

The development of a quality of life instrument for osteoarthritis

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The candidate confirms that the work submitted is her own work and that appropriate credit has been given where reference has been made to the work of others.

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The development of a quality of life instrument for osteoarthritis.

Abstract

Osteoarthritis (OA) is a common condition and a leading cause of pain and disability. The aim of this thesis was to explore issues associated with living with OA, develop an OA specific quality of life instrument and explore the physical and psychosocial factors that contribute to quality of life.

A multiple methodological approach was used in this thesis. In the first study, analysis was undertaken of a large, community based survey to examine the prevalence and impact of joint problems on everyday activities. In the second study, in depth, semi-structured interviews were undertaken with 44 people with OA to explore the issues associated with living with OA. From these interviews, a disease specific, needs-based, quality of life instrument, the OAQoL, was developed and tested for appropriate psychometric properties. In the final study, the effect of physical and psychosocial influences on quality of life was explored. Structured equation modelling was used to construct a model explaining the relationship between pain, function, depression, anxiety, disease characteristics and demographics on quality of life.

The key findings of this programme of work can be summarised as follows: (i) OA has an often considerable and complex impact on the individual; (ii) the OAQoL, a needs-based, disease specific outcome measure to assess of quality of has been derived from a strong conceptual framework and has rigorously tested for its psychometric properties; (iii) Anxiety and depression are high in people with OA and anxiety has a substantial influence on their perceived quality of life; (iv) co-morbidities are common

in OA and are related to impairment of activities of daily living and quality of life; and (iv) while the location and number of painful joints in those with OA impacts on their ability to undertake the tasks of daily living, other aspects, such as anxiety, age and functional ability have a more substantial impact on quality of life.

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Publications and Presentations

The following publications and presentations have resulted from this thesis:

Papers Published

- **Keenan AM**, Tennant A, Fear J, Emery P and Conaghan PG. (2006). Multiple Joint problems in the population: prevalence and impact on function. *Arthritis & Rheumatism*: 55(5): 757-764.

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Papers in Review

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Invited Conference Podium Presentations

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Chapter One

Introduction

Osteoarthritis (OA) is the most common cause of musculoskeletal pain¹ and the most frequent single cause of disability². While the impact on the quality of life in individuals with OA has been identified as important, no disease specific tool exists to assess this impact. Furthermore, while treatment of OA is often focused around knee and hip arthritis as single joint entities, the prevalence of other joint and joint combinations needs to be explored. It is therefore important to establish the prevalence and site of joint pain, that an instrument be developed which measures the impact of OA on quality of life (OoL), and this impact be explored in terms of the general disease, joint specific influence and the impact of multiple joint problems.

The hypothesis explored in this thesis is:

The number and pattern of joint involvement in OA will be reflected in the level of patient perceived quality of life.

This thesis will use four main methodologies in order to explore this hypothesis:

- i. an epidemiological analysis of the prevalence and impact of joint problems
- ii. qualitative analytical techniques to explore the issues associated with the impact of living with osteoarthritis and to form the base to develop a quality of life questionnaire for individuals with OA (OAQoL) at various sites
- iii. quantitative analytical techniques to assess the psychometric properties and clinical responsiveness of the OAQoL questionnaire
- iv. modelling techniques to describe the interrelationships between quality of life (as measured by the OAQoL) and physical and psychosocial factors.

The thesis has been structured thus:

Chapter Two is a review of the literature and provides the background information which has informed the hypothesis of this program of work. In this chapter, the prevalence, classification and site of OA is discussed. Issues associated with ageing, co-morbidities and case ascertainment are identified. An overview of outcome measurements commonly used in OA is presented and factors associated with patient orientated outcomes, disease specific and generic tools are analysed. Finally, the conceptual basis of “quality of life” is explored, with an emphasis on the needs-based approach to quality of life.

Chapter Three provides a detailed examination of the methodologies used in this thesis. Chapter Three provides the conceptual framework for examining the incidence and impact of joint pain in a large community cohort, developing an OA specific quality of life tool and exploring the conceptual framework on which this tool is based through structural equation modelling techniques. Chapter Three also describes the theoretical basis for the qualitative approaches used to explore issues associated with living with osteoarthritis.

The results of the studies are presented in *Chapters Four, Five, Six and Seven*.

Chapter Four reports the prevalence and interrelationships of joint dysfunction at different sites. This chapter is a secondary analysis of a large, community study which evaluated the demand for hip and knee arthroplasty. This analysis examines the prevalence of single and multiple joint problems and examines the impact of patterns of joint problems, particularly multiple-site joint pathology, on everyday activities.

Chapter Five reports the results of a qualitative study exploring the impact of living with OA. In depth, semi-structured interviews were undertaken with 44 people with OA, who were purposefully selected and included those with single site foot, knee, hand and hip OA and multiple-site OA. Thematic analysis was undertaken of the interviews, indicating complex issues associated with living with OA, including loss of personal and societal roles, influences on coping and perceptions of others to their disease.

Chapter Six describes in detail the derivation, development and validation of the OAQoL, a needs-based, quality of life instrument. Items were generated from in-depth interviews with patients, tested on a small group of people with OA for clarity and ease of completion, mailed out to a large patient cohort for analysis of the psychometric properties and then examined for test-retest properties.

Chapter Seven presents the results of a study analysing the effect of physical and psychosocial influences on quality of life. Structured equation modelling was used to construct a model explaining the relationship between pain, function, depression, anxiety, disease characteristics and demographic information on quality of life.

Finally, *Chapter Eight* presents a discussion of the results of each of the studies and an analysis of the thesis as an integrated program of work. The discussion includes the relevance of the studies to the existing body of knowledge and how the current work may impact on clinical practice. This chapter concludes with an outline of further areas of research arising as a result of this thesis.

Chapter Two

Background and Review of the Literature

2.1 Osteoarthritis

2.1.1 The prevalence and burden of Osteoarthritis

Osteoarthritis (OA) is the most frequently reported medical condition within the community³ and is one of the ten most disabling diseases in developed countries⁴. Worldwide estimates indicate that one in ten men and one in five women aged over 60 have symptomatic OA⁴ which represents a considerable burden on health care expenditure^{5,6}. Those with arthritis are more likely to perceive themselves as mentally and physically unhealthy². The influence of the ageing population in developed countries suggests that OA will have an even greater impact on health resources in medium to long term health economic predictions⁷.

Osteoarthritis generally refers to a clinical syndrome of joint pain, functional loss and reduced quality of life. In terms of pathology, OA refers to a process of imbalanced degradation and repair that affects multiple joint tissues. It is classically characterized by focal loss of articular cartilage, degradation of subchondral bone and the development of osteophytes. While OA was previously considered to be a disease of the articular cartilage and bone, it is now recognised that OA is a whole joint organ disease^{8,9}. It has been suggested that the aetiology and progression of OA may be due to any of the tissues of the affected organ, including the subchondral bone, synovium, capsule, peri-articular muscles, sensory nerve endings, ligaments and, if present, menisci¹⁰. Indeed, it has been suggested that muscle and neuromuscular control are of greater importance in the development of OA than the cartilage and bone¹¹.

While the prevalence of OA increases with age, it is not exclusively a disease of the elderly. This is highlighted in a community survey where the incidence of symptomatic OA was shown to increase two to ten fold from 30 to 65 years of age and increased further thereafter, to the highest prevalence in the 70 to 79 age group, after which time the prevalence of symptomatic OA is reduced^{12, 13}. In people aged 25 and over, the prevalence for OA is thought to be about one in ten¹⁴.

OA is a chronic condition initiated by a complex interaction of biochemical, genetic and biomechanical factors. The importance of each has received considerable attention in the recent literature. Geneticists have identified several genes that may be involved in OA¹⁵. What is clear is that biomechanical factors assume a key role, of which we have only limited understanding. Recent findings have suggested that importance of the mechanical loading of joints is not only the progression of OA, but more importantly, the initiation of the disease¹⁶.

One of the key barriers to understanding and treating OA is that OA may be the common final pathway of a group of pathological processes which has pain and joint failure as the clinical presentation¹⁷. OA may therefore represent a number of heterogeneous conditions where joint failure and damage is triggered in a variety of ways.

Several risk factors have been identified which are thought to contribute to OA, although the importance and interrelationship between each differs depending on the site of OA¹⁸. Risk factors which have been associated with OA include genetic predisposition¹⁹, obesity^{20, 21}, diminished bone mineral density²², female gender²¹ and insufficient nutrition¹⁸. In addition to these factors, localised joint or direct mechanical influences which have been identified as predisposing to OA: these include ongoing

joint overloading (including occupational²³ and sporting participation²⁴), joint malalignment^{21, 25, 26}, previous joint trauma²⁷ and existing joint pathology, such as ligament damage²⁸. A summary of these factors are represented in Figure 2.1.

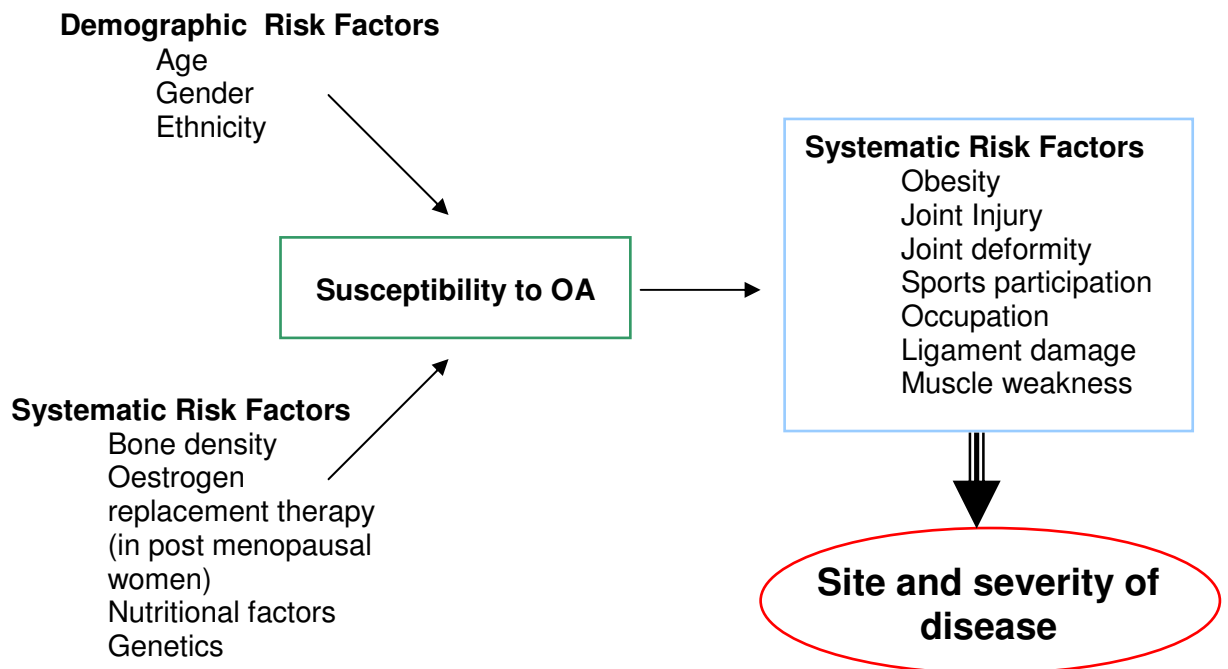


Figure 2.1 Pathogenesis of osteoarthritis with putative risk factors. Modified from Felson et al¹⁸, pg 637.

2.1.2 Diagnostic Criteria

Surprisingly, no diagnostic criteria exist for OA. The diagnosis of OA is often made on radiographic evidence in conjunction with patient reported symptoms, particularly pain and stiffness²⁹. There has been however, considerable debate as to the relevance of radiographs in OA: it is clear that many people have radiographic confirmation of OA yet no symptoms and others have severe symptoms with little radiographic

evidence³⁰. There is evidence to suggest that radiographs are of most use in knee OA in severe or established disease³¹.

The American College of Rheumatologists (ACR) have developed a classification system for OA of the hand³², knee³³ and hip³⁴ with the aim of differentiating OA from other arthritides (Table 2.1). These clinical classification criteria have become widely accepted and are commonly used in both practice and research settings, with moderate to good sensitivity and specificity. However, no such diagnostic criteria exist for the other sites of OA presentation, and diagnosis is often attributed to the presence of radiographic changes according to the Kellgren and Lawrence system³⁵. The validity of the ACR clinical classification criteria for OA has been questioned, because of concerns over inter-observer variability and issues associated with radiographic interpretation³⁶, including agreement over the presence of osteophytes, when there is debate as to what stage in the disease osteophytes may form³⁷.

The lack of clear diagnostic criteria may arise because of disagreement to whether OA is a single disease or many disorders with a common final pathway. Felson¹⁸ suggests the following points support the latter idea:

1. OA of the knee and hip may be associated with different risk factors, suggesting we should regard them as different diseases
2. "Generalised OA" may be a distinct disease in which systemic predisposition (such as genetic factors) are more important than local (such as mechanical) factors.
3. The classification of known (secondary) compared with unknown (primary) cause is often adopted
4. Hip OA has been classified into hypertrophic and atrophic forms on the basis of the tendency to develop large osteophytes

	Criteria	Criteria	
Hip ^a	ACR Criteria for Diagnosis and Classification of Osteoarthritis of the Hip ³⁴	1. Hip pain, and either	
		2(a). Hip Internal rotation less than 15° 2(b) ESR ≤ 45 mm/hour (if ESR not available, substitute hip flexion ≤115°) or 3(a) Hip internal rotation greater than 15° 3(b) Pain on hip internal rotation 3(c) Morning stiffness of the hip ≤60 mins 3(d) Age >50 years	
Hand ^b	ACR Criteria for Diagnosis and Classification of Osteoarthritis of the Hand ³²	1. Hand pain, aching or stiffness	
		2. Hard tissue enlargement of two or more of ten selected joints 3. Fewer than 3 swollen MCPJs 4(a). Hard tissue enlargement of 2 or more DIPJs or 4(b) Deformity of two or more selected joints	
Knee ^c	ACR Criteria for Diagnosis and Classification of Osteoarthritis ³³	Clinical and laboratory	Clinical and radiographic
			Clinical
		1. Knee pain + at least 5 of 9:	1. Knee pain + at least 1 of 3:
		2. Age > 50 years	2. Age > 50 years
		3. Stiffness < 30 minutes	3. Stiffness < 30 minutes
		4. Crepitus	4. Crepitus
		5. Bony Tenderness	5. Bony Tenderness + Osteophytes
		6. Bony enlargement	6. Bony enlargement
		7. No palpable warmth	7. No palpable warmth
		8. ESR <40 mm/hour	
		9. RF <1:40	<i>Alternative for the clinical category would be 4 of 6, which is 84% sensitive and 89% specific</i>
		10. SF OA	
		<i>92% sensitive, 75% specific</i>	<i>91% sensitive; 86% specific</i>
			<i>95% sensitive; 69% specific</i>

Table 2.1 ACR Diagnostic Criteria for Osteoarthritis at the hip, hand and knee.

^aThis classification method yields a sensitivity of 86% and a specificity of 75%. ESR = erythrocyte sedimentation rate.

^bThe 2nd and 3rd DIPJ may be counted in both item 2 and 4(a). The 10 selected joints are the second and third distal interphalangeal (DIP), the second and third proximal interphalangeal, and the first carpometacarpal joints of both hands. This classification method yields a sensitivity of 94% and a specificity of 87%. MCP = metacarpophalangeal. ^c

SF OA = synovial fluid signs of OA (clear, viscous, or white blood cell count <2,000/mm³).

Furthermore, Huch³⁸ supports this multi-disorder concept by demonstrating that

5. There are differences in the pathophysiology of damaged tissues in OA at the different sites.

Given the absence of a clear basis for the objective diagnosis of OA and the importance placed on symptoms, there has been a recommendation that the most compelling definition of OA is one that combines the joint pathology of the disease with the pain that occurs with joint use¹⁸.

Pain in OA

Pain is considered to be one of the most important symptoms in OA: pain as one of key factors considered in the assessment of patients³⁹ and it is the major impetus for people with OA to seek treatment⁴⁰. Pain in OA, particularly frequency of painful episodes, has been related to increased demands on the health services: for example, Dominick et al⁴⁰ found that those who reported higher levels of OA pain were more likely to visit the doctor, use analgesics or anti-inflammatory medication, including narcotic analgesia. However, while patients and clinicians agree that pain is important, the importance that each group place on pain in OA is different⁴¹.

Pain in OA is a complex phenomenon with physical and psychosocial elements. While OA pain had previously been thought to be associated with local tissue damage, greater emphasis has been placed on the theory of central sensitisation of OA pain. It has been noted that people with end stage knee OA waiting for knee arthroplasty had a decreased pain threshold elsewhere in their body, which was reversed after surgery where their pain thresholds return to normal⁴². Furthermore, it has been suggested that pain associated with knee OA behaves as a regional pain syndrome, similar to low back pain⁴³.

While pain is the dominant symptom and is the target for most OA therapies, the severity of pain and its impact on the individual varies enormously. Pain has a strong association with reduced activities⁴⁴, but OA pain has been found to be only weakly associated with health related quality of life⁴³ and is not necessarily predictive of analgesic use⁴⁵ or the decision for them to undergo joint replacement surgery^{46, 47}.

Several factors have been identified which may explain how people adapt and deal with pain, particularly with OA. Pain studies have demonstrated that ability to deal with pain is not just related to pain intensity, but several other physical and psychological factors, including the functional impact of the pain (such as limiting activities or restricting participation) and character traits (such as self efficacy)⁴⁸. The link between reduced coping with OA pain and additional co-morbidities⁴⁸, particularly depression⁴⁹ and anxiety⁵⁰, has been established.

There has been much focus on the relationship between radiographic structure and pain relationships in OA. Traditionally, radiographic changes were thought to be associated with greater disease activity. This approach has been challenged in recent years: there is now evidence to suggest that 50% of people in the general population who have radiographic evidence of OA, report no pain⁵¹. Furthermore, over half of people with pain suspected to be due to OA have no definite radiographic evidence of the disease³⁰.

At the same time a direct relationship between pain and radiographic tissue damage has been questioned⁴², there has also been a growing debate as to the importance of pain in predicting structural progression of OA. Some authors have found that radiographic disease progression is more rapid and more frequent with people who

reported pain 12 to 24 months previously⁵². Contradictory results, however, have challenged this where pain bore no relationship to long term structural progression⁵³.

Several theories have been proposed to explain the lack of concordance between pain and radiographic damage. Firstly, there appears to be a threshold effect between the Kellgren and Lawrence Scores (K-L) and pain: there is very little association between pain and radiographic damage in mild disease (K-L score of 0 and 1) but a much greater association when the damage is greater (KL score 2+)⁵⁴. Secondly, the lack of concordance between symptoms and radiographs may be associated with the inability of radiographs to image the tissues that are the source of the pain, such as synovitis or subchondral bone abnormalities. Finally, others authors refer to the issues that the types of x-rays that are undertaken, particularly in the knee, are inappropriate⁵⁵ and which may not allow optimal examination of the affected area.

The use of MR imaging has enabled a new approach to evaluation of the tissues involved in OA, including cartilage, bone, synovium, ligaments and menisci. Studies have demonstrated the importance of bone marrow oedema in the progression of cartilage loss⁵⁶. However while there is the potential to explore the relationship between these tissues and joint pain, current available data has again demonstrated only a weak association with bone marrow oedema and pain⁵⁷. Furthermore, other studies have found an association between joint tissue which has little neural tissue (menisci and cartilage) and pain^{58, 59}, suggesting that the causes of pain in OA is still not fully understood.

Activity Limitation in OA

Activity limitation (also referred to as functional ability or disability) is also commonly reported by patients with OA. Whilst able to exist independently of one another, typically pain and functional disability occur concurrently⁶⁰. OA is the most common

cause of disability and the impact of activity limitation in people with OA is substantial: people with arthritis are more likely to report impairments in activities of daily living (such as personal care, household management, transportation, employment) compared to other causes of disability⁶¹. Furthermore, reduced physical activity is a risk factor for further functional decline in older people with OA^{62, 63}.

While a direct link has been reported between knee pain and self reported disability⁶⁴, pain is not the only factor related to disability. As with a person's ability to cope with pain, their response to activity limitation will depend on several, complex factors. In hand OA for example, impairment was more strongly associated with personal factors such as self efficacy, rather than functional ability⁶⁵. Several studies have found that in addition to joint pathology and body mass index, functional limitation was related to depressive symptoms and anxiety^{64, 66}. Fear avoidance, pain intensity and pain catastrophising were also found to be predictive of disability⁴⁸; when compared together however, self efficacy was found to be the more powerful predictor of disability⁴⁸.

Depression and Anxiety in OA

While the association between depression and rheumatoid arthritis has received considerable attention, there is only limited literature evaluating the association between depression, anxiety and osteoarthritis. Early literature suggested that the prevalence of anxiety and depression was thought to be similar to that in the general population⁶⁷. More recent data have questioned this, with over one third of a primary care based OA cohort reporting borderline to high levels of anxiety and one quarter reporting borderline to high levels of depression⁶⁸. Much of the information published on anxiety and depression has been in those with severe OA undergoing joint replacement surgery: people with end-stage OA waiting for joint replacement reported high anxiety and depression levels, both of which improved after joint

replacement⁶⁹. Distress has also been reported as high for those waiting for surgery and is also predictive of those who have poorer surgical outcomes⁷⁰. In those with general OA, the focus has been on depression and joint pain: those with knee pain in the community report higher levels of psychological distress⁷¹, depression and anxiety^{50, 72}.

There is thought to be a bi-directional association between depression and functional ability in OA: increased depression results in reduced activity and reduced activity results in increased depression⁶⁶. While the same bi-directional relationship is thought to exist between depression and pain⁷³, this is less clear than the impact of depression on functional outcomes⁵⁰.

Very little attention has been given to the relationship between anxiety and OA: higher levels of anxiety were reported in those with knee pain and the levels of pain and anxiety were correlated⁵⁰. The direction of this relationship, is still unclear: increased anxiety may be a risk factor for reporting more OA pain, or pain may increase anxiety levels⁷⁴.

2.1.3 Site of OA

While prevalence statistics have been reported for different sites of OA, lack of agreement over what constitutes OA has ensured that reported values vary considerably. Prevalence estimates have used radiographic^{30, 75}, symptoms⁷⁶, physician diagnosis⁷⁷ or a combination⁷⁵ to report the incidence of OA. For example, prevalence estimates for knee OA vary from as little as 13%³⁰ (radiographic evidence *and* symptoms) to as high as 66%⁷⁸ (evidence of radiographic change only). The prevalence of knee OA over the age of 60 (based on symptoms and radiographic

evidence) is reported to be between 17% in men and 30% in women^{14, 18, 77, 79, 80}.

Reported prevalence of hip OA, based on radiographic evidence and symptoms, ranges from 7 to 25% in the over 55 age group^{77, 81, 82}.

While OA of the hip and knee account for the largest component of the burden of the disease^{77, 79}, there is, however, evidence to suggest that both hand and foot OA is very common. In people over the age of 65, 70% have radiographic OA in the hand^{83, 84} and those with hand OA are more likely to develop knee and hip OA in the future⁸⁵. Most large prevalence studies have ignored other common sites of pain, particularly the hand and the foot.

Prevalence estimates of foot OA are limited, and most of the data are based on radiographic or cadaveric investigations. Symptomatic foot OA prevalence may be as high one in five in people aged between 24 and 75¹⁴ and in the older population (over 75 years) this could be as high as four in five adults⁷⁸. Only one study, the Clearwater Osteoarthritis study¹⁵, has looked at individual sites of OA in the foot. Data from this study is reproduced in Table 2.2 and suggests that radiographic OA of foot and the hand is more prevalent than that of the knee.

	All (%)	Women (%)	Men (%)
Knee	16.6	15.7	18.6
Hand	23.2	23.9	21.9
Foot	20.0	17.7	25.1
First MTPJ	Not reported	25.0	18.0

Table 2.2 Prevalence of radiographic grade 2+ OA. Adapted from Wilder et al¹⁵, pg 212.

The relative lack of attention paid to foot OA may be associated with a number of factors. Firstly, cadaveric and radiographic studies suggest that the OA pathology in the joints of the foot is often mild to moderate, rather than at the severe end of the spectrum^{14, 78} (Table 2.3). Secondly, it has been suggested that the complex joint functioning of the foot may allow people with OA pain to compensate and therefore deflect pain and pressure away from the painful site¹⁵, which cannot be done as easily at the knee and the hip. Finally, the burden on health services on large joint replacement may have focussed research in these areas at the expense of small joint surgery.

		OA Radiographic Severity (per 1,000)					
		Mild, moderate and severe			Moderate to severe		
Site	Age	Male	Female	Total	Male	Female	Total
Hands	25 to 74 years	289	301	295	48	95	73
Feet	25 to 74 years	202	214	208	15	27	23
Knees	63 to 93 years	309	344	33	16	155	157
Hip	55 to 74 years	30	28	32	14	14	15

Table 2.3. Prevalence of symptomatic OA (symptoms plus radiographic changes) at different site, per 1,000. Data adapted from Lawrence et al¹⁴.

There has been some thought given to the concept that hand and foot OA may represent a more systemic form of the disease and may have a greater association with genetic factors. There is evidence to suggest that the concurrence of foot OA with other sites, particularly the hand and the knee, is suggestive of a heritable association¹⁵. Furthermore, several chromosomal locations have been identified that appear to contain hand OA susceptibility genes⁸⁶.

Clear patterns have emerged for the prevalence of OA related to gender. After the age of 50, women are more likely than men to be affected with hand, foot and knee OA¹⁸. In a recent meta analysis of gender differences in OA¹³, pooled estimates of published literature confirmed that women were more likely than men to report knee and hand OA and that their knee OA was more likely to be severe. The hip was the only location evaluated where men were at a greater risk of OA.

While there is limited recognition that the presentation of multiple joint problems is common⁸⁷, this has not stopped the focus of management strategies within OA being aimed at individual joint problems: indeed, the functional impact on daily tasks of the most common multiple joint combinations has not been explored.

2.1.4 Co-morbidity, Ageing and OA

It has been estimated that almost one third of the population has two or more medical conditions or co-morbidities, with higher incidence reported in females⁸⁸ and an increased incidence of medical complications associated with ageing⁶³. It is not surprising therefore, that people with OA have a higher incidence of medical conditions compared to those of the same age without OA⁸⁹, including obesity, gastritis and heart disease⁸⁹ and depression^{90, 91}.

It is unclear whether OA is a risk factor for other co-morbidities, or whether the impact of OA increases the morbidity with other health conditions. Ettinger⁹² suggested the presence of knee OA with co-existent medical problems increases the amount of disability. Furthermore, Marks⁹³ found that those patients with hip OA and had two or more other medical conditions had greater degrees of functional impairment before and after surgery.

Several studies have identified key themes that illustrate the complex relationship between ageing and OA. Firstly, it is common for older people to normalize their disease as part of ageing rather than a treatable health problem⁹⁴. Secondly, older people with OA tend to minimize their symptoms, preferring to accept their pain rather than seek treatment²⁹, even to the point where they were reluctant to take prescribed painkillers⁴⁵. Finally, this perception that OA is a disease of the elderly has also been attributed to younger people with OA who delay in seeking advice and diagnosis as they consider themselves “too young” to have OA²⁹.

2.2 Measurement issues in OA

Traditionally, the focus of measuring the outcome of OA has centred on assessing the impact of the disease on pain and function. As a consequence, outcome measures that have been developed specifically for OA, such as the Western Ontario and McMasters Universities Osteoarthritis Index (WOMAC)⁹⁵ and the Lequesne Algofunctional Index⁹⁶, focus on such domains. OMERACT (Outcome Measures in Rheumatology Clinical Trials) guidelines expand this slightly with the recommendation that only four domains be evaluated: pain, physical functioning, joint imaging and patient global assessment⁹⁷. Global impact on quality of life or personal issues associated with the disease have commonly been assessed using generic, health-related quality of life outcome measures, particularly the MOS SF-36⁹⁰ and EuroQoL⁹⁸,⁹⁹.

In order to review the outcome measures commonly used and any potential areas for development of new instruments, it is important to understand the framework for the consequences of disease. For over 25 years this framework has been produced by the World Health Organisation's International Classification of Health.

2.2.1 ICF Historical perspective and theoretical constructs

The International Classification of Impairments, Disabilities and Handicaps (ICIDH) was developed as a classification manual of the consequences related to disease¹⁰⁰. The major aim of this document was to provide a framework and common language for the description of health. The theoretical framework for ICIDH was based around the dimensions of health, as presented in Figure 2.2.

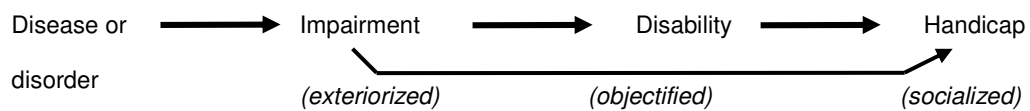


Figure 2.2 Theoretical construct for the development of the ICIDH, adapted from De Kleijn-De, 2003¹⁰¹.

While this classification system was valuable in assisting with disease and consequences, there were several concerns raised as to the linear and unidirectional nature of the connections of the elements of the model¹⁰². Furthermore, the negative portrayal of consequence of disease (ie the logical consequence of disease ends in handicap) was also criticized¹⁰³.

As a consequence, this classification of disease was updated in 2001, with a greater emphasis placed on the more positive aspects (health and functioning) rather than the negative (disease and disability). The new name, the International Classification of Function, Disability and Health (ICF) reflected this change. The new classification also attempted to de-stigmatize disability and recognizes it as a universal experience and shifts the focus from the *cause* of the problem to the *impact*¹⁰⁴. Like the ICIDH,

the ICF provides a scientific basis for understanding health, health outcomes and determinants of health using common language¹⁰⁵.

The ICF has been developed around a biopsychosocial model of disability. This model presents an integration of the social (where disability is a socially created problem and not an attribute of the individual) and the medical model (where disability is a feature of the person caused by disease, trauma or health condition). The other important change in the development of the ICF was a shift in language from negative terms, such as “impairment”, “disability” and “handicap” to the neutral terms of “body function and structure”, “activity” and “participation”. The theoretical construct for the ICF is presented in Figure 2.3.

The ICF is organised into the following components: body function and structures, activities, participation, environmental factors and personal factors. *Body functions and structures* are described as the physiological function of the body system, such as organs, limbs and their components. Impairments to these systems may include loss (such as deformity) of structures (such as joints) and/or function (including pain, reduced range of motion, muscle weakness). *Activities* are the execution of a task or action by an individual and represents functioning. Difficulties in performing these tasks are described as activity limitation (such as walking, using stairs). *Participation* is described as an individual’s ability to be involved in their life situation and problems in experiencing this (such as restrictions in recreation or leisure) is denoted as participation restriction. The contextual factors (personal and environmental) make up the physical, social and attitudinal environment in which people live and conduct their lives.

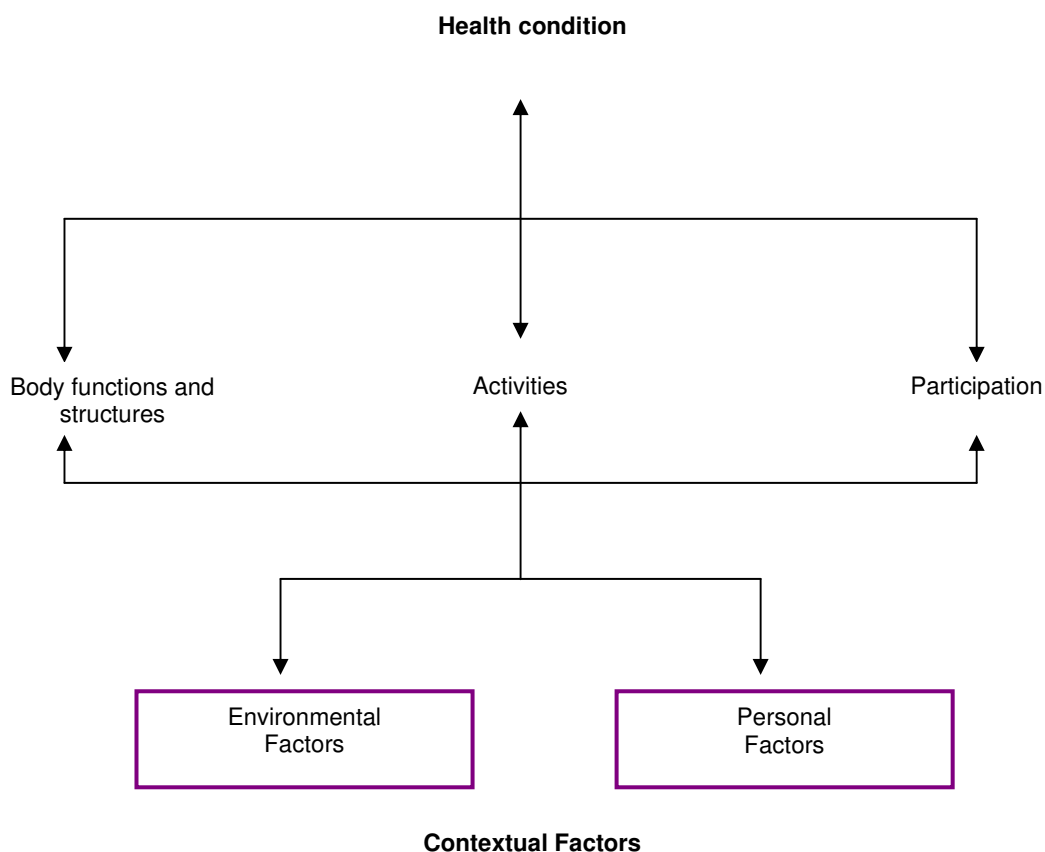


Figure 2.3 Theoretical construct for the development of the ICF, adapted from De Kleijn et al¹⁰¹).

Contextual factors have been described less thoroughly than the other components of the ICF. While body structures, activities and participation are classified and described in chapters. The contextual factors (environmental and personal factors) have not been classified under the ICF chapters, receiving only brief acknowledgement. This may be related to the issues associated with the affect that contextual factors have on individuals: a contextual factor may be considered to be independent, moderating, mediating or confounding¹⁰⁶, depending on the individual and circumstances.

While the ICF was developed as a means to map the different constructs and domains of health and to describe the process of functioning and disability, it was also designed to assist in the development of outcome measures: it was to provide a framework for the assessment of outcome tools by mapping the tools onto the ICF categories in order to gather information for health statistics and health users regarding the burden of disease¹⁰⁷. The two most commonly used outcome measures for OA, the Western Ontario and McMaster Universities (WOMAC) and Lequesne-Algofunctional Index have been mapped¹⁰⁸.

Since 2001, “core sets” of ICF categories for specific health conditions have been developed in part, to link the ICF with the International Classification of Diseases (ID-10) and were primarily intended to provide a comprehensive approach in clinical and research environments. Of note, these core sets were developed “in line with current concepts in outcome and quality of life research of condition-specific measures”¹⁰⁷.

In 2004, a core set was identified for OA, developed by an international panel of health professionals¹⁰⁹. A comprehensive set, containing 55 categories was developed along with the brief, thirteen-category set, as presented in Table 2.4 and have been recently evaluated¹¹³. There remains a question of whether the core sets reflect the needs of patients across a variety of conditions. It is apparent that when health professionals evaluate the comprehensiveness of the core sets, the results are generally positive¹¹⁰; however when patients are asked, the core sets appear to be inadequate^{111, 112}. The only assessment of the OA core set has supported their comprehensiveness in reflecting patient needs¹¹³.

ICF Component	Rank Order	ICF Code	ICF Category Title
Body Functions	1	b280	Sensation of pain
	2	b710	Mobility of joint functions
	3	b730	Muscle power functions
Body Structures	1	s750	Structure of lower extremity
	2	s730	Structure of upper extremity
	3	s770	Additional musculoskeletal structures related to movement
Activities and Participation	1	d450	Walking
	2	d540	Dressing
	4 ^(sic)	d445	Hand and arm use
Environmental Factors	1	e310	Immediate family
	2	e115	Products and technology for personal use in daily living
	3	e580	Health services, systems and policies
	4	e150	Design, construction and building products and technology of buildings for public use

Table 2.4 ICF Categories included in the Brief ICF Core Set for OA. The rank order indicates the perceived importance by health professionals. Taken from Dreinhofer *et al*, pg 78¹⁰⁹.

2.2.2 Key features of a good outcome measure

With the emergence of the biopsychosocial model of health in the last 20 years, the use of patient reported outcomes has become an integral part of the research process. As the field of outcome measures has evolved, so have the methods of assessing the key attributes of what makes an outcome an appropriate tool. Eight key attributes have been identified as appropriate in establishing the usability of an outcome measure¹¹⁴: its conceptual framework and measurement model; reliability; validity; responsiveness; interpretability; administrative burden; alternate forms; and cultural adaptation.

In developing an outcome measure, it is necessary to ensure that the measures have been developed around an appropriate *conceptual framework*. This has been identified as particularly important in quality of life measures where it is often the clinician's interpretation as to what they think that matters their patients¹¹⁵. Recently, the importance of the role of qualitative methodology in developing outcomes has been highlighted¹¹⁶, particularly if the outcome is patient based. The derivation of the items included in an outcome measure should reflect a pre-specified *measurement model*, whereby the relationship between a response to an item in an outcome measure reflects his or her ability as being measured by the outcome^{117, 118}.

The measure should be both reliable and valid, and should include empirical support for criterion and content validity, using an appropriately rigorous method. An outcome measure should also be *reliable*, so that the score obtained each time the questionnaire is administered is the same, all other things being equal¹¹⁹. An outcome should be *valid*, in that it measures what it purports to measure. Other aspects of validity include *content validity*, where a measure includes a representative range of the content of what is being studied; *construct validity* is that concerned with the measure is behaving in the way that is expected from a theoretical and practical perspective; and finally *criterion validity*, which is a special case of construct validity where a measure is assessed against a gold standard. In quality of life measurement, most validity assessment is concerned with construct and content validity in the absence of a true gold standard.

An outcome measure should also be able to detect small, but meaningful changes in a measure. This is referred to as *responsiveness* and should capture change that is of importance to the individual¹¹⁷. Changes in an outcome measure should also be *interpretable*, so that any change in a score has some meaning. The measure must be appropriate for the population to which they are being applied: as such, *cultural*

and language adaptations are necessary outside of the population from which the measure was developed¹²⁰. Finally, the level of *respondent and administration burden*, both to the responder and the researcher/clinician, should be established and acceptable to both groups¹¹⁴.

2.2.3 Outcome measures commonly used in OA

As noted previously, several outcome-based tools have been developed to evaluate pain and physical function in OA, including the WOMAC⁹⁵, Lequesne Index⁹⁶ and the AIMS¹²¹. A summary table of measures commonly used in OA is presented in Tables 2.5 and 2.6. While there are several instruments that have been used to determine pain and physical ability in knee and hip OA, there are, for example, no instruments that have been developed for use specifically in OA of the foot. A recent systematic review of measures for use in hand OA¹²² indicated that only two measures were developed specifically for hand OA: the AUSCAN and the FIHOA. A brief description of commonly used measures is presented below:

(a) The WOMAC

The WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) is a disease specific, self administered questionnaire which was developed for patients with hip and knee OA^{123, 124} and consists of three domains: pain, stiffness and functional ability. The WOMAC contains a series of statements such as “how much pain do you have walking on a flat surface?” which are rated on a zero (no problem) to 4 (extreme problem) Likert scale over three domains, which include pain, stiffness and physical function (WOMAC LK). A version of the WOMAC which uses a 100mm visual analogue scale (WOMAC VAS) was adapted in order to address issues with

summing an ordinal scale. However, the use of either scales as an interval score has not been supported¹²⁵.

The WOMAC in both its forms is widely used in the OA literature, has been shown to be more responsive than other measures of knee pain^{126, 127}. It demonstrates good construct validity^{124, 126} and has been found to be a stable and reliable postal survey tool¹²⁸ for pain and physical function domains.

Both versions of the WOMAC have been assessed for their internal construct validity. Rasch analysis of the WOMAC VAS has indicated that while the pain and function items work well,¹²⁹ the pain and function domains works well individually, but may not define a single construct.¹³⁰ There were problems with several items, including pain at night, rising from sitting¹³⁰, getting in/out of the bath and doing heavy domestic chores¹²⁹. Items were also clustered around the middle of the scale, indicating not only redundancy, but also lack of discriminating items. Problems were also reported with the stiffness domain, most likely due to problems the stiffness domain containing only two items¹³⁰.

The Likert version of WOMAC has also been subjected to Rasch analysis¹³¹ and as with the 100mm VAS version, problems were also found with doing heavy domestic duties, getting in and out of the bath, and getting on and off the toilet). The authors suggest a modified 14 item physical function scale be used in place of the published 17 item scale.

Instrument	Questionnaire Focus	Domains (Number of items)	Derivation	UK Validation	Target population	Comments
WOMAC ¹²⁴	Symptoms Function	Pain (5) Stiffness (2) Physical functional disability (17)	Derived from health care professionals	Yes	Knee and hip OA and for people over the age of 55 yrs	It has been shown to be responsive than other measures of knee pain ^{126, 127} and demonstrates good construct validity ^{124, 126} . Rasch analysis of the instrument indicates problems with the stiffness domains ¹³⁰ and two of the physical function items ^{129, 131} .
Lequesne Index ¹³²	Symptoms Function	Pain or discomfort (5) Max walking distance (1) Activities of daily living (4)	Derived from health care professionals	No	Knee and hip OA	There is no evidence for the internal content validity and unidimensionality of the questionnaire.
AIMS2 ¹²¹	Health Status/ Health Related Quality of Life	Mobility (5) Walking and bending (5) Hand and finger function (5) Arm function (5) Self care (4) Household tasks (4) Social activity (5) Support from family and friends(4) Arthritis pain (5) Work (5) Level of tension (5) Mood (5)	Derived from health care professionals and trialled on participants with OA and RA	Yes	Patients with rheumatic disease	Internal consistency and test re-test in OA patients was reported as good ¹²¹ . There is no evidence for the internal content validity and unidimensionality of the questionnaire.
AUSCAN ^{133, 134}	Symptoms Function	Pain (5) Stiffness (1) Function (9)	Derived from health care professionals and patients with hand OA	Yes	Hand OA	Developed according to the same conceptual framework as the WOMAC instruments.

Table 2.5 Summary table of commonly used OA Specific Outcome Measures

Instrument	Questionnaire Focus	Domains (Number of items)	Derivation	UK Validation	Target population	Comments
OAKHQOL ¹³⁵	Health Status/ Health Related Quality of Life	Pain (?) physical activity (?) Mental health (?) Social functioning(?) Social Support (?) <i>Number of items not stated</i>	Derived from health care professionals and participants with OA of the knee and hip	No	Hip and Knee OA	The internal consistency, reliability and content validity were reported in the original publication as good ¹³⁵ .
HOOS ¹³⁶	Symptoms Function	Pain (9) Symptoms (5) Activity limitations – daily living (17) Activity limitations – sport and recreation (4) Hip related quality of life (4)	Derived from health care professionals and trialled on hip disability and OA	No	Hip OA and disability	As for OAHKQOL
WOOS ¹³⁷	Symptoms Function	Pain and physical symptoms (6) Sport, recreation and work (4) Lifestyle function (5) Emotional functioning (3)	Derived from health care professionals and trialled on shoulder OA	No	Shoulder OA	As for OAHKQOL
Cochin ¹³⁸	Function	Kitchen activities (8) Dressing (2) Hygiene (2) Office (2) Other (4)	Derived from health care professionals	No	Hand function in OA and RA	Developed originally for RA, but has been tested in an OA cohort ¹³⁹ .
FIHOA ¹⁴⁰	Function	Function (10)	Derived from clinicians	No	Hand OA	Interview administered questionnaire.
Ankle Osteoarthritis Scale ¹⁴¹	Symptoms Function	Pain (9) Function (9)	Derived from clinicians	No	Ankle OA	Little evidence is available on this measure.

Table 2.5 Summary table of commonly used OA Specific Outcome Measures (Continued)

(b) The Lequesne Algofunctional Index

The Lequesne's Algofunctional Index was developed to assess the pain and functional status of people with hip or knee OA¹³². It was originally designed as a physician completed tool, however it quickly became adopted as a patient completed questionnaire. The questionnaire contains 10 items which have Likert 3, 5 or 7 point response scales. Rather than have separate scales which assess pain and function, the Lequesne combines both constructs into one scale. The Lequesne Index has been used relatively little, perhaps due to one report suggesting the WOMAC demonstrated superior sensitivity¹⁴² at the time Lequesne was being considered as an outcome measure. No data exists on the internal construct validity (such as fit to the Rasch model) of the Lequesne Index.

(c) AIMS

The Arthritis Impact Measurement Scale (AIMS) is a questionnaire developed for use across the rheumatic diseases in order to measure changes in global health, pain, mobility and social function. It was initially developed in 1980 and revised in 1992 as the 66 item AIMS2¹²¹ and is comprised of the following domains: mobility level, walking and bending, hand and finger function, arm function, self care, household tasks, social activities, support from friends and family, arthritis pain, work, level of tension and mood. It was developed specifically using patients with OA and RA and has been used more extensively in the RA literature. The AIMS demonstrates similar responsiveness compared to a generic impact scale¹⁴³, however there has been little work undertaken on the internal construct validity of the AIMS or AIMS2.

(d) OAKHQOL

The Osteoarthritis Knee and Hip Quality of Life Questionnaire (OAKHQOL)¹³⁵ was developed in France and is a 43 item health status questionnaire that assess five

domains (pain, physical activity, mental health, social functioning and social support). The questionnaire was developed by health care professionals and patients with knee and/or hip OA and was developed in line with the ICF classification of health and, as such, is more appropriately classified as a health related quality of life instrument, rather than a quality of life instrument¹⁴⁴. As this instrument was only published in 2005, there is limited literature assessing its properties. Currently, there is no validated English translation version available.

(e) KOOS

The Knee Injury and Osteoarthritis Outcome Score (KOOS)¹⁴⁵ was developed as a derivation of the WOMAC, but to allow for greater responsiveness in younger people with OA. As such, it included all WOMAC items and an additional 18 items, with evaluated sport and recreation function and knee-related quality of life. KOOS has been validated predominantly for surgical groups¹⁴⁵ and has been recommended for use in younger people with knee injury and OA¹⁴⁶. There have been no studies which have evaluated the instrument's internal construct validity.

(f) HOOS

The Hip disability and Osteoarthritis Outcome Score (HOOS)¹³⁶ was developed to enhance the specificity the WOMAC scale to people with hip disability, with or without OA. Similar to the KOOS, the HOOS includes all 18 items of the WOMAC with the word "hip" inserted instead of "knee" and included an additional 15 items developed specifically for the hip. As with the KOOS, the HOOS contained a group of questions relating to sport and recreation. To date, only one study has investigated the validity and responsiveness of the HOOS and found it to function better than the WOMAC, particularly in the younger age group¹⁴⁷. As for the KOOS, there have been no studies which have evaluated the instrument's internal construct validity.

(g) WOOS

Developed from the same philosophy as the HOOS and KOOS, the Western Ontario Osteoarthritis of the Shoulder (WOOS) index¹³⁷ was developed to assess disease specific dimensions of shoulder OA. It does not, however, contain all WOMAC items, but does contain pain, sport/recreation/work, lifestyle and emotional functioning domains. Apart from the original article, very little information exists on this tool.

(h) Cochin Scale

While the Cochin Scale was developed to determine the functional impact of rheumatoid arthritis in the hand¹³⁸, it has also been validated for use in OA of the hand¹³⁹. The scale consists of 18 function-related items where people are asked if they have problems in the kitchen, dressing hygiene, work or other activities. The items have a six-point scale Likert response option, ranging from 0 (“Yes, without difficulty”) to 5 (“impossible to do”). The test re-test reliability is reported to be high and the scale correlates highly with visual analogue scales for handicap and the FIHOA¹³⁹. While the scale has been published in English, it has not been validated in an English population.

(i) AUSCAN

The Australian/Canadian Osteoarthritis (AUSCAN) Hand Index was developed by the same group who developed the WOMAC^{133, 134}. It was designed to assess pain, stiffness and function of hand OA and has been validated for use in a UK population¹⁴⁸. As with the WOMAC, there are two response versions: a Likert scale (AUSCAN L.K 3.0) with responses from 0 (none) to 4 (extreme) or a visual analogue scales (AUSCAN V 3.0). The test re-test reliability of the AUSCAN has been reported to be moderate¹⁴⁸ and the construct validity against clinician and observed measures of hand function was reported to be good¹³³. While Rasch analysis has not been undertaken on the AUSCAN, a recent study using confirmatory factor analysis¹⁴⁹ has

indicated that all three subscales loaded onto one factor, indicating that there may be some cross-over in what the scales are measuring.

(j) FIHOA

The Functional Index of Hand OA, (FIHOA) was developed for use in a large clinical trial¹⁵⁰ and consists of ten items which focus on the fine motor skills involving the hand. The questionnaire is interview-administered where the participant is asked if they can perform particular tasks on a scale rated 0 (“possible without difficulty”), 1 (“possible with difficulty”) or 2 (“impossible”). There is only limited literature using the FIHOA, however the test re-test of the instrument was reported as moderate to high¹⁴⁰ and the sensitivity to change, while not as powerful as a visual analogue pain scale, was more sensitive than other observed measures, such as grip strength¹⁵¹. As with the Cochin Scale, while the FIHOA scale has been published in English, it has not been validated in an English population.

(k) The Ankle Osteoarthritis Scale

The Ankle Osteoarthritis Scale (AOS) was developed as a patient-completed outcome measure for OA of the ankle¹⁴¹. The scale consists of two sub-scales (pain and disability) each of which is composed of nine items. Individual items are scored on a visual analogue measure to give each sub-scales total score and the overall score. A higher score indicates greater pain or disability. The only literature available on the measurement properties of the AOS is in the original report, which reports good reliability and construct validity when compared to the SF-36 and the WOMAC. To date, it has only been used as to evaluate surgical procedures of the ankle¹⁵².

There are three main generic measures that have been used in OA research over the last ten years: the SF-36, EuroQoL and the Nottingham Health Profile.

(l) SF-36

The Medical Outcomes Study (MOS) 36-item SF-36¹⁵³ is a generic outcome tool that measures “health related” quality of life for the purposes of health service evaluation, particularly across different health conditions. The SF-36 focuses on eight domains: physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional and mental health. The questionnaire comprises statements such as “does your health now limit you in walking up several flights of stairs”, to which the responses, depending on the question, are either Likert scales (yes, limited a lot/yes, limited a little/not limited at all) or dichotomous (yes/no). The answers are then entered into a spread sheet where a loading algorithm is applied and the resulting scores range from “0” (extreme symptoms/poor health) to “100” (no symptoms/perfect health). A shortened version, the SF-12¹⁵⁴ has also been developed, which includes only 12 items.

The SF-36 has been used extensively in OA studies, particularly pharmaceutical studies, however there are doubts as to its sensitivity and discriminate ability in this group. While the SF-36 was able to distinguish between patients with OA (n=122) and rheumatoid arthritis (n=28)¹⁵⁵, there appeared to be little difference between those with OA and an age and gender matched control group¹⁵⁶. Discriminant validity of the SF-36 was compared to the WOMAC in patients after knee replacement¹⁵⁷ and suggested that WOMAC discriminates better among individuals with knee problems, whereas SF-36 discriminates better among individuals with varying levels of self reported general health and co-morbidities. The major advantage of an instrument such as the SF-36 is for cross comparison over the domains across different diseases (see Section 2.4).

(m) EQ-5D

EuroQoL's EQ-5D¹⁵⁸ was developed to assess health outcomes over a wide variety of interventions for the purpose of health economic evaluation and has been recommended specifically for use in rheumatic populations⁹⁹. As it contains five domains, with only three individual responses for each domain, it has been criticised for being unable to discriminate change, particularly in specific diseases. For example, the question relating to mobility gives the following three choices: "I have no problems walking about", "I have some problems walking about" or "I am confined to bed". While it is used in a number of pharmaceutical studies in OA, the major use of the EQ-5D is not to detect change, but for its use as a health utility indicator and is used to measure the QALYS (Quality-Adjusted-Life-Years)¹⁵⁹.

(n) Nottingham Health Profile

The Nottingham Health Profile¹⁶⁰ (NHP) is a generic outcome measure developed to provide an indication of emotional, social and physical aspects of health problems from the individual's perspective. It is divided into two sections, the first addressing the experience of the condition (pain, physical mobility, sleep, emotional reactions, energy and social isolation) and the second, the effect of this experience on aspects of daily life (employment, household work, personal relationships, social life, sexual activity, interest and hobbies and vacations). Items are written as statements, such as "I find it hard to bend" and have a yes/no response, although a recent publication has recommended a 5 point Likert response scale¹⁶¹. While it was recommended for use in OA soon after the original publication¹⁶⁰, there have been concerns raised as to its ability to discriminate change in OA¹⁶². It has been used extensively in hip and knee replacement surgery and indeed it was found to be more responsive than the 15D (see below) in measuring change in this group¹⁶³.

The content validity and psychometric properties of the NHP has been assessed in several diseases, including cardiac surgery, asthma and chronic lung disease and has demonstrated moderate internal consistency. Unfortunately, no assessments of its other psychometric properties in OA have been published.

(o) Other HRQoL instruments

The 15D is a quality of life instrument that was developed in Finland which contains 15 health related quality of life items. While considerable work has been undertaken on this tool in its native language, there is limited information published in English. It has been used for joint replacement studies¹⁶³.

The Quality Well Being Scale (QWB)¹⁶⁴ is a generic health utility and health related quality of life instrument which contains 24 items. It was found to be sensitive to change in people with OA¹⁶⁵. No internal construct validity testing has been undertaken on the QWB.

In order to provide a cross-cultural, generic quality of life measure the World Health Organisation developed the WHOQOL¹⁶⁶, which contains 100 questions that cover 25 dimensions of quality of life. Two modifications of the WHOQOL have been developed: the WHOQOL-BREF¹⁶⁷, a short form 26-item question and the WHOQOL-SRBP¹⁶⁸, which contains an additional 32 questions on spirituality, religion and personal beliefs. Psychometric testing of the WHOQOL and the WHOQOL-BREF have indicated that the questionnaires demonstrates acceptable internal consistency, discriminant validity and construct validity¹⁶⁹⁻¹⁷¹.

To date, only the WHOQOL-BREF has been used in OA patients: a study evaluating the effect of quality of life pre and post joint replacement¹⁶⁹ found that all domains of

the WHOQOL with the exception of social relationships improved after joint replacement surgery.

The Assessment Quality of Life (AQoL)¹⁷² was developed in Australia as a generic, health related quality of life instrument as a shorter alternative to the WHOQOL. It contains 12 items and covers four domains: independent living, social relationships, physical senses and psychological well-being. The internal consistency of the AQoL was found to be adequate¹⁷³. While the AQoL has been used predominantly in an Australian context, its use in an OA cohort has been explored and has been found to discriminate change as consistently as WOMAC and the SF-36¹⁷⁴.

Finally, global scales have been used to assess quality of life where participants are asked to rate their quality of life on a single question. Such measures have included visual analogue scales, where people are asked to place a mark along a 100mm line, with zero indicating “the worst possible quality of life” and 100 “the best possible quality of life”¹⁷⁵; and Likert type scales¹⁷⁶, where people are asked to tick a box indicating that their quality of life is “worse possible”, “poor”, “adequate”, “good” or “best possible”. Ibrahim¹⁷⁷ explored the differences between older African-American and white patients with OA by using a single item, global question based on a five point ordinal scale – “how would you rate your overall quality of life?: excellent, very good, good, fair, poor”. Such tools have been heavily criticised for their lack of theoretical foundation and specificity.

Instrument	Domains (Number of items)	Levels of response	UK Validation	Specific Population	Comments
SF-36 ¹⁵³	Physical function (10) Role limitations – physical (4) Bodily pain (2) Social functioning (2) Mental health (5) Role limitations – emotional (3) Vitality – (4) Health perceptions (5)	Varies with each item	Yes	Male and female, ages 14 years +, across a the spectrum of healthy and various diseases	Commonly used in OA studies, particularly pharmaceutical studies.
EQ-5D ¹⁵⁸	Mobility (1) Self care (1) Usual activities (1) Pain/discomfort (1) Anxiety/depression (1)	3	Yes	Male and female, ages 12 to 90, across a the spectrum of healthy and various diseases	Major use as a clinical utility measure and has been more commonly used in RA compared to OA
NHP ¹⁶⁰	Physical mobility (8) Sleep (5) Pain (8) Emotional reactions (9) Energy (3) Social Isolation (5)	2	Yes	Male and female, ages 12 to 90, across a the spectrum of healthy and various diseases	There are questions as to its sensitivity in an OA population ¹⁶² , however it is commonly used in joint replacement surgery.
15-D ¹⁶³	15 dimension of health (including moving/seeing/hearing/social participation/working etc)	Varies, generally 4-5 levels for each item	Yes	Male and females, 16 years +	Originally designed in Finnish, it has been used in joint replacement surgery
QWB ¹⁶⁴	Symptoms (27) Mobility (4) Physical activity (4) Social activity (4)	Varies, but all scores are combined to a single scale score	No	Male and female, 18 years+	Used predominantly in the calculation of QALYs in the United States.

Table 2.6 Summary table of Generic Quality of Life/Health-Related Quality of life Measures

Instrument	Domains (Number of items)	Levels of response	UK Validation	Specific Population	Comments
WHOQoL ¹⁶⁶	Physical Health (12) Psychological (16) Level of Independence (16) Social relationships (12) Environment (32) Spirituality/Religion/Beliefs (12)	Ordinal scale response with 5 levels for each item	Yes	Male and female, 18 years+	Developed as a cross cultural instrument which included 15 countries in the initial development
WHOQOL- BREF ¹⁶⁷	Physical (7) Psychological (6) Social Relationships (3) Environment (8)	Ordinal scale response with 5 levels for each item	Yes	Male and female, 18 years+	Brief version of the WHOQOL
AQoL	Independent Living (3) Social Relationships (3) Physical senses (3) Psychological well-being (3)	Ordinal scale response with 4levels for each item	No	Male and female, 18 years+	Designed and used predominantly in an Australian Context.

Table 2.6 Summary table of Generic Quality of Life/Health-Related Quality of life Measures (Continued)

2.2.4 Specific vs Generic Outcomes Instruments

When choosing an appropriate outcome for a condition, consideration must be given to whether a disease specific or a generic instrument is used. Generic, non disease specific instruments, including the SF-36¹⁷⁸ and the and the Nottingham Health Profile¹⁷⁹ are commonly used in musculoskeletal research. Each of these tools demonstrates strong psychometric qualities and they have provided an opportunity to compare outcomes across diagnostic groups and between interventions. While a good generic instrument would allow for comparison across diseases, generic measurements are less able to discriminate change across conditions where impairment and disability is due to biological attributes of the disease¹⁸⁰. Several studies have highlighted the differences in results when disease specific and generic outcomes instruments are used^{181, 182}. Disease specific measures have been found to be more sensitive to change¹⁸² and have been found to better predict clinical changes when compared to generic measures specific measures¹⁸¹.

2.2.5 Patient versus clinician based measures

As indicated in Table 2.5, most of the outcome measures that are used in OA have been developed by clinicians in order to provide important information on the level of physical impairment or pain as experienced by the patients. It is therefore not surprising to discover that pain and function, together with the severity of radiographic changes with OA, were considered important in assessing the impact of osteoarthritis on an individual¹⁸³. Concern has been expressed, however, that outcome measures are too often derived from what clinicians, rather than patients, deem to be important. It is argued that the fundamental flaw in this approach is that clinicians are more likely to catastrophise disability¹⁸⁴, ignore the socioeconomic and psychosocial issues¹⁸³

and are simply not good at predicting what patients consider to be important^{185, 186}. Indeed, it has been argued that developing and validating outcome tools that are devised by clinicians without the inclusion of patient needs may be invalid and compromises the usefulness, validity and accuracy of the tool¹¹⁸.

2.3 Quality of Life

In recent years there has been a growing interest in measuring the ‘real world’ impact of disease on patients through formal assessment of Quality of Life (QoL)^{118, 144, 187}. Improvements in the provision of health care over the last 50 years has moved the focus from life threatening illness to the social impact of living with chronic, disabling diseases¹⁸⁸. In addition, the move away from patients as passive recipients of medical care to patients as partners in their own health has been supported by government initiatives^{189, 190}.

The first clinical publications reporting QoL appeared in the 1960s¹⁹¹ and this has since grown exponentially. The use of QoL measures crosses such diverse areas of interest as clinical research, social science, psychology, environmental science, moral philosophy and political science¹⁹². The term has been adopted by economists to evaluate the value of treatments in terms of QALYS (Quality Adjusted Life Years)¹⁹³. It is therefore important to define the term “quality of life” and discuss the theoretical constructs which underpin this understanding and measurement.

2.3.1 Definition

While there has been a growing interest in measuring the QoL, there has been considerable debate as to definition of the term “quality of life”. Nord¹⁴⁴ pointed out

that QoL is a subjective, overall feeling of well being. There appears to be a necessity in the traditional, medically focused environment, for clinicians to describe QoL in terms of the absence or presence of disease and its consequences. This is often referred to as “health-related” QoL and instruments such as the SF36 and EuroQoL measure this construct. While it is important to measure pain and functional impairment, QoL, is a much broader concept than this and encapsulates a good QoL as “life free of disability”. QoL represents a holistic concept and goes beyond the activities of daily living and disease categories - it encompasses social, psychological and spiritual being of the person and how they interact with their environment¹⁹⁴. Under this model, health is not seen as inherent or even necessary component of QoL, but only as a potential influence¹⁹⁵.

2.3.2 The disability paradox

Part of the confusion with QoL can be attributed to the complexity, adaptability and subjective nature of health and well being. It is well documented that people with serious and persistent disabilities or ill health may still report a good or an excellent quality of life. It is often difficult to reconcile that an individual’s well being and life satisfaction can be anything but poor when they face serious, long term disability. This phenomenon is referred to as the disability paradox¹⁹⁶ and represents an important underlying construct in QoL: that quality of life is a balance between body, mind and spirituality in the context of an individual’s interaction with their external environment.

Albrecht and Devlieger¹⁹⁷ interviewed 153 people with physical disability in order to explore the issue of the disability paradox. They found that many of those who reported excellent to good QoL said that in spite of their disabilities, they had control over their mind, bodies and lives. Many reported that their disability had positive

consequences, such as a greater inner strength, resilience and maturity and satisfaction that they were able to provide support to others coming to terms with their disability. In contrast, of those with a poor to fair QoL, many reported loss of control over their body and circumstances, and feeling that their bodies were particularly “vulnerable” or unpredictable. Several people who reported poor QOL also reported pain being important in their perception of QoL. The authors note that across a range of diseases and disabilities, it was not those with very obvious and functional disabilities who reported poor QoL, but those with communicative and cognitive disabilities, impairments that were not necessarily visible and those with episodic pain and/or general fatigue.

This disability paradox highlights the important weaknesses of health related QoL. While impairments such as pain and activity limitation are undoubtedly pivotal in the determination of one’s QoL, the construct is more complex than a simple equating of physical ability with QoL. The overemphasis on physical ability as the determinant in QoL is prevalent within the general community, but particularly emphasized in health care professionals¹⁹⁷, where disabilities are generally seen in terms of only negative consequences. Examples of this are seen specifically in the rheumatology literature: clinicians working with patients with rheumatoid arthritis are more likely to rate patient’s disability higher than the patients themselves rate their disability¹⁹⁸.

2.3.3 Adapting to disease

A further interesting paradox arises in the finding that patients who are disabled or who have a chronic disease generally rate the value of their lives in a given health state higher than individuals imagining themselves to have a disease¹⁸⁴. A source of this unexpected finding is the issue of adaptation or response shift¹⁹⁹. Indeed, Carr and colleagues²⁰⁰ argue that QoL is influenced by expectations and experience, and

as such, cannot be considered linear or constant. A person with a chronic illness may accommodate and adapt to their situation, thereby altering their self reported well-being which causes problems of interpretation of health related QoL, where the emphasis is on pain and disability.

2.3.4 Theoretical Constructs for Measuring Patient Based QoL

Since as far back as 1988, there has been concern expressed about the inadequacy of the conceptual basis for many of the tools developed to measure quality of life²⁰¹. Initial quality of life tools continued to focus on the medical model of measuring success. It was quite common to include “objective” measures of quality of life, that were not undertaken by the person, but assessed by an observer/clinician rating what they considered the patient’s quality of life²⁰².

SEIQoL

Individualized QoL measures, such as the SEIQoL^{203, 204}, offer an assessment of QoL that is developed to be customized for each person. The SEIQoL takes the form of an interview, where the respondent identifies what elements that he/she contributes to their own QoL. The person then identifies their satisfaction with the current status of each element on a visual analogue scale. The person then weights how important each are and the full score is given by the sum of the products of each element. This approach, while clearly beneficial in the clinical situation, cannot be validated by nature of its individual uniqueness, and thus has limited use in research.

Needs-based quality of life

Where it is necessary to make group comparisons, the needs-based QoL approach is gaining wide acceptance. The needs-based approach to QoL was developed by Hunt and McKenna²⁰⁵ and has been used in the development of several condition specific

QoL measures. The model is based upon a validated development technique involving in-depth qualitative interviews with patients who are living with a health condition²⁰⁵ and has been used to develop a number of disease specific QoL tools, including depression²⁰⁶, rheumatoid arthritis²⁰⁷, psoriasis²⁰⁸, psoriatic arthritis²⁰⁹, ankylosing spondylitis²¹⁰ and multiple sclerosis²¹¹. Using this model, the needs relevant to each condition are identified, maximising the content validity and responsiveness of the final instruments.

The needs-based model is drawn from the understanding that individuals are driven or motivated by their need, as described by Maslow's hierarchy of human needs²¹². The needs-based philosophy is centred on the understanding that life gains its quality from the ability and capacity of individuals to satisfy their need¹⁹¹. Functions such as hobbies, social activities and employment are important only insofar as they provide a mechanism by which such needs can be met. When our needs are met, our QoL is high and when such needs are not fulfilled, our QoL low.

Unlike the HRQoL approach, needs-based QoL is a different construct to our physical ability or health status. Indeed, QoL is an complex interaction between the way in which people perceive their health and how it relates to other non medical aspects of their lives²¹³ (Figure 2.4). As such, the needs-based quality of life approach to measuring quality of life presents a conceptual construct which is not dependent on a medical model. It reflects the issues of what is important to defining issues that are important and not simply related to the physician's understanding of quality of life as pain or physical ability.

Interestingly, while OA is the most prevalent of the rheumatic diseases and several needs-based QoL instruments for rheumatological conditions exist^{207, 209, 210}, *currently there is no disease-specific, needs-based QoL instrument available for this condition.*

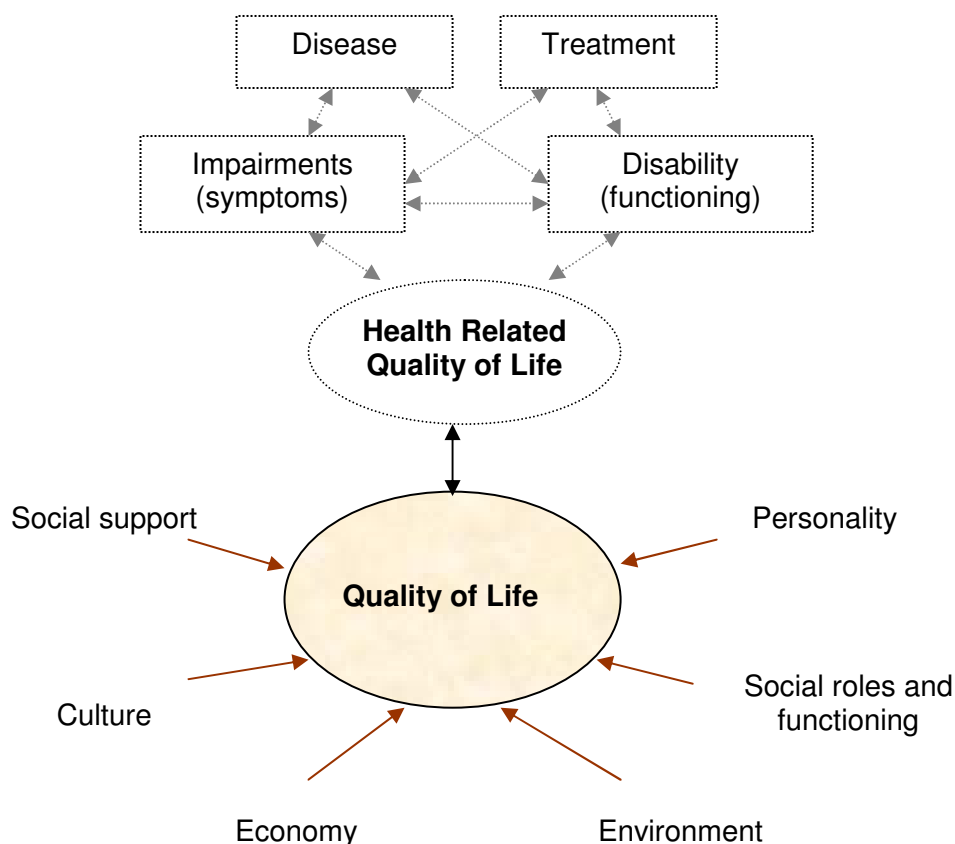


Figure 2.4 Interactions and influences on QoL. Adapted from Doward and McKenna²¹⁴.

2.4 Measuring the impact of OA on Health-Related QoL

While pain and functional limitations have received much attention in OA research, little is known on the impact on an individual's quality of life. A recent systematic review on the impact of hip and knee complaints highlighted the lack of studies which have evaluated quality of life in such patients²¹⁵. This may indeed be related to the lack of an OA specific QoL outcome measure for OA. The handful of studies that

have explored the impact of OA on QoL using health-related quality of life measures, such as the SF-36¹⁵³.

Chronic musculoskeletal problems²¹⁶ and painful joints²¹⁷ in general have been found to account for a lowered HRQoL. However, when the specific effect of OA is explored, the impact is remarkably high. Those with OA had more pain, functional limitations and diminished HRQoL compared to age and gender matched controls. This has been found not only in those with severe OA waiting for joint replacement²¹⁸, but also in a community setting²¹⁹, where the severity of OA would be most likely in the mild to moderate range. While not specifically investigated, there may also be a difference in HRQoL related to the site of OA: combined chronic hip and knee problems demonstrated a much lower HRQoL than those who had only hip or only knee problems²¹⁵ and those with hip OA scored the lowest overall HRQoL⁹⁸.

The major advantage with using a generic instrument for HRQoL is for comparison of the impact of different diseases. In a study comparing chronic conditions and their impact on HRQoL, arthritis had the greatest influence on the SF-36 score of eight chronic conditions, worse than congestive heart failure, ischaemic heart disease and chronic lung disease³. This is highlighted when the SF-36 scores are compared across several medical conditions. Figure 2.5 presents a graphical representation of several chronic diseases, where lower scores represent poorer health. OA of the hip, knee²²⁰ and lower limb²²¹ (presented in grey and black) are compared against Charcot Marie Tooth Disease²²², amputees²²³, Parkinson's Disease²²⁴, stroke^{225, 226}, coronary arterial disease²²⁷, intermittent claudication²²⁸ and population norms²²⁴. Remarkably, OA of the lower limb represents the lowest score across every domain with the exception of general health, where Parkinson Disease and stroke record greater impact.

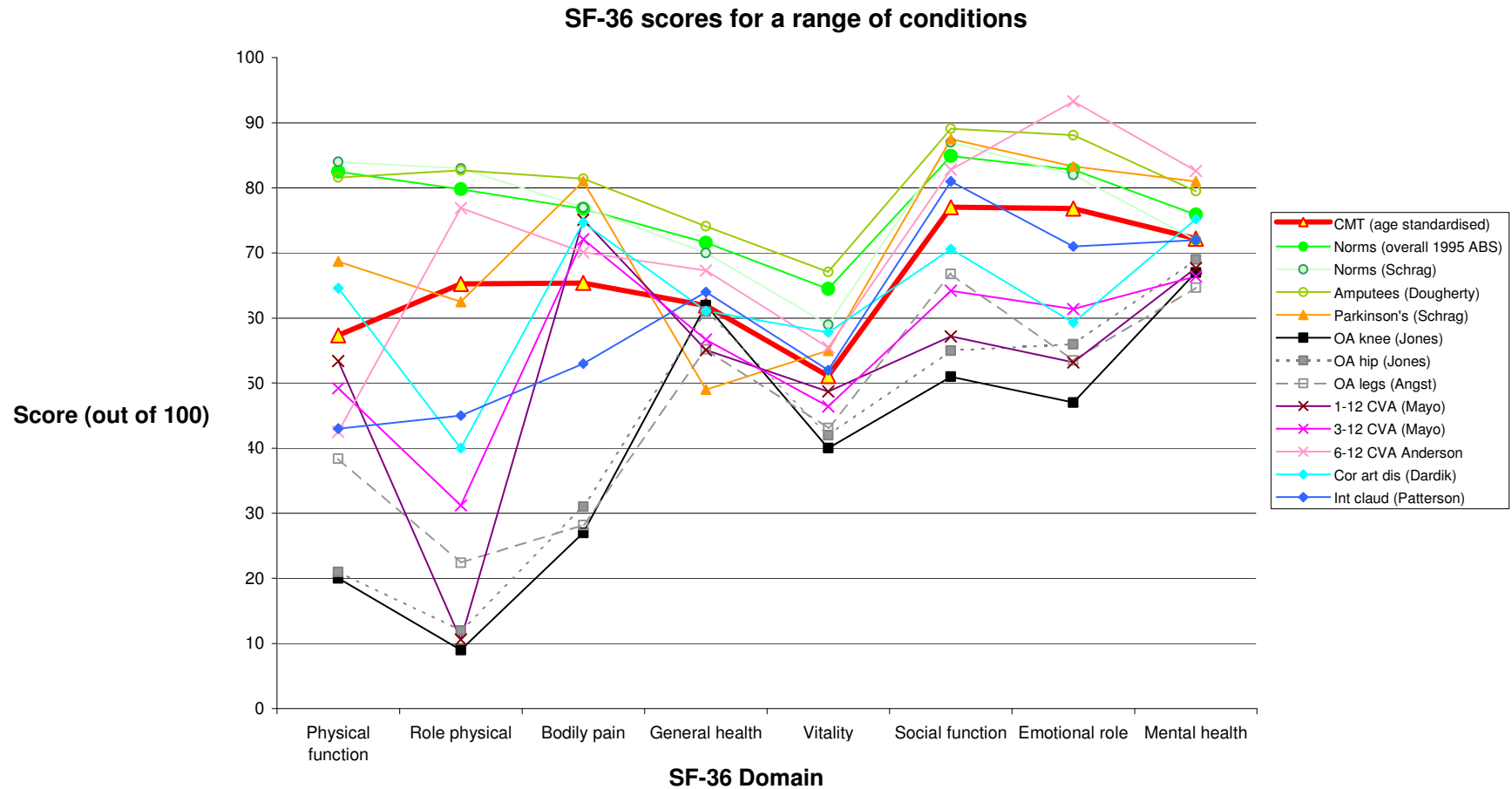


Figure 2.5 Comparison of SF-36 scores across a range of chronic conditions. The SF-36 scores compared with the scores from published studies describing health status in a range of conditions. The ABS population normal population, and a second normative group are presented in green. Parkinson's disease is presented in orange, stroke is presented in pinks/purples, other cardiovascular disease in blues, and OA is presented in shades of grey/black. Image reproduced with permission from Redmond²²⁹.

The complex interaction between HRQoL and psychosocial, personal and environmental factors has been identified, but unfortunately, not fully explored. A direct link has been found between HRQoL and depression²¹⁹, however it is not known whether the depression results in reduced HRQoL or whether reduced HRQoL results in depression. This complex interaction is further highlighted by two other studies which have indicated a direct link between HRQoL and social support²³⁰ and global QoL and ethnicity, where African Americans with OA reported worse QoL than white Americans with OA¹⁷⁶. Whether it is the social support or ethnicity that causes reduced quality of life or whether they are mediators for other factors, such as lower socioeconomic status, remains unclear.

2.5 Summary and Hypothesis

OA is a prevalent and disabling disease which results in a considerable impact on the individual. Most research has focussed on the knee and hip OA, with very little work undertaken on other sites, particularly the hand and foot. While there is limited recognition that the presentation of multiple joint problems is common, little is known about the prevalence of multiple-site pain in OA or indeed which joints are most likely to be affected. This review has highlighted that study of the functional impact on daily tasks of the most common multiple joint combinations is required.

While most research in OA has focused on pain and physical disability, there also been an increasingly well articulated desire to understand and measure in the 'real world' impact of living with OA. Exploring the impact of quality of life in OA has been limited by the lack of a disease specific, quality of life instrument. Quality of life has been measured using the health related quality of life approach, which has a focus on

the function and pain. While pain in OA has received considerable attention, it is unclear how pain contributes to the overall quality of life of the individual.

This review has identified a need in the literature for a true QoL measure devised from people with OA, for assessment of QoL in those with OA, which is grounded in an appropriate conceptual framework and demonstrates appropriate psychometric measurement properties. Furthermore, the interaction and relationships between the physical and psychosocial aspects and their contribution to quality of life needs to be explored.

The hypothesis of this thesis can be summarised as follows:

The number and pattern of joint involvement in OA will be reflected in the level of patient perceived quality of life

Chapter Three

Methodology

3.1 Introduction

This chapter details the methodologies that were used in the studies included in this thesis. In order to fully explore the hypothesis “*the number and pattern of joint involvement in OA will be reflected in the level of patient perceived quality of life*” a mixed methodological approach, using both quantitative and qualitative methods, was adopted. The methods were designed to describe the prevalence and impact of joint pathologies (Section 3.2), to explore the personal issues of living with OA (Section 3.3), to develop a needs-based quality of life questionnaire specifically for OA (Section 3.4) and investigate the key components that contribute to quality of life in OA (Section 3.5). The outline of the thesis is presented in Figure 3.1. The details of each method are described in this Chapter.

In order to understand the prevalence and burden of joint pain, an epidemiological study was undertaken. The first study, *An Epidemiological Investigation of Joint Pain in the Community*, involves secondary analysis of a large, community based dataset. In the original study, which was commissioned to explore the demand for hip and knee arthroplasty, surveys were sent to people 55 years and over in the North Yorkshire region registered with a GP practice. The aim of the secondary analysis undertaken as part of this thesis was to investigate the prevalence of multiple-joint involvement in the community and its impact on activity limitation. Such a large community based survey of more than 16,000 could not include a formal, clinician diagnosis of OA; instead the prevalence and burden of joint pain was explored. This study provides the contextual rationale for focussing on multiple-site pathology by describing the extent and impact of multiple-site presentation in the community. The

frequency and pattern of joint pain was described and the impact of the joint pain on daily activities, such as walking and rising from a seated position, was investigated. The results of this study are presented in Chapter Four.

The second study is a qualitative analysis of the impact of *Living with OA*. The aim of this study was to take a small number of people with OA and explore, in depth, the issues associated with living with OA. This methodology was used in order to capture rich descriptions from the individual's point of view as to what it is like living with OA and the impact on their lives, relationships and sense of well being. The results of this study are presented in Chapter Five.

Based on these interviews, an OA specific quality of life measure, the OAQoL, was developed. The third study, *Development of a Quality of Life Instrument for Osteoarthritis*, describes the development of the disease specific, QoL outcome measure for OA, the OAQoL. Quotes taken directly from the in-depth qualitative analysis interviews were used to form the basis of a draft quality of life questionnaire (OAQoL). This draft OAQoL was then examined for the relevance, clarity and ease of completion by people with OA who participated in structured feedback interviews (n=17). The psychometric properties of the questionnaire were then undertaken using a postal questionnaire (n=259). A second draft of the OAQoL was then investigated for test-retest properties with 60 participants returning a further questionnaire. The results of the development and validation phases of the OAQoL are presented in Chapter Six.

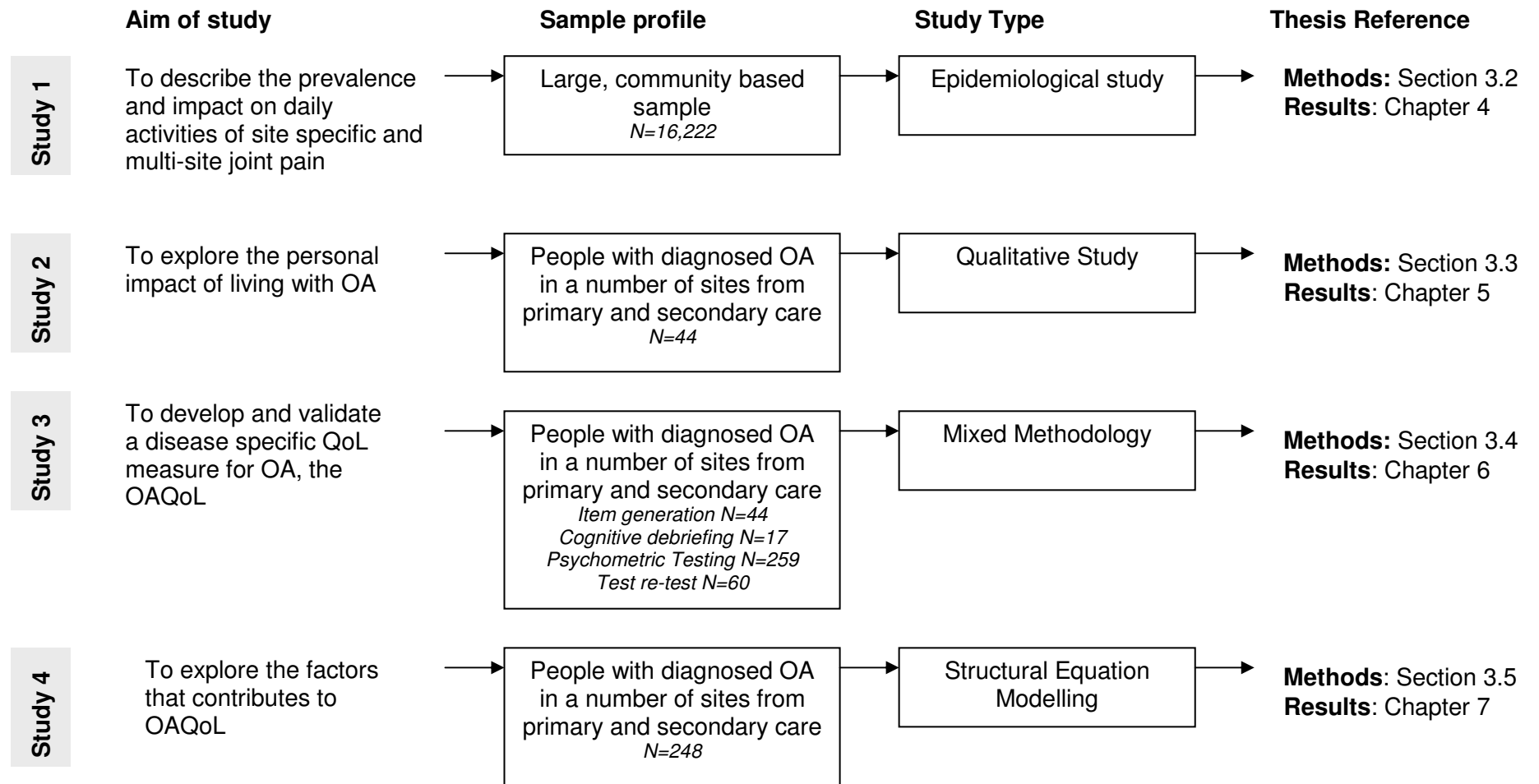


Figure 3.1 An overview of the structure of the studies of the thesis.

The fourth study, *Physical and Psychosocial Influences of Quality of Life in Osteoarthritis*, used structural equation modelling techniques to explore the factors identified in the previous studies that contribute to quality of life in OA. The results of this study are presented in Chapter Seven.

Each study described in this thesis was conducted in compliance with the Helsinki Declaration with institutional review and ethical approval granted by the North Yorkshire Local Research Ethics Committee or the Leeds West Local Research Ethics Committee.

3.2 Epidemiological Investigation of Joint Pathology in the Community

In order to establish the prevalence and burden of multiple-site joint problems, an epidemiological investigation of joint pathology in the community was undertaken. This study was a secondary analysis of an existing, large community based project that had been conducted within the University of Leeds²³¹. As described in Chapter Two, while there is limited recognition that the presentation of multiple joint problems is common⁸⁷, this has not stopped the focus of management strategies being aimed at individual joint problems: indeed, the prevalence and functional impact on daily tasks of the potentially summative effects of most common multiple joint combinations has not been explored.

The aim of the original study was to determine the numbers of people aged 55 years or more who may benefit from knee arthroplasty. The aim of the secondary analysis was to explore the prevalence and associated functional limitations of joint problems

in the older age community, and to evaluate the impact of each joint separately and the interaction of multiple-site joint problems on physical abilities.

3.2.1 Participants

A community based postal survey, approved by the North Yorkshire local ethics committee and was originally commissioned by North Yorkshire Health as part of a study to determine the predicted need for knee arthroplasty in the community. Names of 18,227 people over 55 years were selected randomly from the North Yorkshire Family Health Services Authority, which is coterminous with North Yorkshire District Health Authority. The population estimate for the over 55 age group in this population is 210,000.

As a community based survey, the focus of the questionnaire was built around self reported joint problems and self reported activity limitations. No diagnosis of joint pathology, particularly OA, was possible with this study design.

3.2.2 Questionnaire

A postal questionnaire was used to describe population estimates of joint problems and to identify patients with functional limitations associated with joint pathology. Individuals who reported knee and hip problems in the initial study were invited to complete a more comprehensive questionnaire, which formed the basis of work that has been published elsewhere²³¹. In the original study, data were captured on a whole body manikin but only knee and hip data were analysed. The data used in the current study were derived from this first questionnaire and had not been analysed in this way or published previously.

The questionnaire asked for demographic information and clinician diagnosed co-morbidities (Figure 3.2). Participants were asked whether they had experienced any swelling, pain or stiffness in the any of their joints, neck or back which has lasted for more than six weeks in the previous three months. In order to establish loci of pain, participants indicated the location of joint problems on a manikin, with major joints identified on the manikin as boxes. Participants were also asked to indicate whether they experienced difficulties with a number of activities of daily living or required assistance with daily tasks, as described in Figure 3.2.

3.2.3 Strategy for data analysis

The strategy for data analysis was driven by a need to code the data into clinically meaningful information, explore for non responder bias, establish the prevalence of joint problem at the individual joint site, establish the prevalence of common patterns of joint involvement and finally to investigate the impact of joint problems on simple daily activities.

Non responder bias

In the original study, completed questionnaires were explored for non-response bias. A pre-determined strategy was used to weight data by age and gender to adjust for non response bias and to determine prevalence estimates, with 95% confidence intervals (95% CI) calculated according to Schoenberg²³². For all modelling and inferential statistics, the data were analyzed in its un-weighted form. All prevalence data were expressed per 1,000 members of the population.

Demographics

Age (yrs)
 Gender (Male/Female)

Co-morbidities

Have you ever been told by a doctor or other health professional:

- That you have arthritis or rheumatism? Yes No
- That you have high blood pressure? Yes No
- That you have diabetes? Yes No
- That you have had a stroke? Yes No

Functional ability

In the last three months, have you had any difficulties with any of the following activities because of health problems or disabilities?

- Gripping or holding things Yes No
- Brushing or combing your hair Yes No
- Getting up and down stairs Yes No
- Getting up from a chair or the toilet Yes No
- Putting on shoes, socks or stockings Yes No
- Standing or walking Yes No

Joint pathology

In the last three months, have you suffered from any swelling, pain or stiffness in any of your joints, your neck or back which has lasted for more than six weeks?

- Yes No

Please look at the chart below and tick the joints which are troublesome to you

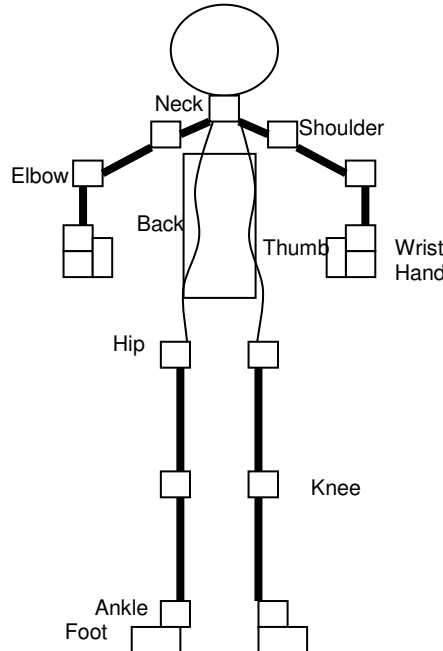


Figure 3.2. Summary of questions and format of items included in the survey.
 Note, other questions asked, but not included in the final analysis as they did not meet the assumptions for the logistic regression are presented in Table 3.1.

Managing the data

While the manikin was designed to collect data on wrist, thumb, hand, ankle and foot, there was some concern that people could not differentiate the pain at that level of refinement accurately. Therefore, data for hands and wrists were combined and are presented as “hand” data, and feet and ankle and are presented as “foot” data. All other joints were reported as indicated on the manikin. In order to explore the geometric patterns of joint involvement, each possible joint combination was established using syntax code. A total of 1,024 possible combinations were established.

In order to determine the prevalence and impact of single or bilateral joint problems, data were coded and explored. In the first instance, joint pain in the right, the left or both joints was considered a positive response for that joint and data in subsequent analyses were explored for the impact of unilateral and bilateral pain. Data were analyzed using the computer program Statistical Package for the Social Sciences (SPSS) Version 11.01.

Strategy for Logistic Regression Modelling

Site of joint problems, presence of one or more co-morbidities, gender and age and were used in logistic regression modelling in order to quantify the “risk” or likelihood of difficulties with activities of daily living. In order to determine the contribution of joints to functional problems (including site of joint pain, the most common joint combinations and then unilateral and bilateral presentations), each was included in a forward, step-wise, logistic regression model.

Assumptions for logistic regression model were checked and multiple co-linearity between variables explored. The Logistic Regression Omnibus of Model Co-efficients were used to determine how well the model performs²³³. Each step-wise regression

was accepted only if the 2-log-likelihood chi-square was significant at $p \geq 0.05$. Multi co-linearity was assessed using a two-step approach. First, all variables were assessed for correlation. For example, age and hip pain, knee pain and hand pain, etc. No variables demonstrating an association of greater than 0.9 were included in the model²³³. Following this process, Hosmer-Lemeshow good-of-fit statistic was calculated for each of the functional indicators. Models were only accepted if the Hosmer-Lemeshow statistic was not significant.

In order to estimate the odds ratio for the risk factor of common joint patterns, a summative odds risk was estimated using a hierarchically well-formulated model. This was calculated by taking the logit of the each joint as a main effect, then the combination of joints as interaction effects, adding the difference between the logits, computing the value and finally exponentiating this value^{234, 235}. For models where there were more than two joints analyzed, all factors were included into the equation, including interaction effects between all joint combinations. For example, to establish the odds ratio for a person with feet, hands and knee problems experiencing difficulty in going up and down stairs, the odds ratios for feet, hands and knee as single joints were undertaken, and then interaction between feet-hands, feet-knees, knees-hands and hands-knees-feet were included in the model. Interaction effects were chosen based on the prevalence of multiple joint sites.

All joints that were considered in the interaction effects were also considered as main effects²³³. In order to estimate the odds ratio for the risk factor and the variable that is interacting with, the following equation is used^{234, 235}:

- (i) Identify the expression for the logit and the two levels of the risk factor being analyzed
- (ii) Algebraically sum the difference between the two logits and compute its value

- (iii) Exponentiate the value obtained in step 2

The equation therefore becomes

$$OR = \exp[\beta_1(f1 - f0) + \beta_2(f1 - f0) + \beta_3x(f1 - f0)]$$

Where

β = Odds ratio

f = Risk factor. Note in dichotomous logistic regression, this value is the value that is given when the factor is present (ie when it equals 1)

x = Interaction

As an example, to describe the total interaction effect between knee and hip, the following equation would be performed to calculate the odds ratio for person who has both hip and knee problems to have difficulty in walking and standing

$$\begin{aligned} OR &= \text{Exp} [(Constant \text{ or intercept}) + (\text{exp hip} \times 1) + (\text{exp knee} \times 1) + (\text{exp} \\ &\quad \text{hip and knee} \times 1)] \\ &= \text{Exp} [-0.897 + 1.329 + 1.024 + (-0.536)] \\ &= \text{Exp} (0.92) \\ &= 2.50929 \end{aligned}$$

For models where there may be more than two joints are being analyzed, a hierarchically well-formulated model was used²³⁶, where all factors are included into the equation, even if they may not have reached statistical significance. Interaction effects between each combination of the independent variables are included for analysis. For example, to establish the odds ratio for a person with feet, hands and knee problems experiencing difficulty in going up and down stairs, the following equation would be used

$$\text{OR} = \text{Exp} [(\text{Constant or intercept}) + (\text{exp feet} \times 1) + (\text{exp knee} \times 1) + (\text{exp hands} \times 1) + (\text{exp feet, knee and hands} \times 1) + (\text{exp feet and knees} \times 1) + (\text{exp feet and hands} \times 1) + (\text{exp knee and hands})]$$

While data for several functional indicators were captured, only those whose predictive capacity was greater than $R^2=0.250$ were included. As such, data captured for the following were not included in the final analysis: putting on shoes, brushing hair, gripping things, regular GP visits, hospital specialists' visits, prescription medication and non prescription medication (Figure 3.1 and Table 3.1).

Results of this study are presented in Chapter Four.

In the last three months, have needed any help with the following:

	Yes	No
Dressing and/or undressing	<input type="checkbox"/>	<input type="checkbox"/>
Getting in or out of bed	<input type="checkbox"/>	<input type="checkbox"/>
Getting in and out of the house	<input type="checkbox"/>	<input type="checkbox"/>
Because of your troublesome joints,		

Have you seen your GP (family doctor) in the last year

	Yes	No
Have you seen a hospital specialist at any time	<input type="checkbox"/>	<input type="checkbox"/>
Do you regularly take medicine or tablets prescribed by a doctor	<input type="checkbox"/>	<input type="checkbox"/>
Do you regularly take non-prescription painkillers (eg aspirin, paracetamol)	<input type="checkbox"/>	<input type="checkbox"/>

Table 3.1 List of items included in the survey, but not included in the final analysis due to restricted predictive capacity ($R^2 < 0.25$).

3.3 Qualitative Analysis of Living with OA

3.3.1 Introduction

The importance of understanding the experience of living with musculoskeletal disease, rather than focusing on the disease processes has recently been highlighted^{237, 238}. The biopsychosocial model²³⁹ looks at complex contextual and personal issues and the interaction with the disease process. Qualitative methodological approaches are particularly effective in exploring an individual's view of living with disease from the biopsychosocial model, as this form of research gives the experience of the individual meaning with reference to their social and cultural context²³⁸. In order to explore the issues of living with OA from the perspective of the individual, qualitative analysis of in-depth, semi-structured interviews was undertaken, using the needs-based approach to quality of life.

3.3.2 Theoretical Philosophy of Methodology

The aim of this study was to understand the 'meaning' of the impact of living with OA and as such, a phenomenological framework was adopted, where the essence of meaning would emerge through the reflective description of participants own world²⁴⁰⁻²⁴². Phenomenology was first described by Edmund Husserl (1859-1938) and was developed as a way to establish meaning, rather than simply the existence, of constructs. Phenomenological qualitative research aims to clarify and explore situations lived by individuals based on their own experiences within the context in which the experience takes place. Phenomenological analysis attempts to seek the meaning of an individual's lived experience within the context of that individual's life.

Thematic analysis is method of organizing and structuring themes in order to gain an understanding into the comprehension or meaning of a concept²⁴³. Thematic analysis

is commonly used in phenomenological approaches to data analysis (Figure 3.3) and is considered a structured method of exploring themes through a conceptual matrix. In essence, it is a method of bringing together components or fragments of an idea that relate, which are often meaningless when viewed alone, but form a comprehensive picture of the collective experience²⁴⁴. Thematic analysis is often used interchangeably with “conceptual analysis” and “content analysis”, although the latter refers to a much broader approach of qualitative analysis and may include data reduction and relational/semantic analysis.

The strength of thematic analysis is the bringing together separate ideas or components which, when linked, together offer insight in a cohesive and meaningful way. It is a particularly useful method when summarising a large body of data and allows for social as well as psychological interpretations of the data. It is particularly useful in large data sets, generating unanticipated insights and when rich descriptions are sought²⁴⁵.

While a useful and potentially powerful tool, thematic analysis is limited when it is not underpinned by a sound theoretical framework or the approach to thematic development and review is not undertaken in a structured and transparent manner²⁴⁵.

In these circumstances, thematic analysis is criticised as simply a shopping list.

Thematic analysis has less interpretive power than other methodologies, particularly those such as Interpretive Phenomenological Analysis²⁴⁶ and Narrative Psychology²⁴⁷, which require a detailed psychological interpretation of the individual’s perceptions and account of events in their life or world²⁴⁵. In these approaches, the number of interviews is, by necessity, small.

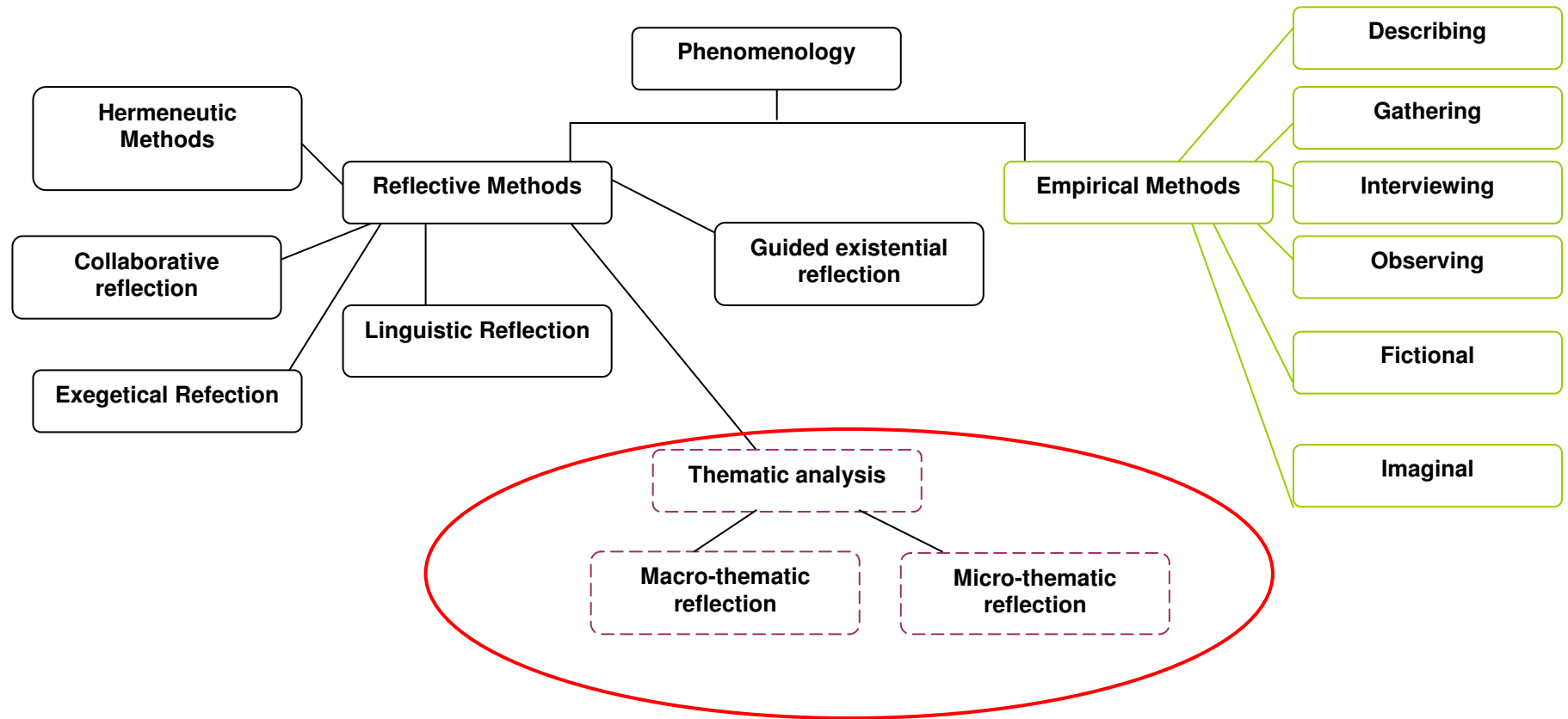


Figure 3.3 Overview of thematic analysis in Qualitative Research Types. Adapted from Aronsen²⁴⁴.

3.3.4 Sampling Technique

In order to explore issues associated with living with OA, in-depth, semi-structured interviews were conducted with participants from the primary care Leeds Musculoskeletal Service and the secondary care Leeds NHS Trust Rheumatology and Orthopaedics Clinics. Patients with OA attending these clinics were invited to participate. It was important that representation was sought from both primary and secondary care as most patients with mild to moderate OA are seen in primary care and only infrequently consult hospital specialists. Those patients attending tertiary care outpatient clinics are more likely to be those at the severe end of the OA symptom spectrum.

To ensure a sample that represented the commonly prevalence of OA, a matrix was constructed with forced representation for gender, age (≤ 55 years; ≥ 56 years) and site of OA (hip, knee, hand, foot and multiple-sites) with approximately equal participation sought for each group. The minimum required sample size was determined to 40. All participants with hip, hand and knee OA fulfilled the ACR Criteria for the Diagnosis of OA³²⁻³⁴. In the absence of any such criteria for patients with OA of the foot, participants were included if they had symptomatic, clinically diagnosed OA that was confirmed by radiographic evidence. Participants with significant co-morbidity, (including heart and circulatory conditions, depression, stroke and other musculoskeletal disorders) were excluded from this phase of the study.

3.3.5 Interviews

In-depth, semi structured interviews were conducted with each participant. The aims of the interviews were two fold: (1) to explore the issues associated with living with

OA and (2) to derive items based on direct quotes from people who had OA to be used in the development of the QoL instrument (Section 3.4).

The interviews were undertaken by eight researchers who were experienced qualitative interviewers and included psychologists and allied health professionals. A panel of interviewers were chosen for two reasons: firstly, the candidate was a novice interviewer and the panel provided a formal mechanism for review and mentorship as the candidate developed these new skills; and secondly, by including a number of interviewers, the aim was to reduce the impact an individual directing the outcome or direction of an interview²⁴⁸. The majority of the interviews (n=25) were undertaken by the candidate. The interviews were conducted either at home or at a location of the participant's choice, including a private room at the outpatient department of the hospital where the patient was visiting and an interview room at the university. The interviews took the form of an informal, focussed conversation²⁴⁸.

In keeping with the needs-based quality of life approach, issues associated with OA impacting on the needs of the individual being fulfilled, as described by Maslow²¹², were explored. A diagrammatic representation of these needs is presented in Figure 3.4.

To initiate the interview, participants were asked a general question about their arthritis: "how long have you had arthritis" and what symptoms do you have". After this initial discussion, participants were then asked "tell me how your arthritis has an impact on your day to day life" and were encouraged to discuss any aspect of their lives. Interviewers were required to probe in depth any issues raised by the interviewees. For example, where a respondent raised an aspect of functioning as being problematic they were then asked to state how they were affected by the

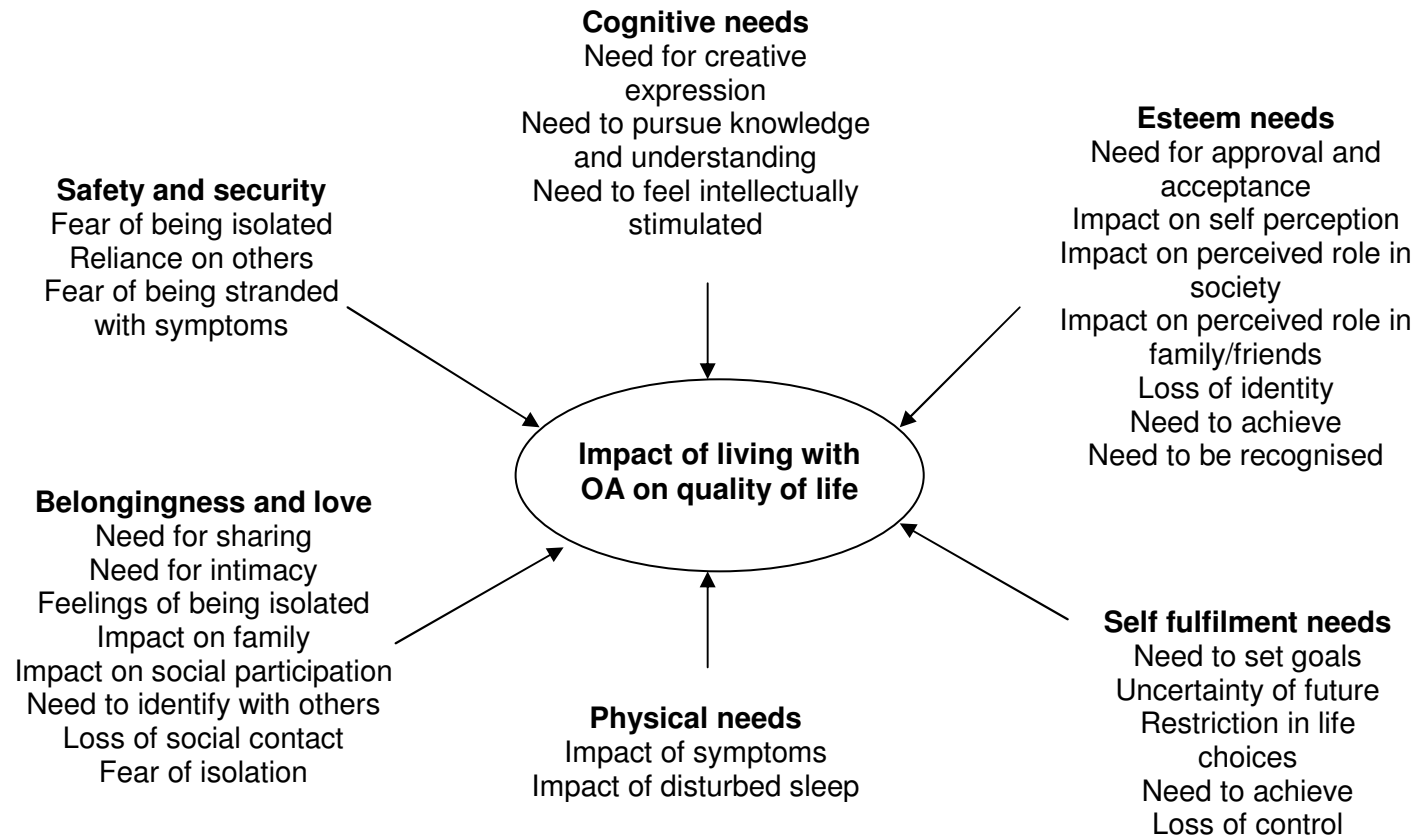


Figure 3.4 Needs-based approach to participant interviews

functional disability. In this way the interview went beyond determining the impact of OA on symptoms and functioning (Health Related QoL) by determining how this affected need fulfilment and about their emotional response to the restrictions. While free conversation was encouraged, if the participants were unable to think of any impact on their lives, prompt questions based on social activities, mood, feelings about the future and relationships with others were asked, according to the interview guide (Appendix 1). Interviews were audio-recorded with the permission of the interviewee and transcribed verbatim for data exploration and analysis.

Following the transcription of each tape, the interview was checked by the interviewer for accuracy and clarity and then cross-checked by one of the other researchers. On completion of the patient interviews, the transcripts were analysed using two different techniques: thematic analysis for the qualitative study (Section 3.3.6) and potential item identification for the quality of life measure (Section 3.4).

3.3.6 Strategy for analysis of the data

Data obtained from the interviews was subjected to qualitative thematic analysis, which involves identifying, categorizing and coding themes that were common throughout the interviews. For the thematic analysis, a coding scheme was developed from the issues identified in the interviews and based around the needs-based approach to quality of life. All transcripts were coded using NVivo 2.0 and all qualitative data analysis was undertaken by the candidate.

The approach to thematic selection and review was taken from Braun²⁴⁵, which involves a rigorous and systematic approach to the analysis. The first step of this process is the familiarisation of the data. While transcripts were checked by the interviewer, and re-checked by a second member of the research team, all transcripts

were read at least twice by the candidate prior to data analysis. An initial coding strategy was developed by the research team during the interview process, each transcript was reviewed and coded. Once the initial coding had been completed, the categories were reviewed and collapsed into clusters in order to reduce duplication of themes and allow appropriate cross referencing of themes. Following coding of the transcripts, themes linking the codes were explored. The themes were then reviewed in relation to individual responses and to the group analysis. The transcripts were then reviewed once more and recoded in order to explore for any evidence of new themes through the revised coding. This iterative process continued until the point was reached that no new information was emerging. The transcripts were then reviewed in order to determine the frequency of interviewees who responded to each code.

Results of this study are presented in Chapter Five.

3.4 Development of a Quality of Life Instrument for Osteoarthritis

The methodology used in the development and validation of the OAQoL was a well recognised method employed in the development of needs-based QoL instruments^{249, 191} and was conducted in four phases: in-depth interviews; cognitive debriefing; initial psychometric testing and test-retest assessment (Figure 3.5).

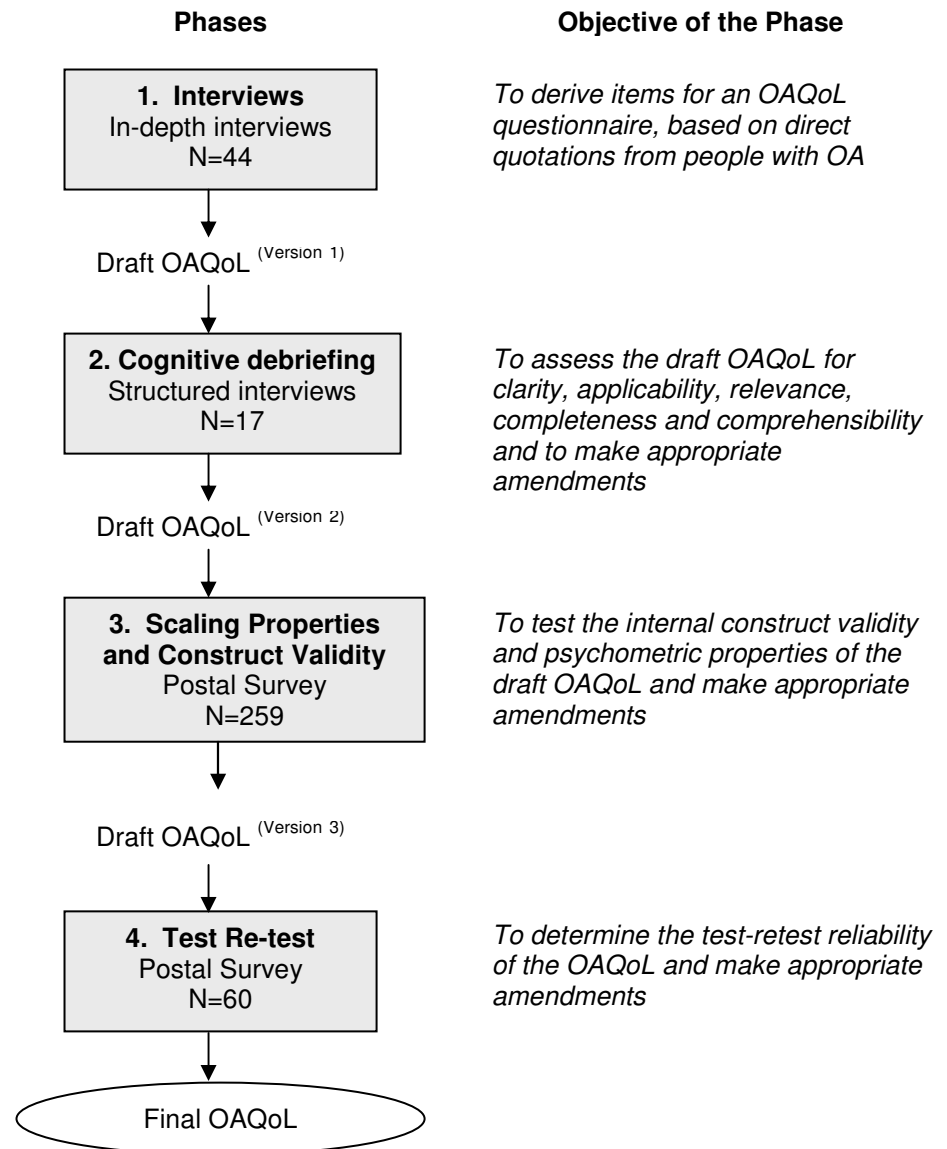


Figure 3.5. Summary of the Project Phases for the Development of the OAQoL

3.4.1 Item Selection from Interviews

On completion of the participant interviews and in conjunction with the qualitative data analysis, the transcriptions were read and coded for item selection. Each transcript was coded by two of the eight researchers to identify statements that related to the impact of OA on the respondents' needs. Actual quotations from the interviewees were used to form potential items for the measure wherever possible. Items were selected if they were consonant with the needs-based model for quality of life, were expressive of a single idea, applicable to all potential respondents (therefore not age or gender biased), capable of being expressed in the first person and, where possible, capable of being expressed in the respondent's own words. Items that were a truism or a statement of fact, such as "I feel tired when I have had a poor night's sleep" were not included.

In order to ensure clarity and ease of future translation into other languages, care was taken to avoid problematic terminology²⁵⁰. Words such as "frustration", which can have a sexual association in Latin languages and "things", which is too non specific for translation, were avoided. The initial list of items was then reviewed by six researchers, four of whom had previous experience in item identification using the needs-based model. Duplicated, idiosyncratic or gender based items were removed at this stage. The remaining 38 items formed the basis of a draft questionnaire (OAQoL Version1).

3.4.2 Cognitive debriefing

The draft OAQoL (Version 1) was field-tested with relevant OA patients in order to test the applicability, relevance, comprehensibility and completeness of the draft questionnaire. A group of 17 patients, different to those who completed the in-depth interviews were recruited. These patients were attending OA clinics at the Leeds

Musculoskeletal Service clinic and fulfilled the OA diagnostic criteria outlined in phase 1. Respondents' general comments and actions during the completion were noted by the interviewer. On completion of the questionnaire, participants were then interviewed and asked general questions about the relevance, clarity and ease of completion of the questionnaire. Following this, participants were asked about any items with which they had appeared to have difficulty. Finally, each participant was asked for their comment on specific items that the research team had identified as potentially problematic.

3.4.3 Scaling Properties and Construct Validity

In order to evaluate the scaling properties and construct validity of the draft questionnaire, a postal survey was sent to 635 patients from primary or secondary care who had a diagnosis of OA, as per the phase 1 criteria. Non-responders were sent two reminders letters, after which they were deemed unwilling to participate in the study. The questionnaire pack included demographic questions, the draft OAQoL and a number of outcome measures commonly used in OA, in order to explore the relation of each to the OAQoL. These measures were the Western Ontario McMasters University (WOMAC) Osteoarthritis Index (for lower limb OA)^{123, 124}, the Cochin Scale (for hand OA)¹³⁸ and the General Well Being Index (GWBI)^{164, 251}.

Scaling properties of the draft OAQoL were assessed using Rasch analysis²⁵² with data entered using SPSS (SPSS Version 14) and analysed using RUMM2020 software package²⁵³. Construct validity was assessed using SPSS Version 14.

Rasch analysis is a probabilistic mathematical modelling technique used to assess properties of outcome measures and is the current standard for the development of quality outcomes in health care²⁵⁴. Data collected from ordinal questionnaires or

scales, that are intended to be summated into an overall score, are tested against the expectations of this measurement model. Rasch analysis has been widely used in the development and validation of a number of outcome measures^{255, 256}.

The Rasch model, named after Georg Rasch (1901-1980) is based on a series of assumptions which, when met, are in line with the measurement being on a metric scale. The model defines the ideal item response characteristics if measurement (at the interval level) is to be achieved. Real data is then tested against this model, and a series of statistics are undertaken in order to evaluate whether the real data and the modelled data are similar. The observed response patterns achieved are tested against expected patterns (a probabilistic form of Guttman scaling)²⁵⁷.

The Rasch model shows what should be expected in responses to items if measurement (at the metric level) is to be achieved. The model assumes that the probability that a person will affirm an item is a logistic function of the difference between the person's level of, for example well-being [θ] and the level of well-being expressed by the item [b], and only a function of that difference

$$\ln\left(\frac{P_{ni}}{1-P_{ni}}\right) = \theta_n - b_i$$

where \ln is the normal log, P is the probability of person n affirming item i ; θ is the person's level of well-being, and b is the level of well-being expressed by the item.

The objective is to test how well the observed data fit the expectations of the measurement model, and so a range of fit statistics are considered²⁵⁸. These fit

statistics, what they represent and their criteria for acceptance are presented in Table 3.2.

Invariance of the items

Invariance of the items quantifies the fit of the observed data to the predicted model across the scale. This statistic, represented by the chi-square (χ^2) value, reflects the degree of invariance of each of the items and how they function together, so it represents how the items function across the one trait (or construct). A significant chi-square indicates that there are problems with fit of all the items: i.e. that the measure is not unidimensional.

Item Difficulty

Components should cover a range of less extreme and extreme characteristics (difficulty or severity) coherently. This is referred to as item difficulty or hierarchy and is expressed as a logit value, the natural logarithm of the odds of a person being able to perform a certain task²⁵⁵. A questionnaire should have a spread of logit values across all items and an appropriate hierarchy in the OAQoL items relates to representation of the range of differing impact on quality of life.

Residual Fit Statistics

A further test to explore the unidimensionality of the instrument is to look at the Residual Fit Statistics. The residuals are the standardized person-item differences between the observed data and what is expected by the model for every person's response to every item. As it is standardized, a perfect fit to the model would give a mean of zero and a standard deviation of one when summed over all items²⁵⁹.

Construct	Interpretation	Assessment Level Individual Item/Questionnaire	Fit test /Criteria
Invariance of the items	A check to explore if the ratios of items remain the same	Individual Item, but taken in consideration of all items in the questionnaire	A non significant χ^2
Item difficulty	The relative difficulty of the items along the Rasch ruler	Individual Item, but taken in consideration of all items in the questionnaire	A range (or spread) of items, as indicated by the item threshold distribution graph
Residual Fit Statistic	The difference (or residuals) between the observed data from the questionnaire and what would be expected from the Rasch Model across all items	Overall questionnaire	A perfect person-item difference would have a mean =0 and a standard deviation =1
Principal Components Analysis	A further test of unidimensionality; a secondary analysis of the data once the Rasch Factor has been taken away	Overall questionnaire	Less than 5% of significant t-tests when comparing items which appear to be loading onto a similar construct
Differential Item Functioning (DIF)	The stability of the items, irrespective of the group being evaluated	Individual item	No DIF
Person separation	Extent to which items distinguish between different levels of functioning	Overall questionnaire	Person separation Index (PSI) should be between 0.7 and 0.8
Unidimensionality	A check to explore if the items belong to the same construct	Overall questionnaire	Individual t-tests

Table 3.2 Summary of Fit Statistics. This table presents the fit statistics used in RUMM2020 and the criteria on which the assessment of each is made. The Assessment Level column represents what level of the questionnaire is being evaluated with each fit statistic.

Principal Components Analysis

Associated with the residual fit statistics, further evidence to support unidimensionality can be gathered by evaluating patterns in the residuals using Principal Components Analysis of the fit residuals. The aim of this is to identify patterns of the residuals once the “Rasch factor” has been extracted. This is important in order to identify any subsets of items that may be loading together. The absence of any meaningful pattern in the residuals will be deemed to support the assumption of local independence of the items²⁵⁹. If any patterns are identified in the residuals, the significance of the pattern can be tested by a method proposed by Smith²⁶⁰. In this method, the patterning of items in the residuals, looking at the correlation between items and the first residual factor, is identified and these patterns are used to define two subsets of items (i.e. the positively and negatively correlated items). The person ability estimates are then compared via independent t-tests. If less than 5% of the independent t-tests are shown to be significant, then the assumption of local independence is supported²⁶⁰.

Differential Item Functioning

As well as considering unidimensionality, the fit statistics also consider the stability of the instrument, irrespective of the group being evaluated. While groups may be expected to vary in their quality of life (for instance a 90 year old person may have a poorer quality of life score than someone who is 30; or people with other co-morbidities may have a poorer quality of life than those who are otherwise generally healthy), their group membership *at any given level of the trait* should not influence how they are scored. This type of analysis is referred to as Differential Item Functioning (DIF) and is identified by a two way analysis of variance (ANOVA) of the residuals²⁶¹ with statistical significance indicating the presence of differential item functioning and compromise to the unidimensionality of the scale.

Person Separation Index

The ability of the scale to discriminate amongst different groups of such patients is determined by the person separation index (PSI). Values above 0.7 indicate the ability to identify at least two groups of patients²⁶². The PSI in the Rasch model is analogous to Cronbach α , and 0.7 is considered a minimal value for group use; 0.85 for individual patient use²⁶³.

Strategy for Rasch Analysis

With the large number of statistics to evaluate in Rasch Analysis and the impact of removing items on total questionnaire fit, an a priori strategy for model and item analysis was devised. In the first instance, the response patterns of individual were evaluated and those with extreme fit residuals were excluded. Following this, items were analysed as for high fit residuals, then DIF and the remaining fit statistics. A diagrammatic representation of the approach to the analysis of fit statistics is represented in Figure 3.6.

Construct Validity

External construct validity, or how the scale performs relative to other measures, was assessed by relating scores on the OAQoL to those on measures of physical ability commonly used in OA research: the WOMAC and the Cochin Scale. In order to provide a comparison with a generic measure of quality of life, the General Well-Being Index (GWBI) was included. The GWBI is a quality of life measure that has been specifically designed to assess psychological distress rather than physical incapacitation. It has been used in numerous clinical and non patient based groups²⁶⁴. It has demonstrated good internal consistency²⁶⁵ and high test re-test reliability²⁶⁴ and has been specifically adapted and validated for use in England²⁶⁶. While it has been used extensively as a measure of well being in cardiac, gastro-intestinal and gynecological studies, it has also been used in rheumatology²⁶⁷, pain management²⁶⁸

and extensively in primary care settings²⁶⁸⁻²⁷⁰. Finally, a 100mm visual analog scale (VAS) indicating “worst possible quality of life” to “best possible quality of life” were included.

It was predicted that there would be moderate associations between the OAQoL and these scales, indicating that they assess related but different outcome constructs. Relations between the instruments were undertaken using Spearman's Rho (ρ) and data were analysed using SPSS Version 14.

3.4.4 Test-retest reliability

The revised OAQoL was sent to 201 patients from the primary and secondary health services. Using the same method as described for phase 3, a further cohort of recently seen patients with OA were sent an invitation to participate. Participants who responded were sent another questionnaire two weeks later and the test-retest reliability of the instrument assessed using Rasch analysis, Spearman's Rho (ρ) and Cohen's kappa (κ).

Results of this study are presented in Chapter Six.

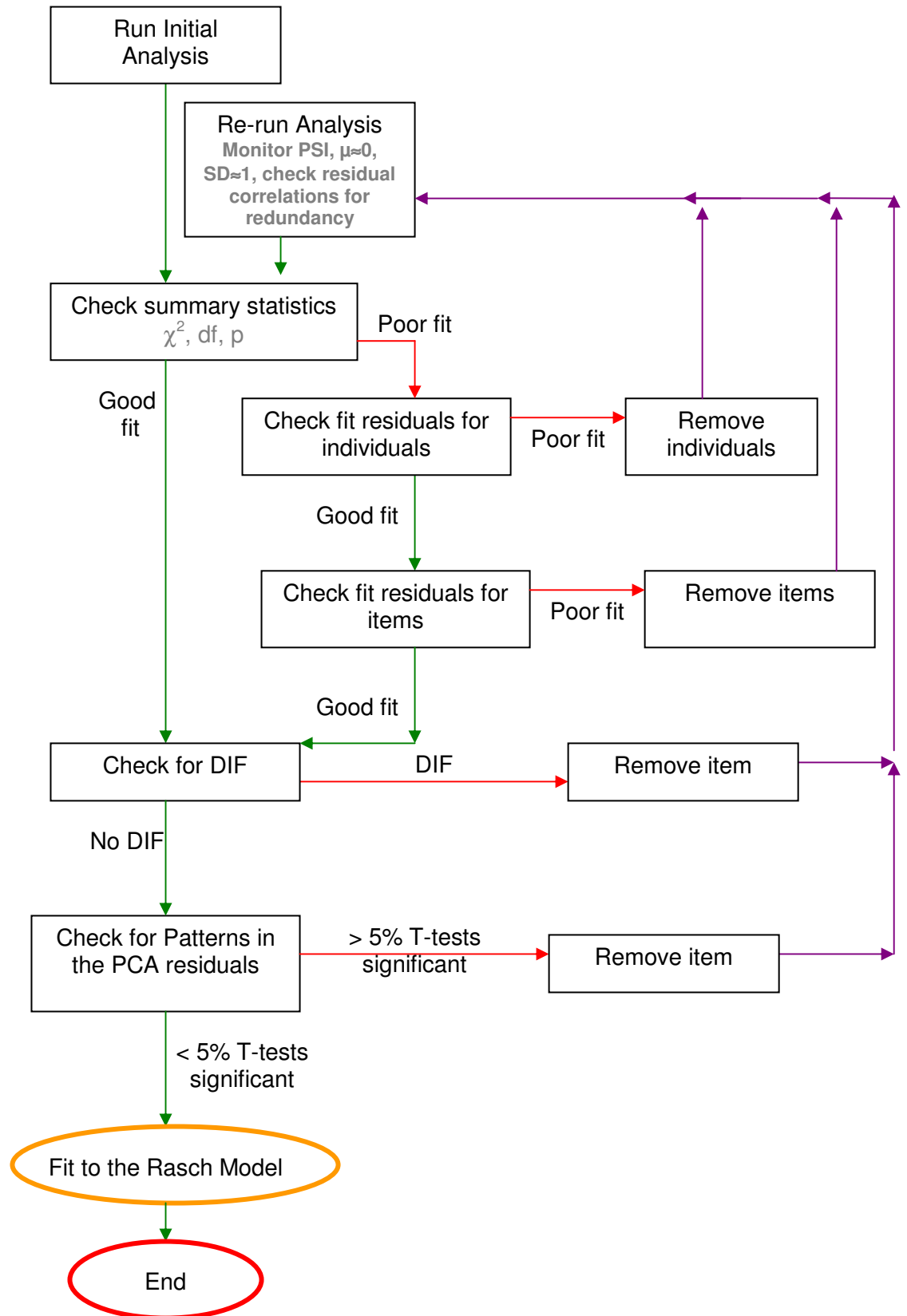


Figure 3.6 Algorithm for Rasch analysis for new scale development.

3.5 Structural Equation Modelling

3.5.1 Introduction

As described in Section 2.3, quality of life is a complex and multifaceted construct. In OA, several factors have been implicated in affecting “quality of life” including physical and psychosocial factors. Traditionally, the complex interaction of these factors in OA has focussed on either pain²⁷¹ or the affect of psychosocial factors on pain^{49, 272} and functional ability²⁷³⁻²⁷⁵. The relationship between such factors and quality of life has not yet been explored. The development of the OAQoL offered the opportunity to investigate the complex relationship between factors identified in the literature as important to those with OA, and quality of life as defined by the needs-based model. The aim of this study was to examine the relationship between physical, psychosocial, demographic and disease factors on quality of life using structural equation modelling.

Overview of Structural Equation Modelling

Structural Equation Modelling (SEM) is a powerful analysis technique used to explore the relationship between several independent and dependent variables. SEM is a sophisticated form of examining correlations and relationships, and addresses some of the limitations with commonly used analysis techniques. For example, to explore the relationship between an independent variable (for example pain) and a dependent variable (such as quality of life), correlation statistics may be used. From such analysis, the strength of the association of the variables is indicated by the correlation value (r or ρ). The disadvantage of correlation is that only one variable can be evaluated at a time and the variables are each considered in isolation, which may also be significant. To explore the combined impact of several independent variables (such as pain, function and age) on a dependent variable (such as quality of life), regression analysis is used. In addition to the impact that each of the independent variables have on the dependent variable when considering all of the variables

together (β weights), regression analysis also provides us with an estimate of *how much* of the dependent variable is explained by all independent variables combined (R^2). While regression is a very powerful analysis tool, it is constrained by three major issues: the first is that only look at one dependent variable can be explored at a time; secondly, the direction of a relationship is treated in only one direction (such as pain impacts on quality of life and not that quality of life may impact on pain perception); and finally, regression does not take into account error associated with the outcome measures.

SEM is an analysis method which explores the relationships between several variables. It has been developed from two areas: path analysis (ie multiple regression, which is concerned with the relationships between measured or *observed* variables of interest) and factor analysis (which considers the extent to which items or measures capture *latent* variables). As such, SEM offers a solution to some of the issues inherent in multiple regression techniques.

SEM is driven by a conceptual theory about a set of variables and how they relate to one another. The procedure requires a theoretical model, underpinned by the hypothesis that is to be tested. As SEM involves an iterative analysis technique where relationship between variables can be changed in order to fit the model, it is essential that the model is hypothesis driven, either by evidence from the literature or a conceptual understanding of the variables²⁷⁶.

In SEM, there are two major types of variables:

- i. observed variables: variables which are measured directly (such as pain visual analogue pain scale). In SEM graphical models (or drawings), these are represented as a rectangular shape.

- ii. latent variables: variables which are not directly measured, but are inferred constructs based on what observed variables we have selected (such as “pain”). In SEM drawings, these are represented as an oval shape.

There are a number of advantages in using SEM to explore the relationship between multiple variables:

- SEM takes into account measurement error that is ignored in regression modelling and factor analysis
- SEM estimates the strength and direction of relationships amongst variables, including direct and indirect effects, feedback (or reciprocal) relationships and mediating relationships
- SEM also estimates relationships amongst latent constructs, that were not directly measured, but are important to the theory underpinning what we are investigating

While SEM is a very powerful technique, it is important to understand the assumptions which underpin this approach. First, as the technique is built around regression, the assumptions are that the data is interval in nature and normally distributed. The data needs to be explored to evaluate the validity of such assumptions. Second, SEM cannot deal with missing data and extreme outliers; such data points need to be explored and accounted for in an appropriate manner, prior to modelling.

SEM and Rasch analysis

While SEM provides a framework for modelling relationships between variables and accounting for error in measurement, Rasch analysis provides us with a strong conceptual basis for determining that error. It is useful in three ways: first, we can

use the Rasch transformed scores of measures as true interval data; secondly we can export the error estimates and regression co-efficients directly from the RUMM2020 results; and finally, Rasch can estimate missing values, which are vital to SEM.

3.5.2 Hypothesis testing

In order to explore the physical and psychosocial factors associated with quality of life in OA, an a priori model was devised, based on the ICF framework and informed by the literature and the results of our qualitative study. The hypothesis to be tested was that there is a relationship between quality of life and personal factors, impairment, factors associated with their OA and psychosocial factors.

3.5.3 Participants

The data for this study were collected in Phase 3 of the development and validation of the OAQoL (Chapter 6). As described in Chapter 6.4, data was received from 259 respondents from both primary and secondary care and with OA at a variety of sites including the knee, foot, hip, hand and multiple-site presentation (Table 6.1). A majority of the respondents were females (68.7% female), with a mean age of 66.5 years (range: 21 to 98, SD+12.5yrs).

3.5.4 Measures for the model

Based on our qualitative interviews with patients (Chapter 5), a range of outcomes that reflected particular constructs were explored for inclusion in the modelling for factors thought to be associated with quality of life. These are summarised in Table 3.3 and included the following: pain, physical ability/function, anxiety, depression. Furthermore, items that had been indicated in the literature that may impact on quality of life and OA were included, particularly age, gender and co-morbidities. Finally,

Construct	ICF Construct	Measure	Data
Demographics	Personal factor	Gender	Nominal: Male/Female
	Personal factor	Age	In Years
	Personal factor	Ethnicity	Nominal: categories taken from UK Census data format
	Environmental factor	Education levels	Nominal: categories reflect UK equivalent achievement levels
Disease Characteristics	Health Condition	Duration of OA	In Years
	Health Condition	Number of joints involved	Count taken from self reported areas of arthritis on the manikin
		Location of OA	
		Joint pattern	
Co-morbidities	NA	Self reported, GP or hospital specialist diagnosed	Nominal, with categories of co-morbidities adapted taken from Wolfe ²⁷⁷ and Kadam ⁸⁹
Pain	Body function and structures	Visual analogue pain scale	How painful has your arthritis been over the last 7 days?
Function	Activities	WOMAC	Composite score of 17 questions with each question rated on a 0 (no difficulty) to 4 (extreme difficulty) scale
Anxiety	Body function and structures	HADS	Composite score of 7 items with each question scored from 0 (no anxiety) to 3 (extreme anxiety)
Depression	Body function and structures	HADS	Composite score of 7 items with each question scored from 0 (no depression) to 3 (extreme depression)
Participation	Participation	PIPP	Twenty-three item which assess the impact and distress of five domains (mobility, participation, self care, psychological well being and relationships)
Quality of life	No corresponding factor	OAQoL	Composite score of 22 questions, each with a “true” or “not true” response

Table 3.3 Summary of constructs and measures considered in the modelling of the quality of life data.

based on our findings reported in Chapter 4, the number and location of joints involved was also captured. As it was not possible to include all joint combinations, the six most prevalent joint combinations (derived from Chapter 4) were included in the analysis. This included the following joint combinations: knee and foot; knee and back; knee and hands; knee, foot and hands; knee and hips; and knee and shoulder. As this was a postal questionnaire, all measures were self reported.

i. Function:

Two measures were included that measure function: WOMAC for lower limb function and the Cochin Hand Function Scale for upper limb function. As described in Chapter 2, the WOMAC is a disease specific, self administered questionnaire which was developed for patients with hip and knee OA^{123, 124}. While three domains are included in the scale (pain, physical ability and stiffness), only the physical ability scale was used for the SEM.

ii. Pain

For modelling purposes, a 100mm visual analogue pain scale (VAS) was used to represent pain. The rationale for using this rather than the pain subscale of the WOMAC was twofold: first the WOMAC subscale relates only to lower limb OA; and secondly, with items such as “how much pain do you have going up and down stairs”, the WOMAC pain subscale is influenced by function.

iii. Anxiety and Depression

In order to establish indicators of anxiety and distress, the Hospital Anxiety and Depression Scale (HADS) was included. HADS is a widely used measure of psychological distress. It was developed to be used in clinical populations, specifically with people with physical symptoms of disease. It has been widely used in musculoskeletal conditions^{278, 279}. HADS consists of 14 items, each answered on a

four point rating scale (0 to 3, with 3 representing higher distress or anxiety). It has been established in the literature that the scale demonstrates two domains (anxiety and depression)^{280 281}. It has seven anxiety items and seven depression items and it is scored by summing the value of each item.

iv. PIPP

While participation has been identified as essential in the ICF framework for classification of disease, there is a dearth of participation based measures. This has been identified specifically as an issue in OA research²⁸². The Perceived Impact of Problem Profile (PIPP) is a recently developed measure which was developed as a generic research and clinical measurement tool to assess the impact and distress of a health problem from the individual's perspective²⁸³. It contains 23 items which focus on five domains: self care, mobility, participation, relationships and psychological well being. Each item, respondents are asked to rate on a six point scale (0 = none, 6 = extreme) "how much *impact* has your current health problems had on .." and "how much *distress* has been caused".

The psychometric properties of the PIPP were previously assessed using Rasch analysis in a sample of those with locomotor disorders²⁸³. While all subscales recorded adequate person separation reliability and no evidence of item bias for sex, age, educational level or rural versus urban residence, it had not been tested in an osteoarthritis population.

v. OAQoL:

Quality of life was measured using the 22-item, final version of the OAQoL, which was developed as part of this candidature and described in this thesis (Section 3.4 and Chapter 6).

3.5.5 Strategy for data analysis

Prior to model testing, all data were explored for descriptive information. Means, standard deviations, assessment for normal distribution and the presence of outliers were checked for each variable. Analysis was undertaken using SPSS (Version 14) and AMOS (Version 6).

i. Input of data into model (Rasch analysis of each instrument)

All outcome measures (WOMAC, OAQoL, HADS and PIPP) were analysed using the Rasch programme in RUMM2020. Due to the problems associated with anchoring items for a VAS²⁸⁴, the pain data was not Rasched. In order for the data to be considered interval, Rasch transformed scores for all Rasch data were imported for all analysis.

ii. Outliers and Missing Data

As data points which are considered to be outliers are problematic in SEM, data for each variable were explored and outliers, and extreme outliers (identified through box plot review) removed. Missing data was adjusted for by using a correlation matrix, which has the added advantage of providing both standardised and non-standardised variables for the analysis²⁷⁶.

Data on continuous scales were explored for normality and appropriate correlation statistics (either Spearman's rho or Pearson's R) were included in the correlation matrix. Correlations between gender (nominal data) and each of the ordinal variables were established using gamma correlations. Data with correlations above 0.8 were noted and relationships between those variables excluded from the final SEM, as these indicate redundancy for modelling.

iii. Sequential linear regression models

In order to explore the multivariate relationships between each of the variables, hierarchical multiple regression analysis for each of the major outcomes: pain, function, depression, anxiety and quality of life. This approach was adopted in order to explore significant relationship for each of the outcomes and the direction of the outcomes which would inform the theoretical model for the SEM. For each dependent variable, blocks were entered into the regression model in the following order: demographic factors (age, gender, ethnicity, educational achievement); disease activity (included duration of disease, number of joints affected and joint pattern); co-morbidities (number of co-morbidities); physical factors (pain and function); psychosocial factors. The sequence and make up of the last two blocks were varied, depending on what factors was included as the dependent variable. The order of the blocks was changed in order to improve the overall regression model and explore the strength of the relationships between the independent variables on the dependent variable.

Co-linearity diagnostics were performed on each analysis. Models were only accepted if the Tolerance was greater than 0.10 and the Variance Inflation Factor was less than 10.

iv. SEM

From the hierarchical regression analysis, an initial structural equation model was developed which proposed a model of relationships between the independent variables, including demographics, disease activity, co-morbidities, physical factors and psychosocial factors. SEM is an iterative process, where a model is proposed, the relationships and directions of the relationship are explored and modifications made to improve the model.

The assessment of model fit for SEM is based on several statistics, as outlined in Table 3.4. The χ^2 goodness-of-fit statistic measures the fit between the expected model correlation matrix and the actual data. A significant χ^2 indicates that there is a difference between the predicted model predicting and the data. Model and data fit is indicated by a non-significant χ^2 . The RMSEA (Root mean-square of approximation) compares the error in the actual data compared to an ideal model. RMSEA should be a significant, or less than 0.05 to indicate that error does not vary from an ideal model. The GFI (Goodness of fit index) is a measure of the amount of variance and covariance in the data and the model being tested. As such, a perfect fit would be 1.0, but values above 0.95 indicate adequate fit the model. Finally, the CFI (Comparative Fit Index) compares the χ^2 for the predicted model with the χ^2 for our data. Once again, a perfect fit would be 1.0, but CFI above 0.95 indicates that the model is working.

As SEM modelling is an iterative process, the following steps were undertaken for each model:

1. Model was generated
2. Output for the notes for the model generated was checked to ensure that the model was acceptable
3. Fit to the model was assessed by the overall fit to the model by examining the global fit statistic (χ^2) statistics
4. Relationships between individual variables were explored (both direct and indirect effects)
5. The amount of variance explained by each solution for each of the endogenous variables (QoL) was explored (R^2 value)

6. Fit indices were checked, including RMSEA, SRMR, CFI and the AGFI (defined in Table 3.4)

If the model did not fit the criteria, modifications were made by exploring the regression weights and variances of each of the variables. Those regression weights or variances that were not significant (ie greater than 0.05) were systematically removed, commencing with the estimate that had the highest p value. Model fit was evaluated after each estimate was removed and continued until there were no significant estimates remaining. Once all significant regression weights and variances were accounted for, the modification indices were then checked. As with the estimates, the modifications were made on an iterative basis, commencing with those relationships with the highest modification index. Model fit was checked following each iteration.

Results of this study are presented in Chapter Seven.

	Statistic	Abbreviation	Interpretation	Fit test /Criteria
Absolute	Chi-square (χ^2) fit statistic	χ^2	Measures the fit between the expected model correlation matrix and the actual data.	Non significant χ^2 p.0.05
	Root mean-square of approximation	RMSEA	Compares the error of approximation in our data compared to an ideal model	RMSEA <0.05 acceptable up to 0.08
Comparative	GFI	Goodness of fit index	A measure of the amount of variance and covariance in the data and the model that we are testing. As such, a perfect fit would be 1.0, but anything above 0.95 indicates our data fits the model.	GFI>0.95 acceptable 0.90
	CFI	Comparative Fit Index	Compares the χ^2 for the predicted model with the χ^2 for our data. Once again, a perfect fit would be 1.0, but CFI above 0.95 indicates fit to the model.	CFI>0.95 acceptable 0.90

Table 3.4 Summary table of fit statistics used in Structural Equation Modelling.

Chapter Four

Epidemiology of Joint Pain in the Community

The results of this study have been published in *Arthritis & Rheumatism*²⁸⁵.

4.1 Overview

This chapter presents the results of the epidemiological investigation of joint pathology in the Community, the methods of which are described in Section 3.2. This study is a secondary analysis of a large community based survey commissioned to determine the prevalence and impact of knee and hip replacement in the community. Surveys were sent to a sample people 55 years and over in the North Yorkshire region who were registered with a GP practice. The results of this initial survey have been published²³¹. The aim of the secondary analysis of the survey that forms the first study in this thesis was to establish the impact of joint pain across the population, including healthy, well individuals, and to explore the consequences of joint pain at individual sites and at several sites on day to day activities and to apply these findings to the general community.

4.2 Participant Profile

Completed questionnaires were received from 16,222 people, a response rate of 86%²³¹. As per the protocol described in Section 3.2, the data were explored for non-response bias. Those who responded were slightly younger than non-respondents (mean age 66.5 vs 66.3 years, $t=5.0$, $p=0.01$) and women were more likely to respond compared to men

(56.5% vs 43.5%, $\chi^2=46.6$, $df=1$, $p=0.01$). Data were therefore weighted by age and gender to adjust for non response bias to determine prevalence estimates. For all modelling and inferential statistics, the data were analyzed in its un-weighted form. All prevalence data were expressed per 1,000 members of the population.

4.3 Prevalence Estimates

Of the respondents, 39.11% of people reported joint pain, swelling or stiffness in their joints over the last three months that lasted for more than six weeks or more, with higher rates in women (417.55 per 1,000) compared to men (330.34 per 1,000, $\chi^2=148.966$, $df=1$, $p<0.001$) and the older age group (75yrs and over=409.71 per 1,000) compared with those 55- to 64 years (362.73; $\chi^2=93.135$, $df=2$, $p<0.001$). People with joint problems were also more likely to report co-morbidities ($\chi^2=30.635$, $df=1$, $p<0.001$).

4.3 Multiple Joint Presentation

Prevalence estimates for joint pain, swelling and/or stiffness per 1,000 population for each site are presented in Table 4.1. The median reported number of joints involved was 4 (range= 1 to 8; 25th quartile=2; 75th quartile=8.00). Only one in eight (12.5%) people who had reported joint problems experienced this in a single joint (Table 4.2). In the most commonly affected joint, the knee, only one in 11 reported pain only in the knee. The most common joint combinations are presented in Table 4.2. Problems with knees and the feet, or the knees and back, or the knees and hands were also regularly reported. The ratio of single to multiple joint problems was even greater in the hands, feet, shoulders, neck, hips and elbows.

Joints	Male	Female	Total
Neck Total	125.26 (<i>112.83 - 138.49</i>)	171.74 (<i>157.85 - 185.63</i>)	151.54 (<i>138.24 - 168.84</i>)
Age: 55 to 64 yrs	130.80 (<i>118.18-143.42</i>)	174.57 (<i>160.61 - 188.53</i>)	153.11 (<i>139.76 - 166.46</i>)
65 to 75 yrs	130.98(<i>118.35 - 143.61</i>)	173.48 (<i>159.55 - 187.41</i>)	154.24 (<i>140.86 - 167.62</i>)
75 year plus	106.14 (<i>94.44 - 117.84</i>)	167.24 (<i>153.48 - 181.00</i>)	146.32 (<i>133.18 - 159.46</i>)
Shoulder Total	131.38 (<i>118.74 - 144.02</i>)	182.80 (<i>168.62 - 196.98</i>)	160.45 (<i>146.88 - 174.02</i>)
Age: 55 to 64 yrs	136.84 (<i>124.01 - 149.67</i>)	159.03 (<i>145.51 - 172.55</i>)	148.15 (<i>134.96 - 161.34</i>)
65 to 75 yrs	125.51 (<i>113.07 - 137.95</i>)	179.48 (<i>165.38 - 193.58</i>)	155.05 (<i>141.64 - 168.46</i>)
75 year plus	130.61 (<i>117.99 - 143.23</i>)	209.60 (<i>194.77 - 224.43</i>)	182.56 (<i>168.38 - 196.74</i>)
Back Total	134.33 (<i>121.59 - 147.07</i>)	183.48 (<i>169.28 - 197.68</i>)	162.12 (<i>148.51 - 175.73</i>)
Age: 55 to 64 yrs	144.60 (<i>131.52 - 157.68</i>)	177.77 (<i>163.72 - 191.82</i>)	161.50 (<i>147.90 - 175.10</i>)
65 to 75 yrs	135.13 (<i>122.36 - 147.90</i>)	182.41 (<i>168.24 - 196.58</i>)	161.00 (<i>147.42 - 174.58</i>)
75 year plus	114.30 (<i>102.28 - 126.32</i>)	190.20 (<i>175.83 - 204.57</i>)	164.22 (<i>150.54 - 177.90</i>)
Elbow Total	59.51 (<i>50.07 - 68.95</i>)	73.64 (<i>63.42 - 83.86</i>)	67.50 (<i>57.61 - 77.39</i>)
Age: 55 to 64 yrs	77.67 (<i>67.25 - 88.09</i>)	73.85 (<i>63.62 - 84.08</i>)	75.72 (<i>64.89 - 85.55</i>)
65 to 75 yrs	48.52 (<i>39.77 - 57.27</i>)	63.71 (<i>54.03 - 73.39</i>)	56.83 (<i>47.55 - 66.11</i>)
75 year plus	43.54 (<i>35.13 - 52.15</i>)	83.24 (<i>72.54 - 93.94</i>)	69.65 (<i>59.64 - 79.66</i>)
Hands Total	133.44 (<i>120.73 - 146.15</i>)	233.66 (<i>218.32 - 249.00</i>)	190.09 (<i>175.72 - 204.46</i>)
Age: 55 to 64 yrs	135.60 (<i>122.81 - 148.39</i>)	214.91 (<i>199.96 - 229.86</i>)	176.02 (<i>162.02 - 200.02</i>)
65 to 75 yrs	142.26 (<i>129.59 - 155.61</i>)	233.20 (<i>217.87 - 248.53</i>)	192.03 (<i>177.61 - 206.45</i>)
75 year plus	115.65 (<i>103.58 - 127.72</i>)	252.66 (<i>236.96 - 268.36</i>)	205.76 (<i>191.02 - 220.50</i>)
Hip Total	94.43 (<i>83.22 - 105.64</i>)	151.53 (<i>138.23 - 164.83</i>)	126.71 (<i>114.23 - 139.19</i>)
Age: 55 to 64 yrs	99.34 (<i>87.92 - 110.76</i>)	137.68 (<i>124.82 - 150.54</i>)	118.88 (<i>106.69 - 131.07</i>)
65 to 75 yrs	102.08 (<i>90.55 - 113.61</i>)	144.43 (<i>131.35 - 157.51</i>)	125.26 (<i>112.83 - 137.69</i>)
75 year plus	73.46 (<i>63.25 - 83.67</i>)	172.26 (<i>158.36 - 186.16</i>)	138.44 (<i>125.56 - 151.32</i>)
Knee Total	176.64 (<i>162.62 - 190.66</i>)	253.92 (<i>238.20 - 269.64</i>)	220.33 (<i>205.26 - 235.40</i>)
Age: 55 to 64 yrs	168.77 (<i>154.97 - 182.57</i>)	207.80 (<i>193.01 - 222.59</i>)	188.66 (<i>174.33 - 202.99</i>)
65 to 75 yrs	187.40 (<i>173.10 - 173.10</i>)	241.84 (<i>226.34 - 257.34</i>)	217.20 (<i>202.20 - 232.20</i>)
75 year plus	174.15 (<i>160.20 - 188.10</i>)	311.51 (<i>294.91 - 328.11</i>)	264.48 (<i>248.57 - 280.39</i>)
Feet Total	136.28 (<i>123.47 - 149.09</i>)	221.28 (<i>206.19 - 236.37</i>)	184.33 (<i>170.11 - 198.55</i>)
Age: 55 to 64 yrs	130.48 (<i>117.87 - 143.09</i>)	186.98 (<i>172.69 - 201.27</i>)	159.28 (<i>145.75 - 172.81</i>)
65 to 75 yrs	140.57 (<i>127.62 - 153.52</i>)	207.18 (<i>192.40 - 221.96</i>)	177.02 (<i>162.99 - 191.05</i>)
75 year plus	140.17 (<i>127.23 - 153.11</i>)	269.17 (<i>253.18 - 283.16</i>)	225.01 (<i>209.84 - 240.18</i>)

Table 4.1. Prevalence estimates of joint pain, swelling and/or stiffness over the last 3 months, lasting for more than 6 weeks, per 1000 for each joint. Estimates have been adjusted for age and gender, with the upper and lower 95%confidence intervals presented in italics.

Specific Joint	Prevalence of specific joint alone problems	Prevalence when the specific joint is involved	Ratio of all joint problems:specific joint problem alone	Most common joint combinations with specific joint*
Knee	18.95 <i>(12.58 - 25.12)</i>	220.33 <i>(20.526 – 235.40)</i>	11.63 : 1	Knee and feet Knee and back Knee and hands Knee and hips
Hands	7.13 <i>(2.51 - 11.75)</i>	190.09 <i>(175.72 – 204.46)</i>	26.66 : 1	Hands and knees Hands, knees and feet Feet and hands
Feet	4.87 <i>(0.71 - 9.03)</i>	184.33 <i>(170.11 – 198.55)</i>	37.85 : 1	Feet and knees Feet, knees and hands Feet, knees and hips Feet and hands
Back	13.59 <i>(7.97 - 19.21)</i>	162.12 <i>(148.51 – 175.33)</i>	11.93 : 1	Back and knees Back and neck Back, knee and feet Knee, back, feet and hip
Shoulders	6.74 <i>(2.19 - 11.29)</i>	160.45 <i>(146.88 – 174.02)</i>	23.81 : 1	Shoulder and neck Shoulder and knee
Neck	7.69 <i>(2.97 - 12.41)</i>	151.54 <i>(138.24 – 168.84)</i>	19.71 : 1	Neck and shoulder Neck and back Neck and knee
Hips	6.42 <i>(1.93 - 10.91)</i>	126.71 <i>(114.23 – 139.19)</i>	19.74 : 1	Hips and knees Hip, knees and feet Hip, back, knee and feet
Elbows	1.55 <i>(-1.65 - 4.75)</i>	67.50 <i>(57.60 – 73.39)</i>	43.55 : 1	Elbow and shoulder

Table 4.2 Prevalence of single joint problems per 1,000. Estimates have been adjusted for age and gender, with the upper and lower 95% confidence intervals presented in italics. *Presented in order of most common combinations.

4.4 Indicators of Functional Ability

Logistic Regression modelling for *standing and walking* is presented in Table 4.3. Almost one third of all respondents reported difficulty waking and standing (32.16%). When adjusted for gender, age and the presence of co-morbidities, people with joint problems reported two to three times more difficulty with this task than those without joint problems ($R^2=0.408$): those people with hip problems were over three and a half times more likely to report difficulty than those without hip problems (OR=3.713, $p<0.001$); people who reported knee problems were three times more likely to report difficulty than those with no knee problems (OR=3.0205, $p<0.001$); and those with foot problems were two and a half times more likely to report difficulty than those with no foot problems (OR=2.5907, $p<0.001$). People who reported back problems were just under two times more likely to report difficulty than those with reported joint problem without back pathology (OR=1.9374, $p<0.001$) and those with neck problems were less likely to report difficulty with standing and walking compared to those with no neck problems (OR=0.0563, $p<0.001$).

One quarter (25.81%) of the cohort reported difficulties *going up and down stairs* and this was particularly influenced by the joints of the lower limb (Table 4.4). People with individual joint problems reported difficulty ($R^2=0.344$): those with knee problems were three and a half times more likely to report problems than those without knee pathology (OR=3.4720, $p<0.001$); foot problems were just under two and a half times more likely than those with no foot pathology (OR=2.3378, $p<0.001$); and people with hip problems just over two and a half times more likely to report difficulty compared to those without hip problems (OR=2.5883, $p<0.001$). Most of the upper limb problems did not influence

	Site	Co-eff (β)	Stan Error	Wald χ^2	P	OR	95% CI		Prevalence (per 1000)
							Lower	Upper	
Main effects	Constant	0.6172	0.451	-	-	-	-	-	
	Co morbidities	1.5754	0.1365	133.1728	<0.001	4.8329	3.6983	6.3155	404.39
	Hip	1.3130	0.1773	54.8343	<0.001	3.7173	2.6260	5.2620	126.71
	Knee	1.1054	0.1228	80.9713	<0.001	3.0205	2.3742	3.8427	220.33
	Foot	0.9519	0.1040	83.8412	<0.001	2.5907	2.1131	3.1762	184.33
	Back	0.6614	0.1005	43.2930	<0.001	1.9374	1.5910	2.3593	162.12
	Neck	-2.8765	0.4440	41.9726	<0.001	0.0563	0.0236	0.1345	151.54
	Shoulder	0.2533	0.1046	5.8649	0.015	1.2883	1.0495	1.5814	160.45
	Elbow	-0.1863	0.1331	1.9594	0.162	0.8301	0.6395	1.0774	67.50
	Hands	0.3199	0.1075	8.8519	0.003	1.3770	1.1154	1.7001	190.09
	Age: 55 to 64 years	-1.0022	0.1293	60.0409	<0.001	0.3671	0.2849	0.4730	
	Gender (Female)	-0.1295	0.1048	1.5276	0.216	0.8785	0.7155	1.0788	

Table 4.3 Logistic regression modelling for standing and walking. This table presents a summary of the main effects for each of the individual joint sites ($R^2=0.408$). Abbreviations co-eff (β) = the mathematical weighting of each variable in the model; Stan Error = the estimated error of the mathematical weighting; OR = odds ratio; 95% CI = the 95% confidence interval for the estimated odds ratio.

	Site	Co-eff (β)	Stan. Error	Wald χ^2	P	OR	95% CI		Prevalence (per 1000)
							Lower	Upper	
Main effects	Constant	-0.4661	0.3748						
	Co morbidities	1.1792	0.1404	70.5675	<0.001	3.2518	2.4696	4.2816	404.39
	Hip	0.9510	0.1249	57.9796	<0.001	2.5883	2.0263	3.3062	126.71
	Knee	1.2447	0.1079	133.0922	<0.001	3.4720	2.8102	4.2896	220.33
	Foot	0.8745	0.1118	61.2101	<0.001	2.3978	1.9260	2.9851	184.33
	Back	0.3423	0.0972	12.4108	<0.001	1.4082	1.1640	1.7036	162.12
	Neck	-1.8567	0.3652	25.8478	<0.001	0.1562	0.0763	0.3195	151.54
	Shoulder	0.1162	0.1025	1.2851	0.2569	1.1232	0.9188	1.3730	160.45
	Elbow	0.1320	0.1231	1.1500	0.2835	1.1411	0.8965	1.4523	67.50
	Hands	0.1794	0.1031	3.0303	0.0817	1.1965	0.9777	1.4643	190.09
	Age: 55 to 64 years	-1.0582	0.1223	74.9161	<0.001	0.3471	0.2731	0.4411	
	Gender (Female)	-0.0780	0.1011	0.5958	0.4402	0.9249	0.7587	1.1276	

Table 4.4 Logistic regression modelling for getting up and down stairs. This table presents a summary of the main effects for each of the individual joint sites ($R^2=0.344$). Abbreviations co-eff (β) = the mathematical weighting of each variable in the model; Stan Error = the estimated error of the mathematical weighting; OR = odds ratio; 95% CI = the 95% confidence interval for the estimated odds ratio.

	Site	Co-eff (β)	Stan. Error	Wald χ^2	P	OR	95% CI		Prevalence (per 1000)
							Lower	Upper	
	Constant	-0.4300	0.3677						
Main effects	Co morbidities	0.8941	0.1392	41.2778	<0.001	2.4451	1.8614	3.2118	404.39
	Hip	1.1417	0.1730	43.5453	<0.001	3.1321	2.2313	4.3964	126.71
	Knee	1.1962	0.1641	53.1378	<0.001	3.3074	2.3978	4.5621	220.33
	Foot	0.6868	0.1003	46.8530	<0.001	1.9873	1.6325	2.4191	184.33
	Back	0.8878	0.1604	30.6214	<0.001	2.4297	1.7742	3.3274	162.12
	Neck	-2.0073	0.3666	29.9781	<0.001	0.1344	0.0655	0.2756	151.54
	Shoulder	0.2125	0.1010	4.4282	0.0353	1.2368	1.0147	1.5075	160.45
	Elbow	0.0856	0.1181	0.5250	0.4687	1.0893	0.8642	1.3731	67.50
	Hands	0.2929	0.1007	8.4554	0.0036	1.3402	1.1002	1.6327	190.09
	Age: 55 to 64 years	-0.7925	0.1186	44.6663	<0.001	0.4527	0.3588	0.5712	
Gender (Female)	-0.3355	0.1000	11.2618	0.0008	0.7150	0.5878	0.8697		

Table 4.5 Logistic regression modelling for rising from a seated position. This table presents a summary of the main effects for each of the individual joint sites ($R^2=0.276$). Abbreviations co-eff (β) = the mathematical weighting of each variable in the model; Stan Error = the estimated error of the mathematical weighting; OR = odds ratio; 95% CI = the 95% confidence interval for the estimated odds ratio.

the risk of difficulty significantly, with the exception of the neck; those with neck problems were six times less likely to report difficulty (OR=0.1562, $p<0.001$).

For difficulty in *rising from a seated position*, twenty percent (20.80%) of all respondents reported difficulty. Those with hip problems or knee problems were three times more likely to report difficulty ($R^2=0.276$; OR=3.1321, $p<0.001$; OR=3.3074, $p<0.001$); those with back problems were two and a half times more likely to report difficulty (OR=2.4927, $p<0.001$); foot problems were two times more likely (OR=1.9873, $p<0.001$); those with shoulder problems were 24% more likely to report difficulty (OR=1.2368, $p=0.0353$) and those with hand problems increased their risk by 34% (OR=1.3402, $p<0.001$). People who reported neck problems were less likely to report difficulty in rising from a seated position. Data are presented in Table 4.5.

4.5 Multiple-site problems

When the most common joint combinations are explained, the penalty for having multiple joint involvement becomes clear (Table 4.6). While those with knee problems were three times more likely to report difficulty in walking and standing, this risk increased dramatically if they had concomitant foot (OR=14.5048, $p<0.001$), back (OR=10.8478) or hip problems (OR=12.4344). Those with knee, back, foot and hip problems were 60 times more likely to report difficulty. A similar pattern emerged with going up and down stairs: those people with knee and hand problems were two and a half times more likely to report difficulty compared to those without knee and hand problems (OR=2.6064) and as did those with combined knee and shoulder problems (OR=2.4468). Once again, those with knee, back, foot and hip problems increased their risk of difficulty by twenty fold (OR=20.6380). Combined knee and foot and knee

Joint Combination	Combined odds ratio for functional indicators		
	Standing and walking	Climbing stairs	Seated position
Knee and foot	14.50 <i>(9.30 – 22.62)</i>	5.22 <i>(3.40 – 8.03)</i>	4.05 <i>(2.55 – 7.18)</i>
Knee and back	10.85 <i>(7.00 – 16.81)</i>	3.33 <i>(2.05 – 4.58)</i>	1.93 <i>(1.15 – 8.96)</i>
Knee and hands	7.71 <i>(4.91 – 12.11)</i>	2.61 <i>(1.72 – 3.94)</i>	1.73 <i>(1.72 – 4.85)</i>
Neck and shoulder	0.13 <i>(0.05 – 0.39)</i>	0.11 <i>(0.04 – 0.28)</i>	0.11 <i>(0.04 – 0.27)</i>
Knee and hips	12.43 <i>(4.45 – 34.71)</i>	5.64 <i>(1.38 – 8.24)</i>	2.21 <i>(0.36 – 11.37)</i>
Knee, hands and foot	19.97 <i>(10.37 – 38.46)</i>	2.61 <i>(1.73 – 11.76)</i>	1.73 <i>(0.11 – 11.72)</i>
Knee and shoulders	7.21 <i>(4.62 – 11.26)</i>	2.45 <i>(1.62 – 3.70)</i>	1.60 <i>(1.08 – 2.37)</i>
Back and neck	0.20 <i>(0.07 – 0.59)</i>	0.15 <i>(0.06 – 0.34)</i>	0.21 <i>(0.08 – 0.60)</i>
Knee and neck	0.32 <i>(0.10 – 0.96)</i>	0.34 <i>(0.13 – 0.86)</i>	0.17 <i>(0.10 – 0.82)</i>
Knee, back and foot	28.10 <i>(14.80 – 53.38)</i>	7.97 <i>(3.95 – 13.69)</i>	6.45 <i>(1.73 – 15.76)</i>
Knee, back, foot and hip	62.41 <i>(14.97 – 260.12)</i>	20.64 <i>(2.59 – 14.97)</i>	16.82 <i>(3.66 – 86.24)</i>
Foot and hands	6.61 <i>(4.37 – 10.01)</i>	1.80 <i>(0.79 – 2.05)</i>	1.73 <i>(1.17 – 2.57)</i>

Table 4.6 Combined odds ratio for most common multiple joint problems for each of the functional indicators. Combined odds ratio are a summative calculation taking into account the odds ratio for each joint, plus the odds ratio for the interactions between all significant joint combinations. The upper and lower 95% confidence intervals presented in italics.

and hip problems had a five fold increase in reporting difficulty using stairs compared to those without such joint pathology (OR=5.2233 and OR=5.6383, respectively).

When the common combinations of joint problems were analyzed for rising from a seated position, the likelihood of reporting difficulty for this category were also increased. Those who had knee and foot problems increased their risk to four fold

(OR=4.0488) and those who had knee and hip problems increased their risk by over two (OR=2.2103). Of note, for those with knee, hip and hand problems had a 10 fold increased risk of reporting difficulty (OR=10.3483). Those with knee and foot (OR=4.0488) increased their risk in reporting difficulty more than if they had either knee or foot problems alone.

4.6 Unilateral vs Bilateral joint problems

To explore the impact of unilateral pain or bilateral pain at each site, logistic regression modelling was repeated for each of the joint sites for main effects and compared analyzing the log likelihood statistics¹³. The predictive capacity of each of the functional activities was only increased marginally: for using stairs the predictive capacity increased from $R^2=0.321$ to 0.330; for walking and standing from $R^2=0.347$ to 0.349; and for rising from a seated position, $R^2=0.264$ to 0.271 for the most influential joints, which were the knee, hip and foot. As expected, bilateral pain increased the risk of reporting difficulty with each of the functional tasks compared to unilateral problems (Table 4.7): bilateral knee problems increased the difficulty in using stairs by three and a half times compared to people with no knee pain, where as those with only one knee affected increased their risk by two fold. In general, there was an increased difficulty reported were both joints were affected compared with unilateral joint problems, and these figures averaged out to that reported when unilateral and bilateral joint problems were considered simply as joint pain.

	Going up and down stairs Odd ratio (95% CI)	Walking and standing Odd ratio (95% CI)	Rising from a seated position Odd ratio (95% CI)
Knees			
One Knee	2.014 (1.924 to 2.097)	1.975 (1.897 to 2.057)	1.387 (1.332 to 1.445)
Both knees	3.628 (3.493 to 3.767)	2.644 (2.545 to 2.748)	2.289 (2.157 to 2.354)
Hips			
One hip	1.540 (1.478 to 1.605)	2.059 (1.972 to 2.150)	1.887 (1.804 to 1.954)
Both hips	2.646 (2.517 to 2.782)	3.031 (2.880 to 3.219)	3.023 (2.882 to 3.170)
Foot and ankle			
One foot	1.364 (1.283 to 1.449)	1.726 (1.623 to 18.35)	1.146 (1.077 to 1.219)
Both feet	1.941 (1.876 to 2.008)	2.512 (2.424 to 2.604)	1.713 (1.665 to 1.773)

Table 4.7 Logistic regression modelling unilateral and bilateral problems at the major joints of the lower limb. Modelling included joint site, gender, age and co-morbidities as main effects. Abbreviations; 95% CI = the upper and lower 95% confidence interval for the estimated odds ratio.

4.7 Discussion of Main Findings

This aim of this study was to report the prevalence, pattern and impact of multiple joint problems in the community. Almost 40% of people in this community cohort aged over 55 years reported some pain, swelling or stiffness lasting for more than 6 weeks over the previous three month period. In addition to the high prevalence, joint pathology represented a substantial impact on a person's ability to undertake common functional tasks.

Whilst the prevalence of individual joint problems was similar to that previously reported, particularly knee pain^{87, 197, 286-289}, this study demonstrates that multiple rather than single joint problems were common (median joint count of 4). While more than 20% of people over the age of 55 had knee problems, fewer than one in 11 of

this group reported pain only in their knee. Other joints were associated with even higher ratios of multiple joint involvement, such as in the hip, where only one in 20 reported hip only pain and the feet, where only one in 38 people reported foot only pain.

Specific joint problems contributed to the difficulty which people found in undertaking particular upper or lower-limb related tasks. People with knee problems were more likely to report difficulty in tasks associated with locomotion, such as standing and going up and downstairs. Those with hip problems were more likely to experience difficulty in rising from a seated position. Of note, the impact of foot and ankle problems, which have been rarely documented in the literature, had an impact similar to that reported for knee and back problems.

The presence of bilateral joint problems increased the likelihood of difficulty in using stairs, rising from a seated position and standing and walking compared to those with only unilateral pathology. However this was only minor in comparison to joint problems that occurred in combination. For example, knee and foot pathology, increased the risk of functional impairment to a much greater degree than if the risk of difficulty for each of the individual joint problems were simply added together. The most obvious example of this disproportionate increase in difficulty was the impact of a combination of the knee, back, foot and hip, which increased the risk of difficulty in climbing stairs 20 fold and walking 60 fold.

The impact of joint problems in the upper limb for locomotor tasks was generally insignificant or even appeared to reduce the risk of difficulty in the tasks associated with locomotion. The exception to this which was hands and shoulder involvement, which increased the risk of difficulty in both walking/standing and rising from a seated

position. We attempted to investigate functional tasks that we predicted would be related to upper limb joint pathology, (such as gripping and holding things) however the resulting poor predictive capacity precluded these results being reported.

While the ability to undertake functional tasks is influenced by many factors, it is important to note the significant effect of co-morbidities. These data considered the effect of co-morbidities in the logistic modelling and it is important to recognize that when considered as a main effect, co-morbidities was the single greatest predictor of who would report difficulty in standing/walking and getting up and down stairs. It was second only to the hip as the single main influence on rising from a seated position. So while we understand that the presence of co-morbidities in the older population is high²⁹⁰, particularly in those with pain²⁹¹ and joint pathologies^{89, 292}, they must be considered as an important factor in the ability to undertake simple functional tasks.

The limitations of this study are acknowledged. While it has been suggested that self reporting can be unreliable²⁹³ and overestimates specific joint pathology, the prevalence figures reported here are similar to those reported in much more rigorously validated data sets reported on hip²⁹⁴ and knee pathology⁸⁰. We also recognize that other variables that were not considered in the logistic regression modelling may also be likely to impact on functional ability.

4.8 Conclusion

There is a high prevalence of joint problems in the older community, which increases with age and is more common in women. Multiple-site involvement of pain is extremely common and the impact and interaction of the different sites of pain will

substantially influence people's ability to undertake the tasks of daily living. Co-morbidities are high in this group and they also have a considerable influence, often above and beyond that of joint problems, in people's functional impairment.

Chapter Five

Living with Osteoarthritis

5.1 Overview

This chapter presents the results of the qualitative study. The purpose of this study was to explore the issues associated with living with OA, and their impact on an individual's quality of life.

5.2 Participant Profile

Forty-five participants were interviewed over a 12 month period, which consisted of 19 males and 26 females. One female participant was excluded after the interview as it emerged during the interview that she had co-morbidities which were not revealed in the screening process. Of the remaining 44 participants, the median age was 65 years, with an age range from 19 to 76 years. Nineteen of the interviewees were 55 years of age or less.

In order to encompass issues associated with OA at different sites, purposeful sampling was undertaken which forced representation across different sites, ages and gender. The majority of those interviewed had knee or hip OA, and fewer reporting hand, foot or mixed site OA as their primary source of concern (Table 5.1). While representation was sought for each cell in the sampling matrix, there was no representation of males 55 years and under with just hand or just foot OA.

The audio recordings of the interviews, which lasted from between 45 minutes to four and a half hours, were transcribed verbatim for data exploration and analysis.

Following the transcription of each tape, the manuscript was checked by the

interviewer for accuracy and clarity and then cross-checked by one of the other members of the researcher team involved with the interviews.

	Male		Female		Total
	< 55 yrs	≥ 55 yrs	< 55 yrs	≥ 55 yrs	
Hip	3	2	2	3	10
Knee	2	6	3	5	16
Foot	1	1	2	2	6
Hand		1	1	3	5
Mixed site		3	1	3	7
Total	6	13	9	16	44

Table 5.1 Sampling matrix and participant numbers for the interviews. The pre-interview strategy was to secure representation for each cell of the matrix.

5.3 Thematic Selection

As described in Section 3.3.6, an initial coding strategy developed by the research team on completion of all interviews. Following this, the entire set of transcripts was reviewed by the candidate in order to get a holistic sense of possible themes and codes. Codes were initially abbreviated phrases, describing concepts or themes, for example “*embarrassment about appearance*”, “*positive success with treatment*” and “*inability to do things*”. The codes were then applied to the data to establish potential

Affected by weather	▪ Can't be bothered
Age vs arthritis	▪ Opting out
Comparison to others	▪ Non acceptance
Control of own destiny	▪ Feeling left out
Dependent on others	Support from others
Feeling embarrassed	▪ Positive support from family and friends
Feeling of being overwhelmed	▪ Negative support from family and friends
Feeling old	▪ Negative support at work
Feeling slowed down	▪ Positive support at work
Impact on family and friends	Medication and treatment
Making a joke of it	▪ Lack of efficacy
Old in other's eyes	▪ Pessimism with treatment
Others perceptions	▪ Dependency on drugs
Pacing yourself	▪ Positive experiences with medications
Planning ahead	▪ Manipulating the system for better treatment
Quality of life	▪ Adverse reactions to treatments
Restrictions of activities	▪ Walking and other aids
Shared dependency	▪ Frustration with how treated
The future	▪ Weight and arthritis
Trouble with activities	▪ Physiotherapy
Pain	▪ Vicious cycle with weight
▪ Pain on activity	▪ Avoiding taking medications
▪ Pain at night	▪ Surgery
Pain relief	▪ Impact of other people's experience with treatment
Coping	▪ Problems in diagnosis
▪ Coping with activities	Impact and site of pain
▪ Coping with pain	▪ Hands
▪ Coping with dependency issues	▪ Knees
Symptoms	▪ Feet
▪ Pain	▪ Footwear
▪ Stiffness	▪ Hip
▪ Fatigue	▪ Other sites
▪ Difficulty sleeping	▪ Multiple-site
▪ Difficulty walking	▪ People ignoring other sites of pain
▪ Possible consequences	Self esteem
▪ Instability	▪ Perception of self before arthritis
▪ Swelling	▪ Perception of self with arthritis
▪ Flares	▪ Appearance
▪ Fluctuating symptoms	Adapting and innovation
Impact on feelings	Working Issues
▪ Fear	▪ Adapting activities
▪ Anger	▪ Perceptions of others
▪ Frustration	▪ Limitations to tasks
▪ Depression	
▪ Helplessness	
▪ Embarrassment	
▪ Dreading the future	
▪ Guilt	
▪ Feeling a nuisance	
▪ Missing out	

Table 5.2 Summary of initial codes used for thematic analysis

categories. Cross referencing between phrases that would come under different codes was also undertaken at this stage of analysis. For example the phrase:

“I am embarrassed when I have to ask my son to come over and help me with to do things around the house, little things that were never a problem before”

was coded under “embarrassment”; “loss of independence”; “impact on family” and “coping with loss of independence”. A summary of the raw codes is provided in Table 5.2.

Following this initial coding, categories were developed which served to organise the code into meaningful clusters. Code and categories were collapsed to evaluate emerging themes until the point was reached where no new information was being generated. The codes are presented in Figure 5.1.

5.4 Emergent Themes

As demonstrated in Figure 5.1, the experiences of living with OA are multi-faceted, consisting of complex associations and relationships. Participants differed in terms of how OA impacted on their day to day life and the relative importance of each in terms of contributing to their overall quality of life. The major emergent themes are described below.

5.4.1 Impact on self perception

Several participants reported a substantial shift in their sense of self and their roles within their family and close personal friends. This was distressing for several of the participants who felt their role within their intimate support network was being lost.

They have all noticed how much my personality has changed because of it, they expect me to always be the one whose shoulder gets cried on, and now I am trying to cry on other peoples shoulders because I am in pain and it doesn't feel right, and it really does not feel right and it upsets me.

DH, Male with multiple-site OA, 62 years

Several participants expressed concern and guilt at how their illness was impacting on their family members, through lack of participation or increased dependency.

This was highlighted with the concerns of a young mother of a two year old:

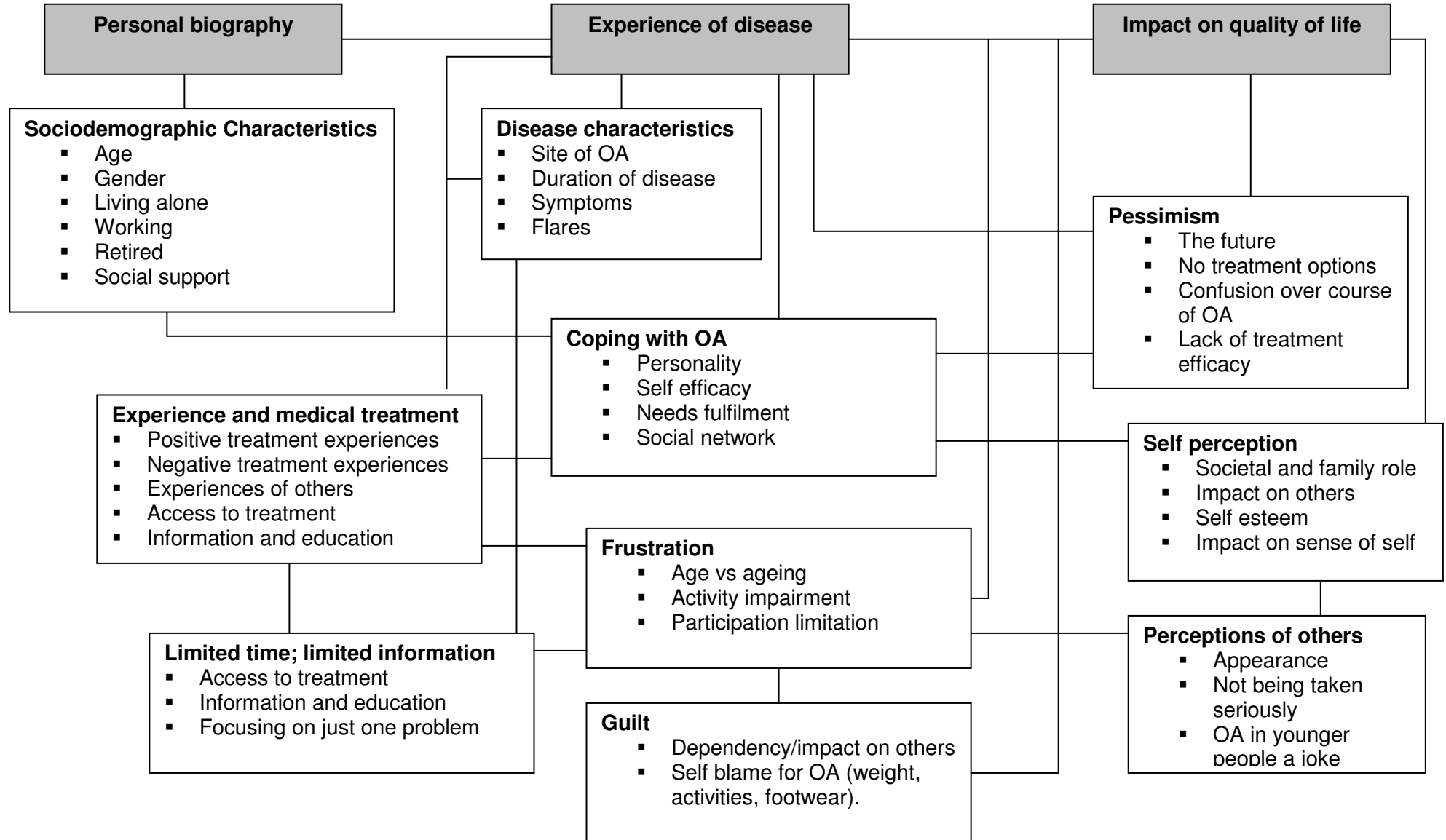
I try and take her to playgroup but if I'm not feeling good I can't because I can't run after her and obviously it restricts, I feel bad because I'm giving the restrictions to her and she's missing out on things you know..

DS, Female with hip OA, 38 years.

The impact on family relationships associated with frustration and anger at the condition was also expressed by several participants. Ill feelings towards family members were often associated with a perceived lack of understanding of what it was like to live with the condition.

She blames me and I blame her, I know for a fact that it makes me queer at times, same as going shopping or, if you go shopping you can guarantee that the way you are walking everybody is walking straight towards you, and I cant move out of way, I cant go sideways and they are coming straight at you with pushchairs and everything and you are getting madder and madder, and I

Figure 5.1 Emergent themes from analysis of the interviews



think well it is a waste of time, I says I will sit down, you carry on, so I don't know I don't what is up with her really, whether she is getting queer and all, and whether it is with her or what, I don't know, you are angry and you are miserable.

AM, Male with multiple-site OA, 65 years.

Several interviewees talked about opting out of life and feeling excluded with their arthritis. One participant expressed their concern particularly succinctly:

Life goes on whether you're there or not. But when you're there you want to be an active part of life, which is rather difficult because arthritis is slowing me down and it makes me feel like that; you're on outside, looking in.

DH, Male with knee, hands and shoulder OA, Age 55.

Two different concerns were raised about the impact of OA on appearance: unsightly or ugly joints and the additional weight gain related to inability to exercise both of which had an impact on their self esteem. Of note, those with hand OA spoke of the embarrassment of the change in appearance of their fingers, particularly in social situations where attention was drawn to their hands, such as shaking hands and handing over money.

Participants commonly expressed an embarrassment about their arthritis. This embarrassment stemmed not only from the physical disfigurement, which was mostly associated with the hands, but also from physical ability. One woman in particular highlighted the feelings that she had when being confronted with her limitations with using stairs:

When you have to walk very slowly because striding out doesn't help - you know it's not an option and you're on a slope going down and it's hurting, so you're going really slowly and carefully and you're on stairs and you're going down one at a time. I just feel, I mean, you know in reality, it doesn't happen - people are rushing with their own agenda, they're off to catch their bus, they're going past and this that and the other, but I feel as if people are looking at you - you are blocking up a pathway. You're blocking the stairs. You're doing things like that and you feel there is a huge embarrassment factor.

PA, Female with knee OA, Age 55.

5.4.2 Perceptions of others

Frustration was expressed by participants that other people did not take their arthritis seriously. There were several issues which emerged through the transcripts: firstly, arthritis is commonly perceived simply as a disease of ageing; secondly, participants were embarrassed at their physical appearance; thirdly there was a perception that OA was thought of as a joke; and finally, seven of the participants expressed concerns that the perception of others was that somehow they were guilty and contributed to their condition.

Issues associated with ageing and OA as part of the ageing process were commonly expressed. However, several of the participants expressed concern that they were perceived to be “whingers” and were making more out of their condition, when it was just part of the aches and pains of getting older and that “everyone” has arthritis.

I think sometimes people think “Oh you know arthritis is nothing”. I think you can tell when they say to you “are you alright, are you in pain”

and when you go “it’s arthritis” end of story. They asked you and that’s it and it’s nowt, there’s nowt wrong with you. I find it, not everybody, a lot of people do understand, but you get people that don’t realise just how much pain you’re in. Yeh.

JG, Female with mixed site OA, Age 75.

Participants reported that others engaged in treating their arthritis as a joke. This was particularly evident in younger people. They felt that as OA is seen as a disease of the elderly, their symptoms were considered funny to others, including their family and friends. This was major concern for both of the younger women who had foot OA and one, who was a competitive sportsperson, expressed concerns that she did not have a “respectable” condition that stopped her participation in her sport:

the fact that it’s my toe I just try and make it like a little joke that it’s and old persons thing and that’s my way of sort of dealing with it..... I remember when I was [participating in sport] people used to think it was really funny, not in a horrible way but that I had to strap up my bunion and everybody else had more respectful injuries like wrist pain or something.

HL, Female with foot OA, Age 22.

The final area of frustration with people’s conception is an issue associated with guilt, that those with OA had consciously done something to cause their disease. Once again, both young female foot OA participants were angry that they had to continually explain that it was not poor footwear choices that lead to their OA:

I get really awful when I think that people think that its my fault, it must be my fault, all older people, saying “oh you’ll get problems with your feet if you wear them shoes.....I feel a bit annoyed actually when

people try and challenge me on it and they say no it's not it's because of shoes and I say well no it's not it's because of my genes and the length of my tendon or something like that and they say no it's not it's because you've worn bad shoes and I say I've never worn bad shoes you know yes it gets a little bit annoying when they try and blame me for it.

HL, Female with foot OA, Age 22.

The reaction of feeling guilty as having been responsible for their symptoms was similarly expressed by several of the participants who were overweight.

I feel guilty because I've let myself get like this, but yet there's been other problems there that's contributed to it, you know, because I can't say, I mean, I suppose a lot of the people will say this, but they don't think they eat a great deal. And I don't think I do. I mean I'm not piggish, you know, 10 bacon butties and chips and whatever, I don't eat, I can't afford to eat anything like that. I just don't do it. Oh, I think probably it's part genes, as well because both my parents were large, so I've probably inherited from them. So you know, it's just part and parcel of my make up, but I feel guilty for being like this, you know, and have I caused the trouble myself.

JCB, Female with knee OA, Age 53.

5.4.3 Coping

During the interviews, it became apparent that there were varied and individual approaches to coping with OA. Strategies for dealing with the impact of OA ranged from behavioural modification

I am more careful now when it comes to decorating and things like that I am more careful and would do it in stages rather than go at it hammer and thongs and get it all done because I know I'm going to suffer if I do it all too quickly.

PD, Female with Knee OA, Age 60.

..to cognitive strategies

Everybody reacts differently I expect but if you let it get down it will do won't it so if you think positive and act positive I think you are half way there to being ok.

JJ, Female with hand OA, Age 54.

Several participants indicated that their ability to cope in the future would be determined by their ability to meet their societal and/or family roles.

As long as you can get out and about really. If I'd come to a full stop where I can't get out which is annoying, I wouldn't like that at all, to be house bound. That wouldn't go down well at all. As long as I can get about and do things, I'll be satisfied

DL, Male with knee OA, Age 75.

5.4.4 Pessimism

A common theme expressed by participants in their interviews was that of pessimism. Several individuals related poor experience with how long it took to be diagnosed and what treatment options were presented to them. Many expressed concern, particularly about taking medications and the potential problems associated with side-

effects. They often felt as though they had been abandoned and left to cope with their condition as best they could.

What else can be done for me, and things like that, because I just feel as though I've been abandoned actually. But I know there's nothing else anybody can do for me, but I feel as though I've been abandoned and left to get on with it.

JCB, Female with knee OA, Age 53.

The issue as to what the future held was associated with grave concerns for the majority of the participants – how the disease was going to progress, whether they could manage pain and physical limitations. This was a particular concern if their current societal and family roles were likely to be compromised.

I want to think that I finish work in five years time, I'm one of the people that can retire at sixty, and I want to feel that that's not the end of everything but if in five years time this has progressed and I'm left not coping, you know. I'm going to be old because I can't go somewhere and I can't do something I can't go trotting off and join in the sixty year old swimming and this sort of thing and there's a sense that physically my life will be older, you know. I don't expect my brain to be older, I just you know it has a restrictive value it's something that you know. You see people retiring and you think well yes they're off in their walking holidays in the Lake District or whatever. They're doing and I can't do it.

PA, Female with knee OA, Age 55.

5.4.5 Limited time; limited information

In describing concerns with their treatment of OA, several participants expressed concern that treatment strategies were not tailored to individual needs. This was particularly, but not exclusively, an issue with younger people with OA.

*I do think that people need a bit more information with arthritis, I think they seem to think you are in a category, you are in a box and the same, everybody is the same, I did find that, I mean talking to doctors, er when doctor ** orthopaedic, his young man referred me, he put me as non-urgent because they thought I could cope, nobody actually did ask if I would be able to cope because I was working and I was doing and they thought you would cope and they tend to put you in boxes and I did find that.*

JA, Female with knee OA, Age 64.

Furthermore, concern was expressed concerning the stress associated with a considerable information exchange between patient and doctor. One participant, with knee and foot OA was particularly vocal that her foot complaint was not addressed in her consultation with her hospital specialist.

*And if I don't know to say something to **** or ****, you know, if I don't mention something, it's taken me how long an hour and a half to rabbit all these bits out - and if I don't say the right thing in the twenty minutes I've got, then something is not missed because it doesn't - it crops up in the end doesn't it? But you know it's not the whole picture isn't there.*

PA, Female with knee, foot and hand arthritis, Age 55

5.5 Discussion main findings

The experience of living with a chronic illness represents a considerable challenge to an individual. This study has identified several themes linked to the impact of living with OA: impact on societal/family roles and the consequential change in self perception; the misconceptions that others have of OA, particularly that the disease is solely related to ageing and that it is self inflicted; coping is an individual experience and is related to complex personality, cognitive and behavioural drivers; and finally there is a distinct sense of pessimism in the lack of treatment strategies, lack of information and limited consultation time, which is a particular issue for people who have complex needs.

Loss of the ability to live as one would like results in a life that is vulnerable and results in a constant influence on family members and significant others²⁹⁵. It has long been recognised that chronic illness has an impact on self perception, which is facilitated and compounded by pain, functional limitation and loss of societal roles. According to Bury²⁹⁶, people with chronic illness suffer from a “biographical disagreement”, a term which refers to a disagreement with in the perception of the individual as to what type of life they see themselves leading with a chronic illness compared to what type of life they think they *should* have. This phenomena results in distress and anxiety, unless the person can adapt this altered life of living with a chronic illness. This adaptation is what was referred to in Chapter 2 as a response shift¹⁹⁹. Several strategies have been identified to reduce associated anxiety and distress associated with this response shift, including activity adjustment, skill enhancement, goal adjustment and a “humanistic” approach which is centred around positive adaptation to altered health¹⁸⁴.

Our participants certainly reflected the idea of a challenged self worth with OA. It was clear that OA substantially influences the sense of self esteem, which is often reflected through others perceptions of their condition. The interrelationship between sense of self and self worth based on other perceptions has previously been identified in people with OA²⁹⁷. In this study, Swift and colleagues reported that feelings of self-worth were being undermined by the attitudes of friends and strangers and that symptoms were perceived by others as being exaggerated. This may indeed be related to the perception that OA is an expression of the ageing process and those who report symptoms are seen to be simply not coping with this process.

Living with a chronic illness is often stressful and traumatic with social isolation, depression, restricted participation and a sense of dependence often reported²⁹⁸. Frustration has also been expressed that in individuals with chronic illness, the focus from those they seek medical advice and treatment from is directed towards functional ability, which does not adequately account for the experience of chronic illness²⁹⁹.

The pessimism expressed by people with OA was evident on several levels. The importance of the loss of power felt by people with a chronic illness with an uncertain progression has been recognised²⁹⁸. However, if this is being continually undermined by referral to others' perception, particularly that their OA is simply part of the ageing process and one which everyone else has to deal with, the ability to cope with the impact of a disease is further diminished.

Being overweight highlighted several issues in those interviewed. Participants felt they were being blamed for their symptoms and were not given the same support and concern as others with OA. They often felt caught in a cycle of being overweight, unable to exercise with their OA pain, which increased their weight even further. Furthermore, this guilt may have been compounded in the interview process as just

prior to this study commencing, several Trusts in the UK refused to provide NHS surgery to those who do not lose an adequate amount of weight prior to their pre-surgical assessment. The link between obesity and psychological factors has been firmly established, with high incidence of depression, negative body image and lower self esteem reported³⁰⁰, which may exacerbate such symptoms in conjunction with OA.

Pessimism was also related to the perceived lack of treatment options, with particular concerns raised over medication and surgery, which has previously been reported in the literature⁴⁵⁻⁴⁷. This may have been heightened by the high profile withdrawal of several drugs commonly used to treat OA during the interview period. While several of those interviewed had very positive experiences with drug therapy, medication was often seen as dangerous and potentially addictive, and patients would often prefer to put up with pain, rather than expose themselves to the risks associated with taking medication. The timing of this study may have contributed to a higher level of cautiousness: there was a high profile withdrawal of several drugs commonly used to treat OA during the period of this study. The widely publicised debate as to the adverse events of the drugs had the effect of undermining further the perception that drugs, if they were effective, were associated with a substantial risk-benefit consideration.

Issues associated with benefits, expectations and side effects in medications taken for OA have been explored in the literature. While variability of response and side effects to NSAIDs and COXII inhibitors have been well documented, patients with OA are less likely to accept side effects of anti-inflammatories and less willing to take risks compared with those with rheumatoid arthritis³⁰¹. While this may be associated with lesser symptoms in osteoarthritis compared to rheumatoid arthritis, it may also reflect that people consider OA not to be a “serious enough” disease to warrant potential side

effects. Furthermore, the perceived risks for medication in OA are often not necessarily reflected by the true risk. There has been a reluctance in patients with symptomatic OA to take pain killers⁴⁵, due in part, to concerns over the side effects, particularly addiction. Interestingly, this concern was not reflected in taking anti-inflammatories⁴⁵, where the risks are potentially greater. This may indicate a need for greater patient education of potential medication's benefits and risks.

The issue of perceived guilt for individuals contributing towards their disease was particularly evident. Younger females with foot pain were frustrated that they contributed towards their arthritis in choosing inappropriate footwear, which was inconsistent with the experiences of their friends and relatives who chose inappropriate shoes, often for many years, without any negative consequence. The frustration at footwear was further compounded by the feeling of unfairness in that they wore "sensible" footwear and very much grieved that as young women, they could not be as fashionable as their peers.

The feeling of abandonment by the system also highlights several issues. If an individual feels that there are no treatment options that would assist, their ability to cope becomes compromised. While patients and health professionals alike are often frustrated by the lack of development in new therapies for OA, it is often pharmacological treatments that are highlighted. However, recent literature had demonstrated the positive benefits of physical therapy programs^{302, 303} in symptomatic treatment of OA. Furthermore, while patients feel they get benefit from educational programs and should receive a high priority in future research³⁰⁴, almost half of knee OA patients have not received any such assistance.

This study has several limitations, which are consistent with qualitative research methodology^{242, 248, 305, 306}. Firstly, the sample size of 44 participants, although

consistent with qualitative methods, limits the generalisability of the findings. While gender, age and OA at different locations were purposefully selected, other factors, such as duration or aetiological factors were not included. Secondly, differences in social support and quality of life were evident, but not well explicated. Thirdly, as the interviewees were recruited from the greater Leeds area, there may be unrecognised problems in accessing appropriate treatment, which may have influenced feelings of pessimism associated with treatment options. Finally, issues associated depression and anxiety, while identified in this study, were not fully explored.

5.6 Conclusion

OA is a chronic and debilitating condition, the impact of which is considerable. Those with OA often feel that their condition is misunderstood as an expected part of the ageing process, which can undermine their self esteem and ability to cope. Younger people with OA are particularly vulnerable to such misunderstanding. Finally, patients are often pessimistic about their treatment options and what the future hold and feel that there are abandoned by the system.

Chapter Six

Development and validation of the OAQoL

The results of this study have been accepted for publication in *Arthritis & Rheumatism*³⁰⁷.

6.1 Overview

This chapter describes the development and validation of a quality of life instrument specific for OA, the OAQoL. As described in Section 3.4, the development of the measure was conducted in four phases: in-depth interviews; cognitive debriefing; initial psychometric testing and test-retest assessment (See Figure 3.2). The results and consequential modification of the OAQoL are described below.

Participant characteristics for each phase of the study are presented in Table 6.1 and described in detail in each of the associated sections.

6.2 Qualitative Interviews

i. Participants

As reported in Chapter 5, forty-five participants were interviewed with different site and location of pain. One participant was not included in the generation of items for the draft OAQoL as one was found to have co-morbidities not identified on screening. Participant characteristics are presented in Table 6.1. Interviews lasted from between 45 minutes to four and a half hours. The results of the qualitative study are presented in Chapter 5.

		Phase 1 Qualitative interviews	Phase 2 Cognitive debriefing	Phase 3 Psychometric testing	Phase 4 Test-retest
N		44	17	259	60
Gender	Male N (%)	19 (43.2)	3 (17.6)	72 (27.8)	27 (45.0)
	Female N (%)	25 (56.8)	14 (82.4)	178 (68.7)	33 (55.0)
	Missing N (%)	0	0	9 (3.5)	0
Age	Mean Age (SD)	58.7 (15.0)	69.2 (10.8)	66.5 (12.5)	66.5 (12.0)
	Median Age (IQR)	64 (53 to 69)	72 (62 to 77.5)	68 (59 to 76)	67 (58 to 67)
	Range	19 to 76	46 to 81	21 to 98	20 to 84
Site of OA	Hip N (%)	11 (25.0)	2 (11.8)	62 (23.9)	24 (40.0)
	Knee N (%)	15 (34.1)	10 (58.8)	104 (40.2)	51 (84.0)
	Foot N (%)	5 (11.4)	3 (17.7)	74 (28.6)	14 (23.3)
	Hand N (%)	5 (11.4)	4 (23.6)	104 (40.2)	21(35.0)
	Multiple-sites N(%)	8 (18.2)	6 (35.4)	221 (85.3)	50 (83.3)
	Median joint pain (n)	NA	NA	4	4
Education Level	No formal qualifications N (%)	NA	5 (29.4)	109 (42.2)	30 (50.0)
	GSCE, O-Level, A-Level or Trade N (%)	NA	6 (35.3)	72 (27.7)	16 (26.7)
	Diploma, degree or higher degree N (%)	NA	5 (29.4)	63 (24.2)	12 (20.0)
	Missing N (%)		1 (5.9)	15 (5.8)	2 (3.3)

Table 6.1. Participant characteristics for each phase of the development of the OAQoL

ii. Item Selection

In order to develop the draft OAQoL questionnaire, direct quotations from the interviews of each participant were identified as possible items, as described in Section 3.4.1. Duplicate items were also identified and through consensus and the item that appeared best to express the concept conveyed (while meeting the aforementioned criteria) was selected. The draft OAQoL (version 1) was developed in this way and consisted of 38 items with a 'true'/'not true' response option. Participants were asked to choose the response that best applied to them at the moment.

6.3 Cognitive debriefing

Field test interviews were conducted with 17 individuals who completed the draft OAQoL (Version 1, Appendix Two) under the supervision of an interviewer. The measure took between 2 and nine minutes to complete (mean 4.4, SD 2.2 minutes). The cohort represented a range of educational experience, with just under 30% reporting no formal qualifications (Table 6.1).

Clarity and Relevance

The seventeen participants reported that the draft questionnaire was clear and easy to complete. Only one participant had difficulty in interpreting how to answer the questionnaire and sought clarification from the researcher. Of the seventeen participants, four did not read the instructions yet completed the questionnaire correctly. The remainder of the participants read the instructions, with two respondents referring back to them as they completed the questionnaire. There were no questions reported by the participants as being too difficult and in general, the participants reported that the items were easy to understand and relevant to someone with OA, even if they did not apply to them as individuals.

Response Scales

Most participants had no difficulties using the dichotomous response format. One participant who misunderstood the instructions completed the questions incorrectly by assuming that questions were grouped in threes and only one of the three questions had to be answered. This was likely to be related to an unequal spacing between the questions. Two participants said they would have preferred more response options for some of the items, but they were still able to answer, even given the response options available.

Problematic Items

Three items were identified as being potentially problematic by the research team prior to the debriefing interviews: *“I get embarrassed using stairs”*, *“I can’t do things spur of the moment”* and *“I worry about being a nuisance to others”*. Respondents were asked their interpretation of the meaning of the question.

Two items were changed on the basis of respondents’ comments. *“I get embarrassed using stairs”* was changed to *“I get embarrassed using stairs in public”* as interviewees stated that people would be unlikely to become embarrassed using stairs when not observed. *“I can’t do things spur of the moment”* was considered to be confusing and was changed to *“I can’t do things on the spur of the moment.”* One member of the research team was concerned that the term “nuisance” may have a predatory interpretation. None of the respondents thought this to be so. With these changes, the questionnaire was reformatted so the spaces between questions were identical.

6.4 Scaling Properties and Construct Validity

Of 635 questionnaires sent out, 397 were returned, a response rate of 62.5%. Of these, 259 completed the questionnaire and were classified as responders, while 138 replied that they would not like to participate and were classified as non-participants. There were no significant differences in age or gender between responders and non-responders, nor responders and non-participants. The majority of the respondents were females (68.7% female), had a mean age of 66.5 years (range: 21 to 98, SD=12.5yrs) and mean symptom duration of 12.6 years (range: 0.5 to 45 years; SD=9.1yrs). While the knee was the most common site of pain (40.2%), this was followed closely by the hand (39.8%), the foot (28.6%) and hip (23.9%), which was similar to that found in the epidemiology of joint pain in the community (Chapter 4). Multiple joint involvement was common, with the median number of joints affected being 4 (range 1 to 20), which was identical to the epidemiological study. Almost one quarter of the sample was in paid employment and there was a wide range of educational achievement (Table 6.1).

The strategy for Rasch Analysis and item reduction is summarised in Section 3.4.3 and the outcomes of the iterations in the analysis are presented in Table 6.2. Rasch analysis of the draft questionnaire (n=259) indicated initial misfit to the model ($\chi^2[114] = 250.036$; $p < 0.0001$) with the item fit residual mean = -0.363 and Person separation index (PSI) = 0.96032. In the first instance, four individuals were removed as they had fit residuals of over 0.25. Once these were removed, the fit to the Rasch model was still poor ($\chi^2 = 261.264$; $df = 114$; $p < 0.0001$), with the item fit residual mean = -0.314 and standard deviation of 11.835 and the PSI = 0.96142. Eleven items demonstrated high fit residuals, indicating that they were contributing to the poor fit. These are presented in Table 6.3. Once these items were removed, the overall fit to the Rasch

Model	Modification	χ^2	df	p Ideal >0.05	PSI > 0.8	Item Fit Residuals	
						Mean Ideal 0.0	Standard Deviation Ideal 1.0
1	Original analysis	250.036	114	p<0.0001	0.96032	-0.036	1.184
2	Remove 4 individuals with a fit residual >0.25	261.264	114	p<0.0001	0.96142	-0.314	1.184
3	Removal of item 32 for high fit residual	257.132	111	p<0.0001	0.96268	-0.326	1.794
4	Removal of item 3 for high fit residual	249.002	108	p<0.0001	0.96232	-.0357	1.695
5	Removal of item 31 for high fit residual	229.667	105	p<0.0001	0.96428	-0.376	1.530
6	Removal of item 28 for high fit residual	172.813	102	p<0.0001	0.96609	-0.412	1.236
7	Removal of item 17 for high fit residual	162.061	99	p<0.0001	0.96723	-0.392	1.245
8	Removal of item 25 for high fit residual	157.715	96	p<0.0001	0.9678	-0.419	1.105
9	Removal of item 23 for high fit residual	149.568	93	p<0.0001	0.9666	-0.431	1.068
10	Removal of item 16 for high fit residual	132.580	90	p=0.0024	0.96717	0.492	0.804
11	Removal of item 26 for high fit residual	109.488	87	p=0.0531	0.96608	-0.465	0.803
12	Removal of item 5 for high fit residual	105.771	87	p=0.0835	0.96712	-0.453	0.730
13	Removal of item 38 for high fit residual	89.513	81	p=0.2422	0.96516	-0.431	0.690
14	Item 34 removed for DIF for site, gender and age	102.420	81	p=0.0542	0.96562	-0.490	0.688
15	Item 36 removed for DIF for gender and age	83.602	75	p=0.2322	0.96334	-0.480	0.680

Table 6.2 Summary table of Iterative analysis for initial OAQoL data

Item No	Item	Reason for removal
3	It is always on my mind	High fit residual
5	Travelling distances is a problem	High χ^2 value
16	I dread the future	High fit residual
17	I take it out on people close to me	High fit residual
23	I am embarrassed about the way I walk	High fit residual
25	I feel older than my years	High fit residual
26	It puts a strain on my personal relationships	High χ^2 value
28	I find it difficult to sit through a film or tv programme	High fit residual
31	I feel the arthritis is affecting my appearance	High fit residual
32	I never get a good night's sleep	High fit residual
34	I feel like a burden to other people	DIF for co-morbidities, gender, age and location of OA
36	Pain controls my life	DIF for age and location of OA
38	I feel lonely	High χ^2 value

Table 6.3 Summary of Items Removed following initial Rasch Analysis

Model was good ($\chi^2[81] = 89.513$; $p = 0.2422$). A summary of the three worst fitting items and best fitting items is presented in Table 6.4. Two items demonstrated differential item functioning (DIF) by age: “*I feel like a burden to others*” and “*pain controls my life*”; and the item “*I feel like a burden to others*” also demonstrated DIF for gender “*I feel like a burden to others*”. Once these items were removed (13 items in total), the data still demonstrated good fit to the model ($\chi^2[75] = 83.602$, $p = 0.232$), with the item fit residual mean = -0.480, standard deviation of 0.680 and a PSI = 0.96334, resulting in a 25 item version of the OAQoL (Version 3). There was no significant DIF by co-morbidity.

Item	Location	SE	Fit Res	χ^2	DF	P value
I find it difficult to sit through a film or TV programme	0.041	0.168	4.665	37.157	3	<0.001
I feel the arthritis is affecting my appearance	0.209	0.169	4.369	22.855	3	0.0004
I take it out on people close to me	1.411	0.188	0.968	15.119	3	0.0018
I feel slowed down	-3.457	0.247	-0.591	0.988	3	0.8040
Walking for pleasure is out of the question	-1.921	0.189	-0.448	0.839	3	0.8401
I get embarrassed using stairs in public	0.569	0.173	-0.282	0.542	3	0.9096

Table 6.4 Summary of worst fitting and best fitting items. Location refers to the location of the item along the metric ruler, SE (the standard error of the measure) and Fit Res (the Fit Residuals or how well each item relates to the overall model). A significant χ^2 indicates that an item does not fit the model.

Distribution of the items indicated the range of difficulty covered by the items was comprehensive. The unidimensionality of the instrument was confirmed by testing of local dependency of items, which indicated that only 3.02% of the independent t-tests (95%CI = -2 to 5%) were found to be outside the range.

The external validity of the OAQoL was assessed by investigating the relations with other measures commonly used in OA. The 25-item version of the OAQoL (version 3) demonstrated significant moderate correlation with the pain and stiffness domains of the WOMAC ($\rho=0.67$ and $\rho=0.71$, $p<0.001$ respectively) and good correlation with the WOMAC disability domain ($\rho=0.80$). There was a good correlation between the OAQoL and the General Well-Being Index ($\rho=-0.68$) and a moderate correlation with the Cochin Scale ($\rho=0.49$).

6.5 Test- retest reliability

In phase 4, 125 of the 201 questionnaires were returned, a response rate of 62.3%, including 49 non-participants. Of the people who agreed to participate, 62 completed the questionnaire on two occasions. Two respondents had to be discounted, due to changes in their treatment and symptoms during the test-retest period. The profile of this group was similar to Phase 3 (Table 6.1) with the exception that more reported knee OA in the test re-test participants. Once again, there were no differences in age or gender between responders and non-responders.

Rasch analysis of the test re-test data indicated that, while the data met model expectations at the summary level ($\chi^2[44] = 47.254$, $p = 0.584$, with the item fit residual mean = -0.279, standard deviation of 1.014 and a PSI = 0.95593), there was a high fit residual for one item (*"I worry I let people down"*), DIF associated with gender for the item *"I worry I hold people back"* and for site of OA for the item *"It takes me longer to complete household tasks"*. These items were removed, leaving a 22 item OAQoL (Final Version, Appendix Three) that demonstrated good fit to the Rasch model ($\chi^2[44] = 44.559$, $p = 0.533$), with the item fit residual mean = -0.228, standard deviation of 1.022 and a PSI = 0.94992. Two items demonstrated borderline DIF for co-morbidities (*"walking for pleasure is out of the question"* and *"I feel slowed down"*) however these were not significant. One item (*"I can't go places I want to go"*) demonstrated borderline DIF for site of OA, but this item was retained in the final questionnaire. The summary of the iterative process is presented in Table 6.5 and the location and details of the final items are presented in Table 6.6. The person item threshold map is represented in Figure 6.1, indicating that the distribution of the items was comprehensive. Once again, testing for unidimensionality indicated that only 4.67% of the independent t-test were significant (95%CI = 2 to 13%), confirming there

Model	Modification	χ^2	df	p Ideal >0.05	PSI > 0.8	Item Fit Residuals	
						Mean Ideal 0.0	Standard Deviation Ideal 1.0
1	Original analysis	47.254	50	0.584223	0.95593	-0.279	1.104
2	Removal of item 5 for hit fit residual	44.572	48	0.614121	0.96550	-0.270	0.956
3	Removal of item 7 for DIF for site of OA	49.168	46	0.347464	0.95471	-0.260	0.983
4	Removal of item 9 for DIF with gender	42.559	44	0.533468	0.95258	-0.243	1.027

Table 6.5 Summary table of iterative analysis for test re-test analysis of OAQoL data

Item	Location	SE	Fit Res	χ^2	DF	p
21. I feel slowed down	-4.19688	0.294	0.006	1.898	3	0.593764
9. Walking for pleasure is out of the question	-2.53514	0.217	-0.808	2.277	3	0.516932
20. I have to limit what I do each day	-2.46136	0.217	0.64	6.316	3	0.097208
17. I can't be as independent as I want	-1.43437	0.198	-0.312	7.816	3	0.049961
6. My arthritis limits the places I can go	-1.27132	0.196	-0.491	0.4	3	0.940225
19. I can't live life to the full	-1.19319	0.195	0.287	1.419	3	0.70099
4. I can't plan things too far in advance	-0.82568	0.192	-0.83	6.169	3	0.103682
7. I can't do things on the spur of the moment	-0.64772	0.191	-0.397	2.836	3	0.417578
1. I'm unable to join in activities with my friends or family	-0.64025	0.191	-0.649	1.823	3	0.609914
15. I worry about being a nuisance to other people	-0.47	0.191	-0.006	2.098	3	0.552347
12. I feel I can't join in with social activities	-0.3184	0.191	-1.395	6.809	3	0.07823
3. I feel like I am missing out on life	-0.26229	0.191	-0.891	4.643	3	0.199879
8. It interferes with everything that I do	0.657439	0.196	-0.831	1.022	3	0.79596
2. I get embarrassed using stairs in public	0.711476	0.196	0.934	5.685	3	0.127995
14. I feel dependant on others	0.816447	0.198	-1.335	3.942	3	0.267764
13. My arthritis controls my life	1.209287	0.203	-0.869	3.724	3	0.292857
16. My life revolves around my arthritis	1.451653	0.207	-0.999	5.183	3	0.1589
11. I feel useless	1.748273	0.216	-0.679	2.093	3	0.553404
10. I can't enjoy myself when I go out	2.042232	0.223	-1.016	2.872	3	0.411732
22. I can't go to the places I want to go	2.119166	0.226	0.556	6.223	3	0.101263
5. I feel as though I'm trapped in my house	2.288998	0.234	-1.151	3.641	3	0.302932
18. I feel very isolated	3.211616	0.277	-0.645	3.198	3	0.362032

Table 6.6 Summary of the final items. Location refers to the location of the item along the metric ruler, SE (the standard error of the measure) and Fit Res (the Fit Residuals or how well each item relates to the overall model). A significant χ^2 indicates that an item does not fit the model.

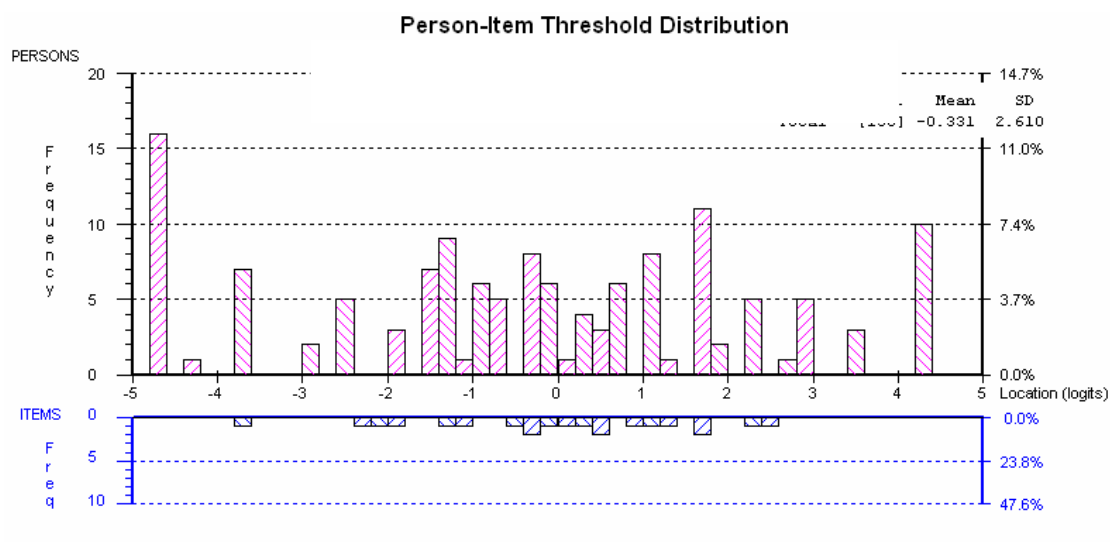


Figure 6.1 Person-Item Threshold Distribution for the final 22 item OAQoL

was no pattern in the residuals, and supporting the strict unidimensionality of the instrument.

The test-retest for the total score was explored using Spearman's Rho and for each item Cohen's Kappa (κ). There was an excellent correlation between the two total OAQoL scores from time 1 to time 2 ($\rho=0.93$, $p<0.001$) with no systematic differences between the scores on each occasion ($z=-0.06$, $p=0.995$), suggesting excellent test-retest reliability. Kappas for each item ranged from moderate ($\kappa=0.512$) to excellent ($\kappa=0.926$), with most items demonstrating kappas in the range 0.65 to 0.85.

In order to re-assess the construct validity of the revised OAQoL, the relationship between the 22 item OAQoL and other measures were again calculated. The results were similar to those found for the draft 25 item OAQoL (version 3): there was a moderate correlation to the pain and stiffness domains of the WOMAC ($\rho=0.67$, $p<0.001$ and $\rho=0.71$, $p<0.001$ respectively) and good correlation with the WOMAC disability domain ($\rho=0.78$, $p<0.001$), a moderate to good correlation with the General

Well-Being Index ($\rho=-0.65$, $p<0.001$) and once again a moderate correlation with the Cochin Scale ($\rho=0.49$, $p<0.001$).

6.7 Discussion of major findings

The aims of this study were to develop a OA-specific quality of life measure from a needs-based conceptual framework. The psychometric properties of this new tool were evaluated. While functional impairment and pain have been reported extensively in the literature, themes identified during the interviews indicated that people with OA often reported substantial restrictions of life choices and an increased dependency on others. Several issues emerged in the development of the OAQoL related to both the affective and cognitive impact of OA. Given that the OAQoL was derived from a needs-based methodology, it was not surprising to find that the final OAQoL included several items that related needs associated with loss of independence, impact on others and a sense of frustration, fear and annoyance related to living with OA.

The 22 item OAQoL is a questionnaire that is brief, easy to use and practical to administer in clinic, in a clinical trial or as a postal survey. The application of the needs-based model in OA is valuable as it provides important information on the global impact of the disease from the patient's perspective. The OAQoL items were generated directly from statements made by patients with OA. Furthermore, the measure was derived from and tested against Rasch measurement principles. It is a unidimensional measure that has the potential for parametric analysis using Rasch transformed scores. As an OA-specific instrument, it is likely to be a more sensitive and specific outcome than that provided by generic measures but this remains to be determined. Finally, given that the current sample included several different OA sites and included participants with OA in a number of joints, the instrument has been validated for use with upper limb, lower limb and combination OA.

Preliminary validation of the OAQoL indicated that there was a moderate association with the three domains of the WOMAC and with the GWBI, indicating that the scales assess related but distinct concepts. Only a low correlation was observed between the OAQoL and the Cochin scale. Unfortunately, as the latter scale is a relatively new instrument, it is difficult to make firm conclusions about the validity of the OAQoL for use with hand OA.

The final OAQoL includes one item (*"I can't go places I want to go"*) which demonstrated borderline DIF during the test-retest phase. The decision to keep this item in the final version was based on two factors. First, the DIF had only borderline statistical significance and was not significant in the initial Rasch analysis of the OAQoL. Secondly, the item is one that is similar to items in several of the other needs-based QoL instruments^{209, 308, 309} and, therefore, has the potential to be included in an item bank of QoL instruments in the rheumatic diseases.

6.8 Conclusion

This study has focused on developing and validating an outcome measure for assessing the impact of OA on QoL using the needs-based model. Further research is necessary to test the clinical responsiveness and applicability of the OAQoL across different cultural contexts, including adaptation for use in other languages and cultures. This measure may provide valuable patient-centred information concerning the experience of individuals with OA and impact on their QoL.

Chapter Seven

Physical and psychosocial influences of quality of life in osteoarthritis

7.1 Overview

This chapter presents the results of the study “The Physical and Psychosocial Influences of Quality of Life in Osteoarthritis”. The purpose of this study was to explore the influences of quality of life using an a priori model, based on ICF framework and informed by the literature, the methods of which are described in Section 3.5. This study describes the relationships between quality of life and personal factors, impairment, factors associated with their OA and psychosocial factors using structural equation modelling (SEM). It explicitly tests the hypothesis of the thesis.

7.2 Participant Profile

Data for this study were collected in Phase 3 of the development and validation of the OAQoL (Chapter 6). As described in Chapter 6.4, data were received from 259 respondents from both primary and secondary care and with OA at a variety of sites including the knee, foot, hip, hand and multiple-site presentation (Table 6.1). All data were explored and checked for distribution and presence of outliers. Data for each individual were checked and outliers were removed, as required for SEM²⁷⁶. As such, 11 people were excluded from the analysis due to extreme scores, leaving 248 participants included in the modelling. The median range of joints involved was four (Figure 7.1). There were more females (72.2%) than males and included those mainly of white, British origin. The group displayed a range of educational

achievement: just over two thirds had no tertiary qualification (70.6%), with 25% completing tertiary qualifications.

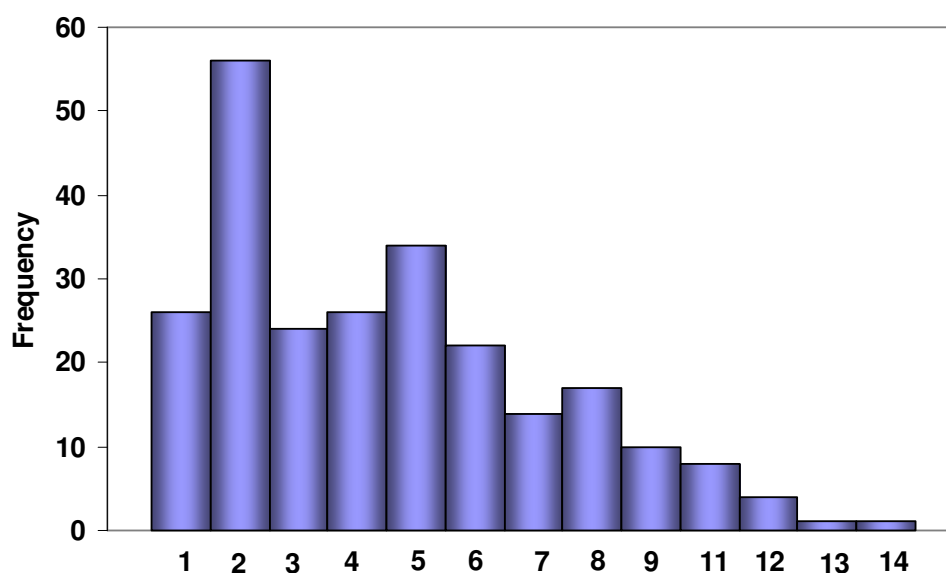


Figure 7.1 Bar chart representing the number of joints affected by OA reported by participants included in the modelling.

7.3 Results

7.3.1 Preparation of the data

Data were also explored for normality of distribution in order to determine the values of the correlation matrix used as the basis for SEM. These figures are presented in Table 7.1. As duration, function and anxiety violated the assumptions of normality, the data for all interval scales would be treated as ordinal. As such, Spearman's rho was used for correlation relationships between the following variables: age, number

	Age	Gender	No of Jts	Pain	Funct	Depr	Anx	OA QoL	Co-morb	Dur	Kn Ft	Kn Bck	Kn Hnd	Nck Shl	Kn Hip	Kn Sh
Age	1															
Gender*	0.025	1														
Number of joints	0.170	0.129	1													
Pain	0.073	0.050	0.252	1												
Function	0.267	0.190	0.262	0.642	1											
Depression	0.005	0.002	0.264	0.348	0.431	1										
Anxiety	0.030	0.022	0.299	0.500	0.601	0.777	1									
OAQoL	0.332	0.242	0.322	0.508	0.761	0.545	0.719	1								
Co-morbid	0.176	0.146	0.330	0.148	0.284	0.315	0.379	0.367	1							
Duration of OA	0.179	0.134	0.523	0.184	0.285	0.148	0.232	0.292	0.192	1						
Knee & foot*	0.018	0.372	0.830	0.165	0.204	0.218	0.223	0.213	0.227	0.37	1					
Knee & back*	0.121	0.205	0.676	0.205	0.206	0.262	0.34	0.31	0.462	0.441	0.604	1				
Knee & hand*	0.158	0.591	0.823	0.269	0.272	0.218	0.296	0.33	0.26	0.435	0.789	0.658	1			
Neck & shoulder*	0.389	0.020	0.792	0.349	0.287	0.365	0.519	0.506	0.43	0.398	0.393	0.767	0.565	1		
Knee & hip*	0.220	0.154	0.714	0.329	0.352	0.274	0.238	0.382	0.262	0.354	0.666	0.73	0.646	0.585	1	
Knee & Shoulder*	0.218	0.389	0.855	0.276	0.287	0.377	0.447	0.43	0.321	0.458	0.539	0.666	0.767	0.986	0.691	1
Standard deviation	12.563	0.449	2.693	27.406	2.961	1.346	1.569	2.679	1.666	9.411	0.465	0.447	0.478	0.231	0.474	0.336
Mean	66.27	1.72	4.63	54.592	-0.44	-1.10	-1.13	-0.43	2.088	12.47	0.315	0.274	0.351	0.056	0.339	0.129

Table 7.1 Correlation matrix for variables entered into the model. All values are Spearman's rho, except for relationships with gender and joint patterns, which are gamma correlations, indicated by an asterix*.

of joints, number of co-morbidities, pain, WOMAC physical function (rasched converted scores), OAQoL (rasched converted scores), depression (rasched converted scores), anxiety (rasched converted scores) and duration. Correlations between gender and joint pattern (nominal data) and each of the ordinal variables were established using gamma correlations²⁷⁶. A summary table of descriptive statistics is presented in Table 7.2.

	Mean <i>SD</i>	Median <i>5 to 95 centile</i>	P value for K-S test*
Age (Years)	66.27 <i>±12.56</i>	68 <i>44 to 83</i>	0.21
Duration of OA (Years)	12.01 <i>±9.41</i>	10 <i>2 to 30.5</i>	<0.00
Number of joints involved (N)	4.65 <i>±2.95</i>	4 <i>1 to 11</i>	<0.00
Number of co-morbidities (N)	2.10 <i>±1.66</i>	2 <i>0 to 5</i>	<0.00
Pain VAS (mm)	54.59 <i>±12.7</i>	56.0 <i>3.2 to 95.8</i>	0.13
WOMAC Function Raw Score	31.87 <i>±17.47</i>	35 <i>0.1 to 56.9</i>	0.03
WOMAC Function Rasch Score	-0.426 <i>±2.963</i>	0.55 <i>-6.56 to 3.51</i>	0.08
HADS Anxiety Raw Score	6.20 <i>±4.01</i>	6 <i>0 to 13</i>	0.02
HADS Anxiety Rasch Score	-1.122 <i>±1.571</i>	-0.841 <i>-4.86 to 1.093</i>	0.04
HADS Depression Raw Score	6.34 <i>±4.03</i>	6 <i>1.0 to 13.6</i>	0.03
HADS Depression Rasch Score	-1.018 <i>±1.348</i>	-1.033 <i>-4.03 to 1.052</i>	<0.00
OAQoL Score Total	9.76 <i>±7.02</i>	9.5 <i>1 to 11</i>	0.03
OAQoL Rasch	-0.431 <i>±2.684</i>	-0.235 <i>-4.95 to 4.53</i>	0.13

Table 7.2 Descriptive statistics used non categorical data for the indicator variables used in the model of quality of life in OA. The p values are for the Kolmogorov-Smirnov Z test to indicate if the data fits normal distribution. A significant p value (less than 0.05) indicates that the data should be strictly considered ordinal and not interval.

Data from three variables were captured and were to be included in the a priori model: location of joint pain, hand function and participation. Unfortunately, analysis of the measures in preparation for the modelling indicated that they could not be included in the final SEM:

i. Location of joint pain:

Exploring the data on the location of OA for modelling presented several problems. First, we wanted to explore the impact of hand, hip, knee and foot OA. There was a statistically significant difference between the OAQoL scores for different anatomical sites ($F=14.668$, $df=4$, $p<0.001$). Those who reported multiple site pain had the worse OAQoL scores, followed by knee, hip, hand and foot. The OAQoL Raw Scores are presented in Figure 7.2. Post hoc analyses revealed that the foot was significantly lower than the multiple site, hip and knee. However, for inclusion in the regression and structural equation modelling, this represented a dilemma: as the sample represented those with pain in at least one joint, and the majority had more than one joint involved, the logic of what we were comparing for the purposes of the modelling became confused. If we were to consider the impact of hip OA, those who did not have hip OA included those who had other site involvement. As we did not include people with no site involvement, the comparison became circular: we would compare those with no hip (and therefore a complex combination of other joint involvement) with hip pain. Secondly, as only had four participants in this group who reported hand only pain, hand only could not be included in such an analysis. As such, it was decided to focus on the number of joints involved and the joint pattern (ie hip and knee / foot, hand and hip) rather than the location, based on the six most prevalent joint combinations (derived from Chapter 4) were included in the analysis. This included the following joint combinations: knee and foot; knee and back; knee and hands; knee, foot and hands; knee and hips; and knee and shoulder.

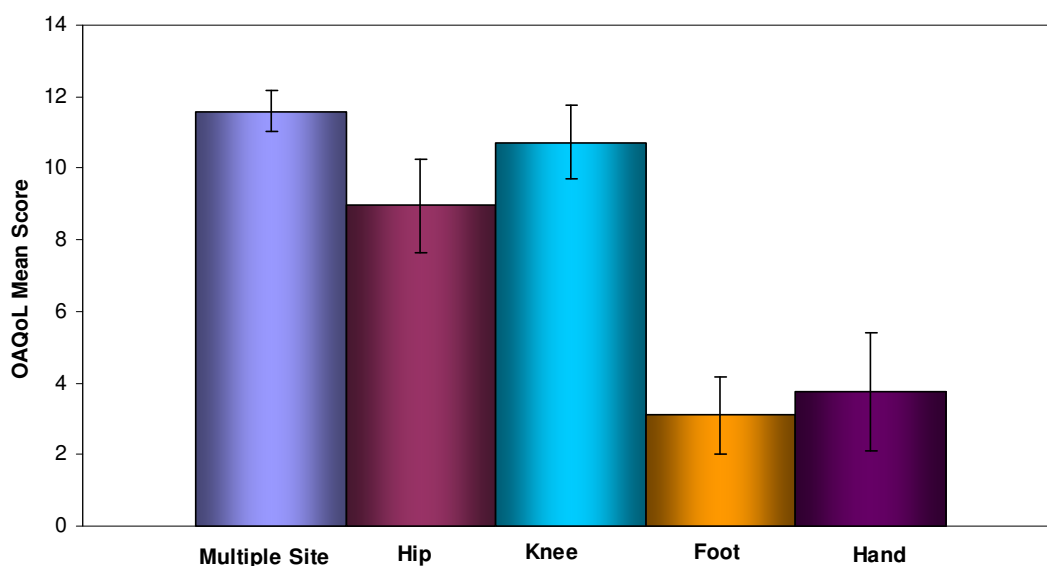


Figure 7.2 Bar chart representing the mean OAQoL raw scores based on the major site of pain. (Note, all statistical testing was undertaken on the OAQoL Rasch transformed scores).

ii. Cochin Hand Functional Scale

The Cochin Scale was not included as there were so few participants in the hand only group. Given that this scale was developed to assess solely hand function, it was considered inappropriate to include this in the modelling. Furthermore, Rasch analysis of the Cochin revealed several problems that would have made inclusion of the scale in the model difficult. Therefore, in the final model, there was no representation of upper limb functioning: only WOMAC physical function data were included as the function variable.

iii. Perceived impact of the Problem Profile (PIPP)

The PIPP³¹⁰ participation subscale was used to capture data on participation. However, our analysis revealed two major problems with the data obtained from the PIPP: first there was a considerable amount of missing data: almost one third of the

data points were missing. This may have been due to confusion and redundancy between the concepts of how much impact your OA has on aspects of your life versus how much distress this causes. Certainly, the amount of missing data was greater in the distress items (39%) than it was in the impact items (24%) and there was a high correlation between the distress and impact items (range $\rho = .85$ to $.96$), indicating redundancy. Second, the Rasch analysis of the five item participation subscale of the PIPP indicated that two of the items demonstrated DIF by age, reducing the subscale to just three items. On the basis of these issues, the participation subscale was not included in the modelling.

7.3.2 Hierarchical Regression Modelling

In order to explore the multivariate relationships between each of the variables that would inform the structural equation modelling, hierarchical multiple regression analysis was performed for each of the major outcomes: pain, function, depression, anxiety and quality of life. This approach was adopted in order to explore significant relationships for each of the outcomes and the likely direction of the outcomes which would inform the theoretical model for the SEM.

i. Function

As described in Section 3.5.2, a series of hierarchical regression models, with function as the dependent variable, were completed. A summary table of the iterative models is presented in Table 7.3. In the first model, demographic, disease related outcomes and pain were included, followed by introducing depression to the model, then depression combined with anxiety and then just depression without anxiety. The best fitting model indicated that age, duration of disease, pain and anxiety contributed directly to function, with pain and anxiety being the largest contributors of the variance ($R^2 = 0.558$). When depression was included in the model, it did contribute to function;

Dependent variable: Function

Model	Factors included in the model	R ² (adjusted)	Factors significant in model	β weights	P values
1	Age, Gender, Duration of disease, Number of joints, Joint pattern, Number of co-morbidities	0.179	Age Number of co-morbidities	0.231 0.228	<0.001 <0.001
2	Model 1 + Pain	0.467	Age Number of co-morbidities Pain VAS	0.223 0.119 0.556	<0.001 <0.001 <0.001
3	Model 1 + Pain and Anxiety	0.560	Age Duration Pain VAS Anxiety	0.233 0.110 0.386 0.378	<0.001 0.045 <0.001 <0.001
4	Model 1 + Pain, Anxiety and Depression	0.558	Age Duration Pain VAS Anxiety	0.233 0.109 0.384 0.396	<0.001 0.045 <0.001 <0.001

Table 7.3 Summary table of Iterations of Hierarchical Regression Modelling with Function as the dependent variable. All models included in the table had tolerance >0.10 and VIF less than 10.

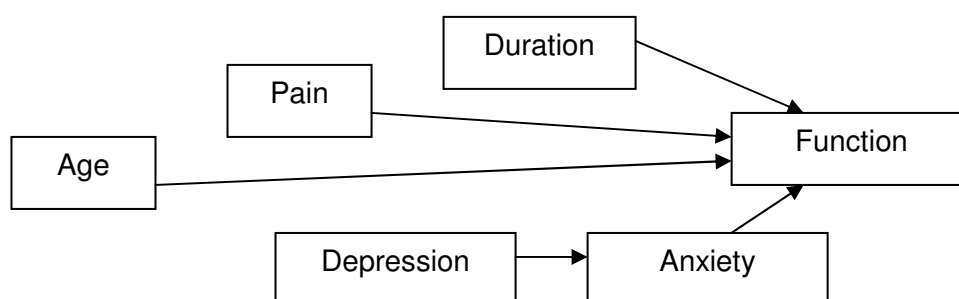


Figure 7.3 Model of resultant factors contributing to function after regression modelling.

however when depression was included with anxiety, it became non-significant. When anxiety was included alone, the amount of variance explained was increased ($R^2=0.467$ to $R^2=0.502$). This suggests that depression works through anxiety to impact on function. This is presented schematically in Figure 7.3.

ii. Pain

The summary table of regression models for pain is presented in Table 7.4. Once again, demographic, disease activity and function was included in the first model. Function explained the largest amount of variance for pain in all models. When anxiety was included, the amount of explained variance improved and produced the best fitting model ($R^2=0.406$). When depression was included, there model was less predictive, indicating that depression did not contribute significantly to pain. Of note, number of joints was not related to pain when all other factors were included. Function, number of co-morbidities and anxiety were related to pain (Figure 7.4).

iii. Depression

The summary table for the regression modelling for depression is in Table 7.5. The first model, which included demographics, disease activity and co-morbidities did not explain much of the variance associated with depression ($R^2=0.105$). However, once anxiety was included, the amount of variance was substantially improved ($R^2=0.542$) and was the only significant contributing factor for depression. This is represented in Figure 7.5.

iv. Anxiety

Several factors were significantly related to anxiety in the hierarchical regression modelling (Table 7.6). The first model which include demographics, disease related measures and co-morbidities was poorly explained ($R^2=0.149$); however, once depression was included, the model substantially improved ($R^2=0.565$). The model

Dependent variable: Pain

Model	Factors included in the model	R ² (adjusted)	Factors significant in model	β weights	P values
1	Age, Gender, Duration of disease, Number of joints, Joint pattern, Number of co-morbidities	0.052	Knee and hip	0.181	0.033
2	Model 1 +Function	0.386	Age Function	-0.134 0.640	0.024 <0.001
3	Model 1 + Function and Anxiety	0.406	Number of co-morbidities Function Anxiety	-0.128 0.521 0.201	0.038 <0.001 0.006
4	Model 1 + Function, Anxiety and Depression	0.405	Number of co-morbidities Function Anxiety	-0.126 0.517 0.256	0.042 <0.001 0.008

Table 7.4 Summary table of Iterations of Hierarchical Regression Modelling with Pain as the dependent variable. All models included in the table had tolerance >0.10 and VIF less than 10.

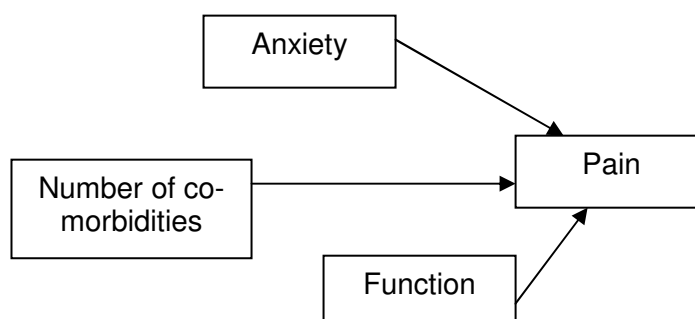


Figure 7.4 Model of resultant factors contributing to pain after regression modelling.

was further enhanced with the addition of pain and again when function was included ($R^2=0.674$). In the best fitting model, number of co-morbidities, pain, function and depression were significantly predictive of anxiety, with depression the greatest predictor. This is represented in Figure 7.6.

v. Quality of Life and Physical components

Regression modelling for the physical components and quality of life was undertaken (Table 7.7). The first model was which included demographics, disease activity and number of co-morbidities demonstrated a borderline fit ($R^2=0.260$), with hip and knee pain contributing to the model. Once pain was added, fit was improved with pain the largest contributing factor to quality of life ($R^2=0.424$). However, when function was added to the model, the model was substantially improved ($R^2=0.622$) and pain became non-significant. A model without pain included produced similar explanation ($R^2=0.622$), suggesting that pain impacts on quality of life only through function and that pain is fully mediated by function. Age and number of co-morbidities were also significant. This relationship is represented in Figure 7.7.

vi. Quality of Life and Psychosocial components

Table 7.7 represents the regression models undertaken for quality of life and the psychosocial components. When demographics, disease activity, number of co-morbidities and depression demonstrated reasonable fit ($R^2=0.448$), with age, number of co-morbidities and depression contributing to quality of life. However, when anxiety was added to the model, the model was substantially improved ($R^2=0.651$) and depression became non-significant. A model without depression produced a slight improvement ($R^2=0.652$), suggesting that depression impacts on quality of life only through anxiety. Age, duration of disease and hip and knee pain also contributed significantly to quality of life. This relationship is represented in Figure 7.8.

Dependent variable: Depression

Model	Factors included in the model	R ² (adjusted)	Factors significant in model	β weights	P values
1	Age, Gender, Duration of disease, Number of joints, Joint pattern, Number of co-morbidities	0.105	Number of co-morbidities	0.253	<0.001
2	Model 1 + Anxiety	0.542	Anxiety	0.718	<0.001
3	Model 1 + Anxiety and Pain	0.541	Anxiety	0.751	<0.001
4	Model 1 + Anxiety, Pain and Function	0.539	Anxiety	0.761	<0.001

Table 7.5 Summary table of Iterations of Hierarchical Regression Modelling with Depression as the dependent variable. All models included in the table had tolerance >0.10 and VIF less than 10.

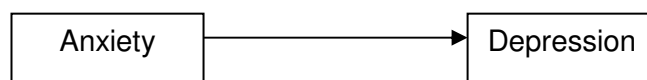


Figure 7.5 Model of resultant factors contributing to depression after regression modelling.

Dependent variable: Anxiety

Model	Factors included in the model	R ² (adjusted)	Factors significant in model	β weights	P values
1	Age, Gender, Duration of disease, Number of joints, Joint pattern, Number of co-morbidities	0.149	Number of co-morbidities	0.308	<0.001
2	Model 1 + Depression	0.565	Depression Number of co-morbidities	0.683 0.135	<0.001 0.008
3	Model 1 + Depression and Pain	0.633	Depression Gender Pain Number of co-morbidities	0.601 0.089 0.286 0.140	<0.001 0.045 <0.001 <0.001
4	Model 1 + Depression, Pain and Function	0.674	Depression Pain Function Number of co-morbidities	0.538 0.141 0.292 0.097	<0.001 0.008 <0.001 0.034

Table 7.6 Summary table of Iterations of Hierarchical Regression Modelling with Anxiety as the dependent variable. All models included in the table had tolerance >0.10 and VIF less than 10.

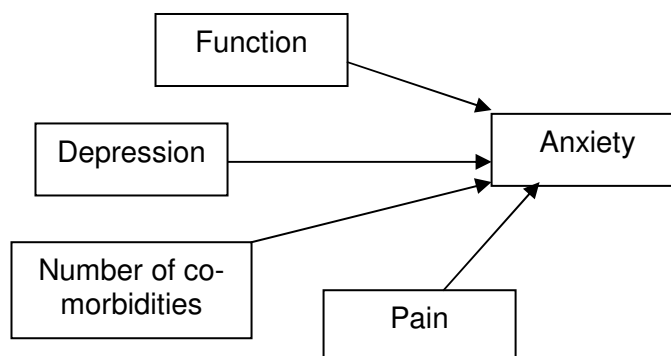


Figure 7.6 Model of resultant factors contributing to anxiety after regression modelling.

Dependent variable: Quality of Life

Model	Factors included in the model	R ² (adjusted)	Factors significant in model	β weights	P values
1	Age, Gender, Duration of disease, Number of joints, Joint pattern, Number of co-morbidities	0.260	Age Knee and Hip Number of co-morbidities	0.268 0.151 0.269	<0.001 0.036 <0.001
2	Model 1 + Pain	0.424	Age Pain Number of co-morbidities	0.262 0.424 0.247	<0.001 <0.001 <0.001
3	Model 1 + Pain and Function	0.622	Age Function Number of co-morbidities	0.124 0.613 0.125	0.008 <0.001 0.010

Table 7.7 Summary table of Iterations of Hierarchical Regression Modelling with QoL as the dependent variable for the physical components. All models included in the table had tolerance >0.10 and VIF less than 10.

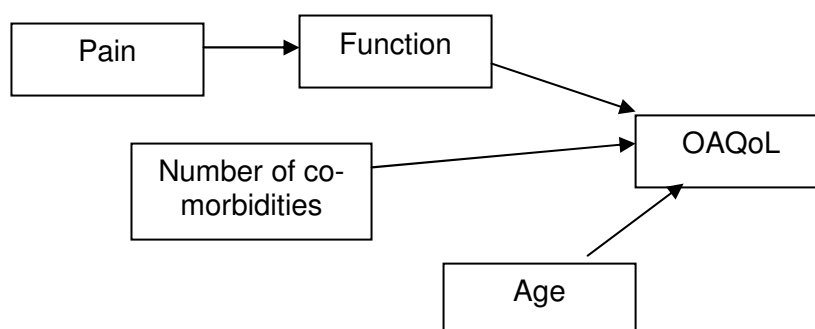


Figure 7.7 Model of resultant factors contributing to QoL (physical component) after regression modelling.

Dependent variable: Quality of Life

Model	Factors included in the model	R ² (adjusted)	Factors significant in model	β weights	P values
1	Age, Gender, Duration of disease, Number of joints, Joint pattern, Number of co-morbidities	0.260	Age Knee and Hip Number of co-morbidities	0.268 0.151 0.269	<0.001 0.036 <0.001
2	Model 1 + Depression	0.448	Age Depression Number of co-morbidities	0.272 0.462 0.152	<0.001 <0.001 0.007
3	Model 1 + Depression and Anxiety	0.651	Age Duration of disease Knee and hip Anxiety	0.281 0.104 0.126 0.686	<0.001 0.026 0.012 <0.001

Table 7.8 Summary table of Iterations of Hierarchical Regression Modelling with QoL as the dependent variable for the psychosocial components. All models included in the table had tolerance >0.10 and VIF less than 10.

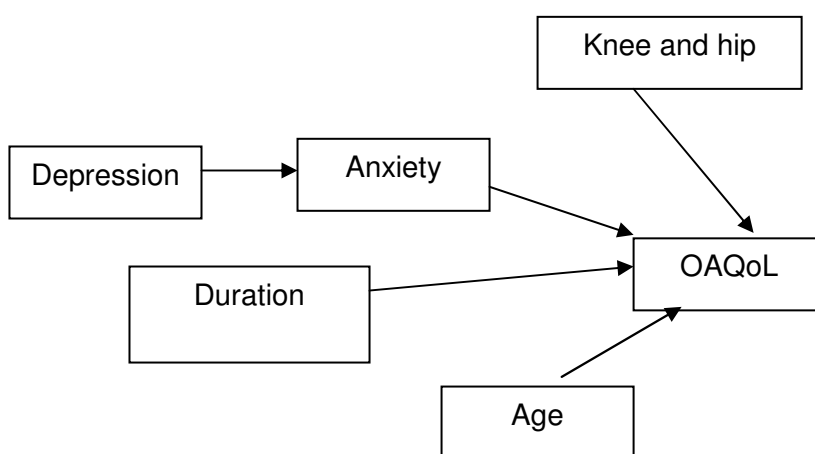


Figure 7.8 Model of resultant factors contributing to QoL (psychosocial component) after regression modelling.

7.3.3 Structural Equation Modelling

From the hierarchical regression modelling of the variables, a structural equation model was formulated to explore the impact of the physical and psychosocial factors on quality of life. This model is presented in Figure 7.9, with the error and regression weight entered onto the model from the Rasch analysis of the anxiety, depression, function and quality of life scales. A correlation matrix based around Table 7.2 was used with means and standard deviations to run the model.

The theoretical model predicted from the regression analysis was not supported: the χ^2 statistic was significant ($\chi^2=119.033$, $df=16$, $p>0.000$), while the fit statistics also indicated poor model fit (RMSEA=0.161, GFI=0.919, CFI=0.893). In order to improve model fit, the regression weights of the linked variables were explored. Those linked variables with non-significant regression weights were removed in an iterative process: the path between the variables with the highest p value was removed first. Upon removal of the variable, overall model fit and the fit statistics were reviewed. Once all non-significant linked variables were removed, modification indices were explored. The modification index suggests possible links between non-linked variables which may improve model fit. A summary table of the iterations of the modelling indicating which variables were removed or linked is presented in Table 7.9.

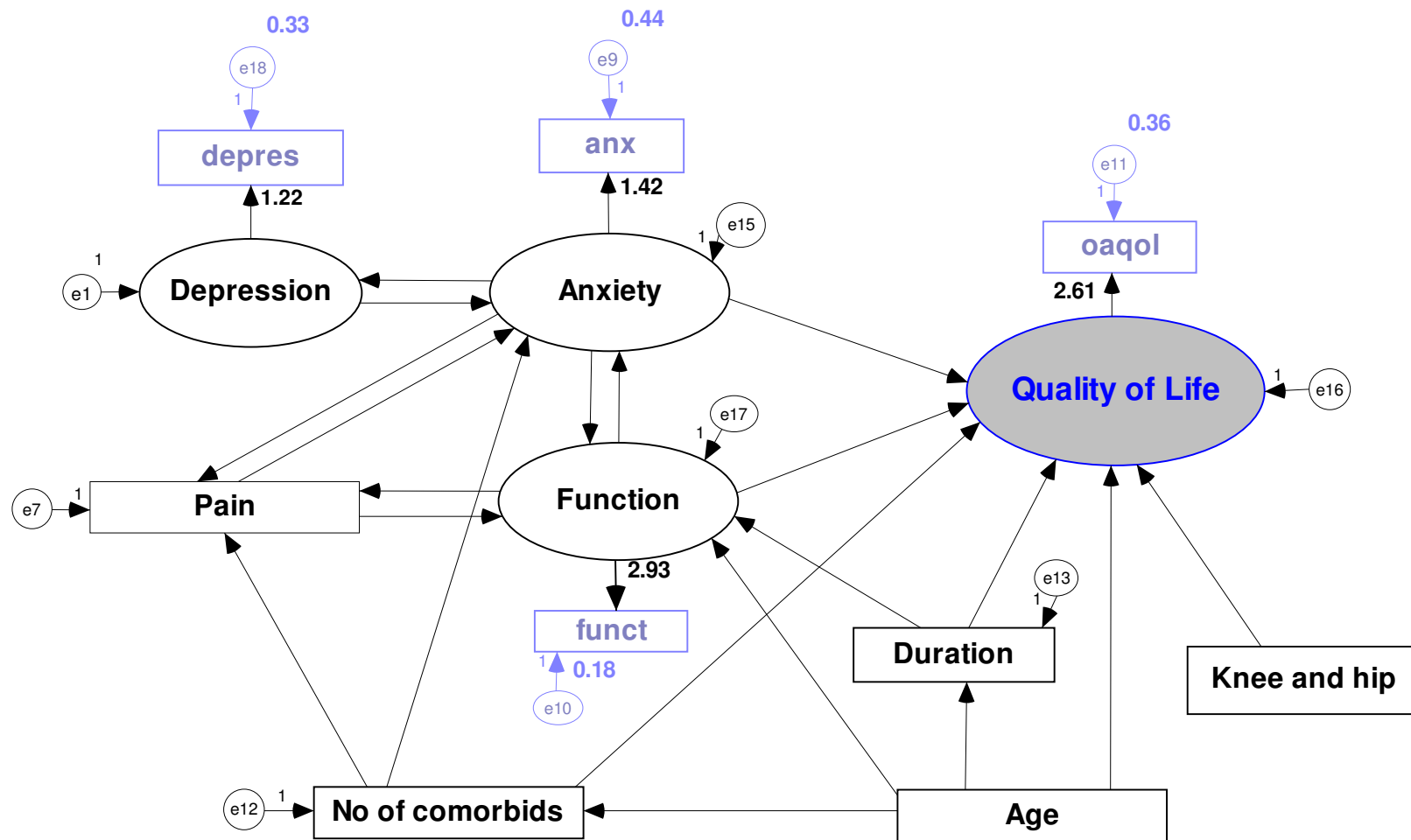


Figure 7.9 Structural equation model testing the effects of on quality of life in OAQoL derived from hierarchical linear regression models. Anx=Rasch transformed anxiety score for HADS, depress=Rasch transformed depression score for HADS, funct= Rasch transformed physical function subscale of WOMAC and oaqol Rasch transformed OAQoL scores. Figures in purple indicate those imported from Rasch analysis.

Model	N	Modification	χ^2	df	P	RMSEA	GFI	CFI
					Ideal: >0.05	Ideal: <0.05	Ideal: >0.95	Ideal: >0.95
1	249	Predicted model from regression analysis	119.033	16	<0.001	0.161	0.919	0.893
2	249	Removal of link anxiety → pain	119.036	17	<0.001	0.156	0.909	0.894
3	249	Removal of link co-morbidities → quality of life	119.037	18	<0.001	0.150	0.909	0.895
4	249	Removal of link co-morbidities → pain	119.375	19	<0.001	0.146	0.909	0.895
5	249	Removal of link duration → quality of life	119.750	20	<0.001	0.142	0.908	0.896
6	249	Removal of link function → anxiety	121.021	21	<0.001	0.139	0.908	0.896
7	249	Add link between knee and hip → duration	92.831	20	<0.001	0.121	0.932	0.924
8	249	Add link between knee and hip → pain	71.318	19	<0.001	0.105	0.944	0.945
9	249	Removal of link function → pain	71.339	20	<0.001	0.102	0.945	0.946
10	249	Add link between knee and hip → co-morbidities	57.558	19	<0.001	0.090	0.956	0.960
11	249	Removal of link knee and hip → quality of life	60.451	20	<0.001	0.090	0.955	0.958
12	249	Add link between anxiety → duration	56.728	19	<0.001	0.089	0.957	0.961
13	249	Add link between age → knee and hip	44.425	18	0.001	0.077	0.967	0.972
14	249	Removal of link duration → function	47.428	19	<0.001	0.078	0.964	0.970
15	249	Removal of link anxiety → depression	99.138	20	<0.001	0.126	0.925	0.917
16	249	Removal of link depression → anxiety	260.245	21	<0.001	0.214	0.863	0.751
17	249	Removal of depression variable	17.728	13	0.168	0.038	0.982	0.993

Table 7.9 Summary table of iterations of Structural Equation Modelling

The best fitting model ($\chi^2=17.728$, $df=13$, $p=0.168$, $RMSEA=0.038$, $GFI=0.982$, $CFI=0.993$) is presented in Figure 7.10. In this model, the fit values estimated a high proportion of the variance of quality of life in OA ($R^2=0.81$), indicating that the model is well supported. Given that models are often published with only 25% of the variance explained, a model explaining over 85% represents a well defined model. Only three variables feed directly into quality of life: anxiety ($R_{\text{gwt}}=0.57$), function ($R_{\text{gwt}}=0.34$) and age ($R_{\text{gwt}}=0.22$), with the anxiety representing the largest predictor of quality of life. Of note, depression, gender and number of joints do not feature in this model.

Pain, duration of disease and number of co-morbidities do affect quality of life, but through mediator variables. While not directly feeding into quality of life, increased pain has a direct impact of increasing anxiety ($R_{\text{gwt}}=0.48$) and decreasing function ($R_{\text{gwt}}=0.39$), each of which in turn has a direct impact on quality of life. Those who have had their disease longer, report greater anxiety ($R_{\text{gwt}}=0.13$) and are more likely to report knee and hip pain ($R_{\text{gwt}}=0.33$). Those with knee and hip pain report significantly more co-morbidities ($R_{\text{gwt}}=0.23$) and report greater pain ($R_{\text{gwt}}=0.33$). Those with more co-morbidities are likely to report higher anxiety levels ($R_{\text{gwt}}=0.33$).

In addition to the direct effect of age on quality of life, age also has an effect through co-morbidities ($R_{\text{gwt}}=0.12$); those who are older are likely to have more co-morbidities and this in turn increases the likelihood of anxiety, which then impacts on their quality of life. Not surprisingly, those who are older are likely to have had OA for a longer period ($R_{\text{gwt}}=0.18$), which is a higher predictor of pain, anxiety and number of co-morbidities. Age was also associated with a greater likelihood of knee and hip pain ($R_{\text{gwt}}=0.16$).

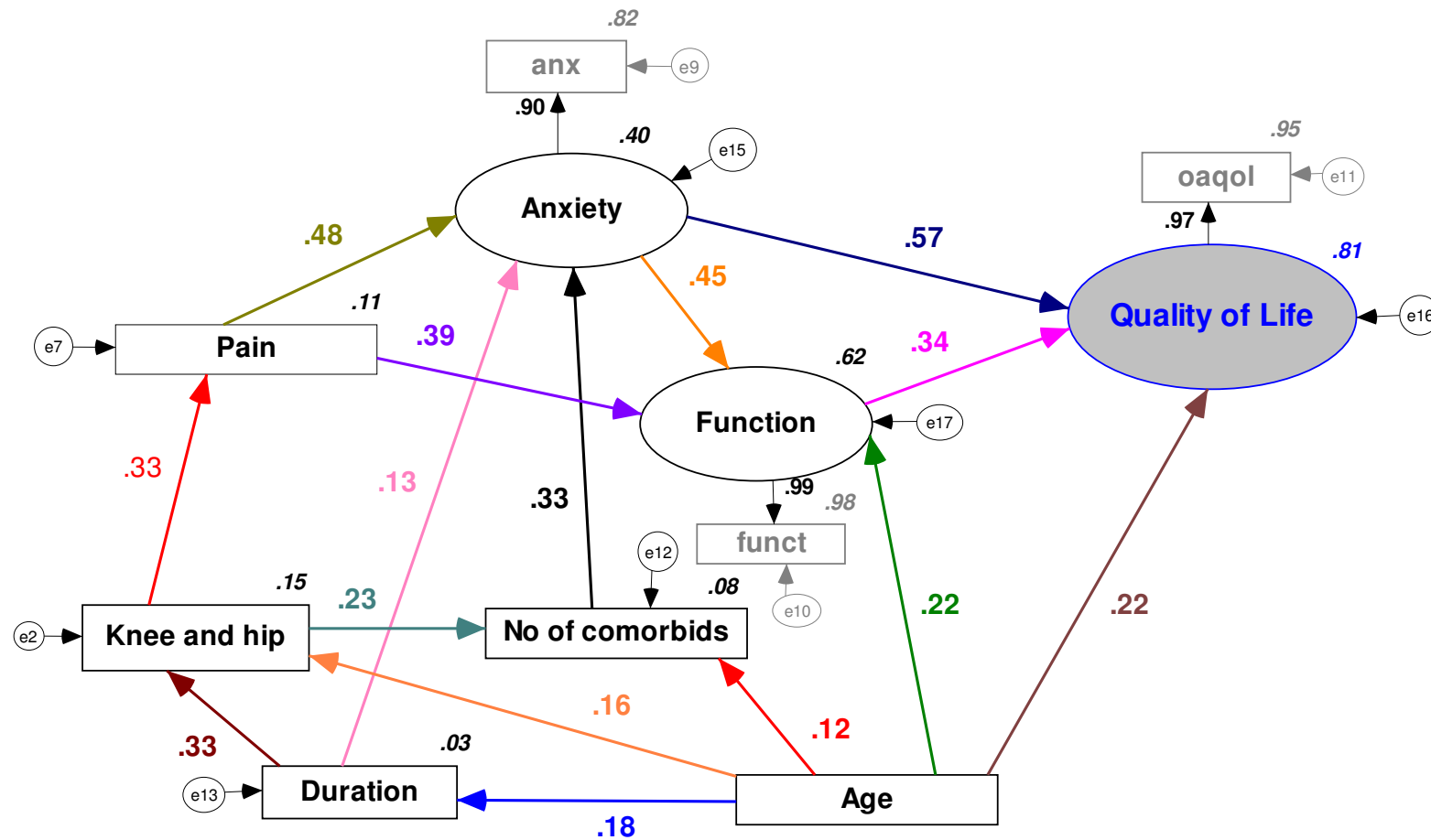


Figure 7.10 Best fitting structural equation model for quality of life in OAQoL. The *italicised* numbers at the top right hand corner of the variables represent the R² value, or the percentage of variance in the variable explained by the model. The lines demonstrate the direction the relationship is in and the values near these lines are the regression weights. Larger regression weights indicate better predictors of the variable the arrow is feeding into. The summary statistics are $\chi^2=17.728$, $df=13$, $p=0.168$, $RMSEA=0.038$, $GFI=0.982$ and $CFI=0.993$.

Anxiety is associated with the greatest number of variables. While pain, number of co-morbidities and duration all predict higher anxiety scores, it is interesting to note that anxiety predicts poor physical function ($R_{\text{gwt}}=0.45$).

A summary table of standardised total effects, direct effects and indirect effects is presented in Table 7.10. Anxiety is the highest single predictor of quality of life in this model, for both direct and total effects (0.721). While function has a higher direct effect on quality of life, pain demonstrates larger total effects (0.473), working through anxiety and function. Age has the third largest total effect on quality of life, closely followed by function.

Variable	Direct effect	Indirect effect	Total effect
Anxiety	0.569	0.152	0.721
Pain	0.000	0.473	0.473
Age	0.217	0.166	0.383
Function	0.337	0.000	0.337
Number of co-morbidities	0.000	0.238	0.238
Duration of OA	0.000	0.160	0.160
Knee and hip	0.000	0.211	0.211
Depression	NA	NA	NA
Gender	NA	NA	NA
Number of joints	NA	NA	NA

Table 7.10 Standardised total, direct and indirect effects for the variables as they related to QoL in the final model.

7.4 Discussion of main findings

While several factors have been implicated in affecting “quality of life” in OA, our proposed model of the interaction between physical, psychosocial, demographic and disease factors explains 81% of the variance, which is a substantial proportion of the impact of OA on quality of life. The single most important factor in predicting quality of life was anxiety, which has received little attention in the OA literature. Our results suggest that it is anxiety and not depression, which has the greatest impact on quality of life. While this is a new finding in OA, the importance of anxiety on health-related quality of life has, however, been reported for other chronic medical conditions including myocardial infarction³¹¹, diabetes and vascular disease³¹². It does suggest an important link between general well-being and an anxious state.

This finding is particularly important in light of the high levels of both anxiety and depression that was found in these OA participants and is consistent with that reported for arthritis in general practice⁶⁸. The mean anxiety raw score for the total OA cohort was 7.15 (Table 7.11), higher than that reported in the literature for breast cancer³¹³, renal disease³¹⁴ and chronic heart disease³¹⁵, but lower than that reported for psychiatric patients³¹⁶. The mean depression raw score for the total group was 6.34, which again was higher than breast cancer³¹³ and renal disease³¹⁴ and equivalent to that reported in chronic heart disease³¹⁵.

Patient Group	Mean HADS Anxiety Score	Mean HADS Depression Score
OA (Current study)	7.15	5.67
Reference Norms ³¹⁷	6.14	3.68
Breast cancer* ³¹³	6.48	2.90
End stage renal disease ³¹⁴	6.90	5.20
Coronary Heart Disease ³¹⁵	6.14	5.41
Psychiatric Patients ³¹⁶	13.5	9.40

Table 7.11. Comparison of HADS scores with the literature. *Breast cancer patients are those who were receiving chemotherapy and hormone therapy.

In the SEM, anxiety was affected by several other factors, including the number of co-morbidities. The effect of co-morbidities has been described on functional impairment in musculoskeletal pain³¹⁸ and in the elderly³¹⁹ and the perception of musculoskeletal pain. The number of co-morbidities has also been reported to impact on health-related QoL in RA³²⁰. As the number of co-morbidities in OA is high⁸⁹, this finding is of considerable importance.

Both function and pain have a considerable impact on quality of life. The link between function and health-related QoL has been established, with poorer SF-36 mental health scores predicting poorer functional outcomes in OA²¹. Our findings also support those of van der Waal who suggest that somatic distress in OA is linked to increased pain intensity, which in turn results in poor function²¹⁵. The bi-directional relationship between anxiety and pain in OA has been reported previously^{48, 272}. Pain was the second highest single factor in predicting quality of life, our study suggests pain does not have a direct impact on quality of life, but has its impact through anxiety and functional impairment.

The impact of age on quality of life is notable: it has both a direct impact, where increasing age is associated with poorer quality of life, and has indirect effects through duration of disease, knee and hip pain and number of co-morbidities. Indeed, age is the third highest contributor to QoL in this model, ranking only behind anxiety and pain (Table 7.10). While a poorer QoL is not necessarily associated with ageing, co-morbidities and somatic symptoms have a considerable impact³²¹ on health-related quality of life³²², particularly in older age³²³.

Of note, the only joint pattern included in the modelling that had a significant impact on QoL was combined knee and hip pain, although their effect was manifest through

other variables. Those with knee and hip pain reported greater co-morbidities and greater pain, both of which had a direct affect on anxiety. The influence of the number of joints affected by OA had neither a direct or nor an indirect association with quality of life.

The findings of the SEM need to be viewed in light of the limitations of the study. Firstly, the elements included in the modelling were based on specific outcome measures, each with their own limitations, as outlined in Chapter 2, and represented a latent, theoretical construct. Secondly, while a functional measure for upper limb was to be included in the model, the hand and upper limb outcome (Cochin Scale) did not perform adequately well to be a candidate for the final model. Consequently, as function was based only on WOMAC function, upper limb problems were not represented. Thirdly, while all patients fulfilled strict criteria for the diagnosis of OA, joint involvement was based on self reported joint pain. As such, joint combination and numbers reflect joint pathology and not necessarily OA. Finally, QoL may be affected by un-modelled factors that contribute to quality of life and were not included in the final model. Examples may include as measures of self efficacy; participation; fatigue; and environmental factors, such as social support. The amount of variance explained in the model is high ($R^2=0.81$) and this indicates that this is a strongly functioning model.

7.5 Conclusion

A model which explores the influence of quality of life in OA has been presented as a robust model. The key influences on quality of life are physical function, anxiety and age. Pain has an influence on quality of life, but only through loss of function or anxiety. The factor associated with the location of joint pain on quality of life was knee

and hip pain, which had an indirect affect. Of note, the number of joints affected by OA was not significant.

Chapter Eight

Discussion and Summary

8.1 Overview

The impact of OA on quality of life has been investigated in this thesis. A robust, multiple methodological approach was adopted to explore issues associated with quality of life. In the first instance, analysis of a large, epidemiological cohort was undertaken to establish the prevalence and impact in the community of joint pain at more than one anatomical site. An in-depth, qualitative study was then undertaken in order to better understand issues associated with living with OA from the individual's perspective. A disease specific, quality of life measure for OA, the OAQoL, was developed based on an articulated, conceptual framework, derived directly from quotes of people with OA and rigorously validated, using state of the art measurement theory. Finally, factors which influence qualities of life were explored through a novel application of structural equation modelling. This technique produced a model in which a substantial 81% of quality of life was explained.

The hypothesis of this thesis as outlined in Chapter 2 was ***“the number and pattern of joint involvement in OA will be reflected in the level of patient perceived quality of life.”*** The number and pattern of self reported joint involvement had a substantial impact on the ability to undertake the tasks of daily living; however this was not reflected in the impact on quality of life. While hip and knee involvement contributed to poorer quality of life, other factors, particularly levels of anxiety, functional ability and age were more important. As such, the hypothesis of this thesis is only partially supported.

Several important findings have been produced by this programme of work which will be explored in this chapter. First, while the individual experience of living with OA is varied, the impact of the disease is substantial. Second, quality of life is driven by a complex interaction of physical and psychological factors. Poorer quality of life reported by those with OA is driven by several factors, particularly when OA impacts on their independence, self perception or fulfilment of their needs. Anxiety is the major predictor of quality of life in OA, with functional impairment and age also directly contributing to quality of life. Third, co-morbidities have a substantial impact on the ability to undertake tasks of daily living and also influence quality of life. Finally, the pattern of joint problems will affect the ability to undertake simple tasks but has only a minor impact on overall quality of life.

8.2 The impact of living with OA

While OA is a common, chronic condition, the individual experience of living with OA is unpredictable and poorly understood. Even though it is one of the most prevalent and disabling conditions^{7,324}, it is often regarded as a trivial disease. OA is commonly seen simply as a normal joint degenerative process and as such, boundaries can become blurred between limitations imposed as part of normal ageing and what is considered a medical condition. This was reflected by several of the people interviewed for this thesis, who reported frustration that OA was viewed by their family and friends as merely part of the ageing process. The impact of such perceptions was not just to trivialise their experiences, but also to categorise them as people who simply could not cope with the ageing process.

These findings are in agreement with a recent study investigating the perceptions of age and arthritis²⁹. Interestingly, both those with and those without OA perceived the disease as part of normal ageing requiring acceptance, not treatment. This was in

spite of those with OA reporting a higher number of problems with relationships, work, leisure, social activities and, not surprisingly, pain²⁹. Attitudes such as this may result in an even greater undermining of the coping ability of people with OA; it may also delay in people not seeking treatment and simply living with the pain rather than being thought of as not coping with the ageing process. As explored in this thesis however, pain and anxiety are considerable in OA: the consequences of under treatment are considerable and may directly result in a reduced functional ability and overall quality of life.

The issue of OA as being dismissed simply as part of the ageing process was particularly highlighted in younger patients, who expressed confusion and frustration of having an “older person’s disease”. They felt that their individual needs were often not considered as they did not fit the profile of a person with OA. Acknowledging these individual needs is of particular importance in managing younger OA patients: particularly so when looking at the effect of OA in areas which may be ignored if OA is perceived solely as an “older person’s disease”, such impairment on work and parenting activities.

Anxiety and distress was reported commonly during the structured interviews. This distress was closely related to pessimism with their prognosis and associated treatment options available. Participants often felt that “nothing could be done for them” as there were no effective treatment strategies for OA and common treatments, particularly surgery and drug therapy, had unacceptable associated risks.

While pessimism associated with medication may have been accentuated by the high profile withdrawal of several drugs used to treat OA during the period of this study, it is more likely to represent an ongoing concern for OA patients. Studies undertaken prior to the withdrawal of these drugs reported similar fears about side effects and potential

addiction when taking medication to control OA⁴⁵. Indeed, the dilemma of patients taking unacceptable risks in managing symptoms through medication may also reflect the perception that OA is simply not a serious disease, which may further result in under medication, poor symptom control, further anxiety and greater impact on QoL.

Concern about the potential risks with surgery was also expressed by participants in this study. While a meta analysis suggests that joint replacement surgery outcomes are good³²⁵, several patients rejected outright the thought of having joint replacement, even as a last resort. This is consistent with previous literature that suggests that the decision on whether to have surgery was an individualised process that was dependent not purely on symptoms or disability⁴⁷, but also non-disease related issues, such as the positive or negative experiences of others and available social support following a procedure⁴⁶. Such issues need to be considered in those who may be assessed for potential surgery.

A lack of understanding of the risk-benefit of treatment options is not isolated to surgery and medications. While several studies have demonstrated the positive outcomes of physical therapy^{302, 303}, exercise³²⁶ and self management strategies^{326, 327} in treatment of symptomatic OA, it was the contention of several of the interviewees that there were no treatment options that could help with OA. This may be associated with a lack of awareness, access to assessment or simply not considering the disease important enough to treat. Of note, almost half of those with severe knee pain do not seek advice from their GP³⁶. It is also reflected in awareness and access to treatment option: almost half of knee OA patients have not received any physical therapy or patient education³²⁸. Of note, patients who have access to such programmes believe that these should receive a high priority in future research³⁰⁴.

It is imperative that those with OA are educated as to the possible risk and benefits associated with their treatments. Educational strategies, which are informed by the literature, should be developed not only for medication and surgery treatments, but other therapies, including self management, exercise and physical therapy. Access to such treatments should be given priority when developing OA services.

Living with OA had a substantial impact on an individual's self perception, particularly if it compromised their ability to fulfill roles and duties that were important to them. In some cases, changed roles within their family unit undermined their self esteem. Furthermore, candidates identified their future coping as being strongly associated with their ability to undertake such roles and tasks. This inability to perform valued tasks and activities in a social identify framework has been referred to in the psychology literature as "illness intrusion"³²⁹. A recent study of people with rheumatic conditions found illness intrusion to be predictive of psychological well being in addition to having a substantial influence on adjustment to the disease and perceived coping³³⁰.

The importance of this concept of being able to undertake valued tasks is at the basis of the needs-based approach to quality of life. Life derives its quality from the ability and capacity of an individual to satisfy certain human needs. Quality of life is good when most needs are fulfilled, and poor when few needs are satisfied²¹⁴.

As the conceptual framework from which these studies were derived was the needs-based approach to quality of life, it was unsurprising that functional status and pain did not adequately describe the experience of living with OA. This is found not only in OA: patients with other conditions, including stroke²⁹⁹, traumatic brain injury²⁹⁹, rheumatoid arthritis³³¹ and HIV/AIDS³³² consistently report "an overemphasis" by clinicians on pain and physical function. This thesis further demonstrates that while

pain and function are indeed important to people with OA, the impact is far wider than these constructs.

8.3 Physical and psychosocial influences on QoL

The key finding of this thesis is that quality of life in OA is associated with a complex relationship between physical and psychosocial factors. An interaction of functional ability, age and anxiety factors strongly influenced self perceived quality of life in OA. These, in turn, were affected by pain, duration of disease and the number of reported co-morbidities. Age was also a significant direct and indirect factor in quality of life in people with OA. A combination of knee and hip pain had an effect of quality of life. Of note, the number of self reported painful joints affected did not contribute significantly to quality of life.

While limited attention has been given to anxiety in OA, the impact of anxiety on general health is substantial: higher anxiety symptoms have been associated with poor functioning, general well-being and increase health care use³³³. This program of work found that not only was anxiety key to quality of life, but levels of anxiety and depression were disturbingly prominent. Patients in this study had anxiety levels that were higher than that reported for breast cancer³¹³, renal disease³¹⁴ and chronic heart disease³¹⁵. In terms of the clinical diagnosis of anxiety, 15% of the OA participants were defined as “possible” cases of anxiety and a further 23% were “probable” cases of anxiety³³⁴. This is much higher than those cases reported in the literature for acute stroke³³⁵ and fractured neck of femur³³⁵, three times that of the normal population³³⁴ and represents a considerable burden in the OA population.

While depression scores in the OA group were lower than anxiety scores, depression was again higher in the OA group compared to that reported in end-stage renal

disease³¹⁴ and breast cancer³¹³. Over one quarter of the OA patients reported possible cases of depression, with one in ten reporting severe depression. Previous literature evaluating depression in OA has tended to focus on those with end-stage OA^{69, 70}. The results of this thesis indicated were similar to those reported waiting for surgical replacement⁶⁹ and indicate that depression is substantial across the spectrum of the OA severity.

In terms of the impact of pain on quality of life, the data presented in this thesis demonstrated that pain is the primary driver in increasing levels of anxiety. There was no direct link demonstrated between depression and quality of life. However, given the high levels of depression reported in this thesis, both depression and anxiety needs to be given greater priority in the assessment and management of OA.

The influence of anxiety and depression on health-related quality of life has been explored in other conditions. While depression has been found to be the most significant predictor of HRQoL in neurological conditions³³⁶ and myocardial infarction³¹¹, anxiety was the most significant predictor in cervical dystonia³³⁷ and cancer³³⁸. This is the first time that depression and anxiety have been explored in the needs-based model of quality of life.

In this thesis, the impact of anxiety on quality of life was influenced by disease activity, with increasing levels of pain, number of co-morbidities and longer disease duration all resulting in higher levels of anxiety. From the qualitative study, pessimism in treatment options was highlighted: it is possible that this pessimism may be associated with increased anxiety. Indeed, a recent study found that the odds of persistent pain after treatment in knee OA were higher in those who were concerned about their prognosis⁴³.

The prominence of anxiety and depression is of particular concern because the psychosocial aspects of OA have been found to be under recognised by GPs³³⁹. Simple therapies targeted to reduce psychological stress have found to be effective in other conditions. In people with rheumatoid arthritis, meditation has been demonstrated to improve psychological distress³⁴⁰ and education strategies have assisted those with a number of conditions, including asthma³⁴¹ and cancer³⁴². Importantly, group interventions have been demonstrated to enhance patient coping in general “arthritis” cohort, which include those with inflammatory and osteoarthritis³²⁷. Such strategies may be targeted towards reducing anxiety in OA and therefore enhancing quality of life.

The issue of ageing and its impact on quality of life has received considerable attention over the last 20 years. The general literature evaluating the impact of age on quality of life is contradictory: while a limited number studies indicate a negative association between subjective well-being and ageing³⁴³, the majority of studies do not^{344, 345}. Indeed, most of the negative impact of the ageing process on QoL and health related QoL has been associated not directly with ageing, but with somatic symptoms, restricted physical function or loss of societal roles^{188, 219, 333}. The literature has demonstrated a diversity of experience within a 'good life', which was inconsistent with the stereotypical picture of old people as a homogeneous group³⁴⁶. Several elements have been identified as important for a good quality of life in older age: relationships, activities, health, philosophy of life, the person's past and present lives and future perspectives³⁴⁴. This complex interaction between age and quality of life is supported by the results of this thesis: age directly impacted on quality of life in those with OA and had an indirect effect through impeding function, number of co-morbidities and the duration of disease.

8.4 Joint location and number of joints affected

One of the main aims of this thesis was to explore the prevalence and impact of OA at more than one joint site and to investigate any association with quality of life. The epidemiological study demonstrated that joint problems are highly prevalent, with multiple-site involvement particularly common in those over 55. The median number of joints involved was consistent at four in all studies included in this thesis. The presence of joint problems was associated with a reduced ability to undertake functional tasks, such as using stairs and standing from a seated position. The location and pattern of joint involvement increased this difficulty substantially.

In the qualitative chapter of this thesis, the major concern expressed by interviewees relating to multiple joint problems was a lack of time during doctor and nurse consultations to discuss complex different problems associated with having multiple-site OA. Patients felt forced into focussing on the site of OA that was of most concern to them at time of consultation, which was generally the knee. Peripheral sites of OA (hands and foot) were often ignored, even when they were causing the patient considerable impairment.

The impact of the location, number and combination of painful joints was an important aspect of this thesis. While the number and pattern of joint pain has a substantial influence on the ability to undertake daily tasks, the impact of this on quality of life is not as important as other factors, such as levels of anxiety and general functional ability. The pattern of joint problems did affect quality of life however. The top six most prevalent joint patterns were included in the modelling in Chapter 7, but the combination of hip and knee pain was the only combination that had a significant impact on quality of life. The number of painful joints had no impact on quality of life, which was fundamental to the hypothesis of this thesis. These results do need to be

considered in light of establishing patterns and numbers of joint problems however. While inclusion for the interviews (Chapter 4), the development of a quality of life instrument (Chapter 5), the test-rest (Chapter 6) and the modelling for quality of life (Chapter 7) was based on strict diagnostic criteria for OA, the presence of OA elsewhere by these individuals was implied from self reporting painful joints. From the data in the programme of work, it was not possible to explore the effect of specific joint location on quality of life. This is an area for future research.

8.5 Co-morbidities and OA

One of the most important findings arising from the work in this thesis was the impact of co-morbidities in joint pain and OA. While the impact of co-morbidities in OA on disability has been recognised^{92, 93}, the results of the epidemiological study demonstrated that the number of co-morbidities was the most significant predictors of impairment in activities of daily living. This finding is in agreement with a previous study which evaluated health related quality of life in OA and found that the most significant predictor of reduced health-related quality of life was the number of co-morbidities³⁴⁷. In this thesis, using a needs-based approach to quantify quality of life and a sophisticated modelling approach, it has been demonstrated that the number of co-morbidities directly influenced anxiety, which in turn impacts on quality of life. That is, co-morbidity was fully mediated by anxiety: having co-morbidities did not directly influence quality of life unless they increased the anxiety. Given the high number of co-morbidities reported with OA⁸⁹, this of considerable importance in the assessment and management of OA.

8.6 Implications for Clinical Practice

Recent data suggests that the cost associated with musculoskeletal pain has extensive economic consequences for the community^{348, 349}. With estimates of the global burden of musculoskeletal conditions reported to be increasing with an ageing population³⁵⁰, it is essential that appropriate strategies be addressed. The data from this programme of work suggests that changes need to be made in the understanding and management of joint problems and that an approach to patient care which includes psychosocial assessment may be of benefit to both population health and provide better use of economic resources.

These data suggest that there is a deficiency in the current management of joint problems, with the vast majority of publications and guidelines being focused on single joints. In published guidelines covering the management of the knee and hip osteoarthritis^{1, 75, 351}, there is no mention of multiple-site assessment and management. While the number of joints involved did not directly influence quality of life, there is an effect on reducing the ability to undertake simple activities. The number and patterns of joint involvement should be considered in a holistic assessment of the individual with OA.

Assessment and management strategies need to reflect the interaction of the psychosocial and physical factors and their impact on quality of life. There is clearly a need for changes to assessment, referral and therapeutic strategies. Intervention for OA should focus not only on the symptoms, but also the coping strategies. Treatment for pain should be given not just to reduce pain, but also with consideration to the functional activities of the person. Particular attention should be given to the psychosocial aspects, with strategies devised for those who have high anxiety or depression levels.

A major finding of this thesis is the levels of depression and anxiety in OA: indeed, given the high levels found in this study, routine screening for anxiety and depression should be incorporated into initial assessment and ongoing review of people with OA. This should not be considered only in those with severe disease, but patients across the spectrum of disease in both primary and secondary care. This is particularly important in light of the substantial impact and complex relationships of anxiety not only to quality of life, but also to pain, function and depression.

Strategies for education of patients on the benefits and risks of treatments need to be provided as routine care for those with OA. This needs to include information on not only medication, but also surgical interventions, exercise and physical therapies.

Finally, the unique experience of the person living with OA should be explored as part of the assessment, management and monitoring of a patient with OA.

8.7 Limitations of the research

This thesis needs to be viewed in light of the limitations of each study, which are explored in the results section of each relevant chapter. The data from the epidemiological study was based on self reported joint pathology and not physician confirmed diagnosis of OA. As such, this study provides us with the impact of joint pain in the community, but not necessarily OA.

In the modelling study, the elements included were based on specific outcome measures, each with their own limitations. As function for the model was based only on WOMAC function, upper limb problems were not represented. As a result, the

modelling, particularly in terms of the relationship of function to other factors, is more reflective of those with lower limb painful joints.

The modelling did not include elements that have been indicated in studies in other diseases which may impact on quality of life, including measures of self efficacy, participation, fatigue and environmental factors, such as social support. This may have meant that the model was not fully explained by the variables that were considered in this thesis: however, given the high amount of variance explained ($R^2=0.81$), the effect of including other measures would add only a moderate enhancement to a very well explained model.

All participants included in the qualitative study, the development of the OAQoL and the modelling chapters fulfilled strict criteria for the diagnosis of OA for at least one joint. Additional number and pattern of joint involvement however, was based self-reported, painful joints. As such, the pattern and number of joints that were included in the analysis were reflective of painful joints, not necessarily confirmed OA. This may over represent the prevalence of multiple joint confirmed OA in this thesis, and instead represents painful joints in those with confirmed OA.

Finally, across all studies, the cohorts were predominantly British Caucasians. Findings in the qualitative study may under represent needs of ethnic groups, particularly in terms of education and understanding of the disease. The OAQoL has been developed and validated for use only in a white Caucasian population and may not represent the impact of OA on individuals from other communities. Furthermore, the results of the modelling may be different when applied to other communities and cultures.

8.8 Directions for Future Research

This thesis provides a platform for further research into quality of life in osteoarthritis.

i. OAQoL

The importance of including quality of life measurements has been recognised: the World Health Organisation, the International League for Rheumatology Task Force⁹⁷ and the OA Research Society³⁵² strongly recommended that QoL measures be used in OA clinical research. While this thesis has developed and validated a disease specific, needs-based quality of life measure for OA, work is required to further explore the application of the OAQoL. Firstly, the clinical responsiveness¹¹⁹ of the tool needs to be explored across a number of common treatments including exercise, drug and surgical interventions. Secondly, an exploration of meaningful change³⁵³ or change in quality of life that is important to the individual is necessary. Finally, cultural and language adaptations²⁵⁰ of the OAQoL are necessary if this instrument is to be used outside a Caucasian, British population.

Novel uses of the OAQoL also need to be explored. Items from the OAQoL could be used to contribute to an item bank of needs-based instruments, particularly in rheumatology. In doing this, comparisons of the impact of QoL between rheumatological diseases would be possible. The use of the OAQoL as a health utility measure specifically for OA should also be explored following developments with the needs-based RAQoL: a recent study comparing the difference between EQ-5D (which is universally used as a health utility measure) and the RAQoL indicated that the RAQoL functioned as well as the EQ-5D³⁵⁴ and was more reliable and responsive in an RA population¹⁹³. The application of a disease specific utility measure would offer greater sensitivity and specificity for a prevalent and important disease such as OA.

ii. Modelling Quality of Life in OA

While this thesis developed a robust model explaining quality of life, further exploration should be undertaken and include other measures to fully map the ICF constructs. Future modelling should include a greater emphasis on environmental factors; a robust tool for measuring participation should be included; and greater exploration of personal factors, including measures such as self efficacy should be considered. Finally, in order to fully test the hypothesis that joint location impacts differently on quality of life, the model should be replicated on large cohorts of those with OA at different sites (knee, hip, foot and hand) in order to explore the impact of joint location on quality of life. A model which includes a robust measure of upper limb function should be included in future work in this area.

iii. Anxiety in OA

The high levels of anxiety and depression and the substantial influence of anxiety on quality of life in OA must be investigated further. Factors that contribute to anxiety levels should be identified and explored in order to reduce the impact of these psychological factors. Treatment strategies targeted in addressing issues that impact on anxiety, particularly from lessons learnt in other conditions (such educational strategies) should be developed and evaluated, particularly in terms of their influence on quality of life.

iv. Multiple Joint Assessment

Finally, given the prevalence of OA in more than one joint, research should reflect multiple-site involvement. Clinical trials need to be more reflective of the true representation of joint pain and involvement across several sites: inclusion criteria which specifically exclude other joint involvement need to be reviewed to ensure that studies are representative of the population to which they are targeting treatment.

Assessment tools need to be explored to address issues the complex issues associated with multiple site involvement. Such tools may require several domains to capture different anatomical sites and responsiveness to change when change may be different between sites.

8.9 Summary

The major findings of this thesis can be summarised as follows:

- i. Osteoarthritis has a considerable and often complex impact on the individual; the OAQoL, a needs-based, disease specific outcome measure to assess of quality of has been derived from a strong conceptual framework and has rigorously tested for its psychometric properties.
- ii. Anxiety and depression are high in people with OA and anxiety has a substantial influence on their perceived quality of life
- iii. Co-morbidities are common in OA and are related to impairment of activities of daily living and quality of life
- iv. While the location and number of painful joints in those with OA impacts on their ability to undertake the tasks of daily living, other aspects, such as anxiety, age and functional ability have a more substantial impact on quality of life.

References

1. Pendleton A, Arden N, Dougados M, et al. EULAR recommendations for the management of knee osteoarthritis: report of a task force of the Standing Committee for International Clinical Studies Including Therapeutic Trials (ESCISIT). *Annals of the Rheumatic Diseases*. 2000;59:936-244.
2. Mili F, Helmick CG, Moriarty DG. Health related quality of life among adults reporting arthritis: analysis of data from the Behavioural Risk Factor Surveillance System, US, 1996-99. *Journal of Rheumatology*. 2003;30(1):160-166.
3. Alonso J, Ferrer M, Gandek B, et al. Health-related quality of life associated with chronic conditions in eight countries: results from the International Quality of Life Association (IQOLA). *Quality of Life Research*. 2004;13:283-298.
4. World Health Organisation. *The burden of musculoskeletal conditions at the start of the new millennium*. Geneva: World Health Organization; 2003.
5. MacLean C, Knight K, Paulus R, Brook P, Sheckelle. Costs attributable to osteoarthritis. *Journal of Rheumatology*. 1998;25(11):2213-2218.
6. Hospital Episode Statistics (HES). Hospital in-patient data. http://www.doh.gov.uk/hes/standard_data/available_tables/index.html. Accessed 1st August, 2002, 2002.
7. World Health Organisation. Ageing and Health: A Global Challenge for the 21st Century. Paper presented at: WHO Symposium, 1998; Kobe, Japan.
8. Pelletier JP, Martel-Pelletier J, Abramson SB. Osteoarthritis, an inflammatory disease: potential implication for the selection of new therapeutic targets. *Arthritis & Rheumatism*. 2001;44(6):1237-1247.
9. Rogers J, Shepstone L, Dieppe P. Is osteoarthritis a systemic disorder of bone? *Arthritis & Rheumatism*. 2004;50(2):452-457.
10. Brandt KD, Radin EL, Dieppe PA, van de Putte L. Yet more evidence that osteoarthritis is not a cartilage disease. *Annals of the Rheumatic Diseases*. Oct 2006;65(10):1261-1264.
11. Brandt KD, Heilman DK, Slemenda C, et al. Quadriceps strength in women with radiographically progressive osteoarthritis of the knee and those with stable radiographic changes. *Journal of Rheumatology*. Nov 1999;26(11):2431-2437.
12. Oliveria SA, Felson DT, Reed JI, et al. Incidence of symptomatic hand, hip and knee osteoarthritis among patients in a health maintenance organization. *Arthritis & Rheumatism*. 1995;38:1134-1141.
13. Srikanth VK, Fryer JL, Zhai G et al. A meta-analysis of sex differences prevalence, incidence and severity of osteoarthritis. *Osteoarthritis & Cartilage*. 2005;13:769-781.
14. Lawrence R, Hemlick C, Arnett F, et al. Estimates of prevalence of arthritis and selected musculoskeletal disorders in the United States. *Arthritis & Rheumatism*. 1998;51(5):778-799.
15. Wilder FV, Barrett JP, Farina EJ. The association of radiographic foot osteoarthritis and radiographic osteoarthritis at other sites. *Osteoarthritis & Cartilage*. Mar 2005;13(3):211-215.
16. Andriacchi TP, Mundermann A, Andriacchi TP, Mundermann A. The role of ambulatory mechanics in the initiation and progression of knee osteoarthritis. *Current Opinion in Rheumatology*. Sep 2006;18(5):514-518.
17. Dieppe P, Dieppe P. Research in osteoarthritis. *Current Opinion in Rheumatology*. Sep 2006;18(5):512-513.

18. Felson D, Lawrence R, Dieppe P, et al. Osteoarthritis: new insights. Part 1: The disease and its risk factors. *Annals of Internal Medicine*. 2000;133(8):635-646.
19. Spector TD, Cicuttini F, Baker J, et al. Genetic influences on osteoarthritis in women: a twin study. *BMJ*. Apr 13 1996;312(7036):940-943.
20. Lau EC, Cooper C, Lam D, et al. Factors associated with osteoarthritis of the hip and knee in Hong Kong Chinese: obesity, joint injury, and occupational activities. *American Journal of Epidemiology*. Nov 1 2000;152(9):855-862.
21. Sharma L, Cahue S, Song J et al. Physical functioning over three years in knee osteoarthritis: role of psychosocial, local mechanical, and neuromuscular factors. *Arthritis & Rheumatism*. 2003;48(12):3359-3370.
22. Hannan MT, Anderson JJ, Zhang Y, et al. Bone mineral density and knee osteoarthritis in elderly men and women. The Framingham Study. *Arthritis & Rheumatism*. Dec 1993;36(12):1671-1680.
23. Felson DT, Hannan MT, Naimark A, et al. Occupational physical demands, knee bending, and knee osteoarthritis: results from the Framingham Study. *Journal of Rheumatology*. Oct 1991;18(10):1587-1592.
24. Buckwalter JA, Lane NE, Buckwalter JA, Lane NE. Athletics and osteoarthritis. *American Journal of Sports Medicine*. Nov-Dec 1997;25(6):873-881.
25. Sharma L, Hurwitz DE, Thonar EJ, et al. Knee adduction moment, serum hyaluronan level, and disease severity in medial tibiofemoral osteoarthritis. *Arthritis & Rheumatism*. Jul 1998;41(7):1233-1240.
26. Brouwer GM, van Tol AW, Bergink AP, et al. Association between valgus and varus alignment and the development and progression of radiographic osteoarthritis of the knee. *Arthritis & Rheumatism*. Apr 2007;56(4):1204-1211.
27. Honkonen SE, Honkonen SE. Degenerative arthritis after tibial plateau fractures. *Journal of Orthopaedic Trauma*. 1995;9(4):273-277.
28. Tan AL, Grainger AJ, Tanner SF, et al. High-resolution magnetic resonance imaging for the assessment of hand osteoarthritis. *Arthritis & Rheumatism*. Aug 2005;52(8):2355-2365.
29. Gignac MA, Davis AM, Hawker G, et al. "What do you expect? You're just getting older": A comparison of perceived osteoarthritis-related and aging-related health experiences in middle- and older-age adults. *Arthritis & Rheumatism*. Dec 15 2006;55(6):905-912.
30. McAlindon TE, Snow S, Cooper C, Dieppe PA. Radiographic patterns of osteoarthritis of the knee joint in the community: the importance of the patellofemoral joint. *Annals of the Rheumatic Diseases*. Jul 1992;51(7):844-849.
31. Duncan R, Peat G, Thomas E et al. Symptoms of radiographic osteoarthritis: not as discordant as they are made out to be? *Annals of the Rheumatic Diseases*. 2007;66(1):86-91.
32. Altman R, Alarcon G, Appelrouth D, et al. The American College of Rheumatology criteria for the classification and reporting of osteoarthritis of the hand. *Arthritis & Rheumatism*. 1990;33(11):1601-1610.
33. Altman R, Asch D, Bloch D, et al. Development of criteria for the classification and reporting of osteoarthritis: classification of OA of the knee. *Arthritis & Rheumatism*. 1986;29(8):1039-1049.
34. Altman R, Alarcon G, Appelrouth D, et al. The American College of Rheumatology criteria for the classification and reporting of osteoarthritis of the hip. *Arthritis & Rheumatism*. 1991;34:505-514.
35. Kellgren JH, Lawrence JS, Kellgren JH, Lawrence JS. Radiological assessment of osteo-arthrosis. *Annals of the Rheumatic Diseases*. Dec 1957;16(4):494-502.

36. Peat G, Thomas E, Duncan R et al. Clinical classification criteria for knee osteoarthritis: performance in the general population and primary care. *Annals of the Rheumatic Diseases*. Oct 2006;65(10):1363-1367.
37. Felson DT, Neogi T. Osteoarthritis: is it a disease of cartilage or bone? *Arthritis & Rheumatism*. 2004;50(2):341-344.
38. Huch K, Kuettner KE, Dieppe P. Osteoarthritis of the ankle and knee joints. *Seminars in Arthritis and Rheumatism*. 1997;26(4):667-674.
39. Dieppe PA, Lohmander S. Pathogenesis and management of pain in osteoarthritis. *The Lancet*. 2005;365:965-973.
40. Dominick KL, Ahern FM, Gold CH, Heller DA. Health-related quality of life and health service use among older adults with osteoarthritis. *Arthritis & Rheumatism*. Jun 15 2004;51(3):326-331.
41. Heijmans M, Foets M, Rijken M et al. Stress in chronic disease: do the perceptions of patients and their general practitioners match? *British Journal of Health Psychology*. 2001;6:229-242.
42. Bradley LA. Recent approaches to understanding osteoarthritis pain. *Journal of Rheumatology - Supplement*. Apr 2004;70:54-60.
43. Palmer KT, Reading I, Calnan M, et al. Does knee pain in the community behave like a regional pain syndrome? Prospective cohort study of incidence and persistence. *Annals of the Rheumatic Diseases*. Sep 2007;66(9):1190-1194.
44. Heuts PHTG, Vlaeyen JWS, Roelofs J, et al. Pain-related fear and daily functioning in patients with osteoarthritis. *Pain*. 2004;In press.
45. Sale JE, Gignac M, Hawker G. How "bad" does the pain have to be? A qualitative study examining adherence to pain medication in older adults with osteoarthritis. *Arthritis & Rheumatism*. 2006;55(2):272-278.
46. Clark JP, Hudak PL, Hawker GA, et al. The moving target: a qualitative study of elderly patients' decision-making regarding total joint replacement surgery. *Journal of Bone & Joint Surgery - American Volume*. Jul 2004;86-A(7):1366-1374.
47. Llewellyn-Thomas HA, Arshinoff R, Bell M, et al. In the queue for total joint replacement: patients' perspectives on waiting times. Ontario Hip and Knee Replacement Project Team. *Journal of Evaluation in Clinical Practice*. Feb 1998;4(1):63-74.
48. Denison E, Asenlof P, Lindberg P. Self-efficacy, fear avoidance, and pain intensity as predictors of disability in subacute and chronic musculoskeletal pain patients in primary health care. *Pain*. 2004;111(3):245-252.
49. Creamer P, Hochberg MC. The relationship between psychosocial variables and pain reporting in osteoarthritis of the knee. *Arthritis Care & Research*. Feb 1998;11(1):60-65.
50. Creamer P, Lethbridge-Cejku M, Costa P et al. The relationship of anxiety and depression with self-reported knee pain in the community: data from the Baltimore longitudinal study of ageing. *Arthritis Care & Research*. 1999;12(1):3-7.
51. Birrell F, Croft P, Cooper C, et al. Health impact of pain in the hip region with and without radiographic evidence of osteoarthritis: a study of new attenders to primary care. The PCR Hip Study Group. *Annals of the Rheumatic Diseases*. Nov 2000;59(11):857-863.
52. Dougados M, Dougados M. Structural progression is also driven by clinical symptoms in patients with osteoarthritis. *Arthritis & Rheumatism*. May 2004;50(5):1360-1365.
53. Dieppe PA, Dieppe PA. Relationship between symptoms and structural change in osteoarthritis. what are the important targets for osteoarthritis therapy? *Journal of Rheumatology - Supplement*. Apr 2004;70:50-53.

54. Creamer P, Lethbridge-Cejku M, Hochberg MC et al. Factors associated with functional impairment in symptomatic knee osteoarthritis. *Rheumatology*. May 2000;39(5):490-496.
55. Szebenyi B, Hollander AP, Dieppe P, et al. Associations between pain, function, and radiographic features in osteoarthritis of the knee. *Arthritis & Rheumatism*. Jan 2006;54(1):230-235.
56. Felson DT, Chaisson CE, Hill CL, et al. The association of bone marrow lesions with pain in knee osteoarthritis. *Annals of Internal Medicine*. Apr 3 2001;134(7):541-549.
57. Felson DT, McLaughlin S, Goggins J, et al. Bone marrow edema and its relation to progression of knee osteoarthritis. *Annals of Internal Medicine*. 2003;139(5 Pt 1):330-336.
58. Wluka AE, Wolfe R, Stuckey S, et al. How does tibial cartilage volume relate to symptoms in subjects with knee osteoarthritis? *Annals of the Rheumatic Diseases*. Mar 2004;63(3):264-268.
59. Raynauld JP, Martel-Pelletier J, Berthiaume MJ, et al. Long term evaluation of disease progression through the quantitative magnetic resonance imaging of symptomatic knee osteoarthritis patients: correlation with clinical symptoms and radiographic changes. *Arthritis Research & Therapy*. 2006;8(1):R21.
60. O'Malley KJ, Suarez-Almazor M, Aniol J, et al. Joint specific multidimensional assessment of pain (J-MAP): factor structure, reliability, validity and responsiveness in patients with knee osteoarthritis. *The Journal of Rheumatology*. 2002;30(534-543.).
61. Verbrugge LM, Lepkowski JM, Konkol LL. Levels of disability among US adults with arthritis. *Journal of Gerontology*. 1991;46(2):571-583.
62. Penninx BWJH, Abbas H, Ambrosius W, et al. Inflammatory markers and physical function among older adults with knee osteoarthritis. *Journal of Rheumatology*. 2004;31:2027-2031.
63. Dunlop DD, Manheim LM, Sohn MW et al. Incidence of functional limitation in older adults: the impact of gender, race, and chronic conditions. *Archives of Physical Medicine & Rehabilitation*. 2002;83(7):964-971.
64. Williams DA, Farrell MJ, Cunningham J, et al. Knee pain and radiographic osteoarthritis interact in the prediction of levels of self-reported disability. *Arthritis & Rheumatism*. 2004;51(4):558-561.
65. Kjekken I, Dagfinrud H, Slatkowsky-Christensen B, et al. Activity limitations and participation restrictions in women with hand osteoarthritis: patients' descriptions and associations between dimensions of functioning. *Annals of the Rheumatic Diseases*. Nov 2005;64(11):1633-1638.
66. Rosemann T, Backenstrass M, Joest K, et al. Predictors of depression in a sample of 1,021 primary care patients with osteoarthritis. *Arthritis & Rheumatism*. Apr 15 2007;57(3):415-422.
67. Meltzer H, Gill B, Pettigrew M. *The prevalence of psychiatric morbidity among adults aged 16-64, living in private households, in Great Britain*. London: Office of Population Census and Surveys: 1994.
68. Memel DS, Kirwan JR, Sharp DJ, Hehir M. General practitioners miss disability and anxiety as well as depression in their patients with osteoarthritis. *British Journal of General Practice*. Aug 2000;50(457):645-648.
69. Orbell S, Espley A, Johnston M, et al. Health benefits of joint replacement surgery for patients with osteoarthritis: prospective evaluation using independent assessments in Scotland. *Journal of Epidemiology & Community Health*. Sep 1998;52(9):564-570.
70. Faller H, Kirschner S, Konig A et al. Psychological distress predicts functional outcomes at three and twelve months after total knee arthroplasty. *General Hospital Psychiatry*. Sep-Oct 2003;25(5):372-373.

71. O'Reilly SC, Muir KR, Doherty M et al. Knee pain and disability in the Nottingham community: association with poor health status and psychological distress. *British Journal of Rheumatology*. Aug 1998;37(8):870-873.
72. Croft P, Jordan K, Jinks C et al. "Pain elsewhere" and the impact of knee pain in older people. *Arthritis & Rheumatism*. Aug 2005;52(8):2350-2354.
73. Zautra AJ, Smith BW. Depression and reactivity to stress in older women with rheumatoid arthritis and osteoarthritis. *Psychosomatic Medicine*. 2001;63:687-696.
74. Hannan MT, Felson DT, Pincus T. Analysis of the discordance between radiographic changes in knee pain and osteoarthritis of the knee. *Journal of Rheumatology*. 2000;27:1513-1517.
75. Zhang W, Doherty M, Arden N, et al. EULAR evidence based recommendations for the management of hip osteoarthritis: report of a task force of the EULAR Standing Committee for International Clinical Studies including Therapeutics (ESCIIT). *Annals of the Rheumatic Diseases*. 2005;64:669-681.
76. Badley E, Tennant A. The changing profile of joint troubles with age: findings from a postal survey of the population. *Annals of Rheumatic Disease*. 1992;51:366-371.
77. Mannoni A, Briganti M, Di Bari M, et al. Epidemiological profile of symptomatic osteoarthritis in older adults: a population based study in Dicomano, Italy. *Annals of Rheumatic Disease*. 2003;62:576-578.
78. Muehleman C, Bareither D, Huch K, Cole AA, Kuettner KE. Prevalence of degenerative morphological changes in the joints of the lower extremity. *Osteoarthritis & Cartilage*. 1997;5(1):23-37.
79. Peat G, McCarney R, Croft P. Knee pain and osteoarthritis in older adults: a review of community burden and current use of primary health care. *Annals of the Rheumatic Diseases*. 2000;60:91-97.
80. Zhang Y, Xu L, Nevitt MC, et al. Comparison of the prevalence of knee osteoarthritis between the elderly Chinese population in Beijing and whites in the United States: The Beijing Osteoarthritis Study. *Arthritis & Rheumatism*. 2001;44(9):2065-2071.
81. Felson DT, Zhang Y. An update on the epidemiology of knee and hip osteoarthritis with a view to prevention. *Arthritis & Rheumatism*. Aug 1998;41(8):1343-1355.
82. Lievense AM, Bierma-Zeinstra SM, Verhagen AP et al. Prognostic factors of progress of hip osteoarthritis: a systematic review. *Arthritis & Rheumatism*. Oct 15 2002;47(5):556-562.
83. van Saase JL, van Romunde LKJ, Cats A, Vandebroucke JP, Valkenberg HA. Epidemiology of osteoarthritis: Zoetermeer survey. *Annals of the Rheumatic Diseases*. 1989;48:271-280.
84. Dahaghin S, Bierma-Zeinstra SM, Ginai AZ et al. Prevalence and pattern of radiographic hand osteoarthritis and association with pain and disability (the Rotterdam study). *Annals of the Rheumatic Diseases*. May 2005;64(5):682-687.
85. Dahaghin S, Bierma-Zeinstra SM, Reijman M et al. Does hand osteoarthritis predict future hip or knee osteoarthritis? *Arthritis & Rheumatism*. Nov 2005;52(11):3520-3527.
86. Hunter DJ, Demissie S, Cupples LA, et al. A genome scan for joint-specific hand osteoarthritis susceptibility: The Framingham Study. *Arthritis & Rheumatism*. Aug 2004;50(8):2489-2496.
87. Thomas E, Wilkie R, Peat G et al. The North Staffordshire Osteoarthritis Project-NorStOP: prospective, 3-year study of the epidemiology and management of clinical osteoarthritis in a general population of older adults. *BMC Musculoskeletal Disorders*. 2004;5(1):2.

88. van den Akker M, Buntinx F, Metsemakers JFM, Roos S, Knottnerus JA. Multimorbidity in general practice: prevalence, incidence and determinants of co-occurring chronic and recurrent diseases. *Journal of Clinical Epidemiology*. 1998;51(5):367-375.
89. Kadam UT, Jordan K, Croft PR. Clinical comorbidity in patients with osteoarthritis: a case-control study of general practice consultants in England and Wales. *Annals of the Rheumatic Diseases*. 2004;63(4):408-414.
90. Ethgen O, Kahler KH, Kong SX et al. The effect of health related quality of life on reported use of health care resources in patients with osteoarthritis and rheumatoid arthritis: a longitudinal analysis. *Journal of Rheumatology*. 2002;29(6):1147-1155.
91. Lin EH, Katon W, Von Korff M, et al. Effect of improving depression care on pain and functional outcomes among older adults with arthritis: a randomized controlled trial. *Jama*. 2003;290(18):2428-2429.
92. Ettinger WH, Davis MA, Neuhaus JM, et al. Long-term physical functioning in persons with knee osteoarthritis from NHANES. I: Effects of comorbid medical conditions. *Journal of Clinical Epidemiology*. Jul 1994;47(7):809-815.
93. Marks R, Allegrante JP, Marks R, Allegrante JP. Comorbid disease profiles of adults with end-stage hip osteoarthritis. *Medical Science Monitor*. Apr 2002;8(4):CR305-309.
94. Sanders C, Donovan JL, Dieppe PA. Unmet need for joint replacement: a qualitative investigation of barriers to treatment among individuals with severe pain and disability of the hip and knee. *Rheumatology*. Mar 2004;43(3):353-357.
95. Ehrich E, Davies G, Watson D et al. Minimal perceptible clinical improvement with the Western Ontario and McMaster Universities osteoarthritis index questionnaire and global assessments in patients with osteoarthritis. *Journal of Rheumatology*. 2000;27(11):2635-2641.
96. Leeb B, Schweitzer H, Montag K, Smolen J. A metaanalysis of chondroitin sulfate in the treatment of osteoarthritis. *Journal of Rheumatology*. 2000;27(1):205-211.
97. Bellamy N, Kirwan J, Boers M, et al. Recommendations for a core set of outcome measures for future phase III clinical trials in knee, hip, and hand osteoarthritis. Consensus development at OMERACT III. *Journal of Rheumatology*. 1997;24(4):799-802.
98. Picavet HS, Hoeymans N. Health related quality of life in multiple musculoskeletal diseases: SF-36 and EQ-5D in the DMC3 study. *Annals of the Rheumatic Diseases*. 2004;63(6):723-729.
99. Wolfe F, Hawley DJ. Measurement of the quality of life in rheumatic disorders using the EuroQol. *British Journal of Rheumatology*. Jul 1997;36(7):786-793.
100. World Health Organisation. *International Classification of Impairment, Activity and Participation (ICIDH-2)*. Geneva: WHO; 1980.
101. De Kleijn-De Vrankrijker MW. The long way from the International Classification of Impairments, Disabilities and Handicaps (ICIDH) to the International Classification of Functioning, Disability and Health (ICF). *Disability & Rehabilitation*. 2003;25(11-12):561-564.
102. Jette AM, Keysor JJ. Disability models: implications for arthritis exercise and physical activity interventions. *Arthritis Care & Research*. 2003;49(1):114-120.
103. Post MW, de Witte LP, Schrijvers AJ, Post MW, de Witte LP, Schrijvers AJ. Quality of life and the ICIDH: towards an integrated conceptual model for rehabilitation outcomes research. *Clinical Rehabilitation*. Feb 1999;13(1):5-15.
104. World Health Organisation. *Towards a common language for functioning, disability and health. ICF*. Geneva: WHO; 2002.

105. Arthanat S, Nochajski SM, Stone J. The international classification of functioning, disability and health and its application to cognitive disorders. *Disability & Rehabilitation*. 2004;46(4):235-245.
106. Wang PP, Badley EM, Gignac M. Exploring the role of contextual factors in disability models. *Disability & Rehabilitation*. 2006;28(2):135-140.
107. Cieza A, Stucki G. New approaches to understanding the impact of musculoskeletal conditions. *Best Practice & Research in Clinical Rheumatology*. Apr 2004;18(2):141-154.
108. Weigl M, Cieza A, Harder M, et al. Linking osteoarthritis-specific health-status measures to the International Classification of Functioning, Disability, and Health (ICF). *Osteoarthritis & Cartilage*. 2003;11(7):519-523.
109. Dreinhofer K, Stucki G, Ewert T, et al. ICF Core Sets for osteoarthritis. *Journal of Rehabilitation Medicine*. Jul 2004(44 Suppl):75-80.
110. Weigl M, Cieza A, Kostanjsek N, Kirschneck M, Stucki G. The ICF comprehensively covers the spectrum of health problems encountered by health professionals in patients with musculoskeletal conditions. *Rheumatology*. Oct 2006;45(10):1247-1254.
111. Stamm TA, Nell PK, Mathis M, et al. Concepts important to people with psoriatic arthritis are not adequately covered by standard measures of functioning. Paper presented at: CARE IV, 2006; Leeds, UK.
112. Mullins R, Barber J, Hay EM. The ICF Core Sets for lower back pain: do they tell us what matters to patients. Paper presented at: CARE IV, 2006; Leeds, UK.
113. Xie F, Thumboo J, Fong KY, et al. Are they relevant? A critical evaluation of the international classification of functioning, disability, and health core sets for osteoarthritis from the perspective of patients with knee osteoarthritis in Singapore. *Annals of the Rheumatic Diseases*. Aug 2006;65(8):1067-1073.
114. Lohr KN. Assessing health status and quality of life instruments: attributes and review criteria. *Quality of Life Research*. 2002;11(3):195-205.
115. Carr A. Problems in measuring or interpreting change in patient outcomes. *Osteoarthritis & Cartilage*. 2002;10(503-505).
116. McColl E. Developing questionnaires. In: Fayers P, Hays R, eds. *Assessing quality of life in clinical trials. Second Edition*. Oxford: Oxford University Press; 2005.
117. Aitkinson M, Lennox RD. Extending basic principles of measurement models to the design and validation of patient reported outcome measures. *Health and Quality of Life Outcomes*. 2006;4(65).
118. Carr AJ, Higginson IJ. Are quality of life measures patient centred? *BMJ*. 2001;322(7298):1357-1360.
119. Hays RD, Revicki D. Reliability and validity (including clinical responsiveness). In: Fayers P, Hays R, eds. *Assessing quality of life in clinical trials. Second Edition*. Oxford: Oxford University Press; 2005.
120. Doward LC, Meads DM, Thorsen H. Requirements for quality of life instruments in clinical research. *Value in Health*. 2004;7(1):Sep-Oct.
121. Meenan R, Mason J, Anderson J et al. AIMS2. The content and properties of a revised and expanded Arthritis Impact Measurement Scales Health Status Questionnaire. *Arthritis and Rheumatology*. 1992;35:1-10.
122. Dziedzic KS, Thomas E, Hay EM et al. A systematic search and critical review of measures of disability for use in a population survey of hand osteoarthritis (OA). *Osteoarthritis & Cartilage*. Jan 2005;13(1):1-12.
123. Bellamy N. Pain assessment in osteoarthritis: experience with the WOMAC osteoarthritis index. *Seminars in Arthritis and Rheumatism*. 1989;18(4):14-17.
124. Bellamy N, Buchanan WW, Goldsmith CH, Campbell J, Stitt L. Validation study of WOMAC: a health status instrument for measuring clinically-important

- patient-relevant outcomes following total hip or knee arthroplasty in osteoarthritis. *Journal of Orthopaedic Rheumatology*. 1988;1:95-108.
125. Stratford PW, Kennedy DM, Woodhouse LJ, Spadoni GF. Measurement properties of the WOMAC LK 3.1 pain scale. *Osteoarthritis & Cartilage*. 2007;15(2):266-272.
 126. Lingard EA, Katx JN, Wright RJ et al. Validity and responsiveness of the Knees Society Clinical Rating System in Comparison with the SF-36 and WOMAC. *The Journal of Bone and Joint Surgery*. 2001;83-A(12):1856-1864.
 127. Theiler R, Sangha O, Schaeren S, et al. Superior responsiveness of the pain and function sections of the Western Ontario and McMaster Universities Osteoarthritis Index in patients with osteoarthritis of the lower extremities. *Osteoarthritis & Cartilage*. 1999;7:515-519.
 128. Jinks C, Jordan K, Croft P. Measuring the population impact of knee pain and disability with the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). *Pain*. 2002;100(1-2):55-64.
 129. Wolfe F, Kong SX. Rasch analysis of the Western Ontario MacMaster questionnaire (WOMAC) in 2205 patients with osteoarthritis, rheumatoid arthritis, and fibromyalgia. *Annals of the Rheumatic Diseases*. Sep 1999;58(9):563-568.
 130. Ryser L, Wright BD, Aeschlimann A et al. A new look at the Western Ontario and McMaster Universities Osteoarthritis Index using Rasch analysis. *Arthritis Care & Research*. Oct 1999;12(5):331-335.
 131. Davis AM, Badley EM, Beaton DE, et al. Rasch analysis of the Western Ontario McMaster (WOMAC) Osteoarthritis Index: results from community and arthroplasty samples. *Journal of Clinical Epidemiology*. 2003;56(1076-1083).
 132. Lequesne MG. The algofunctional indices for hip and knee osteoarthritis. *Journal of Rheumatology*. Apr 1997;24(4):779-781.
 133. Bellamy N, Campbell J, Haraoui B, et al. Clinimetric properties of the AUSCAN Osteoarthritis Hand Index: an evaluation of reliability, validity and responsiveness. *Osteoarthritis & Cartilage*. Nov 2002;10(11):863-869.
 134. Bellamy N, Campbell J, Haraoui B, et al. Dimensionality and clinical importance of pain and disability in hand osteoarthritis: Development of the Australian/Canadian (AUSCAN) Osteoarthritis Hand Index. *Osteoarthritis & Cartilage*. Nov 2002;10(11):855-862.
 135. Rat AC, Coste J, Pouchot J, et al. OAKHQOL: a new instrument to measure quality of life in knee and hip osteoarthritis. *Journal of Clinical Epidemiology*. Jan 2005;58(1):47-55.
 136. Klassbo M, Larsson E, Mannevik E. Hip disability and osteoarthritis outcome score. An extension of the Western Ontario and McMaster Universities Osteoarthritis Index. *Scandinavian Journal of Rheumatology*. 2003;32(1):46-51.
 137. Lo IK, Griffin S, Kirkley A. The development of a disease-specific quality of life measurement tool for osteoarthritis of the shoulder: The Western Ontario Osteoarthritis of the Shoulder (WOOS) index. *Osteoarthritis & Cartilage*. Nov 2001;9(8):771-778.
 138. Duruoz MT, Poiraudau S, Fermanian J, et al. Development and validation of a rheumatoid hand functional disability scale that assesses functional handicap. *Journal of Rheumatology*. Jul 1996;23(7):1167-1172.
 139. Poiraudau S, Chevalier X, Conrozier T, et al. Reliability, validity, and sensitivity to change of the Cochin hand functional disability scale in hand osteoarthritis. *Osteoarthritis & Cartilage*. 2001;9(6):570-577.
 140. Dreiser RL, Maheu E, Guillou GB, et al. Validation of an algofunctional index for osteoarthritis of the hand. *Revue du Rhumatisme (English Edition)*. Jun 1995;62(6 Suppl 1):43S-53S.

141. Domsic RT, Saltzman CL. The Ankle Osteoarthritis Scale. *Foot and Ankle International*. 1998;19(7):466-471.
142. Gentelle-Bonnassies S, Le Claire P, Mezieres M, Ayrat X, Dougados M. Comparison of the responsiveness of symptomatic outcome measures in knee osteoarthritis. *Arthritis Care & Research*. Oct 2000;13(5):280-285.
143. Veenhof C, Bijlsma JW, van den Ende CH, et al. Psychometric evaluation of osteoarthritis questionnaires: a systematic review of the literature. *Arthritis & Rheumatism*. Jun 15 2006;55(3):480-492.
144. Nord E, Arnesen T, Menzel P, Pinto JL. Towards a more restrictive use of the term "quality of life". *Quality of Life Newsletter*. 2001;26:3-4.
145. Roos EM, Roos HP, Lohmander LS, Ekdahl C, Beynnon BD. Knee Injury and Osteoarthritis Outcome Score (KOOS)-development of a self-administered outcome measure. *Journal of Orthopaedic & Sports Physical Therapy*. 1998;28(2):88-96.
146. Paradowski PT, Bergman S, Sunden-Lundius A, Lohmander LS, Roos EM. Knee complaints vary with age and gender in the adult population. Population-based reference data for the Knee injury and Osteoarthritis Outcome Score (KOOS). *BMC Musculoskeletal Disorders*. 2006;7:38.
147. Nilsson AK, Lohmander LS, Klassbo M, Roos EM. Hip disability and osteoarthritis outcome score (HOOS)--validity and responsiveness in total hip replacement. *BMC Musculoskeletal Disorders*. 2003;4:10.
148. Dziedzic KS, Thomas E, Myers H, Hill S, Hay EM. The Australian/Canadian osteoarthritis hand Index in a community-dwelling population of older adults: reliability and validity. *Arthritis Care & Research*. 2007;57(3):423-428.
149. MacDermid JC, Wessel J, Humphrey R, Roth JH. Validity of self-report measures of pain and disability for persons who have undergone arthroplasty for osteoarthritis of the carpometacarpal joint of the hand. *Osteoarthritis & Cartilage*. 2006;15:524-530.
150. Dreiser RL, Gersberg M, Thomas F, et al. Ibuprofen 800 mg in the treatment of arthrosis of the fingers or rhizarthrosis. *Revue du Rhumatisme Edition Francaise*. Nov 30 1993;60(11):836-841.
151. Dreiser RL, Maheu E, Guillou GB et al. Sensitivity to change of the functional index for hand osteoarthritis. *Osteoarthritis & Cartilage*. 2000;8 Suppl A:S25-28.
152. Knecht SI, Estin M, Callaghan JJ, et al. The Agility total ankle arthroplasty. Seven to sixteen-year follow-up. *Journal of Bone & Joint Surgery - American Volume*. Jun 2004;86-A(6):1161-1171.
153. Ware JE, Jr., Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Medical Care*. Jun 1992;30(6):473-483.
154. Ware JE, Kosinski M, Keller SD. A 12-item short form health survey: construction of scales and preliminary tests of reliability and validity. *Medical Care*. 1996;34(3):220-233.
155. Matsen FA, 3rd, Smith KL, DeBartolo SE, Von Oesen G. A comparison of patients with late-stage rheumatoid arthritis and osteoarthritis of the shoulder using self-assessed shoulder function and health status. *Arthritis Care & Research*. Feb 1997;10(1):43-47.
156. Croft P, Lewis M, Wynn Jones C, Coggon D, Cooper C. Health status in patients awaiting hip replacement for osteoarthritis. *Rheumatology*. Sep 2002;41(9):1001-1007.
157. Hawker G, Melfi C, Paul J, Green R, Bombardier C. Comparison of a generic (SF-36) and a disease specific (WOMAC) (Western Ontario and McMaster Universities Osteoarthritis Index) instrument in the measurement of outcomes after knee replacement surgery. *Journal of Rheumatology*. Jun 1995;22(6):1193-1196.

158. Anonymous. EuroQol--a new facility for the measurement of health-related quality of life. The EuroQol Group. *Health Policy*. Dec 1990;16(3):199-208.
159. Marra CA, Wollcott JC, Kopec JA, et al. A comparison of generic, indirect utility measures (the HU12, HU13, SF-6D and the EQ-5D) and disease specific instruments (the RAQoL and the HAQ) in rheumatoid arthritis. *Social Science & Medicine*. 2005;60:1571-1582.
160. Hunt SM, McKenna SP, McEwan J, Williams J, Papp E. The Nottingham Health Profile: Subjective health status and medical consultations. *Social Science Medicine*. 1981;15(A):221-229.
161. Cleopas A, Kolly V, Perneger TV, Cleopas A, Kolly V, Perneger TV. Longer response scales improved the acceptability and performance of the Nottingham Health Profile. *Journal of Clinical Epidemiology*. Nov 2006;59(11):1183-1190.
162. Salek MS. Measuring the quality of life in patients with arthritis: validation and clinical implications of self administered health status instrument (UKSIP). *Journal of Applied Therapeutics Research*. 1997;1:219-236.
163. Rissanen P, Sogaard J, Sintonen H. Do QOL instruments agree? A comparison of the 15D and NHP in hip and knee replacements. *International Journal of Technology Assessment in Health Care*. 2000;16(2):696-705.
164. Kaplan RM, Anderson JP, Wu AW et al. The Quality of Well-being Scale. Applications in AIDS, cystic fibrosis, and arthritis. *Medical Care*. Mar 1989;27(3 Suppl):S27-43.
165. Groessl EJ, Kaplan RM, Cronan TA. Quality of well-being in older people with osteoarthritis. *Arthritis & Rheumatism*. Feb 15 2003;49(1):23-28.
166. The, WHOQoL, Group. Study protocol for the development of the World Health Organisation project to develop a quality of life assessment instrument. *Quality of Life Research*. 1993;2:153-159.
167. The, WHOQoL, Group. Development of the WHOQOL-BREF quality of life assessment. *Psychological Medicine*. 1998;28:551-558.
168. The, WHOQoL, Group. WHOQOL-SRPB Field Test-Instrument. In: WHO, ed: Department of Mental Health and Substance Dependence, Geneva.; 2002.
169. Ackerman IN, Graves SE, Bennell KL, Osbourne RH. Evaluating quality of life in hip and knee replacement: psychometric properties of the World Health Organization Quality of Life Short Version Instrument. *Arthritis & Rheumatism*. 2006;55(4):583-590.
170. Skevington SM, Lofty M, O'Connell KA. The World Health Organization's WHOQOL-BREF quality of life assessment: psychometric properties and results of the international field trial. A report from the WHOQOL Group. *Quality of Life Research*. 2004;13(2):299-310.
171. The, WHOQoL, Group. The World Health Organization Quality of Life Assessment (WHOQOL): development and general psychometric properties. *Social Science & Medicine*. 1998;46(12):1569-1585.
172. Hawthorne G, Richardson JC, Osbourne RH, McNeil H. *The Assessment of Quality of Life (AQoL) Instrument: Construction, initial validation and utility scaling*. West Heidelberg: Centre for Health Program Evaluation; 1997.
173. Hawthorne G, Richardson JC, Osbourne RH. The Assessment Quality of Life (AQoL) instrument: a psychometric measure of health-related quality of life. *Quality of Life Research*. 1999;8(3):209-224.
174. Whitfield K, Buchbinder R, Segal L, Osborne RH. Parsimonious and efficient assessment of health-related quality of life in osteoarthritis research: validation of the Assessment of Quality of Life (AQoL) instrument. *Health & Quality of Life Outcomes*. 2006;4:19.
175. Mrus JM, Tsevat J, Wu AW, Gorski H, Zackin R, Freedber KA. Estimating quality of life and health utility using visual analogue scale (VAS) scores in the adult AIDS clinical trials group longitudinal linked randomized trials (ALLRT)

- Cohort. Paper presented at: International Conference of AIDS.; July 7 to 12 2002, 2002; Cincinnati.
176. Ibrahim SA, Siminoff LA, Burant CJ, et al. Differences in expectations of outcome mediate African American/white patient differences in "willingness" to consider joint replacement. *Arthritis & Rheumatism*. Sep 2002;46(9):2429-2435.
 177. Ibrahim SA, Burant CJ, Siminoff LA, Stoller EP, Kwok CK. Self-assessed global quality of life: a comparison between African-American and white older patients with arthritis. *Journal of Clinical Epidemiology*. May 2002;55(5):512-517.
 178. Brazier J, Harper R, Jones N, et al. Validating the SF-36 health survey: new outcome measure for primary care. *British Medical Journal*. 1992;305:160.
 179. Lescoe-Long M, Long M, Johnston D. Quality of life improvement with osteoarthritis: the potential for office-based assessment. *Arthritis Care and Research*. 1996;9(3):177-181.
 180. Carr A. Beyond disability: measuring the social and personal consequences of osteoarthritis. *Osteoarthritis & Cartilage*. 1999;7(2):230-238.
 181. Ritva K, Pekka R, Harri S. Agreement between a generic and disease-specific quality-of-life instrument: the 15D and the SGRQ in asthmatic patients. *Quality of Life Research*. 2000;9(9):997-1003.
 182. Bradley C. Importance of differentiating health status from quality of life. *The Lancet*. 2001;357:7-8.
 183. Rosemann T, S. J, Koerner T, Szechseny J, Laux G. Comparison of AIMS2-SF, WOMAC, x-ray and a global physician assessment in order to approach quality of life in patients suffering from osteoarthritis. *BMC Musculoskeletal Disorders*. 2006;7(6).
 184. Menzel P, Dolan P, Richardson J, Olsen JA. The role of adaptation to disability and disease in health state valuation: a preliminary normative analysis. *Social Science and Medicine*. 2002;55(2149-2158).
 185. Janse AJ, Gemke RJB, Uiterwaal CSPM, van der Tweel I, Kimpen JLL, Sinnema G. Quality of life: patients and doctors don't always agree: a meta-analysis. *Journal of Clinical Epidemiology*. 2004;57:653-661.
 186. Janse AJ, Uiterwaal CSPM, Gemke RJB, Kimpen JLL, Sinnema G. A difference in the perception of quality of life in chronically ill children was found between parents and pediatricians. *Journal of Clinical Epidemiology*. 2005;58:495-502.
 187. Bernheim JL. How to get serious answers to the serious question: "how have you been?". Subjective quality of life (QOL) as in individual experiential emergent construct. *Bioethics*. 1999;13(3/4):271-287.
 188. Ayis S, Gooberman-Hill R, Ebrahim S et al. Long-standing and limiting long-standing illness in older people: associations with chronic diseases, psychosocial and environmental factors. *Age & Ageing*. May 2003;32(3):265-272.
 189. National Health Service Review. *Working Paper No 6 Medical Audit*. London: HMSO; 1989.
 190. National Service Frameworks. *Chronic disease management and self-care*. London: Department of Health; August, 2002 2002.
 191. McKenna SP, Doward LC. The needs-based approach to quality of life assessment. *Value in Health*. 2004;7(1):Sep-Oct.
 192. Hayry M, Hayry M. Measuring the quality of life: why, how and what? *Theoretical Medicine*. Jun 1991;12(2):97-116.
 193. Marra CA, Rashidi AA, Guh D, et al. Are indirect utility measures reliable and responsive in rheumatoid arthritis patients? *Quality of Life Research*. Jun 2005;14(5):1333-1344.
 194. Diener E. Subjective well-being. *Psychological Bulletin*. 1984;95:542-575.

195. Sarvimaki A, Stenbock-Hult B. Quality of life in old age described as a sense of well-being, meaning and value. *Journal of Advanced Nursing*. 2000;32(4):1025-1033.
196. Brickman P, Coates D, Janoff-Bulman R. Lottery winners and accident victims: is happiness relative? *Journal of Personality and Social Psychology*. 1978;36(8):917-927.
197. Albrecht GL, Devlieger PJ. The disability paradox: high quality of life against all odds. *Social Science & Medicine*. 1999;48(8):977-988.
198. Kwok CK, O'Connor GT, Regan-Smith MG, et al. Concordance between clinician and patient assessment of physical and mental health status. *The Journal of Rheumatology*. 1992;19(7):1031-1037.
199. Schwartz CE, Sprangers MAG. Methodological approaches for assessing response shift in longitudinal quality of life research. *Social Science and Medicine*. 1999;48(1531-1548).
200. Carr AJ, Gibson B, Robinson PG. Measuring quality of life: Is quality of life determined by expectations or experience? *Bmj*. 2001;322(7296):1240-1243.
201. Mor V, Guadagnoli E. Quality of life measurement: a psychometric tower of Babel. *Journal of Clinical Epidemiology*. 1988;41(11):1055-1058.
202. van Knippenberg CCE, de Haes JCJM. Measuring the quality of life in cancer patients: psychometric properties of instruments. *Journal of Clinical Epidemiology*. 1988;41(1043-1053).
203. Joyce CR, Hickey A, McGee HM, O'Boyle CA. A theory-based method for the evaluation of individual quality of life: the SEIQoL. *Quality of Life Research*. 2003;12(3):275-280.
204. Waldron D, O'Boyle CA, Kearney M, Moriarty M, Carney D. Quality-of-life measurement in advanced cancer: assessing the individual. *Journal of Clinical Oncology*. 1999;17(11):3603-3611.
205. Hunt S, McKenna S. The QLDS: a scale for the measurement of quality of life in depression. *Health Policy*. 1992;22:307-319.
206. Hunt SM, McKenna SP, Doward LC. Preliminary report on the development of a disease-specific instrument for assessing quality of life of adults with growth hormone deficiency. *Acta Endocrinologica*. 1993;2:37-40.
207. Whalley D, McKenna S, de Jong Z, van der Heijde D. Quality of life in rheumatoid arthritis. *British Journal of Rheumatology*. 1997;36:884-888.
208. McKenna SP, Cook SA, Whalley D, et al. Development of the PSORIQoL, a psoriasis-specific measure of quality of life designed for use in clinical practice and trials. *British Journal of Dermatology*. 2003;149(2):323-331.
209. McKenna SP, Doward LC, Whalley D, Tennant A, Emery P, Veale DJ. Development of the PsAQoL: a quality of life instrument specific to psoriatic arthritis. *Annals of the Rheumatic Diseases*. 2004;63(2):162-169.
210. Reynolds S, Doward L, Spoorenberg A, et al. The development of the Ankylosing Spondylitis quality of life questionnaire. *Quality of Life Research*. 1999;8:651.
211. Ford HL, Gerry E, Tennant A, Whalley D, Haigh R, Johnson MH. Developing a disease-specific quality of life measure for people with multiple sclerosis. *Clinical Rehabilitation*. 2001;15(3):247-258.
212. Maslow A. *Motivation and Personality*. Second ed. New York: Harper and Row; 1970.
213. Gill TM, Feinstein AR, Gill TM, Feinstein AR. A critical appraisal of the quality of quality-of-life measurements. *JAMA*. Aug 24-31 1994;272(8):619-626.
214. Doward LC, McKenna SP. Defining patient-reported outcomes. *Value in Health*. 2004;7(1):Sep-Oct.
215. van der Waal JM, Terwee CB, van der Windt DA, Bouter LM, Dekker J. Health-related and overall quality of life of patients with chronic hip and knee

- complaints in general practice. *Quality of Life Research*. Apr 2005;14(3):795-803.
216. Kempen GI, Ormel J, Brillman EI, Relyveld J. Adaptive responses among Dutch elderly: the impact of eight chronic medical conditions on health-related quality of life. *American Journal of Public Health*. Jan 1997;87(1):38-44.
 217. Abell JE, Hootman JM, Zack MM, Moriarty D, Helmick CG. Physical activity and health related quality of life among people with arthritis. *Journal of Epidemiology & Community Health*. May 2005;59(5):380-385.
 218. Nunez M, Nunez E, Segur JM, et al. Health-related quality of life and costs in patients with osteoarthritis on waiting list for total knee replacement. *Osteoarthritis & Cartilage*. Mar 2007;15(3):258-265.
 219. Jakobsson U, Hallberg IR. Quality of life among older adults with osteoarthritis: an explorative study. *Journal of Gerontological Nursing*. Aug 2006;32(8):51-60.
 220. Jones CA, Voaklander DC, Johnston DW, et al. The effect of age on pain, function, and quality of life after total hip and knee arthroplasty. *Archives of Internal Medicine*. Feb 12 2001;161(3):454-460.
 221. Angst F, Aeschlimann A, Steiner W, Stucki G. Responsiveness of the WOMAC osteoarthritis index as compared with the SF-36 in patients with osteoarthritis of the legs undergoing a comprehensive rehabilitation intervention. *Annals of the Rheumatic Diseases*. 2001;60(9):834-840.
 222. Redmond AC, Ouvrier R, Crosbie J, Peat JK. *The development and validation of a novel foot posture measurement: the Foot Posture Index (FPI)*. [Doctoral]. Sydney: Faculty of Medicine, University of Sydney; 2004.
 223. Dougherty PJ, Dougherty PJ. Transtibial amputees from the Vietnam War. Twenty-eight-year follow-up. *Journal of Bone & Joint Surgery - American Volume*. Mar 2001;83-A(3):383-389.
 224. Schrag A, Jahanshahi M, Quinn N, Schrag A, Jahanshahi M, Quinn N. How does Parkinson's disease affect quality of life? A comparison with quality of life in the general population. *Movement Disorders*. Nov 2000;15(6):1112-1118.
 225. Anderson C, Rubenach S, Mhurchu CN, et al. Home or hospital for stroke rehabilitation? results of a randomized controlled trial : I: health outcomes at 6 months. *Stroke*. May 2000;31(5):1024-1031.
 226. Mayo NE, Wood-Dauphinee S, Cote R, et al. There's no place like home : an evaluation of early supported discharge for stroke. *Stroke*. May 2000;31(5):1016-1023.
 227. Dardik A, Minor J, Watson C, et al. Improved quality of life among patients with symptomatic carotid artery disease undergoing carotid endarterectomy. *Journal of Vascular Surgery*. Feb 2001;33(2):329-333.
 228. Patterson RB, Pinto B, Marcus B, et al. Value of a supervised exercise program for the therapy of arterial claudication. *Journal of Vascular Surgery*. Feb 1997;25(2):312-318; discussion 318-319.
 229. Redmond AC. *Foot posture in neuromuscular disease: development and evaluation of a novel method for quantifying change in foot posture using Charcot-Marie Tooth disease as a clinical model*. Sydney: School of Medicine, University of Sydney; 2004.
 230. Ethgen O, Vanparijs P, Delhalle S, Rosant S, Bruyere O, Reginster JY. Social support and health-related quality of life in hip and knee osteoarthritis. *Quality of Life Research*. 2004;13(2):321-330.
 231. Tennant A, Fear J, Pickering A, Hillman M, Cutts A, Chamberlain A. Prevalence of knee problems in the population aged 55 years and over: identifying the need for knee arthroplasty. *British Medical Journal*. 1995;310:1291-1293.
 232. Schoenberg BS. Calculating confidence intervals for rates and ratios. *Neuroepidemiology*. 1983;2:257-265.

233. Glantz SA, Slinker BK. *Primer of applied regression and analysis of variance*. New York: McGraw-Hill Inc.; 1990.
234. Hosmer DW, Lemeshow S. *Applied Logistic Regression*. Second Edition ed. New York: John Wiley and Sons, Inc.; 2000.
235. Kleinbaum DG, Klein M. *Logistic Regression. A self-learning text*. New York: Springer-Verlag; 2002.
236. Jaccard J. *Interaction effects in logistic regression*. Thousand Oaks, CA: Sage University Paper; 2001.
237. Foster NE, Pincus T, Underwood MR, Vogel S, Breen A, Harding G. Understanding the process of care for musculoskeletal conditions - why a biomedical approach is inadequate. *Rheumatology*. 2003;42:401-403.
238. Ong BN, Richardson JC. The contribution of qualitative approaches to musculoskeletal research. *Rheumatology*. 2006;45:369-370.
239. Ustun TB, Chatterji S, Bickenbach J et al. The International Classification of Functioning, Disability and Health: a new tool for understanding disability and health. *Disability & Rehabilitation*. 2003;25(11-12):565-571.
240. Roche M. *Phenomenology, Language and the Social Sciences*. Boston: Routledge & Keegan Paul; 1973.
241. Ricoeur P. *Interpretation Theory: Discourse and Surplus of Meaning*. Fort Worth, Texas: Christian University Press; 1976.
242. Smith JA. *Qualitative Psychology. A Practical Guide to Research Methods*. London: Sage Publications; 2003.
243. Miles MB, Huberman AM. *Qualitative data analysis: an expanded source book*. Thousand Oaks, CA.: Sage Publications; 1994.
244. Aronsen J. A pragmatic view of thematic analysis. *The Qualitative Report*. 1994;2(1).
245. Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative Research in Psychology*. 2006;3:77-101.
246. Bennell KL, Hinman RS, Metcalf BR, et al. Relationship of knee joint proprioception to pain and disability in individuals with knee osteoarthritis. *Journal of Orthopaedic Research*. 2003;21(5):792-797.
247. Sarbin T. *Narrative Psychology: the Storied Nature of Human Conduct*. New York: Praeger; 1986.
248. Kvale S. *Interviews: an introduction to qualitative research interviewing*. California: SAGE Publications; 1996.
249. McKenna SP, Doward LC, Niero M, Erdman R. Development of needs-based quality of life instruments. *Value in Health*. 2004;7(1):Sep-Oct.
250. Swaine-Verdier A, Doward LC, Hagell P, Thornsens H, McKenna SP. Adapting quality of life instruments. *Value in Health*. 2004;7(1):S27-S30.
251. Groessl EJ, Kaplan RM, Cronan TA. Quality of well-being in older people with osteoarthritis. *Arthritis & Rheumatism*. Feb 15 2003;49(1):23-28.
252. Rasch G. *Probabilistic models for some intelligence and attainment tests*. Chicago: University of Chicago Press; 1960.
253. Andrich D, Lyne A, Sheridon B. *RUMM 2020*. Perth: RUMM Laboratory; 2003.
254. Tennant A, McKenna SP, Hagell P. Applications of Rasch analysis in the development and application of quality of life instruments. *Value in Health*. 2004;7(s1):s22-s66.
255. Duncan PW, Bode RK, Min Lai S, Perera S. Rasch analysis of a new stroke-specific outcome scale: the Stroke Impact Scale. *Archives of Physical Medicine & Rehabilitation*. 2003;84(7):950-963.
256. Gerber BS, Pagcatipunan M, Smith EV, Jr., et al. The assessment of diabetes knowledge and self-efficacy in a diverse population using Rasch measurement. *Journal of Applied Measurement*. 2006;7(1):55-73.
257. Guttman LA. The basis for Scalogram analysis. In: Stouffer SA, Guttman LA, Suchman FA, Lazarsfeld PF, Star SA, Clausen JA, eds. *Studies in social*

- psychology in World War II: Volume 4. Measurement and prediction.* Princeton: Princeton University Press; 1950:60-90.
258. Hunt AE, Fahey AJ, Smith RM. Static measures of calcaneal deviation and arch angle as predictors of rearfoot motion during walking. *Australian Journal of Physiotherapy.* 2000;46(1):9-16.
 259. Pallant JF, Tennant A. An introduction to the Rasch measurement model: an example using the Hospital Anxiety and Depression Scale (HADS). *British Journal of Clinical Psychology.* 2006;in press.
 260. Smith Jr EV. Metric development and score reporting in Rasch measurement. *Journal of Applied Measurement.* 2000;1(3):303-326.
 261. Hagquist C, Andrich D. Is the sense of coherence-instrument applicable on adolescents? A latent trait analysis using Rasch-modelling. *Personality and Individual Differences.* 2004 36:955-958.
 262. Fisher Jr WP. Physical disability construct convergence across instruments: towards a universal metric. *Journal of Outcome Measurement.* 1997;1(2):87-113.
 263. Streiner DL, Norman GR. *Health measurement scales.* Second ed. Oxford: Oxford University Press; 1995.
 264. Gaston JE, Vogl L. Psychometric properties of the general well-being index. *Quality of Life Research.* 2005;14(1):71-75.
 265. Revicki DA, Leidy NK, Howland L. Evaluating the psychometric characteristics of the Psychological General Well-Being Index with a new response scale. *Quality of Life Research.* 1996;5(4):419-425.
 266. Hunt S, McKenna S. A British adaptation of well-being, the General Well-Being Index: a new tool for clinical research. *British Journal of Medical Economics.* 1992;2:49-60.
 267. Valtysdottir ST, Gudbjornsson B, Hallgren R, Hetta J. Psychological well-being in patients with primary Sjogren's syndrome. *Clinical & Experimental Rheumatology.* 2000;18(5):597-600.
 268. Persson E, Rivano-Fischer M, Eklund M. Evaluation of changes in occupational performance among patients in a pain management program. *Journal of Rehabilitation Medicine.* 2004;36(2):85-91.
 269. Jones MP, Maganti K. Symptoms, gastric function, and psychosocial factors in functional dyspepsia. *Journal of Clinical Gastroenterology.* 2004;38(10):866-872.
 270. Farkkila M, Sarna S, Valtonen V, Sipponen P. Does the 'test-and-treat' strategy work in primary health care for management of uninvestigated dyspepsia? A prospective two-year follow-up study of 1552 patients. *Scandinavian Journal of Gastroenterology.* 2004;39(4):327-335.
 271. Lachance L, Sowers M, Jamada D et al. The experience of pain and emergent osteoarthritis of the knee. *Osteoarthritis and Cartilage.* 2001;9:527-532.
 272. Creamer P, Lethbridge-Cejku M, Hochberg MC et al. Determinants of pain severity in knee osteoarthritis: effect of demographic and psychosocial variables using 3 pain measures. *Journal of Rheumatology.* Aug 1999;26(8):1785-1792.
 273. Maly MR, Costigan PA, Olney SJ, Maly MR, Costigan PA, Olney SJ. Contribution of psychosocial and mechanical variables to physical performance measures in knee osteoarthritis. *Physical Therapy.* Dec 2005;85(12):1318-1328.
 274. Botha-Scheepers S, Riyazi N, Kroon HM, et al. Activity limitations in the lower extremities in patients with osteoarthritis: the modifying effects of illness perceptions and mental health. *Osteoarthritis & Cartilage.* Nov 2006;14(11):1104-1110.
 275. Rosemann T, Laux G, Kuehle T, Rosemann T, Laux G, Kuehle T. Osteoarthritis and functional disability: results of a cross sectional study

- among primary care patients in Germany. *BMC Musculoskeletal Disorders*. 2007;8:79.
276. Schumacker RE, Lomax RG. *A beginners guide to structural Equation Modeling*. Second ed. New Jersey: Lawrence Erlbaum Associates; 2004.
277. Wolfe F, Hawley DJ, Wolfe F, Hawley DJ. Evidence of disordered symptom appraisal in fibromyalgia: increased rates of reported comorbidity and comorbidity severity. *Clinical & Experimental Rheumatology*. May-Jun 1999;17(3):297-303.
278. Harter M, Reuter K, Gross-Hardt K, Bengel K. Screening for anxiety, depressive and somatoform disorders in rehabilitation - validity of HADS and GHQ-12 in patients with musculoskeletal disease. *Disability and Rehabilitation*. 2001;23(16):737-744.
279. Johnston M, Bollard B, Hennessey P. Construct validation of the hospital anxiety and depression scale with clinical populations. *Journal of Psychosomatic Research*. 2000;48:579-584.
280. Bjelland I, Dahl AA, Haug TT, Neckelmann D. The validity of the Hospital and Depression Scale: An updated literature review. *Journal of Psychosomatic Research*. 2002;52:69-77.
281. Pallant JE, Bailey CM. Assessment of the structure of the Hospital Anxiety and Depression Scale in musculoskeletal patients. *Health and Quality of Life Outcomes*. 2005;3(82).
282. Wilkie R, Peat G, Thomas E, Croft PR. Measuring the consequences of osteoarthritis and joint pain in population-based studies: can existing health measurement instruments capture levels of participation? *Arthritis Rheum* 2004;51:755-762.
283. Pallant J, Misajon R, Bennett E, Manderson L. Measuring the impact and distress of health problems from the individual's perspective: development of the Perceived Impact of Problem Profile (PIPP). *Health and Quality of Life Outcomes*. 2006;4(1):36.
284. Linacre JM. Visual Analog Scales. *Rasch Measurement Transactions*. 1998;12(2):639.
285. Keenan AM, Tennant A, Fear J, Emery P, Conaghan PG. Multiple Joint problems in the population: prevalence and impact on function. *Arthritis & Rheumatism*. 2006;55(5):757-764.
286. Dawson J, Linsell L, Zondervan K, et al. Epidemiology of hip and knee pain and its impact on overall health status in older adults. *Rheumatology*. 2004;43:497-504.
287. Garrow AP, Silman AJ, Macfarlane GJ. The Cheshire Foot Pain and Disability Survey: a population survey assessing prevalence and associations. *Pain*. 2004;110:378 - 384.
288. Urwin M, Symmons D, Allison T, et al. Estimating the burden of musculoskeletal disorders in the community: the comparative prevalence of symptoms at different anatomical sites, and the relation to social deprivation. *Annals of the Rheumatic Diseases*. 1998;57(11):649-655.
289. Walker-Bone K, Palmer KT, Reading I, Coggon D, Cooper C. Prevalence and impact of musculoskeletal disorders of the upper limb in a general population. *Arthritis and Rheumatism*. 2004;51(4):642-651.
290. Benvenuti F, Ferrucci L, Guralnik JM, Gangemi S, Baroni A. Foot pain and disability in older persons: an epidemiologic survey. *Journal of the American Geriatrics Society*. 1995;43(5):479-484.
291. Blyth FM, March LM, Brnabic AJ, Cousins MJ. Chronic pain and frequent use of health care. *Pain*. 2004;111:51-58.
292. Gabriel SE, Crowson CS, O'Fallon WM. Comorbidity in arthritis. *Journal of Rheumatology*. 1999;26(11):2475-2479.

293. March LM, Schwarz JM, Carfrae BH, Bagge E. Clinical validation of self-reported osteoarthritis. *Osteoarthritis & Cartilage*. 1998;6(2):87-93.
294. Frankel S, Eachus J, Pearson N, et al. Population requirement for primary hip-replacement surgery: a cross-sectional study. *Lancet*. 1999;353(9161):1304-1309.
295. Ohman M, Soderberg S, Lundman B. Hovering between suffering and enduring: the meaning of living with serious chronic illness. *Qualitative Health Research*. Apr 2003;13(4):528-542.
296. Bury M, Bury M. Chronic illness as biographical disruption. *Sociology of Health & Illness*. Jul 1982;4(2):167-182.
297. Swift TL, Ashcroft RE, Tadd W, et al. Living well through chronic illness: the relevance of virtue theory to patients with chronic osteoarthritis. *Arthritis & Rheumatism*. Oct 15 2002;47(5):474-478.
298. Asbring P, Narvanen AL, Asbring P, Narvanen A-L. Patient power and control: a study of women with uncertain illness trajectories. *Qualitative Health Research*. Feb 2004;14(2):226-240.
299. Ironside PM, Scheckel M, Wessels C, et al. Experiencing chronic illness: cocreating new understandings. *Qualitative Health Research*. Feb 2003;13(2):171-183.
300. Greenberg I, Perna F, Kaplan M, Sullivan MA. Behavioral and psychological factors in the assessment and treatment of obesity surgery patients. *Obesity Research*. 2005;13(2):244-249.
301. Bagge E, Traub M, Crotty M, et al. Are rheumatoid arthritis patients more willing to accept non-steroidal anti-inflammatory drug treatment risks than osteoarthritis patients? *British Journal of Rheumatology*. Apr 1997;36(4):470-472.
302. Fransen M, Nairn L, Winstanley J, et al. Physical activity for osteoarthritis management: a randomized controlled clinical trial evaluating hydrotherapy or Tai Chi classes. *Arthritis & Rheumatism*. Apr 15 2007;57(3):407-414.
303. Bennell KL, Hinman RS, Metcalf BR, et al. Efficacy of physiotherapy management of knee joint osteoarthritis: a randomised, double blind, placebo controlled trial. *Annals of the Rheumatic Diseases*. Jun 2005;64(6):906-912.
304. Tallon D, Chard J, Dieppe P, Tallon D, Chard J, Dieppe P. Exploring the priorities of patients with osteoarthritis of the knee. *Arthritis Care & Research*. Oct 2000;13(5):312-319.
305. Crabtree BF, Miller WL. *Doing Qualitative Research*. (Second) ed. Thousand Oaks: Sage Publications Inc; 1999.
306. Penzin NK, Lincoln YS. Entering the field of qualitative research. In: Penzin NK, Lincoln YS, eds. *The landscape of qualitative research: theories and issues*.: Sage Thompson Oaks; 1998.
307. Keenan AM, McKenna SP, Doward LC, Conaghan PG, Emery P, Tennant A. OAQoL: the development and validation of a needs-based quality of life instrument for osteoarthritis. *Arthritis & Rheumatism*. 2008; 59(6): 841-848.
308. Doward LC, Whalley D, Dewar AL, et al. The development of the SLE-QoL: a quality of life instrument specific to Systemic Lupus Erythematosus. *Quality of Life Research*. 1999;8:609.
309. Doward LC, Spoorenberg A, Cook SA, et al. Development of the ASQoL: a quality of life instrument specific to ankylosing spondylitis. *Annals of the Rheumatic Diseases*. 2003;62(1):20-26.
310. Pallant JF, Misajon RA, Bennett E, Manderson L. Measuring the impact and distress of health problems from the individual's perspective: development of the Perceived Impact of Problem Profile (PIPP). *Health and Quality of Life Outcomes*. 2006;4(36).

311. Dickens CM, McGowan L, Percival C, et al. Contribution of depression and anxiety to impaired health-related quality of life following first myocardial infarction. *British Journal of Psychiatry*. Oct 2006;189:367-372.
312. Katon W, Lin EH, Kroenke K, Katon W, Lin EHB, Kroenke K. The association of depression and anxiety with medical symptom burden in patients with chronic medical illness. *General Hospital Psychiatry*. Mar-Apr 2007;29(2):147-155.
313. Rodgers J, Martin CR, Morse RC, et al. An investigation into the psychometric properties of the Hospital Anxiety and Depression Scale in patients with breast cancer. *Health & Quality of Life Outcomes*. 2005;3:41.
314. Martin CR, Thompson DR. Utility of the Hospital Anxiety and Depression Scale in patients with end-stage renal disease on continuous ambulatory peritoneal dialysis. *Psychology, Health and Medicine*. 1999;4(4):369-376.
315. Barth J, Martin CR, Barth J, Martin CR. Factor structure of the Hospital Anxiety and Depression Scale (HADS) in German coronary heart disease patients. *Health & Quality of Life Outcomes*. 2005;3:15.
316. Bedford A, de Pauw K, Grant E. The structure of the Hospital Anxiety and Depression Scale (HAD): an appraisal with normal, psychiatric and medical patient subjects. *Personality and Individual Differences*. 1997;23(3):473-478.
317. Crawford JR, Henry JD, Crombie C, Taylor EP. Brief Report. Normative data for the HADS from a large non-clinical sample. *British Journal of Clinical Psychology*. 2001;40:429-434.
318. Adamson J, Hunt K, Ebrahim S. Association between measures of morbidity and locomotor disability: diagnosis alone is not enough. *Social Science & Medicine*. 2003;57(8):1355-1360.
319. Verbrugge LM, Lepkowski JM, Imanaka Y, Verbrugge LM, Lepkowski JM, Imanaka Y. Comorbidity and its impact on disability. *Milbank Quarterly*. 1989;67(3-4):450-484.
320. Rupp I, Boshuizen HC, Jacobi CE, et al. Comorbidity in patients with rheumatoid arthritis: effect on health-related quality of life. *Journal of Rheumatology*. Jan 2004;31(1):58-65.
321. Xuan J, Kirchdoerfer LJ, Boyer JG, et al. Effects of comorbidity on health-related quality-of-life scores: an analysis of clinical trial data. *Clinical Therapeutics*. Feb 1999;21(2):383-403.
322. Kempen GI, Ormel J, Brilman EI, et al. Adaptive responses among Dutch elderly: the impact of eight chronic medical conditions on health-related quality of life. *American Journal of Public Health*. Jan 1997;87(1):38-44.
323. Kempen GI, Jelicic M, Ormel J, Kempen GI, Jelicic M, Ormel J. Personality, chronic medical morbidity, and health-related quality of life among older persons. *Health Psychology*. Nov 1997;16(6):539-546.
324. Alonso J, Ferrer M, Gandek B, et al. Health-related quality of life associated with chronic conditions in eight countries: results from the International Quality of Life Assessment (IQOLA) Project. *Quality of Life Research*. Mar 2004;13(2):283-298.
325. Callahan CM, Drake BG, Heck DA, et al. Patient outcomes following unicompartmental or bicompartamental knee arthroplasty. A meta-analysis. *Journal of Arthroplasty*. Apr 1995;10(2):141-150.
326. Hurley MV, Walsh NE, Mitchell HL, et al. Economic evaluation of a rehabilitation program integrating exercise, self management and active coping strategies for chronic knee pain. *Arthritis & Rheumatism*. 2007;57(7):1220-1229.
327. Savelkoul M, de Witte L, Post M, Savelkoul M, de Witte L, Post M. Stimulating active coping in patients with rheumatic diseases: a systematic review of controlled group intervention studies. *Patient Education & Counseling*. Jun 2003;50(2):133-143.

328. Tallon D, Chard J, Dieppe P, Tallon D, Chard J, Dieppe P. Relation between agendas of the research community and the research consumer. *Lancet*. Jun 10 2000;355(9220):2037-2040.
329. Devins GM, Edworthy SM, Guthrie NG, et al. Illness intrusiveness in rheumatoid arthritis: differential impact on depressive symptoms over the adult lifespan. *Journal of Rheumatology*. May 1992;19(5):709-715.
330. Abraido-Lanza AF, Revenson TA, Abraido-Lanza AF, Revenson TA. Illness intrusion and psychological adjustment to rheumatic diseases: a social identity framework. *Arthritis & Rheumatism*. Apr 15 2006;55(2):224-232.
331. Hewlett S, Carr M, Ryan S, et al. Outcomes generated by patients with rheumatoid arthritis: how important are they? *Musculoskeletal Care*. 2005;3:131-142.
332. Friedland J, Renwick R, McColl M, Friedland J, Renwick R, McColl M. Coping and social support as determinants of quality of life in HIV/AIDS. *AIDS Care*. Feb 1996;8(1):15-31.
333. de Beurs E, Beekman AT, van Balkom AJ, et al. Consequences of anxiety in older persons: its effect on disability, well-being and use of health services. *Psychological Medicine*. May 1999;29(3):583-593.
334. Herrmann C. International experiences with the Hospital Anxiety and Depression Scale (HADS). *Journal of Psychosomatic Research*. 1997;42(1):17-41.
335. Bond J, Gregson B, Smith M, et al. Outcomes following acute hospital care for stroke or hip fracture: how useful is an assessment of anxiety or depression for older people? *International Journal of Geriatric Psychiatry*. Sep 1998;13(9):601-610.
336. Mitchell AJ, Benito-Leon J, Gonzalez JM, et al. Quality of life and its assessment in multiple sclerosis: integrating physical and psychological components of wellbeing. *Lancet Neurology*. Sep 2005;4(9):556-566.
337. Ben-Shlomo Y, Camfield L, Warner T, et al. What are the determinants of quality of life in people with cervical dystonia? *Journal of Neurology, Neurosurgery & Psychiatry*. May 2002;72(5):608-614.
338. Herschbach P, Keller M, Knight L, et al. Psychological problems of cancer patients: a cancer distress screening with a cancer-specific questionnaire. *British Journal of Cancer*. Aug 2 2004;91(3):504-511.
339. Memel DS, Kirwan JR, Sharp DJ, et al. General practitioners miss disability and anxiety as well as depression in their patients with osteoarthritis. *British Journal of General Practice*. Aug 2000;50(457):645-648.
340. Pradhan EK, Baumgarten M, Langenberg P, et al. Effect of mindfulness-based stress reduction in rheumatoid arthritis patients. *Arthritis & Rheumatism*. 2007;57(7):1134-1142.
341. Bolton MB, Tilley BC, Kuder J, et al. The cost and effectiveness of an education program for adults who have asthma. *Journal of General Internal Medicine*. Sep-Oct 1991;6(5):401-407.
342. Specia M, Carlson LE, Goodey E, et al. A randomized, wait-list controlled clinical trial: the effect of a mindfulness meditation-based stress reduction program on mood and symptoms of stress in cancer outpatients. *Psychosomatic Medicine*. Sep-Oct 2000;62(5):613-622.
343. Jonler M, Moon T, Brannan W, et al. The effect of age, ethnicity and geographical location on impotence and quality of life. *British Journal of Urology*. May 1995;75(5):651-655.
344. Nilsson M, Ekman S-L, Sarvimaki A. Ageing with joy or resigning to old age: older people's experiences of quality of life in old age. *Health Care in Later Life*. 1998;3(2):94-110.

345. Gooberman-Hill R, Ayis S, Ebrahim S, Gooberman-Hill R, Ayis S, Ebrahim S. Understanding long-standing illness among older people. *Social Science & Medicine*. Jun 2003;56(12):2555-2564.
346. Farquhar M, Farquhar M. Elderly people's definitions of quality of life. *Social Science & Medicine*. Nov 1995;41(10):1439-1446.
347. Rabenda V, Burlet N, Ethgen O, Raeman F, Belaiche J, Reginster JY. A naturalistic study of the determinants of health related quality of life improvement in osteoarthritic patients treated with non-specific non-steroidal anti-inflammatory drugs. *Annals of the Rheumatic Diseases*. May 2005;64(5):688-693.
348. Mapel DW, Shainline M, Paez K, Gunter M. Hospital, pharmacy, and outpatient costs for osteoarthritis and chronic back pain. *Journal of Rheumatology*. 2004;31(3):573-583.
349. Mantyselka PT, Kumpusalo EA, Ahonen RS, Takala JK. Direct and indirect costs of managing patients with musculoskeletal pain-challenge for health care. *European Journal of Pain: Ejp*. 2002;6(2):141-148.
350. Reginster JY, Khaltsev NG. Introduction and WHO perspective on the global burden of musculoskeletal conditions. *Rheumatology*. 2002;1:1-2.
351. Jordan KM, Arden NK, Doherty M, et al. EULAR Recommendations 2003: an evidence based approach to the management of knee osteoarthritis: Report of a Task Force of the Standing Committee for International Clinical Studies Including Therapeutic Trials (ESCISIT). *Annals of the Rheumatic Diseases*. 2003;62(12):1145-1155.
352. Altman R, Brandt K, Hochberg M, Moskowitz R. Design and conduct of clinical trials in patients with osteoarthritis. *Osteoarthritis and Cartilage*. 1996;4:217-243.
353. Hawker GA, Gignac MA. How meaningful is our evaluation of meaningful change in osteoarthritis? *Journal of Rheumatology*. 2006;33(4):639-641.
354. Marra CA, Woolcott JC, Kopec JA, et al. A comparison of generic, indirect utility measures (the HUI2, HUI3, SF-6D, and the EQ-5D) and disease-specific instruments (the RAQoL and the HAQ) in rheumatoid arthritis. *Social Science & Medicine*. Apr 2005;60(7):1571-1582.

Appendix 1 Guidance Notes for OAQoL Interviews

Pre-interview Introduction

- ☑ Explain the purpose of the interview and confidentiality
- ☑ Confirm that they have read the participant information sheet and informed consent.
- ☑ Ask if they have any questions regarding the information sheet and informed consent.
- ☑ Confirm that they give permission for tape record the interview. Explain that the transcripts will be produced from the recording and that all references or names that might identify the interviewee will be removed.
- ☑ Collect the informed consent sheet.

1. Personal Illness History

1.1. *Could you tell me about when you first developed osteoarthritis (OA)?*

- ⇒ At what age did you start noticing problems? What made you realize that you had a problem (symptoms)
- ⇒ What were the main types of symptoms that you were experiencing? (Including frequency, duration etc)

1.2. *Can you tell me about your arthritis at the moment?*

- ⇒ Can you describe your symptoms? What happens when you have a flare-up (ie increased symptoms)? When was the last time that you had a flare?
- ⇒ What about between flares-ups? Do you have any ongoing symptoms?
- ⇒ Are you currently on any treatment (explore positive and negative, adverse events, compliance issues).

2. Impact of OA on daily life

2.1. *We've talked about the symptoms that you've experienced. I'd like you to think about how these effect your daily life.*

Note: We are interested in exploring the impact of the patient's condition in relation to the following areas. Please pay attention to the impact of pain, fatigue, cognitive dysfunction.

- ⇒ In the home – **performing necessary tasks, shopping, cooking, cleaning, other household chores. Doing jobs around the house (for example painting, mending, do-it-yourself etc).**
- ⇒ Occupation – **ability to perform necessary tasks at work (or at school); to concentrate, think, remember details, use equipment/machinery, drive/travel to work. Relationships and attitudes of people at work.**
- ⇒ Personal relationships - **marital life, interactions with partners, family, friends etc, interest in other people. Reactions of other people, attitudes and behaviour. Looking after children/grandchildren, dependents, caring for them. Sexual activity, interest in love and sex.**
- ⇒ Social Life – **Seeing people, going out: for example to the pub, theatre, cinema, bingo, visiting friends/relatives, having people to visit at home, staying away from home.**
- ⇒ Cognition – **ability to concentrate, think clearly, perform routine intellectual tasks including, for example, keeping finances in order**
- ⇒ Personal Hygiene – **keeping clean, having clean clothes, washing, ironing, caring for self, getting hair cut. Appetite, eating, giving oneself treats.**

- ⇒ Leisure Pursuits – **ability to follow usual interests, hobbies, sports etc. Watching TV, listening to radio and music, reading, knitting, sewing, crosswords, playing a musical instrument etc.**
- ⇒ Sleep and Rest – **ability to relax, ability to sleep, disturbing others by not sleeping, disruption to normal pattern of rest and activity, energy level.**

Sample questions

Does your OA/specific symptoms make it difficult for you to do anything/stop you doing anything?

How do you feel that you family react to your OA?

What kind of things do you do for fun or relaxation?

How does that make you feel?

Tell me more about that?

Can you explain that a bit more so I'm sure I understand?

3. Key areas of impact

3.1. We've talked about the different ways your mood changes affect you and your day to day life. I'd now like you to think about what are the best and worse things about having OA. Are there any particularly positive or good things about it?

3.2 What would you say are the worst things about having OA?

4. Views on quality of life

4.1 What does the term "quality of life" mean to you?

⇒ How would you define it?

⇒ What kind of things gives your life its "quality"?

4.2 How would you describe your quality of life at the moment? How would you rate the quality of life when your arthritis is bad? How would you rate the quality of life when your arthritis is good?

⇒ Good, bad, etc

⇒ Why do you rate it that way?

5. Any other areas

5.1 We've just talked about how you feel about your OA and about how this affects your day to day life. Is there anything else that you would like to mention?

⇒ In relation to the impact of OA on your life?

⇒ The impact of OA on your quality of life?

⇒ Any other areas that you think we've missed?

Interview closure

I would like to thank you for taking the time to talk with me. This has been a really useful and interesting interview. I would just like to re-assure you again that all of this information that you have given me will remain confidential.

OAQoL

Quality of Life in People with
Osteoarthritis

Please read this carefully

On the following pages you will find some statements which have been made by people who have Osteoarthritis.

Please read each statement carefully. We would like you to tick **'True'** if you feel the statement applies to you
And tick **'Not true'** if it does not

Please choose the response that applies best to you
at the moment

Please read this carefully

On the following pages you will find some statements which have been made by people who have Osteoarthritis. Please read each statement carefully. We would like you to tick '**True**' if you feel the statement applies to you And tick '**Not true**' if it does not.

Please choose the response that applies best to you **at the moment**

- | | |
|---|--|
| 1. I'm unable to join in activities with my friends or family | True <input type="checkbox"/>
Not true <input type="checkbox"/> |
| 2. I get embarrassed using stairs in public | True <input type="checkbox"/>
Not true <input type="checkbox"/> |
| 3. It is always on my mind | True <input type="checkbox"/>
Not true <input type="checkbox"/> |
| 4. I feel like I am missing out on life | True <input type="checkbox"/>
Not true <input type="checkbox"/> |
| 5. Travelling distances is a problem | True <input type="checkbox"/>
Not true <input type="checkbox"/> |
| 6. I can't plan things too far in advance | True <input type="checkbox"/>
Not true <input type="checkbox"/> |
| 7. I worry that I let people down | True <input type="checkbox"/>
Not true <input type="checkbox"/> |

Please read each item carefully and tick the **one** response that applies best to you **at the moment**

8. I feel as though I'm trapped in my house True

Not true

9. It takes me a long time to complete household tasks True

Not true

10. My arthritis limits the places I can go True

Not true

11. I worry that I hold others back True

Not true

12. I can't do things on the spur of the moment True

Not true

13. It interferes with everything that I do True

Not true

14. Walking for pleasure is out of the question True

Not true

15. I can't enjoy myself when I go out True

Not true

Please read each item carefully and tick the ***one*** response that applies best to you ***at the moment***

16. I dread the future True
Not true
17. I take it out on people close to me True
Not true
18. I feel useless True
Not true
19. I feel I can't join in with social activities True
Not true
20. My arthritis controls my life True
Not true
21. I feel dependant on others True
Not true
22. I worry about being a nuisance to other people True
Not true
23. I am embarrassed about the way I walk True
Not true

Please read each item carefully and tick the ***one*** response that applies best to you ***at the moment***

24. My life revolves around my arthritis True
Not true
25. I feel older than my years True
Not true
26. It puts a strain on my personal relationships True
Not true
27. I can't be as independent as I want True
Not true
28. I find it difficult to sit through a film or TV programme True
Not true
29. I feel very isolated True
Not true
30. I can't live life to the full True
Not true

Please read each item carefully and tick the **one** response that applies best to you **at the moment**

31. I feel the arthritis is affecting my appearance True
Not true

32. I never get a good night's sleep True
Not true

33. I have to limit what I do each day True
Not true

34. I feel like a burden to other people True
Not true

35. I feel slowed down True
Not true

36. Pain controls my life True
Not true

37. I can't go to the places I want to go True
Not true

38. I feel lonely True

Appendix 3 OAQoL Final Draft



OAQoL

Please read this carefully

On the following pages you will find some statements which have been made by people who have Osteoarthritis.

Please read each statement carefully. We would like you to tick **'True'** if you feel the statement applies to you
And tick **'Not true'** if it does not

Please choose the response that applies best to you
at the moment

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Please read this carefully

On the following pages you will find some statements which have been made by people who have Osteoarthritis. Please read each statement carefully. We would like you to tick '**True**' if you feel the statement applies to you and tick '**Not true**' if it does not.

Please choose the response that applies best to you **at the moment**.

1. I'm unable to join in activities with my friends or family True
Not true

2. I get embarrassed using stairs in public True
Not true

3. I feel like I am missing out on life True
Not true

4. I can't plan things too far in advance True
Not true

5. I feel as though I'm trapped in my house True
Not true

6. My arthritis limits the places I can go True
Not true

7. I can't do things on the spur of the moment True
Not true

Please read each item carefully and tick the **one** response that applies best to you **at the moment**

- | | | |
|--|-------------------------------|-----------------------------------|
| 8. It interferes with everything that I do | True <input type="checkbox"/> | Not true <input type="checkbox"/> |
| 9. Walking for pleasure is out of the question | True <input type="checkbox"/> | Not true <input type="checkbox"/> |
| 10. I can't enjoy myself when I go out | True <input type="checkbox"/> | Not true <input type="checkbox"/> |
| 11. I feel useless | True <input type="checkbox"/> | Not true <input type="checkbox"/> |
| 12. I feel I can't join in with social activities | True <input type="checkbox"/> | Not true <input type="checkbox"/> |
| 13. My arthritis controls my life | True <input type="checkbox"/> | Not true <input type="checkbox"/> |
| 14. I feel dependant on others | True <input type="checkbox"/> | Not true <input type="checkbox"/> |
| 15. I worry about being a nuisance to other people | True <input type="checkbox"/> | Not true <input type="checkbox"/> |

Please read each item carefully and tick the **one** response that applies best to you **at the moment**

16. My life revolves around my arthritis True
Not true

17. I can't be as independent as I want True
Not true

18. I feel very isolated True
Not true

19. I can't live life to the full True
Not true

20. I have to limit what I do each day True
Not true

21. I feel slowed down True
Not true

22. I can't go to the places I want to go True
Not true