each of the items to be viewed and compared to each other (table 7.13). Items were deleted if they failed to meet the criteria detailed in the analysis and results. The decision to delete some items was definitive, that is, they were clearly unrelated to the parent concept (correlations <.40) or were redundant (highly correlated with other items representing that facet >.70 or more highly associated with core facets). However, as highlighted in chapter five, consideration must also be given to the fact that high correlations are not necessarily evidence of conceptual similarity or redundancy, but might indicate that these variables covary to a high degree (Melzack and Katz, 1994). In cases where the decision to select one item over another was not definitive, consideration was given to the face value heterogeneity of the items comprising a facet in order to select the best item. The need for parsimony to avoid patient burden is of central importance, without compromising the multidimensional nature of, and conceptual richness of the facets.

Of the 10 facets represented by the items in the PDM, 4 were retained. These were; pain relief, anger and frustration, vulnerability/ fear/ worry and uncertainty. These represent an elaboration of 3 of the 6 WHOQOL domains, namely, physical, psychological and level of independence. A detailed discussion of the item selection process follows. Consistent with the core WHOQOL-100 structure, each facet should consist of 4 items. Thus, 16 items representing 4 facets have been derived from an original 68 items representing 10 facets. Furthermore, 5 importance items were selected from 16, that is, one per facet with the exception of pain relief, which has 2 items covering its dual components, which are relief and control.

7.5.2 Item reduction by facet

7.5.3 Domain I – Physical

7.5.4 Flare-ups – facet deleted

Cognitive interviewing reduced the number of flare-up items from 5 to 3 and despite the importance attributed to this facet, three items is not sufficient to make up a multidimensional facet in its own right (4 is the standard WHOQOL model). Furthermore, high inter-item correlations (>0.71) suggested that the items were too unidimensional and conceptually similar and this redundancy further reduced the potential of the facet to exist in its own right. Additionally, this facet raises the issue of psychometrics versus clinimetrics, whereby the inclusion of items is based on the performance in psychometric tests, as opposed to how items perform clinically, in terms of the importance and severity ratings given by patients. For example, despite the importance attributed to being free from flares, which is consistent with the literature described in chapter three, this facet was not elaborate or multidimensional enough to hold up to psychometric scrutiny. Indeed, there involves a trade-off between these two approaches, which, it is argued can be complementary rather than conflicting (Marx et al., 1999). Flare-ups can be viewed as a symptom rather than an outcome or consequence of pain and items pertaining to this would therefore be considered inappropriate for an instrument measuring subjective QoL relating to pain and discomfort. Rather, it is the consequences of such flares that are captured in subjective reports of QoL, further justifying its exclusion.

7.5.5 Pain relief

All 9 of the pain relief items were retained during cognitive interviewing, suggesting that they were all comprehensive and clearly phrased, which supported their face validity. Two of the 9 items (those relating to medication) performed consistently poorly across the psychometrics tests and were only weakly associated with the other items in their facet (<0.18) and formed a separate cluster in the HCL. Although the item about being bothered by medication made a significant contribution to explaining G in the stepwise regression analysis, this item was more strongly associated with the core pain and discomfort facet, which was evidence of redundancy. Of the remaining 7 items, 3 were significant variables in a multiple regression and were thus retained given their contribution to G. Selecting one item from the remaining 4 involved systematically eliminating those that performed badly in relation to each other. Another item was deleted because of its weak association with 2 of the selected items, which would mean that those items were not related enough to produce a conceptually robust facet. Another deletion occurred due to being highly correlated with one of the selected items, which would render that item redundant because of its conceptual proximity. There is, of course, a trade off between heterogeneity and homogeneity when constructing facets and the final item selection ultimately reflects this. A potential problem with this facet is that the final item to be selected correlates marginally more with domain V (environment) than it does with domain I (physical). However, being able to obtain relief and controlling pain received the highest importance ratings of all the 10 facets, providing further justification for its retention.

7.5.6 Domain II – Psychological

7.5.7 Anger and frustration

The face validity of the items representing anger and frustration was also confirmed by the cognitive interviewing. Of the 7 items, 3 were found to be significant variables in a multiple regression explaining G. These were retained and the process of selecting one item from the remaining 4 involved choosing the item that performed above the other 3 items. There was some difficultly with redundancy due to items being highly correlated (>0.76). Three items were deleted because they were strongly associated with selected items and would compromise the heterogeneity of the facet. Although the final item to be selected was strongly associated with the 3 selected items, it passed more tests than deleted items. This facet correlated more highly with domain I rather than its parent domain, domain II. However, given that this correlation was only marginally higher (0.67 versus 0.60), that anger and frustration explicitly describe psychological features of QoL and not physical aspects and that a strong correlation with the physical domain would be hypothesised given that anger and frustration have been shown to be a consequence of pain, this facet will remain in the psychological domain. The high correlation with the physical domain can be explained, in part, because of the close relationship between, and the concurrence of, the experience of pain and discomfort and its emotional sequalae. In the importance ratings, being free from frustration was rated as marginally more important than being free from anger, although both were considered important.

7.5.8 Vulnerability/ fear/ worry

All 8 vulnerability/ fear/ worry items were retained remained following cognitive interviewing and 3 items were significant variables in a multiple regression explaining G. Of these, the item predicting the greatest variance (distressed by pain) was deleted because of its strong association with the core pain and discomfort facet, suggesting that the core items already account for this aspect of QoL. Of the remaining 5 items, feelings or worry was deleted because of being strongly associated with negative feelings. A further 2 items were deleted because of their unacceptably high correlations with selected items (>0.70). Being free from worry was rated as more important than being free from fear, although both were important to the QoL of people with CP in this study. The retention of this facet is important given the literature supporting the role of fear and worry in patients with CP discussed in chapter three.

7.5.9 Uncertainty

Of the 7 uncertainty items, 4 were significant variables in the multiple regression explaining G, which supports the importance of uncertainty in explaining overall QoL and health. Of the 4 items, 2 were highly associated with each other and another was strongly related to negative feelings. Despite the contribution of the 4 items to explaining G, freedom from uncertainty was rated as moderately important. Furthermore, although being hypothesised to belong to the psychological domain, uncertainty was more strongly associated with level of independence.

7.5.10 Loss/ loneliness/ feeling alone

Despite the face validity of 6 of the 7 loss/ loneliness/ feeling alone items confirmed by the cognitive interviewing, this facet was deleted following the psychometric tests reported here. One item was deleted because it correlated more highly with other PDM and core facets than with its own facet. All the remaining items were highly correlated, which reflected an unacceptably homogenous concept. Consequently, this did not leave enough items to form a coherent multidimensional facet. Furthermore, freedom from loss and not feeling alone were given relatively low importance ratings compared to other facets (with the exception of freedom from guilt, which received the lowest), although they still received ratings > 3.0. This concurs with evidence suggesting that loneliness is not a prominent psychological symptom amongst patients with pain (VonKorff and Simon, 1996). On conceptual grounds, this facet was represented by 2 loosely related concepts illustrated by the weak association between the item relating to being alone and the items relating to loss (<.4.0). Consequently, there was not scope to retain a facet pertaining to either loss or loneliness/ feeling alone.

7.5.11 Positive strategies

Of the 7 items representing positive strategies, 5 were retained following cognitive interviewing. However, this facet proved to be particularly problematic and was deleted. Two of the 5 items were only weakly associated with the facet mean, which was reflected in the low facet Cronbach's alpha showing only marginal internal consistency reliability, which was the lowest and least acceptable of all the new facets. The 3 remaining items were not sufficient to create a multidimensional facet. Furthermore, the item addressing optimism was more strongly associated with the core positive feelings facet. Moreover, positive strategies correlated more highly with the spirituality, religion and personal beliefs (SRPB) than with the psychological domain, suggesting that SRPB may already account for the concept of hope. As with the loss/ loneliness/ feeling alone facet, it appears that positive strategies consisted of two related concepts, hope and humour that do not form a conceptually robust, internally consistent facet. Moreover, there is insufficient material from either hope or humour to create a multidimensional facet. Consequently, it is argued that hope is a component of core WHOQOL facets such as positive feelings and SRPB. Despite the problems associated with the two concepts include in this facet, having a sense of humour was considered important, and indeed more important than feelings of hope. However, this is not sufficient to warrant its inclusion because of its unidimensionality. The high importance attributed to humour could reflect a social desirability bias, that is, the need to convey this desirable attribute. Conversely, it could be part of the growing body of evidence showing the co-occurrence of positive and negative affectivity despite adversity (for example, Folkman, 1997; Sodergren and Hyland, 2000, 2002; Huppert and Whittington, 2003). Although it is likely that pain would lead to few positive emotional experiences, given that pain is an inherently unpleasant experience, the use of such strategies might be more realistically conceptualised as process variables rather than outcomes *per se*, that is, active coping strategies.

7.5.12 Domain IV – Social relationships

7.5.13 Communication

Of the 12 communication items, cognitive interviewing and expert reading eliminated 2. This facet was deleted because of the 3 significant variables in a multiple regression, the most significant variable was highly associated with the anger and vulnerability facets. The least significant variable was also strongly associated with the anger facet. Only one item remained G and of the remaining items, 2 were only weakly associated with the other items in the facet and 2 were highly associated with other items, suggesting that these items were too conceptually homogenous. Of the 4 remaining items, only one of these was a significant variable in the multiple regression and how other people see ones condition was not considered to be important by cognitive interviewees. More generally, communication was ranked as moderately important by respondents and this facet correlated more highly with the psychological domain than with the social relationships domain in which it was hypothesised to belong too. Moreover, the face validity of this facet was compromised by the fact that it appeared to be addressing quite a general concept.

7.5.14 Guilt and burdening others

This facet was deleted primarily because items were more strongly associated with domains other than their own in an inconsistent pattern. Consequently, it was not clear which domain this facet would belong to. The conceptual integrity of this facet was compromised because perceptions of burdening others related more to the level of independence domain, guilt to the psychological domain and resources for others to the environment domain. Despite being the most significant regressor, satisfaction with support for others was more strongly associated with other facets and only weakly associated with the other items in the facet. Further justification for the deletion of this facet was the relatively low importance attributed to freedom from guilt and burdening others (although still > 3.0). Not being a burden to others was considered to be more important than being free from guilt (4.22), which suggests that these two components are conceptualised differently by people when assessing the importance of various aspects of their QoL. Furthermore, evidence suggests that guilt is not a prominent psychological symptom amongst people with pain (Vonkorff and Simon, 1996). Consequently, guilt and burdening other does not form a cohesive, internally consistent, multidimensional facet.

7.5.15 Relationship with HCP

Eight items pertaining to an individual's relationship with health care providers were retained following cognitive interviewing, however, this facet was deleted because 5 items were more strongly associated with core WHOQOL facets (availability and quality of health and social care, physical safety and security and opportunities for acquiring new information and skills), suggesting that the core instrument already accounts for these aspects of QoL, most notably environment domain. Further justification for the deletion of this facet derived from the high inter-item correlations, suggesting that the underlying concept was probably too unidimensional. Given the range of inter-item correlations (ranging from -.33 to .74), the items do not form a cohesive, internally consistent facet. Although this facet has been deleted, relationship with HCP's was considered to be important. However, due to the strong association of items with core facets, including availability and quality of health and social care it is argued that the concept represented in this facet is already addressed by the core instrument.

To summarise, pain relief, anger and frustration, vulnerability/ fear/ worry and uncertainty were retained as new facets accounting for the impact of pain on QoL. With the exception of pain relief, the other three facets represent psychological consequences of pain. However, due to its higher correlation with the level of independence domain, uncertainty will be moved from the psychological to the level of independence domain. Although the 6 discarded facets were clearly important to people with pain, as evidenced by their elicitation by FG and web survey participants and by the importance ratings attributed to them, the elimination can be explained by a number of factors. Main reasons for the deletion of items and facets were unacceptably high correlations with core or other new facets, which suggests that those items or facets were adequately accounted for. Moreover, other facets, such as positive strategies and loss/ loneliness/ feeling alone did not form coherent multidimensional facets in their own right. It is of course possible that concepts vary in their degree of multidimensionality, however, the WHOQOL framework does not allow for the inclusion of narrow unidimensional aspects of QoL, which may be accounted for by other core facets.

7.5.16 Format of the WHOQOL and PDM

Following item reduction, the WHOQOL and PDM was prepared for the longitudinal survey reported in chapter eight. Each set of items with the corresponding Likert scale was inserted in the appropriate response scale block after the core WHOQOL items to ensure a seamless finish and to avoid unnecessary additional text before each new section. The 5 importance items will be inserted after the core WHOQOL importance items and this will be placed before the 'About you' questions as some respondents of this survey left these items blank because they believed the 'About you' questions to signal the end of the questionnaire. It is hoped that this will ensure that fewer questions will be left unintentionally blank. This does have implications for the psychometric integrity of the WHOQOL-100 in terms of the ordering and structure of the instrument, however, the decision to integrate the new items into the existing structure ensures that once validation is complete, the PDM is not used as an entity by itself rather than in conjunction with the WHOQOL, which is necessary for a holistic and comprehensive assessment of QoL.

7.5.17 Critique

Chapter six considered the face validity and heterogeneity of the items comprising each facet. During the analysis of the cross-sectional survey data reported here, items were selected based on their performance on each of the tests. When the case for retaining or deleting an item was not definitive, for example, when two items performed equally as well, but are highly associated with each other, decisions were taken on the face validity of the items which involved an element of subjectivity. However, decisions taken at this stage are subject to further testing in subsequent stages.

7.5.18 Conclusion and further work

Psychometric analysis was conducted on the core WHOQOL items and the 68 PDM items. All new facets received importance ratings of >3.0, underscoring their importance to people with CP. Based on the psychometric tests reported here, 6 facets were deleted, leaving 4 facets in the PDM; pain relief; anger and frustration; vulnerability/ fear/ worry; uncertainty. Cronbach's alphas for the new facets ranged from .77 to .85, demonstrating good internal reliability. Further analysis is carried out on the data in chapter nine, where the importance of these facets of QoL is examined and an abbreviated form is derived to be used in conjunction with the WHOQOL-Bref. In the meantime, chapter eight reports a longitudinal survey to examine sensitivity to change and test-retest reliability.

Chapter eight

The Longitudinal Study: Sensitivity to Change and Test-retest Reliability of the PDM

8.1 Introduction

Psychometric analysis of data from the cross-sectional survey reported in chapter seven was utilised to reduce the number of PDM items from 68 to 16. This chapter aims to examine the psychometric properties of the 16-item PDM. Specifically, to examine internal consistency reliability, construct validity, concurrent validity, sensitivity to change when applied to a clinical population undergoing an intervention known to be effective and test-retest reliability.

8.1.1 Validity

Validity has been discussed in greater detail in chapter seven. If an instrument is strongly correlated with a 'gold standard' instrument known to measure the variables being assessed, this provides evidence of concurrent or criterion validity (Juniper, Guyatt and Jaeschke, 1996). For example, if the WHOQOL and PDM were applied concurrently with a generic health status instrument, purporting to measure similar concepts, these two instruments would be expected to be highly associated. Although this is a central component of psychometric testing, patient burden must be a consideration with respect to the length of questionnaire batteries. Consequently, selecting a relatively brief, yet validated instrument is an important goal. In general, the SF-36 is the most widely used, although as detailed below, the SF-12, derived from the parent measure has also been shown to be suitable (Jenkinson and Layte, 1997). Construct validity is conducted in the absence of a gold standard (Juniper, Guyatt and Jaeschke, 1996), where for example, a global QoL rating (for example, general QoL and Health (G) of the core WHOQOL) is used as a benchmark against which to show that the concepts are measuring QoL. Discriminant validity can also evaluated by looking at the differences between categories of individuals known to differ on the construct being measured (Campbell, 1960), for example, on pain intensity or whether respondents define themselves as ill or well. An instrument has discriminant validity if it is able to distinguish between such groups.

8.1.2 Sensitivity to change

The ability of an instrument to detect changes over time is essential to determine a patient's response to treatment (Fitzpatrick et al., 1992). In order to test this feature of a measure, it needs to be applied to a specified population undergoing an intervention known to be effective. The goal is not to examine the effectiveness of the intervention *per se*, but to look at its impact in order to test the measure itself. If the instrument is shown to be sensitive to changes in underlying symptoms or condition, it can be used in trials to assess the impact of different treatments on QoL. Given these issues, an appropriate intervention must be selected that is efficacious, accessible and feasible. Furthermore, it is essential to ascertain the most suitable interval between baseline and follow up to maximise any potential measure of change. The inclusion of questions about whether or not the patient felt satisfied with the intervention and so on can be used as a benchmark against which to measure change, such questions are known as transition questions (see below).

Longitudinal studies have shown that the WHOQOL is able to detect changes over time following pain management for patients with CP (Skevington, Carse and Williams, 2001) and following antidepressant medication for patients with depression (Skevington and Wright, 2001), suggesting that the WHOQOL can be used as evaluative instrument. The purpose of the PDM was to increase its specificity to measure change in people with CP and consequently, it is predicted that following an intervention, QoL should improve on the facets that are most important in understanding the impact of pain on QoL.

8.1.3 Test-retest reliability

Test-retest reliability is about the reproducibility of the measure, that is, whether the instrument obtains the same results on repeated applications, when the respondents have remained stable. Scores should be comparable across time if no intervention has been applied or life-altering events occurred. Streiner and Norman (1995) suggest that there should be a time delay of between 2 and 14 days between the first and second application of the instrument, preferably so that respondents do not recall their previous responses. Although 2 days is probably not a sufficient interval as respondents are likely to remember their responses, 14 days is more acceptable as forgetting is more likely to occur. In order to check that a person's health condition has remained stable, Streiner and Norman (1995) suggest the addition of a transition question to determine whether change has perceived to have taken place, for example, 'Is your health better, the same or worse than at the last assessment?' However, when assessing a complex multidimensional phenomenon such as QoL, other life events or aspect of life may change despite a relatively stable condition. Consequently, asking whether other life events or occurrences have impacted on their QoL in the time that has elapsed since the first application is recommended (see below).

To determine test-retest reliability, the population being studied needs to be relatively stable, that is, a population not undergoing intervention or experiencing any life altering events (The WHOQOL Group, 1998). In practice this is problematic given the flares and fluctuations that have been shown to characterise the pain experience (Skevington, 1994; Mason, Skevington and Osborn, 2004). To overcome this, the measure can be applied to a relatively homogenous patient group who are waiting for treatment at baseline and after a 2-week interval with the addition of transition questions, to determine whether scores remain stable when there are no underling changes. Given the multidimensionality of QoL, scores could change as a function of a change in another aspect of a persons' life. Hence the need for a transition question asking respondents about whether there have been any specific life events or occurrences that have impacted on their QoL since baseline assessment.

Test-retest reliability is examined using the Pearson product moment correlation coefficient or an intra-class correlation coefficient. This later approach assesses how much variability in scores is due to differences between individuals or variability in measurement, using analysis of variance. Larger sample sizes relate to greater confidence in the reliability of a measure (Eliasziw and Donner, 1987). Streiner and Norman (1995) propose that to test reliability accurately, sample sizes of less than 200 are satisfactory, providing a confidence interval of +/- 0.10 is accepted. Although minimal standards for reliability coefficient are 0.7, higher is better. Confidence in reliability also increases with repeated application of the measure in different populations or samples (Williams and Naylor, 1992). In the original field trial reported in the WHOQOL manual (WHOQOL Group, 1998) test-retest was assessed in four of the centres. Intervals ranged from 2-8 weeks and correlations between facets at baseline and follow-up were high, ranging from .68 for safety and security and .95 for dependence on medication, demonstrating good test-retest reliability.

8.1.4 Background to the intervention

There are a myriad of interventions to treat and manage pain with varying degrees of effectiveness. The best evidence for any intervention is the randomised controlled trial (RCT) and subsequent systematic reviews of these trials, which provide an evidence base of the effects of health care interventions. However, there is a relative dearth of rigorously designed and implemented RCT's of interventions designed to reduce pain. Moreover, very few studies of interventions include QoL as an outcome and the authors of systematic reviews and meta-analysis frequently argue for better-designed trials for these treatments and interventions (Nelemans et al, 2001; 2003). For this study, it was important to select an intervention of known efficacy, that is quick acting and feasible in terms of access to required number of patients. Before the evidence for lumbar epidural steroid injections (LES) is presented, the evidence for other interventions is summarised. It is not possible to review all interventions given that they are so numerous, consequently, the summary focuses only on randomised trials (RT's), systematic reviews or meta-analyses of widely used interventions. Consideration was not only given to the efficacy of such interventions, but also to the feasibility of recruiting patients undergoing such interventions.

8.1.5 Evidence of effectiveness of other interventions to reduce pain

Table 8.1 summarises studies examining the effectiveness of interventions used in the management of CP. Despite some compelling evidence for the use of a range of treatments for CP, in general, the evidence is inconclusive and the number of patients involved in the trials is relatively small. Moreover, the authors of such trials highlight the need for more rigorously designed trials before conclusions can be drawn about the efficacy of interventions (Ezzo et al., 2000; Verhagen et al., 2002; Brosseau et al., 2002; Milne et al., 2001). Additionally, given that anticonvulsants such as gabapentin are used to patients with neuropathic pain syndromes, compared to patients with CLBP, this represents a relatively low prevalence group. Consequently, applying the WHOQOL and PDM to patients with a more prevalent condition was a more effective form of validation for the instrument. It is also possible that complementary or alternative medical practices such as massage and acupuncture might be more subject to variability in delivery, which presents a challenge to assessing outcomes reliably. This provides further justification for favouring a more systematically delivered and extensively used medical treatment.

8.1.6 Evidence for lumbar steroid epidural injections

Having explored the range of treatments for CP, evidence is presented here for the efficacy of LES for CLBP. Numerous studies have evaluated the efficacy of LES with mixed results, however precedence is give here to key systematic reviews of trials given that sample size of individual trials is relatively small. For example, Papagelopoulos and colleagues (2001) found that of 50 patients with lumbosacral radicular pain, 80% could anticipate early pain relief after LES. More recently, Konig and colleagues (2002) found only short duration benefits of LES for LBP in a study of 74 patients. In another study looking at the effectiveness of LES for 69 patients with herniated lumbar discs, 77% had a decrease in symptoms and were able to avoid surgery for twelve to twenty-seven months (Wang et al., 2002). A study of 48 patients with lumbosacral radiculopathy secondary to herniated nucleus pulposus, LES injections were compared with saline trigger-point injections and after 1.4 years the active treatment group had a success rate of 84% compared with 48% for the saline trigger-point group (Vad et al., 2002).

Koes and colleagues (Koes et al., 1995) and Watts and Silagy (1995) conducted systematic reviews of the RCT's published up to 1994. Koes and colleagues found that of the 4 studies with the highest methodological quality, 2 had a positive outcome and 2 had a negative outcome. McQuay and Moore (1998) are critical of this review for failing to report any meta-analytic judgments. In their meta-analysis of epidural corticosteroids, Watts and Silagy (1995) found that compared to controls, epidural steroids do have an analgesic effect on sciatica. In a re-analysis of this data with addition of a subsequent trial by Carette and colleagues (1997), McQuay and Moore (1998) used number needed to treat (NNT) as a measure of clinical benefit. NNT refers to the number of patients who need to be treated in order to prevent one additional bad outcome (NHMRC Acute Pain Management, 1999 p. 159). For example, if LES has a NNT of 12 (e.g. Klenerman et al., 1984), 12 people would need

Table 8.1 Summary of evidence of effectiveness of interventions for CP

Intervention and author	Study type	Key evidence and conclusions
Acupuncture, Ezzo et al., 2000	Systematic review	Review of 51 studies for the effectiveness of acupuncture. The results were positive in 21 studies, negative in 3 and neutral in 27. Three fourths of the studies were of low methodological quality and a significant positive relationship was found between low quality studies and positive results. Limited and inconclusive evidence of effectiveness and a need for more rigorously designed trials
Cognitive behaviour therapy (CBT), Moore et al., 2000	RT	Brief CBT for primary care patients with LBP (n=226) has been shown to have significant effects on reducing worry and fear avoidance compared to usual care, but only modest effects on pain ratings and interference with activities
Massage, Furlan et al., 2000	Systematic review	Of 5 RCT's, 3 were of high methodological quality. Massage was compared to detuned laser therapy (placebo), acupuncture and spinal manipulation. Massage was more effective than placebo, relaxation, acupuncture and self-care education, less effective than manipulation, shiatsu and TENS and comparable to treatment with corsets and exercise. Conclude that massage might benefit those with sub-acute and chronic non-specific LBP
Massage, Guthlin et al., 2000	RT	Patients with non-inflammatory back pain received 10 sessions of classic massage or usual care for 5 weeks. Greater pain relief at 3-months follow-up for patients receiving massage therapy
Hydrotherapy, Verhagen et al., 2002	Systematic review	10 RCT's examining the effectiveness of balneotherapy for RA and OA (n=607). QoL outcome only reported by 2 trials. Although most studies reported positive findings, the quality of the trials was poor. Conclude that the evidence for the efficacy of this type of therapy is not presently sufficient
Hydrotherapy, Queneau et al., 2001	Review	Review of 20 RT's assessing CLBP, OA, FMS, RA and psoriasic arthritis, 4 of which were double blind. Beneficial and prolonged improvements found for pain, handicap, QoL, consumption of analgesics and NSAIDs
Hydrotherapy, Hall et al., 1996	RCT	RA patients (n=139) randomly assigned to hydrotherapy, seated immersion, land exercise or progressive relaxation. Hydrotherapy produced the greatest improvements, which were maintained at 3-month follow-up
Anticonvulsants, Wiffen et al., 2000	Systematic review	Twenty-three trials of 6 anticonvulsants in a range of patient populations (n=1074). Although widely used, few trials show analgesic effectiveness and the reviewers conclude that anticonvulsants should be withheld except for trigeminal neuralgia until other interventions have been tried
Transcutaneous electrical nerve stimulation (TENS), Brosseau et al., 2002; Milne et al., 2001	Meta-analysis	Five trials with patients randomised to a placebo group receiving sham TENS (n=170) or active TENS (251). There was considerable variability in the course and length of the treatments and the difference between active and placebo group were not significant. No evidence for its use or non-use. Better trials are needed with standardised outcome measures reporting information on type, site, duration and optimal intensity and frequency

to be treated in order to prevent one additional bad outcome. McQuay and Moore used the outcome of at least 75% pain relief for short-term outcomes (defined as 1-60 days) and at least 50% pain relief for long-term outcomes (defined as 12 weeks to one year). Of 11 trials reporting short-term relief data, only 3 showed a statistically significant benefit although overall there was a significant benefit. The NNT was 7.3 which means that of 7 patients being treated with epidural steroid, one will obtain more than 75% pain relief who would not have done if they had received a placebo or control treatment (local anaesthetic). In their analysis of the 6 trials giving long-term relief data, McQuay and Moore (1998) found an overall statistically significant benefit despite only one study being significant. The NNT was 13 for 50% pain relief which means that for 13 patients being treated with epidural steroid, one will obtain more pain relief over 12 weeks to one year who would not have done if they had received a placebo or control treatment (local anaesthetic).

Despite evidence for the efficacy of LES in patients with LBP (Watts and Silagy, 1995; McQuay and Moore, 1998), other systematic reviews have shown insufficient evidence to enable a conclusion to be drawn (Van Tulder et al., 1997; Koes et al., 1999). The methodological quality and design of studies has been questioned with the best studies showing inconsistent results with benefits being of short-term duration only (Koes et al., 1995). Studies not including a placebo arm have also been criticised (Nelemans et al., 1999; 2001; 2003) and choice of methods used by the reviewers has been shown to alter the strength of the conclusions made about the effectiveness of treatment (Hopayian and Mugford, 1999).

In summary, the advantages of using patients undergoing LES were that, despite mixed evidence of efficacy, studies have produced positive results and this type of intervention is widely used in clinics across the UK. The effects of LES occur relatively soon after the intervention which compares favourably to other types of intervention such as surgery or a course of CBT where the rehabilitation period may be lengthy. Furthermore, the patient group undergoing LES are accessible and numerous which satisfies the required sample size. Again this is comparable to the smaller number of patients undergoing pain management programmes or hip replacement surgery in the region. Given the numerous treatment options for people with CP and with respect to the evidence of efficacy, feasibility and access, the decision to choose LES was a pragmatic one given that it is a relatively quick acting, standardised intervention applied to a relatively homogenous group in terms of symptomatology and diagnosis.

8.1.7 Acceptance of pain and QoL

In addition to determining the psychometric properties of the PDM as described above, an additional aim was to explore the relationship between acceptance of pain and QoL, which was identified and reported as a process mediating QoL in the qualitative studies reported in chapters three and four. Given that the core WHOQOL facet definition for pain and discomfort also encompasses the concept of acceptance, this provided further justification for examining the relationship between acceptance of pain and QoL. Acceptance describes the acknowledgement that one has pain, giving up unproductive attempts to control pain, acting as if pain does not necessarily imply disability, and being able to commit to living a satisfying life by focusing on life goals and activities in despite pain (Geiser, 1992; Hayes et al., 1994; McCracken, 1998). It has been suggested that changing the self and accepting pain could be a more useful coping strategy than attempts to change the pain (Schmitz et al., 1996). McCracken (1998) argues that avoidance of pain, through for example, persistent unsuccessful attempts to eliminate it, has detrimental consequences and so adjustment involves reducing avoidance and attempts to control pain, accepting it and focusing on more realistic goals such as functional restoration (McCracken, 1998). This is supported by Aldrich and colleagues (2000), who found that an excessive focus on eliminating pain resulted in feelings of frustration and distress which brought about more suffering and a poorer QoL (Aldrich et al., 2000).

In a study of 160 adults with CP, McCracken (1998) found that acceptance of pain was associated with reports of lower pain intensity, less pain-related anxiety, avoidance, depression, physical and psychosocial disability, more daily uptime, and better work status. However, a relatively low correlation between acceptance and pain intensity ($r=-0.28$) suggested that acceptance is not simply a function of having less intense pain. Given that the relationship between acceptance of pain and QoL has not previously been elucidated, an additional goal of this study was to test the hypothesis that greater acceptance of pain will be related to a better QoL. Furthermore, given that acceptance has been characterised by disengaging from pain and engaging in activities for their own sake (McCracken, 1999), acceptance might also be strongly associated with activities of daily living and mobility.

8.2 Aims

The aim was to examine the psychometric properties of the PDM to be used in conjunction with the WHOQOL-100. Sensitivity to change will be examined by assessing the QoL of people undergoing a LES for CLBP. Concurrently, test-retest reliability of the new PDM facets will be determined to find out whether the assessment of QoL remains the same when there is no clinical change. The internal consistency reliability and criterion, construct and discriminant validity of the PDM will also be elucidated and the relationship between acceptance of pain and QoL.

8.3 Method

8.3.1 Sample

Data was collected from the Royal United Hospital (RUH) in Bath and the Salisbury District Hospital (SDH). The RUH has an outpatient's pain clinic, staffed by a multidisciplinary team, specialising in chronic pain and its management. Consultant anaesthetists conduct LES injections. The SDH runs an epidural clinic in day surgery and a consultant rheumatologist carries out LES injections. All new patients with a diagnosis of LBP with or without sciatica attending consultant and nurse led clinics at the RUH Pain Clinic between April and October 2003 were identified for the longitudinal field test. Those not being offered treatment or those waiting for treatment were identified opportunistically for test-retest reliability. These patients formed the test-retest group as the RUH clinic operates on a 'see and treat' basis, that is, the decision to administer an LES is taken during the appointment and not before. Consequently, as baseline measures are taken before patient appointments, the pragmatic decision was taken to include those not having treatment as the test-retest group as baseline data had already been collected from them. Patients were excluded from the study if they did not have a diagnosis of BP or sciatica. Other exclusion criteria included patients with known depressive personality disorder, somatization disorder, anxiety or other psychiatric problems such substance addiction or misuse. All new patients attending an LES clinic at the SDH for their LBP and or sciatica between June and September 2003 were invited to take part.

8.3.2 Sample size calculations

Power calculations for the intervention group gave a sample size of 63 where two-tailed α is 0.05, β is 0.20 and the effect size required is .50 (moderate). For the test-retest group, if, two-tailed α is 0.05, β is 0.20 and the r^a (expected correlation coefficient) is .50, a sample size of 29 would be required. The expected positive correlation coefficient of .50 was chosen (Hulley and Cummings, 1988) given that the strength of the relationship, reflected in the size of the correlation, must be large enough to show that the data at follow-up is not dissimilar to the baseline data.

8.3.3 Intervention procedure

LES are administered to people with LBP and or sciatica who have not responded to other treatments. A local anaesthetic and cortisone (anti-inflammatory steroid) is delivered by injection to the problem area. The injection may be given above the tailbone (caudal epidural) or at the lower back (lumbar epidural) (Salisbury Health Care NHS Trust, Patient information leaflet, Morgan, 2002). Although it is possible that LES may bring about a range of side effects, such as transient headache, transient increase in pain, irregular menstrual cycle, puncture of the spinal fluid sac causing severe headache, small risk of bruising or infection a the site of injection (McQuay, Moore and Justins, 1997; Patient information sheet, Steroid Epidural Injection, 2003), this must be balanced against any pain relief or improvement in QoL and may impact on measurement. Clearly, no invasive intervention is without potential risks or contraindications. However, patients are informed verbally by their consultant and by information leaflet of these risks prior to the intervention and give written consent.

8.3.4 Time frame

For the study assessing sensitivity to change, the questionnaire battery was administered at baseline prior to the intervention, and 4-weeks following the intervention. This time period was based primarily on the known evidence of the most suitable interval of measuring change, but also on clinical judgement (Deyo, 2003, personal communication). For the test-retest group, the interval between baseline and follow-up was 2 weeks (recommended by Streiner and Norman, 1995).

8.3.5 Concurrent measures

In addition to the WHOQOL-100 (102 items), the PDM (16 items) and the corresponding importance items for the core (26 items) and the PDM (5 items) other measures were applied concurrently to examine the construct validity of the measure, and these are detailed in the following section.

8.3.6 Short-form 12 (SF-12)

The SF-12 is an abbreviated form of the SF-36 Health Status Questionnaire, consisting of a 12-item sub-set of questions, which can provide physical and mental health component scores. The advantage of using the SF-12 is that it reduces respondent burden by only taking 2-3 minutes to complete (as opposed to 10-15 minutes for the SF-36) (Ware et al., 1994). Precision of the measure is compromised because it consists of single items for each health dimension, as opposed to the multi-item measures in the SF-36 (Ware, Kosinski and Keller, 1996). However, it provides a useful compromise between comprehensiveness and precision on the one hand, and reducing respondent burden on the other (Sturgis et al., 2001; Jenkinson and Layte, 1997). Its validation with patients with LBP (Deyo et al., 1998), osteoarthritis (Theiler et al., 2002) and Ankylosing Spondylitis (Haywood et al., 2002) and its brevity provide support for its use.

8.3.7 Short-form McGill Pain Questionnaire (SF-MPQ)

The SF-MPQ was first published in 1987 (Melzack, 1987) and was derived from the McGill Pain questionnaire (LF-MPQ, Melzack, 1975). The instrument can be used with adults with pain in multiple settings and was based on the earlier work of Melzack and Torgerson (1971) in a seminal work on the language of pain. The instrument provides a way of capturing all the dimensions of the pain experience, including its quality and intensity. It aims to get away from describing pain simply in terms of intensity alone using a visual analogue scale (Melzack and Torgerson, 1971; Melzack and Katz, 1992) and enables quick assessment when time is limited (Melzack and Katz, 1994). The SF-MPQ contains 15 pain words, selected from the LF-MPQ on the basis of how frequently they were endorsed by patients from different diagnostic groups (Melzack and Katz, 1994). The SF-MPQ has been shown to correlate highly with the scores of the LF-MPQ (Melzack, 1987; Dudgeon et al., 1993), to be sensitive to clinical changes brought about by analgesics (Melzack, 1987;

Harden et al., 1991) and epidurally or spinally administered agents (Harden et al., 1991; Serrao et al., 1992) and to distinguish between different pain syndromes (Melzack, 1987). It takes 2-5 minutes to complete (Wilkie et al. 1990), and therefore minimises respondent burden.

8.3.8 Chronic Pain Acceptance Questionnaire (CPAQ)

The CPAQ (Geiser, 1992) measures acceptance of pain and consists of 34 items rated from 0 (never true) to 6 (always true). Of the 34 items, 24 are summed to calculate the total score and 9 require reverse scoring (instrument Cronbach's alpha (α) = .85, Geiser, 1992). Recently, McCracken and colleagues (2004) have reduced the number of items in the CPAQ to create a short-form, the SF-CPAQ, consisting of 20 items. Three separate scores can be derived; a total score (α. 78) and two subscales representing the concepts of activities engagement (degree to which life activities are engaged in spite of pain) (α. 82) and pain willingness (willingness to experience pain) (α. 78) (McCracken, Vowles and Eccleston, 2004). Studies have shown that measures of emotional distress and daily functioning correlate with the CPAQ and therefore provide support for its use as a measure of acceptance (Geiser, 1992; McCracken, 1998, McCracken et al., 1999). McCracken and Eccleston have shown that acceptance, as measured with the CPAQ, accounts for more variance in explaining distress and disability than measures of coping (as measured by the Coping Strategies Questionnaire (CSQ) (McCracken and Eccleston, 2003).

8.3.9 Measuring change with transition questions

At follow-up, administering transition questions enables an accurate assessment to be made about whether any perceived changes have taken place. This ensures that self-reported changes in QoL correspond to self-reported changes in underlying symptoms. Thus, such questions can be used as a benchmark to view any changes against. For example, a study examining changes in QoL in primary care patients receiving antidepressant medication asked about how much general health and depression had changed during treatment with five point scales (Skevington and Wright, 2001). The use of a single item is cautioned against because they are not sensitive enough to change, particularly with respect to detecting deterioration in health (Baker, 1998). The follow-up transition questions (see appendix 5) asked about whether QoL, health and pain were worse, a little worse, the same, a little better or better since they last completed the questionnaire. A question also asked about satisfaction with treatment (intervention group only), whether they had begun any new treatment since their last assessment and if any significant life events have impacted on their QoL since the last assessment (recommended by Streiner and Norman, 1995). Including this range of questions avoids the limitations of asking one question, by covering numerous dimensions of possible change (Baker, 1998). Furthermore, attaching 5-point Likert scales widens the possible response options available to respondents.

8.3.10 Procedure

All new patients attending the Pain Clinic at the RUH or LES clinic at SDH who had a diagnosis of LBP or sciatica received a letter from the clinic inviting them to attend an appointment with the consultant anaesthetist. An additional letter was enclosed inviting them to take part in the study and informing them that they should expect to receive a questionnaire pack in the post before they attend their appointment. Two weeks prior to their appointment, patients were sent a letter, information sheet, consent form and questionnaire pack to allow time for completion. Patients were asked to bring the completed questionnaire with them to their appointment.

Potential respondents were greeted as they attended their appointment and asked if they had had time to complete the questionnaire and if they had any comments or questions that they would like to ask relating to filling it in. Consent forms were obtained from all those taking part. Following the appointments, those undergoing LES formed the intervention group and those who did not have treatment, or who were waiting for treatment (such as TENS, acupuncture, physiotherapy and so on) were the test-retest group. The intervention group were sent questionnaire packs with the additional transition questions 4 weeks after their injection. The test-retest group were sent packs with the additional transition questions 2 weeks after their appointment. A new cover letter was sent explaining the aims of re-administering the questionnaire and inviting potential respondents to complete questionnaire for a second time. Stamped addressed envelopes were included and patients were asked to complete and return the measures within 2 weeks of receiving them. Reminder phone calls were conducted for those not returning packs within the specified time to reduce attrition. Patients had the opportunity to decline to take part at any stage and were reassured about confidentiality and anonymity.

8.4 Analysis

8.4.1 Scoring the instruments

The WHOQOL-100 scoring has been described in detail in chapter seven. The core syntax file was extended to cover the 16 PDM items, including the reversal of 11 items and calculation of mean facet ratings. The SF-12 syntax file provides instructions for scoring the instrument. Four of the 12 items require reverse scoring so that a high score always represents best health. Two summary scores are produced, the PCS and MCS. Five scores are derived from the SF-MPQ, these are; Sensory Pain Rating Index (S-PRI), Affective Pain Rating Index (A-PRI), Total Pain Rating Index (T-PRI), Present Pain Intensity-Visual Analogue Scale (PPI-VAS) and the evaluative overall intensity of total pain experience. The S-PRI is calculated by summing the first 11 pain adjectives, the A-PRI by summing the 4 last pain adjectives, the T-PRI by adding together the S-PRI and the A-PRI. The PPI-VAS is a VAS from no pain to worst possible pain and is scored by dividing the line into 10, 1cm sections, giving a score between 1 and 10. Finally, the evaluative overall pain intensity of total pain experience has a score between 0 and 5, where 0 is no pain and 5 is excruciating. The CPAQ is scored by summing 24 of the 34 items to give a total score. Of the 24 items contributing to the total score, 9 require reverse scoring. It is also possible to derive a 20-item short-form, which consists of 2 subscales representing activities engagement (11 items) and pain willingness (9 items). The syntax file for baseline and follow-up measures is given in appendix 6.

8.4.2 Validity of the PDM

Criterion validity can be examined by correlating the PDM facet scores with the core WHOQOL facet scores. As these are known to assess QoL, Pearson's r should be between 0.4- 0.8 (Streiner and Norman, 1995). The PDM facets in the physical domain (pain relief) should correlate more highly with the PCS of the SF-12 and facets in the psychological domain (anger and frustration and vulnerability/ fear/ worry) should be more strongly associated with the MCS of the SF-12, so that subjective QoL in the physical domain is more highly associated with physical health status functioning and psychological aspects of QoL are more strongly associated with psychological health status functioning. QoL assessed by the PDM should be significantly negatively correlated with the SF-MPQ scores between -0.4- -0.8 (Streiner and Norman, 1995) so that more severe or intense pain is associated with a poorer QoL, demonstrating construct validity. Discriminant validity is shown if the instrument is able to distinguish between patients known to differ on certain characteristics such as pain intensity or whether respondents define themselves as ill or well.

8.4.3 Sensitivity to change of the PDM

To examine the extent of change at following LES, a paired samples t-test can be conducted for all facets at baseline and follow-up to see whether there are significant differences between the mean facet scores of the PDM. Effect size determines the difference between scores gained at baseline and follow-up and is an important statistic for looking at sensitivity to change (Kazis et al., 1989). To do this, baseline data is subtracted from follow-up data and then the mean change in score is divided by the baseline standard deviation. An effect size of 0.2 is small, 0.5 is moderate and 0.8 is large. Responsiveness can also be examined by using analysis of variance (ANOVA) to evaluate differences in change scores between individuals who experienced an improvement in QoL and those who did not experience an improvement (perceived improvement was assessed by the transition questions). Larger average change scores between baseline and follow-up and smaller *P* values would reflect greater responsiveness.

8.4.4 Test-retest reliability of the PDM

Test-retest reliability examines the stability of scores on repeated applications when no underlying change has occurred. To do this Pearson's correlation between baseline and follow-up PDM facet scores should be >0.70.

8.4.5 Hypotheses

It is proposed that the PDM will:

- Demonstrate good internal consistency reliability (Cronbach's alpha (α) = 0.70-0.90) to show that the facet items represent a different aspect of a cohesive construct.

- Be significantly positively associated with the general QoL and health facet (G) of the core WHOQOL and with health status as measured by the MCS and PCS of the SF-12 to demonstrate criterion validity.
- Be significantly negatively associated with pain severity or intensity assessed by the SF-MPQ to demonstrate construct validity.
- Distinguish between those defining themselves as ill or well and between people with different reported levels of health, where higher scores on the PDM (or good QoL) should be associated with being well and having good health and vice versa.
- Change in response to LES so that successful treatment is associated with higher scores.
- Be stable when no change in underlying condition or intervention has been applied, so that baseline-follow-up facet scores should correlate >0.70.

The results will also elucidate which facets of QoL are poorest, which are most important and explore the relationship between acceptance of pain and QoL.

8.4.6 Data cleaning

Data cleaning involved checking that data had been entered correctly and that all WHOQOL item data was a numerical value between 1 and 5. Each variable was systematically examined to ensure that no incorrect entries had been made. This included running descriptive statistics such as means, frequencies and distributions to ensure that errors have not been made. Box plots were also examined to view the spread of data for each item and check for any outliers (Tabachnick and Fidell, 1996).

8.5 Results

8.5.1 Response rate at baseline and follow-up

Of the 228 questionnaire packs sent out at baseline to patients from the RUH, 118 were completed and returned achieving a response rate of 52%. Of the 30 packs sent to patients attending the LES clinic at the SDH, 15 questionnaires were completed and returned at baseline, a response rate of 50% (overall response rate, 52%). Of the 133 completed baseline assessments, 76 (57.1%) formed the intervention group and 57 (42.9%) the test-retest group. Of the 76 patients undergoing LES and completing baseline measures, 57 successfully completed follow-up measures (75.0%). For the no treatment (NT) group, 30 of the 57 patients completed baseline and follow-up measures (52.6%).

8.5.2 Socio-demographic composition of the combined LES and NT groups

The sample consisted of 87 (65.4%) females and 46 (34.6%) males. The mean age of the 133 baseline participants was 55.9 (SD 16.87, range 17-92); 76 (57.1%) were married, 16 (12.0%) living as married, 16 (12.0%) widowed, 14 (10.5%) single, 9 (6.8%) divorced and 2 (1.5%) separated; 65 (48.9%) had achieved secondary school education, 43 (32.3%) further education such as technical/ clerical, 15 (11.3%) were university educated, 6 (4.5%) primary school and 2 (1.5%) had no education. Of the sample, 43 (32.3%) were currently employed.

8.5.3 Health characteristics of both groups at baseline

Of the sample, 9 (6.8%) described their health as very poor, 45 (33.8%) as poor, 43 (32.3%) as neither good nor poor, 31 (23.3%) as good, 2 (1.5%) as very good and 3 (2.3%) failed to answer the question; 68 (51.1%) described themselves as currently ill, 52 (39.1%) as not currently ill, 13 (9.8%) did not state.

8.5.4 Characteristics relating to pain of both groups at baseline

Mean duration of pain in months was 84.59 (SD 120.86, range 3-720) although 12 failed to report pain duration; 3 (2.3%) described the temporal characteristics of their pain as brief, 94 (70.7%) as continuous and 31 (23.3%) as intermittent; 1 (0.8%) had no current pain. Of the sample, 5 (3.8%) described their pain as mild, 44 (33.1%) as discomforting, 35 (26.3%) as distressing, 33 (24.8%) as horrible, 10 (7.5%) as excruciating. Of the participants, 15 (11.3%) did not describe their condition, although all participants had a diagnosis of back pain (BP) and or sciatica and substantial co-morbidity was apparent. The most common site of pain was the lower back and spine (n=116, 87.2%), followed by the legs (n=93, 69.9%), upper shoulder and arms (n=38, 28.6%), pelvis (n=30, 22.6%), middle back or chest (n=29, 21.8%), upper back, (n=28, 21.1%), abdomen (n=14, 10.5%) and the head, face and or mouth (n=8, 6.0%). Respondents identified 12 more specific pain locations, including ankle, feet, bottom, groin, hands, hip, jaw, ear, knee, neck, rectum and stomach.

8.5.5 Mean facet ratings and missing value analysis at baseline

Analysis was conducted on the 133 completed baseline questionnaire batteries. Mean WHOQOL facet ratings are shown in table 8.2. For the 25 core facets, QoL was highest for home environment, transport, personal relationships and social support facets and lowest for pain and discomfort, mobility, energy and fatigue and ADL. Of the PDM facets, QoL was highest for vulnerability/ fear/ worry, followed by anger and frustration and then uncertainty and pain relief. Most missing data was about the availability and quality of health and social care and the sex facets and from the PDM facets, for pain relief due to the question asking about the extent to which having treatment has improved QoL. The core facets demonstrated good internal consistency reliability with 23 of the 25 facets having α >.70 with the exception of personal relationships (α >.69) and the physical environment (α >.65) on account of the low inter-item correlations. Of the core facets, financial resources, SRPB, sleep and rest, working capacity and mobility had α levels exceeding .90, suggesting that these are highly homogenous facets.

Table 8.2 Ranked mean core and PDM facet ratings, SD, number missing, inter-item correlation range and Cronbach's α at baseline (PDM facets in bold)

Facet	**Mean**	**SD**	**Missing**	**Inter-item correlation range**	**α**
Home environment	15.73	3.15	1	.52-.72	.88*
Transport	15.26	3.64	1	.58-.88	.88*
Personal relationships	14.68	3.08	0	.23-.48	.69
Social support	14.64	3.35	2	.46-.75	.84*
Physical environment	14.52	2.45	1	.19-.49	.65
Body image and appearance	14.05	3.57	0	.50-.70	.87*
Thinking, learning, memory and concentration	13.49	2.78	2	.31-.54	.75*
Financial resources	13.42	4.24	1	.69-.81	.93
Safety and security	13.38	2.58	2	.24-.61	.74*
Vulnerability/ fear/ worry	**13.14**	**2.74**	**1**	**.10-.64**	**.67**
Negative feelings	12.99	3.51	1	.55-.82	.88*
Information	12.83	2.81	8	.30-.86	.81*
Services	12.70	2.60	15	.44-.77	.83*
Esteem	12.52	3.14	3	.26-.73	.79*
Anger & frustration	**12.00**	**3.26**	**1**	**.39-.72**	**.81***
Positive feelings	11.94	3.00	0	.53-.83	.88*
SRPB	11.80	3.73	1	.60-.83	.91
Leisure activities	11.52	3.26	1	.50-.74	.86*
Overall QoL	11.27	3.21	5	.36-.71	.85*
Uncertainty	**11.08**	**3.19**	**1**	**.34-.70**	**.79***
Sleep and rest	11.06	3.17	0	.65-.84	.91
Sex	11.04	3.84	13	.11-.80	.79*
Work	10.46	3.51	3	.67-.84	.93
Medication	10.38	3.88	5	.53-.82	.90*
Pain relief	**10.20**	**2.44**	**4**	**.12-.43**	**.66**
ADL	10.12	3.22	1	.53-.79	.88*
Energy and fatigue	9.90	3.14	1	.46-.71	.83*
Mobility	9.89	3.38	2	.66-.82	.91
Pain and discomfort	8.84	2.53	1	.30-.50	.75*

* Acceptable α levels

8.5.6 WHOQOL-100 and Bref domain scores at baseline

For the WHOQOL-100 domain scores (excluding the PDM facets) shown in table 8.3, QoL was highest for the environment and social relationships domains and lowest for physical and level of independence. All WHOQOL-100 domains demonstrated good internal consistency reliability with α >.70 with the exception of social relationships (α >.67). Excluding the 76 items from the WHOQOL-100, the Bref is comprised of 26 items; one from each of the 24 facets of QoL, and two from the G facet asking about overall QoL and health. Four Bref domain scores were calculated from the longitudinal data and consistent with the WHOQOL-100, these are scaled in a positive direction where higher scores represent a better QoL. Domain scores are calculated by multiplying the mean score of items by four (WHOQOL user manual, 1998). WHOQOL Bref scores were calculated using a syntax file to extract the Bref items embedded in the WHOQOL-100 structure. It is acknowledged that this data is extracted from the WHOQOL-100 data and consequently it is possible that the other items influence the way that participants respond to the Bref items. For the WHOQOL-Bref, the best QoL was reported for the social relationships domain, followed by the environment, the psychological and was lowest for the physical domain. The WHOQOL-Bref physical, psychological and environment domains demonstrated good internal consistency reliability (range α=.77- .82) and the social domain demonstrated marginal reliability (α=.63).

Table 8.3 Frequencies and Cronbach's α for WHOQOL-100 and Bref domain scores

Domain	**WHOQOL-100**			**WHOQOL-Bref**		
	Mean	**SD**	**α**	**Mean**	**SD**	**α**
Physical	9.93	2.33	.70	10.16	2.83	.82
Psychological	13.01	2.49	.84	12.78	2.58	.77
Independence	10.18	2.95	.87	-	-	-
Social relationships	13.57	2.65	.67	13.96	3.37	.63
Environment	13.73	2.14	.82	13.53	2.39	.78
SRPB	11.80	3.73	.91	-	-	-

- WHOQOL-Bref is scored in 4 domains

8.5.7 Baseline importance ratings

All facets had a mean rating of >3.0 reinforcing the importance of these aspects of life to people with pain (table 8.4). The most important core facets were being able to carry out ADL, being pain free, being able to move around and having energy; the least important were sex, personal beliefs and body image appearance. The most important PDM facets were the being able to control pain, obtaining pain relief, followed by being free from fear and worry, anger and frustration and the least important was being free from uncertainty.

Table 8.4 Ranked mean core and PDM importance ratings at baseline

Importance	**Mean**	**SD**
ADL	4.59	.57
Free from pain	4.49	.67
Pain control	**4.49**	**.55**
Pain relief	**4.48**	**.61**
Mobility	4.48	.57
Energy	4.34	.67
Health	4.34	.60
Adequate healthcare	4.34	.59
Hone environment	4.25	.63
Independence from treatment	4.22	.76
Restful sleep	4.20	.83
Relationship with others	4.19	.79
Fear and worry	**4.18**	**.64**
Anger & frustration	**4.15**	**.79**
Free negative feelings	4.15	.68
Thinking problems	4.13	.63
Overall QOL	4.11	.64
Being able to work	4.08	.97
Safety and security	4.06	.74
Positive about self	4.06	.66
Feel contented	4.05	.64
Uncertainty	**4.02**	**.80**
Financial resources	3.98	.73
Adequate transport	3.98	.72
Provide support for others	3.90	.92
Relaxation & leisure	3.89	.78
Physical environment	3.86	.73
Information & knowledge	3.78	.78
Body image appearance	3.52	.88
Personal beliefs	3.50	.98
Sex life	3.07	1.45

8.5.8 Baseline concurrent measures - SF-12, SF-MPQ and CPAQ scores

Table 8.5 shows the mean and SD for the SF-12 PCS, MCS and items. Most missing scores were from items pertaining to emotional problems and consequently, PCS and MCS scores were calculated for 117 of the 133 baseline participants. For the SF-MPQ, most missing items were from the present pain intensity item assessed with a visual analogue scale. Sensory pain rating index scores can range from 0-33, affective rating index scores from 0-12, total pain rating scores from 0-45, present pain intensity from 0 to 10 and evaluative overall intensity from 0-5. The CPAQ was administered to 75 of the 133 participants. The mean and SD for the CPAQ items and the activity engagement, pain willingness, SF-CPAQ total and CPAQ total scores are shown. Items are scored on 6-point scales from never true (0) to always true (6).

Table 8.5 Frequencies, range and % missing for SF-12, SF-MPQ and CPAQ scores and items

SF-12 score or item	**Mean**	**SD**	**Missing %**
PCS	19.05	10.82	12.03
MCS	41.92	11.55	12.03
General health	2.20	.97	6.02
Moderate activities	1.43	.56	3.76
Climbing stairs	1.52	.69	4.51
Accomplished less physical	1.10	.31	6.77
Limited in work	1.09	.28	6.02
Accomplished less emotional problems	1.48	.50	7.52
Work carefully as usual emotional problems	1.48	.50	8.27
Pain interfere	2.03	.93	4.51
Felt calm peaceful	3.01	1.23	3.01
A lot of energy	2.43	1.33	3.01
Downhearted and low	3.92	1.35	3.01
Physical or emotional interfere social	2.98	1.27	3.01
MPQ Score	**Mean**	**SD**	**Missing %**
MPQ sensory pain rating index	10.46	6.19	4.51
MPQ affective pain rating index	2.93	2.59	4.51
MPQ total pain rating index	13.34	7.83	4.51
MPQ present pain intensity vas	7.33	2.06	12.03
MPQ evaluative overall intensity	2.64	1.16	3.01
CPAQ score and items	**Mean**	**SD**	**Missing %**
Activity engagement	32.74	10.36	12.00
Pain willingness	19.16	8.47	9.33
SF-CPAQ total	52.00	14.88	13.33
CPAQ total	61.11	14.79	14.67
*Getting on no matter	4.13	1.38	0
*Life going well	3.32	1.42	2.67
*Ok to exp pain	1.89	1.60	1.33
Decrease pain level	3.08	1.71	2.67
*Sacrifice important things	3.59	1.76	5.33
*Not necessary to control pain	2.34	1.93	5.33
Hassle of rid pain	1.81	1.73	4.00
Control negative and irrational	2.45	1.61	5.33
*Normal life despite pain	2.68	1.57	5.33
*Concentrate on rid pain	4.01	1.75	4.00
Done best to control pain	3.86	1.77	5.33
Thoughts and feelings	2.11	1.88	6.67
Before I take action	4.65	1.58	5.33
*Activities	4.00	1.78	4.0
*Full life	2.87	1.80	5.33
*Controlling pain less important	2.17	1.69	5.33
Live with idea of pain for life	2.74	1.95	4.0
Fighting pain	5.04	1.24	4.0
*Thoughts and feelings change	2.84	1.78	4.0
*Sticking to certain life course	3.71	1.60	8.0
Disturbing thoughts	3.49	1.77	5.33
*Keeping pain level under control	4.24	1.59	5.33

*Before make serious plans	4.06	1.76	5.33
*Responsibilities	3.61	1.68	5.33
*Better control if control negative thoughts	3.17	1.82	5.33
Control feelings assoc with pain	3.06	1.39	6.67
Accept something, feel good	3.80	1.45	5.33
Accept basic pain level	3.04	1.87	5.33
Right beliefs	2.56	1.75	9.33
*Avoid situations	4.65	1.30	5.33
*Worries and fears	3.58	1.66	5.33
*Don't have to change pain	2.53	1.72	6.67
Control by happy and positive	2.49	1.72	6.67
*Struggle to do things	4.94	1.13	5.33

* Items retained in the SF-CPAQ

8.5.9 Psychometric properties of the WHOQOL and PDM

The psychometric properties of the PDM were explored using a variety of statistical tests described in chapter seven. Table 8.6 shows the mean, SD, skewness and kurtosis of the 16 items in the PDM for the baseline data. Most missing data was from the item asking about the extent to which treatment had improved QoL and the full range of scores was not used for 4 of the items. Poorest QoL was reported for the extent to which pain limits life and the highest for anger interfering and fear bothering.

8.5.10 Baseline distribution of scores

To ensure that ceiling and floor effects are not observed in the items, the whole range of scores must be used, specifically, at least 10% of participants must have used each of the five points of the scale. Table 8.7 illustrates the percentage for each point on the scale for each of the 16 PDM items. Where there is a low percentage for 5 (highest QoL), this suggests a floor effect, that is, respondents are treating the scale as a 4-point scale and improvements will not be picked up if they perceive the verbal label for the 5-anchor point to be too extreme. The reverse is true for items where 1 (poorest QoL) has not been used. Of the 16 items, satisfaction with control of pain, comfortable and concern about experiencing pain had no responses at '5' suggesting that the anchor point representing the best QoL for these items is not being utilised by participants. The item about the extent to which vulnerability interfered had no response for '1', suggesting that the anchor point representing the poorest QoL is not being used for this item.

Table 8.6 Frequencies, range, skewness and kurtosis for the 16 PDM items

Item	Mean	SD	Missing	Range	Minimum	Maximum	Skew	Std. error of skew	Kurtosis	Std. error of Kurtosis
Treatment improved QoL	2.43	.97	11	4	1	5	.21	.22	-.68	.44
Satisfied control of pain	2.42	.90	1	3	1	4	.39	.21	-.63	.42
Cope with level of pain	2.96	.75	3	4	1	5	-.16	.21	1.19	.42
Comfortable	2.40	.82	4	3	1	4	.06	.21	-.51	.42
Anger interfere	3.69	1.11	1	4	1	5	-.59	.21	-.39	.42
Frustration interfere	2.88	1.03	2	4	1	5	.16	.21	-.54	.42
Pain angry	2.95	1.04	0	4	1	5	.07	.21	-.39	.42
Pain irritable	2.49	.88	0	4	1	5	.20	.21	-.06	.42
Vulnerability interfere	3.64	1.00	3	3	2	5	-.20	.21	-1.01	.42
Fear bother	3.69	.99	2	4	1	5	-.48	.21	-.38	.42
Worry about treatment	3.33	.99	1	4	1	5	-.00	.21	-.54	.42
Concern exp pain	2.49	.83	1	3	1	4	.23	.21	-.52	.42
Uncertainty interfere	3.02	1.13	1	4	1	5	.12	.21	-.67	.42
Difficulty planning	3.13	1.03	3	4	1	5	-.09	.21	-.39	.42
Pain limit life	2.11	.93	2	4	1	5	.72	.21	.32	.42
Satisfied make future plans	2.82	.96	0	4	1	5	.11	.21	-.80	.42

Table 8.7 Distribution of scores for the 16 items in the PDM

Item	Responses for each scale point (%)				
	1	2	3	4	5
Treatment improved QoL	18.0	36.9	30.3	13.9	0.8
Satisfied control of pain	12.1	49.2	22.7	15.9	0
Cope with level of pain	3.8	16.2	62.3	15.4	2.3
Comfortable	13.2	41.9	36.4	8.5	0
Anger interfere	3.8	12.1	22.0	35.6	26.5
Frustration interfere	7.6	30.5	34.4	21.4	6.1
Pain angry	8.3	24.1	39.8	20.3	7.5
Pain irritable	12.8	37.6	39.1	9.0	1.5
Vulnerability interfere	0	16.2	26.2	35.4	22.3
Fear bother	1.5	12.2	23.7	41.2	21.4
Worry about treatment	2.3	17.4	38.6	28.0	13.6
Concern experiencing pain	9.1	45.5	32.6	12.9	0
Uncertainty interfere	8.3	25.0	34.8	19.7	12.1
Difficulty planning	6.2	19.2	39.2	26.2	9.2
Pain limit life	27.5	43.5	21.4	6.1	1.5
Satisfied make future plans	6.0	36.1	30.1	25.6	2.3

8.5.11 Reliability of the WHOQOL and PDM

Internal consistency reliability for the whole PDM scale (excluding the WHOQOL-100 items) was found to be good (standardised item α=.88). For the PDM facets, α=.81 for anger and frustration and α=.79 for uncertainty, demonstrating good internal consistency reliability. Pain relief (α=.66) and vulnerability/ fear/ worry (α=.67) were only marginally internally consistent (table 8.8). For pain relief, inter-item correlations ranged from .12 to .43 and α was lowest with the removal of the item asking about satisfaction with control of pain, reflecting the importance of this item in contributing to the reliability of this facet. For the anger and frustration facet, inter-item correlations ranged from .39 to .72 and α was lowest with the removal of the item asking about how often pain makes a person feel angry, reflecting the importance of this item in contributing to the reliability of this facet. For vulnerability/ fear/ worry, inter-item correlations ranged from .10 to .64 and α was lowest with the removal of the item asking about how much fear bothers a person, again reflecting the importance of this item in contributing to the reliability of this facet. For uncertainty, inter-item correlations ranged from .34 to .70 and α was lowest with the removal of the item asking about difficulty planning. For item-facet correlations, 2 items from pain relief and one from vulnerability/ fear/ worry fell below .4 and for item-total correlations, one item fell below .4 for both pain relief and vulnerability/ fear/ worry.

Table 8.8 Item-facet, item-total, facet-total correlations and Cronbach's α for the PDM facets

Domain, facet and item	Item-facet correlation	α if item deleted	Item-total correlation	α if item deleted
Physical domain - Pain relief facet α= .66	-	-	**.52**	**.80**
Treatment improved QoL	.38	.64	.28	.89
Satisfied control of pain	.57	.49	.45	.88
Cope with level of pain	.36	.64	.46	.88
Comfortable	.46	.57	.45	.88
Psychological domain - Anger & frustration facet α= .81	-	-	**.66**	**.73**
Anger interfere	.64	.76	.58	.87
Frustration interfere	.57	.79	.62	.87
Pain angry	.68	.73	.60	.87
Pain irritable	.63	.76	.62	.87
Psychological domain - Vulnerability/ fear/ worry facet α= .67	-	-	**.52**	**.80**
Vulnerability interfere	.52	.58	.52	.88
Fear bother	.62	.50	.55	.87
Worry about treatment	.48	.61	.29	.88
Concern experiencing pain	.25	.73	.36	.88
Level of independence domain - Uncertainty facet α= .79	-	-	**.80**	**.65**
Uncertainty interfere	.61	.73	.72	.87
Difficulty planning	.75	.65	.70	.87
Pain limit life	.51	.77	.63	.87
Satisfied make future plans	.52	.77	.58	.87

8.5.12 Inter-item correlations for each PDM facet

Inter-item Pearson's correlations (2-tailed) for each new facet ranged from .12- .43 for pain relief, .39- .72 for anger and frustration, .10- .64 for vulnerability/ fear/ worry and .34- .70 for uncertainty. The correlations for anger and frustration and uncertainty were acceptable, although the relativity low inter-item correlations for the pain relief and vulnerability/ fear/ worry facets reflect the low α levels. The relative strength of these correlations reflects the cohesiveness of the underlying constructs and pain relief and vulnerability/ fear/ worry are less internally consistent and the items are less homogenous than those representing anger and frustration and uncertainty.

8.5.13 Item-domain correlations

Table 8.9 shows how the PDM items correlate with each of the core WHOQOL domains. Each item should correlate more highly with its parent domain, if it is housed under the correct domain. For pain relief, 3 out of 4 items correlated more highly with the parent physical domain, where treatment improved QoL correlated more highly with the level of independence domain. Only one of the anger and frustration items correlated more highly with the parent psychological domain; 2 correlated more with the physical domain and one with level of independence. For vulnerability/ fear/ worry, 2 items correlated more highly with the parent psychological domains, for the other two items one correlated more with the environment and another with level of independence. For uncertainty, 2 items correlated more with the parent level of independence domain and 2 with the psychological domain. Although this poses a challenge to the conceptual integrity of the facets, it also shows that the items representing these facets might affect QoL in different ways, despite belonging to the same concept. In general, the PDM items relate most to the physical, psychological and level of independence domains of QoL.

Table 8.9 Item-domain Pearson's correlations and significance levels (2-tailed)

Item	**Domain I**	**Domain II**	**Domain III**	**Domain IV**	**Domain V**	**Domain VI**
Treatment improved QoL	.262	.192	.315*†	.313*	.205	.084
Satisfied control of pain	.587*†	.303*	.527*	.349*	.330*	.188
Cope with level of pain	.419*†	.296*	.418*	.267	.237	.087
Comfortable	.597*†	.376*	.494*	.255	.418*	.135
Anger interfere	.407*	.478*†	.289*	.347*	.438*	.156
Frustration interfere	.459*	.460*	.531*†	.349*	.405*	.099
Pain angry	.376*†	.311*	.374*	.102	.190	.022
Pain irritable	.486*†	.378*	.458*	.202	.262	.109
Vulnerability interfere	.354*	.536*	.414*	.367*	.558†*	.045
Fear bother	.338*	.596*†	.342*	.295*	.470*	.075
Worry about treatment	.132	.233†	.192	.121	.239	-.045
Concern experiencing pain	.307*	.125	.316*†	.126	.187	-.062
Uncertainty interfere	.431*	.501*†	.450*	.302*	.455*	.144
Difficulty planning	.516*	.514*	.568*†	.341*	.449*	.043
Pain limit life	.605*	.371*	.740*†	.327*	.349*	.021
Satisfied make future plans	.501*	.576*†	.548*	.421*	.458*	.249

* *p*> .001

† Highest item-domain correlation

8.5.14 Facet-domain correlations

Table 8.10 shows the facet-domain correlations. Each facet should correlate more highly with its parent domain. With the exception of anger and frustration, all facets correlated more highly with their own domains. Anger and frustration correlated marginally more highly with the physical rather than the psychological domain, this might be a consequence of the co-occurrence of pain and anger and frustration. However, given that anger and frustration are clearly a psychological constructs and that the correlation is only marginally higher with the physical rather than the psychological domain the argument for moving the facet is not strong enough. Lowest correlations were found for each of the facets and the SRPB domain, suggesting that QoL relating to pain is least related to spiritual aspects of QoL.

Table 8.10 Facet-domain Pearson's correlations (r) and significance levels (2-tailed)

Facet	Domain I	Domain II	Domain III	Domain IV	Domain V	Domain VI
Pain relief	.649*†	.401*	.616*	.418*	.408*	.190
Anger	.534*†	.513*	.510*	.317*	.413*	.123
Vulnerability/ fear/ worry	.387*	.533*†	.435*	.316*	.516*	.009
Uncertainty	.649*	.632*	.723*†	.446*	.552*	.152

* p> .001
† Highest facet-domain correlation

8.5.15 Construct validity of the WHOQOL and PDM – the relationship between the PDM facets and pain severity, quality, intensity and subjective QoL relating to pain and discomfort

Examining whether the facets are significantly associated with measures of pain intensity or severity tested the construct validity of the new items. Pearson correlations (1-tailed) between baseline scores and MPQ scores showed that all facets are significantly negatively correlated with the sensory pain rating index, affective pain rating index, total pain rating index, present pain intensity and overall intensity, as measured with the SF-MPQ (table 8.11). Pain relief is most associated with present pain intensity and anger and frustration with the sensory qualities of pain, reflecting the facets high correlation with the WHOQOL physical domain. Vulnerability/ fear/ worry had the lowest correlations with each of the MPQ scores, although the highest was with the sensory aspects. Finally, uncertainty was most highly associated with the total pain-rating index. Overall, higher pain intensity and severity is associated with poorer QoL assessed by the PDM facets. Each PDM facet was also significantly positively correlated (1-tailed) with the core pain and discomfort facet. Pain relief and uncertainty were most strongly associated, demonstrating that subjective QoL relating to pain and discomfort is associated with these pain related aspects of QoL.

Table 8.11 Pearson correlations (1-tailed) between baseline PDM facet scores, MPQ scores and the core pain and discomfort facet

Facet	**S-PRI**	**A-PRI**	**T-PRI**	**PPI-VAS**	**Overall pain intensity**	**Core pain & discomfort**
Pain relief	-.360**	-.348**	-.397**	-.565**	-.415**	.630**
Anger & frustration	-.416**	-.228**	-.404**	-.315**	-.325**	.482**
Vulnerability/ fear/ worry	-.267**	-.173*	-.265**	-.234**	-.214**	.316**
Uncertainty	-.447**	-.371**	-.474**	-.445**	-.445**	.611**

** Correlation is significant at the 0.01 level (1-tailed)
* Correlation is significant at the 0.05 level (1-tailed)

To explore the relationship between QoL and pain severity, quality and intensity each core WHOQOL facets was correlated against the MPQ scores (table 8.12). All WHOQOL facets were negatively correlated with MPQ scores, with the exception of affective pain and social support and affective pain and present pain intensity with SRPB. MPQ scores were most strongly negatively associated with pain and discomfort, energy and fatigue, mobility and ADL (r >-.35). Of these, the highest correlation was between pain and discomfort and present pain intensity (r=-.68). MPQ scores were least associated with social support and SRPB (r<-.15). Of these, the weakest relationship was between social support and the total pain-rating index (r=-.004). Although reports of pain are least associated with social support and spiritual aspects of QoL, in general more reported pain is associated with poorer QoL assessed by the WHOQOL facets.

Table 8.12 Pearson's correlations (2-tailed) between MPQ scales and core WHOQOL facets

Facet	S-PRI	A-PRI	T-PRI	PPI-VAS	Overall pain intensity
Pain	-.451**	-.360**	-.477**	-.678**	-.547**
Energy and fatigue	-.369**	-.400**	-.422**	-.472**	-.354**
Sleep and rest	-.326**	-.192*	-.321**	-.283*	-.312**
Positive feelings	-.175*	-.142	-.181*	-.233*	-.267*
Thinking, learning	-.212*	-.168	-.211*	-.133	-.188*
Esteem	-.064	-.068	-.066	-.149	-.137
Body image	-.109	-.084	-.108	-.050	-.014
Negative feelings	-.218*	-.099	-.199*	-.152	-.156
Mobility	-.352**	-.376**	-.393**	-.569**	-.499**
ADL	-.371**	-.379**	-.413**	-.564**	-.447**
Medication	-.237*	-.374**	-.307**	-.395**	-.414**
Work	-.297**	-.303**	-.329**	-.486**	-.448**
Relationships	-.206*	-.125	-.200*	-.248*	-.209*
Social support	-.014	.024	-.004	-.152	-.030
Sex	-.125	-.133	-.145	-.377**	-.292**
Safety	-.135	-.037	-.110	-.248*	-.076
Home environment	-.147	-.131	-.149	-.194*	-.085
Financial	-.424**	-.226*	-.403**	-.114	-.220*
Services	-.316**	-.066	-.266*	-.080	-.023
Information	-.253*	-.238*	-.274*	-.244*	-.234*
Leisure	-.280**	-.276*	-.308**	-.434**	-.314**
Physical environment	-.149	-.129	-.156	-.086	.003
Transport	-.231*	-.084	-.205*	-.109	-.162
SRPB	-.034	.050	-.007	.021	-.037
Overall QoL	-.320**	-.290**	-.339**	-.453**	-.364**

** Correlation is significant at the 0.01 level
* Correlation is significant at the 0.05 level

8.5.16 Concurrent validity of the WHOQOL and PDM – the relationship between health status and QoL

The relationship of the facets to the MCS and PCS of the SF-12 and G of the WHOQOL were examined to determine the concurrent validity of the PDM facets. Table 8.13 shows that there are significant associations between the PDM facets and these measures. Each new facet was significantly correlated with the PCS and MCS of the SF-12. Pain relief was more highly correlated with the PCS and the anger and frustration, vulnerability/ fear/ worry and uncertainty with the MCS. Uncertainty and pain relief were most highly associated with G, suggesting that perception of QoL in these areas is strongly associated with rating of overall QoL. Overall, a higher QoL assessed by the PDM facets is associated with a higher QoL as measured by G of the WHOQOL-100 and with health status as assessed by the SF-12.

All core WHOQOL facets were positively associated with the PCS and MCS of the SF-12, with the exception of availability and quality of health and social care, which was negatively associated with the PCS, although this correlation was not significant. The MCS was most highly associated with negative feelings, leisure activities and overall QoL and health (r>. 61 at *P*>.001) and least associated with physical environment and social support (r<.21 at <.032). The PCS was most strongly associated with mobility, work capacity and ADL (r>.62 at *P*>.001) and least with social support and the availability and quality of health and social care (r<.06 at *P*<.88).

Each facet was also correlated with G to see which facets were most related to overall QoL and health. Leisure activities, ADL and positive feelings were most highly correlated with G (r>.67 at P>.001), suggesting that decisions about global QoL are closely associated with the perception of QoL in these areas. Lowest correlations with G were found for body image, transport and the physical environment facets (r>.28 at P>.001), indicating that overall QoL and health is least related to perception of QoL in these facets.

8.5.17 Discriminant validity of the WHOQOL and PDM

Discriminant validity can be examined by dividing respondents into groups known to differ on certain characteristics such as those who are ill or well, by those reporting different health status or by those undergoing treatment and those who are not. Consequently, it is possible to determine whether there are any observable differences in QoL assessed by the PDM facets between these groups. Table 8.14 shows the mean, standard deviation, F and P values for each of the core and PDM facets for those who define themselves as ill or well. With the exception of body image and appearance, physical safety and security, the physical environment and SRPB, all facets show significant differences between ill and well participants. This provides support for the discriminant validity of 25 of the 29 facets (including the PDM) and suggests that perception of QoL for the facets not able to discriminate is not closely associated with being ill or well.

Table 8.13 Pearson's correlations (2-tailed) between core and PDM WHOQOL facets, PCS, MCS and G

Facet	**PCS**	**MCS**	**G**
Pain	.479**	.353**	.507**
Energy and fatigue	.416**	.520**	.666**
Sleep and rest	.199*	.386**	.495**
Positive feelings	.337**	.557**	.670**
Thinking, learning	.309**	.525**	.564**
Esteem	.327**	.511**	.612**
Body image	.120	.331**	.284**
Negative feelings	.186*	.688**	.590**
Mobility	.706**	.481**	.661**
ADL	.623**	.444**	.717**
Medication	.600**	.269*	.466**
Work	.685**	.494**	.664**
Relationships	.333**	.560**	.662**
Social support	.058	.214*	.354**
Sex	.341**	.301*	.435**
Safety	.230*	.332**	.390**
Home environment	.155	.367**	.424**
Financial	.166	.559**	.523**
Services	-.016	.419**	.385**
Information	.139	.475**	.516**
Leisure	.435**	.645**	.774**
Physical environment	.135	.199*	.303**
Transport	.166	.288*	.300**
SRPB	.151	.261*	.333**
Overall QoL	.565**	.611**	-
Pain relief	**.461****	**.369****	**.604****
Anger & frustration	**.277***	**.548****	**.487****
Vulnerability/ fear/ worry	**.325****	**.362****	**.434****
Uncertainty	**.438****	**.573****	**.643****

** Correlation is significant at the 0.01 level

* Correlation is significant at the 0.05 level

Table 8.14 Differences between core and PDM facet means for well and ill groups

Facet	Well mean (SD)	Ill mean (SD)	F	*p*
Pain	9.46 (2.81)	8.07 (1.93)	10.08	.00
Energy and fatigue	11.35 (3.21)	8.88 (2.67)	21.11	.00
Sleep and rest	12.02 (2.97)	10.37 (3.24)	8.19	.01
Positive feelings	13.10 (2.61)	10.88 (2.84)	19.24	.00
Thinking, learning	14.68 (2.26)	12.68 (2.77)	17.52	.00
Esteem	13.68 (2.79)	11.59 (3.03)	14.56	.00
Body image	14.74 (3.43)	13.85 (3.52)	1.92	.17
Negative feelings	14.25 (2.77)	12.18 (3.62)	11.68	.00
Mobility	11.55 (3.44)	8.45 (2.54)	31.82	.00
ADL	11.73 (3.43)	8.87 (2.27)	29.96	.00
Medication	12.43 (3.83)	8.81 (3.31)	29.39	.00
Work	12.17 (3.29)	9.09 (3.07)	27.39	.00
Relationships	15.97 (2.79)	13.75 (2.88)	18.16	.00
Social support	15.40 (2.98)	14.14 (3.54)	4.28	.04
Sex	12.11 (3.91)	10.15 (3.38)	7.83	.01
Safety	13.88 (2.60)	13.20 (2.24)	2.33	.13
Home environment	16.65 (2.93)	15.34 (2.86)	6.06	.02
Financial	14.96 (3.38)	12.22 (4.68)	12.64	.00
Services	13.59 (2.29)	12.22 (2.77)	7.17	.01
Information	13.88 (2.67)	12.23 (2.58)	10.81	.00
Leisure	13.04 (3.04)	10.20 (2.93)	26.66	.00
Physical environment	15.04 (2.27)	14.29 (2.45)	2.97	.09
Transport	16.42 (3.50)	14.55 (3.75)	7.72	.01
SRPB	12.50 (3.77)	11.25 (3.82)	3.17	.08
Overall QoL	13.18 (3.03)	9.80 (2.56)	42.05	.00
Pain relief	**11.06 (2.75)**	**9.39 (1.81)**	**15.41**	**.00**
Anger & frustration	**13.12 (3.07)**	**11.30 (3.01)**	**10.50**	**.00**
Vulnerability/ fear/ worry	**13.98 (2.73)**	**12.82 (2.57)**	**5.64**	**.02**
Uncertainty	**12.42 (2.97)**	**10.05 (2.89)**	**19.20**	**.00**

When those rating their health from very poor to very good were compared (table 8.15), significant differences were found for all facets with the exception of transport and SRPB, showing that for most aspects of QoL, the WHOQOL facets are able to distinguish between those reporting different health status as measured by the single item enquiring about health.

Table 8.15 Differences between core and PDM facet means for groups of people reporting different levels of health

Facet	**Very poor**		**Poor**		**Neither good nor poor**		**Good**		**Very good**		**F**	***p***
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**		
Pain	6.89	1.83	7.95	1.52	8.86	2.52	10.54	2.87	9.50	4.95	7.41	.00
Energy and fatigue	6.44	2.60	8.82	2.34	10.01	2.46	12.08	3.32	16.00	4.24	13.23	.00
Sleep and rest	10.67	4.27	9.80	3.16	10.98	2.65	12.97	2.63	14.00	4.24	5.74	.00
Positive feelings	10.00	3.08	10.44	2.62	11.98	2.41	14.10	2.48	17.50	3.54	12.98	.00
Thinking, learning	10.89	1.76	13.11	2.61	13.14	2.52	15.29	2.60	16.00	1.41	7.27	.00
Esteem	11.11	3.52	11.27	2.72	12.26	2.77	14.74	2.84	16.00	1.41	8.36	.00
Body image	16.33	3.28	12.59	3.79	13.64	3.19	15.87	2.81	17.00	4.24	6.02	.00
Negative feelings	11.22	3.90	12.27	3.56	12.63	3.19	14.97	2.66	13.00	8.49	3.99	.00
Mobility	6.22	2.05	8.75	2.41	9.66	2.53	13.07	3.64	10.00	7.07	15.14	.00
ADL	7.89	2.42	8.56	2.15	10.08	2.40	13.15	3.26	12.00	8.49	15.78	.00
Medication	6.33	2.06	8.36	2.88	11.09	3.52	13.37	3.64	13.00	.	14.58	.00
Work	6.33	1.94	9.23	2.84	10.18	2.84	13.83	3.12	13.00	4.24	17.48	.00
Relationships	13.67	2.32	13.93	2.46	13.89	3.28	16.91	2.74	17.33	3.77	7.20	.00
Social support	16.22	3.11	14.36	3.42	13.53	3.39	15.91	2.71	17.00	4.24	3.30	.01
Sex	6.80	2.48	10.18	3.10	11.25	3.65	12.77	4.05	20.00	.	6.99	.00
Safety	12.67	2.74	13.13	2.48	12.81	2.60	14.52	2.08	20.00	.	4.38	.00
Home environment	15.89	2.98	15.34	2.85	14.68	3.56	17.45	2.32	19.00	.	4.33	.00
Financial	13.00	6.14	12.56	3.88	12.53	4.20	15.52	3.43	20.00	.	3.74	.01
Services	12.56	3.47	12.53	2.67	12.03	2.14	13.59	2.53	16.83	3.06	2.80	.03
Information	11.67	3.54	12.59	2.78	12.31	2.64	14.04	2.36	16.00	5.66	2.82	.03
Leisure	8.11	3.10	10.53	2.31	11.24	2.69	14.15	3.23	13.33	9.43	11.45	.00
Physical environment	14.11	1.83	14.14	2.72	14.19	2.66	15.40	1.41	18.00	2.83	2.65	.04
Transport	14.11	3.41	15.07	4.13	14.69	3.05	16.67	3.31	13.50	9.19	1.80	.13
SRPB	11.89	5.56	11.09	3.96	11.35	2.98	13.29	3.68	13.50	3.54	1.88	.12
Overall QoL	6.88	2.03	9.97	1.85	10.71	2.32	14.68	2.86	15.00	4.24	29.02	.00
Pain relief	**8.79**	**2.48**	**9.51**	**1.83**	**9.54**	**2.01**	**12.29**	**2.58**	**12.00**	**2.83**	**10.67**	**.00**
Anger & frustration	**11.22**	**3.38**	**10.95**	**3.34**	**11.79**	**2.51**	**13.97**	**3.02**	**12.00**	**9.90**	**4.50**	**.00**
Vulnerability/ fear/ worry	**11.74**	**2.95**	**12.83**	**2.68**	**12.59**	**2.34**	**14.71**	**2.60**	**15.00**	**5.66**	**4.35**	**.00**
Uncertainty	**8.67**	**2.55**	**9.88**	**2.61**	**10.53**	**2.81**	**14.13**	**2.17**	**12.00**	**8.49**	**14.57**	**.00**

8.5.18 Are there any differences in QoL between those having a lumbar steroid epidural (LES) and those receiving no treatment (NT) at baseline?

In an examination of the differences between the LES and NT group, the LES group were slightly older (58.26 ± 17.02) than the NT group (52.68 ± 16.28) although this difference was not significant (F=3.633, P>.059). There were more women (n=87) than men (n=46) in both groups. Approximately equal numbers of men were in each group (LES n=24, NT n=22) but more women had LES than NT (LES n=52, NT n=35). There were no significant differences between the LES and NT group for the questions asking 'how is your health' *F* (1,128) of .001, (*P*<.991), and although the LES group had had pain for slightly longer (86.6 months for LES group, 81.9 for NT group) this difference was not significant *F* (1,119) of .045, (*P*<.833).

QoL was significantly lower in the LES group for the pain, mobility, ADL, pain relief, anger and uncertainty facets (table 8.16, only core facets with significance at the 0.05 level shown). Perception of QoL relating to vulnerability/ fear/ worry was not different for the LES and NT groups. For the WHOQOL-100 domain scores, QoL was significantly lower for the LES group in the level of independence domain and for the physical WHOQOL-Bref domain. For the SF-MPQ scores, significant differences were only found for present pain intensity and evaluative pain intensity, which indicated that patients undergoing LES reported more intense pain than those not having treatment. For the SF-12 MCS and PCS and CPAQ scores, no significant differences were found between those having an LES and those having NT and these are not shown ($p>0.05$).

8.5.19 Relationship between acceptance of pain and facets and domains of QoL, health status and pain severity and intensity

Internal consistency reliability for the subscales and total scores of the CPAQ was good with $\alpha >.75$. The 20-item SF-total score ($\alpha= .81$) and the 11-item activity engagement scale ($\alpha= .80$) were the most internally consistent, followed by the 9-item pain willingness scale ($\alpha= .76$) and the 24-item CPAQ total score ($\alpha= .75$). Table 8.17 shows Pearson's correlations between acceptance of pain scores and the facets of QoL. In general, correlations were greatest for the SF-CPAQ total. Each of the PDM facets correlated significantly with each of the dimensions for acceptance. Overall, uncertainty and anger were most highly correlated with acceptance. Of the core facets, work, mobility, ADL, overall QoL and pain and discomfort were most highly correlated with acceptance of pain. Conversely, body image and appearance, social support, self-esteem, sleep and rest, the environment, transport and SRPB were least related to acceptance of pain. The level of independence domain was most highly correlated with acceptance of pain on all but the pain willingness score, which was most highly correlated with the physical domain. This provides support for the CPAQ given that it measures the extent to which people engage in activity in spite of pain. These results also suggest that reporting a good QoL is associated with acceptance of pain.

Table 8.16 Frequencies and significance level for the core facets and domains, PDM facets and SF-MPQ scores for the LES and NT groups

Facet, domain or score	**NT**		**LES**		**F**	*p*
	Mean	**SD**	**Mean**	**SD**		
Core WHOQOL facets†						
Pain	9.63	2.64	8.24	2.28	10.43	.00*
Mobility	11.05	3.83	9.02	2.70	12.71	.00*
ADL	11.17	3.20	9.35	3.03	11.04	.00*
PDM facets						
Pain relief	10.74	2.53	9.81	2.32	4.65	.03*
Anger & frustration	12.88	3.05	11.33	3.27	7.66	.01*
Vulnerability/ fear/ worry	13.19	2.53	13.10	2.90	.04	.84
Uncertainty	11.74	3.27	10.58	3.05	4.37	.04*
WHOQOL-100 domains						
Physical	10.25	2.54	9.68	2.14	1.96	.16
Psychological	13.00	2.36	13.02	2.61	.00	.96
Level of independence	11.04	3.25	9.54	2.54	8.73	.00*
Social relationships	13.69	3.02	13.47	2.35	.23	.63
Environment	13.62	2.06	13.81	2.21	.25	.62
SRPB	11.42	3.65	12.09	3.79	1.04	.31
WHOQOL-Bref domains						
Physical	10.81	3.14	9.67	2.48	5.30	.02*
Psychological	12.72	2.39	12.83	2.74	.05	.82
Social	13.93	3.70	13.99	3.12	.01	.92
Environment	13.31	2.32	13.68	2.44	.77	.38
MPQ scores						
MPQ sensory pain rating index	9.67	5.22	11.06	6.82	1.56	.21
MPQ affective pain rating index	2.58	2.59	3.19	2.57	1.76	.19
MPQ total pain rating index	12.22	7.02	14.19	8.34	2.00	.16
MPQ present pain intensity vas	6.83	2.23	7.75	1.83	6.03	.02*
MPQ evaluative overall intensity	2.35	1.21	2.85	1.08	6.26	.01*

* Significant at the 0.05 level
† Only significant core facets shown

Each of the acceptance scores was more highly correlated with the MCS than the PCS, suggesting a stronger relationship between acceptance of pain and mental health status than with physical health status. Acceptance was negatively correlated with all MPQ scores, so that lower acceptance was associated with higher pain scores. Acceptance was most highly negatively associated with overall evaluative intensity and present pain intensity.

Table 8.17 Pearson's correlations (2-tailed) between core WHOQOL facets and domains, the PDM, PCS, MCS, MPQ scores and the CPAQ scores

Facet/ domain/ score	**SF-CPAQ total**	**CPAQ total**	**Activity engagement**	**Pain willingness**
Pain	.552**	.380*	.450**	.465**
Energy and fatigue	.535**	.394**	.398**	.482**
Sleep and rest	.263*	.097	.140	.334*
Positive feelings	.490**	.271*	.410**	.360*
Thinking, learning	.335*	.184	.355*	.172
Esteem	.289*	.176	.325*	.179
Body image	.185	.115	.169	.174
Negative feelings	.369*	.079	.280*	.363*
Mobility	.631**	.504**	.604**	.380**
ADL	.623**	.444**	.595**	.394**
Medication	.399**	.312*	.399**	.267*
Work	.645**	.429**	.605**	.397**
Relationships	.415**	.252*	.423**	.268*
Social support	.165	.149	.114	.210
Sex	.340*	.208	.309*	.277*
Safety	.362*	.180	.302*	.289*
Home environment	.305*	.248*	.349*	.141
Financial	.373*	.191	.345*	.256*
Services	.351*	.283*	.208	.363*
Information	.415**	.216	.340*	.336*
Leisure	.543**	.301*	.434**	.419**
Physical environment	.316*	.196	.238*	.291*
Transport	.282*	.217	.325*	.096
SRPB	.173	.122	.228	.089
Overall QoL	.582**	.376*	.455**	.493**
Pain relief	**.427****	**.322***	**.396****	**.324***
Anger & frustration	**.510****	**.274***	**.288***	**.585****
Vulnerability/ fear/ worry	**.462****	**.288***	**.337***	**.419****
Uncertainty	**.656****	**.453****	**.532****	**.528****
Domain I	.553**	.356*	.399**	.521**
Domain II	.423**	.205	.387*	.320*
Domain III	.662**	.481**	.628**	.412**
Domain IV	.419**	.270*	.376*	.341*
Domain V	.526**	.333*	.473**	.367*
Domain VI	.173	.122	.228	.089
PCS	.438**	.349*	.455**	.279*
MCS	.597**	.438**	.456**	.469**
MPQ S-PRI	-.335*	-.234	-.229	-.315*
MPQ A-PRI	-.447**	-.441**	-.346*	-.363*
MPQ T-PRI	-.396**	-.313*	-.281*	-.358*
MPQ PPI-VAS	-.450**	-.323*	-.327*	-.415**
MPQ evaluative overall intensity	-.579**	-.479**	-.451**	-.468**

** Correlation is significant at the 0.01 level

* Correlation is significant at the 0.05 level

8.5.20 Stepwise multiple regression to determine predictors of overall QoL and health

The data was analysed by stepwise multiple regression to examine the contribution of each PDM facet to explaining overall QoL and health. Consideration was given to the assumptions underlying regression, discussed in chapter seven. PDM facets were regressed against the G facet. Thus, in each case, the facets were the IV's and G was the DV. Table 8.18 summarises the results from the multiple regression and includes the standardised beta coefficients and r square change statistic (shown as %), which can to used to identify facets that contribute most to explaining G. When overall QoL was entered as the DV and the PDM facets as IV's, uncertainty and pain relief facets were retained in the model explaining the variance observed in G. The regression fit was (R^2_{adj} = 48.2%) and the overall relationship was significant (F=59.16 (2,213) P< 0.001). On inspection of the r square change statistic, uncertainty explained 41.5% of the variance in G and pain relief 7.5%. This indicates that of the PDM facets, pain relief and uncertainty are most important in explaining overall QoL and health.

Core and PDM facets were regressed against the G facet and leisure activities (61.5%), ADL (9.0%), sleep (2.9%), energy (1.6%), SRPB (1.8%) and mobility (1.1%) contributed to explaining overall QoL and health. All other facets, including the PDM facets were excluded from the model. The regression fit was (R^2_{adj} = 76.4%) and the overall relationship was significant (F=53.34 (6,91), P< 0.001). This suggests that the perception of QoL relating to these six facets are most important in explaining QoL, to the exclusion of 18 core facets and the 4 PDM facets.

When the 5 MPQ scores were entered as IV's, present pain intensity was the only IV retained in the model, explaining 20.6% of the variance. The regression fit was (R^2_{adj} = 19.9%) and the overall relationship was significant (F= 29.00 (1,112) P< 0.001). When entering the SF-12 scores as IV's, the MCS and PCS of the SF-12 accounted for 37.3% and 25.9% of the variance respectively in overall QoL. The regression fit was (R^2_{adj} = 62.5%) and the overall relationship was significant (F=93.64 (2,109) P< 0.001). A patient's present pain intensity and their health status are important to explaining overall QoL and health.

Table 8.18 Standardised coefficient beta, t, significance levels and the contribution (r square change statistic shown as %) of facets and scores to G from the stepwise multiple regression

Facet or score	Standardised coefficients beta	t	Sig.	*Contribution %
PDM facets				
Uncertainty	.441	5.512	.001	41.5
Pain relief	.341	4.257	.001	7.5
Core and PDM facets				
Leisure	.353	4.885	.001	61.5
ADL	.220	2.630	.010	9.0
Sleep	.140	2.380	.019	2.9
Energy	.157	2.277	.025	1.6
SRPB	.154	2.881	.005	1.8
Mobility	.175	2.163	.033	1.1
MPQ scores				
Present pain intensity	-.453	-5.384	.001	20.6
SF-12 scores				
MCS	.562	9.623	.001	37.3
PCS	.511	8.755	.001	25.9

* r square change shown as %

8.5.21 Stepwise multiple regression to determine predictors of pain

Given the importance of present pain intensity in explaining the variance in overall QoL, the present pain intensity VAS was entered as the DV and the PDM and core facets as IV's. Pain and discomfort, leisure activities and negative feelings were retained in the model explaining the variance observed in PPI (table 8.19). The regression fit was (R^2_{adj} = 53.7%) and the overall relationship was significant (F=36.88 (3, 90) P< 0.001). On inspection of the r square change statistic, pain and discomfort explained 45.5% of the variance in PPI, leisure activities 4.2% and negative feelings 5.5%. This result suggests that QoL relating to pain and discomfort, leisure activities and negative feelings are most important in explaining present pain intensity.

Table 8.19 Standardised coefficient beta, t, significance levels and the contribution (r square change statistic shown as %) of facets to present pain intensity from the stepwise multiple regression

Facet	Standardised Coefficients Beta	t	Sig.	*Contribution %
Pain and discomfort	-.599	-7.600	.001	45.5
Leisure activities	-.410	-4.275	.001	4.2
Negative feelings	.304	3.311	.001	5.5

* r square change shown as %

8.5.22 Stepwise multiple regression to determine predictors of acceptance of pain

In a further analysis, the relationship of facets of QoL to acceptance of pain was examined by regressing the core and PDM facets against the CPAQ scores (table 8.20). Firstly, when the SF-total score was entered as the DV, uncertainty and ADL were retained in the model explaining the variance observed in acceptance. The regression fit was (R^2_{adj} = 48.0%) and the overall relationship was significant (F=24.07 (2, 48) P< 0.001). On inspection of the r square change statistic, uncertainty explained 44.0% and ADL 6.1% of the variance in acceptance of pain assessed by the short-form instrument. This suggests that QoL relating to certainty and ADL are most important in explaining acceptance of pain.

For the activity engagement score, only mobility was retained in the model. The regression fit was (R^2_{adj} = 41.3%) and the overall relationship was significant (F=36.25 (1, 49) P< 0.001). On inspection of the r square change statistic, mobility explained 42.5% of the variance in activity engagement. This confirms the relationship between perception of QoL relating to mobility and engaging in activity in spite of pain. For pain willingness, anger and frustration and vulnerability/ fear/ worry were retained in the model. The regression fit was (R^2_{adj} = 35.9%) and the overall relationship was significant (F=15.29 (2, 49) P< 0.001). On inspection of the r square change statistic, anger and frustration explained 32.9% and vulnerability/ fear/ worry 5.5% of the variance in pain willingness. Overall, the contribution of anger and frustration and vulnerability/ fear/ worry to explaining the willingness to experience pain and uncertainty to acceptance, supports an important relationship between perception of QoL relating to the new facets and acceptance of pain.

Table 8.20 Standardised coefficient beta, t, significance levels and the contribution (r square change statistic shown as %) of facets to CPAQ scores from the stepwise multiple regression

Score	Standardised Coefficients Beta	t	Sig.	*Contribution %
SF-CPAQ				
Uncertainty	.421	2.950	.005	44.0
ADL	.346	2.424	.019	6.1
Activity engagement				
Mobility	.652	6.021	.001	42.5
Pain willingness				
Anger & frustration	.471	3.854	.001	32.9
Vulnerability/ fear/ worry	.256	2.097	.041	5.5

* r square change shown as %

8.5.23 Intervention group

Of the 76 patients undergoing lumbar steroid epidural (LES) injections for their LBP, 57 successfully completed baseline and follow-up measures. The following analysis examines the transition questions, sensitivity to change and the importance items for the LES group.

The transition questions assessed the extent to which change was perceived to have occurred in QoL, health and pain since baseline by patients undergoing LES. In response to these questions, QoL was rated as about the same or better (3.40 ± 1.15) as was health (3.31 ± 1.10) and pain (3.36 ± 1.19). Participants were moderately satisfied with treatment (3.21 ± 1.22). Of those undergoing LES, 13.8% had begun other treatments and 14.0% reported experiencing significant life events.

8.5.24 Sensitivity to change of the PDM facets

The ability of the WHOQOL and PDM to detect changes brought about by the LES intervention can be examined by looking at how many of the 25 core and 4 PDM WHOQOL facets show improvements and which have the biggest change scores. To examine the extent of change following LES, a paired-samples t-test was conducted for all facets at baseline and follow-up to see whether there are significant differences between the mean scores (table 8.21). Following LES, QoL was significantly better for 9 of the core WHOQOL facets ($P>0.05$) and 3 of the PDM facets ($P>0.01$). The core facets showing improvement were, pain and discomfort, energy and fatigue, sleep and rest, self esteem, mobility, ADL, dependence on medication, work capacity, leisure activities, overall QoL. The PDM facets showing improvement were pain relief, anger and frustration and uncertainty. Baseline α ranged from .56 (physical environment) to .93 (financial resources). Follow-up α ranged from .72 (physical environment) to .95 (work capacity). With the exception of personal relationships, sexual activity, physical environment and pain relief at baseline, all baseline and follow-up facets demonstrated good internal consistency reliability (α >.70).

Table 8.21 T-test (2-tailed) showing differences between baseline and follow-up scores for the PDM facets and Cronbach's α for the LES group (n= 57)

Facet	**Baseline**		**Follow-up**		**t**	***p***	**α**	
	Mean	**SD**	**Mean**	**SD**			**Baseline**	**Follow-up**
Pain	8.23	2.45	9.85	3.07	-4.41	.001*	.71	.82
Energy and fatigue	9.96	3.32	10.81	3.63	-2.60	.012*	.82	.89
Sleep and rest	11.26	3.06	12.19	3.37	-2.98	.004*	.90	.93
Positive feelings	12.04	3.19	12.48	2.92	-1.34	.186	.89	.88
Thinking, learning	13.38	3.19	13.84	3.11	-1.79	.079	.78	.85
Esteem	12.51	3.05	13.11	3.34	-2.11	.040*	.76	.87
Body image	13.99	3.82	14.05	3.71	-.24	.814	.90	.91
Negative feelings	12.91	3.42	13.00	3.74	-.23	.818	.88	.92
Mobility	9.08	2.86	10.91	3.76	-4.38	.001*	.87	.89
ADL	9.57	3.16	11.46	3.43	-5.18	.001*	.86	.88
Medication	10.58	3.53	11.49	4.12	-2.48	.017*	.89	.92
Work	10.24	3.06	11.07	3.65	-2.78	.007*	.89	.95
Relationships	14.76	3.01	15.08	3.17	-1.07	.290	.64	.74
Social support	14.44	3.29	14.65	3.39	-.78	.440	.79	.87
Sex	10.72	3.47	11.14	3.43	-1.18	.244	.67	.74
Safety	13.84	2.49	14.13	2.38	-1.109	.272	.77	.75
Home environment	16.29	2.50	16.41	2.85	-.52	.605	.87	.91
Financial	13.61	4.50	13.43	4.08	.68	.499	.93	.94
Services	12.65	2.84	12.83	2.83	-.67	.504	.84	.91
Information	12.74	2.74	13.30	2.91	-1.89	.064	.87	.90
Leisure	11.24	3.28	12.21	3.22	-2.73	.008*	.82	.88
Physical environment	14.85	2.21	14.88	2.54	-.09	.928	.56	.72
Transport	15.22	3.90	15.16	4.08	.16	.873	.90	.93
SRPB	11.78	3.74	12.20	3.48	-1.31	.195	.92	.92
Overall QoL	11.25	3.00	12.50	3.46	-3.42	.001*	.80	.90
Pain relief	**10.08**	**2.28**	**11.32**	**2.95**	**-3.20**	**.002***	**.63**	**.77**
Anger & frustration	**11.58**	**3.18**	**12.61**	**3.54**	**-2.54**	**.014***	**.81**	**.88**
Vulnerability/ fear/ worry	**13.12**	**3.07**	**13.70**	**3.23**	**-1.64**	**.107**	**.71**	**.83**
Uncertainty	**10.68**	**3.01**	**12.19**	**3.62**	**-4.46**	**.001***	**.76**	**.89**

8.5.25 Effect size of the WHOQOL and PDM scores

Effect size determines the difference between scores gained at baseline and follow-up and is an important statistic for looking at sensitivity to change (Kazis et al., 1989). One method of calculating effect size is to subtract baseline data from follow-up data and then divide the mean change in score by the baseline standard deviation. An effect size of 0.2 is small, 0.5 is moderate and 0.8 is large (Kazis et al., 1989). As table 8.22 illustrates, 16 of the core facets had very low effect sizes below 0.2 (-.04-.19) showing that these facets were not responsive to the LES intervention. Of the core facets, financial resources and transport had small negative effect sizes (-.02- -.04), showing that facet scores had decreased slightly at follow-up. Largest effect sizes were found for pain and discomfort, mobility and ADL (.62- .69) showing that these facets were most responsive to the LES intervention. Moderate effect sizes were found for pain relief and uncertainty (.50- .53), which were the most responsive PDM facets. Small effect sizes were found for energy and fatigue, sleep and rest, dependence on medication, information, leisure activities, anger and frustration and vulnerability/ fear/ worry (.20- .32). Although only modest effect sizes were found, overall impressions of change in QoL, health and pain assessed by the transition questions was variable. Such findings support the sensitivity of a selection of core facets and suggest that facets relating to the physical and level of independence domains are more responsive to LES than those representing the psychological, social relationship, environment or SRPB domains of QoL.

Table 8.22 Effect size for core WHOQOL and PDM facets (ranked)

Facet	Change mean	Change SD	Effect size*	Effect size SD
Pain	1.57	2.61	.69	1.15
Mobility	1.82	3.09	.68	1.14
ADL	1.89	2.75	.62	.91
Pain relief	**1.24**	**2.90**	**.53**	**1.25**
Uncertainty	**1.51**	**2.57**	**.50**	**.84**
Anger & frustration	**1.04**	**3.08**	**.32**	**.94**
Leisure	.97	2.69	.31	.85
Sleep and rest	.93	2.36	.30	.77
Medication	.91	2.66	.26	.76
Energy and fatigue	.85	2.38	.26	.72
Vulnerability/ fear/ worry	**.57**	**2.64**	**.20**	**.91**
Information	.57	2.18	.20	.75
Esteem	.60	2.11	.19	.67
Thinking, learning	.46	1.94	.15	.64
Positive feelings	.44	2.51	.14	.81
Sex	.42	2.46	.12	.71
SRPB	.42	2.40	.11	.63
Relationships	.32	2.27	.11	.80
Safety	.29	1.93	.11	.74
Work	.83	2.21	.08	.22
Social support	.20	1.99	.07	.63
Services	.18	1.87	.06	.69
Financial	-.18	1.96	-.04	.45
Home environment	.12	1.71	.04	.59
Negative feelings	.09	2.87	.03	.82
Body image	.06	2.05	.02	.52
Transport	-.06	2.75	-.02	.74
Physical environment	.02	1.96	.01	.89

* Mean change divided by the standard deviation of the change.

8.5.26 Do importance items change in importance following LES?

To examine the stability of importance scores, baseline and follow-up means were compared in a paired-samples t-test to look at the extent of any changes in the importance attributed to core and PDM facets of QoL from baseline to 4 weeks following LES. Table 8.23 shows the baseline and follow-up means and significance values for facets that were significantly different at follow-up. With the exception of freedom from pain, all of the core importance scores remained stable and these have not been shown. Of the PDM facets, the importance of relief, the importance of control and the importance of being free from fear and worry were significantly less important at follow-up ($P>0.05$). Freedom from anger and frustration and uncertainty remained stable from baseline to follow-up. These results suggest that the importance attributed to certain facets of QoL changed following a LES.

Table 8.23 T-test (2-tailed) showing differences between baseline and follow-up importance ratings for the LES group

Importance item	**Baseline**		**Follow-up**		t	*p*
	Mean	**SD**	**Mean**	**SD**		
Free from pain	4.54	.66	4.33	.69	2.12	.038*
Pain relief	4.54	.60	4.32	.69	2.36	.022*
Pain control	4.54	4.38	4.38	.59	2.42	.019*
Anger & frustration	4.25	.74	4.20	.67	.45	.651
Fear & worry	4.30	.60	4.04	.73	2.67	.010*
Uncertainty	4.18	.78	4.04	.71	1.31	.197

* Significant at >0.05

8.5.27 No-treatment group

Of the 57 patients in the no-treatment (NT) group, 30 successfully completed baseline and follow-up measures. The following results show the response to the transition questions, test-retest reliability and the stability of importance items.

The transition questions assessed the extent to which change was perceived to have occurred in QoL, health and pain since baseline by patients not undergoing treatment. In response to these questions, QoL was rated as about the same (3.11 ± .92, versus 3.40 ± 1.15 for LES), and health (2.89 ± .96, versus 3.31 ± 1.10 for LES) and pain (2.93 ± 1.09, versus 3.21 ± 1.22 for LES) as the same or a little worse, reflecting the differences greater perceived change amongst patients in the LES groups. Of those in the NT group, 50.0% (versus 13.8% LES group) had begun other treatment and 19.2% (versus 14.0% LES group) reported experiencing significant life events.

8.5.28 Test-retest reliability

Test-retest reliability refers to the relationship between scores (or score consistency) when the patient completes the instrument on two separate occasions. Pearson's correlations (2-tailed) were conducted between baseline and follow-up facet means. Table 8.24 shows the test-retest reliability of the core and PDM WHOQOL facets. Pearson's correlations for the core facets ranged from .57- .85 and for the PDM facets .52- .71 (p>0.01). In general for the NT group, overall QoL and health at baseline and follow-up was more highly associated than for the LES group (r=.77 versus r-.65), providing support for the stability of QoL in those not undergoing treatment.

Table 8.24 Pearson's correlations (2-tailed) between baseline and follow-up core and PDM facets for the NT group

Facet	**Baseline**		**Follow-up**		**Pearson r**	***p***
	Mean	**SD**	**Mean**	**SD**		
Pain	9.63	2.64	9.90	3.01	.60	.00
Energy and fatigue	10.27	2.94	10.38	2.82	.74	.00
Sleep and rest	10.85	3.33	11.60	3.36	.80	.00
Positive feelings	11.81	2.91	12.31	2.92	.78	.00
Thinking, learning	13.57	2.40	12.88	2.33	.57	.00
Esteem	12.21	3.13	12.41	2.97	.65	.00
Body image	14.32	3.06	14.45	3.11	.67	.00
Negative feelings	13.09	3.54	12.92	3.32	.68	.00
Mobility	11.05	3.83	11.43	3.33	.72	.00
ADL	11.17	3.20	11.86	2.84	.83	.00
Medication	10.87	4.32	10.51	3.83	.85	.00
Work	11.03	4.04	11.09	3.82	.85	.00
Relationships	14.51	3.36	14.33	3.27	.75	.00
Social support	14.78	3.66	14.57	3.37	.82	.00
Sex	11.55	4.26	11.00	3.88	.74	.00
Safety	13.31	2.54	13.43	2.45	.61	.00
Home environment	15.25	3.40	14.93	3.34	.76	.00
Financial	13.18	4.02	12.80	3.68	.83	.00
Services	12.88	2.44	13.28	2.45	.80	.00
Information	13.04	2.71	13.17	2.19	.64	.00
Leisure	11.90	3.40	11.73	2.88	.80	.00
Physical environment	14.25	2.73	14.03	2.79	.81	.00
Transport	15.13	3.53	14.89	3.56	.66	.00
SRPB	11.42	3.65	12.07	3.14	.74	.00
Overall QoL	11.28	3.48	11.66	3.20	.77	.00
Pain relief	**10.74**	**2.53**	**11.46**	**2.27**	**.55**	**.00**
Anger & frustration	**12.88**	**3.05**	**12.82**	**2.71**	**.71**	**.00**
Vulnerability/ fear/ worry	**13.19**	**2.53**	**13.31**	**2.67**	**.52**	**.00**
Uncertainty	**11.74**	**3.27**	**12.62**	**2.73**	**.69**	**.00**

8.5.29 Stability of importance items in the NT group

The stability of importance items was examined by comparing baseline and follow-up means in a paired-samples t-test. All baseline to follow-up importance scores were non-significant with the exception of overall QoL and health, which was significantly less important at follow-up (values not shown). At baseline, overall QoL was 4.23 ± .63, versus 4.03 ± 61 at follow-up (t=2.26, p> .05). This contrasts with the decreased importance of freedom from pain and discomfort, pain relief, pain control and vulnerability/ fear/ worry following LES.

8.6 Discussion

The aim of this chapter was to test the psychometric properties of the PDM, specifically the internal consistency reliability, construct validity, discriminant validity, sensitivity to change and test-rest reliability of the PDM. Sensitivity to change was examined following a lumbar epidural steroid injection (LES) injection for low back pain (LBP) and test-retest reliability in a group not undergoing treatment (NT). The combined baseline LES and NT groups consisted of more females than males, who were mostly married and not currently in employment. The health of participants was described as poor (34%) or neither poor nor good (32%) by most, and 51% described themselves as currently ill. The majority of participants described their pain as continuous and discomforting and pain was most often reported in the lower back, spine and legs. For both groups at baseline, QoL was highest for the home environment, transport, personal relationships and social support and lowest for pain and discomfort, mobility, energy and fatigue and ADL. Consistent patterns of missing data were found for sexual activity and availability and quality of health and social care. That most missing data was found for items representing these facets is consistent with the pattern of missing data from the cross-sectional survey reported in chapter seven and might be a consequence of the personal nature of these aspects of QoL. For the PDM, the question about the extent to which having treatment has improved QoL was most frequently missed, which may have been due to the fact that patients were attending their first appointment and had not yet received any treatment.

When domain scores were calculated, QoL was highest for the environment and social relationships domains and lowest for physical and level of independence. Following extraction of Bref items and calculation of Bref domains, QoL was highest for the social relationships domain, followed by the environment, the psychological and the physical domain. All core and PDM facets were considered important to participants (range 3.07- 4.59) and the most important were being able to carry out ADL, being pain free, being able to move around and having energy. The least important were sexual activity, personal beliefs and body image and appearance. This finding is particularly important given that it is these facets that were most compromised by living with pain and it is this discrepancy, between perception of QoL and the importance attributed to it, that may prove to be key targets for intervention (discussed in more detail in chapter nine). Of the PDM facets, the most important was being able to control pain and obtaining pain relief, followed by being free from fear and worry, anger and frustration and the least important was being free from uncertainty (range 4.02- 4.49), reflecting the importance of these aspects of QoL to people with CP.

8.6.1 Psychometric properties

In addition to describing the characteristics and QoL of the study sample, the goal of this chapter was to look specifically at the psychometric properties of the new module when applied to two populations; one undergoing an intervention aimed at reducing pain and another not receiving treatment. Firstly, the baseline data was used to calculate the internal consistency reliability, construct, concurrent and discriminant validity of the module, before going on to examine sensitivity to change and test-retest reliability by comparing baseline and follow-up data. Of the 16 items, only 12 used the full range of scores (1-5) and none of these had 10% at each point in the scale. Given that the population is relatively homogenous with respect to diagnosis, the distribution of scores reflects this and the items would need to be subject to further testing in a more heterogeneous population of people with CP from diverse diagnostic groups. Internal consistency reliability for the 16-item module was good (α=.88) and for the four facets, α ranged from .66 to .81. Internal consistency was acceptable for uncertainty (α=.79) and anger and frustration (α=.81), but only marginal for pain relief (α=.66) and vulnerability/ fear/ worry (α=.67). This observation was largely due to low inter-item correlations for the pain relief and vulnerability/ fear/ worry facets. Item-facet correlations were all above .4, with the exception of 2 pain relief items and one vulnerability/ fear/ worry item. The results for the pain relief and vulnerability/ fear/ worry facets suggest that, when tested with patients with LBP, these facets are less cohesive and the items representing the facets are more heterogeneous than those representing the uncertainty and anger and frustration facets which have been shown to be internally consistent. Given the structure of the WHOQOL framework adopted for the development of the PDM, it is not possible to carry out further item deletion, although further testing with item substitution would be feasible.

Items should correlate more highly with their parent domain than with other domains of QoL. Of the 4 pain relief items, one correlated more highly with level of independence. For anger and frustration, 2 items correlated more with the physical domain and one with level of independence. For vulnerability/ fear/ worry, one item correlated more with the environment and another with level of independence. Finally, for uncertainty, 2 items correlated more with the psychological domain. This raises issues for the conceptual integrity of the facets, however, also reflects the complex relationship and interconnectedness of the concomitants of pain. Each facet should also correlate more highly with its parent domain and this was the case for 3 of the 4 PDM facets, where anger and frustration correlated marginally more highly with the physical domain, highlighting the salience of these emotions for people with pain. This finding also mirrors the strong negative association between the sensory qualities of pain assessed by the sensory pain-rating index of the McGill Pain Questionnaire and the anger and frustration facet.

8.6.2 Construct and concurrent validity

Construct validity was examined by looking at the relationship between the SF-MPQ and the new PDM. As predicted, each facet was significantly negatively correlated with each MPQ scale so that a higher pain intensity and severity is associated with poorer QoL in these aspects of a patient's life. A higher QoL assessed by the PDM was associated with better health status demonstrating concurrent validity. Moreover, pain relief correlated more highly with the physical functioning assessed by the SF-12 and anger and frustration, vulnerability/ fear/ worry and uncertainty with the mental health functioning of the SF-12, further demonstrating concurrent validity. When the relationship between overall QoL and health and facets and domains of QoL was examined, all facets and domains were significantly correlated with overall QoL, although highest correlations were found for leisure activities, ADL and positive feelings and the level of independence and physical domains of QoL, suggesting that for the patients with LBP in this study, perception of overall QoL assessed by the G facet is highly associated with these aspects of QoL.

8.6.3 Discriminant validity

The core and PDM WHOQOL facets were able to distinguish between participants defining themselves as ill or well, where QoL was significantly lower for ill participants ($P>0.05$), with the exception of body image and appearance, physical safety and security, physical environment and SRPB. The instrument also distinguished between those reporting different levels of health, with the exception of transport and SRPB. The SF-MPQ, SF-12 and CPAQ also demonstrated good discriminant validity with significant differences between those defining themselves as ill and well.

8.6.4 Acceptance of pain and QoL

This study also examined the relationship between acceptance of pain and QoL in a subset of participants. The CPAQ derives a total score and 3 scores based on a shortened version with items extracted from the full instrument; activity engagement, pain willingness and a short-form total score. Internal consistency was good for the total scores and subscales of the CPAQ (>.75). All of the PDM facets were significantly correlated with acceptance of pain, with anger and frustration and uncertainty being most highly associated, suggesting that patients who are more accepting of their pain also report less anger, frustration and uncertainty. Pain relief, vulnerability/ fear/ worry and uncertainty were most associated with the SF-CPAQ and anger and frustration with pain willingness, which suggests that those who report less anger are more accepting of their pain. Of the core facets, working capacity, mobility, ADL, overall QoL and pain and discomfort were most highly associated with acceptance ($r>.55$, $P>0.01$), suggesting that those who are highly accepting of their pain report fewer problems with these physical and level of independence aspects of QoL than those who are not accepting of their pain. The CPAQ and SF-CPAQ total scores and activity engagement were most associated with the level of independence domain and pain willingness with the physical domain. Acceptance was also significantly associated with health status; however, it was more associated with the MCS of the SF-12. Lower acceptance of pain was also associated with higher pain scores on the SF-MPQ, with higher negative correlations for present pain intensity and evaluative overall intensity. Thus patients reporting a high present pain intensity and overall intensity reported being less accepting of their pain. This finding contrasts with that of McCracken who found that the correlation between acceptance and pain intensity was relatively low (McCracken, 1998). Given that it is not possible to elucidate the direction of this relationship, these results raise the question of whether those reporting a higher QoL and less pain are consequently more accepting of their pain or whether greater acceptance of pain results in a fuller engagement in life and consequently reports of a better QoL and less pain. This relationship is worthy of further investigation, for example by prospectively testing an intervention that specifically targets acceptance of pain.

8.6.5 What contributes to explaining overall QoL and health, pain intensity and acceptance of pain?

Regression analyses showed that of the PDM facets, uncertainty explained most of the variance in overall QoL followed by pain relief. Of the core facets, participation in and opportunities for recreation and leisure explained most of the variance in overall QoL, followed by ADL, sleep and rest, energy and fatigue, SRPB and mobility. Of the MPQ scores, present pain intensity explained most of the variance in overall QoL, suggesting that of the dimensions of the pain experience, it is the present intensity of pain that is most important in explaining observed QoL. Given this finding, core facets were regressed against present pain intensity and pain and discomfort, leisure activities and negative feelings explained most of the variance. The mental health component score of the SF-12 accounted for a greater proportion of variance than the physical health component score, reflecting the importance of the psychological consequences of pain in explaining and determining the assessment of QoL. Uncertainty and ADL explained the variance in acceptance of pain assessed by the short-form CPAQ. Mobility accounted for the variance in activity engagement and anger and frustration and vulnerability/ fear/ worry explained the variance in pain willingness.

8.6.6 LES and NT groups

More women than men made up both samples and the LES group was slightly older and had longer pain duration, although these differences were not significant. The QoL of people undergoing LES was found to be significantly lower for pain, mobility, ADL, pain relief, anger and uncertainty and for the WHOQOL-100 level of independence domain and the WHOQOL-Bref physical domain. Present pain intensity and evaluative pain intensity were also significantly higher for the LES group.

8.6.7 Sensitivity to change

Responses to the transition questions asked at follow-up suggest that most patients undergoing LES reported that their QoL, health and pain had stayed the same or improved and that they were moderately satisfied with treatment. A small number of patients reported beginning other new treatments and experiencing significant life events. The perception of treatment efficacy reported by patients is important in understanding the results and shows that the response to LES amongst the patients in this study was variable. Following LES, QoL was significantly better for pain and discomfort, energy and fatigue, sleep and rest, self esteem, mobility, ADL, dependence on medication, work capacity, leisure activities, overall QoL, pain relief, anger and frustration and uncertainty. With the exception of personal relationships, sexual activity, the environment and pain relief, all baseline facets demonstrated good internal consistency reliability and for follow-up facets, all facets demonstrated good internal consistency reliability, providing further evidence of the strength of the measure to assess QoL. Largest effect sizes were found for pain and discomfort, mobility, ADL, moderate effect sizes were found for pain relief and uncertainty and small effect sizes were found for energy and fatigue, sleep and rest, dependence on medication, information, leisure activities, anger and frustration and vulnerability/ fear/ worry demonstrating that these facets are the most sensitive to changes brought about by LES.

Such selective improvements to QoL are unremarkable given that LES is a unimodal intervention. Consequently, only modest improvements would be expected relative to a more multifaceted intervention such as a pain management programme. Enhancing QoL across the entire range of facets would be beyond the scope of purely medical interventions. Obtaining a global assessment still confers advantages given that it is also possible to identify and focus on aspects of QoL that are perceived to be good relative to other areas.

8.6.8 Test-retest reliability

Given that an instrument should yield the same score for each participant when it is taken on another occasion if that person's status on that variable has not changed (Kline, 1998), a challenge to the assessment of test-retest reliability is the reported variability in perceptions of changes in QoL, health and pain over a 2-week period. Most of the NT group reported that their QoL had remained the same and that their health and pain were the same or a little worse. A larger proportion of the NT group than the LES group reported beginning other treatment and experienced significant life events. That health and pain were described as the same or worse could reflect the fluctuating nature of pain, already identified in previous chapters (Skevington, 1994; Mason, Skevington and Osborn, 2004) and reveals that despite perceptions of changes in pain, QoL can remain stable. It is also possible that this result could be a response to not receiving treatment, that is, respondents wished to register that their pain had become worse to maximise the chances of receiving treatment at a subsequent appointment. Consequently, correlations below 0.7 for pain and discomfort, thinking, learning, memory and concentration, self-esteem, body image and appearance, negative feelings, physical safety and security, opportunities for acquiring new information and skills, transport, pain relief, vulnerability/ fear/ worry and uncertainty could reflect changes in pain over the 2-week interval, a bias associated with wishing to appear worse to increase the likelihood of receiving treatment or that these facets do not meet the criteria for test-retest reliability. However, it has already been shown that core WHOQOL facets produce comparable scores across time in the absence of significant life occurrences or medical interventions, with facet correlations between baseline and follow-up ranging from .68- .95 (The WHOQOL Group, 1998). Furthermore, given that patients reported other life events occurring during the interval between assessments, this presents a methodological challenge because such events or experiences are likely to influence the response to a holistic, subjective assessment of QoL.

The drawback of selecting different time intervals for intervention and non-intervention groups is that the groups will not be comparable at follow-up. However, if the NT group baseline-follow-up interval had been lengthened, this would have increased the likelihood of changes occurring during this time, for example, alternative treatment could have commenced, confounding the results.

8.6.9 Importance items

The stability of the importance attributed to facets of QoL was examined for the LES and NT groups. For the LES group, the importance of facets of life remained stable over the 4 week interval between baseline and follow-up with the exception of the importance of being pain free, the importance of relief, the importance of control and the importance of being free from fear and worry, which were significantly less important at follow-up. For the NT group, all baseline to follow-up importance scores were non-significant with the exception of overall QoL and health, which was significantly less important at follow-up. Given the small sample size of the NT group, this result should be interpreted with caution and is worthy of further investigation. Although perceived importance remained relatively stable for most facets, the reported changes suggest that an intervention, such as LES, may mediate the importance attributed to these facets of QoL. Given the important relationship between a persons' rating of an aspect of QoL and the perceived importance attributed to it (Skevington, O'Connell, The WHOQOL Group, 2004), further work exploring these shifts in importance might produce useful insights in the light of contemporary theoretical approaches relating to changes to the way that QoL is perceived.

8.6.10 Critique

In any longitudinal test involving an intervention the question arises of the extent to which treatment is consistent and equally efficacious across different consultants and different clinic sites. This potential source of variability may influence the response to treatment and the completion of instruments assessing outcomes. Furthermore, improvements were only found for 10 of the core facets and 3 of the PDM facets which is unremarkable given that LES is a very specific unimodal medical intervention and any reported decrease in pain may not lead to improvements in broader aspects of patient functioning, well-being and QoL. Such changes might come about through targeted multidisciplinary, multifaceted interventions. Despite the multifaceted consequences of pain, a reduction in symptoms (i.e. pain) would not necessarily improve QoL in areas not pertaining to health such as aspects of the physical environment. Indeed Skevington found that some aspects of QoL are not affected by the presence of pain, for example SRPB (Skevington, 1998). This adds weight to the argument for developing the PDM to increase the specificity and sensitivity of the generic core instrument, because not all core facets are sensitive to the influence of CP.

Given the variable response to LES shown by the transition questions, a change in QoL may not have taken place, which explains the modest effect sizes. It is also possible that the measure may not be sensitive enough to pick up changes, particularly as 2 of the 4 PDM facets address the psychological concomitants of pain rather than physical ones. However, the instrument did detect selective improvement in QoL following LES. A response shift may also have occurred, that is, the processes utilised to make decisions about QoL may have changed the way that participants evaluate aspects of their life quality (Sprangers and Schwartz, 1999). Indeed, changes to the importance attributed to freedom from pain and fear and worry and pain relief and control suggest that this is a plausible explanation. However, as such processes were not directly assessed during this study, this remains an important issue for further research to elucidate the process of adaptation to chronic conditions characterised by pain.

It was not feasible or ethical to design and implement a RCT, as this would involve denying patients access to treatment to form a control group, consequently, the sample was opportunistic. The sample used in this study was also older in age and represented a more homogenous diagnostic group than previous chapters have reported, however, it was necessary to recruit people with CLBP due to the selected intervention. Engaging people at baseline to prevent attrition at follow-up was important to maximise the extent to which generalisations can be made about the QoL of people with pain. However, some attrition was inevitable and despite follow-up telephone reminders. A higher response rate at follow-up was achieved for the LES than the NT group. Given the limited resources, the sample had sufficient power to enable conclusions to be made on the properties of the measure; which was the goal of the research.

8.6.11 Concluding remarks

This chapter reported a longitudinal test to elucidate the psychometric properties of the PDM, including sensitivity to change and test-retest reliability and presented a summary of its psychometric properties. Chapter nine focuses on the importance of facets of QoL and derivation of the WHOQOL-Bref using data derived from the cross-sectional survey reported in chapter seven. In the final chapter, all the major findings are summarised and discussed.

Chapter nine

The Importance of Facets of QoL and Derivation of a Short-form PDM

9.1 Introduction

The previous chapter described the longitudinal survey to examine sensitivity to change and test-retest reliability of the pain and discomfort module (PDM) and summarised its psychometric properties. This chapter makes a preliminary assessment of the QoL of people with chronic pain (CP). Specifically, the facet and domain scores of the WHOQOL and the PDM are examined, in addition to the importance attributed to facets of quality of life (QoL). A particular focus is the relationship between facet scores and their corresponding importance item. Additionally, an abbreviated form of the PDM is derived from the cross-sectional survey data reported in chapter seven.

The relationship between aspects of QoL and the importance attributed to such areas has been shown to be important in understanding QoL (Skevington and O'Connell, 2004) (discussed in chapter five). Indeed, instruments such as the Patient-Generated Index is based on patients rating the importance of aspects of their QoL they would most like to improve (Haywood et al., 2003). Interpreting the discrepancy between the rating of QoL and the importance attributed to that aspect could provide useful insights into QoL. For example, where a person reports a low QoL, but attributes high importance to a facet, this might be a locus for intervention. Conversely, less heed would need to be paid to areas where QoL is good, but importance is low. Consequently, examining the relationship between how good or poor an aspect of QoL is and the importance attributed to it enables a more detailed assessment of QoL.

The development of short-form instruments represents a trade-off between comprehensiveness and brevity. Examples include the MOS health status instruments, in particular, the derivation of the SF-12 (discussed in chapter eight) and the SF-8 (Turner-Bowker et al., 2003) from the SF-36 (Ware and Sherbourne, 1992) and the development of the WHOQOL-Bref (WHOQOL group, 1998). The use of such instruments confers advantages both in clinical practice and in research where time is limited and where patients are already faced with an extensive battery of instruments (Sturgis et al., 2001; Jenkinson and Layte, 1997). However, limitations include compromised precision (Ware, Kosinski and Keller, 1996) and reduced comprehensiveness. The development and validation of the WHOQOL-Bref was described in chapter two and given the brevity of the Bref compared to the core WHOQOL-100, deriving a short-form PDM to be used in conjunction with the Bref would confer further advantages when clinical time is limited or patient burden is high (Skevington, Lofty and O'Connell, 2004). An additional goal was therefore to extract WHOQOL-Bref items from the core data and to select one item from each of the PDM facets to derive an abbreviated form.

9.2 Results

The analysis that follows consists of two parts. The first explores the importance of different aspects of QoL and the second on comparing the WHOQOL-100 and WHOQOL-Bref and deriving an abbreviated form. Analysis was conducted on the cross-sectional survey data reported in chapter seven using the 16 retained items of the PDM, where the characteristics of the study sample and the psychometric analysis were reported. The rationale for using the data derived from the cross-sectional study rather than the longitudinal study was twofold. Firstly, the sample size was larger (n=216) which gives greater confidence in the conclusions drawn and secondly, the sample consisted of people from heterogeneous diagnostic groups as opposed to relative homogeneity of the low back pain patients participating in the longitudinal study.

9.2.1 Part 1 - Facet and domain scores for the WHOQOL and PDM

Table 9.1 shows the mean scores for the 25 WHOQOL facets and 4 retained PDM facets. For the core facets, highest QoL was in the home environment, social support and transport facets and lowest for the pain and discomfort, energy and fatigue and dependence on medication facets. For the PDM facets, QoL was highest for vulnerability/ fear and worry, followed by anger and frustration, pain relief and lowest for uncertainty. Of the domain scores, QoL is highest in the environment domain (13.59 ± 2.34), followed by the social relationships (13.55 ± 2.93), psychological

(12.74 ± 2.69), SRPB (12.53 ± 4.03), level of independence (10.38 ± 3.30) and is lowest in the physical domain (9.99 ± 2.67). This concurs with the results from the longitudinal study reported in chapter eight.

9.2.2 Importance of aspects of QoL

As described in chapter two, the original WHOQOL pilot contained 41 importance items (Szabo et al., 1997) and this has subsequently been reduced to 26 (Skevington and O'Connell, 2004), one representing each facet, one overall QoL and another general health. As table 9.1 illustrates, all of the core and PDM importance items where rated at >3.0 underscoring their importance to people with CP. The most important facets were ADL, mobility and the availability and quality of health and social care. The least important were sexual activity, body image and appearance and SRPB. Of the PDM facets, the most important was obtaining relief and controlling pain (pain relief), followed by freedom from anger, worry and the least important was freedom from uncertainty. Such information is important because it provides an indication of the relative priority given to different aspects of life.

9.2.3 Relationship between the WHOQOL facets and the importance items

In order to examine the relationship between facets of QoL and the importance attributed to them by CP patients, Pearson's correlations were conducted between each facet mean and the importance item representing that facet. Due to the inevitably skewed data because of the predetermined importance of these facets of QoL (>3.0 on the 5-point Likert scale), the importance scores were log transformed. The transformed importance scores were also correlated with G. Table 9.1 shows the mean ranked importance items, corresponding facet score, ranked facet score, correlation with core facet and with G. Overall, the correlations were relatively weak. Ten of the 26 importance-core facet correlations were significant. Significant negative correlations between importance ratings and corresponding facet mean were found for pain and discomfort, energy and fatigue, sleep, financial resources, negative feelings, physical safety and security and body image and appearance. For the PDM facets, all importance ratings were significantly negatively correlated with their corresponding facet. Working capacity, social support and SRPB were significantly positively correlated with their corresponding facet, suggesting that a good QoL in these areas is associated with high importance. The largest correlation was found between the importance of SRPB and its core facet (r=.61). For correlations with G, significant negative correlations were found for pain and discomfort and dependence on medication. Of the PDM importance ratings, pain relief, anger and frustration, and uncertainty were significantly negatively correlated with G (P> .05). Only SRPB was significantly positively correlated with G.

Table 9.1 Mean ranked importance items with corresponding facet mean, rank, log-transformed importance correlated with facet mean and G

Item no.	**Item**	**Importance ± (SD)**	**Facet score ± (SD)**	**Ranked facet score†**	**Pearson's r with core facet**	**Pearson's r with G**
12	Care ADL	4.54 (.598)	2.67 (.89)	7	.01	-.04
11	Able to move around	4.47 (.590)	2.58 (1.00)	4	-.05	-.11
28	**Obtain relief**	**4.43 (.692)**	**2.71 (.74)**	**8**	**-.17***	**-.20***
29	**Control pain**	**4.43 (.664)**	**2.71 (.74)**	**8**	**-.18***	**-.25***
21	Adequate healthcare	4.35 (.612)	3.24 (.72)	20	.04	-.12
19	Home environment	4.34 (.610)	3.93 (.84)	29	.11	-.03
15	Relationships with others	4.34 (.713)	3.55 (.86)	26	.14	.01
4	**Energy**	**4.32 (.658)**	**2.46 (.76)**	**2**	**-.23***	**-.15**
2	Health	4.31 (.610)	2.80 (.91)	10	-.12	-
3	**Pain free**	**4.28 (.810)**	**2.25 (.74)**	**1**	**-.31***	**-.21***
5	**Restful sleep**	**4.25 (.708)**	**2.78 (.91)**	**9**	**-.29***	**-.16**
7	Thinking problems	4.20 (.686)	3.25 (.77)	21	.03	-.03
1	QoL	4.19 (.640)	2.80 (.91)	8	-.12	-
8	Positive re self	4.15 (.804)	3.08 (.83)	15	.08	-.07
10	**Free negative feelings**	**4.11 (.817)**	**3.17 (.93)**	**18**	**-.38***	**-.17**
20	**Financial resources**	**4.11 (.711)**	**3.15 (1.02)**	**17**	**-.24***	**-.11**
6	Feel contented	4.05 (.677)	3.03 (.80)	13	.05	-.00
33	**Free from worry**	**4.02 (.855)**	**3.23 (.78)**	**19**	**-.29***	**-.04**
13	**Independence medication/ treatment**	**4.01 (1.150)**	**2.50 (1.01)**	**3**	**-.03**	**-.22***
14	**Able to work**	**4.01 (1.150)**	**2.63 (1.09)**	**5**	**.22***	**-.14**
18	**Safe and secure**	**4.00 (.801)**	**3.34 (.75)**	**23**	**-.26***	**-.05**
25	Adequate transport	3.98 (.878)	3.69 (1.04)	27	-.12	-.12
30	**Free from anger**	**3.95 (.944)**	**3.04 (.86)**	**14**	**-.36***	**-.22***
23	Relaxation and leisure	3.94 (.776)	3.00 (.86)	12	.15	-.02
24	Environment	3.86 (.831)	3.52 (.72)	25	-.08	.02
34	**Free from uncertainty**	**3.85 (.922)**	**2.66 (.89)**	**6**	**-.18***	**-.20***
16	**Support others**	**3.78 (.843)**	**3.72 (.85)**	**28**	**.21***	**-.00**
22	Information and knowledge	3.78 (.808)	3.29 (.74)	22	.00	-.08
26	**Personal beliefs**	**3.64 (1.025)**	**3.13 (1.01)**	**16**	**.61***	**.19***
9	**Body image and appearance**	**3.54 (1.060)**	**3.40 (.97)**	**24**	**-.38***	**-.03**
17	Sex life	3.11 (1.345)	2.86 (1.05)	11	.03	-.03

* Correlation is significant at the 0.05 level (2-tailed).

† Highest represents best QoL

9.2.4 Part 2 - Comparison of the WHOQOL-100 and the WHOQOL-Bref – the derivation of WHOQOL Bref scores from the WHOQOL-100

Analysis was also carried out on the 26 items that form the WHOQOL-Bref, derived from the WHOQOL-100 items, in order to make a preliminary assessment of QoL with the WHOQOL-Bref in this population. It is acknowledged that this data is extracted from the WHOQOL-100 data and consequently it is possible that the other items influence the way that participants respond to the Bref items. Excluding the 76 items from the WHOQOL-100, the Bref is comprised of 26 items; one from each of the 24 facets of QoL, and two from the G facet asking about overall QoL and health. Four Bref domain scores were calculated from the cross-sectional data and consistent with the WHOQOL-100, these are scaled in a positive direction where higher scores represent a better QoL. Domain scores are calculated by multiplying the mean score of items by four (WHOQOL user manual, 1998). Table 9.2 shows the means, SD and missing items for the Bref items. Item means ranged from 2.12 (satisfied with health) to 3.95 (conditions of living space), suggesting that QoL was highest for the home environment and lowest for satisfaction with health. All items had less than 10% missing data, although most missing data was for the item asking about sexual activity (6.5%). Satisfaction with health was lower than for overall QoL. The means and SD for the four WHOQOL-Bref domains are also shown. Mean domain scores were highest for social relationships domain, followed by the environment and psychological domains and lowest for the physical domain.

9.2.5 Internal consistency reliability for the four Bref domains

The four Bref domain scores were found to be internally consistent. For social relationships α=.66, for psychological α=.79, for the environment α=.81 and for physical α=.86, although caution must be applied in interpreting the alpha for the social domain as this is based on only three items. For the whole scale, α= .92 and for the four domains scores (excluding the 2 items about overall QoL and health) α=.81.

Table 9.2 Facet and domain scores for the WHOQOL-Bref

Item no.	Item content	Mean	SD	Missing %
General health				
G1	Rating of QoL	3.16	1.03	.5
G4	Satisfaction with health	2.12	.95	.5
Physical domain		10.28	3.20	-
F14	Pain prevents you from doing	2.17	1.02	.5
F21	Do you have enough energy	2.85	.97	.5
F33	Satisfaction with sleep	2.64	1.19	.5
F91	Able to get around	2.88	1.14	.5
F103	Ability to perform daily activities	2.67	1.07	.5
F112	Need medical treatment	2.33	1.10	.9
F124	Work capacity	2.46	1.20	2.3
Psychological domain		12.81	2.73	-
F41	Enjoy life	3.24	.93	.9
F53	Able to concentrate	3.07	.78	.5
F63	Satisfaction with yourself	3.06	1.06	.9
F71	Accept bodily appearance	3.47	1.07	.9
F81	Negative feelings, despair	3.05	.98	1.4
F242	Feeling life is meaningful	3.31	1.03	0
Social relationships domain		13.85	3.51	-
F133	Personal relationships	3.73	1.15	1.9
F153	Sex life	2.89	1.27	6.5
F144	Support from friends	3.75	.97	0
Environment domain		13.48	2.56	-
F161	Feeling safe in daily life	3.37	.95	.9
F173	Conditions of living space	3.95	.94	0
F181	Enough money to meet needs	3.08	1.01	.9
F193	Access to health services	3.31	1.01	.5
F201	Availability of information	3.42	.93	1.4
F211	Opportunities for leisure activities	2.75	1.09	.5
F221	Health of physical environment	3.40	.84	1.4
F233	Transportation	3.65	1.03	.5

9.2.6 Selection of Bref items from the PDM facets

In order to select items for an abbreviated version of the PDM, the protocol used to derive the WHOQOL-Bref items was followed (WHOQOL Group, 1998). To select the ‘best’ item from each new facet, the most general question is selected which is the item that correlates most highly with the total score (mean of all facets). The standardised item alpha for the 16 PDM items extracted from the cross-sectional data was .91, demonstrating high internal consistency reliability. Table 9.3 shows the corrected item-total correlation and the alpha (with the contribution of that item excluded) for each of the 16 items. The following items had the highest correlation with the total PDM score (with the contribution of that item deleted) and the lowest alpha if that item was deleted reflecting the importance of its contribution.

- F615i How satisfied are you with the control of your pain?
- F627 How much do feelings of frustration interfere with your everyday life?
- F633 How much does feeling vulnerable interfere with your everyday life?
- F642 How much does uncertainty about the future interfere with your everyday life?

Table 9.3 Scale mean, item-total correlation and Cronbach's α for each PDM item

Item	Scale mean if item deleted	Corrected item-total correlation	α if item deleted
Pain relief α= .77			
F613I	43.46	.55	.9089
F615I*	43.92	.59	.9076
F616I	43.88	.35	.9152
F617	44.02	.54	.9092
Anger & frustration α= .84			
F622	42.83	.629	.9067
F623	43.54	.657	.9057
F625	43.97	.59	.9077
F627*	43.54	.68	.9048
Vulnerability/ fear/ worry α= .81			
F632	43.06	.53	.9097
F633*	42.81	.633	.9065
F635I	43.98	.58	.9082
F638	43.27	.58	.9082
Uncertainty α= .85			
F642*	43.65	.71	.9039
F644	43.56	.69	.9043
F645	43.83	.67	.9053
F647	44.32	.64	.9062

* Selected items

9.3 Discussion

The data used for the analysis reported in this chapter comes from the cross-sectional study of a heterogeneous sample of people with CP reported in chapter seven. The analysis used the core WHOQOL-100 data and the 16 items embedded in the pilot PDM. For people with CP, QoL was found to be highest for the home environment, social support and transport facets and the environment and social relationships domain. Conversely, QoL was worse for the pain and discomfort, energy and fatigue and dependence on medication facets and for the physical and level of independence domain. For the PDM facets, highest QoL was found for vulnerability/ fear and worry, followed by anger and frustration, pain relief and lowest for uncertainty. QoL was poorer for overall health than for overall QoL, indicating that when making global assessments, people rated their health as lower than QoL confirming the importance of holistic measurement.

9.3.1 Importance of facets of QoL to people with pain

In an examination of the importance of different aspects of QoL to people with CP reported in part one of the results, a number of facets were found to be significantly inversely correlated with their corresponding facet score. The higher the negative association, the greater the discrepancy between reported QoL and importance attributed to that aspect of life. Such incongruities represent areas of life where QoL is poor, but are considered to be most important. Such facets are worthy of attention because they could provide potential locus for intervention. Conversely, such discrepancies could reflect good aspects of QoL that are considered less important relative to other life areas. In general, correlations between importance items and their corresponding facet were weak or negative suggesting that they are addressing different aspects of the concepts. Significant negative correlations were found for pain and discomfort, energy and fatigue, uncertainty, pain relief, sleep and rest, anger and frustration, financial resources, negative feelings, vulnerability/ fear and worry and physical safety and security, suggesting that these are very important to people with CP, yet QoL is worse in these areas. Conversely, body image and appearance does not appear to be compromised by living with CP (represented by a higher facet score) but is not as important as other facets. Working capacity, social support and SRPB were significantly positively associated with their corresponding facet score suggesting that there is no discrepancy between perceived QoL and the importance attributed to these facets. A therapeutic goal might be to facilitate a convergence of perception of QoL in a particular area with the importance attributed to it, that is, to target areas where the discrepancy is greatest. In general, the low correlations between an importance item and its corresponding facet show that these are tapping into quite different aspects of QoL supporting previous work in this area (Skevington and O'Connell, 2004).

In general, all core facets were considered to be important by the respondents of the cross-sectional survey. The most important were ADL, mobility and availability and quality of health and social care, reflecting the centrality and importance of these aspects of functioning to people with CP. Of the PDM facets, obtaining relief was the most important, followed by pain control, being free from anger, being free from fear and the least important was being free from uncertainty. Sex life, body image and appearance and SRPB were considered to be the least important of the core WHOQOL facets. In explaining such a finding, sex life and body image may not be important relative to other facets, or may have declined in importance relative to other areas. Such a decline could represent a shift in perceived importance. Given the preliminary evidence for a change in the importance attributed to aspects of QoL following treatment which was reported in chapter eight, exploring changes in the importance attributed to aspects of QoL longitudinally would provide additional evidence that, when faced with adverse circumstances, people undergo fundamental shifts in internal standards as proposed in the theory of response shift (Sprangers and Schwartz, 1999; Schwartz and Sprangers, 1999). Such shifts could mediate the importance of different areas of QoL both overtime and in relation to other aspects of life.

It is also possible that the low importance attributed to sexual activity and body image could indicate that participants gave socially desirable and culturally appropriate answers, given that these areas are considered to be private and personal aspects of a person's life. Focus group participants (chapter three) alluded to the problem of sexual activity being painful and the impact of pain on relationships with significant others, which concurs with research demonstrating a trend towards deterioration in sexual activity following the onset of painful conditions (Maruta et al., 1981) and the high prevalence of sexual difficulties amongst patients attending inpatient and outpatient pain management programmes (Ambler et al., 2001). Consequently, the missing data found for items pertaining to sexual activity and the relatively low importance attributed to it in the present study suggests that subjective reports of QoL relating to sexual activity might be more influenced by biases in reporting than other facets. In general, a further examination of the importance attributed to different facets of life over time and across groups or individuals who are know to differ on certain characteristics, such as underlying condition, is warranted as this provides important information about the relative priorities of different areas of life.

9.3.2 WHOQOL-Bref and a short-form PDM

The second part of the results reported a WHOQOL-Bref analysis by extracting the 26 items embedded in the WHOQOL-100 and derived an abbreviated form of the PDM. QoL was highest for home environment, social support, personal relationships and transportation. Lowest QoL was reported for satisfaction with health, pain and discomfort, dependence on medication and work capacity. For the domain scores, QoL was highest for the social relationships domain, followed by the environment and psychological domains and lowest for the physical domain. These findings reveal the way in which pain influences physical well-being, which is also shown by poorer satisfaction with health than with ratings of overall QoL. The internal consistency reliability for 4 Bref domains and the whole scale was good. Following this analysis, a preliminary attempt to derive an abbreviated PDM was undertaken by selecting one item from each of the 4 facets that correlated most highly with the total score, which could then be used in conjunction with the WHOQOL-Bref. Although detail and breadth of coverage is compromised by the selection of a small number of items to represent the important consequences of CP, further work should involve checking the reliability and validity of the WHOQOL-Bref and the abbreviated PDM to ensure that this adequately captures the impact of pain on QoL.

The purpose of the studies reported in this thesis was to describe the development and psychometric properties of the PDM. Elucidating the correlates of QoL for people with CP is still an important goal to be explored further in subsequent research. For example, in depth analysis of the relationship between variables on which participants were known to differ and their QoL such as socio-demographic characteristics (age, gender, employment status), reported pain intensity, duration, temporal characteristics, reported health status, illness and so on. The rationale for excluding such an analysis here was because the goal of the cross-sectional survey was to derive the PDM from the larger pilot instrument and elucidate its psychometric properties (reported in chapter seven) rather than to evaluate QoL per se. Furthermore, the QoL of people with CP using the core WHOQOL instrument has been previously described (Skevington, 1998; Skevington, Carse and Williams, 2001). The data from chapter seven was used for this analysis due to the larger sample size compared to chapter eight and the greater heterogeneity of diagnostic groups included in the sample.

9.3.3 Conclusions

This chapter explored the quantitative data derived from the cross-sectional survey reported in chapter seven by examining which facets of QoL were worse for people with CP and those that were most important. This work highlights the need to take account of the importance that is attributed to different aspects of QoL and the potential for targeting interventions at areas where there is an observed discrepancy between a rating of QoL and its importance. In particular, if QoL is found to be poor for an area such as anger and frustration, yet being free from anger and frustration is rated as extremely important, this might provide a useful locus for delivering anger management interventions. Conversely, if an area is problematic, yet not rated as important, it might be less urgent to intervene to improve this area of QoL, providing a way of maximising the usefulness and appropriateness of interventions. Having also looked extracted WHOQOL-Bref items from the data, a short-form would clearly be advantageous both in clinical and research settings, where patient burden and comprehensibility must be balanced. The final chapter draws together and summarises the preceding chapters and discusses issues pertaining to pain and its consequences for QoL. Furthermore, it provides a critique of the chapters and outlines important implications of this work.

Chapter ten

General Discussion

10.1 Introduction

Given the extent of the problem of pain in medicine shown in chapter one and the important debates associated with defining and measuring chronic pain (CP) and quality of life (QoL), the aim of this thesis was to develop an instrument to assess the impact of CP on QoL. Although measures of pain intensity or severity and health status are important and necessary, they are limited by their narrow focus. Similarly, generic QoL assessments alone tend to be insensitive to the subtleties of the impact of pain, hence the need for a pain specific module to be used in conjunction with a generic QoL instrument, which takes account of the subjective perception of the sufferer. That its impact is so broad is not remarkable given the salience of pain and the sense of intrusion and perception of threat that pain represents to the sufferer (Price, 1999), which reinforces the multidimensional and all pervasive nature of pain due to its chronicity and omnipresence. Pain pervades every aspect of a person's physical, psychological, social and spiritual being (Ahmedzai, 1995) and it is argued here that its influence on perceptions of life quality can be measured.

In chronic conditions where patients must learn to live with and accept their pain, its impact on QoL becomes even more central than if it was an acute or transient symptom. The reason for this is twofold; firstly because of the long-term nature of the pain and its consequences, and secondly, because of the uncertainties surrounding the trajectory of this long-term situation. Consequently, measuring the QoL of people who live with the constant presence of pain was the central goal of this research. Measurement was based on a model developed by the WHOQOL Group (WHOQOL Group, 1995, 1998) in the development of the WHOQOL instruments. The extension of this model to account for the impact of pain introduced novel elements such as the web-survey; an innovative approach utilising the World Wide Web and the method of cognitive interviewing derived from cognitive aspects of survey methodology, which combines cognitive psychology with survey research.

The experience of persistent pain can be said to impact on the QoL of an individual in a complex way through their physical health, psychological state, level of independence, social relationships, and their relationship with the environment, mirroring the WHOQOL Groups' definition of QoL (The WHOQOL Group, 1995). QoL is both subjectively defined and multidimensional. Above the core elements of QoL identified by the WHOQOL Group, additional aspects have been found that contribute to, and influence the QoL of people living with physical pain and discomfort. These new elements can be conveniently housed under the existing core domains and items can be meaningfully constructed that reliably inquire into these in such a way as to tap the experience of the individual. Specifically, this thesis has shown that QoL is influenced through the presence of flare-ups, the ability to obtain relief, through feelings such as anger, frustration, vulnerability, fear and worry, the experience of uncertainty, loss loneliness and feeling alone and the ability to draw on positive strategies such as hope and humour. Furthermore, an individual's relationship with others also impacts on QoL through the ability to communicate, the experience of guilt and perceptions of burdening others and the relationship with health care providers. However, of these aspects of QoL, only pain relief, anger and frustration, vulnerability/ fear/ worry and uncertainty formed cohesive internally consistent facets of QoL. It seems that, over and above general QoL (that is, areas important to all individuals regardless of health state), it is the psychological concomitants of a person's reaction to pain that are in need of elaborating to fully account for its impact.

10.2 Theoretical framework

The theoretical framework underpinning this work is conceptualised by the WHOQOL definition, that QoL is defined by a person's perception of their life position within the context and culture within which they are embedded. Furthermore, it is an inherently relational concept and thus varies as a function of a person's changing goals, expectations and so on. Consequently, it is an outcome affected in complex ways by diverse life domains that are represented and assessed by the WHOQOL instruments. The definition itself encapsulates the processes of making decisions about QoL and the instruments assess the outcomes of such decisions. This is an important conceptual point as the outcomes in themselves do not give us insight into the process of making a decision about a particular aspect of QoL only the consequence of that decision making. The qualitative studies reported in chapters three and four demonstrated that social comparison judgements and acceptance contribute to decision making about the way that pain affects QoL, which might be utilised to enhance the effectiveness of interventions targeted at improving QoL. These and other processes could be further elucidated through in-depth qualitative analysis of the narrative accounts of people describing their QoL and through co-administration of instruments purporting to measure process orientated aspects of decision-making. A challenge for work on QoL and CP is that an overarching theory of the consequences of pain has not been elaborated over and above cognitive behavioural models (e.g. Sharp, 2001) and the biopsychosocial approaches (e.g. Turk and Okifuji, 2002) discussed in chapter one, which represent the dominant paradigms and other more narrowly defined theories which aid in explaining particular responses to pain such as fear avoidance (Vlaeyen and Linton, 2000), catastrophising (Rosenstiel and Keefe, 1983; Sullivan et al., 2001) and so on. In the work presented here, theoretical ideas are also held up in the cognitive interviewing based on the protocol analysis of cognitive psychology where verbal accounts are said to represent underlying cognitive processes (Ericsson and Simon, 1980; Loftus, 1984) and by the psychometric approach that is articulated and tested in chapters seven and eight.

Embodied in the WHOQOL definition is the notion of the relative nature of QoL, which is supported in the narratives of FG participants who drew heavily on social comparison in articulating aspects of their experience and understanding of QoL. Social comparison theory has been integrated into the theory of response shift, where social comparison mediates the relationship between life events, such as the experience of ill health and the change in self-perspective or response shift (Gibbons, 1999) and evidence was found in the verbal accounts of patients describing their adaptation to living with CP in chapters three and four. Furthermore, a preliminary exploration of the importance attributed to different QoL facets over time during the longitudinal survey reported in chapter eight found that being pain free, pain relief, control and being free from fear and worry became less important following treatment. This suggests that people re-appraise the importance of different aspects of life during periods of chronic illness, although this should be tested further with follow-up periods of longer duration.

The theory of response shift explains why scores on a particular dimension do not change on repeated applications because people change how they appraise their health status and it has been suggested that such re-appraisals confound outcome measurement (Rapkin and Schwartz, 2004). Consequently, no detected change could reflect true underlying stability or that the same response to a question might have a different meaning because the scale has been recalibrated to include ‘worst worlds’ (Gibbons, 1999). Conversely, a changed response to an item may occur in the absence of any change because a reappraisal of the situation has occurred. In light of this, the need for measuring the actual appraisal process as an adjuvant to QoL instruments has been proposed (Rapkin and Schwartz, 2004; Schwartz and Rapkin, 2004).

10.3 Four new facets of QoL

Pain has been shown to have important consequences for QoL. Of the 10 facets derived from the FG work and the web survey, 4 were retained following psychometric testing. Pain relief, anger and frustration, vulnerability/ fear/ worry and uncertainty were retained as comprehensive, multidimensional constructs representing aspects of QoL. These can be seen as outcomes or consequences of pain. Pain relief relates to the physical aspects of pain and was most highly associated with the physical domain. Anger, frustration, vulnerability, fear and worry can be seen as emotional components of pain and are strongly associated with the psychological domain. Uncertainty was found to be more closely associated with level of independence than the psychological domain in which it was originally placed. Despite the face validity of the remaining 6 facets, these were deleted due to the results of the extensive psychometric testing reported in chapter seven. For example, relationship with health care providers was found to be highly associated with core facets and was therefore redundant. Flare-ups represented a concept that was poorly elaborated, because only 3 items were constructed to represent this aspect of QoL. Other facets, most notably positive strategies, failed to reach an acceptable level of internal consistency and were therefore deleted. The content and importance of these facets was discussed in more detail in chapters three, four and five.

Pain relief has been shown to be important to QoL. The core WHOQOL pain and discomfort facet accounts for the presence of pain but not to pain relief. Consequently, including this facet was seen as central to a module pertaining to the impact of CP. This study found pain relief and control to be an important aspect of QoL for people with CP which concurs with previous studies showing that lower average pain ratings are associated with higher functioning and QoL (e.g. Zelman et al., 2003) and that control of pain has been associated with improved outcomes (Jensen, Karoly and Huger, 1987; Harkapaa, 1991). Alleviating pain or maximising relief remains an important goal of biopsychosocial interventions and assessing pain relief in a pain specific QoL instrument addresses this.

The experience of anger and frustration was widely reported by study participants and became a facet of QoL. An unexpected finding was the close relationship of anger and frustration to the pain and discomfort facet and the physical domain, which demonstrates that pain and anger co-occur, highlights the salience of these emotions to people with CP and demonstrates the anger and frustration are distinct from negative feelings. Assessing the impact of anger on QoL is an important goal and potential locus for intervention, through anger management and so on. Discussed in chapter three, studies have shown that anger is a salient emotional correlate of pain (Fernandez and Turk, 1995), that it can exacerbate pain (Suinn, 2001), that the differential expression of anger can influence the reported pain intensity of different conditions in different ways (Bruehl, Yung Chung and Burns, 2003) and that anger has a role in the depression of patient spouses, average pain and level of marital satisfaction (Schwartz et al., 1991). Although these studies show that the relationship between anger and pain has been elaborated, the present study has shown the importance of including such correlates of pain into a CP specific QoL instrument.

The concept of frustration represented part of this multidimensional facet. As well as frustration generated through unsatisfactory interaction with the health care system, the present study also found that frustration could result from not being able to engage in previous activity levels and so on, which illustrates that intrapersonal comparative strategies are drawn upon. There is limited evidence for the role of patient frustration in CP although it is recognised that competing theories explaining non-specific LBP can generate patient frustration because of the consequent competing and conflicting treatments offered (Deyo and Phillips, 1996). Assisting patients to manage feelings of frustration by presenting realistic alternatives could be an important aspect of promoting effective self-management in addition to encouraging active engagement in life activities in spite of the pain and a willingness to experience pain, which represent acceptance of pain (McCracken, Vowles and Eccleston, 2004).

FG participants spontaneously elicited vulnerability, fear and worry as important aspects of the pain experience influencing their QoL, which were endorsed by subsequent stages. Identifying the variables that mediate the impact of vulnerability fear and worry on QoL is an important goal in addition to assessing the extent of its impact on QoL. Fear has become a central concept in understanding the response to CP and is characterised by the avoidance of activity for fear of irreversible damage due to catastrophic interpretations of benign physical sensations (Vlaeyen et al., 1995). Feelings of vulnerability to injury or re-injury have been described as 'kinesiophobia' (Kori et al., 1990) and although fear and anxiety are closely associated, the distinction is said to come from the specificity of the threat (Rachman, 1998), where fear describes a situation where the threat is identifiable, such as in the case of pain, whereas in anxiety the source of threat is more elusive. Fear and anxiety have also been shown to predict adjustment to pain (McCracken et al., 1993; Waddell et al., 1993; Vlaeyen et al., 1995). Worry can be conceptualised as a cognitive response and research has shown the distress associated with worry related to somatic sensations (Eccleston et al, 2001). Integrating these concepts into an instrument assessing QoL has shown to be feasible and acceptable to patients, which concurs with the literature demonstrating the importance of these variables in understanding the complex response to CP.

Conceptually, uncertainty represents a multifaceted construct. In this study, uncertainty was represented as the inverse of life control, that is, in the absence of life control, the future is uncertain, which is important because QoL has been shown to improve with increased life control (Burton et al., 1998). It can also be viewed within the context of diagnostic uncertainty or when physical symptoms are unexplained, which is a typical feature when evidence of underlying pathology and reason for the persistence of pain is scant. In chapter three, previous studies illuminated the uncertain future for people with CP (Thomas, 2000) and the stigmatising consequences of medical uncertainty in the absence of a diagnosis (Lillrank, 2003). The research reported in this thesis shows that uncertainty was more closely associated with the level of independence domain than with the psychological domain in which it was hypothesised to belong to, highlighting that living with uncertainty compromises a person's independence and the extent to which they can engage fully in life. Where possible, the WHOQOL model conceptualises facets and domains of QoL in positive ways, for example, in level of independence rather than dependence or mobility rather than immobility and so on. For this reason, the facet title uncertainty should be changed to 'certainty' to express a more positive aspect of QoL.

Each of the new facets has been described and discussed in light of the literature. Pain relief relates to beliefs corresponding to the subjective perception of actual nociception and the extent to which one is able to control such sensations. Anger and frustration represent emotional consequences of living with CP and vulnerability, fear and worry encompass the emotional reaction to beliefs held about pain. Uncertainty is characterised as a belief about an uncertain future and trajectory and can be better conceptualised as 'certainty'. These four new facets represent the PDM to be used in conjunction with the WHOQOL-100.

10.4 The Pain and Discomfort Module

10.4.1 Psychometric properties of the PDM

The psychometric properties of the WHOQOL and PDM were outlined in chapters seven and eight. In general, the core WHOQOL facets performed well with Cronbach's alpha ranging from .65 - .93 (19 of 25 facets had Cronbach's alpha between .70 - .90). Similarly the core domain scores were found to be internally consistent, although the social relationship domain was only marginally acceptable. In the longitudinal survey, the PDM facets performed well and the scale had good internal consistency reliability (Cronbach's alpha = .88). Significant positive correlations were found between the PDM facets and health status (physical and mental component scores of the SF-12) supporting its concurrent validity, by confirming that pain related QoL is poorest amongst those reporting poorer physical and mental health functioning. Furthermore, pain relief was most highly related to physical functioning, whilst anger and frustration, vulnerability/ fear and worry and uncertainty were most highly associated with emotional functioning, demonstrating that QoL pertaining to the psychological consequences of pain is more closely associated with mental health functioning, and the physical with physical functioning. Significant negative correlations were found between the PDM facets and pain intensity and severity (assessed by the SF-MPQ) providing evidence of construct validity. Furthermore, the PDM was able to distinguish between ill and well patients and those reporting different levels of health, demonstrating discriminant validity.

The test-retest reliability (2 week) of pain relief, vulnerability/ fear/ worry and uncertainty was lower than acceptable levels (>.70). However, patients reported perceived changes in QoL, health and pain, in addition to commencing new treatment and experiencing significant life events (assessed by the transition questions), which could have influenced mood, pain relief and so on. Given the findings reported in chapters three and four that pain fluctuates and flares-up and the consequent difficulties reported in the cognitive interviewing in chapter six of the difficulty in generalising experience over two weeks (the time period patients are asked to consider when answering items) the challenges of assessing test-retest in a clinical population with a condition characterised by fluctuations are highlighted. Indeed, Skevington (1994) highlights this as a special methodological problem for QoL scale development for people with arthritis because the disease itself, characterised by flare-ups and periods of relief, affects the stability of measurements over time. It was not possible to ensure that patients were not exposed to other treatment modalities in this study; however, future work could overcome this by using a waiting list control group who were not currently undergoing treatment.

Sensitivity to change of the PDM was examined by investigating whether the QoL of patients with LBP improves following lumbar epidural steroid injection (LES). Responses to the transition questions indicated that QoL, health and pain was the same or better following the intervention, suggesting only modest improvement 4 weeks after a LES injection. QoL was significantly better for 10 of the 25 core facets and 3 of the 4 PDM facets. These were pain and discomfort, energy and fatigue, sleep and rest, self esteem, mobility, ADL, dependence on medication, work capacity, leisure activities, overall QoL, pain relief, anger and frustration and uncertainty. Largest effect sizes were found for pain and discomfort, mobility and ADL (>.62) demonstrating that these facets were most sensitive to change. Moderate effect sizes were found for pain relief and uncertainty (>.50) and small effect sizes were found for energy and fatigue, sleep and rest, dependence on medication, information, leisure activities, anger and frustration and vulnerability/ fear/ worry (all >.20). Of the PDM facets, pain relief and uncertainty were only moderately responsive to change and anger and frustration and vulnerability/ fear/ worry were less responsive. Given that LES should bring about pain relief, this provides support for this PDM facet and the experience of treatment may have increased certainty. Anger and frustration and vulnerability/ fear/ worry may need more targeted psychological intervention, to demonstrate greater responsivity.

In general, the WHOQOL-100 performed well with patients with CP, which concurs with previous studies (Skevington, 1998; Skevington, Carse and Williams, 2001). The results also supported the concurrent, construct and discriminant validity of the PDM. Although test-retest reliability was found to be lower than acceptable, a partial explanation can be found in the reported variation in the no treatment group. The results also indicate that QoL was selectively enhanced by the LES intervention, and given that LES is a unimodal intervention, the selective sensitivity to change of the core WHOQOL and PDM is unremarkable.

10.4.2 Structure and scoring of the PDM

The PDM (16 items) should be administered in conjunction with the UK WHOQOL-100 (102 items) as a self-administered questionnaire. In addition, the core WHOQOL importance items (26 items) and PDM importance items (5 items) can also be administered. The PDM has been designed for use in adults with CP from broad diagnostic groups, to assess the impact of CP on QoL. The items that comprise the 4 facets representing the PDM must be used in conjunction with the core WHOQOL-100, by integrating them into their appropriate response scale block for ease of administration and completion. The importance items corresponding to the PDM facets are located after the core importance items. Additional questions addressing the duration, location, severity, temporal characteristics and so on are located in the 'about you' section of the core instrument, which asks for socio-demographic information. The WHOQOL is scored by summing facets (25) and calculating domain scores (6) and the PDM is scored by calculating facet scores (4). The development and scoring of the WHOQOL instruments has been extensively reported elsewhere (WHOQOL Group User Manual, 1998). The instrument and syntax file are given in appendix 7 and 8.

The PDM should be used concurrently with the WHOQOL-100 to assess the QoL people undergoing interventions aimed at improving QoL. To this end, the instrument should be used for outcome research, clinical trials, audit and clinical governance. It has been has proposed that the instrument might also be used as the basis of a clinical interview to explore different areas of QoL and the extent to which it might be possible to affect change in those areas (Skevington, 1995). It might also be possible to use the instrument as a screening tool to identify those with the poorest QoL and target resources at those most in need, or by using it to identify those who would be most suitable for interventions such as pain management programmes.

10.4.3 A short-form

Chapter nine reported on the derivation of a 4-item short-form PDM from the 16-item PDM. Following the WHOQOL-Bref model, one item from each 4-item facet was selected. Such a short-form could be used in conjunction with the WHOQOL-Bref to see how this performs when applied to clinical populations. Although this might compromise comprehensibility, precision and detail, it would produce an instrument with wider applications, which would be favoured over the WHOQOL-100 in clinical situations where time is limited or when patients are being asked to complete questionnaires whilst waiting in clinics for their appointment. This trade-off forms part of decision-making regarding the selection of instruments and is driven by pragmatic factors such as feasibility, length, ease of administration, scoring and so on. When a comprehensive assessment is necessary and feasible, the WHOQOL-100 and the 16-item PDM would confer advantages over the abbreviated forms, which would be more appropriate when time is limited and respondent burden is high. Given the limitations of selecting the 4 items from the large number of items piloted in the cross-sectional survey reported in chapter seven, further testing in larger, more diverse populations of people with CP would increase confidence in identifying which items best explain the variance in overall QoL and which seem to best represent the underlying concept.

10.5 The QoL of people with pain

In general, living with conditions characterised by pain selectively impacted QoL. QoL was worst for pain and discomfort, energy and fatigue, dependence on medication, mobility and ADL and best for the home environment, social support, transport and personal relationships. For the heterogeneous patient groups reported in chapters seven and nine, QoL relating to uncertainty was poorest and for the LBP patients reported in chapter eight, pain relief. Such a finding suggests that LBP patients seeking treatment may report greater dissatisfaction with relief and control of pain than the diverse group of patients because they were actively seeking treatment. Moreover, uncertainty may have been reduced given that the offer of treatment represented a potential source of long-term relief. Overall QoL and health was mostly explained by the physical domain, followed by the psychological, level of independence and then social relationships, highlighting the importance of physical aspects of QoL such as fatigue and sleep and psychological features such as positive and negative feelings and so on. The selective impairment of particular aspects of QoL provides further support for using the generic core instrument and the PDM to obtain a holistic assessment of the impact of pain management interventions on QoL. This is important given that people simultaneously reported positive and negative perceptions of their QoL across different life domains, which concurs with work in the field of positive psychology discussed in chapter three (e.g. Folkman, 1997) and with evidence that people are able to derive benefits from adversity (Tennen and Affleck, 1996) and from illness (Sodegren and Hyland, 2000; Sodergren et al., 2002).

A range of facets explained most of the variance in overall QoL and health from the physical, level of independence, environment and SRPB domains represented by participation in and opportunities for recreation and leisure, ADL, sleep and rest, energy and fatigue, SRPB and mobility. Of the PDM facets, uncertainty and pain relief contributed most to explaining overall QoL and health, confirming the importance of pain relief, control and life certainty to people with CP. Of the dimensions of pain, present pain intensity was most important in explaining overall QoL and health. For health status, mental health explained a larger proportion of variance than physical functioning, providing evidence of the importance of the psychological concomitants of pain. Thus despite the physical limitations and impairment of functioning, psychological consequences remain a key target of intervention to moderate the impact of pain. This reiterates the importance of multimodal interventions including a psychological component to bring about important improvements in QoL given the impairment of psychological functioning, compared to a unimodal physical intervention such as the LES reported in chapter eight.

In general, more intense and severe pain was shown to be associated with a poorer QoL assessed by the PDM. Pain relief was most highly associated with present pain intensity; anger and frustration and vulnerability/ fear/ worry with the sensory qualities of pain and uncertainty with the total pain-rating index. These findings concur with previous work showing that anger is associated with reports of higher pain intensity (Burns et al., 1998; Kerns, Rosenburg and Jacob, 1994; Bruehl et al., 2002) and that QoL in patients with CP is improved with increased life control or greater certainty (Burton et al., 1998). Designing anger management interventions to target reductions in its impact on QoL could affect reports of pain and vice versa. It is clear that different dimensions of pain appear to be associated with different aspects of QoL. Elucidating the relationship between dimensions of pain and QoL is an important goal given that we now have a better understanding of the measurement of QoL.

10.5.1 Importance of facets of QoL

The 24 facets of QoL comprising the core WHOQOL are based on empirical research confirming their importance to sick and well people (Saxena et al., 2001). The inclusion of importance items allows people to rate how important each of the facets is to their QoL. Given that no *a priori* assumptions are made about which items are more of less important to people, inclusion of such items allows for individual differences to be expressed. This overcomes the assumption that people with CP are a homogenous group and challenges what has been described as the patient uniformity myth where individual variation is discounted (Turk, 1990). In general, ADL, mobility, pain relief and control were shown to be most important to people with pain. For the patients in the cross-sectional study, receiving adequate health and social care was also very important, and for the patients with LBP reported in chapter eight, being pain free. Conversely, body image and appearance, sexual activity and SRPB were the least important and freedom from uncertainty. Such findings illustrate the relative importance of different facets of QoL.

Furthermore, as Skevington and O'Connell (2004) have demonstrated, exploring the discrepancy between a person's assessment of QoL on a particular facet and the importance attributed to that facet allows for better identification of problem areas (Skevington, O'Connell and the WHOQOL Group, 2004). Biggest discrepancies were found for pain and discomfort, energy and fatigue, sleep, financial resources, negative feelings, physical safety and security and body image and appearance, where facet means were significantly negatively correlated with their corresponding importance item. Discrepancies were also found for the PDM facets and their corresponding importance item, suggesting that despite being very important, these aspects of QoL are poor. The importance of these aspects of QoL and the size of the discrepancy, suggests that priority should be given to targeting interventions at such areas. Conversely, the importance of working capacity, social support and SRPB were significantly positively correlated with their corresponding facet, suggesting that a good QoL in these areas is associated with high importance. Discrepancies between the way people rate a particular aspect of QoL and the importance they attribute to it also show that these items are measuring quite different aspects of QoL.

Such discrepancies are also important when considering the finding that the importance of being pain free, pain relief, pain control and freedom from fear and worry were significantly less important following LES. This suggests that the importance attributed to certain aspects of QoL changes over time. Such evidence provides support for designing interventions to target the relative importance attributed to areas of QoL where treatment has had limited success. Further investigation of the stability of importance ratings over time would be advantageous given that they might reflect important shifts in perception of life quality. These changes could provide additional evidence that people re-evaluate aspects of their lives or successfully adapt to new experience through acceptance and what has been described as response shift (Sprangers and Schwartz, 1999). Inclusion of the importance items, although adding to the size of the instrument and thus to patient burden, may provide an invaluable way of identifying and prioritising loci for intervention, by directing resources at aspects of life where a person reports a poor QoL, but attributes a high importance.

10.5.2 Acceptance and QoL

Chapter eight explored the relationship between acceptance of pain and QoL because the core WHOQOL pain and discomfort facet embodies the notion of acceptance in its definition in the sentence 'It is acknowledged that people respond to pain differently, and differing tolerance and acceptance of pain is likely to affect its impact on QoL' (WHOQOL Group, 1995). Furthermore, chapters three and four highlighted this as a possible process mediator of decision making about subjective QoL. Acceptance is conceptualised as a process that affects QoL outcomes and this study found that a good QoL assessed by the PDM was associated with acceptance of pain, particularly less reported anger and uncertainty. Acceptance of pain was also related to good mobility and overall QoL, the ability to work, engage in ADL, less pain and discomfort and better mental health. This concurs with the assumption underlying acceptance that a shift, change or adaptation has occurred for a person to move from the unrealistic goal of completely eliminating the pain to one of accepting it and focusing on other life goals (Geiser, 1992; McCracken, 1998, McCracken et al., 1999). This is also consistent with the cognitive processes elaborated in the theory of response shift, in explaining the process of adaptation to disease.

Acceptance represents two components; engaging in activity in spite of pain and a willingness to experience pain (Geiser, 1992; McCracken, 1998, McCracken et al., 1999). Engaging in activity in spite of pain was most strongly associated with good pain relief, certainty, mobility, the level of independence domain and physical functioning. In contrast, patients with a greater willingness to experience pain reported less anger, frustration, vulnerability, fear and worry and better QoL in the physical domain and better mental health. However, although acceptance was associated with better QoL, mental and physical functioning and lower pain scores, the direction of this relationship remains to be elucidated. Such outcomes may affect willingness to engage in life or conversely, patients who are less willing may report more a worse QoL. However, the strong association between acceptance of pain and QoL suggests that this might be an important process in making QoL decisions and consequently, interventions might be targeted at the facets that are most highly associated to facilitate acceptance of pain or vice versa. Further investigation of acceptance, along with other theoretical constructs such as response shift and comparative strategies may contribute to the explanation of adaptation to chronic conditions and how people define their QoL by explaining the processes that mediate the response to ill health and the perception of life quality in the face of adversity.

10.6 Strengths

The strengths of the work reported in this thesis include the qualitative exploration of the QoL of people with CP, the novel methodological approach of the web survey and the application of the WHOQOL methodology to CP with the addition of cognitive interviewing as a technique for improving the process of developing and refining items before psychometric methods are applied. Moreover, the development of patient derived facets is central to this work and contrast with the top down development of many patient questionnaires. The work reported here takes empirically derived facets, transforms them into a theoretical framework based on their semantic and conceptual attributes and tests the relationship between these theoretical constructs empirically using statistical techniques. The research adopted a holistic approach to QoL and its measurement and made no *a priori* assumptions about the relationship between pain and QoL. Despite the deletion of 6 of the 10 new facets identified in chapters three and four, they remain important features of the pain experience as evidenced by their spontaneous elicitation by people with CP. Further exploration of the factors mediating the response to pain to bring about such consequences for QoL is warranted, particularly on the processes that mediate QoL outcomes. This work has enabled a preliminary assessment to be made about the QoL of people with heterogeneous pain conditions by developing a pain and discomfort specific module to be used in conjunction with the WHOQOL-100 that combines the advantages of generic QoL assessment with the increased specificity the PDM for a holistic assessment that can be used to generate a profile of QoL.

10.7 A critique

Each empirical chapter addressed the potential caveats of the research reported, including a critique of the constructs assessed by the PDM. This discussion summarises the main methodological issues arising from this work. This research has been approached from the point of view of a health psychologist and is therefore embedded in the biopsychosocial model, which is the dominant paradigm in the field, and the methodology reflects this. The methodology adopted during this research was underpinned by a number of assumptions, namely that self-report is a way of tapping into the experience and thoughts of people and that certain cognitive processes take place and are accessible through this self-report, as illustrated by the use of cognitive interviewing.

With regard to the samples used, it must be acknowledged as a limitation that only 1% of people with CP reach speciality pain clinics (Smith et al., 1996) and that pain clinic samples are a highly selected group (Crombie and Davies, 1998) reporting higher levels of disability (Crook et al., 1986). However, at the defence of the sampling adopted, any QoL instrument must be appropriate for those attending such clinics and therefore this limitation can be said to have a limited impact on the results of the study. Furthermore, the inclusion of patients from primary care, a registered charity and the Internet minimised the potential for idiosyncratic results. Given the problems associated with generalising to others outside of the study sample, a more diverse patient group could have been recruited if more centres had been involved. Subsequent testing of the instrument would address such a limitation.

Despite extensive validation work on the WHOQOL-100 instrument (Skevington, 1999; Skevington, Bradshaw and Saxena, 1999; Skevington, Carse and Williams, 2001), the research presented here found that items addressing sexual activity (10%) and availability and quality of health and social care (11%) were missed more frequently than items addressing other facets of QoL, although the extent of this is low. Such a finding could be due to modesty and the perception that some issues are private, which does not promote the disclosure of sensitive issues. Although it might be possible to minimise this by a more explicit assurance of confidentiality in future work, such patterns are likely to reflect cultural values, rather than a methodological problem *per se*.

A potential drawback of using generic instruments is the inevitable inclusion of items that may be of little importance or at least unlikely to change during targeted intervention such as satisfaction with climate or religion and personal beliefs. Indeed, although these aspects might be pertinent to individuals at different times, it could be argued that these aspects are not only outside of the control of, but are not within the remit of the public health services, consequently, the inclusion of such items reduces sensitivity and specificity of the instrument. Thus there is a balance between narrowing the concept of QoL (for example with the Rheumatoid Arthritis Quality of Life Questionnaire, Whalley et al., 1997) and including items that are relevant, acceptable and that relate to the purpose of interventions. Despite this, it is possible to predict *a priori* which facets are likely to change during an intervention and test these hypotheses. Moreover, the enduring strength of the WHOQOL instruments is their holistic, multidimensional nature and the inclusion of importance items, which assesses the relative importance of different aspects of life. Furthermore, the holistic view allows for the inclusion of positive areas of QoL such as positive feelings in an area that has dominated by the assessment of pain and disability. This concurs with research focusing on the positive experiences associated with ill health (Sodergren and Hyland, 2000; Sodergren et al., 2002) and that positive and negative affect can co-occur (Folkman, 1997), which is described in chapter three.

Losing patients to follow-up is an inevitable feature of longitudinal designs. Furthermore, given the limitations of unimodal medical interventions alone, greater changes in QoL scores might have been predicted if patients had undergone a psychosocial intervention such as a PMP. Such an intervention would have enabled further validation of the instrument and allowed more definitive conclusions to be drawn about QoL given that the explicit aims of such interventions are to improve functioning in different life domains. Further validation of the WHOQOL-100 and the PDM in patients involved in a PMP would be advantageous given that such interventions target much broader areas of patient functioning than simply reducing pain, which would be expected to bring about changes in more diverse aspects of QoL.

It should also be acknowledged that factor analytic techniques could have been used on the data reported in chapters seven and eight as a method to reduce the number of items or for looking at the underlying factor structure of the PDM. For example, a principle components analysis could show how many factors are yielded from the PDM items. Although this could demonstrate how the items fitted into the 4-item facet model of the WHOQOL, this 4-item facet model limits the extent to which factor analytic techniques could determine the number of items comprising the facets. Furthermore, it is still important to consider the face validity and importance of the items representing each facet. Future analyses and studies using the WHOQOL and PDM should consider such a method, along with Rasch methodology (e.g. Prieto, Alonso and Lamarca, 2003).

10.8 Implications

It has been shown that it is possible to adequately measure QoL in people with CP. Consequently, we need to develop interventions that target the important aspects of people's lives that are impacted by their pain. Given that the WHOQOL items address the subjective perception and meanings associated with aspects of QoL, all aspects of QoL are potentially amenable to intervention or modifiable, although some may require change at macro levels, such as through health policy. This thesis has made progress in identifying aspects of life that are most important to people with pain, although individual differences and priorities should be considered in a clinical context. This supports the advantage of using an instrument that gives a profile (i.e. facet or domain scores) rather than a single index of QoL, which does not indicate which aspects of QoL are best and which are worst. Additionally, including an assessment of the importance of various aspects of life offers further advantages as described above.

Further implications of this work include the use of the WHOQOL and PDM in clinical trials as an outcome of clinical effectiveness and in epidemiological research investigating trends in different diagnostic and social or cultural groups. In clinical practice, interventions could also be tailored to selectively enhance QoL. Such an instrument could also be used in the audit of health and social care through clinical governance to monitor the response of patients to treatments to justify the continued delivery of such services and to ensure that patients are deriving benefits. Furthermore, it provides confidence to the health professionals involved in the delivering of health care that the procedures are worthwhile and have measurable benefits. Well-validated instruments also have potential to inform and influence policy decisions regarding the delivery of health care, although this may be a politically sensitive area given that a challenge to the status quo might be necessary (Skevington, 1995), however, this should not be a barrier to change.

10.9 Future research

Given that the work of the WHOQOL Group is firmly rooted in cross-cultural research, further work should focus on the cultural context of QoL judgements relating to CP, for example, by testing the PDM in diverse cultural groups both within and outside of the United Kingdom. It is clear from decades of research that cultural differences exist in the expression of pain (for example, Sanders et al., 1992) and since this study has relied upon the verbal behaviour of people with pain through self-report and therefore rest on the communicative aspects of pain, cultural differences in the expression of QoL would be anticipated and should be subject to further study.

Research shows the need to investigate how the presence of a family member with CP affects QoL and whether family perceptions of patients QoL could influence treatment outcomes (e.g. Williamson, Robinson and Melamed, 1997; Fillingim et al., 2003). For proxy assessment, research has shown that the perception of patient QoL by family is more consistent with patient report than the perception of friends or health care professionals (Andresen, Vahle and Lollar, 2001). Consequently, revealing the extent and nature of the observed discrepancies might be an important goal, for example by looking at the level of concordance between ratings of QoL in different life domains, in addition to exploring the factors or processes that influence the ways people make sense of the experience of others, particularly in respect of the more or less observable features of that experience. Although proxy assessment might be more important in situations when patients are unable to answer questions for themselves, exploring proxy-patient similarities and differences could illuminate the complexity of the social and communicative aspects of pain.

Much research has focused on gender differences in response to pain, and this clearly has implications for management, treatment and potentially QoL. Indeed, many of the prevalence studies described in chapter one report differences in the prevalence of pain amongst men and women of different age groups and numerous theories have been proposed to explain differences in reporting pain (Holdcroft and Power, 2003). Conducting large-scale survey work to examine important similarities and differences in reports of QoL by men and women could be conducted with the WHOQOL, PDM and other concurrent measures. It was also beyond the scope and resources of this research to focus on the QoL of children, adolescents and older adults given the different issues pertinent to QoL. Other WHOQOL projects have looked at QoL in children (For example, Jirojanakul, Skevington and Hudson, 2003). However, future research might focus on the impact of pain on the QoL of adolescents and older adults using modified and tested instruments derived from the WHOQOL.

Further testing with diverse pain populations will be necessary to complement the preliminary psychometric properties reported here to examine whether the instrument is able to discriminate between different groups such as people with RA and BP. The more frequently the measure is applied to relevant populations, the greater the confidence in how it performs (Juniper, Guyatt and Jaeschke, 1996). Consequently, the goal is to apply the measure as frequently as possible. Additionally, interpretability must also be established to ensure that the scores relate to the perceived meanings held by patients about the magnitude of change (Juniper, Guyatt and Jaeschke, 1996). Establishment of population norms would be an additional aid to interpreting high or low scores, which have been derived for health status measures such as the SF-36, providing a way of comparing the health status of particular groups with that of the general population (Wright and Harwood, 1992). Establishing population norms for the WHOQOL for different cultural groups would be an admirable goal enabling researchers and clinicians to compare QoL across conditions. In the meantime, calculation of effect sizes, as described in chapter eight, goes some way to addressing this issue by showing which facets have changed most following an intervention.

10.10 Concluding remarks

In addition to the core facets of QoL assessed by the WHOQOL-100, people from diverse diagnostic groups and backgrounds share a common set of factors influencing QoL pertaining to pain. These areas relate to different life domains and consequently reflect the multidimensional impact of CP, demonstrating that taking a holistic approach to QoL allows for the identification of positive as well as negative aspects of life for people with CP. Given the importance of a range of facets, although CP compromises life quality, it is not synonymous with a poor QoL, but as a salient symptom, it impacts on life through its complex, multidimensional consequences by comparative processes and acceptance of pain and so on.

The new PDM will assess the QoL of adults over the age of 16 with CP, as defined by the IASP as pain or discomfort that persists continuously or intermittently for longer than three months. The PDM should be used in conjunction with the UK WHOQOL-100 to provide a comprehensive assessment of the QoL of people with CP. It will address subjective assessment of physical, psychological and level of independence domains of QoL, be self-administered and address 4 pain and discomfort facets represented by 16 items. Following further field-testing, it is likely that the instrument will be a discriminative and evaluative instrument for use in clinical trials, to examine the effectiveness of pain management interventions and as a clinical tool to assess the QoL of patients with CP.

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Coded focus group transcript (Chapter three)

The following sample of transcript is taken from focus group (FG) one. The text representing a theme is shown in **bold**, and the theme is highlighted in grey.

1. Themes were listed from each FG under the facet and domain structure of the WHOQOL and new themes were listed under the most appropriate domain.
2. A large table was drawn showing the themes identified from each group.
3. Facets common to all FG's were identified from this table and re-tabulated.
4. Themes not already addressed by the core WHOQOL were identified.
5. These themes were refined by subsuming related themes into superordinate categories and ensuring that they were placed under the most appropriate domain heading.

The second rater undertook the same process in a sample of 17% of the FG transcripts.

B: Cause **even if they understood the pain, they can't understand the restrictions**. You go to do something and you learn not to reach don't you? I suppose it's a bit like Pavlov's dogs. NOT UNDERSTOOD, COMMUNICATION

A: It's like having a bad back for a week, you know, 'I've got a bad back I can see how you feel'.

C: Yeah

A: I mean my partner said that to me a couple of months back, he said to me, 'I dread to think what it feels like living like this all day'. A couple of weeks later he's all better again. 'Yeah but, you're all better now'.

C: Yeah

A: I said, 'I haven't got that nice little sort of luxury, **I've got to do this until whenever, you know, for the next twenty, fifty, sixty years I don't know**. I said 'you're alright, you rubbed a bit of thing in, took a few painkillers, rested up for a few days and you feel wonderful again. You might have a little glimpse of how I felt. But that's it, you just have the tiniest little rung at the bottom of the ladder, of how I felt', no, you know, **I can get out of bed one morning and I'll be fine, but the next morning I put my feet on the ground and I fall flat on my face, and I think, 'oh here we go, this is a good start to the day'. But I don't know how I'm going to be in the morning. I don't know how I'm going to be at the end of the day. Some days I'm in what I call minimal pain, and other days, I'm literally, I put my feet on the ground and I've got pain shooting down my legs.** UNCERTAINTY, FLARE-UPS, PAIN RELIEF

C: I do make an effort though, more so as the time has gone on. **When I do get a really good day, I'll say to my husband 'today has been a really good pain, it's been the lowest level pain I've had for days'** and he'll go **'oh, I knew that, but I didn't like to [say]'.** He knows. BEING POSITIVE, BEING UNDERSTOOD

A: They do though.

C: **But my family knows, but on another bad day when I am snapping and horrible and evil sometimes.** PERSONAL RELATIONSHIPS, LASHING OUT, ANGER

A: You do, you do feel that, you do get to the point where…

C: You are evil sometimes

A: Anything anyone says anything, it doesn't matter to you

C: And I'm thinking 'why are you being like this? It's not his fault'

A: That's it; they can be so nice to you

B: **You sometimes think if I didn't have this, I'd be a completely different person, and I would have lived a different life, and you almost sort of grieve. Cause mine started when I was 22, I was just starting in life, just sort of blossoming, and I feel that I have grieved for that person that should have been really.** Seeing someone doing something sometimes when it was all the aerobics and everything. Cause I was in P.E and English at college, and I think 'well I could have done that, I could have walked in this room all gracefully' and, but you can't, you've got to hobble in. LOSS, RESENTMENT AT AGE OF ONSET

A: Yeah

C: Yeah

B: Do you?

D: Yeah I do, and I seem to put myself in that position all the time. I still go, I still go to the Gym

LAUGHS

B: Do you?

D: I don't do much; I just do what I can

C: I swim

D: **But the trouble is, there's all these people around me that are going (GESTURES WEIGHT LIFTING) and doing this, and doing that, and I still keep putting my self there**, but I don't like being there because I don't like feeling as you're describing UPWARD SOCIAL COMPARISON

B: Coming face to face with it

D: I just still keep doing it for some reason (LAUGHS)

C: I swim because it helps my condition, but I'm still, **even though I am still able bodied in comparison with a lot of people, and can actually get in that water and swim, but I'm still looking at those who have got there goggles on and are bombing up and down**, whereas I'm like, well when I was, well **I've made quite good friends since I've been down there, you know, with other people who've got problems and it was a joke - the speed that I swam**. I've got a little bit better now, but I've learnt to enjoy what I've got, and my friends there. But I still find myself thinking 'if only I could go in that fast lane and really get to grips and do some real exercise, you know' UPWARD SOCIAL COMPARISON, HUMOUR

A: Come in and do the same in half an hour that I'm doing in an hour and a half

C: Absolutely

CO-MODERATOR: You talked then about friends and you've all talked about your relationships with your families and partners. How does your chronic pain affect your other relationships would you say?

D: **It certainly affects me working**. Because first of all I found, I had, I don't know how to describe this but I think I felt sort of embarrassed about having pains and things, and walking into a room and trying to do work and stand there like there was nothing wrong with me. **I pretended for a long time that there was nothing wrong with me, um, and I think that was sort of an embarrassment**, and the reason I say that is now I've got this walking stick, and wouldn't come out of the house with it for a long time LAUGHS, and I've only just learnt now to walk into a room of people with this walking stick LAUGHS. And I know it sound silly but it's hard. WORK, SOCIAL RELATIONSHIPS, EMBARRASSMENT, COMMUNICATION

B: Do you find the stick helps though; I used to feel, before my legs were sorted out. **I used to feel very vulnerable like you about falling over, and I was frightened of being bumped into, because if someone knocked me and I was on the floor, I wouldn't be able to get up, I still wouldn't be able to get up now**. With a stick there, people do just give you a bit more of a wide berth or open a door or something, you know, and it helps VULNERABILITY, FEAR

D: Well, I am sorry to say, but I do find a lot of people, particularly in shops, don't take any notice what so ever, and I've been bumped and almost pushed over …

A: **They look at you and your age or whatever, don't they? And they look at you physically and think, you know 'what's wrong with her then? She's young', cause the face doesn't fit the problem, they don't see.** INVISIBILITY OF PAIN, COMMUNICATION

CO-MODERATOR: We've just talked a lot about how relationships with other people, how it makes you feel and what you think they're thinking, a lot about how it effects you psychologically, but do you think that has any affect on how you behave and your actual, the physical relationships or you're behaviour with other people socially?

D: Yeah, it does, it does quite often. Sometimes, because everything's going fine in a room and everyone's ok, I can feel more as though I'm not ok, and consequently, I can for no apparent reason get a bit…

B: **Narky?** IRRITABLE

D: Yeah, and I know it happens, and I don't mean to do it, but I sometimes I can' t help it and I suppose a lot of the time I tend to shut up now, I'm even finding it a little bit difficult to, um...

B: **Does it make you feel a little bit on the edge of things? Cause you feel slightly different because you might all be sat down having a meeting and that's what everyone's doing, they're all having a meeting and so are you, but you've got this extra thing, you've got this pain that you are dealing with all the time as well, just to be, to keep normal and be the same as everyone else.** FEELING APART FROM OTHERS, SOCIAL RELATIONSHIPS

D: Yeah, I tried to describe this to my family actually over Christmas, they actually asked me about it, which is, **I think we've got to the point now where we don't talk about it really, and, um, my wife asked me to try and explain how I felt.** And the only way I could explain it is, I don't know whether it makes sense to you but, I remember when I was young I was carrying a rucksack, you know, when I first put it this rucksack on, I thought 'oh this is heavy', but I got on with it and I was going where I was going. And I thought, the more I keep walking the heavier it gets, and the heavier it gets, the more I start to think about weight that's on my back, and so it gets more and more like that and after a while, because I'm thinking about that I might not hear what somebody says to me, because it takes over me some times. **That's the only way I could describe it. I think she understood what I meant. I said it's not that I'm not listening** (interrupted). PERSONAL RELATIONSHIPS, COMMUNICATION, BEING UNDERSTOOD

A: You do get lost in yourself.

C: You can drown in that feeling

A: **It's like somebody said you can be alone in a room full of people as being in a room by yourself.** FEELING ALONE, ISOLATED

C: Yeah

A: **You can feel just as lonely in a group of people.** LONELINESS

C: Your personality definitely does change, doesn't it?

A: **You feel like such a different person, because you do get treated so differently.** People do, you know, not necessarily always so much in your family, but other people that only know a little bit about you, and that, treat you so, like your some kind of weird person, or you know or there is something definitely seriously wrong with you. They can't cope with it, so they sort of push you away and it starts making you feel outside LOSS, FEELING ALONE, SOCIAL RELATIONSHIPS, BEING TREATED DIFFERENTLY

B: I was going to say, I don't know whether it's always how people treat you, it's how you see yourself

A: Yeah, that's it, you think that a comment they make, **you take it personally, rather than, maybe just a comment that, normally you wouldn't make anything of, but on certain days you can make it into such a big thing.** SELF ESTEEM

B: I think with the way D is feeling, it's more like in your head, and it's getting too big. **I generally am able to just carry on and try and think about all the good things**, and oh god I sound a bit like… I don't know, um. POSITIVE STRATEGIES

D: It's glass half empty, isn't it?

B: **But when it gets, when the pain is worse, and you're not coping with it, it does grow in your head, and I think you start… you know, I have in the past had quite black thoughts about the future and where it's going to go and how I'm going to end up and how long you can sort of keep up this smiley face or whatever.** COPING, NEGATIVE FEELINGS, UNCERTAINTY, PUTTING ON A BRAVE FACE

The web survey http://www.bath.ac.uk/~pspvm/painqol.html (Chapter four)

Chronic Pain and Quality of Life Survey
DO YOU HAVE CHRONIC PAIN?
HAVE YOU BEEN IN PHYSICAL PAIN OR DISCOMFORT CONTINUOUSLY OR INTERMITTENTLY FOR 3 OR MORE MONTHS?

We are working on a long-term project on quality of life and health. We would like you to tell us how your pain affects your quality of life. We are interested in the ways in which **YOU** think and talk about **YOUR** quality of life. If you would like to tell us more about how quality of life is affected by pain, please fill in the brief questionnaire below. This should only take you 10 minutes and your answers will be kept **STRICTLY CONFIDENTIAL.**

1. **What is your date of birth?** (please type in the box day/month/year)
2. **What is your gender?** (Please use your 'mouse' to click one box) Male/ Female
3. **What is the highest level of education that you have achieved?** (Please use your 'mouse' to click one box) Primary school/ Secondary school/ Further education/ Sixth form college/ Higher education/ University/ Post-graduate
4. **What is your current marital status?** (Please use your 'mouse' to click one box) Single/ Married/ Living as married/ Separated/ Divorced/ Widowed/
5. **Do you work?** (Please use your 'mouse' to click one) Yes/ No
   If yes, what type of work do you do? (Please use your 'mouse' to click the appropriate box/ boxes) Voluntary work/ Full-time study/ Part-time study/ Taking care of home/ Taking care of children/ Full-time work (paid)/ Full-time work (unpaid)/ Part-time work (paid)/ Part-time work (unpaid)/
6. **If you do work, briefly describe what you do?**
7. **Are you in pain?** (please use your 'mouse' to click one) Yes/ No
8. **What is the nature of your medical condition/ diagnosis if known?** (Please describe)
9. **Has a Doctor confirmed your diagnosis?**(please use your 'mouse' to click one) Yes/No
10. **Which parts of your body hurt?** (Please describe)
11. **How long have you had pain?** (please say in months and years)
12. **How intense is your present pain level?** (Please use your 'mouse' to click one box) No pain/ Mild/ Discomforting/ Distressing/ Horrible/ Excruciating
13. **Is your pain....?** (Please use your 'mouse' to click one box) Brief/ Intermittent/ Continuous
14. **Have you had surgery for your pain?** (please use your 'mouse' to click one) Yes/ No
    If yes, how long ago? (Please describe)
15. **Do you take any prescribed medicine for your pain?** (please use your 'mouse' to click one) Yes/ No
    If yes, please tell us which prescribed medications you take for your pain
16. **Do you take any other medication for your pain (for example, over the counter medicine)?** (please use your 'mouse' to click one)Yes/ No
    If yes, please tell us which other medications you take for your pain
17. **Do you take or use any alternative treatment or herbal medicine for your pain?** (please use your 'mouse' to click one) Yes/ No
    If yes, please list the alternative treatment or herbal medicine that you use for your pain
18. **In what ways do you think that your pain affects your quality of life?**
19. **Please could you tell us which country you are from and add any other comments related to this issue?**

Thank you for your valuable time.

Cognitive interviewing items and response scales (chapter six)

This table shows the items, response scale and code for each of the new pain and discomfort facets. The column on the right contains an 'R' if the item has been retained or an 'X' if the item has been deleted. If the wording of the item has changed to improve its clarity the words are highlighted in the item and the new words are given in the third column. If a more appropriate response scale has been attached, this is also indicated in the right hand column.

Response scale type	**Item code**	**Item changed, retained (R) or deleted (X)**
Flare-ups		
How much		
1.To what extent do flare-ups affect your quality of life?	F60.1	R
2.To what extent do you worry about experiencing a flare up?	F60.2	R
3.How much are you bothered by flare-ups?	F60.3	R
4.To what extent does your pain vary over time?	F60.4	X
5.How much do changes in pain bother you?	F60.5	X
How important		
1.How important is it to you to be free from flares in your pain?	Imp60.1	R
2.How important is it for you to be free from changes in your pain?	Imp60.2	X
Pain relief		
How much		
6.To what extent do the treatments available to you offer you relief from pain?	F61.1	R
7.How much control do you have over your pain?	F61.4i	R
8.To what extent has having treatment improved your quality of life?	F61.6i	R
9.How easy is it for you to get into a comfortable position?	F61.7	Changed to 'completely' response scale
10.How much are you bothered by taking medication?	F61.8	R
11.How much are you bothered about the side effects of medication?	F61.9	R
How completely		
57.How well do you cope with your level of pain?	F61.3i	R
How satisfied		
63.How satisfied are you with your ability to obtain relief from pain?	F61.2	R
64.How satisfied are you with the control of your pain?	F61.5i	R
How important		
3.How important is it for you to be able to obtain relief from pain?	Imp61.1	R
4.How important is it to be able to control your pain?	Imp61.2	R
5.How important is it for you to be able to find a comfortable position?	Imp61.4	X
6.How important is it for you to be free from the side effects of treatment?	Imp61.5	X
Anger and frustration		
How much		
12.How much are you bothered by feelings of anger?	F62.1	R
13.How much do feelings of anger interfere with your every day life?	F62.2	R

Response scale type	**Item code**	**Item changed, retained (R) or deleted (X)**
14.To what extent do feelings of anger affect your relationships with other people?	F62.4	R
15.How much do feelings of frustration bother you?	F62.6	R
16.How much do feelings of frustration interfere with your everyday life?	F62.7	R
How often		
74.How often does your pain make you feel angry?	F62.3	R
75.How often does your pain make you feel irritable?	F62.5	R
How important		
7.How important is it for you to be free from anger?	Imp62.1	R
8.How important is it for you to be free from frustration?	Imp62.2	R
Vulnerability, fear, worry		
How much		
17.How much are you bothered by **feelings of vulnerability**?	F63.1	Changed to 'feeling vulnerable'
18.How much **do feelings of fear bother you**?	F63.2	Changed to 'does fear bother you?'
19.How much **do feelings of vulnerability** interfere with your everyday life?	F63.3	Changed to 'does feeling vulnerable'
20.To what extent do you feel threatened by the possibility of pain?	F63.4i	Changed to 'how much do you feel that pain is a threat?'
21.How **afraid are you of** experiencing pain?	F63.5i	Changed to 'concerned are you about'
22.Are you distressed by the fear of pain?	F63.6i	Changed to 'how much are you distressed by pain?'
23.How much are you bothered by feelings of worry?	F63.7	R
24.How much do you worry about having treatment?	F63.8	R
How important		
9.How important is it for you to be free from feelings of vulnerability?	Imp63.1	X
10.How important is it for you to be free from fear?	Imp63.2	R
11.How important is it for you to be free from worry?	Imp63.3	R
Uncertainty		
How much		
25.How much does uncertainty about the future interfere with your everyday life?	F64.2	R
26.To what extent do difficulties with planning affect your everyday life?	F64.4	R
27.Does pain prevent you from doing what you want to do?	F64.6i	R
28.Does pain or discomfort limit your life?	F64.7	R
How completely		
58.To what extent does your pain prevent you from making plans?	F64.3	R
How satisfied		
65.How satisfied are you with your ability to make future plans?	F64.5	R
How often		
76.How often do feelings of uncertainty bother you?	F64.1	R

Response scale type	**Item code**	**Item changed, retained (R) or deleted (X)**
How important		
12.How important is it for you to be free from uncertainty?	Imp64.1	R
13.How important is it to you to be able to make plans for the future?	Imp64.2	X
Loss/ loneliness/ feeling alone		
How much		
29.How much are you bothered by feelings of loss?	F65.1	R
30.How much do feelings of loss interfere with your everyday life?	F65.2	R
31.To what extent are you bothered by not being able to carry out the activities that you used to do?	F65.3	R
32.How much are you able to carry out the activities that you once could?	F65.4	X
33.To what extent do feelings of loneliness bother you?	F65.6	R
34.How much does being alone bother you?	F65.7	R
How completely		
59.How lonely do you feel?	F65.5	R
How important		
14.How important is it for you to be free from feelings of loss?	Imp65.1	R
15.How important is it for you to be able to continue carrying out the activities that you once could?	Imp65.2	X
16.How important to you is it to feel that you are not alone?	Imp65.3	R
Positive strategies		
How much		
35.How much does **humour help you to deal with your problems**?	F66.2	Changed to 'the use of humour improve your quality of life?'
36.How much do you hope for relief from pain?	F66.3	R
37.How much does hope for relief from pain improve your quality of life?	F66.4	X
38.How much do you experience feelings of hope?	F66.5	R
39.How hopeful and optimistic do you feel about the future?	F66.6i	R
40.How much does hope and optimism help you to deal with your problems?	F66.7	R
How often		
77.How often are you able to see the humorous side of things?	F66.1	X
How important		
17.How important to you are feelings of hope?	Imp66.1	R
18.How important to you is having a sense of humour?	Imp66.2	R
Communication		
How much		
41.How much are you bothered by the fact that other people cannot see the extent of your pain and suffering?	F67.1	R
42.To what extent does your pain affect your relationships with other people?	F67.2	R
43.How much **do you feel that other people recognise your condition and the consequences it has for you**?	F67.5	Changed to 'does it bother you that your pain is invisible to others'

Response scale type	Item code	Item changed, retained (R) or deleted (X)
44.To what extent are you bothered by any difficulties in communicating your feelings to others?	F67.8	R
45.How much are you concerned about how other people see your condition?	F67.10	R
46.How much do you feel that your health interferes with your personal relationships?	F67.11i	R
47.How much are you concerned about society's attitude toward how you use health and social care?	F67.12	X
How completely		
60.To what extent do you feel that other people appreciate the nature of your condition?	F67.3	R
61.To what extent do you think people understand and acknowledge your condition?	F67.4	R
How satisfied		
66.How satisfied are you that other people recognise your condition? X	F67.6	X
67.How satisfied are you with your ability to communicate your needs to other people?	F67.7	R
68.How satisfied are you with your ability to express your feelings?	F67.9i	R
How important		
19.How important is it to you that people cannot see your pain?	Imp67.1	X
20.How important is it to you to feel that other people understand your pain?	Imp67.2	X
21.How important is how other people see your condition?	Imp67.3	X
22.How important is it to be able to communicate your feelings to others?	Imp67.4	R
23.How important are the attitudes of others to your use of health and social services?	Imp67.5	X
Guilt and burdening others		
How much		
48.To what extent are you concerned about burdening others?	F68.1	R
49.How much do you worry about the effect your pain has on others?	F68.2	R
50.How much are you bothered by feelings of guilt?	F68.3	R
51.How concerned are you that you do not have enough resources to provide for others?	F68.5i	R
How satisfied		
69.How satisfied are you with your ability to support others?	F68.4i	R
How important		
24.How important is it to be free from feelings of guilt?	Imp68.1	R
25.How important is it to feel that you are not a burden to others?	Imp68.2	R
Relationship with health care providers		
How much		
52.To what extent do you feel supported by the health service?	F69.3	R
53.To what extent do you feel that you are dependent on health and social services?	F69.4	R

Response scale type	**Item code**	**Item changed, retained (R) or deleted (X)**
54.How much do you benefit from the use of complimentary therapies?	F69.6	Added '(for example, acupuncture and herbal medicine etc.)'
55.To what extent does the use of complimentary therapy contribute to your quality of life?	F69.7	X
56.How much access do you have to the information you require about your health?	F69.9	R
How completely		
62.To what extent do you have access to information about the range of available treatments?	F69.8	R
How satisfied		
70.To what extent are you satisfied with your relationship with your **doctor/s**?	F69.1	Changed to 'health professionals'
71.To what extent are you satisfied with your relationship with those health professionals that you have regular contact with?	F69.2	X
72.How satisfied are you with the support you receive from the **medical** service?	F69.5	Changed to 'health'
73.How satisfied are you with the information that is made available to you about your health?	F69.10	R
How important		
26.How important is it to you to have a good relationship with your doctor/s?	Imp69.1	X
27.How important is it to you to have a good relationship with your health care professionals?	Imp69.2	R
28.How important is it to you to feel supported by the health service?	Imp69.3	X
29.How important is it for you to be free from dependency on the health service?	Imp69.4	X
30.How important to you is the availability of non-prescribed and complimentary therapy?	Imp69.5	X
31.How important is it to have adequate information regarding your condition and the availability of treatment for it?	Imp69.6	X

Item-total reliability analysis for 68-item PDM for cross-sectional survey (over all scale alpha .96) (Chapter seven)

Item	Scale mean if item deleted	Scale variance if item deleted	Corrected item-total correlation	Alpha if item deleted
F601	195.91	1487.30	.50	.96
F602	195.413	1473.34	.59	.96
F603	195.73	1480.02	.54	.96
F611	195.46	1498.84	.33	.96*
F614I	195.59	1497.07	.41	.96
F616I	195.42	1493.62	.37	.96
F618	194.93	1495.51	.28	.97*
F619	195.48	1492.15	.36	.96
F621	194.82	1460.09	.72	.96**
F622	194.34	1468.03	.70	.96**
F624	194.37	1468.29	.66	.96**
F626	195.53	1466.81	.69	.96**
F627	195.10	1465.75	.70	.96**
F631	194.72	1469.32	.64	.96**
F632	194.58	1477.72	.56	.96
F633	194.34	1475.24	.66	.96**
F634I	195.21	1472.45	.58	.96
F635I	195.52	1483.43	.56	.96
F636I	195.67	1478.78	.62	.96
F637	195.21	1468.72	.66	.96**
F638	194.80	1471.30	.61	.96**
F642	195.17	1463.90	.70	.96**
F644	195.10	1461.67	.71	.96**
F646I	195.89	1467.72	.64	.96**
F647	195.87	1470.47	.65	.96**
F651	195.36	1464.43	.64	.96**
F652	194.89	1458.84	.71	.96**
F653	195.88	1467.76	.67	.96**
F656	194.63	1470.92	.57	.96
F657	194.57	1475.29	.52	.96
F662	194.36	1505.77	.26	.96*
F663	193.96	1542.26	-.27	.97*
F665	195.02	1505.52	.23	.97*
F666I	195.15	1489.05	.44	.96
F667	195.03	1488.66	.47	.96
F671	195.27	1471.48	.58	.96
F672	195.04	1470.27	.69	.96**
F675	195.09	1472.46	.53	.96
F678	194.85	1469.35	.62	.96**
F6710	194.79	1470.50	.59	.96
F6711I	195.06	1456.51	.73	.96**
F681	195.79	1479.84	.55	.96
F682	195.48	1483.75	.50	.96
F683	194.95	1458.96	.65	.96**
F685I	195.13	1465.69	.58	.96
F693	195.17	1503.24	.26	.96*
F694	194.91	1497.00	.27	.97*
F696	195.96	1517.46	.05	.97*
F699	195.17	1490.83	.42	.96
F613I	195.01	1490.13	.51	.96

Item	Scale mean if item deleted	Scale variance if item deleted	Corrected item-total correlation	Alpha if item deleted
F617	195.59	1482.37	.53	.96
F643	195.38	1474.37	.60	.96
F655	194.46	1465.82	.63	.96**
F673	195.29	1498.28	.35	.96
F674	195.33	1504.28	.27	.96*
F698	195.35	1495.73	.36	.96
F612	195.38	1479.03	.56	.96
F615I	195.48	1480.11	.57	.96
F645	195.36	1468.56	.69	.96**
F677	194.78	1481.77	.55	.96
F679I	194.79	1477.27	.56	.96
F684I	195.07	1478.25	.51	.96
F691	194.59	1489.91	.42	.96
F695	194.87	1486.90	.42	.96
F6910	194.95	1479.03	.54	.96
F623	195.07	1464.20	.67	.96**
F625	195.53	1480.78	.59	.96
F641	195.21	1469.28	.69	.96**

** Contributes most

* Contributes least

Transition questions for no treatment group (Chapter eight)

You last completed this questionnaire on ______/______/_____. When answering these questions, please consider how you are NOW compared to when you last completed this questionnaire?

1. Since you last completed this questionnaire, has your **quality of life** been… *(please circle only one number).*

Worse	A little worse	The same	A little better	Better
1	2	3	4	5

2. Since you last completed this questionnaire, has your **health** been… *(please circle only one number).*

Worse	A little worse	The same	A little better	Better
1	2	3	4	5

3. Since you last completed this questionnaire, has your **pain** been… *(please circle only one number).*

Worse	A little worse	The same	A little better	Better
1	2	3	4	5

4a. Since you last completed this questionnaire, have you begun any **new treatment or medicine?** *(please tick one box)*

Yes ☐ No ☐

4b. If YES, please give details of **any treatments or medicines** you have been taking (please include everything, including any herbal remedies, acupuncture etc.)

5a. Since you last completed this questionnaire, have there been any **important life events or experiences** that have affected your quality of life? *(please tick one box)*

Yes ☐ No ☐

5b. If YES, please give details ____

5c. Please tell us when these occurred (approximate dates)

Transition questions for lumbar epidural steroid group (Chapter eight)

You last completed this questionnaire on ______/_______/_____. When answering these questions, please consider how you are NOW compared to when you had your injection about one month ago.

1. Since your injection, has your **quality of life** been… *(please circle only one number).*

Worse	A little worse	The same	A little better	Better
1	2	3	4	5

2. Since your injection, has your **health** been… *(please circle only one number).*

Worse	A little worse	The same	A little better	Better
1	2	3	4	5

3. Since your injection, has your **pain** been… *(please circle only one number).*

Worse	A little worse	The same	A little better	Better
1	2	3	4	5

4. Overall, how do you feel about the **treatment you have received**? *(please circle only one number).*

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

5a. Since you had your injection about one month ago, have you begun any **new treatment or medicine?** *(please tick one box)*

Yes ☐ No ☐

5b. If YES, please give details of **any treatments or medicines** you have been taking (please include everything, including any herbal remedies, acupuncture etc.)

6a. Since your injection, have there been any **important life events or experiences** that have affected your quality of life? *(please tick one box)*

Yes ☐ No ☐

6b. If yes, please give details ____

6c. Please tell us when these occurred (approximate dates)

Syntax files and scoring for the WHOQOL-100, PDM, SF-12 and CPAQ (Chapter eight)

```
SUBTITLE 'BASELINE WHOQOL AND PDM SCORING'

RECODE f11t1 f12t1 f13t1 f14t1 f21t1 f22t1 f23t1 f24t1 f31t1
f32t1 f33t1 f34t1 f41t1f42t1 f43t1 f44t1
f51t1 f52t1 f53t1 f54t1 f61t1 f62t1 f63t1 f64t1 f71t1 f72t1 f73t1
f74t1 f81t1 f82t1 f83t1 f84t1 f91t1 f92t1 f93t1 f94t1 f101t1 f102t1
f103t1
f104t1  f111t1 f112t1 f113t1  f114t1  f121t1 f122t1 f123t1 f124t1
f131t1 f132t1 f133t1 f134t1 f141t1 f142t1 f143t1 f144t1 f151t1
f152t1
f153t1 f154t1 f161t1 f162t1 f163t1 f164t1 f171t1 f172t1 f173t1
f174t1 f181t1 f182t1 f183t1 f184t1 f191t1 f192t1 f193t1 f194t1
f201t1
f202t1 f203t1 f204t1 f211t1 f212t1 f213t1 f214t1 f221t1 f222t1
f223t1 f224t1 f231t1 f232t1 f233t1 f234t1 f241t1 f242t1 f243t1
f244t1 g1t1
g2t1 g3t1 g4t1 f616it1 f622t1 f627t1 f633t1 f632t1 f638t1 f635it1
f642t1 f644t1 f647t1 f613it1
f617t1 f615it1 f645t1 f623t1 f625t1
(1=1) (2=2) (3=3) (4=4) (5=5) (ELSE=SYSMIS).


RECODE f11t1 f12t1 f13t1 f14t1 f22t1 f24t1 f32t1 f34t1 f72t1
f73t1 f81t1 f82t1 f83t1 f84t1 f93t1 f94t1 f102t1 f104t1 f111t1
f112t1 f113t1
f114t1 f131t1 f154t1 f163t1 f182t1 f184t1 f222t1 f232t1 f234t1
f622t1 f623t1 f625t1 f627t1 f632t1 f633t1 f635it1 f638t1 f642t1
f644t1
f647t1
(1=5)(2=4)(3=3)(4=2)(5=1).

SUBTITLE 'COMPUTE BASELINE FACET AND DOMAIN
SCORES'

COMPUTE pain=(MEAN.3(f11t1,f12t1,f13t1,f14t1))*4.
COMPUTE energy=(MEAN.3(f21t1,f22t1,f23t1,f24t1))*4.
COMPUTE sleep=(MEAN.3(f31t1,f32t1,f33t1,f34t1))*4.
COMPUTE pfeel=(MEAN.3(f41t1,f42t1,f43t1,f44t1)) *4.
COMPUTE think=(MEAN.3(f51t1,f52t1,f53t1,f54t1))*4.
COMPUTE esteem=(MEAN.3(f61t1,f62t1,f63t1,f64t1))*4.
COMPUTE body=(MEAN.3(f71t1,f72t1, f73t1, f74t1))*4.
COMPUTE neg=(MEAN.3(f81t1, f82t1,f83t1, f84t1))*4.
COMPUTE mobil=(MEAN.3(f91t1,f92t1,f93t1,f94t1))*4.
COMPUTE activ=(MEAN.3(f101t1,f102t1,f103t1,f104t1))*4.
COMPUTE medic=(MEAN.3(f111t1,f112t1, f113t1, f114t1))*4.
COMPUTE work=(MEAN.3(f121t1, f122t1, f123t1, f124t1))*4.
COMPUTE relat=(MEAN.3(f131t1, f132t1, f133t1, f134t1))*4.
COMPUTE supp=(MEAN.3(f141t1, f142t1, f143t1, f144t1))*4.
COMPUTE sexx=(MEAN.3(f151t1,f152t1,f153t1,f154t1))*4.
COMPUTE safety=(MEAN.3(f161t1, f162t1, f163t1, f164t1))*4.
COMPUTE home=(MEAN.3(f171t1,f172t1, f173t1, f174t1))*4.
COMPUTE finan=(MEAN.3(f181t1, f182t1,f183t1,f184t1))*4.
COMPUTE servic=(MEAN.3(f191t1, f192t1, f193t1,f194t1))*4.
COMPUTE inform=(MEAN.3(f201t1,f202t1,f203t1,f204t1))*4.
COMPUTE leisur=(MEAN.3(f211t1, f212t1, f213t1, f214t1))*4.
COMPUTE enviro=(MEAN.3(f221t1, f222t1,f223t1,f224t1))*4.
COMPUTE transp=(MEAN.3(f231t1,f232t1, f233t1, f234t1))*4.
COMPUTE spirit=(MEAN.3(f241t1,f242t1, f243t1, f244t1))*4.
COMPUTE overll=(MEAN.3(g1t1,g2t1,g3t1,g4t1))*4.
COMPUTE relief=(MEAN.3(f616it1, f613it1, f615it1, f617t1))*4.
COMPUTE anger=(MEAN.3(f622t1, f623t1, f625t1, f627t1))*4.
COMPUTE vulner=(MEAN.3(f632t1, f633t1, f635it1, f638t1))*4.
COMPUTE uncert=(MEAN.3(f642t1, f644t1, f645t1, f647t1))*4.
COMPUTE DOM1=MEAN.2(pain,energy,sleep).
COMPUTE DOM2=MEAN.4(pfeel,think, esteem, body, neg).
COMPUTE DOM3=MEAN.3 (mobil,activ, medic,work).
COMPUTE DOM4=MEAN.2(relat,supp,sexx).
COMPUTE
DOM5=MEAN.6(safety,home,finan,servic,inform,leisur,enviro,tr
ansp).
COMPUTE DOM6=spirit.

COUNT TOTAL=f12t1 to f625t1 (1 THRU 5).
FILTER OFF.

EXECUTE.

SUBTITLE 'BASELINE SF12  SCORING'

COMMENT            Reverse codes so that high score is always
best health.  t1 added to all variable names to
denote time 1 (baseline).

COMPUTE h1t1=6-h1t1.
COMPUTE h5t1=6-h5t1.
COMPUTE h6_at1=7-h6_at1.
COMPUTE h6_bt1=7-h6_bt1.


COMMENT Make MCS/PCS with US regression weights
combining responses 3 & 4 on question h6t1 (some of the time
& a good bit of the time).

COMPUTE pf02_1=h2_at1=1.
COMPUTE pf02_2=h2_at1=2.

COMPUTE pf04_1=h2_bt1=1.
COMPUTE pf04_2=h2_bt1=2.

COMPUTE rp2_1=h3_at1=1.
COMPUTE rp3_1=h3_bt1=1.

COMPUTE bp2_1=h5t1=1.
COMPUTE bp2_2=h5t1=2.
COMPUTE bp2_3=h5t1=3.
COMPUTE bp2_4=h5t1=4.

COMPUTE gh1_1=h1t1=1.
COMPUTE gh1_2=h1t1=2.
COMPUTE gh1_3=h1t1=3.
COMPUTE gh1_4=h1t1=4.

COMPUTE vt2_1=h6_bt1=1.
COMPUTE vt2_2=h6_bt1=2.
COMPUTE vt2_3=h6_bt1=3.
COMPUTE vt2_4=h6_bt1=4.
COMPUTE vt2_5=h6_bt1=5.

COMPUTE sf2_1=h6t1=1.
COMPUTE sf2_2=h6t1=2.
COMPUTE sf2_3=h6t1=3 OR h6t1=4.
COMPUTE sf2_4=h6t1=5.

COMPUTE re2_1=h4_at1=1.

COMPUTE re3_1=h4_bt1=1.

COMPUTE mh3_1=h6_at1=1.
COMPUTE mh3_2=h6_at1=2.
COMPUTE mh3_3=h6_at1=3.
```

```
COMPUTE mh3_4=h6_at1=4.
COMPUTE mh3_5=h6_at1=5.

COMPUTE mh4_1=h6_ct1=1.
COMPUTE mh4_2=h6_ct1=2.
COMPUTE mh4_3=h6_ct1=3.
COMPUTE mh4_4=h6_ct1=4.
COMPUTE mh4_5=h6_ct1=5.


COMPUTE
rawpcs12=(pf02_1*-7.23216)+(pf02_2*-3.45555)+(pf04_1*-
6.24397)+(pf04_2*-2.73557)+(rp2_1*-4.61617)+(rp3_1*-
5.51747)
+(bp2_1*-11.25544)+(bp2_2*-8.38063)+(bp2_3*-
6.50522)+(bp2_4*-3.80130)+(gh1_1*-8.37399)+(gh1_2*-
5.56461)
+(gh1_3*-3.02396)+(gh1_4*-1.31872)+(vt2_1*-
2.44706)+(vt2_2*-2.02168)+(vt2_3*-1.61850)+(vt2_4*-1.14387)
+(vt2_5*-0.42251)+(sf2_1*-0.33682)+(sf2_2*-0.94342)+(sf2_3*-
0.18043)+(sf2_4*0.11038)+(re2_1*3.04365)+(re3_1*2.32091)
+(mh3_1*3.46638)+(mh3_2*2.90426)+(mh3_3*2.37241)+(mh3_
4*1.36689)+(mh3_5*0.66514)+(mh4_1*4.61446)+(mh4_2*3.415
93)
+(mh4_3*2.34247)+(mh4_4*1.28044)+(mh4_5*0.41188).


COMPUTE
rawmcs12=(pf02_1*3.93115)+(pf02_2*1.86840)+(pf04_1*2.682
82)+(pf04_2*1.43103)+(rp2_1*1.44060)+(rp3_1*1.66968)
+(bp2_1*1.48619)+(bp2_2*1.76691)+(bp2_3*1.49384)+(bp2_4*
0.90384)+(gh1_1*-1.71175)+(gh1_2*-
0.16891)+(gh1_3*0.03482)
+(gh1_4*-0.06064)+(vt2_1*-6.02409)+(vt2_2*-
4.88962)+(vt2_3*-3.29805)+(vt2_4*-1.65178)+(vt2_5*-
0.92057)+(sf2_1*-6.29724)
+(sf2_2*-8.26066)+(sf2_3*-5.63286)+(sf2_4*-3.13896)+(re2_1*-
6.82672)+(re3_1*-5.69921)+(mh3_1*-10.19085)+(mh3_2*-
7.92717)
+(mh3_3*-6.31121)+(mh3_4*-4.09842)+(mh3_5*-
1.94949)+(mh4_1*-16.15395)+(mh4_2*-10.77911)+(mh4_3*-
8.09914)
+(mh4_4*-4.59055)+(mh4_5*-1.95934).

COMMENT          This standardises by OHLSII.
```

```
COMPUTE pcs12=(((rawpcs12-(-4.7938))/7.6510)*10)+50.
COMPUTE mcs12=(((rawmcs12-(-11.3215))/9.3733)*10)+50.

EXECUTE.

SUBTITLE 'BASELINE CPAQ SCORING'

RECODE cpaq5t1 cpaq8t1 cpaq10t1 cpaq13t1 cpaq18t1
cpaq19t1 cpaq22t1 cpaq23t1 cpaq25t1
cpaq26t1 cpaq27t1 cpaq29t1 cpaq30t1 cpaq31t1 cpaq33t1
cpaq34t1 (0=6) (1=5) (2=4) (3=3) (4=2)
(5=1) (6=0) INTO rcpaq5t1 rcpaq8t1 rcpa10t1 rcpa13t1
rcpa18t1 rcpa19t1 rcpa22t1 rcpa23t1 rcpa25t1
rcpa26t1 rcpa27t1 rcpa29t1 rcpa30t1 rcpa31t1 rcpa33t1
rcpa34t1 .

COMPUTE
cpaqtot=cpaq1t1+cpaq2t1+cpaq3t1+cpaq4t1+rcpaq5t1+cpaq6t1
+cpaq7t1+
cpaq9t1+rcpa10t1+cpaq12t1+cpaq14t1+cpaq16t1+cpaq17t1+rc
pa19t1+cpaq20t1+
rcpa22t1+rcpa23t1+cpaq24t1+rcpa27t1+cpaq28t1+rcpa30t1+rc
pa31t1+cpaq32t1+rcpa34t1.

EXECUTE.

SUBTITLE 'SCORING FOR SHORT FORM CPAQ'

RECODE cpaq5t1 cpaq10t1 cpaq19t1 cpaq22t1 cpaq23t1
cpaq25t1
cpaq30t1 cpaq31t1 cpaq34t1 (0=6) (1=5) (2=4) (3=3) (4=2)
(5=1) (6=0) INTO rsfcpaq5 rsfcpa10 rsfcpa19 rsfcpa22 rsfcpa23
rsfcpa25
rsfcpa30 rsfcpa31 rsfcpa34.

SUBTITLE 'ACTIVITIES ENGAGEMENT SCORE'

COMPUTE activeng=cpaq1t1+cpaq2t1+cpaq3t1+cpaq6t1+
cpaq9t1+cpaq14t1+cpaq15t1+cpaq16t1+cpaq20t1+
cpaq24t1+cpaq32t1.

SUBTITLE 'PAIN WILLINGNESS SCORE'
```

```
COMPUTE
painwill=rsfcpaq5+rsfcpa10+rsfcpa19+rsfcpa22+rsfcpa23+rsfcp
a25+rsfcpa30+rsfcpa31+rsfcpa34.

SUBTITLE 'SF CPAQ TOTAL'

COMPUTE
sfcpatot=cpaq1t1+cpaq2t1+cpaq3t1+rsfcpaq5+cpaq6t1+
cpaq9t1+rsfcpa10+cpaq14t1+cpaq15t1+cpaq16t1+rsfcpa19+cp
aq20t1+
rsfcpa22+rsfcpa23+cpaq24t1+rsfcpa25+rsfcpa30+rsfcpa31+cpa
q32t1+rsfcpa34.

EXECUTE.

SUBTITLE 'FOLLOW UP WHOQOL AND PDM SCORING'

RECODE f11t2 f12t2 f13t2 f14t2 f21t2 f22t2 f23t2 f24t2 f31t2
f32t2 f33t2 f34t2 f41t2 f42t2 f43t2 f44t2
f51t2 f52t2 f53t2 f54t2 f61t2 f62t2 f63t2 f64t2 f71t2 f72t2 f73t2
f74t2 f81t2 f82t2 f83t2 f84t2 f91t2 f92t2 f93t2 f94t2 f101t2 f102t2
f103t2
f104t2  f111t2 f112t2 f113t2  f114t2  f121t2 f122t2 f123t2 f124t2
f131t2 f132t2 f133t2 f134t2 f141t2 f142t2 f143t2 f144t2 f151t2
f152t2
f153t2 f154t2 f161t2 f162t2 f163t2 f164t2 f171t2 f172t2 f173t2
f174t2 f181t2 f182t2 f183t2 f184t2 f191t2 f192t2 f193t2 f194t2
f201t2
f202t2 f203t2 f204t2 f211t2 f212t2 f213t2 f214t2 f221t2 f222t2
f223t2 f224t2 f231t2 f232t2 f233t2 f234t2 f241t2 f242t2 f243t2
f244t2 g1t2
g2t2 g3t2 g4t2 f616it2 f622t2 f627t2 f633t2 f632t2 f638t2 f635it2
f642t2 f644t2 f647t2 f613it2
f617t2 f615it2 f645t2 f623t2 f625t2
(1=1) (2=2) (3=3) (4=4) (5=5) (ELSE=SYSMIS).


RECODE f11t2 f12t2 f13t2 f14t2 f22t2 f24t2 f32t2 f34t2 f72t2
f73t2 f81t2 f82t2 f83t2 f84t2 f93t2 f94t2 f102t2 f104t2 f111t2
f112t2 f113t2
f114t2 f131t2 f154t2 f163t2 f182t2 f184t2 f222t2 f232t2 f234t2
f622t2 f623t2 f625t2 f627t2 f632t2 f633t2 f635it2 f638t2 f642t2
f644t2
f647t2
(1=5)(2=4)(3=3)(4=2)(5=1).
```

```
SUBTITLE 'COMPUTE FOLLOW UP FACET AND DOMAIN
SCORES'

COMPUTE paint2=(MEAN.3(f11t2,f12t2,f13t2,f14t2))*4.
COMPUTE energyt2=(MEAN.3(f21t2,f22t2,f23t2,f24t2))*4.
COMPUTE sleept2=(MEAN.3(f31t2,f32t2,f33t2,f34t2))*4.
COMPUTE pfeelt2=(MEAN.3(f41t2,f42t2,f43t2,f44t2)) *4.
COMPUTE thinkt2=(MEAN.3(f51t2,f52t2,f53t2,f54t2))*4.
COMPUTE esteemt2=(MEAN.3(f61t2,f62t2,f63t2,f64t2))*4.
COMPUTE bodyt2=(MEAN.3(f71t2,f72t2, f73t2, f74t2))*4.
COMPUTE negt2=(MEAN.3(f81t2, f82t2,f83t2, f84t2))*4.
COMPUTE mobilt2=(MEAN.3(f91t2,f92t2,f93t2,f94t2))*4.
COMPUTE activt2=(MEAN.3(f101t2,f102t2,f103t2,f104t2))*4.
COMPUTE medict2=(MEAN.3(f111t2,f112t2, f113t2, f114t2))*4.
COMPUTE workkt2=(MEAN.3(f121t2, f122t2, f123t2, f124t2))*4.
COMPUTE relatt2=(MEAN.3(f131t2, f132t2, f133t2, f134t2))*4.
COMPUTE suppt2=(MEAN.3(f141t2, f142t2, f143t2, f144t2))*4.
COMPUTE sexxt2=(MEAN.3(f151t2,f152t2,f153t2,f154t2))*4.
COMPUTE safetyt2=(MEAN.3(f161t2, f162t2, f163t2, f164t2))*4.
COMPUTE homet2=(MEAN.3(f171t2,f172t2, f173t2, f174t2))*4.
COMPUTE finant2=(MEAN.3(f181t2, f182t2,f183t2,f184t2))*4.
COMPUTE servict2=(MEAN.3(f191t2, f192t2, f193t2,f194t2))*4.
COMPUTE informt2=(MEAN.3(f201t2,f202t2,f203t2,f204t2))*4.
COMPUTE leisurt2=(MEAN.3(f211t2, f212t2, f213t2, f214t2))*4.
COMPUTE envirot2=(MEAN.3(f221t2, f222t2,f223t2,f224t2))*4.
COMPUTE transpt2=(MEAN.3(f231t2,f232t2, f233t2, f234t2))*4.
COMPUTE spiritt2=(MEAN.3(f241t2,f242t2, f243t2, f244t2))*4.
COMPUTE overllt2=(MEAN.3(g1t2,g2t2,g3t2,g4t2))*4.
COMPUTE relieft2=(MEAN.3(f616it2, f613it2, f615it2,
f617t2))*4.
COMPUTE angert2=(MEAN.3(f622t2, f623t2, f625t2, f627t2))*4.
COMPUTE vulnert2=(MEAN.3(f632t2, f633t2, f635it2,
f638t2))*4.
COMPUTE uncertt2=(MEAN.3(f642t2, f644t2, f645t2,
f647t2))*4.
COMPUTE DOM1t2=MEAN.2(pain,energy,sleep).
COMPUTE DOM2t2=MEAN.4(pfeel,think, esteem, body, neg).
COMPUTE DOM3t2=MEAN.3 (mobil,activ, medic,work).
COMPUTE DOM4t2=MEAN.2(relat,supp,sexx).
COMPUTE
DOM5t2=MEAN.6(safety,home,finan,servic,inform,leisur,enviro,t
ransp).
COMPUTE DOM6t2=spirit.
```

```
COUNT TOTAL=f12t2 to f625t2 (1 THRU 5).
FILTER OFF.

EXECUTE.

SUBTITLE 'FOLLOW UP SF12 SCORING'

COMMENT          Reverse codes so that high score is always
best health.  t2 added to all variable names to
denote time 2 (follow up).

COMPUTE h1t2=6-h1t2.
COMPUTE h5t2=6-h5t2.
COMPUTE h6_at2=7-h6_at2.
COMPUTE h6_bt2=7-h6_bt2.


COMMENT Make MCST2/PCST2 with US regression weights
combining responses 3 & 4 on question h6t2 (some of the time
& a good bit of the time).

COMPUTE pf02_1t2=h2_at2=1.
COMPUTE pf02_2t2=h2_at2=2.

COMPUTE pf04_1t2=h2_bt2=1.
COMPUTE pf04_2t2=h2_bt2=2.

COMPUTE rp2_1t2=h3_at2=1.
COMPUTE rp3_1t2=h3_bt2=1.

COMPUTE bp2_1t2=h5t2=1.
COMPUTE bp2_2t2=h5t2=2.
COMPUTE bp2_3t2=h5t2=3.
COMPUTE bp2_4t2=h5t2=4.

COMPUTE gh1_1t2=h1t2=1.
COMPUTE gh1_2t2=h1t2=2.
COMPUTE gh1_3t2=h1t2=3.
COMPUTE gh1_4t2=h1t2=4.

COMPUTE vt2_1t2=h6_bt2=1.
COMPUTE vt2_2t2=h6_bt2=2.
COMPUTE vt2_3t2=h6_bt2=3.
COMPUTE vt2_4t2=h6_bt2=4.
COMPUTE vt2_5t2=h6_bt2=5.
```

```
COMPUTE sf2_1t2=h6t2=1.
COMPUTE sf2_2t2=h6t2=2.
COMPUTE sf2_3t2=h6t2=3 OR h6t2=4.
COMPUTE sf2_4t2=h6t2=5.

COMPUTE re2_1t2=h4_at2=1.

COMPUTE re3_1t2=h4_bt2=1.

COMPUTE mh3_1t2=h6_at2=1.
COMPUTE mh3_2t2=h6_at2=2.
COMPUTE mh3_3t2=h6_at2=3.
COMPUTE mh3_4t2=h6_at2=4.
COMPUTE mh3_5t2=h6_at2=5.

COMPUTE mh4_1t2=h6_ct2=1.
COMPUTE mh4_2t2=h6_ct2=2.
COMPUTE mh4_3t2=h6_ct2=3.
COMPUTE mh4_4t2=h6_ct2=4.
COMPUTE mh4_5t2=h6_ct2=5.


COMPUTE
rawpcsT2=(pf02_1t2*-7.23216)+(pf02_2t2*-
3.45555)+(pf04_1t2*-6.24397)+(pf04_2t2*-2.73557)+(rp2_1t2*-
4.61617)+(rp3_1t2*-5.51747)
+(bp2_1t2*-11.25544)+(bp2_2t2*-8.38063)+(bp2_3t2*-
6.50522)+(bp2_4t2*-3.80130)+(gh1_1t2*-8.37399)+(gh1_2t2*-
5.56461)
+(gh1_3t2*-3.02396)+(gh1_4t2*-1.31872)+(vt2_1t2*-
2.44706)+(vt2_2t2*-2.02168)+(vt2_3t2*-1.61850)+(vt2_4t2*-
1.14387)
+(vt2_5t2*-0.42251)+(sf2_1t2*-0.33682)+(sf2_2t2*-
0.94342)+(sf2_3t2*-
0.18043)+(sf2_4t2*0.11038)+(re2_1t2*3.04365)+(re3_1t2*2.320
91)
+(mh3_1t2*3.46638)+(mh3_2t2*2.90426)+(mh3_3t2*2.37241)+(
mh3_4t2*1.36689)+(mh3_5t2*0.66514)+(mh4_1t2*4.61446)+(m
h4_2t2*3.41593)
+(mh4_3t2*2.34247)+(mh4_4t2*1.28044)+(mh4_5t2*0.41188).


COMPUTE
```

```
rawmcsT2=(pf02_1t2*3.93115)+(pf02_2t2*1.86840)+(pf04_1t2*
2.68282)+(pf04_2t2*1.43103)+(rp2_1t2*1.44060)+(rp3_1t2*1.66
968)
+(bp2_1t2*1.48619)+(bp2_2t2*1.76691)+(bp2_3t2*1.49384)+(b
p2_4t2*0.90384)+(gh1_1t2*-1.71175)+(gh1_2t2*-
0.16891)+(gh1_3t2*0.03482)
+(gh1_4t2*-0.06064)+(vt2_1t2*-6.02409)+(vt2_2t2*-
4.88962)+(vt2_3t2*-3.29805)+(vt2_4t2*-1.65178)+(vt2_5t2*-
0.92057)+(sf2_1t2*-6.29724)
+(sf2_2t2*-8.26066)+(sf2_3t2*-5.63286)+(sf2_4t2*-
3.13896)+(re2_1t2*-6.82672)+(re3_1t2*-5.69921)+(mh3_1t2*-
10.19085)+(mh3_2t2*-7.92717)
+(mh3_3t2*-6.31121)+(mh3_4t2*-4.09842)+(mh3_5t2*-
1.94949)+(mh4_1t2*-16.15395)+(mh4_2t2*-
10.77911)+(mh4_3t2*-8.09914)
+(mh4_4t2*-4.59055)+(mh4_5t2*-1.95934).

COMMENT This standardises by OHLSII.

COMPUTE pcsT2=(((rawpcsT2-(-4.7938))/7.6510)*10)+50.
COMPUTE mcsT2=(((rawmcsT2-(-11.3215))/9.3733)*10)+50.

EXECUTE.

SUBTITLE 'FOLLOW UP CPAQ SCORING'

RECODE cpaq5t2 cpaq8t2 cpaq10t2 cpaq13t2 cpaq18t2
cpaq19t2 cpaq22t2 cpaq23t2 cpaq25t2
cpaq26t2 cpaq27t2 cpaq29t2 cpaq30t2 cpaq31t2 cpaq33t2
cpaq34t2 (0=6) (1=5) (2=4) (3=3) (4=2)
(5=1) (6=0) INTO rcpaq5t2 rcpaq8t2 rcpa10t2 rcpa13t2
rcpa18t2 rcpa19t2 rcpa22t2 rcpa23t2 rcpa25t2
rcpa26t2 rcpa27t2 rcpa29t2 rcpa30t2 rcpa31t2 rcpa33t2
rcpa34t2 .

COMPUTE
cpaqtot2=cpaq1t2+cpaq2t2+cpaq3t2+cpaq4t2+cpaq5t2+cpaq6t
2+cpaq7t2+
cpaq9t2+cpaq10t2+cpaq12t2+cpaq14t2+cpaq16t2+cpaq17t2+rc
pa19t2+cpaq20t2+
rcpa22t2+rcpa23t2+cpaq24t2+rcpa27t2+cpaq28t2+rcpa30t2+rc
pa31t2+cpaq32t2+rcpa34t2.

EXECUTE.

SUBTITLE 'FOLLOW UP SCORING FOR SHORT FORM
CPAQ'

RECODE cpaq5t2 cpaq10t2 cpaq19t2 cpaq22t2 cpaq23t2
cpaq25t2
cpaq30t2 cpaq31t2 cpaq34t2 (0=6) (1=5) (2=4) (3=3) (4=2)
(5=1) (6=0) INTO rsfcp5t2 rsfc10t2 rsfc19t2 rsfc22t2 rsfc23t2
rsfc25t2
rsfc30t2 rsfc31t2 rsfc34t2.

SUBTITLE 'ACTIVITIES ENGAGEMENT SCORE'

COMPUTE activeng=cpaq1t2+cpaq2t2+cpaq3t2+cpaq6t2+
cpaq9t2+cpaq14t2+cpaq15t2+cpaq16t2+cpaq20t2+
cpaq24t2+cpaq32t2.

SUBTITLE 'PAIN WILLINGNESS SCORE'

COMPUTE
painwill=rsfcp5t2+rsfc10t2+rsfc19t2+rsfc22t2+rsfc23t2+rsfc25t2
+rsfc30t2+rsfc31t2+rsfc34t2.

SUBTITLE 'SF CPAQ TOTAL'

COMPUTE
sfcpatot=cpaq1t2+cpaq2t2+cpaq3t2+rsfcp5t2+cpaq6t2+
cpaq9t2+rsfc10t2+cpaq14t2+cpaq15t2+cpaq16t2+rsfc19t2+cpa
q20t2+
rsfc22t2+rsfc23t2+cpaq24t2+rsfc25t2+rsfc30t2+rsfc31t2+cpaq3
2t2+rsfc34t2.

EXECUTE.
```

The UK WHOQOL-100 and PDM

ID____________

****Please remember to bring this pack with you when you attend your appointment*****

IMPORTANT - What is today's date? ______ day ______ month _______ Year

WHOQOL

UK VERSION with WHOQOL-based pain and discomfort module

Department of Mental Health

World Health Organisation

Geneva

The UK WHOQOL and Pain and Discomfort Module
Instructions
Please read this carefully

This questionnaire asks how you feel about your quality of life, health and other areas of your life. Please answer all the questions. If you are unsure about which response to give to a question, please choose the best one you can. There are no right or wrong answers. Your answer will be kept strictly confidential. Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life in the **last two weeks**.

For example, thinking about the **last two weeks**, a question might ask:

How much do you worry about your health?

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

You should circle the number that best fits how much you have worries about your health over the last two weeks. So you would circle the number 4 if you worried about your health "very much", or circle number 1 if you have worried "not at all" about your health. Please read each question, assess your feelings, and circle the number on the scale for each question that gives the best answer for you.

Thank you for your help, please turn over page

The following questions ask about **how much** you have experienced certain things in the last two weeks, for example, positive feelings such as happiness or contentment. If you have experienced these things an extreme amount, circle the number next to "An extreme amount". If you have not experienced these things at all, circle the number next to "Not at all". You should circle one of the numbers in between if you wish to show that your answer lies somewhere between "Not at all" and "Extremely". **Questions refer to the last two weeks.**

1. How much do you worry about pain or discomfort?(F1.2)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

2. How difficult is it for you to handle pain or discomfort? (F1.3)

Not at all	Not much	Moderately	Very much	Extremely
1	2	3	4	5

3. How much do you feel that pain prevents you from doing what you need to do? (F1.4)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

4. How easily do you get tired? (F2.2)

Not at all	Not much	Moderately	Very much	Extremely
1	2	3	4	5

5. How much are you bothered by fatigue? (F2.4)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

6. To what extent do you have difficulty sleeping? (F3.2)

None at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

7. How much do sleep problems worry you? (F3.4)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

8. How much do you enjoy life? (F4.1)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

9. How positive do you feel about the future? (F4.3)

Not at all	Not much	Moderately	Very much	Extremely
1	2	3	4	5

10. How much do you feel positive about your life? (F4.4)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

11. How well are you able to concentrate? (F5.3)

Not at all	Not much	Moderately	Very well	Extremely
1	2	3	4	5

12. How much do you value yourself? (F6.1)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

13. How much confidence do you have in yourself? (F6.2)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

14. How much do you feel inhibited by your looks? (F7.2)

Not at all	Not much	Moderately	Very much	Extremely
1	2	3	4	5

15. Is there any part of your appearance which makes you feel uncomfortable? (F7.3)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

16. How worried do you feel? (F8.2)

Not at all	Not much	Moderately	Very much	Extremely
1	2	3	4	5

17. How much do feelings of sadness or depression interfere with your everyday functioning? (F8.3)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

18. How much do feelings of depression bother you? (F8.4)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

19. To what extent do you have difficulty in performing your routine activities? (F10.2)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

20. How much are you bothered by limitations in performing everyday living activities?(F10.4)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

21. How much do you need medication to function in your daily life? (F11.2)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

22. How much do you need medical treatment to function in your daily life? (F11.3)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

23. How much does your quality of life depend on the use of medical substances or medical aids? (F11.4)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

24. How alone do you feel? (F13.1)

Not at all	Not much	Moderately	Very much	Extremely
1	2	3	4	5

25. How well are your sexual needs fulfilled? (F15.2)

Not at all	Not much	Moderately	Very much	Extremely
1	2	3	4	5

26. How bothered are you by difficulties in your sex life? (F15.4)

Not at all	Not much	Moderately	Very much	Extremely
1	2	3	4	5

27. How safe do you feel in your daily life? (F16.1)

Not at all	Not much	Moderately	Very much	Extremely
1	2	3	4	5

28. To what extent do you feel you are living in a safe and secure environment? (F16.2)

Not at all	Not much	Moderately	Very much	Extremely
1	2	3	4	5

29. How much do you worry about safety and security? (F16.3)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

30. How comfortable is the place where you live? (F17.1)

Not at all	Not much	Moderately	Very much	Extremely
1	2	3	4	5

31. How much do you like where you live? (F17.4)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

32. To what extent do you have financial difficulties? (F18.2)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

33. How much do you worry about money? (F18.4)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

34. How easily are you able to get good medical care? (F19.1)

Not at all	Not much	Moderately	Very much	Extremely
1	2	3	4	5

35. How much do you enjoy your free time? (F21.3)

Not at all	Not much	Moderately	Very much	An extreme amount
1	2	3	4	5

36. How healthy is your physical environment? (F22.1)

Not at all	Not much	Moderately	Very much	Extremely
1	2	3	4	5

37. How concerned are you with the noise in the area where you live? (F22.2)

Not at all	Not much	Moderately	Very much	Extremely
1	2	3	4	5

38. To what extent do you have problems with transport? (F23.2)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

39. How much do difficulties with transport restrict your life? (F23.4)

Not at all	A little	A moderate amount	Very much	An extreme amount
1	2	3	4	5

40. How fed up do you feel? (F8N)

Not at all	A little	A moderate amount	Very much	An extreme amount
1	2	3	4	5

41. To what extent has having treatment improved your quality of life? (F61.6i)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

42. How much do feelings of anger interfere with your every day life? (F62.2)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

43. How much do feelings of frustration interfere with your everyday life? (F62.7)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

44. How much does feeling vulnerable interfere with your everyday life? (F63.3)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

45. How much does fear bother you? (F63.2)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

46. How much do you worry about treatment? (F63.8)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

47. How concerned are you about experiencing pain? (F63.5i)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

48. How much does uncertainty about the future interfere with your everyday life? (F64.2)

Not at all	Not much	A moderate	Very much	An extreme

		amount		amount
1	2	3	4	5

49. To what extent do difficulties with planning affect your everyday life? (F64.4)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

50. Does pain or discomfort limit your life (F64.7)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

The following questions ask about **how completely** you experienced, or were able to do certain things in the last two weeks, for example activities of daily living like washing, dressing or eating. If you have been able to do these things completely, circle the number next to "Completely". If you have not been able to do these things at all, circle the number next to "Not at all". You should circle one of the numbers in between if you wish to show that your answer lies somewhere between "Not at all" and "Completely". **Questions refer to the last two weeks.**

51. Do you have enough energy for everyday life? (F2.1)

Not at all	Not much	Moderately	A great deal	Completely
1	2	3	4	5

52. How much are you able to accept your bodily appearance? (F7.1)

Not at all	Not much	Moderately	A great deal	Completely
1	2	3	4	5

53. To what extent are you able to carry out your daily activities? (F10.1)

Not at all	Not much	Moderately	A great deal	Completely
1	2	3	4	5

54. How dependent are you on medications? (F11.1)

Not at all	Not much	Moderately	A great deal	Completely
1	2	3	4	5

55. To what extent do you get the kind of support from others that you need? (F14.1)

Not at all	Not much	Moderately	A great deal	Completely
1	2	3	4	5

56. How much can you count on your friends when you need them? (F14.2)

Not at all	Not much	Moderately	A great deal	Completely
1	2	3	4	5

57. To what degree does the quality of your home meet your needs? (F17.2)

Not at all	Not much	Moderately	A great deal	Completely
1	2	3	4	5

58. To what extent do you have enough money to meet your needs? (F18.1)

Not at all	Not much	Moderately	A great deal	Completely
1	2	3	4	5

59. How available to you is the information that you need in your day-to-day life? (F20.1)

Not at all	Not much	Moderately	A great deal	Completely
1	2	3	4	5

60. To what extent do you have the opportunities for acquiring the information that you need? (F20.2)

Not at all	Not much	Moderately	A great deal	Completely
1	2	3	4	5

61. To what extent do you have the opportunity for leisure activities? (F21.1)

Not at all	Not much	Moderately	A great deal	Completely
1	2	3	4	5

62. How much are you able to relax and enjoy yourself? (F21.2)

Not at all	Not much	Moderately	A great deal	Completely
1	2	3	4	5

63. To what extent do you have adequate means of transport? (F23.1)

Not at all	Not much	Moderately	A great deal	Completely
1	2	3	4	5

64. How well do you cope with your level of pain? (F61.3i)

Not at all	Not much	Moderately	A great deal	Completely
1	2	3	4	5

65. How easy is it for you to get into a comfortable position? (F61.7)

Not at all	Not much	Moderately	A great deal	Completely
1	2	3	4	5

The following questions ask you to say how **satisfied, happy or good** you have felt about various aspects of your life over the last two weeks, for example, about your family life or you energy level. Decide how satisfied or dissatisfied you are with each aspect of your life and then circle the number that best fits how you feel about this. **Questions refer to the last two weeks.**

66. How satisfied are you with the quality of your life? (G2)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

67. In general, how satisfied are you with your life? (G3)

Very dissatisfied	Dissatisfied	Neither satisfied	Satisfied	Very satisfied

		nor dissatisfied		
1	2	3	4	5

68. How satisfied are you with your health? (G4)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

69. How satisfied are you with your energy? (F2.3)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

70. How satisfied are you with your sleep? (F3.3)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

71. How satisfied are you with your ability to learn new information? (F5.2)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

72. How satisfied are you with your ability to make decisions? (F5.4)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

73. How satisfied are you with yourself? (F6.3)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

74. How satisfied are you with your abilities? (F6.4)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

75. How satisfied are you with the way your body looks? (F7.4)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

76. How satisfied are you with your ability to perform daily living activities?(F10.3)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied

1	2	3	4	5

77. How satisfied are you with your personal relationships? (F13.3)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

78. How satisfied are you with your sex life? (F15.3)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

79. How satisfied are you with the support you get from your family? (F14.3)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

80. How satisfied are you with the support you get from your friends?(F14.4)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

81. How satisfied are you with your ability to provide for, or support others? (F13.4)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

82. How satisfied are you with your physical safety and security? (F16.4)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

83. How satisfied are you with the conditions of your living place? (F17.3)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

84. How satisfied are you with your financial situation? (F18.3)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

85. How satisfied are you with your access to health services? (F19.3)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied

1	2	3	4	5

86. How satisfied are you with the social care services? (F19.4)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

87. How satisfied are you with your opportunities for acquiring new skills? (F20.3)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

88. How satisfied are you with your opportunities to learn new information? (F20.4)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

89. How satisfied are you with the way you spend your spare time? (F21.4)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

90. How satisfied are you with your physical environment e.g. pollution, climate, noise, attractiveness? (F22.3)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

91. How satisfied are you with the climate of the place where you live? (F22.4)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

92. How satisfied are you with your transport? (F23.3)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

93. How happy do you feel about your relationships with your family? (F13.2)

Very unhappy	Unhappy	Neither happy nor unhappy	Happy	Very happy
1	2	3	4	5

94. How would you rate your quality of life? (G1)

Very poor	Poor	Neither poor nor good	Good	Very good

1	2	3	4	5

95. How would you rate your sex life? (F15.1)

Very poor	Poor	Neither poor nor good	Good	Very good
1	2	3	4	5

96. How well do you sleep? (F3.1)

Very poor	Poor	Neither poor nor good	Good	Very good
1	2	3	4	5

97. How would you rate your memory? (F5.1)

Very poor	Poor	Neither poor nor good	Good	Very good
1	2	3	4	5

98. How would you rate the quality of social services available to you? (F19.2)

Very poor	Poor	Neither poor nor good	Good	Very good
1	2	3	4	5

99. How satisfied are you with your level of happiness (F4N)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

100. How satisfied are you with the control of your pain? (F61.5i)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

101. How satisfied are you with your ability to make future plans?(F64.5)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

The following questions refer to **how often** you have felt or experienced certain things, for example the support of your family or friends, or negative experiences such as feeling unsafe. If you have not experienced these things at all in the last two weeks, circle the response "never". If you have experienced these things, decide how often and circle the appropriate number. So for example if you have experienced pain all the time in the last two weeks, circle the number next to "Always". **Questions refer to the last two weeks.**

102. How often do you suffer pain? (F1.1)

Never	Seldom	Quite often	Very often	Always
1	2	3	4	5

103. Do you generally feel content? (F4.2)

Never	Seldom	Quite often	Very often	Always
1	2	3	4	5

104. How often do you have negative feelings, such as blue mood, despair, anxiety, depression? (F8.1)

Never	Seldom	Quite often	Very often	Always
1	2	3	4	5

105. How often does your pain make you feel angry? (F62.3)

Never	Seldom	Quite often	Very often	Always
1	2	3	4	5

106. How often does your pain make you feel irritable? (F62.5)

Never	Seldom	Quite often	Very often	Always
1	2	3	4	5

The following questions refer to any **work** that you do. **Work here means any major activity that you do. This includes voluntary work, studying full-time, taking care of the home, taking care of children, paid work, or unpaid work. So work, as it is used here, means the activities you feel take up a major part of your time and energy. Questions refer to the last two weeks.**

107. How much are you able to work? (F12.1)

Not at all	Not much	Moderately	A great deal	Completely
1	2	3	4	5

108. To what extent do you feel able to carry out your duties? (F12.2)

Not at all	Not much	Moderately	A great deal	Completely
1	2	3	4	5

109. How satisfied are you with your capacity for work? (F12.4)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

110. How would you rate your ability to work? (F12.3)

Very poor	Poor	Neither poor nor good	Good	Very good
1	2	3	4	5

The next few questions ask about **how well you were able to move around** in the last two weeks. This refers to your physical ability to move your body in such a way as to allow you to move about and do the things you would like to do, as well as the things that you need to do. **Questions refer to the last two weeks.**

111. How well are you able to get around? (F9.1)

Very poor	Poor	Neither good nor poor	Good	Very good
1	2	3	4	5

112. How much do any difficulties in mobility bother you? (F9.3)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

113. To what extent do difficulties in movement affect your way of life? (F9.4)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

114. How satisfied are you with your ability to move around? (F9.2)

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
1	2	3	4	5

The following questions are concerned with **your personal beliefs** and how these affect your quality of life. These questions refer to religion, spirituality and any other personal beliefs you may hold. Once again these questions refer to the **last two weeks.**

115. How much do personal beliefs give meaning to your life? (F24.1)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

116. To what extent do you feel life to be meaningful? (F24.2)

Not at all	Not much	Moderately	Very much	Extremely
1	2	3	4	5

117. How much do your personal beliefs give you the strength to face difficulties? (F24.3)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

118. To what extent do your personal beliefs help you to understand the difficulties in life? (F24.4)

Not at all	Not much	A moderate amount	Very much	An extreme amount
1	2	3	4	5

IMPORTANCE QUESTIONS

The following questions ask about how important various aspects of your life are to you. We ask that you think about how much these affect your quality of life. For example one question asks about how important sleep is to you. If sleep is not important to you, circle the number next to "not important". If sleep is "very important" to you, but not "most important", you should circle the number next to "Very important". Unlike earlier questions, these questions **do not refer only to the last two weeks.**

1. How important to you is your overall quality of life? ImpG.1

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

2. How important to you is your health? ImpG.2

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

3. How important to you is it to be free of any pain? Imp1.1

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

4. How important to you is having energy? Imp2.1

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

5. How important to you is restful sleep? Imp3.1

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

6. How important to you is it to feel contented? Imp4.1 (Imp4.2)

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

7. How important to you is being able to think through everyday problems and make decisions? Imp5.1 (Imp5.2)

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

8. How important to you is feeling positive about yourself? Imp6.1

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

9. How important to you is your body image and appearance? Imp7.1

Not important	A little important	Moderately important	Very important	Extremely important

1	2	3	4	5

10. How important to you is it to be free of negative feelings like sadness, depression, anxiety, worry...? Imp8.1

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

11. How important to you is it to be able to move around? Imp9.1

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

12. How important to you is being able to take care of your daily living activities e.g. washing, dressing, eating? Imp10.1

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

13. How important to you is it to be free of dependence on medicines or treatments? Imp11.1

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

14. How important to you is being able to work? Imp12.1

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

15. How important to you are relationships with other people? Imp13.1

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

16. How important to you is support from others? Imp14.1

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

17. How important to you is your sex life? Imp15.1

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

18. How important to you is feeling physically safe and secure? Imp16.1

Not important	A little important	Moderately	Very important	Extremely

		important		important
1	2	3	4	5

19. How important to you is your home environment? Imp17.1

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

20. How important to you are your financial resources? Imp18.1

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

21. How important to you is being able to get adequate health care? Imp19.1

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

22. How important to you are the chances for getting new information or knowledge? Imp20.1

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

23. How important to you is relaxation and leisure? Imp21.1

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

24. How important to you is your environment e.g. pollution, climate, noise, attractiveness? Imp22.1

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

25. How important to you is adequate transport in your everyday life? Imp23.1

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

26. How important to you are your personal beliefs? Imp24.1

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

27. How important is it for you to be able to obtain relief from pain? (Imp61.1)

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

28. How important is it to be able to control your pain? (Imp61.2)

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

29. How important is it for you to be free from anger and frustration? (Imp62.1)

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

30. How important is it for you to be free from fear and worry? (Imp63.1)

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

31. How important is it for you to be free from uncertainty? (Imp64.1)

Not important	A little important	Moderately important	Very important	Extremely important
1	2	3	4	5

ABOUT YOU

We would like you to answer a few general questions about yourself: by **circling** the correct answer or by **filling in the space provided.**

What is your gender? **MALE / FEMALE**

What is your date of birth? ____/____/____ (day / month / year)

What is the highest education you have received?
None at all
Primary School
Secondary School
Further Education e.g. Technical/Clerical
University

What is your marital status?
Single **Separated**
Married **Divorced**
Living as married **Widowed**

How is your health?

(F9.1)

Very poor	Poor	Neither good nor poor	Good	Very good
1	2	3	4	5

Are you currently ill? **YES / NO**

If something is wrong with your health, what do you think it is? Please write your illness(s) or problems here____

____

How long have you been in pain? _______________ months ________________ years

What do you think is causing your pain? _____________________________________

____

Which parts of your body hurt? **(Please tick <u>all</u> those that apply to you)**

Head, face and/ or mouth	
Upper back	
Upper shoulder and/ or arms	
Middle back or chest	
Abdomen	
Lower back and spine	
Legs	
Pelvis	
Other (please specify)	

Is your pain………? **(Please tick only <u>one</u>)**

Brief	
Continuous	
Intermittent	

How intense is your present pain level? **(Please tick only <u>one</u>)**

No pain	
Mild	
Discomforting	
Distressing	
Horrible	
Excruciating	

Are you currently in paid work? **YES / NO**

What is your occupation? ____

Syntax files and scoring for the WHOQOL-100 and PDM

```
SUBTITLE 'WHOQOL AND PDM SCORING'

RECODE f11 f12 f13 f14 f21 f22 f23 f24 f31 f32 f33 f34 f41 f42
f43 f44
f51 f52 f53 f54 f61 f62 f63 f64 f71 f72 f73 f74 f81 f82 f83 f84 f91
f92 f93 f94 f101 f102 f103
f104  f111 f112 f113  f114  f121 f122 f123 f124 f131 f132 f133
f134 f141 f142 f143 f144 f151 f152
f153 f154 f161 f162 f163 f164 f171 f172 f173 f174 f181 f182
f183 f184 f191 f192 f193 f194 f201
f202 f203 f204 f211 f212 f213 f214 f221 f222 f223 f224 f231
f232 f233 f234 f241 f242 f243 f244 g1
g2 g3 g4 f616i f622 f627 f633 f632 f638 f635i f642 f644 f647
f613i
f617 f615i f645 f623 f625
(1=1) (2=2) (3=3) (4=4) (5=5) (ELSE=SYSMIS).

RECODE f11 f12 f13 f14 f22 f24 f32 f34 f72 f73 f81 f82 f83 f84
f93 f94 f102 f104 f111 f112 f113
f114 f131 f154 f163 f182 f184 f222 f232 f234 f622 f623 f625
f627 f632 f633 f635i f638 f642 f644
f647
(1=5)(2=4)(3=3)(4=2)(5=1).

SUBTITLE 'COMPUTE FACET AND DOMAIN SCORES'

COMPUTE pain=(MEAN.3(f11,f12,f13,f14))*4.
COMPUTE energy=(MEAN.3(f21,f22,f23,f24))*4.
COMPUTE sleep=(MEAN.3(f31,f32,f33,f34))*4.
COMPUTE pfeel=(MEAN.3(f41,f42,f43,f44)) *4.
COMPUTE think=(MEAN.3(f51,f52,f53,f54))*4.
COMPUTE esteem=(MEAN.3(f61,f62,f63,f64))*4.
COMPUTE body=(MEAN.3(f71,f72, f73, f74))*4.
COMPUTE neg=(MEAN.3(f81, f82,f83, f84))*4.
COMPUTE mobil=(MEAN.3(f91,f92,f93,f94))*4.
COMPUTE activ=(MEAN.3(f101,f102,f103,f104))*4.
COMPUTE medic=(MEAN.3(f111,f112, f113, f114))*4.
COMPUTE work=(MEAN.3(f121, f122, f123, f124))*4.
COMPUTE relat=(MEAN.3(f131, f132, f133, f134))*4.
COMPUTE supp=(MEAN.3(f141, f142, f143, f144))*4.
COMPUTE sexx=(MEAN.3(f151,f152,f153,f154))*4.
COMPUTE safety=(MEAN.3(f161, f162, f163, f164))*4.
COMPUTE home=(MEAN.3(f171,f172, f173, f174))*4.
COMPUTE finan=(MEAN.3(f181, f182,f183,f184))*4.
COMPUTE servic=(MEAN.3(f191, f192, f193,f194))*4.
COMPUTE inform=(MEAN.3(f201,f202,f203,f204))*4.
COMPUTE leisur=(MEAN.3(f211, f212, f213, f214))*4.
COMPUTE enviro=(MEAN.3(f221, f222,f223,f224))*4.
COMPUTE transp=(MEAN.3(f231,f232, f233, f234))*4.
COMPUTE spirit=(MEAN.3(f241,f242, f243, f244))*4.
COMPUTE overll=(MEAN.3(g1,g2,g3,g4))*4.
COMPUTE relief=(MEAN.3(f616i, f613i, f615i, f617))*4.
COMPUTE anger=(MEAN.3(f622, f623, f625, f627))*4.
COMPUTE vulner=(MEAN.3(f632, f633, f635i, f638))*4.
COMPUTE uncert=(MEAN.3(f642, f644, f645, f647))*4.
COMPUTE DOM1=MEAN.2(pain,energy,sleep).
COMPUTE DOM2=MEAN.4(pfeel,think, esteem, body, neg).
COMPUTE DOM3=MEAN.3 (mobil,activ, medic,work).
COMPUTE DOM4=MEAN.2(relat,supp,sexx).
COMPUTEDOM5=MEAN.6(safety,home,finan,servic,inform,
leisur,enviro, transp).
COMPUTE DOM6=spirit.

SUBTITLE 'TRANSFORM SCORES TO A 0-100 SCALE'

COMPUTE tpain =(pain-4)*(100/16).
COMPUTE tenergy=(energy-4)*(100/16).
COMPUTE tsleep=(sleep-4)*(100/16).
COMPUTE tpfeel=(pfeel-4)*(100/16).
COMPUTE tthink=(think-4)*(100/16).
COMPUTE testeem=(esteem-4)*(100/16).
COMPUTE tbody=(body-4)*(100/16).
COMPUTE tneg=(neg-4)*(100/16).
COMPUTE tmobil=(mobil-4)*(100/16).
COMPUTE tactiv=(activ-4)*(100/16).
COMPUTE tmedic=(medic-4)*(100/16).
COMPUTE twork=(work-4)*(100/16).
COMPUTE trelat=(relat-4)*(100/16).
COMPUTE tsupp=(supp-4)*(100/16).
COMPUTE tsexx=(sexx-4)*(100/16).
COMPUTE tsafety=(safety-4)*(100/16).
COMPUTE thome=(home-4)*(100/16).
COMPUTE tfinan=(finan-4)*(100/16).
COMPUTE tservic=(servic-4)*(100/16).
COMPUTE tinform=(inform-4)*(100/16).
COMPUTE tleisur=(leisur-4)*(100/16).
COMPUTE tenviro=(enviro-4)*(100/16).
COMPUTE ttransp=(transp-4)*(100/16).
COMPUTE tspirit=(spirit-4)*(100/16).
COMPUTE toverl=(overll-4)*(100/16).
COMPUTE trelief=(relief-4)*(100/16).
COMPUTE tanger=(anger-4)*(100/16).
COMPUTE tvulner=(vulner-4)*(100/16).
COMPUTE tuncert=(uncert-4)*(100/16).
COMPUTE TPHYS=(dom1-4)*(100/16).
COMPUTE TPSYCH=(dom2-4)*(100/16).
COMPUTE TIND=(dom3-4)*(100/16).
COMPUTE TSOCIAL=(dom4-4)*(100/16).
COMPUTE TENVIR=(dom5-4)*(100/16).
COMPUTE TSPIR=(dom6-4)*(100/16).

COUNT TOTAL=f12 to f625 (1 THRU 5).
FILTER OFF.

EXECUTE
```