JOINT EFFECTS:

WATER EXERCISE AND MANUAL THERAPIES FOR ARTHRITIS

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ABSTRACT

This thesis was an investigation of the relative effects of manual therapies and warm-water exercise on the health-related quality of life (HRQOL) of people with common arthritides (rheumatoid arthritis [RA] or osteoarthritis [OA]). The thesis comprised a pilot study and three linked clinical studies.

The three clinical studies were randomised, unblinded, controlled, clinical trials of three or four groups with repeated measures. The mixed design allowed comparison between and within groups. The intervention component of each clinical study lasted for 10 weeks (concurrent with one Victorian school term). Each clinical study included adjunctive therapy and control (usual care) groups, to which participants were randomly allocated. Participation in each of the studies was voluntary. Participants were free to withdraw from any study at any time. Participants who were unable or unwilling to participate in the intervention groups were re-allocated to the control group or withdrew from the studies.

The Pilot Study (see Chapter 3) concerned validation of the data collection tools prior to use in the clinical studies. A battery of standardised, validated questionnaires was used for data collection in each of the clinical studies. Measures of generic quality of life (SF-36; Ware & Sherbourne, 1992), pain (Short Form McGill Pain Questionnaire, SF-MPQ; Melzack, 1987), arthritis-specific health status (AIMS2; Meenan, Mason, Anderson, Guccione, & Kazis, 1992) and social support (Medical Outcomes Study Social Support Survey, MOS-SS; Sherbourne & Stewart, 1991) were collected at baseline, week 5 and week 9 of each of the10-week trials, and at 2 weeks and 14 weeks after completion of the interventions in Study 3 (i.e., weeks 12 and 24).

Analyses of covariance (ANCOVA) were used to assess group differences for the SF-36, AIMS2, SF-MPQ, and MOS-SS measures. Pre-intervention (i.e., week 1, baseline) scores for each HRQOL subscale and total social support at week 9, were used as

covariates to control for initial differences between groups and any social support afforded by the interventions.

In Study 1 (people with OA) improvements in HRQOL were consistently observed in the joint mobilisation group, and on many HRQOL domains, these improvements were associated with large to very large effect sizes. Participants in the massage group improved only moderately compared with the control group across the same measures.

Results differed according to disease profiles. Several participants with RA assigned to manual therapy groups reported worsening pain and withdrew from Study 2. Results from Study 2 were inconclusive, and hampered by small sample sizes. Reasons for, and lessons arising from, the failure of Study 2 are discussed in detail (see Chapter 5). Results from Studies 1 and 2 informed the design of Study 3, which did not include a massage group or any people with RA.

In Study 3, 22 adults with an average of 15 years of osteoarthritis were randomly assigned to usual care (control; $n = 4$), joint mobilization ($n = 4$), warm-water exercise ($n = 8$), or combined joint mobilization and warm-water exercise ($n = 6$) groups. At week 9 participants in the intervention groups reported better HRQOL across most subscales than participants in the control (usual care) group. The combined therapies group outperformed the control and single therapy groups on the mobility, household tasks, arthritis pain, mood, and satisfaction subscales of the AIMS2, as well as the sensory pain, total pain, and present pain index components of the SF-MPQ, and the physical role limitations, bodily pain, general health, social function, and health transition subscales of the SF-36. Many of the improvements in HRQOL reported at week 9 were maintained at week 12 and week 24 (2 and 14 weeks post intervention).

Repeated measures analyses of covariance (ANCOVA), using baseline measures and week 9 social support scores as covariates, revealed that large to very large effects (improvements) on the arthritis pain ($\eta^2 = .25$), mood ($\eta^2 = .35$), and satisfaction ($\eta^2 = .21$)

subscales of the AIMS2 could be attributed to participation in the combined therapies. The same pattern was evident for the sensory pain ($\eta^2 = .29$), total pain ($\eta^2 = .23$), and present pain index ($\eta^2 = .37$) components of the SF-MPQ, and the physical role limitations ($\eta^2 = .26$), bodily pain ($\eta^2 = .18$), social function ($\eta^2 = .33$), and health transition ($\eta^2 = .28$) subscales of the SF-36.

Differences in social support, and medication use, across time and between groups were negligible, and do not account for the reported improvements. The results are interpreted, as recommended by Kazis, Anderson, and Meenan (1989), in terms of clinically meaningful effect sizes, rather than statistical significance, due to the small sample size and the increased probability of Type II errors. Omnibus effect sizes are reported as η^2. Eta squared (η^2) represents the amount of variance in a variable accounted for by group membership (Tabachnick & Fidell, 2001), and is therefore a relevant measure of effect size because it explains the strength of association between treatments and the variables measured. Univariate effect sizes (Cohen's *d*) are reported as estimates of the magnitude of change between and within groups for each intervention and each HRQOL domain.

Overall the results indicate that the combination of joint mobilisation and warm-water exercise appears to be more effective than either therapy in isolation for improving quality of life in people with OA. The usefulness of combined therapies needs to be balanced against the financial costs of the same. The persistence of HRQOL improvements at 2 weeks post therapy suggests that fortnightly therapy is worthy of investigation, an approach that would make combined therapies more affordable.

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DECLARATION OF AUTHORSHIP

I, Melainie Cameron, declare that the thesis entitled JOINT EFFECTS: WATER EXERCISE AND MANUAL THERAPIES FOR ARTHRITIS is my own work and has not been submitted previously, in whole or in part, in respect of any other academic award.

Signature: 

Date: 20/01/2005

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My family completed this work along side me. My husband, Blair Cameron, understood the value of this task, and buoyed me through it with kindness, patience, and love. Our children, Anja and Robin, have never known a time when I was not studying. I hope that I have modelled for them that learning is exciting and fun. My father Jim, and my sisters, Nina, Jane, and Faith, have graciously tolerated "Melainie the Nerd," and loved me all the same.

Through these studies, I investigated the quality of life of people with arthritis. Through her life, my mother, Carrolle, taught me a great deal about the effects of arthritic disease. With gratitude and love, I dedicate this thesis to her memory.

DISCLOSURE

I am a member of Arthritis Victoria. Arthritis Victoria provided in kind support for this study in terms of low cost advertising for participant recruitment. Jane Barnes (Hawke) of Arthritis Victoria enrolled research participants in water exercise classes on my behalf, and invoiced my research account for the cost of these classes.

LIST OF TABLES, FIGURES, AND GRAPHS

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PUBLICATIONS AND PRESENTATIONS ARISING FROM THESIS

Publications

Cameron, M. (2002) Is manual therapy a rational approach to improving health related quality of life in people with arthritis? *Australasian Chiropractic and Osteopathy, 10*, 9-15.

Cameron, M. (2004) Chapter 17: Arthritides. In Kolt, G. & Andersen, M. B. (Eds.). *Psychology in the physical and manual therapies* (pp. 269-291). Edinburgh: Elsevier Science.

Conference Presentations

Cameron, M., Andersen, M. B., & Speed, H. (2004) Pushing to get better: Joint mobilisation, massage, and quality of life in osteoarthritis [Abstract]. *Annals of the Rheumatic Diseases, 63*(Suppl. 1), 549.

Cameron, M., Andersen, M. B., & Speed, H. (2004) Is more better? Synergistic effects of manual therapy and warm water exercise in osteoarthritis [Abstract]. *Annals of the Rheumatic Diseases, 63*(Suppl. 1), 549.

CHAPTER 1

INTRODUCTION

Arthritides are diseases that cause the symptom picture known as *arthritis*. That picture may contain, but is not limited to, joint pain and swelling, reduced range of motion, and malaise. The arthritides are chronic illnesses that can have a significant impact on the quality of life of those with the disorder and the people around them. There are over 100 forms of arthritis, and the clinical presentations of arthritides vary substantially both between and within forms (Klippel, 2001). The pathogeneses of arthritic diseases are not well understood (Ferrari, Cash, & Maddison, 1996; Simon, 2000), and although there are disease modifying drug therapies that might slow, or substantially arrest, disease progression, no cures have been discovered or developed to date. Many people with arthritides experience their disorders as chronic, incurable, progressive illnesses, and attempt to adapt their lives and daily activities accordingly.

Osteoarthritis (OA) and rheumatoid arthritis (RA) are the two most common forms of arthritic disease. Sometimes OA may be considered part of the normal aging process that affects most humans if they live long enough, but some people develop OA in middle age or earlier, or experience considerable pain and disability with OA and seek the assistance of medical practitioners to manage their OA (Klippel, 2001). In these people, OA is considered a disease process.

RA is clearly identified as a disease process. The clinical presentation and symptom picture of this disease have been well documented (Ferrari et al., 1996), but its etiology is not clear. RA is a multisystem disease that may cause dysfunction, destruction, and eventual failure in organs far removed from the musculoskeletal system. People living with RA may experience loss of functional capacity and diminished quality of life, not only due to joint and bone damage, but also due to pathology of the heart, lungs, kidneys, or gastrointestinal system (Ferrari et al., 1996).

Joint damage, usually marked by pain and progressive decline in function, is the hallmark of most types of arthritis. Because the causes of arthritides are usually unknown, specific, targeted treatments are unavailable, and clients may try many therapies in attempts to reduce joint pain, improve function, and delay or prevent joint damage.

Treatments for Arthritis

Typically, outpatient (non-hospitalised) medical care for people with arthritides comprises an array of medications, usually provided under the care of a rheumatologist (Kavanaugh, 1999; Klippel, 2001; Simon, 2000). Medications for arthritis can be grouped into four classes, each with a different therapeutic purpose: (a) analgesics, to reduce or limit pain (Simon, 1999); (b) non-steroidal anti-inflammatory drugs (NSAIDs), to reduce inflammation in joints and surrounding tissues; (c) corticosteroids, to reduce severe inflammation (Simon, 1999); and (d) disease modifying anti-rheumatic drugs (DMARDs), to modify the course of the disease by preventing joint and tissue damage (Kavanaugh, 1999). Several varieties of each drug type are available, and advances in drug treatment are ongoing. Surgical procedures may be used to repair or replace damaged joints when joint deterioration has not be arrested by drug therapies.

Alternative and complementary therapies (e.g., dietary supplements, yoga, manual therapies, homoeopathy, acupuncture) are also used by people with arthritis (Rao et al., 1999; Rao, Kroenke, Mihaliak, Grambow, & Weinberger, 2003), and may sometimes be recommended by rheumatologists and other medical personnel (Klippel, 2001; Lam & Horstman, 2002). Alternative therapies may be divided into two types: active therapies, in which the client takes a driving role; and passive therapies, in which the therapy cannot proceed unless driven by a practitioner. The contribution required of the client differs according to the type of therapy, and optimal treatment may differ due to the client's psychological responses to the disease.

For the past two decades, exercise and other active (client-driven) forms of therapy have been used to improve the health-related quality of life (HRQOL) of people with arthritis (Fries, Lorig, & Holman, 2003). Lorig's work helped initiate the widespread acceptance of client-driven interventions, including exercise, as viable therapies for people with arthritis (Lorig & Fries, 2000). Lorig and colleagues particularly encouraged people with arthritis to learn about arthritis, engage in regular physical activity such as warm-water exercise, and enter into partnerships with health care providers in order to plan and manage their arthritis. Many arthritis foundations, including Arthritis Victoria, presently offer members exercise-based Arthritis Self-Management Programs (ASMP) that stem from Lorig's work.

Kerns and Rosenberg (2000) suggested that client-driven therapies may not engage some people, and are associated with high drop-out rates. Keefe et al. (2000) followed up this observation in a group of people with OA or RA, and found that 55% of participants identified themselves at a stage associated with failure to complete a course of therapy.

Many manual therapists consult with patients who have arthritic diseases, may receive referrals from rheumatologists, and consider the arthritic diseases to be within their fields of practice. In Australia, the Australian Osteopathic Association (AOA), Australian Physiotherapy Association (APA), and the Chiropractors Association of Australia (CAA), consider the treatment of people with arthritis within the remit of their members. The APA (n.d.) stated categorically that: "The treatment of arthritis and musculoskeletal conditions is a core function of physiotherapy practice." (p. 1).

Specific details of the treatments of arthritis, and claims of efficacy for these therapies, are included on association websites. The CAA (n.d.) made particular mention of manual therapy for pain control in arthritis: "a drug-free approach to ease osteoarthritis in particular, includes a combination of chiropractic techniques, nutritional products, and gentle exercise to keep joints moving and overcome painful swelling." (p. 1). The APA

(n.d.) emphasised the use of manual therapy to improve joint function and increase quality of life: "Patients with arthritis benefit from joint mobilisation, electrotherapy, hydrotherapy [warm-water exercise], muscle strengthening exercises.... Physiotherapy reduces arthritic pain and reliance on drug therapy. Unlike pharmaceuticals physiotherapy has no side effects and no contraindications....Quality of life is improved by therapy" (p. 1). Similarly, the AOA (n.d.) claimed that: "Osteopathy can also play a significant role in pain management in arthritic conditions." (p. 1).

Despite these claims, the efficacy and effectiveness of manual therapies for specific arthritic complaints is under-researched. Manual therapists working with people with arthritis, and their respective professional associations, make claims of efficacy based upon (non-experimental) empirical evidence and clinical experience rather than published scientific literature. Some arthritis foundations and other authorities are reluctant to endorse manual therapies for arthritis due to a lack of scientific evidence demonstrating efficacy, safety, and cost effectiveness (Kramer, 1999; Panush, 1997).

Physical and manual therapies may be helpful for people with arthritis, and in some forms, have been supported by previous research (e.g., exercise as a component of the ASPM; Lorig, Mazonson, & Holman, 1993). Even when direct scientific evidence in support of physical and manual therapies is lacking, they are intuitively logical therapies for arthritis because they are aimed at redressing the physical effects of these diseases (e.g., reduced joint range of motion). Different types of therapies may be best suited to people according not only to their specific symptomatologies but also their psychological states (Prochaska & DiClemente, 1998; Keefe et al., 2000). In this thesis, I attempted to determine whether manual therapists' claims of effectiveness were justified, that is, whether two types of manual therapy (joint mobilisation and massage) and warm-water exercise were effective in improving the HRQOL of people with OA or RA. I compared

the effects of the manual therapies with the effects of warm-water exercise, alone, and in combination.

Health-Related Quality of Life

HRQOL fluctuates throughout the course of diseases and treatments. Effective treatments for patients with arthritis may afford pain relief, and reduction in disability, morning stiffness, and fatigue, along with prevention of future disability, and improvement in social activity and body image. Arthritides, and some arthritis treatments, may also produce gastritis, vomiting, diarrhoea, renal insufficiency, liver failure, and lead to hospitalisations and financial loss. In the words of Fries (1999), "the quality of life issue in RA [and most chronic diseases] boils down to whether the positives of treatment outweigh the negative aspects of the disease process and its treatment—and if so, by how much?" (p. 35).

Exactly how *health outcome* and *quality of life* are defined depends upon the underlying conceptual frameworks for these contructs (Wan, Counte, & Cella, 1997). Traditionally, outcomes in medicine and health-care have been measured by medical tests (e.g., erythrocyte sedimentation rate [ESR] as a marker of inflammatory disease activity). In most chronic illnesses, including arthritides, the problems are not exclusively medical ones. Arthritides can have a substantial negative impact on a person's quality of life in terms of physical, emotional, and social functioning, pain perception, and mental health (Centers for Disease Control and Prevention [CDCP], 2000), and these domains are the components of HRQOL examined in this thesis. Because these aspects of HRQOL cannot be measured by laboratory tests, "the perspective of the patient [participant/client] is a critical variable" (Fontaine, n.d., p. 2) in the assessment of health care outcomes.

HRQOL is typically assessed using self-report questionnaires, which may be: (a) generic, (b) dimension specific, or (c) disease specific. Generic measures allow comparison of health domains across medical conditions, and may be administered to different

populations to assess the effectiveness of a therapy. Dimension specific measures usually assess a single aspect of health (e.g., pain), and are useful for detecting changes in that health dimension over time. Disease specific measures are used to gather data on the aspects of HRQOL known to be affected by a given disease, and by virtue of their design, Fontaine (n.d.) argued that disease specific instruments are likely to be more useful than generic instruments in the detection of treatment effects. Many authors have recommended combining different types of instruments into a package to suit the needs of a research design (Fontaine, n.d.; Guyatt, Feeny, & Patrick, 1993; Schug, 1996). In this thesis, a combination of HRQOL measures, comprising generic (general health), disease specific (arthritis), and dimension specific (pain) instruments, was used to determine the effectiveness of manual therapy and warm-water exercise programs as adjunctive treatments for people with OA or RA.

Why Do this Research?

Significance of the Research

The two arthritides (rheumatoid and osteoarthritis) investigated in this project are common diseases of substantial morbidity for which there are no known cures, and they are associated with poor health-related quality of life (CDCP, 2000). Because these diseases are common, chronic, and often severe, they are major international health problems (Lorig & Fries, 2000; Klippel, 2001).

Pharmacological intervention, surgical joint repair or replacement, and patient-driven exercise programmes are the mainstays of current therapies for people with arthritides. These therapeutic strategies, however, do not meet the needs of many clients; some people develop tolerance to medications; others develop complications and experience unwanted side-effects, and over 50% of clients are not psychologically prepared to undertake and complete a self-driven exercise regime (Keefe et al., 2000).

Costs of medical care for people with OA and RA may be underestimated (Kaplan, Coons, & Anderson, 1992; Kaplan, Alcaraz, Anderson, & Weisman, 1996). Regardless of the specific costs, arthritic diseases affect more than 1 person per 100, and have a substantial impact on national health costs. In this thesis, I investigated whether manual therapies, either in isolation, or in conjunction with group exercise, are viable adjunctive care alternatives for people with arthritic diseases. The analyses include assessments of financial factors, as well as HRQOL outcomes.

Manual therapies are practitioner-driven, demanding less personal discipline from the patient than self-driven exercise. Manual therapies comprise procedures of low risk, with high patient acceptance and satisfaction, and few side-effects (Ernst, 2003). Cost effective manual therapies that have positive influences on HRQOL may be offered as reasonable therapeutic alternatives, or adjuncts, for people with OA and RA. If the HRQOL of people with arthritides can be improved, the burden of health costs produced by the long-term morbidity of these diseases may be reduced.

Contribution to Knowledge

Despite widespread use, manual therapies in rheumatology are under-researched. In contrast, exercise programmes for arthritis care have been well researched, and provide standards against which other therapies may be benchmarked. The series of three clinical studies in this thesis is an original piece of work, which contributes to the understanding of manual therapy and arthritis care in three ways: (a) by thorough investigation of the health-related quality of life outcomes that may be derived from manual therapy, (b) by direct comparison of HRQOL outcomes from manual therapy with those from structured exercise, and (c) in Study 3, through investigation of the disjunctive and conjunctive contributions of manual therapy and structured exercise to HRQOL.

CHAPTER 2

REVIEW OF LITERATURE

Overview of Arthritis

The arthritides are chronic, progressive diseases, for which the causes are mostly unknown, and cures remain elusive. All forms of arthritis, and some connective tissue diseases, are grouped together as the arthritides (over 100 diseases). Arthritis is generally characterized by pain and joint damage, and may be accompanied by organ and system degradation. Connective tissue diseases are similarly painful and destructive, but damage soft tissue rather than joint structures (e.g., skin, ligament, muscle). Consistent features of arthritides include pain and stiffness (impairment) and reduced function (disability). People with arthritides may experience the general psychological consequences of chronic illness, pain, and disability, along with psychological sequelae specific to these conditions.

Epidemiology

Arthritides and other musculoskeletal diseases are common, and they substantially influence public health through decreases in quality of life and increased use of health care resources (Brooks, 2002). To emphasise the public health importance of musculoskeletal diseases, the World Health Organization has declared the decade from 2000 to 2010 to be the *Bone and Joint Decade* (Woolf, 2002). The chronic nature of the majority of arthritides is such that if a person has developed arthritis at some time in the past, that person will most likely have arthritis now. Consequently, arthritic diseases are of particular public health concern in aging populations (Åkesson, 2003; Betteridge, 2003). Regardless of the specific epidemiology, there is consensus that arthritides are significant international health problems that take considerable toll on the quality of human life.

Incidence

The incidence of arthritides is often difficult to determine because many of these diseases have gradual onsets, diagnosis is unclear from early symptoms, and some

(incident) cases may be overlooked. Broad-based statistics (e.g., incidence in adults) are overly general because the incidence of OA increases with age, and varies according to sex, body site, and diagnostic criteria (Felson, Zhang et al., 1995; Fife, 1997). Incidence is an estimate of the number of new cases of a disease at a point in time–answering the question "What percentage of the population are developing OA at this time?" In a large-scale population study in the USA, Oliveria, Felson, Reed, Cirillo, and Walker (1995) reported the incidence of OA in the hand, when standardised for age and sex, as 100 per 100,000 person years. Put simply, 0.1% of the United States' population developed new cases of OA in the hand every year. From the same study, incidence estimates for OA varied from 0.08% for the hip, to 0.24% for the knee. Incidence increases with age, and at ages over 50 years this increase was more pronounced in women than men, such that at 70 years or older, new cases of knee OA among women peaked at 1% per year.

Prevalence

OA and RA are chronic, and usually progressive, conditions. Measures of lifetime prevalence–asking "What percentage of the population have ever had OA or RA in their lifetime?"–provide a picture of the burden of these diseases in the community. The American College of Rheumatology (ACR, 2003a, 2003b) reported that more than 21 million people in the USA have OA, and 2 million people have RA. Assuming no remission of arthritic diseases, these figures translate to prevalence estimates of approximately 7.5% and 0.7% respectively.

In the Framingham Study, a population based study of 12,000 people in Massachusetts, the prevalence of symptomatic OA of the knee was estimated at 11% of adults aged 70 years or more (Felson et al., 1987). Consistent with the patterns observed for incidence, Felson et al. found that OA is more prevalent in women than men, and the prevalence of OA increases with age.

Peyron and Altman (1992) demonstrated that the prevalence of OA varies among racial groups. For example, their epidemiological investigation identified that in British Caucasians aged over 35 years, approximately 70% displayed diagnostic features of OA, but in Alaskans Inuit aged over 40 years, the same features were identified in only 24% of women and 22% of men.

Rheumatoid arthritis (RA) has a worldwide distribution and involves people of all ethnic groups. Depending upon the stringency of the diagnostic criteria used in population-based studies, lifetime prevalence estimates vary between 0.3% and 1.5% of the North American adult population (Fife, 1997). RA is approximately three times more prevalent in women than men, and in both men and women the prevalence of RA increases with age (ACR, 2003a).

Types of Arthritides

The diversity of the arthritides necessitates some classification of the diseases to aid this area of medical practice. Arthritides may be primary (idiopathic, of unknown cause), or secondary to another disease process. For example, primary OA is eventual, age-related "wearing out" of the weightbearing synovial joints of almost everyone who lives long enough, and secondary OA may occur in the synovial joints of people with haemophilia following haemarthroses (joint bleeds; Flores & Hochberg, 1998). Arthritides may be classified as monoarthritic or localised (one or very few types of joints), polyarthritic or generalized (three or more types of joints), or systemic (multiple organs or systems).

Arthritides may be further classified according to the pathophysiological mechanisms active in each disease. These mechanisms are not always well understood, and a single disease may fit more than one classification. An overview and comparison of several of the arthritides is shown in Table 2.1.

In classifications according to pathophysiology, RA is identified as an inflammatory arthritis because it involves a prostaglandin mediated inflammatory process,

and thereby produces joints that are red, hot, swollen, painful, and dysfunctional (Ferrari et al., 1996). Some inflammatory arthritides, including RA, are classified as autoimmune diseases (e.g., lupus), in which the immune system identifies "self" as "foreign" and mounts an inflammatory response to its own articular tissues (Shephard & Shek, 1997). In other arthritides (e.g., Lyme disease, reactive (enteropathic) arthritis, Reiter's arthritis) the inflammatory process is triggered by an infection (Yu & Kuipers, 2003), and may be maintained by antigen-driven processes (Sigal, 1999).

OA is a usually categorised as a degenerative disease that occurs when physical forces (e.g., macrotrauma, repeated mircrotrauma) damage articular cartilage. Although the precise mechanism of inflammation is unclear, a moderate inflammatory process follows cartilage damage in OA. It is likely that the by-products of cartilage breakdown stimulate synovitis (Ferrari et al., 1996). Radiographically, osteoarthritis is demonstrated by loss of functional joint space, sclerosis and osteophytic outgrowths at joint margins, roughened articular cartilage, and subchondral cyst formation (Yochum & Rowe, 1996). OA in the hands produces characteristic nodal formations, Heberden's nodes at the distal interphalangeal joints and Bouchard's nodes at the proximal interphalangeal joints.

Table 2.1 *Comparison of Types of Arthritis*

Arthritis	F:M	Age	Location/s	Distribution	Pathophysiology
Ankylosing Spondylitis	1:10	15-30	Sacroiliac joint (SIJ), spine	Polyarticular	Inflammatory / autoimmune
Enteropathic	F > M	15-30	Lumbar spine, hips, SIJ	Polyarticular	Inflammatory, post-infectious
Erosive Osteoarthritis	F > M	40-50	Small joints of hands, feet	Polyarticular	Inflammatory
Forrestier's disease	M > F	50+	Spine, entheses	Polyarticular	Degenerative
Gout	1:20	40-50	Metacarpophalangeal (MCP), thumb Metatarsophalangeal joints, great toe	Monoarticular	Metabolic, crystal deposition
Jaccoud's	1:1	variable	Small joints of hands, feet	Polyarticular	Inflammatory
Lupus (Discoid form)	F > M	15-35	Skin (patchy lesions)	Connective tissue	Inflammatory / autoimmune
Lupus (Systemic)	F > M	15-35	Hands, face, lungs, soft tissues	Connective tissue	Inflammatory / autoimmune
Lyme disease	variable		Small joints of hands, feet	Polyarticular	Inflammatory, post-infectious
Neuropathic	variable		Variable	Polyarticular	Degenerative
Osteoarthritis	F > M	40+	Previously injured joint	Monoarticular	Degenerative, post-traumatic
Osteoarthritis	F > M	40+	Weightbearing joints, hips, knees	Polyarticular	Degenerative

Table 2.1 continues overleaf

Table 2.1 continued

Arthritis	F:M	Age	Location/s	Distribution	Pathophysiology
Pseudogout	1:1	30-60	Knees, toes	Monoarticular	Metabolic, crystal deposition
Reiter's arthritis	1:50	15-30	Spine, lower limbs	Polyarticular	Inflammatory, post-infectious
Rheumatoid	3:1	20-30	MCP, interphalangeal joints, elbows wrists, shoulders, knees, hips	Polyarticular	Inflammatory / autoimmune
Ross River fever	variable		Small joints of hands, feet	Polyarticular	Inflammatory, post-infectious
Scleroderma	F > M	20-50	Small joints of hands, feet Skin, hair, nails, smooth muscle	Connective tissue	Inflammatory / autoimmune

Note. Age is typical age in years at *onset* of symptoms.

Table 2.1 highlights that arthritides are not, as frequently assumed, exclusively diseases of the elderly. The symptoms of many arthritides (e.g., joint pain, muscle pain, weight loss) may commence in early adulthood, and continue through life. Juvenile and adolescent onset forms also occur, but are less common than the adult onset diseases. Some arthritides are progressively destructive, worsening with increasing age (e.g., OA, RA). In other types, symptoms are somewhat static but may be persistent (e.g., post-infectious arthropathies, such as Lyme disease and Ross River fever).

Regardless of the type, extent, or location of arthritis, the resultant pain, tissue atrophy, and tissue damage may reduce health-related quality of life (HRQOL) and contribute to the development of disability (CDCP, 2000). Social and psychological sequelae may include social withdrawal, loss and grief, anxiety, depression, and reduced well-being.

Diagnoses and Diagnostic Criteria

Rheumatology is a complex and specialist area of medical practice and research. Most people with arthritis experience a gradual onset of symptoms, although acute onset of symptoms can occur. Typically, in early stages of arthritis symptoms may be vague, with radiographs and serology negative or indistinguishable from other diseases, and the diagnosis unclear. The diagnostic uncertainty in early arthritic disease may give way to two equally unfortunate scenarios: people with early arthritic symptoms may be told that they have a range of relatively innocuous musculoskeletal conditions (e.g., bursitis, tendonitis, metatarsalgia), or they may be subject to extensive, but often inconclusive and relatively unhelpful, tests to investigate for arthritis. As arthritides progress, the clinical markers listed above (symptom picture, radiography, serology) become clearer and the diagnosis apparent.

The ACR and American Rheumatism Association, in conjunction with other experts in the field, developed explicit diagnostic criteria for most arthritides (Arnett et al., 1988). ACR criteria for the diagnosis of RA are presented in Table 2.2.

Table 2.2 *ACR Criteria for Rheumatoid Arthritis (Arnett et al., 1988)*

1. Morning stiffness lasting longer than one hour.
2. Soft tissue swelling (arthritis) in at least three joint areas.
3. Swelling (arthritis) of the hand / wrist (proximal interphalangeal, metacarpophalangeal, or carpal) joints.
4. Symmetrical distribution of swelling (arthritis).
5. Rheumatoid nodules.
6. Rheumatoid factor.
7. Joint erosions or periarticular osteopenia on radiographs of wrist and hand.

An individual must meet at least four criteria to be diagnosed with RA. Items 1-4 must be present for at least six weeks, because polyarthritis of shorter duration may not be due to RA, and may resolve spontaneously. When applied according to these guidelines, the ACR criteria detect 91-94% of people with RA (sensitivity), and distinguish between them and people without RA in 89% of cases (specificity).

The plain film radiographic (x-ray) appearance of joints has limited clinical usefulness in the diagnosis of RA because early radiographic changes tend to be similar across a range of diseases. Furthermore, plain film radiography uses potentially carcinogenic ionizing radiation, and the sensitivity of plain film radiography is such that 30% to 50% reduction in bone density is required before bone loss is observed on plain films (Yochum & Rowe, 1996). Put simply, plain radiography is a rather blunt and minimally useful instrument for the diagnosis of RA.

Similarly, serology is rarely useful in the diagnosis of RA, because the available tests lack specificity. Rheumatoid factor may be detected in the blood of many people, including healthy people and people with diseases other than RA. Screening for rheumatoid factor is not a rheumatoid arthritis test. Rheumatoid factor is one of seven possible diagnostic criteria (Arnett et al., 1988). Because four criteria are required to make the diagnosis, it is possible for an individual to be diagnosed with RA despite the absence of rheumatoid factor on blood testing. Ferrari et al. (1996) made a case for the use of serology to confirm likely diagnoses in people who demonstrate several ACR diagnostic criteria, and cautioned that "if a patient lacks these [other diagnostic criteria], one should not order serology, because positive results will not take the diagnosis any further, but will only lead to confusion, worry, added expense, and inappropriate referrals." (p. 18).

Diagnostic issues are similar in OA and RA. ACR criteria for the diagnosis of OA differ according to body regions, and there are two sets of criteria for most regions. One set of diagnostic criteria includes laboratory and radiographic criteria, and the other set comprises clinical criteria only. A diagnosis of OA may be made using either criteria set. For most body regions the two criteria sets have comparable sensitivity and specificity, further emphasising that radiography and serology add little in the differential diagnosis of arthritides. ACR criteria for the diagnosis of OA of the knee are presented in Table 2.3.

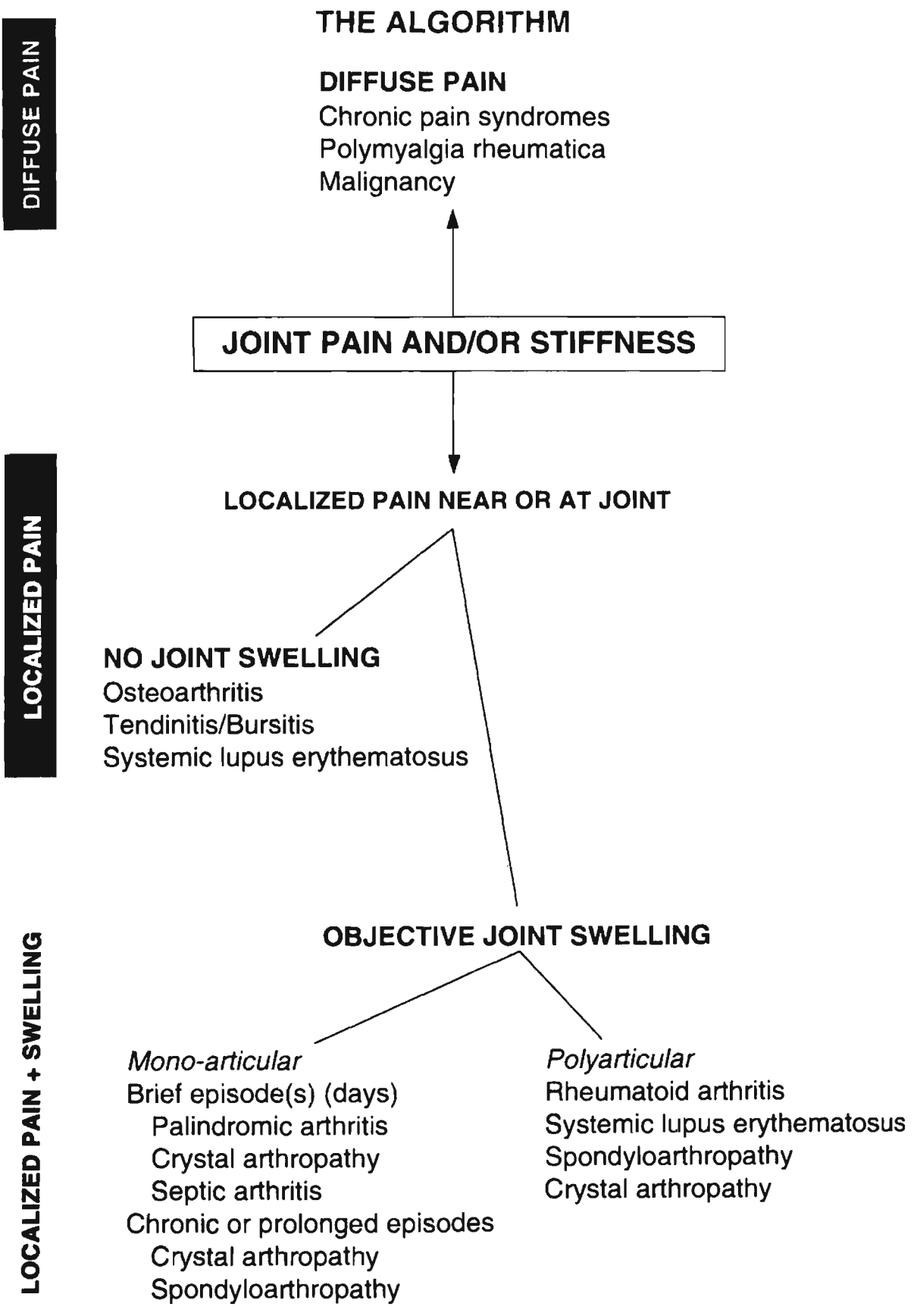
Table 2.3 *ACR Criteria for Osteoarthritis of the Knee (Flores & Hochberg, 1998)*

Clinical Criteria	*Clinical, Laboratory, and Radiographic Criteria*
1. Knee pain for most days of prior month.	1. Knee pain for most days of prior month.
2. Crepitus on active joint motion.	2. Osteophytes at joint margins (x-ray).
3. Morning stiffness < 30 minutes duration.	3. Synovial fluid typical of OA (laboratory).
4. Age > 38 years.	4. Age > 40 years.
5. Bony enlargement of the knee on examination.	5. Morning stiffness < 30 minutes.
	6. Crepitus on active joint motion.
Note. OA diagnosed if items 1-4, or 1, 2, 5, or items 1, 5, are present. Sensitivity is 89% and specificity is 88%.	Note. OA diagnosed if items 1, 2, or items 1, 3, 5, 6, or items 1, 4, 5, 6, are present. Sensitivity is 94%, and specificity is 88%.

To assist non-rheumatologists in the diagnosis of arthritis, Ferrari et al. (1996) developed a diagnostic algorithm for use in conjunction with ACR criteria (see Figure 2.1). This stringent approach to diagnosis gives the primary contact practitioner confidence in diagnosis and prevents established arthritic disease from being overlooked. ACR criteria also provide consistency in diagnosis adequate for participant selection into clinical trials.

Strict adherence to the ACR criteria for RA (Arnett et al., 1988) is not without weaknesses. Harrison, Symmons, Barrett, and Silman (1998) studied a cohort of people in rural England with inflammatory polyarticular arthritis. Participants were admitted to the study, conducted using the Norfolk Arthritis Register (a register of people with arthritis, compiled in Norfolk, England), upon first (non-specific) signs of arthritis. Harrison et al. concluded that the ACR criteria do not clearly identify those people with early arthritis who will go on to develop RA. ACR criteria for the diagnosis of RA were last reviewed in 1987. Experts are divided over the adequacy of the ACR criteria, and some have called for a review of these criteria (Visser, le Cessie, Vos, Breedveld, & Hazes, 2002).

Figure 2.1 *Diagnostic algorithm (from Ferrari et al, 1996).*



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Treatment and Management of Arthritides

Although much research has been directed toward the identification of causes of arthritides, the pathogeneses of these diseases remain unclear in most cases. Furthermore, although many therapies are available, none clearly and consistently arrest the natural course of arthritic diseases. More than two decades ago, Meenan, Yelin, Nevitt, and Epstein (1981) suggested that:

> barring significant basic research breakthroughs, we are probably at the point of diminishing returns in the treatment of most chronic diseases [including athritides], since we have reached the stage where additional medical or surgical therapy is apt to produce progressively smaller improvements in individual health status. (p. 544).

People with arthritides usually experience incurable, progressive illnesses, and will most likely need to adjust their lives and daily activities. Improvements in quality of life and functional ability are now regarded as important goals of treatment for arthritis (Meenan et al., 1981). Kavanaugh (1999) suggested that improvement in quality of life is a key goal of therapy for people with RA. Simon (1999) argued the same case for people with OA, and summarised the ethos of current care approaches:

> Given that most patients must learn to live with a disease that may significantly alter their earning potential, basic function, and lifestyle, it is important to develop a treatment system that views the patient as a whole, using methods enlisting the patient's enthusiasm for therapy and allowing them to participate in their own care. (p. 26).

Usual Medical Care

Typically, outpatient (non-hospitalised) medical care for people with arthritides comprises an array of medications, often provided under the care of a rheumatologist (Kavanaugh, 1999; Klippel, 2001; Simon, 2000). The aims of drug therapy in arthritis are to reduce symptoms and simultaneously prevent, limit, or control, joint damage.

Combinations of drugs may be required to achieve these aims. Several varieties of each drug type are now available (Crichton & Green, 2002; Kessenich, 2001). Individuals with arthritis may trial different drug regimes before settling upon the combination that is most effective for them. Commonly used pharmaceutical agents can be grouped into four classes, each with a different therapeutic purpose: (a) analgesics, to reduce pain, (b) non-steroidal anti-inflammatory drugs (NSAIDs), including cycoloxygenase-2 specific (COX-2) inhibitors, to reduce inflammation in joints and surrounding soft tissues, (c) corticosteroids, to reduce severe inflammation, and (d) disease modifying anti-rheumatic drugs (DMARDs), including "biologic" agents (e.g., etanercept, infliximab, leflunomide), to slow the course of inflammatory arthritic diseases (e.g., RA) by preventing joint and tissue damage.

There are pros and cons to drug use in arthritis. Each class of drugs has side effects, and not all clients find the same drugs effective to the same degree. Paracetamol (acetaminophen) is widely used as a first-line analgesic for people with OA. The European League Against Rheumatism (EULAR) recommended paracetamol over NSAIDs as initial therapy for pain control because it is: (a) cheaper, (b) thought to be less irritating to the gastric lining than NSAIDs, and (c) appropriate therapy for non-inflammatory, or mildly inflammatory, pain (Pendleton et al., 2000). Even this intuitively logical, evidence-based, guideline is open to debate because some people find NSAIDs more effective than paracetamol for pain relief (Pincus, Swearingen, Cummins, & Callahan, 2000), and there is some recent evidence that paracetamol may produce similar gastric irritation to NSAIDs (Garcia Rodriquez & Hernandez-Diaz, 2001).

In the late 1980s people with arthritides were no better served by early diagnosis than by waiting until their symptoms fulfilled the ACR criteria because DMARDs were prescribed only for those clients with advanced joint destruction. DMARDs are expensive drugs, with considerable side effects. DMARDs were reserved as second-line therapy

because of the expense and side effects (e.g., liver toxicity) of their use, and because the understanding at that time was that erosion and joint damage were long-term consequences of synovitis, inflammation, and swelling (O'Dell, 2002). Current understanding is that joint damage occurs far earlier than previously believed. In people with RA, joint erosions may occur within the first year (van der Heijde, 1995), and early initiation of drug therapy considerably improves long-term outcomes (Symmons, Jones, Scott, & Prior, 1998). Three independent clinical trials have demonstrated that treatment with DMARDs early in the course of RA is superior to delaying DMARDs for as little as 8 to 12 months (Egmose et al., 1995; Tsakonas et al., 2000; Van der Heide et al., 1996).

The safety and efficacy profiles of the recently developed biologic DMARDs are mostly positive (Bathon et al., 2001; Moreland et al., 2001). For example, rapid clinical improvements have been demonstrated in people with RA treated with etanercept (Moreland et al., 1999). Etanercept is considered useful for clients with moderate to severe RA who had incomplete responses to other DMARDs. Despite much interest and hope in the newest generation of DMARDs for the treatment of RA, biologic agents are expensive, and the cost may be prohibitive for some clients. Furthermore, these medications are not always easy to administer. Etanercept is given as a twice-weekly subcutateous injection, and consequently, is only suitable for clients who are comfortable to self-inject (Kessenich, 2001) or have someone willing to help administer the medication.

If drug therapy is inadequate to control joint deterioration, then surgical procedures may be used to repair, reconstruct, or replace a damaged joint. Joint debridement, resurfacing, and cartilage grafts are used to repair articulating joint surfaces. Osteotomies, stabilization procedures, and resection arthroplasties (partial joint replacements) are used to re-align joints, to improve stability, or to maximize congruency between joint surfaces. Joint replacement arthroplasty is used in people with arthritis when a particular joint has become so extensively damaged as to prevent normal function. Total joint replacement is

an established surgical procedure for the hip, knee, elbow, shoulder, and interphalangeal joints of the hands, and experimental procedures for other joints (e.g., intervertebral body joints of the spine) are under development (Knutson, 1998).

Decisions about surgery are of considerable importance for people with arthritis. In a recent survey of 1024 Norwegian adults with RA, Heiberg and Kvien (2002) asked participants to identify the areas of their own health in which they would most like to see improvement. Hand and finger function (45%), walking and bending (33%), and mobility (24%) were rated as the three priorities immediately behind pain (69%). Joint surgeries are undertaken for the express purpose of improving health in these priority areas, but typically require general anesthesia for the surgery, and weeks to months of rehabilitation to gain anticipated function. Both the extent of most arthritides, and the risk of complications from major surgery increase with advancing age (Knutson, 1998).

Monitoring Arthritis

Rheumatologists usually monitor clients' disease progress with clinical physical examinations, blood tests, and imaging techniques. Flowers and Wolfe (1999) conducted a survey of rheumatologists to determine which enquiries and procedures were performed in routine assessment (i.e., monitoring) of clients with RA. A sample of 645 rheumatologists in the USA reported whether they performed certain examinations rarely (fewer than 25% of consultations), sometimes (25-74% of consultations), or usually (75% or more consultations). The most commonly performed procedures, asking about morning stiffness in joints (see Tables 2.2 and 2.3), and physical examination of joints for swelling (swollen joint count), were reported to be performed by 70% of rheumatologists in greater than 75% of consultations. The next most common test, erythrocyte sedimentation rate (ESR), was reportedly conducted by more than 75% of rheumatologists during at least one consultation in four. More than 80% of rheumatologists reported rarely collecting any health status data

(e.g., patients' assessments of global disease severity, fatigue, satisfaction, physical function, general health and well-being, psychological state).

Joint Counts

Counting the number of tender and swollen joints is a commonly used method of assessing disease extent and activity in arthritis. A complete joint count comprises assessment of 70 joints scored for swelling, tenderness, pain on motion, limited motion, and deformity (ACR Glossary, cited in Callahan, Pincus, Huston, Brooks, Nance, & Kaye, 1997). Variations of joint count include the Ritchie articular index, an assessment of 68 joints for tenderness (Ritchie et al., 1968), and simplified 42 and 28 joint articular indices (Fuchs, Brooks, Callahan, & Pincus, 1989). Several studies have demonstrated that joint counts based on 28 joints (i.e., 10 metacarpophalangeal and 10 proximal interphalangeal joints of the hands, two joints each in the wrists, elbows, shoulders, and knees) are comparably informative as counts based on more joints (Fuchs, Brooks et al., 1989; Fuchs & Pincus, 1994; Pincus, Brooks, & Callahan, 1994). Joint counts are clinically useful measures for assessing the progress of arthritis because they are easy to conduct, non-invasive, reliable, and responsive to change over time (Anderson, 1993; Escalante, 1998).

Usually, health care practitioners conduct joint counts. Houssien, Stucki, and Scott (1999) compared joint counts conducted by 100 people with RA (self-assessment) with those conducted by physicians on the same clients, and used a regression analysis to determine that there was no significant difference between the two types of joint counts. Correlations between physicians' and clients' joint counts were higher for the assessment of tender joints ($r = .88$, $p < .01$) than swollen joints ($r = .63$, $p < .01$). Kappa analyses demonstrated good agreement between examiners (physician and client) for assessment of tenderness in each type of joint, and fair agreement for the assessment of swelling. Agreement was greatest for assessment of the knee (tenderness: right knee $\kappa = .84$, left knee $\kappa = .78$; swelling: right knee $\kappa = .50$, left knee $\kappa = .61$) Additionally, both physician-

derived and client-derived joint counts were demonstrated to correlate significantly with self-report measures of disease status, disability, and quality of life.

Serology

Blood tests commonly used in the monitoring of arthritis are ESR and serum C-reactive protein (CRP) level. Both these measures are general inflammatory markers, which may be elevated during active phases (flares) in RA. These acute phase reactants (ESR and CRP) are not disease specific markers, and, therefore, are of limited use in isolation (Ferrari et al., 1996). CRP may be used as an alternative to ESR in the monitoring of RA progress because it is a more direct measure of inflammation than ESR, and is more sensitive to short-term changes (Kushner, 1991). Both ESR and CRP are strong predictors of radiological progression in RA (Wolfe, 1997; Wolfe & Sharp, 1998), but the relationship between radiographic progression and disability in RA is complex (Scott et al., 2000), and the clinical meaningfulness of acute phase reactants is unclear.

Callahan et al. (1997) studied inflammatory activity and joint damage, among other variables, in a cohort of 210 people with RA over five years. Serology (ESR and rheumatoid factor) and joint counts for swelling and tenderness were used as measures of inflammatory activity. Radiographs and joint deformity were used as measures of articular damage. Functional tests (grip strength, walk time, button time) and self-report measures were also undertaken, but may represent both joint damage and disease activity. In most of the 169 people who survived five years and completed the study, measures of inflammatory activity were unchanged or sometimes improved, but measures of joint damage were worse. Callahan et al. concluded that measures of inflammatory activity, particularly serology, may underestimate disease status in people with RA, and do not adequately predict long-term outcomes.

Because OA is a degenerative, rather than an inflammatory disease, serological markers of inflammation provide little useful information in the monitoring of OA. An elevated ESR does not exclude OA because a client may have co-morbidities (Fife, 2002).

Imaging

Osteoarthritis. Peterfy (2002) reported that despite the extraordinary advances in medical imaging on the past 30 years, "conventional radiography continues to be the primary imaging technique used to evaluate OA. This modality, however, is fundamentally limited by its inability to directly visualize articular cartilage, synovium, menisci, and other nonosseous structures involved in the pathophysiology of OA." (p. 590). In plain film radiography, the size of the joint space is used as an estimate of cartilage loss: the narrower the joint space, the more cartilage has been destroyed. This measure of cartilage loss lacks both sensitivity and specificity. Joint space size may be influenced by the flexion-extension position of the joint in space (Yochum & Rowe, 1996), and in the knee, meniscal resection or subluxation may simulate articular cartilage loss (Peterfy).

Radiographic changes do not well explain clinical symptoms in OA. Felson et al. (1987) obtained radiographs of the knees, and symptoms profiles, of 1424 adults aged between 63 and 94 years. Radiographs were graded 0-4 for the presence of osteoarthritic changes. Radiographic OA was defined as grade 2 changes (i.e., osteophytes) or higher. There was a statistically significant trend of increasing symptoms with increasing age. There was also a general pattern of increased prevalence of symptoms with increased severity of radiographic changes, but the relationship between these variables was not linear. A small proportion of people with normal knee radiographs, 7.6% of people with grade 0 radiographic changes, and 10.8% of people with grade 1 changes, reported symptoms consistent with OA of the knee. Of the people with grade 2 radiographs, 19.2% reported symptoms. Neither were severe radiographic changes consistently accompanied by symptoms. Only 40% of people with grade 3 or 4 radiographs had symptoms of OA.

Rheumatoid arthritis. Plain film radiographs are useful for assessing disease progress in RA. They are used for following the natural history of the disease, defining disease severity at a single time point, and determining whether DMARDs have been effective in preventing joint erosions. The main difficulties in interpreting plain film radiographic progress in RA are: (a) the quantification of changes over time, and (b) the reliability of any scoring system. Despite significant correlation between radiographic damage and duration of disease, the relationship between these variables is not linear (Fuchs, Kaye, Callahan, Nance, & Pincus, 1989). Joint damage, as seen radiographically in the hands, progresses rapidly in the first five years, less so in the next five years, and slowly after 10 years (Sharp, Wolfe, Mitchell, & Bloch, 1991).

Several methods have been developed to evaluate radiographic changes in RA, but no system has achieved universal acceptance. The method described by Sharp, Lidsky, Collins, and Moreland (1971) is the most commonly used in the United States of America, grading erosions from 0-5 and evaluating joint space narrowing on a scale ranging from 0-4 for each joint. In Larsen, Dale, and Eek's (1977) method, mainly applied in Europe, the amount of joint destruction is ranked with a single score and uses a series of standard radiographs for comparison. Several modifications of these methods have been reported. A quantitative score for feet was developed because radiographic damage in RA may be seen in the feet prior to the hands (van der Heijde, van Leeuwen, van Riel, & van de Putte, 1995). Kaye et al.'s (1987) modification of the Sharp method included scoring individual joints for malalignment, and deletion of certain joints that were found difficult to score.

Because plain film radiographic changes in RA are non-linear, interpretation of the clinical meaning of these changes is complex. The identification of joint erosions on radiographs is important because it is "inconceivable that joint destruction does not inevitably cause some disability." (Scott, 2002, p. 286). Early in the course of RA, radiographic changes and disability appear unrelated. In established RA, correlations

between joint damage and disability are significant, but change in one variable accounts only for approximately 25% of change in the other variable (Scott et al., 2000). Because there is no internationally agreed best method for quantifying radiographic changes in RA, practitioners reporting radiographs need to include a description of the scoring method used. These drawbacks limit the clinical usefulness of plain film radiography for assessing RA progression.

Magnetic resonance imaging. Of the newer imaging techniques, magnetic resonance imaging (MRI) is particularly useful for the assessment of arthritic joints. It offers multiplanar views of a joint without projectional distortion, provides high-resolution images of soft tissue structures, and can be used to measure the volume and thickness of articular cartilage that is damaged in arthritis (Peterfy, 2002). MRIs can be reliably interpreted for the assessment of disease progress in RA. The revised Rheumatoid Arthritis MRI Score (RAMRIS Version 3), developed during the 5th meeting of the Outcome Measures in Rheumatology interest group (OMERACT 5), has acceptable inter-reader reliability (r = .60 to r = .98) for measures of disease activity (synovitis and bone edema) and damage (bone erosion; Lassere et al., 2003).

There are three main drawbacks to using MRI in regular clinical practice: expense, time, and client claustrophobia. MRI is a financially expensive imaging modality (Yochum & Rowe, 1996), and the cost is not covered by many third party payors (public or private health funds). MRI measures of articular cartilage take 12 minutes or longer to conduct per joint (Peterfy, 2002), making these studies too time consuming for usual medical practice, as well as further increasing the cost, and risking deterioration of the image if the client moves. Most MRI machines are cylindrical, and some clients experience distress in the confined environs of the machine (Scott, 1997). Furthermore, because the MRI uses a magnetic field, it is an unsuitable imaging technique for any client with fixed internal metal fittings (e.g., prosthetic hip, surgical staples) that may be moved during the imaging

process. Despite the quality of the images, MRI is of limited usefulness for monitoring arthritis in usual medical care.

Self-report Measures

The most concerning thing about Flowers and Wolfe's (1999) findings is that they documented inertia in rheumatology practice. The use of health status data had been recommended in rheumatological assessment of clients almost 20 years prior (Fries, Spitz, Kraines, & Holman, 1980; Meenan, Gertman, & Mason, 1980). Generic, domain-specific, and disease-specific self-report tools have each been recommended for use in people with arthritides (Burckhardt, & Jones, 2003; Carr, 2003).

Ten years prior to Flowers and Wolfe's (1999) study, Pincus, Callahan et al. (1989) developed the case for client-report measures when they demonstrated that such measures: (a) are correlated with traditional measures of clinical status (joint count, blood tests, and radiography), (b) provide information similar to that sourced from traditional measures, and (c) are a cost-effective approach to assessing and monitoring the health status of individuals with RA. Furthermore, self-report measures are non-invasive to administer, and do not share the risks inherent in other disease monitoring procedures (e.g., ionizing radiation from plain film radiographs).

It is now well established that client self-report measures are some of the best representations of functional status (Pincus, Mitchell, & Burkhauser, 1989) and disease activity (Mason et al., 1992) in arthritis. They are better predictors of work disability (Wolfe & Hawley, 1998), mortality, disability, and chronicity (Pincus et al., 1994), than traditional medical tests. Callahan, Bloch, and Pincus (1992) found that a functional status questionnaire (Modified Health Assessment Questionnaire [MHAQ]; Pincus, Summey, Soraci, Wallston, & Hummon, 1983) was the best measure in a series of physical, radiographic, laboratory, and self-report tests to identify whether someone with RA is working or not. People receiving work disability payments had worse scores on almost all

RA assessments, including joint count, radiographs, ESR, and grip strength, than people in paid employment, but the results of physical, radiographic, and laboratory tests added no explanatory power to the information gleaned from the MHAQ.

Improvement Criteria

Criteria to monitor RA and identify improvement have been developed by the ACR (Felson, Anderson et al., 1995) and the European League Against Rheumatism (EULAR; van Gestel et al., 1996). The sets of criteria are similar, and are summarised in Table 2.4. Both the ACR and the EULAR improvement criteria are used as a-priori-defined measures of response (response versus no response) in clinical trials (Anderson, Bolognese, & Felson, 2003).

The ACR criteria are known as the ACR20, because of the requirement for 20% improvement from baseline in both the swollen and tender joint counts, and at least three out of the other five criteria. The ACR20 is a dichotomous measure; clients are categorised to have improved or not. More stringent criteria, the ACR50 and the ACR70, comprise the same components, and require 50% or 70% improvement respectively.

The EULAR improvement criteria are also reduced to a dichotomous variable, but the binary score is derived from the degree of change in a continuous measure: the Disease Activity Score (DAS). The EULAR improvement criteria incorporate change in disease activity and current disease activity. To be classified as responders, clients must have a significant change in DAS and low current disease activity. Three categories are defined: good, moderate, and non-responders, which may be reduced to the binary measure of responder versus non-responder (van Gestel et al, 1996). Response criteria calculating the DAS from a 28 joint count (DAS28) were developed and validated against the original EULAR improvement criteria and the ACR20, and are comparable to the criteria based on the comprehensive joint counts (Prevoo et al., 1995; van Gestel, Haagsma, & van Riel, 1998).

The complexity of the DAS formulae means that they are not readily calculable in clinical practice. In Europe, where the EULAR response criteria are preferred, some rheumatologists use electronic DAS calculators in routine practice. Because these response criteria are comprised, in part, from client self-report measures, they may be less than widely used in clinical rheumatology practice, if, as Flowers and Wolfe (1999) suggested, traditional measures of patient history, joint examination, and blood tests are the most common examinations performed.

Dougados (2004) recommended that the progression of OA should be monitored in a similar way, using valid and reliable outcome measures such as pain and physical function scales, and client's global self-assessment. He further argued that:

> Although evaluation of these variables is often based on the average improvement in the study population as a whole, evaluation in terms of individual patients is more relevant. Therefore, continuous data collected from individuals (e.g., pain VAS 1-100mm) require conversion to a dichotomous variable (e.g., improvement yes/no) so that the percentage of responders can be determined. (p. S55).

Dougados (2004) wrote about monitoring OA over the course of a clinical trial (i.e., research). His recommendation to use dichotomous data may not be meaningful in clinical practice. Self-report data are, by their very nature, subjective. To convert continuous data to dichotomous variables is to impose a fixed interpretation of "improvement" upon individuals. In a clinical trial it may be important to know how many people in a group are better, but in clinical practice it is probably more important to understand what "better" means for the client. Beaton, Tarasuk, Katz, Wright, and Bombardier (2001) explored the meaning of "better" in interviews with 24 people with musculoskeletal disorders, and determined that better is "highly contextualized in the experience of the individual." (p. 270). It may mean improvement, complete recovery, or adaptation.

Table 2.4 *Criteria for Improvement in RA*

ACR20	EULAR Disease Activity Score
20% improvement in tender joint count, and	Comprises tender joint count of 68 or 28 joints (TJ68 or TJ28)
20% improvement in swollen joint count, and	swollen joint count of 44 or 28 joints (SJ44 or SJ28)
20% improvement in at least 3 of	erythrocyte sedimentation rate (ESR: mm/hour)
patient's assessment of pain	general health on a 0–100 visual analogue scale
patient's assessment of disease activity	according to either formulae
patient's assessment of disability	$DAS = 0.54(\sqrt{TJ68}) + 0.065(SJ44) + 0.33(ESR) + 0.0072(\text{general health})$
physician's assessment of disease activity	High disease activity >3.7, low disease activity <2.4, remission <1.6
acute phase reactant (ESR or C-reactive protein)	$DAS28 = 0.56(\sqrt{TJ28}) + 0.28(\sqrt{SJ28}) + 0.70(ESR) + 0.014(\text{general health})$
	High disease activity >5.1, low disease activity <3.2, remission <2.6

Note. Versions of the DAS and DAS28 comprising three variables (without ESR) have also been developed.

Allied Medical, Complementary, and Alternative Therapies

Allied medical, complementary, and alternative therapies are often used by people with arthritis (Rao et al., 1999; Rao et al., 2003; Ramsey, Spencer, Topoloski, Belza, & Patrick, 2001), and may sometimes be recommended by rheumatologists and other medical personnel (Panush, 1997). For the purposes of organisation in this chapter, physical and manual therapies of all disciplines are grouped under this heading. Not all complementary and alternative therapies used by people with arthritis are physical or manual therapies (e.g., herbal supplements), neither will all physical and manual therapists see themselves as alternative or complementary.

The classification of therapies as complementary or alternative varies between studies and over time. Rao et al. (1999) investigated the use of complementary therapies among the clients of rheumatologists and "defined complementary and alternative medicine as any intervention not usually prescribed by physicians" (p. 410). Under this definition, chiropractic manipulation, a manual therapy, was a complementary therapy but all exercise programs, including Tai Chi, Qigong, and Feldenkrais, were not. Furthermore, therapies that were once complementary or alternative may become mainstream if there is sufficient scientific evidence, or consumer popularity, to prompt physicians to recommend them (Lam & Horstman, 2002).

Physical and manual therapies may be broadly divided into two types: active therapies, in which the client takes a driving role, and passive therapies, in which the therapy cannot proceed unless driven by a therapist. This division requires an understanding of how therapy is delivered, and is important from a psychological perspective (Mitchell & Cormack, 1998). The active-passive categorisation of interventions is, despite its simplicity, widely used in the physical and manual therapies. Some physical therapies used by people with arthritis do not fit neatly into active or passive subdivisions (e.g., wax therapy, portable transcutaneous electrical nerve

stimulation: TENS). These therapies may be active if investigated, sought out, and administered by the client, or somewhat passive if adopted exclusively under the direction of a therapist.

Active Therapies: Exercise

Active therapies include exercise and movement programs. Arthritis associations the world over, recommend exercise and movement as self-management strategies for arthritis. Lorig and Fries (2000) recommended many exercise programs for arthritis management, including land, water, and chair-based aerobic exercises, bicycling, flexibility and strengthening exercises for use in the home, and weight training. Movement-based programs recommended for people with arthritides include various forms of Tai chi and Qigong, Feldenkrais, and Alexander technique (Lam & Horstman, 2002).

The evidence for exercise programs as specific therapies for arthritis is somewhat lacking, but the positive effects of exercise on general health and physical function are well documented. Keysor (2003), on the basis of a review of recent clinical trials, reported that "exercise–particularly walking–increases muscle strength and aerobic capacity and reduces functional limitations." (p. 129). People with arthritis are not exempt from the training-related benefits of exercise (Cyarto, Moorhead, & Brown, 2004). Regardless of arthritis, people who do resistance training become stronger (Maurer, Stern, Kinossian, Cook, & Schumacher, 1999), and people who do aerobic exercise on a regular basis improve their cardiorespiratory capacity (de Jong et al., 2003). Philbin, Groff, Ries, and Miller (1995) demonstrated that even in elderly people with very advanced and severe OA, regular tailored training programs led to improvements in cardiovascular fitness and muscle strength without exacerbation of arthritic symptoms.

Thomas et al. (2002) demonstrated in a clinical trial of 786 people, aged over 45 years, with self-reported knee pain that home-based exercise was consistently better than no exercise in controlling pain over 6, 12, and 18-month follow-ups. Thomas and

colleagues did not distinguish between OA and other causes of knee pain, and did not require that participants meet the ACR criteria for the diagnosis of OA of the knee (see Table 2.3) at recruitment. OA of the knee is the most common cause of knee pain in adults aged over 45 years, but there is room to question whether the gains of exercise reported in this study showed a direct influence of exercise on OA, or a more generalized effect of exercise on pain.

The American Society (ASG) Panel on Exercise and Osteoarthritis (2001) reviewed randomised controlled trials of exercise interventions for people with OA. Generally, results indicated that "increased physical activity does not produce or exacerbate joint symptoms and, in fact, confers significant health benefits." On the basis of these data, the AGS panel recommended moderate physical activities, including flexibility, strength, and endurance training, 3-7 times per week for adults aged 65 years and older with OA (ASG, 2001).

Van den Ende, Vliet Vlieland, Munneke, and Hazes (1998) completed a systematic review of the evidence for structured, aerobic exercise in treating rheumatoid arthritis. This review was later prepared for the Cochrane Library (Van den Ende et al., 2002); Cochrane reviews are updated periodically as new evidence is published. Only four of the 30 studies reviewed met both inclusion and methodological criteria, and because of the heterogeneity of outcome measures, the data could not be pooled. The Van den Ende et al. (1998, 2002) reviews were not meta-analytical, and they did not report the effect sizes of structured exercise on any outcomes. Van den Ende et al. concluded that dynamic exercise at 60% of maximal heart rate for 20 minutes, twice per week, for at least six weeks, was effective in increasing aerobic capacity and muscle strength in people with RA. Furthermore, this level of training produced no detrimental effects on RA progression. The evidence was inadequate for Van den Ende et al. to conclude whether such exercise programs had any detrimental effects on joint stability or radiological markers of RA progression, or

produced any improvements in functional ability. It is possible that people with RA who undertake regular, dynamic exercise may become physically fitter, but not necessarily demonstrate increased physical function.

de Jong et al. (2003) conducted a randomised, controlled clinical trial of the efficacy and safety of two years of high-intensity exercise training in 309 adults with RA. The 1.25 hour-long exercise program, undertaken twice each week, comprised warm up and cool down exercises as well as 20 minutes of stationary bicycle training, 20 minutes of circuit training, and 20 minutes of games such as badminton, volleyball, indoor soccer, or basketball. Participants in both the exercise and control groups were assessed at baseline and 6-monthly intervals for functional ability (measured using the McMaster Toronto Arthritis [MACTAR] Patient Preference Disability Questionnaire (Tugwell et al., 1987) and the Health Assessment Questionnaire [HAQ; Fries et al., 1980]), physical capacity (aerobic fitness, muscle strength), emotional status (measured using the Hospital Anxiety and Depression Scale [HADS; Zigmond & Snaith, 1983]), radiographic progression of disease (measured using the Larsen score for large joints), and disease activity (measured using the DAS with four variables).

After two years 281 people remained in the study. The exercise group (n = 136) reported significantly better functional ability than the control group (n = 145) using the MACTAR Patient Preference Disability Questionnaire ($p < .02$) but not on the HAQ. This discrepancy between measures was attributed by the authors to the "HAQ's lack of sensitivity to change in exercise trials" (p. 2421). Significant improvements in aerobic fitness ($p < .01$) and emotional status ($p < .01$) were also demonstrated in the exercise group, but declines in these variables in the control group contributed to these results. Muscle strength increased, and DAS decreased gradually, in both groups over time, and the groups did not differ significantly on these measures at the end of the study.

Participants with more radiographic evidence of joint damage at baseline showed more progression in joint damage over time, and this trend was more obvious in the exercise group, but the differences between groups were not statistically significant. The authors considered that this non-significant finding demonstrated the safety of the exercise program. Because only participants without prosthetic joints were recruited for this study, it is likely that the sample represented people with RA with relatively low levels of joint damage. de Jong et al. (2003) offered a caution that until further research supported their findings clinicians might prefer to tailor for patients exercise programs that spare damaged joints.

Passive Therapies: Manual Therapy

Passive manual therapies used in arthritis management include manipulative physical therapy (physiotherapy), osteopathy, chiropractic, massage, and craniosacral therapy. There is little evidence as to whether these manual therapies influence arthritis progression or symptoms, but they are widely used by people with arthritis (Lorig & Fries, 2000). In Ramsey et al.'s (2001) analysis of the use of alternative therapies by 124 older adults (aged 55 to 75 years) with OA, the most commonly used alternative therapies were massage (57%) and chiropractic manipulation (21%).

Few studies provide evidence of efficacy of manual therapies in the treatment of arthritides. de Jong et al. (2003) reported their study as a comparison of high-intensity exercise against physical therapy, but this description is inaccurate. Participants in both the exercise and control groups sought physical therapy treatment during the trial period. Participants in the control (usual care) group were restricted in their capacity to seek physical therapy care: "Patients assigned to the UC [usual care] group were treated by a physical therapist only if this was regarded as necessary by their attending physician." (p. 2416). Furthermore, the precise type of physical therapy was not defined in the study, and included any combination of "hydrotherapy [exercise in water], and different types of

physical therapy (active, passive, or applications)." (p. 2419). A physical therapy consultation might be sought because a participant is injured, because a participant has experienced a disease flare, or for an issue unrelated to the trial or indeed to RA. In de Jong et al.'s study, the distinction between groups was that the exercise group undertook a structured program of high-intensity weight bearing exercise twice per week whereas the control group did not. It is not reasonable to draw conclusions regarding water exercise or physical therapy from the de Jong et al. study.

Hallas et al. (1997) developed a model of arthritis by injecting methylated bovine serum albumin (m-BSA) into the knees and ankles of the rats to induce an auto-immune-like response that degraded articular (hyaline) cartilage. The rats were divided into three groups, and arthritis induced in the hind limbs of the rats in 2 groups. To account for injection trauma to the joints as a confounding factor, normal saline was injected into the knees and ankles of rats in the control group. Rats in one of the arthritis groups were treated with modified manual therapy (active resisted motion and passive stretching of the hind limbs, sustained for 10 seconds, repeated 10 times) and exercise (five minutes running on an exercise wheel) five times per week, for a total of 23 therapy sessions. At the conclusion of the study, the rats with arthritis that received manual therapy and exercise scored better on a range of physical measures than the untreated rats with arthritis. Mean ankle and knee circumference (swelling) was less in the treated group than in the untreated group, and at the knee these differences were statistically significant ($p < .01$). Mean stride length of the treated rats approximated that of the control group, and was significantly longer than that of the rats in the untreated group. Although these results are not automatically applicable to the human situation, they suggest that manual therapy and exercise may be useful to redress some of pathophysiological changes induced by articular cartilage destruction. Because all rats in the treated group received a treatment protocol of

combined manual therapy and exercise, it is impossible to draw conclusions about the relative efficacy of these two therapies.

Many manual therapists consult with people who have arthritic diseases, receive referrals from rheumatologists, and consider the arthritic diseases to be within their field of practice. Professional associations representing manual therapists promote manual therapies to people with arthritic pain (APA, n.d.; CAA, n.d.), sometimes making claims of efficacy in the absence of evidence from clinical trials. Because the absence of evidence does not equal evidence of absence, therapists may argue that when clinical trials are conducted it is likely they will demonstrate the efficacy of manual therapy in arthritis management. Anecdotal evidence from years of continued client use suggests that some improvements in HRQOL may be derived from alternative and complementary therapies. Arthritis Foundations (Australia, USA, UK) and other authorities, however, are reluctant to endorse manual therapies for arthritis due to a lack of scientific evidence demonstrating efficacy, safety, and cost effectiveness (Kramer, 1999; Panush, 1997).

Astin (1998) compared three explanations of why Americans use complementary and alternative medicines: (a) dissatisfaction with conventional treatment, (b) a need to control their own health care, and (c) agreement with the philosophy and ideas of alternative therapies. He found that the most common reason people sought alternative health care was philosophical congruence. These therapies appealed ideologically to clients. Astin's results, interpreted alongside Rao et al.'s (1999) and Ramsey et al.'s (2001) reports that manual therapies (e.g., chiropractic, massage) are among the alternative therapies most commonly sought by people with arthritis, indicate that it is likely that clients will continue to seek manual therapies for arthritis care regardless of the paucity of research demonstrating efficacy or effectiveness.

Physical and Manual Therapies: Possible Mechanisms of Action

Little is known about the effects of physical and manual therapies on healthy joints, let alone joints altered by arthritic disease. Physical and manual therapies are aimed at redressing the physical effects of arthritides. For example, passive joint mobilisation and range-of-motion exercises are undertaken with the same aim: to increase the range of motion available at a joint. These therapies seem sensible approaches to arthritis, but there is little evidence to validate them.

Vilensky argued (1998), consistent with Melzack and Wall's (1965) gate control theory of pain, that "physical stimuli such as superficial or deep heat, massage, and range-of-motion exercise reduce pain because cutaneous afferent impulses inhibit transmission of articular nociceptive impulses in the spinal cord." (p. 180). Vilensky applied the gate control theory particularly to OA, but there appear to have been no studies specifically investigating pain inhibition in OA. Logically, spinal interneuronal inhibition of pain transmission should occur following the stimulation of healthy and diseased joints alike. It seems unlikely that any particular type of arthritis would dampen or enhance the inhibitory process, provided that that joint sensation remains intact (e.g., not neuropathic osteoarthropathy).

Synovial fluid of healthy joints contains high concentrations of hyaluronan (hyaluronic acid), which seems to be important for joint lubrication and maintaining the viscosity of joint fluid (Ogston & Stanier, 1953). Hyaluronan concentrations are lower in the synovial fluid of joints affected by RA than in healthy joints (Balazs, Watson, Duff, & Roseman, 1967), and may be increased by the intra-articular injection of corticosteroids (Pitsillides, Will, Byliss, & Edwards, 1993).

Pitsilledes, Skerry and Edwards (1999) demonstrated the importance of movement and loading on joint function in mammals. They surgically immobilised the left hock (tibiotalar) joints of five female Welsh mountain sheep using internal fixation that

prevented both loading and articulation of the joints for 12 weeks. The sheep were then killed by phenobarbitone injection, and synovial fluid samples aspirated from both the left (immobilised) and right (control) hock joints. Then the joints were dissected, and samples of synovial tissue (membrane) collected from the anterior and posterior compartments of all joints. Synovial fluid samples were assayed to determine the concentration of hyaluronan, and synovial tissue samples were analysed, using cellular staining and microdensitometry scanning, for evidence of enzyme activity (non-specific esterase and uridine diphosphoglucose dyhydrogenase) essential for hyaluronan formation. In the immobilised joints, hyaluronan concentrations were significantly decreased, and cellular evidence of enzyme activity was also lower, than in their corresponding controls. Pitsillides et al. suggested that joint homeostatic mechanisms for the production of hyaluronan are controlled by mechanoreceptors. Despite the obvious limitations of applying a study on the healthy joints of animals to humans with arthritis, it is plausible that physical and manual therapies that mechanically stress joints (e.g., walking, Tai Chi, passive joint mobilisation) may contribute to improved joint function through the production of hyaluronan.

Health-Related Quality of Life

The World Health Organization (WHO; 1958) defined health as "not merely the absence of disease or infirmity, but a state of complete physical, mental, and social well-being." In these terms health is not a commodity readily purchased from a therapist. "This broad and inclusive definition of health transcends the medical model" (Berzon, 1998, p. 4). Similarly all-emcompassing, the term *quality of life* involves all aspects of a person's well-being, including, for example, spiritual and economic well-being.

Health-related quality of life (HRQOL) is a more specific concept, which comprises clients' appraisal of their current physical, social, and psychological functioning, as far as this functioning is influenced by disease, treatments, health care

delivery, and perceptions of ideal function (Berzon, 1998). HRQOL assessment is an individual's subjective evaluation of, and reaction to, illness (Fontaine, n.d.). In this thesis, HRQOL is considered to include current health status, well-being, pain perception, and psychosocial functioning, both in general, and specifically due to arthritis.

The Australian Bureau of Statistics (ABS; 1997) published Australian population norms for the Medical Outcomes Study 36-item Health Survey (SF-36: Ware & Sherbourne, 1992), and included a profile of mean scores for sample of 3490 adults with arthritis. The SF-36 is a generic HRQOL instrument. Australians with arthritis (all forms of arthritis pooled together) perceived themselves, on average, to be less well across each of the eight key aspects of HRQOL assessed in the SF-36 (i.e., physical function, role limitations due to physical problems, bodily pain, general health, vitality, social function, role limitations due to emotional problems, mental health) than their peers without arthritis. This difference between groups persisted even after controlling for the influences of age and sex on HRQOL.

Kaplan (1990) argued that behaviour change is the outcome that matters most in health care delivery. Although Sechrest, McKnight, and McKnight (1996) referred to outcome measures in psychotherapy, their comment applies equally to outcomes in most types of clinical interventions, including physical and manual therapies:

> Actual change in behavior or functioning is critical for assessing treatment outcome, rather than simply inferring change from a metric of uncertain meaning. Effective treatment ought to signify that as a result of undergoing a particular procedure, a person is better in demonstrable ways (p. 1065).

Kaplan (1994) later embellished this argument with an example from the comic strip Ziggy, in which Ziggy climbs a mountain to ask a guru the meaning of life. The Guru responds that "The meaning of life is doin' stuff." When Ziggy queries this response, he is told "As opposed to death, which is NOT doin' stuff." "Doin' stuff" is behaviour and

functioning, and unless treatments influence these variables, then their usefulness is questionable.

Changes in two general categories of outcomes can be expected from health care interventions: functional status and well-being (Sechrest et al., 1996). If people can do more, or feel better (e.g., perceive less pain, feel calmer), after an intervention, then their HRQOL may be said to have improved following the intervention.

Impairment, Disability, and Handicap

Impairment is the physical and organic effects of illness. In arthritides, physical impairment includes pain, loss of range of motion of joints, and atrophy and weakness of associated soft tissues. At simplest, impairment is the direct effects of the disease on the tissues of the individual. In RA inflammatory pannus attacks the joint synovium (membrane lining) and produces tissue level inflammation felt as pain. Impairment may continue for months or years. Over time, some therapies, and the behaviour of the client, may limit or exacerbate impairment.

Disability is a task-oriented measure. A person is disabled if unable to perform individual tasks considered to be within normal adult limits. Disabilities associated with arthritis of the small joints of the hands may include inability to turn door handles, open jars, turn on taps, hold or turn keys, type, write, and so forth. Disabilities may be overcome with the use of aids (e.g., a rubber grip for opening jars).

Impairment and disability are linked, but not so closely, nor directly, as it first appears. The initial supposition is that impairment leads to disability-muscle weakness (impairment) means that I cannot carry heavy shopping bags (disability). Muscle tissue, however, is dynamic and responds to stressors. Muscle that is not stressed through use weakens; muscle that is stressed strengthens. Impairment may lead to disability, and disability may worsen impairment, which in turn, may promote further disability.

A downward spiral of worsening impairment and disability is a common theme across many chronic diseases. Regardless of the disease under investigation, impairment and disability are not always well correlated. Secondary psychological gain, catastrophising, and depression may promote disability in the absence of worsening physical impairment. Determination, strategic goal setting, and social support may promote increased function, or maintain current function, despite increasing impairment.

The distinction between impairment and disability in musculoskeletal pain syndromes has been well documented. Despite stable symptoms, progressively declining function is likely in some people with intractable musculoskeletal pain. Pincus, Burton, Vogel, and Field (2002) completed a systematic review of studies investigating the predictors of chronic disability in people with stable low back pain. These investigators found that psychological and social markers are consistently more accurate predictors of chronic disability than are measures of pain severity, quality, or type. Measures of current function are moderate predictors of future function. The most accurate markers for future disability are the psychosocial "yellow flags" of depression and catastrophising. The vast majority of low back pain is non-specific; the pathophysiology is not well understood and cannot be demonstrated via imaging or laboratory tests. The basic pathophysiology of arthritides is better understood than is that of back pain, but parts of the picture are still unclear. The findings of Pincus et al. (2002) may apply to other chronic, painful musculoskeletal conditions including the arthritides.

Disability and psychosocial factors appear to be better than impairment as predictors of mortality in RA. As previously mentioned, Callahan et al. (1997) followed a cohort of 210 people with RA for five years. Over the course of the study, 37 participants died and four were lost to follow-up. A range of impairment, disability, and psychosocial measures were compared between survivors and non-survivors in both univariate and multivariate analyses. In multivariate Cox regressions, age, co-morbidities, Modified

Health Assessment Questionnaire (MHAQ; Pincus et al., 1983) scores, and other measures of functional status were the best predictors of 5-year mortality. In contrast, laboratory, joint count, and radiographic tests consistently underpredicted long-term outcomes.

Death is a devastating outcome of RA. The death of 37 out of 206 participants is an annual mortality rate of 3.6%. Callahan et al.'s (1997) objective was not to determine an absolute mortality rate, but to identify predictors of mortality. Morbidity was also investigated, and for the 169 participants who survived until the end of the study period, the prospect of five years of pain and declining function may be equally or more concerning than death.

Given the less than clear relationship between impairment, disability, and psycholsocial factors, it would be helpful in therapeutic investigations of arthritides to separate measures of disability (e.g., a behavioural function scale) from measures of impairment (e.g., range of motion). The concurrent use of psychosocial measures (e.g., social support surveys) may provide insight into the mechanisms underlying disability.

Handicap is the social loss that arises from disease, impairment, and disability. A person who is disabled may be unable to continue in employment and experience reduced income (financial handicap), loss of collegial relationships (social handicap), and lack of recognition for past achievements (social handicap). Handicap due to arthritides may be individual or shared, and because it may mean different things to different people, it is particularly difficult to measure.

Psychological Considerations

Arthritic diseases correlate to variable extent with several psychological factors and markers of psychological dysfunction. Well-documented associations are found between physical function and depression (Katz & Yelin, 1993, 1995), and depression and bodily pain (Dexter & Hayes, 1998) in people with arthritis. Furthermore, satisfaction with self and abilities (Katz & Neugebauer, 2001), self-efficacy (Brekke, Hjortdahl, & Kvien,

2001a), internal health locus of control (Norman, Bennett, Smith, & Murphy, 1998), and positive social support (Riemsma et al., 2000) appear to buffer some of the negative psychological correlates of arthritic disease.

In most studies of the association between psychological and physical variables in arthritic disease, a temporal relationship was not established, and so causality cannot be demonstrated (e.g., Dekkers et al., 2001). For example, depression and pain are linked in rheumatoid arthritis. What remains unclear is which causes the other, or even if the relationship is causal. Clinically, sorting out these cause and effect quandaries matters little (Dexter & Hayes, 1998). It is important, however, that physical and manual therapists do not overlook the psychological aspects of arthritic disease. A person with arthritis, who is also depressed, will be inadequately served by a physical or manual therapist who skirts around (or does not recognise) depressive symptoms.

Psychological Constructs Important in Arthritis Care

Working alliance. In counseling psychology, "the quality of the counseling relationship has proved to be the most significant factor in facilitating treatment adherence and positive counseling outcomes." (Petitpas, Giges, & Danish, 1999, p. 344). The working alliance is the collaborative relationship between the client and the therapist, working together to improve the psychological functioning (health) of the client. The quality of the working alliance influences treatment outcomes, partly because a strong working alliance is an important factor in a client persisting with treatment through a plateau or setback.

Mitchell and Cormack (1998) identified that "in most complementary therapies, the patient is seen as an active participant rather than a passive recipient of treatment," and that this perspective is distinct from mainstream therapy, in which "patients may be expected to 'comply' with medical treatment but not necessarily takes steps to promote their well-being through lifestyle changes." (p. 13). This generalisation about mainstream health care

delivery is probably unfair, and not readily applicable to arthritis care. As previously explained, rheumatology literature has been used to argue that improvement in HRQOL is an explicit goal of arthritis care (Kavanaugh, 1999; Simon, 1999), subjective health assessment is an important part of monitoring arthritic disease processes (Pincus, Callahan et al., 1989), and clients should be routinely encouraged to engage in health promoting behaviours such as self-managed exercise (Lorig et al., 1993). On paper, rheumatology has moved towards a working alliance model of health care delivery, but as Flowers and Wolfe (1997) demonstrated, this profession's published literature and current practice may not be quite congruent.

There is dispute among health care professionals as to whether the people they serve should be referred to as *patients* or *clients*. Both words conjure up images: patient has the same Greek roots as *passive*, and implies the neediness and dependence of one who is unwell. Client implies payment for a service, but also identifies the person as a stakeholder in service delivery. Throughout this thesis I have elected to refer to those people who seek health care services as clients, and in so doing, demonstrate my bias-a desire to see people take control of their own health care.

Manual therapies may be considered passive because they are practitioner-driven. Clients attend, and often pay for treatment, but are not responsible for developing, planning, or conducting the therapy. A criticism commonly leveled at manual therapists is that the use of passive therapies may reinforce behaviour patterns of dependency and learned helplessness in clients (Mitchell & Cormack, 1998). This warning is particularly valid when working with clients who, because they experience chronic illness, seek therapy over many years. Mitchell and Cormack (1998) argued that "laypeople always stand in danger of being disempowered by expert professionals," and encouraged practitioners to construct the therapeutic relationships that recognise the "mutuality of the participants." (p. 111). Some dependency is necessary to forge a working alliance. That is,

the client needs to look to the therapist for guidance and trust in the therapist as an investment in the process of health care. If clients do not feel some degree of dependence, they may not continue with treatment. Ideally, clients report consistent improvement over the course of therapy, and cease to receive manual therapy when they and the therapist agree that satisfactory gains have been made. The client who becomes pathologically dependent on a manual therapist may either: (a) not acknowledge gains in functional ability to avoid discharge from care, or (b) resist discharge from care claiming inability to cope with symptoms without the therapist. Pathologically dependent clients may also experience exacerbations of symptoms or declining functional ability if the therapy is curtailed (e.g., therapist or client moves, relationship ceases).

Locus of control. Health locus of control (HLC) is one of the most widely researched constructs in health psychology. Studies of HLC investigate the assumption that people who believe they have control over their own health are more likely to engage in health promoting behaviours and consciously avoid health damaging ones. The Multi-dimensional Health Locus of Control Scale devised by Wallston, Wallston, and DeVellis (1978), can be used to measure beliefs about health control along three dimensions, that is, the extent to which individuals believe that their health: (a) results from their own actions (internal locus of control), (b) is under the control of other powerful people (e.g., doctors; powerful others locus of control), and (c) due to fate (chance locus of control).

Norman et al. (1998) used the Multi-dimensional Health Locus of Control Scale with a stratified sample of 11,632 people representative of the general population of Wales (UK). They identified weak, statistically significant, correlations of each of the HLC dimensions with health behaviours. Belief that health was under one's own control was significantly correlated ($r = .05, p < .01$) with engagement in positive health behaviours. The statistical significance of these small correlations is probably due to the very large sample size, and the clinical meaningfulness of small correlations is open to question. The

effect size for this correlation is small (i.e., when $r = .05$, then $r^2 = .0025$), indicating that variance shared between internal HLC and positive health behaviours is a quarter of one percent.

In Norman et al.'s (1998) study, the strongest correlation observed was a negative relationship between chance HLC and health promoting behaviours ($r = -.16, p < .01$). The effect size for this correlation is small ($r^2 = .026$). It is intuitively logical that clients with strong chance HLC, who see themselves as being under the influence of erratic external forces, might not undertake client-driven positive health behaviours (e.g., arthritis self-management program). Alternatively, they might commence such a program, but discontinue it within a few weeks, explaining with a statement such as 'The program wasn't helping me.' Unfortunately, the small correlations identified by Norman et al. do not clarify the relationship between HLC and health promoting behaviours.

Norman et al. (1998) found a small negative correlation ($r = -.09, p < .01$) between powerful others HLC and health promoting behaviours, but this association is not consistent across other studies of HLC (e.g., Brown, Muhlenkamp, Fox, & Osborn, 1983). Furthermore, because the variance shared by these variables is small ($r^2 = .0081$) the meaningfulness of this correlation is doubtful. Norman et al. qualified their results with the comment that:

> Strong powerful others HLC beliefs may indicate receptivity to health messages endorsed by medical authorities and may lead to the adoption of health promoting behaviours. However, they [people with strong powerful others HLC] may also indicate a strong belief in the medical profession to cure subsequent illnesses and may therefore be unrelated, or even negatively related, to the performance of health-promoting behaviours. (p. 173).

The relationship between powerful others HLC and health behaviour may be dependant upon the quality of the relationship between the client and the therapist (i.e., the working

alliance). Clients with strong powerful others HLC may be more likely to undertake self-management strategies for arthritis care if so encouraged by health care practitioners.

Self-efficacy. Self-efficacy is a measure of clients' perceptions of, or feelings about, their ability to successfully do things for themselves. People with high self-efficacy feel able to influence their own recovery, through action, deliberate rest, and engagement in positive health behaviours. Self-efficacy is a central construct in arthritis care because in this population, self-efficacy is negatively correlated with the severity of pain (Brekke, Hjortdahl, & Kvien, 2001b; Lefebvre et al., 1999), and clients with high self-efficacy display fewer pain behaviours than those with low self-efficacy (Lorig, 1998). Because of the close relationship between self-efficacy and physical symptoms (e.g., pain), Rejeski, Ettinger, Martin, and Morgan (1998) argued that improvement in self-efficacy should be a goal of physical therapy programs for people with arthritis, but physical and manual therapists are not always trained to use psychological interventions aimed at increasing self-efficacy.

Stages of change. Prochaska and DiClemente (1983, 1998) developed a transtheoretical model of change to explain the stages a person moves through to change health behaviours. The stages of change, in chronological order, are: pre-contemplation, contemplation, preparation, action, and maintenance. This model has been used as the basis for developing interventions to effect health behaviour change, both ceasing health damaging behaviours (e.g., smoking, heroin addiction) and commencing health promoting behaviours (e.g., regular exercise).

Kerns and Rosenberg (2000) identified that client-driven (active) therapies may fail to engage a portion of the targeted population, and are associated with high drop-out and relapse rates. They found that in a group of people with chronic pain, the Pain Stages of Change Questionnaire (PSOCQ; Kerns, Rosenberg, Jamison, Caudill, & Haythornthwaite, 1997) could be used to discriminate between those who would complete a course of client-

driven treatment, and those who would not. Kerns and Rosenberg suggested that increased commitment to self-management for chronic pain improved the probability of therapeutic success. That is, people who were further along in the stages of change were more likely to continue with self-management, and those people in early stages of change were likely to drop out.

In a related study, Keefe et al. (2000) specifically applied the transtheoretical model of change to people with RA (n = 103) and OA (n = 74), and reported that 55% of respondents identified themselves in the pre-contemplation and contemplation stages of change. People in these early stages of change are unlikely to participate in client-driven therapies for arthritis. For example, these clients are likely to respond to an invitation to join an arthritis exercise class with comments such as "That's not something I have thought about before," or "I'll consider it and let you know." Information gathering and deliberation need to occur before these clients will be prepared to undertake the life change of commencing a client-driven therapy. Using Prochaska and DiClemente (1983, 1998), and Keefe et al.'s (2000) work as a basis, I have applied the transtheoretical model of stages of change to positive health behaviours for arthritis care (see Figure 2.2).

Figure 2.2 *Application of the transtheoretical model of stages of change to positive health behaviours for arthritis care (based on Prochaska & DiClemente, 1998; Keefe et al., 2000).*

Pre-contemplation. Has not thought about the health behaviour (e.g., Arthritis Self-Management Program; ASMP) specifically. May not even be aware that ASMPs are available. Therapist can mention ASMP specifically to encourage progress to the next stage of change.

⇩

Contemplation. Is thinking about the ASMP. Begins to ask questions like: 'Do you know about…' or 'I really must look into….' Therapist can provide practical information about ASMP to encourage progress to the next stage of change.

⇩

Preparation. Gathers information about the ASMP. Finds out course time, location, cost, etc. May discuss ASMP with trusted friends or therapist to seek support for progress to the next stage of change.

⇩

Action. Enrols and commences ASMP. Clients who commence an ASMP at this stage are likely to complete it.

⇩

Maintenance. Completes ASMP, and continues with learned health promoting behaviours on a regular basis.

Process is repeated for any new health promoting behaviours.

Life Events, Disease Onset, Diagnosis, and Psychological Health

Arthritides are stressful for people because of the life changes associated with most stages of an arthritic disease (Dekkers et al., 2001). The course of an arthritic disease may extend 30 years or more, dominating substantial periods of peoples' lives. Over that time, clients experience symptoms, seek diagnoses, receive diagnoses, accept and disclose those diagnoses to others, seek assistance for pain and declining function, and progressively adapt activities to accommodate these changes.

Life events, both major events (e.g., death of a loved one, marriage, divorce) and daily hassles (e.g., arguments, losing things), affect psychological and physical health, but inter-relationships between these variables are far from clear cut (Dohrenwend, Dohrenwend, Dodson, & Shrout, 1984). Diagnosis with a serious or chronic illness is usually considered a major life event. The process of managing a chronic illness (e.g., appointments with doctors, medication regimes) may contribute to elevated daily hassles.

Dekkers et al. (2001) investigated the relationships between major life events, daily hassles, psychological well-being, and biological markers of disease activity in 54 people (38 women, 16 men) with a recent diagnosis of RA. They found that major life events and daily hassles were significantly correlated ($r = .38, p < .01$), and given that diagnosis with RA was a recent major life event for all participants, this finding raises the question of whether a diagnosis of RA ipso facto increases daily hassles. They also demonstrated significant correlations between major life events and anxiety ($r = .38, p < .01$), and daily hassles and anxiety ($r = .35, p = .01$), but small, insignificant correlations between either major life events or daily hassles with either pain or erythrocyte sedimentation rate (a biological marker of inflammation). Dekkers et al. (2001) concluded that in RA "major life events, and daily hassles were correlated with psychological distress but not with disease activity." (p. 310).

Arthritides may be acute, sub-acute, or chronic in onset. Acute arthritides are easily identified and diagnosed according to ACR criteria, but carry a poor prognosis. Acute onset rheumatic disease can turn a client's world upside down because a client may cease working, be confined to bed, and commence major drug therapy in the period of a few days. People with acute onset arthritis experience considerable distress associated with rapidly ensuing major life changes (Evers, Kraaimaat, Geenen, & Bijlsma, 1997).

Alternatively, the onset of arthritis may be slow, commencing with arthralgia (joint pain) or stiffness. As previously explained, chronic onset arthritis presents diagnostic difficulties, because the symptoms and signs may be non-specific, and serology and radiographic imaging are often negative (Ferrari et al., 1996). There is consensus among rheumatologists that the ACR criteria allow diagnostic certainty (Ferrari et al., 1996), but adherence to these criteria forces clients to wait until their clinical signs are obvious before diagnoses are confirmed.

Prognostically, chronic onset arthritis is better than any other presentation because joint damage occurs later in the disease, and sometimes may be prevented. Clients with chronic onset arthritides have time to adapt to major life events because these changes occur slowly. These clients, however, may complain that it took a long time for a diagnosis to be found. The uncertainty of the "waiting game" has negative psychological consequences, including self-doubt ("maybe it's all in my head") and fear of the unknown ("what if it's…?"), which may lead to catastrophising, doctor blaming, or avoidance of doctors (a form of denial). The process of continuing to seek a diagnosis may increase daily hassles. Given the conclusions of Dekkers et al. (2001), it is in interest of clients' psychological well being that arthritic diagnoses should be made accurately, and as early in the disease course as possible, regardless of the nature of symptom onset. Clients with RA are likely to be prescribed powerful drugs with many side effects soon after diagnosis, and

are likely to experience rapid life changes, and psychoemotional distress associated with these changes.

Pain

Pain is a highly subjective phenomenon, and may produce emotional as well as physical responses. "Psychological and physical pain have similar phenomenological structures. Both are felt bodily… entail at least temporarily a disabling of a potentiality for action" (Kugelmann, 2000, p. 305). There is no single type of arthritic pain. Pain is a feature of all types of arthritic disease, but is not a consistent marker of any one physiological or pathological process (Klippel, 2001). Kugelmann conducted a qualitative investigation of pain, and demonstrated that the experience of pain differed little according to cause, making it questionable to differentiate between biological and psychological pain. Hadler (1998) applied this argument specifically to OA of the knee: "progression of radiographic OA of the knee is slow, and not predictable, whereas symptoms can exacerbate or regress, regardless of radiographic presentation. Clearly, knee pain is the malady, not OA."

As mentioned earlier, Heiberg and Kvien (2002) surveyed 1024 Norwegians with RA. These participants reported that pain was their highest priority for health improvement. The preference for pain as the most desired area of health improvement was "explicit and consistent across all subgroups" (p. 395). It follows that pain is probably the central feature of reduced quality of life for people with arthritis.

A surprising finding in Heiberg and Kvien's (2002) survey was that one-third of those participants with a preference for improvement in pain did not use analgesic medication. Reasons for this finding were not explored within the study, but many medications used in arthritis management have substantial side effects. Pharmaceutical control of pain comes at a price. For example, NSAIDs are prescribed to reduce inflammation within joints, and thereby, reduce pain. These drugs are associated with the

development of upper gastrointestinal tract toxicity (e.g., nausea, ulcer formation, upper gut hemorrhage). When age is accounted for, dyspepsia (nausea) occurs approximately twice as commonly in people taking regular NSAIDs as in the general population (Hogan, Campbell, Crutcher, Jennett, & MacLeod, 1994; Smalley, Griffin, Fought, & Ray, 1996). Dyspepsia is a symptom that decreases quality of life (Parr, Darekar, Fletcher, & Bulpitt, 1989), and in using NSAIDs to control pain, people with arthritis might improve one aspect of HRQOL and sacrifice another.

Minnock, FitzGerald, and Bresnihan (2003) surveyed 58 women aged between 40 and 60 years, who were diagnosed with RA at least three years prior. Using the Arthritis Impact Measurement Scales 2 (AIMS2: Meenan et al., 1992) participants were asked to rate the impact of RA on 12 health status domains. Most respondents (82%) attributed their health impairments entirely or largely to RA, and the largest median impairment (5.9/10) was reported in the pain dimension. Minnock et al. (2003) acknowledged that many factors have been found to influence health perceptions, including: "age, sex, socioeconomic status, education, marital status and culture" (pp. 998-999), and although they collected demographic data, they did not attempt to control for the effects of these variables. Rather, they argued that these unique and individual influences on health perceptions are important because through the lens of these factors clients "assign weight, importance and meaning to symptoms" (p. 999). Regardless of confounding factors, pain is a symptom of great concern to clients.

Pain is related to several areas of psychological health, and is consistently positively correlated with depression in people with arthritis (Salaffi, Cavalieri, Nolli, & Ferraccioli, 1991; Wolfe & Hawley, 1993). In some studies the strength of this correlation is such that depression may more accurately predict pain variability than disease progress markers (e.g., radiographic changes, joint counts, ESR; Dexter & Hayes, 1998).

The type and stage of arthritis may influence the nature of pain. For example, people with RA experience episodic flaring of symptoms, in which painful joints become tender, hot, and red. The majority of people with arthritic diseases experience chronic pain as well as episodes of acute pain, and in due course, may adopt pain behaviours associated with chronic pain states.

Pain Behaviour

Avoidance of pain is a basic human response. Retraction from a painful stimulus is a reflex that is preserved even in some unconscious states. In arthritic disease, pain is often chronic but variable, and may be aggravated by certain activities. A particularly common pain behaviour of people with arthritic disease is to avoid those activities that aggravate pain. Initially, this pain behaviour seems logical and reasonable, but avoidance of an activity may worsen arthritis over the long term despite the short-term benefit of reduced pain.

Despite evidence that regular, low impact exercise (e.g., walking, water aerobics, Tai Chi) is of long-term benefit for pain (Maurer et al., 1999; Thomas et al., 2002), some people with arthritis experience increased joint pain when attempting activities that mechanically stress joints (Lorig & Fries, 2000). When daily activities aggravate pain, negative self-talk and reluctance to exercise may follow. For example, people with arthritis may comment that "It hurts just putting on my sports shoes, how will I ever manage to go for a walk?" or "I can't turn door handles or taps without pain. I couldn't possibly use a hand held weight for exercises." The problem with this pain behaviour is that lack of physical activity leads to further physical deterioration such as reduced muscle strength and cardiovascular fitness. Furthermore, avoidance of an activity may not resolve pain.

Multon et al. (2001) tested the effects of stress management training on pain behaviours in 131 people with RA. Although participants in the intervention group reported reduced pain and reduced stress, their pain behaviours (e.g., grimacing, active

rubbing of muscles, sighing) did not differ significantly from the non-intervention or attention control groups. Results suggested that these pain behaviours are not necessarily a direct response to pain, but a more complex pattern of behaviours, a product of "disease activity, age, and disease duration" (p. 122). Multon et al.'s work demonstrated that pain behaviours become ingrained over time.

The Sick Role: Joint Protection as a Case Study

Adoption of the sick role is a psychobehavioural part of the illness process. For a relatively uncomplicated example, adoption of the sick role occurs when a person with an acute viral infection takes to bed for a couple of days. The behaviour (bed rest) is an illness behaviour, and it marks the person as sick, but it also affords recovery. The sick role is not so clear in chronic illness.

Adoption of the sick role in arthritic disease is much more complicated because illness behaviour does not necessarily promote recovery. Regardless of illness behaviour, people with arthritic diseases are likely to remain sick. Strategic use of illness behaviour may prevent deterioration, but it will not reverse the disease process. Poorly used illness behaviour may exacerbate arthritic disease. It is helpful for people with arthritides to understand the sick role and adopt it in a healthy manner.

Joint protection is an illness behaviour widely promoted for people with arthritis. In a joint protection program, the sick role is used for the purpose of preventing joint damage. Joint protection comprises avoiding joint movements that are particularly painful, that place mechanical stress on joints, and that render joints vulnerable to injury (Mahowald & Dykstra, 1997). Gait aids (e.g., walking sticks) and orthotic devices such as splints may be used to prevent loading of joints. These highly visible aids label the client as sick.

Joint protection is an intuitively logical therapy. If a joint can be protected from mechanical stress, and thereby from inflammation, that joint is less likely to deteriorate. Hammond, Lincoln, and Sutcliffe (1999) conducted a cross-over trial comparing two

education programs of joint protection in 35 people. Results indicated that adherence to joint protection strategies was greater following one educational strategy rather than the other, but no significant physical or psychological improvements were identified at any point post-intervention. Measures of pain, functional disability, grip strength, self-efficacy, and helplessness did not alter significantly from the pre-intervention state. If joint protection education does not improve physical or psychological well-being, then how it is taught is probably not important. The question might be "Why is it taught?"

When the sick role is publicly visible, as it is often in joint protection, at least two possible reactions may follow. Some clients abhor the idea of being seen as sick, reject the sick role outright, deny any benefits the sick role may offer, and continue to engage in activities that may worsen their health. For example, people may turn down the opportunity to use a disabled parking permit and aggravate their condition by having to walk greater distances than necessary for activities of daily living (e.g., shopping for food). Persistence with health damaging behaviours is not a likely explanation of Hammond et al.'s (1999) findings, because they measured adherence to joint protection and found it to be increased when strong educational strategies were employed.

Other people enjoy the benefits of a visible sick role, and may favour the sick role in order to reap such benefits (e.g., use of a walking stick may result in preferential treatment in shopping queues). Adoption of the sick role is not usually a deliberate manipulation to seek benefit. Rather, when secondary gains arise from the sick role, the client's motivation to adopt the sick role may increase. A client with pain and swelling in her small finger joints, who happens not to enjoy her job as a word processor due to interpersonal conflict in her workplace, may experience considerable secondary gain (e.g., avoiding the interpersonal conflict) when she takes time off work for her pain. She is likely to continue this behaviour. Similarly, family, friends, and concerned loved ones may leap to the assistance of a person with arthritic disease, taking on unpleasant duties usually done

by that person. This behaviour affords secondary gain to the sick role and decreases the likelihood of relinquishing that role (Gatchel & Epker, 1999). Possibly Hammond et al.'s (1999) investigation of joint protection showed no observable benefits because joint protection programs that emphasise the sick role may lessen total physical activity, and be compromised by secondary gain from the sick role.

Depression

As previously mentioned, depression is common in people with arthritides. Depression rates in people with OA and RA do not differ substantially from those in other populations with chronic diseases, but more people with arthritis are depressed than in the general population (Hawley & Wolfe, 1993; Wolfe & Hawley, 1993).

Pain and depression are covarying phenomena in arthritic diseases (Salaffi et al., 1991; Wolfe & Hawley, 1993). It is unclear whether arthritis contributes to depression, or depression to arthritis, or both. There is overlap between the symptoms associated with arthritides and symptoms of depression (e.g., fatigue, insomnia, weight loss; American Psychiatric Association, 2000). Bodily pain is an inherent feature of arthritis, but pain, regardless of cause, is described in bodily terms by most people (Kugelmann, 2000). Regardless of whether the client is a depressed person who has arthritis, or a person with arthritis who becomes depressed, the symptom pictures interplay (Wolfe & Hawley, 1993). Pincus and Williams (1999) commented on the conceptual difficulties of measuring depression in people with bodily pain (diseases or pain syndromes) because of the overlap among these variables. Many self-report measures for depression contain somatic items (e.g., bodily pain), which may inflate depression scores in people with pain.

Depression following a diagnosis of arthritis often appears exogenous, that is external to the physiology of the individual, arising as a psychological consequence of physical and social loss. Because the pathophysiology of the arthritides is poorly understood, there is room to question whether associated depression may be endogenous

(Scammell & Brown, 1998), possibly a response to some unidentified biochemical mediator. Pain stimulating cellular secretions, cytokines, have been shown to produce the symptoms of major depression (Melzack, 1999). This theory of endogenous depression in people with arthritis may help explain why depression is so common in this client group, and why depression does not always resolve in those people who regain physical function (Dexter & Hayes, 1998). To offer therapy only to ameliorate joint pain may be an example of suboptimal care. It is important to identify and treat depression in people with arthritis, because depression may aggravate pain, compromise activities of daily living, and promote social withdrawal. Depression can exacerbate many of the negative psychosocial consequences of arthritis. Clients have a far greater chance of success in managing their arthritis if they are not concomitantly depressed (Dexter & Hayes, 1998).

Antidepressant medications are sometimes used in the management of arthritides, particularly when depressive symptoms include disturbed sleep patterns. Adequate sleep is necessary for pain control in arthritis (Lorig & Fries, 2000), and poor sleep patterns can start a downward spiral of pain, causing fatigue and reduced function, which leads to altered levels of daily activity and to further disturbances of sleep patterns. Antidepressants may help break this cycle, and even clients who do not recognise their own depression may be willing to use low dose antidepressants to rectify sleep patterns (Ferrari et al., 1996).

Anxiety

Conceptually, anxiety and depression differ, but clinically, there can be significant symptom overlap between these conditions (American Psychiatric Association, 2000). Much of the time anxiety and depression occur together (Dexter & Hayes, 1998). Anxiety is to be expected in people with arthritis as they worry about their future health, wellbeing, and function (Lorig & Fries, 2000). Edwards, Mulherin, Ryan, and Jester (2001) reported that people with RA were particularly anxious about intra-articular corticosteroid injections and first hospital admissions.

Anxiety is associated with biochemical changes, including increased cortisol and noradrenaline secretion, which may contribute to chronic pain (Melzack, 1999). Anxiety also contributes to immune system suppression, although the mechanisms that connect immune suppression to chronic pain are not well understood.

There is little evidence that mild anxiety exacerbates arthritis, except if concurrent depression aggravates pain. The astute clinician may use or induce mild anxiety, associated with the contemplation stage of change, to motivate the client to manage their disease responsibly in order to shore up some certainty for the future (Prochaska & DiClemente, 1998). For example, a client who is worried (mildly anxious) about future muscle function may be encouraged to undertake regular strengthening exercises. That said, tapping into health related anxiety to motivate clients to change should be used with some caution, because of recent evidence that the process of thinking about personal health risks may increase anxiety and the need for reassurance (Lister, Rode, Farmer, & Salkovskis, 2002).

Moderate to severe anxiety may compromise the care of a person with arthritic disease by limiting engagement with the processes of management. The person who is worried about the side effects of medication may either not take medication as prescribed, or identify side effects in themselves, whether or not such side effects are actually present (e.g., catastrophising). Because of the potentially stifling nature of moderate to severe anxiety, it needs to be identified and treated as part of the overall management of arthritis.

Loss and Grief

General losses associated with arthritides include loss of bodily function and body image, loss of social role, and loss of social support. These losses are experienced psychologically as any significant loss, and may produce grief responses. Grief may involve shock, labile emotions, depression, physical symptoms of distress, guilt, hostility, resentment, and an inability to continue usual activities. Because these losses may be protracted, grief may be experienced over a prolonged period. Individuals also experience

specific and unique losses (e.g., a musician may grieve the loss of dextrous hand function required to play the piano).

Loss of Bodily Function

Over the long term, all arthritides reduce body function and produce impairment (Lorig & Fries, 2000). Physical impairments consistent in arthritis are loss of joint range of motion and loss of muscle strength. These impairments lead to reduced capacity for activity and exercise, which produces further impairments such as loss of cardiovascular endurance and lowered bone density. Loss of bodily function in arthritis can be delayed by early and judicious drug therapy (Symmons et al., 1998), but it cannot be prevented altogether. Even people with mild or static forms of arthritis will eventually face issues associated with loss of bodily function, even if it occurs as a result of the interaction of mild arthritis with the frailty of old age (Philbin et al., 1995).

Turner, Barlow, and Ilbery (2002) interviewed 12 ex-professional football (soccer) players about their experiences of developing OA. Five of the 12 participants had retired early, from all paid employment, not just football, due to OA. Recurrent themes emerging from these interviews were of physical impairment producing loss of bodily function and negative social consequences, including reduced work capacity, and often, lowered income, and loss of both self-image and self-worth.

Loss of Social Role

Social role is partly determined by physical function and work capacity (Turner et al., 2002). Social roles allow people to identify their places in society, and to contribute to the structure and life of the community. Because some social roles attract status people may draw self-esteem from them.

People with arthritis often experience a decline in social roles because the damage to their joints, weakness and atrophy of their muscles, and fatigue and lack of endurance that characterise arthritis prevents them from participating in the physical tasks required in

such roles. Social roles that may diminish in this way range from manual-based employment to caring for family members. Loss of social roles may occur slowly, with a gradual realisation that the person with arthritis is not keeping up with everyone else. One of Turner et al.'s (2002) ex-footballers described his gradual loss of work-related social role thus:

> I have got an FA coaching badge, which has got me a [sic] work over in Norway, Iceland and South Africa, and I coached a few clubs here [UK]. But nobody wants you with a bad limp. You know it is embarrassing. Like if you are a coach you've got to demonstrate. You don't want to be stood there with a walking stick. So in 1992, I had to really call it a day (p. 293).

People with arthritis, like almost everyone else, are reluctant to reduce involvement in social roles they enjoy, and so they may try to prevent these losses by modifying the way they perform physical tasks. This strategy is successful in many situations, and clinicians are well placed to assist clients in adapting activities (Lorig & Fries, 2000).

Barlow, Wright, and Kroll (2001) conducted, and assessed the effectiveness of, the Into Work Personal Development (IWPD) with people with arthritis (all types). The IWPD program is aimed at preventing work disability by reducing the internal and external barriers to employment presented by disease. People with arthritis ($N = 79$) were divided (not randomly) into intervention and control groups, and assessed pre and post delivery of the program via self-report questionnaires and in-depth interviews. Participants in the IWPD program demonstrated significant decreases in measures of anxiety, depression, negative mood, and improvements in positive mood, satisfaction with life, and self-esteem. Participants described their changed outlook in detail in the interviews. An omission in Barlow et al.'s study is that they did not measure how many participants actually entered work of any kind. Furthermore, not all of the post intervention gains were maintained at 6-month follow up. Removing perceived barriers to employment for people with arthritis is

only part of the issue. Physical capacity to do work must also be addressed if people with arthritis are to enter, or stay in, gainful employment.

Economic Loss

Due to the diversity and far reaching effects of arthritides, broad-based estimates of the public health impact of arthritic diseases are difficult to ascertain. Kaplan et al. (1992) argued that the costs of osteoarthritis might be underestimated by commonly used public health measures (e.g., mortality rate) because many people with OA live normal life spans. Measuring only mortality rates may not fully capture the impact of disease related dysfunction and loss. Comparing the HRQOL of people with arthritis against that of the general population may give some measure of the broad social, physical, and psychological costs of arthritis.

Economic costs of arthritis are both direct (e.g., money spent on medical care, including drugs, hospital admissions, consultations with health care practitioners) and indirect (e.g., wages lost through reduced capacity for paid work). Yelin and Callahan (1995) reported that the economic impact of all forms of arthritis on the economy in the USA during 1992 was $15.2 billion USD in direct medical costs and $49.6 billion USD in indirect costs. Arthritis seriously impairs work ability and leads to reduced individual and household incomes. Meenan et al. (1981) found that people with RA had a 50% decline in earnings over a 9-year period, accounting for an average 37% reduction in family income.

Lapsley, March, and Tribe (2001) conducted an investigation to determine the out-of-pocket expenses associated with living with OA. Because the study was conducted in Sydney, all costs were reported in Australian dollars. Women spent significantly more than men on arthritis care, a mean of $537.15 per annum compared with $258.31, and higher expenditure was also related to more advanced disease. Most of the additional expenditure by women was on prescription and non-prescription medications and private services. It is reasonable, in the Australian health care context, to assume that private services were

allied health care, such as physiotherapy or osteopathy, which, at the time of the study, were not covered under the Australian government's universal free access medical scheme (i.e., Medicare). Lapsley et al.'s data are consistent with the general data on the use of health services in Australia; that women use both public and private health services to a greater extent than men (ABS, 2002). Against the backdrop of the Australian health care system that provides heavily subsidised health services and a pharmaceutical benefits scheme, Lapsley et al.'s findings emphasise the personal economic cost of OA.

Loss of Social Support

Social roles, in most cases, offer social support. Employed people have the social role of employees, and by meeting other people in the workplace are often afforded the social support of colleagues. People who are unable to maintain a social role may experience reduced social support. Rarely are communities so generous as to support those who do not contribute to the life of the community, so a corollary of being unable to contribute is loss of social support. In Lapsley et al.'s (2001) study of the costs (including social costs) of OA, 33% of women identified reduced opportunities for sporting and outdoor activities as a mode by which OA affected family and other close relationships.

Social support may be positive if it provides affirmation or timely assistance, or problematic if it is neither desired nor needed, or if the support offered does not match the client's needs. Riemsma et al. (2000) demonstrated in a study of 229 people with RA, that problematic and positive social support each explain a portion of the variance in depression, but in opposite directions. Positive social support counters feelings of depression, but problematic social support correlates positively with depression. Problematic and positive social support also moderate each other, such that "the negative aspects of problematic support may be partly diminished by positive support" (p. 221).

When people with arthritis become socially disabled, they may seek social support from a small circle of family members and intimate friends. Sometimes professional carers

and clinicians are recruited into this social network, but the burden of social support is primarily borne by those who live with the individual. Burnout and illness are common amongst those who care for chronically ill people with arthritis (Pollard, 2000).

Body Image

It is intuitively logical that potentially disfiguring arthritides might influence clients' body image, but this topic has received little coverage in the published literature. Since 1987, six English language studies on the effects of arthritides on body image have been published in peer-reviewed medical journals, and four of these studies recruited female participants only. One participant in Turner et al.'s (2002) study of men with OA mentioned feelings of embarrassment, but none spoke explicitly of body image. Lorig and Fries (2002) discussed in detail many of the feelings that clients with arthritis report, but did not mention distress over body image. It seems scientists and practitioners alike, tend to overlook the negative effects of arthritides on body image, especially for male clients.

Body image is linked to arthritic disease process, and also to age and self-esteem, but the relationships between these variables are unclear. People with RA rarely describe themselves as "attractive" (Skevington, Blackwell, & Britton, 1987), however, this finding is not solely a product of arthritis. Healthy undergraduate students do not commonly describe themselves as attractive. Attractiveness tends to be included in the self-concept of people with high self-esteem, and is unlikely in people who are in pain, or chronically ill.

Cornwell and Schmitt (1990) compared the perceived health status, self-esteem, and body image of women with RA or systemic lupus erythematosis (SLE) with healthy controls, and found perceived health status significantly related to self-esteem, but not to body image. Women with SLE had lower mean body image scores than women in the other two groups. A client with SLE typically develops a red, butterfly shaped facial rash (across cheeks and nose), and may develop photosensitive rashes on the face and arms. These highly visible signs of arthritic disease present a considerable challenge to even the

most robust body image. According to Cornwell and Schmitt (1990), a woman with SLE may see herself as quite healthy yet have poor body image, and a woman with RA may see herself as sick but have positive body image.

Using semi-structured interviews and a battery of questionnaires, Gutweniger, Kopp, Mur, & Gunther (1999) investigated the various aspects of body image in 40 adult women with RA. They concluded that morning stiffness was an important influence on women's perceptions of their bodies. Women with high levels of morning stiffness were more anxious about their health, and experienced health-related sexual problems.

Vamos (1990) surveyed 80 adult women with RA to determine body image concerns, hand adornment and concealment behaviours, and desire for hand surgery. Factor analysis and two-stage general linear modelling was used to determine that body image, especially negative feelings about their hands, was a significant predictor of these women seeking hand surgery, and remained so after accounting for age, grip strength, and duration of arthritis. Poor body image may motivate clients to select therapies that improve physical appearance (e.g., reconstructive surgery), and, as a covert motivator for seeking aggressive, and potentially risky, therapies, is worthy of considerable attention.

Psychological Intervention in Physical and Manual Therapies

Many physical and manual therapies have been inadequately researched, and because of the physical contact component of these therapies, they do not fit well into the double-blind randomised clinical trial model of efficacy research (Chambless & Hollon, 1998). This issue makes it difficult to determine the effective ingredients in the therapeutic encounter.

The therapist-client relationship may be one of the prime therapeutic aspects of treatment (Mitchell & Cormack, 1998; Petitpas et al., 1999), and for clients with arthritic disease, who experience loss of social support, this aspect of therapy is likely to be particularly important. For people not ready to adopt self-management approaches,

practitioner-driven manual therapies may offer rational, but largely untested, approaches to pain management. The purpose of physical and manual therapy in arthritis care is at least partly as a vehicle of communication with the client, to encourage the client to move towards self-management.

Physical and manual therapists are ideally placed to encourage clients to see things in a new light. Personal discussions with clients often occur during treatment sessions. The physical or manual therapy provides a setting for the discussion, and some distraction if the discussion becomes too sensitive (Kolt, 2000). Therapists' language, and behaviour towards clients can be used to reinforce discussion of psychological issues.

Physical and manual therapists are in a powerful position to influence assumption or rejection of the sick role. The sick role is to be encouraged in so far as it prevents progression of disease and protects against further joint damage, however, the sick role is to be discouraged when its adoption would allow disease progression or the development of comorbidities. A delicate balance between simultaneously adopting and rejecting the sick role is required, so that the sick role might be used to promote health not undermine it.

The relationship between exercise (physical activity) and health, in both clinical and nonclinical populations, has been widely researched and well documented (Paluska & Schwenk, 2000). Physical activity is associated with improvement in key markers of psychological well being and HRQOL, including mood, self-perception, health perception, and self-efficacy (Rejeski et al., 1998), anxiety, depression, and subjective well-being (Morgan, 1997). The exact processes by which exercise promotes changes in psychological well-being and HRQOL are uncertain, but the value of exercise for enhancing both mental and physical health is well supported by research.

Physical inactivity leads to substantial negative effects on health, including muscle weakness, atrophy, and fatigue. Leading a sedentary life may compound the loss of quality

of life associated with chronic illness. Inactivity is well correlated with depressed mood, reduced sociability, and a decline in well-being (Morgan, 1997).

Explicit psychological interventions demonstrated to be effective in arthritis care include relaxation, electromyographic (EMG) biofeedback, counseling, and cognitive-behavioural therapy (Astin, Beckner, Soeken, Hochberg, & Berman, 2002). In a meta-analysis of these psychological interventions for RA, Astin et al. found small to medium significant pooled effect sizes (Cohen's *d*s) for the effects of psychological interventions on pain (0.22), functional disability (0.27), psychological status (0.15), coping (0.46), and self-efficacy (0.35). Effects on coping and self-efficacy were maintained at 8.5 months follow-up. An important trend emerging from Astin et al.'s work was that psychological interventions appeared to be more effective in clients who had shorter illness duration.

Measurement and Statistical Issues

Measuring Health-Related Quality of Life

Quality of life measures are increasingly used as indicators of effectiveness in clinical trials. Although HRQOL outcome measures do not offer an explanation as to the mechanism of therapeutic action, they can provide broad-based measures of how a person feels in the physical, mental, and social aspects of life before, during, and after an intervention (Goldfried & Wolfe, 1998). Schug (1996) argued that such measures are useful when, as in this project, researchers are interested in measuring change over time and participant follow-up, and when sociological or humanistic views of health are preferred.

As previously discussed, pain is of considerable importance to people with arthritis, who consistently identify pain as a high priority, both as a dimension in which arthritis impairs health status (Minnock et al., 2003), and the dimension in which health status improvement is most desired (Heiberg & Kvien, 2002). Physical function, psychological well-being, and social support, are also aspects of HRQOL of particular importance in

arthritis care. Assessment of general health includes perceptions of well-being and opinions of health status, both in isolation, and in comparison to the health of others.

Schug (1996) and Hyland (2003) maintained that the idea of a "best" HRQOL instrument is a fallacy. Each data collection tool has strengths and weaknesses, and is best selected according to purpose. There is consensus among researchers that a combination of disease-specific and generic instruments provides the most robust package of tools for getting at most of the aspects of health relevant to a project (Fontaine, n.d.; Guyatt, 1993; Schug, 1996). In this thesis, I selected HRQOL instruments to assess the domains of general health, arthritis-related function and disability, psychological and social well-being, and pain. The particular HRQOL instruments used in this thesis are described in detail in Chapter 3.

Statistical Concerns

A test of statistical significance is the usual process to compare treatment outcomes (efficacy) in arthritis research. Conclusions regarding efficacy may be misleading if drawn solely from tests of statistical significance (Andersen & Stoové, 1998). In studies with small sample sizes, differences between intervention and control groups may not be statistically significant due to low statistical power, yet such differences may be clinically important (Speed & Andersen, 2000). Because the meaning of improvement is subjective (Beaton et al., 2001), small changes may be important to individuals. In these circumstances, it is unjustifiable to equate "no statistically significant difference" with "no difference." The cost of doing so may be a Type II error, that is, an effective therapy is dismissed as ineffective.

The reader is better able to make a judgement of the practical importance of an intervention, statistically significant or not, if the effect size is also reported (Cohen, 1988). Fifteen years ago Kazis, Anderson, and Meenan (1989) argued in favour of the systematic

use of effect sizes in arthritis research, but their recommendation has been largely unheeded.

Tests of significance are ingrained in arthritis research, and are unlikely to be abandoned. Statistical significance has many determinants, such as sample size, variability, directional hypotheses, range restrictions, and so forth. Whether statistical significance is achieved also varies according to the sensitivity of the measures used to determine responses to treatments. Anderson et al. (2003) demonstrated, via a series of simulation studies, that data-driven measures are more sensitive to change (response to therapy) than a-priori dichotomous measures (e.g., ACR20, EULAR improvement criteria; See Table 2.4). Because data-driven measures are more sensitive, fewer participants (smaller sample sizes) are required in data-driven studies to achieve adequate power.

Anderson et al. (2003) stated that a shift to data-driven methods would sacrifice trial standardisation, but an alternative possibility is that ACR, EULAR, and other authorities, might agree upon a set of outcome measures to be used in data driven arthritis research. Regular reporting of effect sizes in arthritis research, particularly in studies investigating issues such as HRQOL, would allow results to be compared across studies, and thereby allow comparison of the relative merits of interventions.

In this thesis, the ACR20 and EULAR improvement criteria have been excluded in favour of data-driven methods. Estimates of significance are presented along with indicators of effect size as combined tools for judging whether an intervention is effective. A discuss of the clinical meaningfulness of effect sizes in included. As Cohen (1990) stated:

> The primary product of research is one or more measures of effect size, not *p*.... Effect size measures include mean differences (raw or standardized), correlations and squared correlations of all kinds, odds ratios, kappas–whatever conveys the

magnitude of the phenomenon of interest appropriate to the research context. (p. 1310).

Limitations of these Studies

This research was conducted with severely limited funds. The expense and logistics of conducting clinical trials restricted the number of people who could receive treatment. As discussed previously, small sample sizes present problems in interpretation of both significant and non-significant results. In this thesis, the results are interpreted primarily in terms of clinically meaningful effect sizes, and not statistical significance, due to the small sample size and increased probability of Type II errors. Inferential statistics, and corresponding effect sizes, are presented as suggestions of effectiveness that need to be confirmed by future studies with larger samples.

CHAPTER 3

PILOT STUDY: USING HEALTH-RELATED QUALITY OF LIFE INSTRUMENTS

Introduction

Arthritic diseases take considerable toll on individuals' health-related quality of life (ABS, 1997; CDCP, 2000). An understanding of health-related quality of life may include assessment of physical function, activity and mobility, pain (severity and nature), and psychological well-being (Fontaine, n.d.; Guyatt et al., 1993).

Living with a chronic and potentially disabling condition, such as RA or OA, often involves some adjustment in activity levels. Exercise is widely advocated as a component of the management of arthritic disease (Lam & Horstman, 2002; Lorig & Fries, 2000; Sobel & Klein, 1989), but clearly, many people with arthritis do not partake in regular exercise. Mobility and fatigue-related problems in arthritis lead some individuals to cease recreational and other physical activities altogether. Other people are not psychologically ready to consider, begin, or maintain, a regular exercise schedule (Keefe et al., 2000; Prochaska & Velicer, 1997).

Pain is a prominent feature of arthritic disease, and a high priority for clients when making decisions about their health care (Heiberg & Kvien, 2002). Pain is a complex, subjective phenomenon (Melzack, 1975), influenced by gender, age, education, and culture, and has both physical and psychological effects (Wells, Frampton, & Bowsher, 1996).

Arthritic diseases are closely related to several psychosocial health variables. Physical function, depressed mood, and bodily pain (Dexter & Hayes, 1998; Katz & Yelin, 1995) covary in people with arthritis. Satisfaction with self and abilities (Katz & Neugebauer, 2001), self-efficacy (Brekke et al., 2001a), internal health locus of control (Norman et al., 1998), and positive social support (Riemsma et al., 2000), however, appear to buffer some of the negative psychological correlates of arthritic disease.

The physical and psychological sequelae of arthritis are complex, and probably interdependent. Pain may produce physical disability, particularly limited mobility, which in turn produces social disability and handicap, which compromises well-being. Disuse of joints and muscle because of physical disability in turn produces muscle atrophy, bone density loss, and may lead to further pain, perpetuating a cycle of reduced HRQOL (Lorig & Fries, 2000).

In order to assess the function, pain, and well-being components aspects of HRQOL, a battery of questionnaires assessing these domains was selected for use in this thesis. Behaviour change is a central outcome of health care delivery (Kaplan, 1990). It makes good sense in clinical studies of people with arthritis, therefore, to use data collection tools that measure change in the aspects of behaviour predominantly affected by arthritic disease. Client self-report measures are at least as useful as traditional laboratory, radiographic, and physician-reported clinical measures to assess disease progression in arthritis (Houssien et al.,1999; Pincus, Callahan et al., 1989), and are powerful predictors of important health care outcomes and social sequelae of arthritic disease (Callahan et al.,1992). Self-report measures are cheaper than laboratory, radiographic, or physician-reported tests, are non-invasive, and are easy to administer (Wolfe & Pincus, 1999). Importantly, self-report measures can be used to assess outcomes that are meaningful to clients (e.g., pain; Heiberg & Kvien, 2002; Minnock et al., 2003) and provide subjective data (e.g., descriptors of pain) that are omitted in other tests (Melzack, 1975, 1987).

The purpose of this pilot study was to test the package of data collection tools in a small sample of people similar to the prospective participants in the planned clinical studies. This pilot study was necessary because four of the data collection tools (questionnaires) were developed and validated in North America, and for three of these tools Australian versions do not exist.

Method

This pilot study was the measurement of HRQOL at a single point in time, in people with arthritis who satisfied the inclusion criteria for Studies 1 to 3, using the data collection tools proposed for those studies. An invitation to participate in the pilot study was distributed to Arthritis Victoria water exercise leaders as a notice within a regular Arthritis Victoria bulletin.

Participants

Four adults with arthritis volunteered for this pilot study. All reported that they satisfied the eligibility criteria for the clinical studies and were: (a) able to walk unassisted for 20 meters, (b) able to undress to their underwear unaided, and (c) literate in English. Participants were aged between 62 and 78 years. All participants regularly engaged in water-based exercise, and led water exercise classes as volunteers for Arthritis Victoria.

Measures

The data collection booklet comprised five questionnaires and surveys: (a) Arthritis Impact Measurement Scales 2 (AIMS2; Meenan et al., 1992), (b) Short-form McGill Pain Questionnaire (SF-MPQ; Melzack, 1987), (c) Medical Outcomes Study 36-Item Short Form Health Survey (SF-36; Ware & Sherbourne, 1992), (d) Medical Outcomes Study Social Support Survey (MOS-SS; Sherbourne & Stewart, 1991), and (e) Medication Use Survey. Four of these five data collection tools are well recognised, widely used tools, available in the public domain. I developed the Medication Use survey specifically for the studies that constitute this thesis.

AIMS2. The Arthritis Impact Measurement Scales 2 (Meenan et al., 1992) is a quantitative data collection tool used to ascertain current health status. This 78-item questionnaire covers the constructs of health status impairments attributable to arthritis, overall arthritis impact, perceptions of current and future health status, priorities for health improvement, and expected long-term outcome.

The AIMS2 is regarded as a more comprehensive and sensitive instrument than the original Arthritis Impact Measurement Scales (Meenan et al., 1980) due to the addition of subscales to assess arm function, work, and social support, as well as assessment of satisfaction with function, attribution of problems to arthritis, and self-designation of priority areas for improvement (Meenan et al., 1992; Carr, 2003). AIMS2 is disease-specific (arthritides), and can be administered either by interview or by self-completion. Although originally developed for the assessment of health status in people with RA, the self-administered AIMS2 questionnaire has been pilot tested in a mixed arthritis population (Meenan et al., 1992).

Of the 78 items, the first 57 items are broken into 12 subscales that assess the impact of arthritis on12 discrete aspects of health: (a) mobility, (b) walking and bending, (c) hand and finger function, (d) arm function, (e) self-care, (f) household tasks, (g) social activity, (h) support from family and friends, (i) arthritis pain, (j) work, (k) level of tension, and (l) mood. Internal consistency estimates (Cronbach's alpha) of these subscales range from .72 to .91 (Carr, 2003). These 12 subscales can be grouped into three or five component models. The final two subscales, satisfaction and health perceptions, are single item subscales, derived from items 58 and 61 respectively. These subscales are not included in either component models. Responses on the items forming each subscale are summed and transformed to continuous scores on a scales ranging from 0-10, such that the lower the score, the better the health status.

Co-morbidities are also reported and an estimate of their influence on each aspect of health status is used to weight scores. Participants are asked to report co-morbid diagnoses by indicating *yes* or *no* against a list of common disease types known to influence HRQOL. This list is not exhaustive. For example, multiple sclerosis (MS) and other neurological diseases are not included although the effects of MS on HRQOL are well documented (Petajan et al., 1996). Participants are also asked to nominate the impact

of arthritis on each HRQOL domain, indicating whether health status impairments are due *entirely*, *largely*, or *partly* to arthritis, or *largely* or *entirely* to other causes (Meenan et al, 1992). When participants aged over 60 years report more than two co-morbidities, their scores are weighted (i.e., multiplied by 0.25 or 0.5) on domains they identified as influenced by other causes.

The remaining 21 items include questions that assess the client's satisfaction with each of the 12 health status dimensions, problems attributed to arthritis, priority areas for improvement, perception of current and future health status, the presence of co-morbidities, and clinical and demographic details.

The AIMS2 returns scalable, reliable, and valid measures of both aggregated and disaggregated health status. Responsiveness to change of the AIMS2 is better than any other disease-specific, and most generic, HRQOL questionnaires (e.g., generic Sickness Impact Profile [SIP]; Bergner, Bobbitt, Carter, & Gilson, 1981; RA-specific SIP; Sullivan, Ahlmen, Bjelle, & Karlssm, 1993), therefore, AIMS2 is an ideal tool for evaluating the health status outcomes of arthritis treatments and programs (Carr, 2003). A complete copy of the AIMS2 is provide in Appendix C.

SF-MPQ. The McGill Pain Questionnaire exists in both standard (20 items) and short (15 items) forms. The standard McGill Pain Questionnaire consists primarily of 3 major classes of word descriptors–sensory, affective, and evaluative–that participants choose to specify subjective pain experience. It also contains an intensity scale and other items (visual analogue scale, pain map) to determine the properties of pain experience. The McGill Pain Questionnaire was designed to provide quantitative measures of clinical pain that would capture its sensory, affective and other qualitative components, and allow statistical analysis of these data collected during clinical research and practice (Melzack, 1975). Most features of the standard McGill Pain Questionnaire are preserved in the short form. Both questionnaires were originally developed in Canadian English, and have been

translated into several other languages, but there are no regional English variations (e.g., Australian English) of these questionnaires.

The Short Form McGill Pain Questionnaire (Melzack, 1987) comprises three sections: a word list, a visual analogue scale, and a 0-5 ordinal scale with descriptive labels. The word list is used to capture the subjective pain experience. It comprises 15 words: 11 sensory descriptors of pain and 4 affective descriptors, with four intensity levels (i.e., none, mild, moderate, severe, scored 0-3 respectively) possible for each word. Numerical scores can be calculated in each of these domains. Score range in the sensory domain is 0-33, and 0-12 in the affective domain. Scores in these domains are not weighted; all analyses are conducted upon the total raw scores for each domain. A total subjective pain score is calculated by adding the sensory and affective scores. A measure of present pain severity is recorded on a visual analogue scale (VAS), anchored *no pain* and *worst possible pain*. VAS scores can be converted to percentages. Overall experience of present pain (present pain index: PPI) is reported on a 0 (*no pain*) to 5 (*excruciating*) ordinal scale.

Burckhardt (1984) found that the standard McGill Pain Questionnaire had adequate content validity for use in populations with arthritis because respondents tended to select word from all subclasses of pain descriptors. The SF-MPQ was developed from the original McGill Pain Questionnaire (MPQ; Melzack, 1975), and correlations between the two forms ranged between $r = .67$ and $r = .87$ in groups of people with either post-surgical or dental pain (Melzack, 1987). Burckhardt and Bjelle (1994) reported that the internal consistencies (Cronbach's alphas) of the word lists (subjective, affective, total pain) in the SF-MPQ (Swedish version) ranged between .73 and .89. In the same study, test-retest reliability in people with RA ranged from $r = .45$ to $r = 73$. The SF-MPQ provides information that can be treated statistically, is reliable, is valid for use in adult populations with chronic pain, including arthritis pain, and is sensitive to detect differences between

different methods of pain relief (Burckhardt & Bjelle, 1994; Burckhardt & Jones, 2003; Melzack, 1987). A copy of the complete instrument is provided in Appendix C.

SF-36. General HRQOL was measured using the Australian / New Zealand adaptation of the Medical Outcomes Study 36-Item Short Form Health Survey version 1 (Ware & Sherbourne, 1992), and coded according to the developers' scoring guide (Medical Outcomes Trust [MOT], 1997). The SF-36 is a widely used HRQOL data collection tool, arguably the most extensively used in the world (Carr, 2003). Designed for use in surveys of general and specific populations, health policy evaluations, clinical practice, and research, the SF-36 was developed during the Medical Outcomes Study to measure generic health variables regardless of age, disease, or treatment regime. The SF-36 can be self-administered, requires no training, and is appropriate for use with literate people aged 14 years or older. It is available for use in doctoral research at no cost (one must register with the copyright holder; QualityMetric).

The SF-36 is a 36-item instrument for measuring health status and outcomes from the client's point of view. Health status is measured in eight subscales (domains): (a) limitations in physical activities because of health problems (physical function), (b) limitations in usual role activities because of physical health problems (physical role limitations), (c) bodily pain, (d) general health perceptions, (e) energy and fatigue (vitality), (f) limitations in social activities because of physical or emotional problems (social function), (g) limitations in usual role activities because of emotional problems (emotional role limitations), and (h) psychological distress and well-being (mental health).

The standardised scoring system yields a profile of eight scaled scores and a self-evaluated change in health status (health transition). All SF-36 domains except health transition are transformed to scores out of 100, and a higher score denotes better health-related quality of life (MOT, 1997). Health transition is scored from1-5. A score of 3

denotes stable health status, a score from 1-2.9 denotes health improvement, and a score from 3.1-5 denotes health decline.

The SF-36 is both reliable and valid. The median internal consistency estimate (Cronbach's alpha) across the eight subscales is .95 (range .73-.96), and the median test-retest reliability estimate is $r = .76$ (range .60-.81; Ware, Snow, Kosinski, & Gandek, 1993). The SF-36 is able to discriminate between groups with physical or mental morbidities (construct validity; Carr, 2003).

The original SF-36 has been through at least two modifications since initial publishing. The SF-36 Version 2 in English for the USA is currently recommended in place of Version 1 for studies in US populations (Carr, 2003). The English language adaptation for Australia and New Zealand was based on the original SF-36, and so this modified form of SF-36 Version 1 is the appropriate version for use in the Antipodes (MOT, 1997; Sanson-Fisher & Perkins, 1998).

There are other tools that are comparable to the SF-36 in coverage of health concepts, validity, reliability, cost, and utility (Kaplan, Ganiats, Sieber, & Anderson, 1998). I selected the SF-36 for this project because: (a) an Australian / New Zealand language variation was available, (b) Australian population data is available for comparison (ABS, 1997), and (c) use of a common data collection tool would allow the data to be compared directly to many other studies worldwide. For the full instrument, please see Appendix C.

MOS-SS. Perceived social support was measured using the Medical Outcomes Study Social Support Survey (Sherbourne & Stewart, 1991). This brief, self-administered social support survey was developed for patients in the Medical Outcomes Study, a two-year study of patients with chronic conditions. It is easy to administer because the items are short, simple, and readily understandable. The survey consists of four social support subscales (emotional/informational support, tangible support, affectionate support, and

positive social interaction), administered as a 19-item questionnaire. Participants are asked to indicate how often, on a scale ranging from 1 (*none of the time*) to 5 (*all of the time*), different types of support are available to them (Sherbourne & Stewart, 1991). Examples of items include: *Someone who hugs you*, and *Someone to have a good time with.* All items and subscales are oriented such that a higher score indicates more support.

Sherbourne and Stewart (1991) reported that the overall index (mean of the scores for the four subscales) could be used as a composite measure of social support. For comparison to published means, subscale and overall scores can be transformed to scores ranging 0-100. The four subscales and the overall index have been demonstrated to be internally consistent (all Cronbach's alphas > .91). Multitrait scaling analyses supported the dimensionality of four subscales and the construction of the overall index (Sherbourne & Stewart). For the full instrument, please see Appendix C.

Medication Use Survey. Medication use was recorded through participants' self-reporting on the Medication Use Survey comprising three items: a list of "medications you currently take for your arthritis" completed at baseline, and two items to report change in medication use over a recall period of four weeks. In the change of medication use items, participants are asked to indicate how their medication use compares with previous weeks on five-point Likert scales scored from –2 to +2 (*a lot more, a little more, about the same, a little less, a lot less*). In the studies in this thesis, participants would complete these Likert scaled items one at a time, at week 5 and week 9 of Studies 1, 2, and 3, and again at week 12 and week 24 in Study 3. A copy of the complete Medication Use Survey is provided in Appendix C.

Procedures

The data collection tools were photocopied onto four sets of coloured A4 paper (pink, yellow, green, and blue) and stapled to form booklets. One booklet, a cover letter with information about the study, and a reply-paid envelope, were distributed by mail to

each participant. Participants were informed that completion and return of their questionnaires implied their consent to participate in this study.

Two types of data collection occurred in this pilot study. In the cover letter, participants were asked to provide feedback on the data collection booklet, particularly: (a) whether the questionnaires were easy to follow, (b) suggestions for improvement of the questionnaires, (c) whether the language of the questionnaires was appropriate for an Australian audience (four of the questionnaires were developed in North America), and (d) if the coloured paper was helpful in any way. Participants' feedback on the data collection tools formed the first data set.

Participants were asked to complete the data collection booklet as though they were research participants, that is, to complete the booklet on the morning of their next water exercise class, before attending the class. Participants' responses to the questionnaires and surveys formed the second data set analysed in this pilot study.

Data Analysis

Participants' feedback on the data collection booklet was tabulated and examined for (a) common themes, and (b) suggestions for improvement (see Table 3.2). Participants' responses to the questionnaires and surveys were examined for omissions, errors, and misunderstandings. Each questionnaire was coded by hand according to the developers' instructions, the scores transformed or scaled if possible (see Tables 3.3 and 3.4), and the results examined for potential ceiling and floor effects. The SF-36 profiles of each participant were compared with the Australian population norms for people with arthritis (see Figure 3.1).

Results

All participants ($N = 4$) completed the questionnaire booklet, and provided feedback. Demographic details of the participants are provided in Table 3.1, and participants' responses to feedback questions are collated in Table 3.2.

Table 3.1 *Participant Profiles*

Measure	Participant			
	A	B	C	D
Age	68	62	78	75
Sex	F	F	F	M
Retired	yes	yes	yes	yes
Types of arthritis	RA, OA	OA	OA, gout	OA, gout
Years since diagnosis	23	11	18	30

Table 3.2 *Participants' Responses to Feedback Questions*

Question	Yes	No	Suggestions and comments
Easy to follow?	4	0	Some items repetitious No items regarding joint replacement
Language easy to understand?	4	0	Possibly more difficult for people who read and write English as a second language
Language suitable for Australian audience?	4	0	Change "bath" to "bath / shower"
Coloured paper helpful?	2	2	Two participants said coloured paper made no difference, and two said coloured paper was less likely to be misplaced

All participants fully completed the SF-36 and AIMS2. All participants completed the Medication Use Survey as if it was week 1 of a study. They provided lists of their current medications including the dose and frequency of use. On the SF-MPQ, three participants omitted the visual analogue pain scale (VAS). On the MOS-SS, two participants omitted the close friends / relatives item, and one participant omitted this survey completely. Participants' scaled scores on each of the AIMS2, SF-MPQ, SF-36, and MOS-SS are presented in Table 3.3. Missing data are shown as two en dashes (--). The Medication Use Survey has not been included in Table 3.3 because these data comprise

medication lists only. Comparisons of participants' SF-36 profiles with Australian population norms for adults with arthritis are presented in Figure 3.1.

Table 3.3 *Participants' Scores on AIMS2, SF-MPQ, SF-36, and MOS-SS*

Measure	Participant				
AIMS2	A	B	C	D	Mean
Mobility	0.5	2.0	5.0	0.0	1.9
Walking & Bending	4.0	8.5	7.5	0.9	5.2
Hand Function	3.0	0.5	0.5	0.5	1.1
Arm Function	1.0	0.0	0.5	0.1	0.4
Self-care	0.0	0.0	0.0	0.0	0.0
Household Tasks	0.0	3.8	1.9	0.0	1.4
Social Activity	3.0	3.5	1.0	8.0	3.9
Family Support	3.8	0.0	0.3	0.0	1.0
Arthritis Pain	3.5	1.5	5.0	0.5	2.6
Work	--	--	10.0	--	--
Tension	1.5	0.5	1.8	4.0	1.9
Mood	1.5	0.0	0.4	0.5	0.6
Satisfaction	0.6	2.3	4.0	1.5	2.1
Health Perceptions	3.3	3.3	6.7	3.3	4.2
Arthritis Impact	0.0	2.5	5.0	0.0	1.9
Co-Morbidities	1	1	3	2	--

Note. Scaled scores out of 10 (except co-morbidities). Low score represents low arthritis impact on HRQOL (i.e., high function).

Table 3.3 continues overleaf

Table 3.3 continued

Measure	Participant			
MPQ	A	B	C	D
Sensory	3	4	5	4
Affective	4	0	0	0
Total Pain	7	4	5	4
Visual Analogue (%)	--	--	26.2	--
Present Pain Index	2	1.5	2	1

Note. Lower scores denote less intense pain.

Measure	Participant				
SF-36	A	B	C	D	Mean
Physical Function	60	25	10	60	39
Role Physical	0	25	25	50	25
Bodily Pain	41	74	41	74	58
General Health	97	72	55	72	74
Vitality	60	60	50	55	56
Social Function	100	75	75	100	88
Role Emotional	100	100	100	100	100
Mental Health	80	80	70	83	78
Health Transition	3	1	2	4	--

Note. Scaled scores out of 100 (except health transition subscale). High score represents high function.

Measure	Participant			
Social Support Survey	A	B	C	D
Overall Index	--	100	58.5	96.5

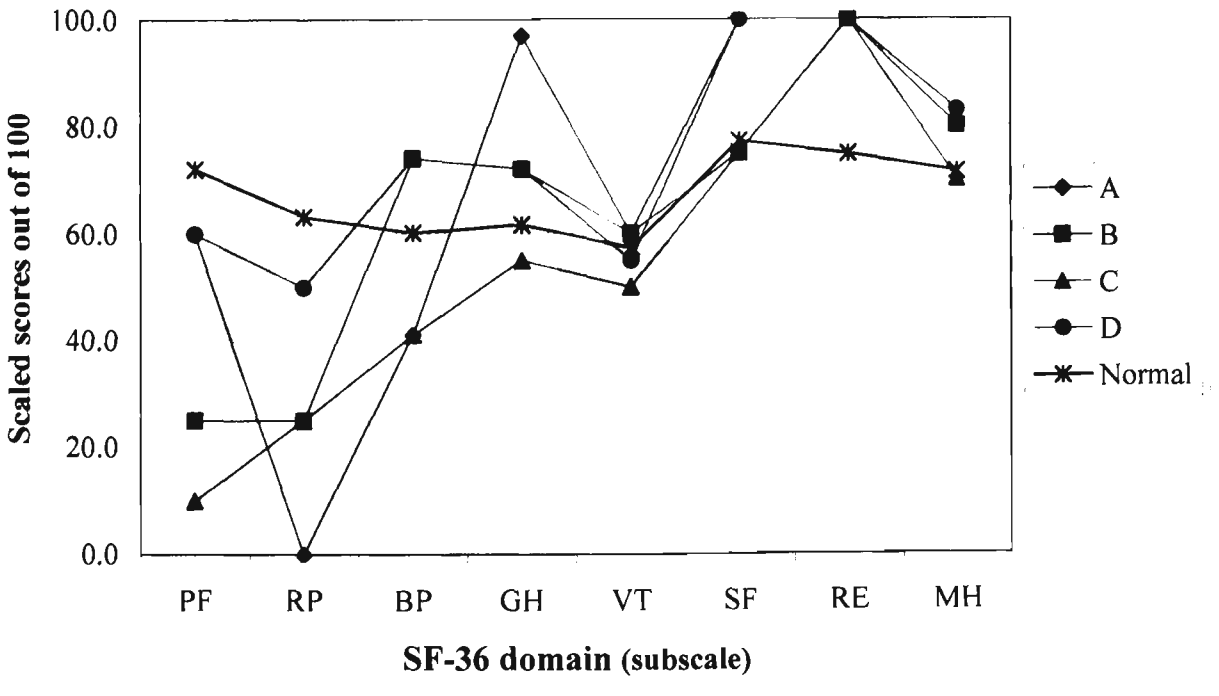
The AIMS2 includes a descriptive section on priorities for health improvement, and participants' responses to this section are tabulated in Table 3.4. Participants were invited

to nominate up to three priorities for health status improvement. Participant A selected hand function as the only priority area. The other participants nominated three areas each. Dashes (--) in Table 3.4 indicate that an area received no nominations as a priority for health status improvement.

Table 3.4 *Participants' Priorities for Health Improvement*

Priority area	Nominations	Priority area	Nominations
Mobility	B, C, D	Social Activity	--
Walking & Bending	B, C, D	Family Support	--
Hand Function	A	Arthritis Pain	B, C
Arm Function	D	Work	--
Self-care	--	Tension	--
Household Tasks	--	Mood	--

Figure 3.1 *Participants' SF-36 profiles compared with Australian population norms for adults with arthritis*



Discussion

The pilot study participants' feedback on the utility and comprehensiveness of the questionnaire booklet was important for informing the design of the clinical studies, but because they differed markedly from the general population of adults with arthritis, their scaled scores on the questionnaires could not be assumed to be a guide to the likely scores of clinical study participants on those same questionnaires.

Participants' Feedback

Hyland (2003) argued, consistent with Guyatt, Kirschner, and Jaeschke (1992), that HRQOL scales can be classified according to purpose (e.g., for longitudinal comparison, for cross-sectional comparison). Hyland recommended that short HRQOL questionnaires (1-40 items) are best suited for use in longitudinal studies, particularly clinical trials in which changes in health status are measured over time. He also advocated that floor and ceiling effects should be avoided whenever possible.

The package of five data collection tools used in this pilot exceeded Hyland's (2003) recommendation of 40 or fewer items, but no participants reported that the questionnaires were overly long or took excessive time to complete. One participant reported that some items were repetitious, probably identifying areas of commonality across the pain, physical function, social function, and social support domains of the AIMS2 and SF-36.

Participants were not informed, and could not reasonably be expected to know, that the AIMS2 is an arthritis-specific measure and the SF-36 is for general health assessment. These two questionnaires were developed and validated as complete data tools. Despite commonality across some items, I did not contemplate deleting items or subscales from either questionnaire because of the risk of compromising the validity of the tools (Schug, 1996) and the statistical analyses. Because repetitive questioning without explanation might annoy some participants in the clinical studies, who would each complete the

questionnaires between three and five times, a note was made to amend the cover letter to explain of the purpose of each questionnaire and that there would be some redundancies in the items.

The data collection tools used in this thesis have been used in several other studies of HRQOL in people with arthritis. Brekke et al. (2001a, 2001b), Brekke, Hjortdahl, and Kvien (2003), and Heiberg and Kvien (2002), combined the SF-36 and AIMS2 in order to get at both disease-specific and general aspects of HRQOL in samples of people with arthritis. Roche, Klestov, and Heim (2003) used the MPQ in conjunction with other pain scales to observe pain in people with RA over time. Covic, Adamson, and Hough (2000) similarly combined the pain scale from the AIMS (original) and a VAS for pain. Use of combinations of apparently overlapping questionnaires is not uncommon when the domains under investigation are complex or multifaceted.

One pilot study participant commented that the questionnaires covered most aspects of living with arthritis, but included no specific questions on joint replacement or other surgical procedures used in arthritis management. The AIMS2, and its predecessor, the Arthritis Impact Measurement Scales, have been found to have acceptable reliability and validity in several arthritis populations, including people with prosthetic joints (Meenan et al., 1980, 1992; Meenan, Gertman, Mason, & Dunaif, 1982). Kaplan's (1994) "Ziggy theorem" is worth remembering at this juncture, that the meaning of life is "doin' stuff." It matters not so much that a person with arthritis has had a joint replaced, but whether a person with a prosthetic joint is able to do the "stuff" he or she wants and needs to do. To complete the clinical studies I needed instruments that would provide snapshots of participants' HRQOL before, during, and after physical and manual therapies. Clearly, other therapies, such as surgery and medication, influence HRQOL in people with arthritis, but provided the participants did not have joint replacement surgery during or immediately preceding the clinical studies, then the influence of pre-existing prostheses on HRQOL

would be accounted for in baseline measures. Despite lacking specific questions on joint replacement, the questionnaires selected for this thesis appeared to be comprehensive for the assessment of HRQOL in people with arthritis.

Recall

When completing the AIMS2, participants are asked to recall the impact of arthritis on their HRQOL over the past month. The SF-MPQ refers to pain perception at a point in time, that is, participants complete it regarding their pain at the time of survey. In the SF-36 most items require recall for the past 4 weeks, but on some subscales recall periods vary between 12 months and the present. For example, the reported health transition subscale is a one-item scale using the question: "Compared to one year ago, how would you rate your general health now?" Although participants in this pilot study did not report difficulty with recall, it is important to recognise that the greater the period of recall, the less likely the response is accurate.

Health-Related Quality of Life

Although the data are not generalisable, individuals' questionnaire responses provide personal detailed pictures of their HRQOL. An underlying postulate of this thesis is that in addition to relieving symptoms, a primary objective of any health care intervention is the enhancement of quality of life and well-being (Berzon, 1998; Kaplan, 1990). There are generic components of quality of life and well-being, such as those measured in the SF-36, that remain important to people across age, disease, therapy, and cultural divides. Some aspects of HRQOL, however, may be highly personal and individualised. Callahan and Pincus (1990) suggested that participants' idiosyncratic responses on self-report questionnaires might give diagnostic clues. Assessment of HRQOL that provides a picture of the individual may also be useful in planning tailored, individualised therapy (Roche et al., 2003), but such an application is not part of this research.

Impact of Arthritis: AIMS2

Scores on the AIMS2 are transformed to scores out of 10, and the influences of co-existing diseases (co-morbidities) on HRQOL are accounted for in the scoring process (Meenan, n.d.). All subscales are oriented so that high scores represent greater impact of arthritis on HRQOL than lower scores. In this pilot study the largest mean impact of arthritis scores on HRQOL were seen in the domains of walking and bending (5.2), health perceptions (4.2), social activity (3.9), and pain (2.1).

A potential floor effect was evident in the self-care domain, and this effect was likely explained by the selection criteria for these studies. To be eligible to participate in these studies, participants needed to be able to walk unassisted for 20 meters, climb in and out of a swimming pool safely, and undress to their underwear unaided. People who can do these things are likely to report that they *never* need help to: (a) take a bath / shower, (b) get dressed, (c) use the toilet, or (d) get in or out of bed, which are the four items that constitute the self-care subscale of the AIMS2 (Meenan et al., 1992).

Three of the four participants omitted the work subscale of the AIMS2. These omissions were consistent with the instructions of the questionnaire: *If you answered unemployed, disabled, or retired, please skip the next four questions and go to the next page.* (Meenan et al., 1992). Consequently, these omissions were considered to be unimportant. Participant C reported a maximum score of 10 on the work subscale, indicating that the participant had been unable to engage in any work for the past month because of limitations due to arthritis. This participant also reported that she was 78 years of age, had been educated to professional or graduate school level, was retired, and was in receipt of an annual income of less than $20,000 Australian. I suspect that participant C, who was retired from employment, overlooked the instructions not to complete the work subscale. Because the incidence of OA increases with increasing age, it was reasonable to expect that adults of retirement age might volunteer for Studies 2 and 3. A note was made

to check the employment status of participants in the clinical studies to clarify whether they would be required to complete the work subscale of the AIMS2.

An important aspect of the AIMS2 is the way co-morbidities (i.e., diseases other than arthritis) weight scores. This weighting system accounts for the influence of most co-morbidities on health status, but it does not account for other causes that are not disease states. Recent emotional stressors or life events such as the death of a loved one or moving house are unlikely to be reported by participants as "mental illness" but might well have considerable influence on health status in the domains of mood and tension during the past month. Some participants added brief notes to their questionnaires, particularly on this section of the AIMS2, and on the MOS-SS, providing personal information to clarify their responses.

General Health-Related Quality of Life: SF-36

Scores on the SF-36 are scaled to scores out of 100. The scale is oriented so that a high score represents high HRQOL and high function. In this pilot study the lowest mean HRQOL scores were seen in the domains of physical role limitations (25), physical function (39), vitality (56), and bodily pain (58).

Although the SF-36 is a generic HRQOL measure, and the AIMS2 is a disease specific measure, there is some commonality in the findings across these measures. In particular, the AIMS2 walking and bending subscale is likely to capture some of the same aspects of HRQOL as the physical role limitations and physical function subscales of the SF-36. If walking and bending are difficult, then physical functioning, particularly exercise and leisure activities, may be compromised. If walking and bending are required in the fulfilment of roles, then reduction in these physical capacities may limit role performance.

A potential ceiling effect was observed on the emotional role domain of the SF-36 (i.e., all participants reported the maximum score for this domain). Because the AIMS2 and the SF-36 are scaled in opposite directions, the possible floor effect observed for self-

care and the ceiling effect for emotional role both indicate maximum functioning on the respective subscales.

Comparison of participants' SF-36 profiles with the Australian population norms for people with arthritis demonstrated, as expected, that participants in this pilot study are not typical of the population of adults with arthritis (see Figure 3.1). These participants demonstrated lower than normal HRQOL in the domains of physical function and physical role domains, and normal, or better than normal, HRQOL in the domains of emotional role and mental health. On the other domains of bodily pain, general health, vitality, and social function, participants' scores showed no consistent pattern in comparison to the Australian population of people with arthritis.

Pain

In comparing responses across the pain scales of the SF-36, SF-MPQ, and AIMS2. Pain is the domain that returned the fourth lowest mean score on the SF-36, and the fourth highest mean score on the AIMS2. Because these questionnaires are scaled in opposite directions, these results place pain as the fourth most compromised HRQOL domain on both questionnaires. Two out of four participants also identified pain as a priority area for health improvement. These results demonstrate that for these individuals, pain is an important aspect of HRQOL, but not the overshadowing feature.

The original McGill Pain Questionnaire and the subsequent short form were developed expressly to assess the subjective nature of pain (Melzack, 1975, 1987). The SF-MPQ is unlike the pain subscales in the SF-36 and AIMS2. The SF-MPQ is used to quantify the sensory and affective (emotional) components of pain, as well as the severity and overall experience of present pain. The SF-36 and AIMS2 pain subscales are similar to each other in that they are used to quantify the severity of pain over the past 4 weeks / month. The AIMS2 also quantifies the frequency (few days, some days, all days) of pain, and the SF-36 quantifies the influence of pain on activities of daily living.

Because of the subjective and individual nature of pain, caution is warranted in comparing one participant's SF-MPQ results to another's. It is reasonable to use SF-MPQ scores to assess a participant's change in pain perception over time, but not necessarily to compare between participants. Comparison of SF-MPQ scores between groups is reasonable if there is a systematic method of accounting for differences between individuals at baseline (e.g., use baseline scores as covariates, or convert data to change scores).

How This Study Informed Subsequent Studies

This pilot study provided me with experience in the licensing, copying, distribution, scoring, and interpretation of HRQOL questionnaires. At the end of the pilot study, I was confident that I could use the questionnaires properly, and score them according to the developers' recommendations. As previously discussed, I also identified strengths and weaknesses in the questionnaires.

Hyland's (2003) caution against subscales returning floor or ceiling effects was noted, but there were only a couple of subscales out of all the scales piloted that showed potential ceiling or floor effects, and those results may have been due to the selection of rather homogenous participants. Schug (1996) recommended investigators "Use the instruments in their original form, do not change them or…use only parts of them: validation only refers to the complete instruments" (p. 3). In order to preserve the validity of the AIMS2, the self-care subscale was retained for the clinical studies, and a floor effect on this subscale was expected. Similarly, the SF-36 was retained in entirety, and the possibility of a ceiling effect on the emotional role subscale noted.

There were no misinterpretations evident in any of the data collection booklets. Participants understood the questions and were able to answer them. It is reasonable to conclude that this battery of questionnaires is appropriate for the investigation of people with arthritic diseases. Because all participants found the questionnaires and surveys easy

to follow, I considered that no major changes to the data collection booklet were necessary. Consistent with participant feedback, items in the AIMS2 about bathing were expanded to read "bath / shower" to reflect Australian terms and usage.

Items left blank in the data collection booklets, however, were worrisome. The visual analogue scale of the MPQ, and the close friends / relatives item of the Social Support Survey, were left incomplete by 3 out of 4 participants. In an attempt to reduce missing data during the three studies, the cover letter was modified to: (a) include a reminder to complete all sections, (b) state the purpose of each questionnaire in the package, and (c) clarify that, unless otherwise specified, questions referred to how the participant was feeling at the time of completing the questionnaire (see Appendix C).

No participants found coloured paper distracting or unhelpful. Two participants felt that a coloured document was easier to keep track of than a white one, and two participants were ambivalent about the value of coloured paper. To assist people who find visual cues helpful, I decided to continue to print the data collection booklets on coloured paper.

Conclusions

The results of this pilot study confirmed that the data collection booklet comprising the AIMS2, SF-MPQ, SF-36, Social Support Survey, and Medication Use Survey, was a manageable tool for inquiry into the HRQOL, particularly function, well-being, and pain, of Australian adults with arthritides. Although the pilot sample was small, the data suggest that there was considerable variability in participant responses to questionnaires, possibly reflecting the wide-ranging symptomatology, and the mercurial qualities of these diseases. Minor modifications were made to the cover letter and data collection booklet for the clinical studies in response to the data gleaned during this pilot study (see Appendix C for the final version of the data collection booklet). In particular, a clearer explanation of the purpose of each questionnaire was included in the cover letter, and participants were

reminded to: (a) complete all sections of the questionnaires, and (b) note the recall period required for each item.

CHAPTER 4

STUDY 1: MANUAL THERAPIES FOR OSTEOARTHRITIS

Introduction

People with arthritis use manual therapies (Fiechtner & Brodeur, 2002a; Ramsey et al., 2001; Rao et al., 1999, 2003) but such treatments have received little attention in the research literature. Advice to clients about when to use manual therapies, and which types to use, is based on clinical, rather than experimental, evidence (APA, n.d.; AOA, n.d.; CAA, n.d.; Kramer, 1999; Lam & Horstman, 2002). There is some evidence that manual therapies, particularly spinal manipulation, may be effective in reducing back and neck pain, possible symptoms of arthritis (Fiechtner & Brodeur, 2002b). This evidence is tenuous at best, because participants in most of the studies reviewed by Fiechtner and Brodeur did not necessarily meet the diagnostic criteria for arthritides.

Manual therapies such as massage and joint mobilisation are intuitively logical therapies for osteoarthritis (OA), because they are aimed at redressing the physical changes associated with this disease (e.g., joint restriction, muscle tightness; APA, n.d.). Mechanisms by which manual therapies may reduce pain in OA involve cutaneous afferent neurones stimulated during manual therapy making inhibitory synapses on the spinal neurones receiving nociceptive impulses from joints, and blocking the transmission of these impulses to the brain (Melzack & Wall, 1965; Vilensky, 1998).

Joint range of motion and muscle tension can be measured with goniometry and electromyography, respectively, but these measures often mean little to clients. Reduced joint range of motion affects a person's life because it contributes to the impairment of mobility and dexterity, which may be experienced as physical and social disability. People with arthritis may complain of myalgia (muscle pain) and display associated with pain behaviours. Muscle tightness as an explanation of myalgia is tenuous at best (Bogduk, 1997). Electromyographic studies have not consistently demonstrated an association

between muscle activity and pain. There is a need to test the effectiveness of manual therapies for enhancing the physical, mental, and social functionality of people with OA regardless of how these interventions perform on other measures (e.g., electromyography). If people with OA add a course of manual therapy to their existing care regimens, what sort of influence will that intervention have on perceived HRQOL (e.g., mobility, dexterity) and pain?

Method

The first two studies of this thesis were undertaken concurrently. These studies were similar in design, but volunteers with different types of arthritis were recruited for each study. Study 1 was a comparison of two forms of manual therapy (massage and joint mobilisation) with usual care (control) in people with osteoarthritis. Self-report questionnaires were used to record the effects of these treatments on the aspects HRQOL previously identified as important to people with arthritis.

Participants

Adults (12 females, 7 males) previously diagnosed with OA were recruited via an invitational flyer (see Appendix A) distributed in a normal mailing of Arthritis Victoria's members' magazine *Update*. Participants had a mean age of 64.5 years (range 40-82) and a mean time since diagnosis of OA of 13.6 years (range 3-31). To be eligible to participate in this study, participants needed to be able to: (a) walk unassisted for 20 meters, (b) undress to their underwear unaided, and (c) read and write in English. Participants were excluded from this study if they: (a) attended fewer than eight manual therapy sessions, or (b) were diagnosed during the study with an illness or disorder other than that attributable to OA. Participation in this study was voluntary, and participants were free to withdraw from the study at any time.

Measures

Primary outcomes of interest in this thesis were those related to the physical function and well-being components of health-related quality of life (HRQOL). In this study, three questionnaires assessing generic and disease-related physical and psychological function and pain were used to determine the influence of the exercise and manual therapy programs on dimensions of HRQOL and well-being. The individual scales were the Australian / New Zealand adaptation of the Medical Outcomes Study 36-Item Short Form Health Survey Version 1 (SF-36; Ware & Sherbourne, 1992), the Short-Form McGill Pain Questionnaire (SF-MPQ; Melzack, 1987), and the Arthritis Impact Measurement Scales Version 2 (AIMS2; Meenan et al., 1992). These measures were described in the Method section of Chapter 3 (Pilot Study).

The Medical Outcomes Study Social Support Survey (MOS-SS; Sherbourne & Stewart, 1991) was used as a statistical control for the potential positive effect of an increased social support network associated with exercising in a group or attending consultations with a therapist. The Medication Use Survey developed for this thesis was used to control for the effects of altered medication intake, particularly analgesics, on pain scores. These measures were also described in the Method section of the Pilot Study (see Chapter 3).

Compliance data. Participants' attendance at intervention sessions was documented by osteopathic students. Attendance at an exercise session was assumed to mean participation in that session. Drop-out rates were recorded for all groups.

Procedures

From my knowledge and experience as an osteopath, I developed two structured manual therapy regimes, not specific to any particular discipline of manual therapy. One regime comprised soft tissue massage techniques only, and the other regime comprised passive joint mobilisation techniques only. Copies of these regimes were distributed to experts in the field (i.e., a panel of manual therapists, rheumatologists, and representatives

from Arthritis Victoria) for comment and feedback. Experts were asked to comment upon whether the manual therapy regimes were: (a) generic or discipline specific, and (b) safe and appropriate for use with people with osteoarthritis. The manual therapy regimes were modified according to feedback received.

A flyer inviting participants for this study was distributed to all members of Arthritis Victoria (AV) as part of the ordinary mailing of the AV members' magazine *Update.* Interested volunteers contacted me by telephone at Victoria University, and an information sheet outlining the research, and an informed consent form, were mailed to these volunteers two weeks prior to the scheduled start of the study. People who returned the signed, completed informed consent form prior to the start of the study were assigned to one of the four groups using a table of random numbers.

There were two intervention groups and one control group in this study. Participants were assigned to: (a) joint mobilisation ($n = 6$), (b) massage ($n = 7$), or (c) usual care (control: $n = 6$) groups. All participants remained in the care of their rheumatologists and general medical practitioners throughout this study. With participants' permission, medical practitioners (specialists and general practitioners) were notified of their clients' involvement in the study, provided with a copy of the information sheet distributed to participants, and invited to contact me if they had any concerns or queries regarding the study. No existing care regimes (i.e., medication, exercise, alternative therapies) were altered during the study. Participants in the intervention groups undertook the manual therapy treatments in addition to their usual care. Participants in the control group continued with all usual care but commenced no new therapies.

All interventions were undertaken once a week for ten consecutive weeks. Data on HRQOL, including functionality and pain perception of participants in the three groups were collected before any therapy was administered at week 1 (baseline), and repeated at weeks 5 and 9. Final measures were taken at week 9 instead of the last week of the 10-

week program because, according to Petajan et al. (1996), anticipation of the end of a course of therapy, and the associated removal of social support, may negatively influence psychological aspects of health.

All interventions (manual therapies) were undertaken in sessions of approximately 40 minutes in duration, and were conducted at the Victoria University Osteopathic Medicine Clinic. Standardised manual therapies (i.e., soft tissue massage, joint mobilisation) were provided by Masters level osteopathic student volunteers. All osteopathic student therapists taking part in this study were enrolled in 4th or 5th year Clinical Practicum subjects as part of their full-time enrolment in the Master of Health Science (Osteopathy) course at Victoria University. Students were informed of the project aims and design, formally consented to participate, and received training in how to deliver the standardised manual therapies. Students were teamed with participants according to availability (i.e., students met with research participants during the students' usual clinical shifts). Because of the interest in social support and other psychosocial factors influencing HRQOL, continuity of care was maintained as far as was reasonably possible throughout the study by booking appointments for any given participant with the same students at the same time each week.

All interventions in this study were provided at no charge to participants. Students are not paid for consultations at the Osteopathic Medicine Clinic because these consultations form part of the students' clinical training. Participants paid for their usual arthritis care exactly as they did prior to the study. No participant was paid for involvement in the study or offered any inducement, other than free manual therapy, for participation.

Data Analysis

All questionnaires were scored by hand, according to the developers' instructions, and results are reported as mean scores for each group, on each subscale, at each data

collection time. Composite data (means and standard deviations) for each group at each time of data collection are presented in Appendix E.

Week-5 data were used as a mid-point check to monitor participants' progress and ensure that continuing the study was in participants' interests. To avoid the confusion caused by the interaction of group and time associated with mixed designs, week-5 data were not used in inferential analyses (Huck & McLean, 1975).

Despite the small group sizes and relatively non-normal distribution of data, analyses of covariance (ANCOVAs) were used to assess group (treatment groups versus control) differences for the SF-36, the AIMS2, and the MPQ measures. ANCOVA was selected as the preferred analysis because it is a method to reduce systematic bias and between-groups differences at baseline (Coakes & Steed, 2001). For all HRQOL subscales, respective pre-intervention (i.e., week 1, baseline) measures were used as covariates to control for initial differences between groups. Social support, as measured at week 9, was also used as a covariate, to partial out the variance accounted for by any changes in social networks (e.g., therapist-client relationship) over the course of the intervention. Statistical significance (alpha) was set at $p < .05$. Changes in medication use and social support over time (baseline to week 9) were also analysed separately using ANCOVAs with respective baseline scores as covariates.

The statistical significance of any result needs to be interpreted with caution. Analyses of covariance were conducted on 29 HRQOL subscales (27 main subscales, 2 covariate subscales) without alpha adjustment for multiple tests of significance. Bonferroni adjustments, especially with small sample sizes, greatly increase the probability of Type II error, and because of that problem and the exploratory quality of these studies such adjustments were not made. In the words of Andersen and Stoové (1998), "the sanctity of $p < .05$ obfuscates good stuff," (p. 168) to wit, these results are most sensibly interpreted in terms of effect size rather than statistical significance.

Omnibus effect sizes were calculated as η^2, which represents the amount of variance in a variable accounted for by group membership (i.e., being in intervention or control groups), and is therefore a relevant measure of effect size because it explains the strength of association between treatments and the variables measured (Tabachnick & Fidell, 2001). The effect size, η^2, also has some limitations associated with other omnibus indicators. As stated in the *Publication Manual of the American Psychological Association* (APA, 2001) "multiple degree-of-freedom effect indicators tend to be less useful than effect indicators that decompose multiple degree-of-freedom tests into meaningful one degree-of-freedom effects–particularly when these are the effects that inform the discussion." (p. 26). To this end, omnibus effect sizes (η^2) were reported, and univariate effect sizes (Cohen's *d*) for within- and between-group results were also calculated for more precise determination of where among the groups, and over time, differences appeared.

Results

Missing Data

All participants completed the study and returned pre-, mid-, and post- (i.e., weeks 1, 5, and 9) intervention questionnaires. All participants in intervention groups completed at least eight sessions of manual therapy; two participants attended eight sessions; one attended nine sessions, and the remaining ten participants took part in all of their intervention sessions. One participant did not return her week-9 questionnaires. Scores from her week-5 questionnaires were re-entered for analysis with the week-9 data, representing no change in that participant over the last four weeks of the study.

Consistent with the questionnaire completion patterns observed in the Pilot Study, three participants omitted the visual analogue scale (VAS) of the SF-MPQ in each of their questionnaires, and seven participants omitted the VAS on at least one occasion. Eleven participants identified themselves as *retired, unemployed,* or *disabled*, and consequently,

did not complete the work subscale of the AIMS2. These subscales (i.e., AIMS2-work, SF-MPQ-VAS) were excluded from the analyses because of inadequate sample sizes.

Missing data in the remaining subscales was replaced according to scoring instructions from the questionnaire developers. Where participants had omitted single items from multi-item subscales, scores for these subscales were calculated by assigning the mean score for the subscale to the missing item. If a score for a subscale could not be calculated in this way, then the mean score for the corresponding group on that subscale at that time was assigned instead. Data replacement of these types was required for approximately 2% of data points (35 out of 1653 data points; 29 subscales x 3 administrations x 19 participants), and was distributed randomly across subscales and data collection times. The benefits of retaining these data points for analysis outweigh the lowered participant *n*s that would occur if these data points were excluded from analysis.

Floor and ceiling effects. As anticipated from the Pilot Study, a floor effect was observed on the self-care subscale of the AIMS2. Because all participants completed this subscale, it was included in analyses, but effect sizes derived from these data are probably not meaningful, and have not been discussed. Unlike the Pilot Study, a ceiling effect was not observed on the emotional role subscale of the SF-36.

Analysis of the Covariates

Differences in medication use and social support across time and between groups were small to moderate, and do not appear to account for the reported improvements. Means and standard deviations for these covariate measures in each group at each time point are reported in Appendix E. Medication use was analysed using change scores. Social support was analysed via analysis of covariance (ANCOVA) using the baseline measure as the covariate and the week-9 measure as the dependant variable. Consistent with analyses of the dependant variables, week-5 measures were not included, thereby avoiding the confusion caused by the interaction of group and time associated with mixed

designs (see Huck & McLean [1975] for a discussion of this problem).

Medication use. Change in medication use was scored on a 5-point Likert scale ranging from –2 to +2. A decrease in medication use is indicated by a negative score, and an increase in medication use by a positive score. A score of zero indicates that medication use is unchanged. Mean scores for medication use at week 9, indicating the change in medication use from baseline, were 0.17 for the control group, 0.00 for the massage group, and –0.17 for the joint mobilisation group. The change in medication use associated with group membership was medium ($\eta^2 = .08$) in effect size terms and not statistically significant ($p = .50$). The increase in medication use in the control group was of the same magnitude as the decrease in medication use in the mobilisation group. Changes of this small magnitude (+/-0.17) might have occurred as natural fluctuation in the medication use behaviour of people with OA, and are probably not clinically meaningful, representing background "noise" rather than a treatment effect.

Social support. Measures of total social support are scores out of 100, and oriented so that a higher score indicates more social support. Social support scores at week 9 were $M = 67$, $SD = 19$ for the control group; $M = 69$, $SD = 20$ for the massage group; and $M = 81$, $SD = 8$ for the mobilisation group. A very large portion of the variance in social support between groups at week 9 was accounted for by the covariate baseline scores ($\eta^2 = .39$). Differences in social support between the groups at baseline were statistically significant ($p < .01$). The amount of variance in social support associated with group membership (treatment or control group allocation) at week 9 once baseline measures were accounted for was medium ($\eta^2 = .06$) and not statistically significant ($p = .65$). These results indicate that the groups were dissimilar in terms of social support at baseline. Although some increase in social support was associated with being in a treatment group, the largest proportion of the variance in social support at the end of the trial was accounted for by social support at baseline.

Changes Within and Between Groups

The mixed design of this study allows comparison of results both between and within groups. Within-group results are expressed as Cohen's *d* for dependent means (see Table 4.1). Mean change scores from baseline to week 9 were used to calculate these effect sizes, and are reported in Appendix E. Between-group results are expressed as *F* values and η^2 (see Table 4.2), and as Cohen's *d* for independent means (see Table 4.3). The SF-36 subscales, except health transition, are oriented so that a higher score denotes better health-related quality of life, and subscales of the SF-MPQ and AIMS2 are oriented so that a lower score denotes better health-related quality of life. For ease of interpretation of these results, however, all change scores and Cohen's *d* are oriented such that a positive sign indicates an improvement in health status and a negative sign indicates health status decline. Cohen's (1988) conventions for *d* as a measure of effect size (all types) are that a small effect is identified if $d = .20$, a medium effect if $d = .50$, a large effect if $d = .80$ or greater.

Within-Groups Analyses

In effect size terms, moderate to large positive effects over time (Cohen's *d* of .50 or greater) were identified in the mobilisation group on 7 of the 14 AIMS2 subscales, two of the SF-MPQ subscales, and two of the SF-36 subscales. The largest improvements were observed in the health perceptions ($d = 1.29$), arthritis pain ($d = 1.19$), and walking and bending ($d = 1.04$) subscales of the AIMS2, and the general health ($d = 1.05$) subscale of the SF-36.

Moderate to large positive effects over time were also identified in the massage group on three AIMS2 subscales (social activity, $d = 0.75$; mood, $d = 1.07$; satisfaction, $d = 1.29$), two SF-MPQ subscales (sensory pain, $d = 0.93$; total pain, $d = 0.81$), and one SF-36 subscale (physical function, $d = 0.78$).

An unexpected, large effect size was identified in the control group on the mood

subscale of the AIMS2 (d = .91). This improvement in the control group over time was comparable in magnitude to that of mobilisation group, and approximately twice the magnitude of the massage group's improvement on the same subscale. The control group also displayed improvements over time on the emotional role limitations, physical role limitations, and mental health subscales of the SF-36 (role: physical, d = .82; role: emotional, d = .49; mental health, d = .44). On each of these subscales, improvements in the control group over time exceeded the magnitude of improvements in the other two groups.

Although the massage and mobilisation groups improved on most subscales over time, negative effect sizes, indicating decline over time, were observed for these groups on some subscales. In the mobilisation group, medium negative effect sizes were observed on the tension (d = -.40) and arthritis impact (d = -.59) subscales of the AIMS2, the present pain index (d = -.41) of the SF-MPQ, and the emotional role limitations (role: emotional, d = -.41) subscale of the SF-36. The massage group also showed medium to small declines on the family support (d = -.64) subscale of the AIMS2, and the general health (d = -.31) subscale of the SF-36.

Table 4.1 *Within-Group Effects: Effect Sizes (d) for the Change Over Time (Baseline-Week 9) in Each Group for Each HRQOL Domain*

	Group		
AIMS2 subscales	Control	Mobilisation	Massage
Mobility	- .82	.38	.20
Walk & Bend	- .54	1.04	.06
Hand Function	- .76	.75	.24
Arm Function	- .25	.85	.32
Self-care	.41	.41	- .18
Household Tasks	- .64	.55	.00
Social Activity	- .79	.30	.75
Family Support	.23	.06	- .64
Arthritis Pain	- .15	1.19	.35
Tension	.26	- .40	.57
Mood	.91	.45	1.07
Satisfaction	.40	.68	1.29
Health Perceptions	- .65	1.29	.30
Arthritis Impact	- .91	- .59	- .30
	Group		
SF-MPQ subscale	Control	Mobilisation	Massage
Sensory Pain	- .08	.57	.93
Affective Pain	- .14	.11	.12
Total Pain	- .14	.52	.87
Present Pain Index	- .03	- .41	- .01

Table 4.1 continues overleaf

Table 4.1 continued

	Group		
SF-36 subscales	Control	Mobilisation	Massage
Physical Function	- .68	.19	.78
Role: Physical	.82	.34	.18
Bodily Pain	- .02	.52	.37
General Health	- .49	1.05	- .31
Vitality	- .00	.32	.29
Social Function	- .20	- .07	.12
Role: Emotional	.49	- .41	.44
Mental Health	.44	.21	.41
Health Transition	- .22	- .17	.30

Between-Groups Analyses

Cohen's (1988) conventions for η^2 as a measure of effect size in analysis of variance are that a small effect is identified if $\eta^2 = .01$, a medium effect if $\eta^2 = .06$, a large effect if $\eta^2 = .14$ or greater. Analyses of covariance (ANCOVAs), using the relevant baseline measures, medication use, and week-9 social support scores as covariates, revealed that at week 9 of the 10-week trial, group membership accounted for a large portion of improvement on some key domains of HRQOL. Omnibus between-groups effect sizes (η^2) are reported in Table 4.2. The largest improvements (very large effect sizes) were observed in the walking and bending ($\eta^2 = .36$, $p = .06$), hand function ($\eta^2 = .18$, $p = .28$), social activity ($\eta^2 = .32$, $p = .08$), and health perceptions ($\eta^2 = .32$, $p = .08$) subscales of the AIMS2 and the sensory pain ($\eta^2 = .44$, $p = .02$), affective pain ($\eta^2 = .27$, $p = .06$), and total pain ($\eta^2 = .48$, $p = .02$) subscales of the SF-MPQ. A similarly large effect size was evident on the general health ($\eta^2 = .35$, $p = .06$) subscale of the SF-36.

Table 4.2 *Between-Group Effects: F-values, Significance Levels, Effect Sizes (η^2) for HRQOL Domains, and Power, using Social Support at Week 9, Medication Use, and appropriate Baseline Scores as Covariates*

Scale	Subscale	*F*-value	*p*	η^2	Power
AIMS2	Mobility	.18	.84	.03	.07
	Walking & Bending	3.58	.06	.36	.56
	Hand Function	1.42	.28	.18	.25
	Arm Function	.10	.91	.02	.06
	Self-care	1.33	.30	.17	.24
	Household Tasks	.36	.71	.05	.10
	Social Activity	3.07	.08	.32	.49
	Family Support	.19	.83	.03	.07
	Arthritis Pain	.56	.58	.08	.13
	Tension	.31	.74	.05	.09
	Mood	.30	.74	.04	.09
	Satisfaction	.39	.69	.04	.10
	Health Perceptions	3.06	.08	.32	.49
	Arthritis Impact	.37	.70	.05	.10

Table 4.2 continues overleaf

Table 4.2 continued

Scale	Subscale	*F*-value	*p*	η^2	Power
SF-MPQ	Sensory Pain	5.14	.02	.44	.72
	Affective Pain	1.44	.27	.18	.25
	Total Pain	5.95	.02	.48	.79
	Present Pain Index	.01	.99	.00	.05
SF-36	Physical Function	.76	.49	.10	.15
	Role: Physical	.05	.96	.01	.06
	Bodily Pain	.20	.82	.03	.08
	General Health	3.51	.06	.35	.55
	Vitality	.14	.87	.02	.07
	Social Function	.02	.98	.00	.05
	Role: Emotional	.73	.50	.10	.15
	Mental Health	.05	.96	.01	.16
	Health Transition	.28	.76	.04	.09

Univariate between-groups effect sizes (Cohen's *d* for independent means) are reported in Table 4.3. Three between group comparisons were conducted (i.e., usual care with massage, *UC-Massage*; usual care with mobilisation, *UC-Mobilisation*; massage with mobilisation, *Massage-Mobilisation*), and effects sizes, representing the magnitude of difference between groups, are reported for each comparison on each subscale at week 9. These between-group effect sizes are oriented such that a positive effect size indicates improvement in the second group compared with the first, and a negative effect size indicates a decline in the second group compared with the first. In head-to-head comparisons, the mobilisation group improved over the massage group on all subscales,

although some improvements were quite small. The mobilisation group also improved compared to the control group on all variables except the physical function scale of the SF-36.

Table 4.3 *Between-Group Effects: Effect Sizes (d) for the Differences Between Groups at Week 9 for HRQOL Domains (UC = Usual Care Control Group)*

	Between-group comparison		
AIMS2 subscale	UC- Massage	UC-Mobilisation	Massage-Mobilisation
Mobility	- .14	.57	.75
Walking & Bending	- .24	.34	.55
Hand Function	- .02	.35	.61
Arm Function	- .26	.42	.55
Self-care	- .65	.58	.77
Household Tasks	- .17	.57	.60
Social Activity	1.56	1.84	.15
Family Support	.29	.76	.59
Arthritis Pain	.11	.81	.68
Tension	- .23	.70	.84
Mood	- .09	1.27	.92
Satisfaction	- .38	.50	1.52
Health Perceptions	0.13	1.01	.92
Arthritis Impact	.41	1.33	1.15

Note. Between-group effect sizes are oriented such that a positive effect size indicates improvement in the second group compared with the first, and a negative effect size indicates a decline in the second group compared with the first.

Table 4.3 continues overleaf

Table 4.3 continued

	Between-group comparison		
SF-MPQ subscale	UC- Massage	UC-Mobilisation	Massage-Mobilisation
Sensory Pain	1.21	1.42	.80
Affective Pain	.79	.84	.31
Total Pain	1.29	1.27	.78
Present Pain Index	- .03	.62	.42

	Between-group comparison		
SF-36 subscale	UC-Massage	UC-Mobilisation	Massage-Mobilisation
Physical Function	- .21	- .13	.09
Role: Physical	.36	.46	.10
Bodily Pain	.48	.52	.06
General Health	- .42	.73	1.21
Vitality	.35	.45	.24
Social Function	.13	.62	.60
Role: Emotional	- .70	.40	1.00
Mental Health	- .69	.61	1.81
Health Transition	.04	.72	.57

Note. Between-group effect sizes are oriented such that a positive effect size indicates improvement in the second group compared with the first, and a negative effect size indicates a decline in the second group compared with the first.

Direct comparisons of the groups at week 9 need to be interpreted with some caution because the calculation of Cohen's *d* for independent means does not account for differences between the groups at baseline (Aron & Aron, 1999). Because the sample sizes were small, it is not surprising that the groups were dissimilar at baseline, but this dissimilarity compromises the meaningfulness of the univariate between-groups comparison at week 9. By way of example, the mean sensory pain subscale scores on the

SF-MPQ for each group at baseline, week 9, and the change in these scores over time, are shown in Table 4.4. Sensory pain is scored on a range from 0-33 and larger scores represent more pain. Change scores are oriented such that a positive score represents health status improvement and a negative score represents decline.

Table 4.4 *Comparison of Mean Sensory Pain Scores in Each Group Over Time*

Group	Baseline	Week 9	Change Scores
Control	11.83	12.33	- 0.50
Massage	10.29	6.07	+ 4.22
Mobilisation	8.67	4.67	+ 4.00

These data demonstrate why the within-groups effect size for this subscale is largest for the massage group and the between-groups effect size is largest for the mobilisation group. Participants in the mobilisation group reported the lowest mean sensory pain scores of any group at both the start and the end of the study. Their pain scores reduced over the course of the study, but slightly less so than those of the massage group participants. Notably, pain scores in the control group increased over time. Mobilisation group participants experienced the least pain at the end of the study, and massage group participants experienced the greatest reduction in their pain over the course of the study. From these data it is reasonable to conclude that both massage and joint mobilisation may reduce sensory pain.

This conclusion is further supported by the omnibus effect size arising from the sensory pain analysis of covariance ($\eta^2 = .44, p = .02$). A very large proportion (44%) of the variance in sensory pain scores is accounted for by group membership, after baseline scores, medication use, and social support are accounted for as covariates. Because sensory pain scores reduced in both the intervention groups, and increased in the control group

over time, it is likely that both manual therapies are more effective than usual care in reducing sensory pain.

Discussion

Health-Related Quality of Life

Results from this study indicate that generally a 10-week program of joint mobilisation, and to a lesser extent, massage, can positively affect HRQOL and psychosocial well-being in people with OA, both over time, and compared with massage and usual care. Both manual therapies (joint mobilisation, massage) were associated with some improvements in HRQOL, but most of the improvements were of greater magnitude (larger effect sizes) in the mobilisation group. When the mobilisation group was compared directly with other groups at the end of the study (week 9), participants' HRQOL was greater in the mobilisation group than the massage group on all subscales, and greater than the control group on all but one subscale, although in a few comparisons the effect sizes were small.

Two of the tools used in this study, the AIMS2 and the SF-MPQ, are often used in research to measure dependent variables of known import for people with arthritis (Burckhardt, 1984; Burckhardt & Bjelle,1994; Meenan et al., 1980, 1992). The third dependent measure, the SF-36, is a widely used general health survey. Consensus among HRQOL researchers is that disease-specific measures are usually more sensitive to treatment effects than are generic measures (Berzon, 1998; Guyatt et al., 1993; Schug, 1996). To this end, greater clinical meaning is attributed to the improvements reported on the AIMS2 than to improvements identified using the SF-36. A one percent improvement (small effect size) in a variable known to be important to a client (e.g., pain) may be more meaningful than a large improvement in a less salient domain.

Covariate Measures

Medication use. Participants' medication use did not change significantly over the course of this study. Stability of drug use over the course of this study suggests that improvements in HRQOL, such as reduced pain, are not because participants took new, or larger doses of, medication. Also, the study is readily relatable to clinical manual therapy practice. Usually, drug regimes for clients with OA are overseen by general medical practitioners or rheumatologists, and not altered by manual therapists as part of routine arthritis care (AOA, n.d., APA, n.d.).

Social support. Total social support (TSS) at the completion of the study (week 9) was used as a statistical control in all analyses of covariance, to attempt to control for the social support afforded by the treatments (e.g., building a relationship with a therapist). Most participants' social support remained generally stable throughout the study. Participants' small changes in social support over time may have accounted for some, but not most, of their perceived improvements in HRQOL.

Impact of Arthritis: AIMS2

Participants in both the mobilisation and massage groups reported improvements over time on most of the fourteen AIMS2 subscales, but the magnitude of the improvements (effect sizes) varied markedly (see Table 4.1). By contrast, the control group reported declines in health status on most subscales. Between-groups comparisons indicated that at the end of the study the mobilisation group outperformed both the usual care and massage groups on all AIMS2 subscales (see Table 4.3). When baseline differences between the groups are accounted for, being in the mobilisation group explains a large portion of the variance in four AIMS2 subscale scores: walking and bending, hand function, social activity, and health perceptions (see Table 4.2). These results suggest that joint mobilisation can positively influence some aspects of arthritis-related health status.

In keeping with the recommendation of Sechrest et al. (1996), I selected intuitively comprehensible outcome measures. The walking and bending and hand function subscales of the AIMS2 are closely linked with activities of daily living. For example, the hand function subscale includes items about writing with a pen or pencil, buttoning clothes, turning a key, tying a bow or knot, and opening a new jar of food. A lowering of the AIMS2 score on this subscale by 0.4 points indicates that a person can do one of these things more easily, or more often, than at the previous data collection time (see Table E.5 in Appendix E).

Affective and physical components of health status of both the intervention groups generally improved over time, but to differing extents. The mobilisation group demonstrated medium to very large improvements over time in the physical components of the AIMS2, notably walking and bending, hand function, arm function, and household tasks. In the affective component, and other psychological subscales, of the AIMS2 (i.e., affective: tension, mood; other psychological: satisfaction, health perceptions), both manual therapy groups displayed some improvements over time. The massage group reported very large improvements in mood and satisfaction over time, but improvements on the same subscales in the mobilisation group were of medium effect size. The mobilisation group reported very large improvement in health perceptions (d = 1.29), but worsening of perceived tension (d = -.40), over time.

Obviously there are correlations between the AIMS2 components. The relationship between physical function and satisfaction, or other psychosocial variables, is complex. Pincus et al. (1983) demonstrated that satisfaction levels vary considerably among people with comparable physical health status. Meenan et al. (1992) confirmed that in groups of people with OA or RA assessed using the AIMS2, satisfaction and function are moderately correlated. For participants in this study, it appears that mobilisation was most effective in improving the physical components of health status, and massage similarly so for the

affective components. This distinction between therapeutic effects is interesting, but may be undistinguishable in clinical practice because massage and mobilisation procedures are often used in concert.

General Health-Related Quality of Life: SF-36

Improvements in some generic HRQOL domains, ranging from small to very large effect sizes, were identified in each of the three groups over time (see Table 4.1). Between-group comparisons indicate that the mobilisation group reported the highest levels of general HRQOL at the end of the study, however, because the groups were dissimilar at the start of the study, the most meaningful analysis is the ANCOVA, which accounts for baseline differences (see Table 4.2). A very large omnibus effect size was found for the general health ($\eta^2 = .35$) subscale of the SF-36. Via the univariate analyses, this improvement is identified as occurring in the mobilisation group, both within that group over time, and in comparison with the other groups.

Generic health-profile measures, such as the SF-36, have been criticised because "they may not be responsive to small but important clinical changes experienced by the patient" (Berzon, 1998, p. 5). With this caveat in mind, it is likely that large and consistent effects (i.e., improvement in the mobilisation group on the general health subscale both within- and between-groups) observed using a generic instrument are real effects. Subtle improvements may have been lost due to lack of instrument sensitivity to change, but this large effect suggests that something meaningful has changed.

General health perception is a measure of what people feel and believe about their health. It is arguably the broadest concept assessed in the SF-36, including perceptions of current health status, health in relation to others, and expectations for future health. The general health perception subscale of the SF-36 is particularly robust, and correlates highly with comprehensive measures of general health used in the Medical Outcomes Study (Ware & Sherbourne, 1992). Ware and Sherbourne acknowledged that the use of broad

concept scales with multiple levels might sacrifice detail. In this study, I can be confident participants' that general health perceptions improved with a course of joint mobilisation, both over time and relative to other interventions. This confidence is amplified by the very large effect sizes for general health perceptions also found on the AIMS2, but, because of the small to medium omnibus effect sizes on the other SF-36 subscales, I cannot explain how participants' concepts of general health were constituted.

Although participants in the mobilisation group felt their general health had improved, they did not report substantial changes in depressive or anxious symptoms (mental health) or vitality. Fatigue (reduced vitality) is a common problem among people with arthritis (all types). Also, fatigue is an important aspect of some mental health pathologies, particularly depression, that are prevalent among people with arthritis (American Psychiatric Association, 2000). Fatigue and depression covary in arthritis, and accurate diagnosis and effective management may be complicated by the overlap between these conditions (Pincus & Williams, 1999).

Wolfe, Hawley, and Wilson (1996) investigated fatigue in 1488 people with rheumatic diseases, and identified clinically important levels of fatigue (visual analogue score of ≥ 2 on a scale ranging 0-10) in 41% of people with OA. In multivariate analyses, the strongest independent predictors of fatigue were pain, sleep disturbance, and depression. Regression modelling demonstrated that combinations of these variables explained up to 90% of fatigue variance. If vitality is considered the inverse of fatigue, then the relationship between vitality and mental health implied by Wolfe et al.'s (1996) study is partly replicated in this study. The correlation between vitality and mental health scores at week 9 is $r = .76$, indicating that changes in vitality were strongly associated with changes in mental health.

Future research might be directed to understanding the elements that contribute to general health perceptions for people with OA. Turner et al. (2002) found that pain,

functional impairment, and disability were repeatedly cited by 12 male ex-professional footballers with OA as important components of their general health. Turner et al.'s work may be coloured by the vocational background and gender of participants, but it raises the possibility that in people with OA, improvements in general health may be more closely associated with physical function (measured using the AIMS2), and pain (measured using the SF-MPQ), than with vitality, mental health, or other constructs measured by the SF-36.

Pain

Some of the most substantial improvements noted in this study occurred in both manual therapy groups across the gamut of pain scales. Of particular note are the univariate effect sizes for change in the sensory ($d = .93$), affective ($d = .12$), and total ($d = .87$) pain domains of the SF-MPQ within the massage group over time. The pain subscales of the AIMS2 and SF-36 are measures of pain severity, and do not directly assess the sensorial and affective components of pain. A reasonable conclusion to draw from these data is that both massage and joint mobilisation decrease pain in people with OA, but these therapies influence different components of pain. It is not surprising that massage, a sensual practice, might have a large effect on the sensory components of pain.

In the SF-36 and AIMS2, pain is described as a physical domain, "bodily pain" and "arthritis pain," respectively. Bodily pain is something of a misnomer for the domain of pain, because, as Kugelmann (2000) identified, physical and psychological pain hurt equally, and are perceived and described similarly. The site and quality of pain varies according to the type of arthritis, and the kind of pain may vary during the course of arthritic disease (Ferrari et al., 1996). Because the AIMS2 is a disease-specific HRQOL instrument, Meenan et al. (1992) asked participants to distinguish between pain caused by arthritis and pain caused by other diseases. This discrimination may not always be possible (Kugelmann), but a participant's self-report is the only logical way to seek such data.

As previously discussed, pain is of central importance to people with arthritis (Heiberg & Kvien, 2002; Minnock et al., 2003). It is a subjective experience, coloured by emotion, stress, culture, and personal background (Melzack, 1975, 1999; Payer, 2000). It is also difficult to capture in surveys or questionnaires. Some qualitative representations of pain have provided more personal glimpses into this complicated phenomenon. Padfield (2003), a photographer, asked 25 people with chronic pain to construct visual representations of their pain, which she photographed. Participants also provided brief written explanations of their artwork as images of pain. A striking feature of Padfield's book, *Perceptions of Pain*, is the diversity of images. Pain means markedly different things to different people. Because pain is both personal and of high priority, improvements of almost any size, in most aspects of pain, might be clinically important and individually meaningful.

Social Functioning: Disparity Between Instruments

There is disparity between the results on the social activity subscale of the AIMS2 and the social function subscale of the SF-36. On the arthritis-specific measure, improvements in social activity were observed in both intervention groups over time and in comparison to the usual care group. In the mobilisation group, these improvements were of large effect size. On the general HRQOL measure, change in social function accounted for by group membership was negligible. The way in which social function is reported also differs between these two scales, and may explain these apparently incongruous results. In the SF-36 participants are asked to score on 5-point Likert scales *to what extent* and *how much of the time* their physical health or emotional problems interfered with social activities (Ware & Sherbourne, 1992). By contrast, in the AIMS2 social function is a 5-item subscale, and includes specific indications of what constitutes social function (e.g., *How often did you get together with friends or relatives?*; Meenan et al., 1992). The meaning of interference is not made explicit in the SF-36, but would seem to imply

regularity in social activity. If I usually attend church on Sundays, but last weekend my arthritis made it difficult to get out of bed, and I missed church, that would be one day on which my health interfered with my social functions. Consider instead that I have not attended church for some years because I can no longer drive my own car, climb the stairs to enter the building, or stand while singing hymns, but a member of clergy visits me each Sunday afternoon to bring me eucharist and an audio tape of that morning's service. Although I am somewhat physically impaired, and that impairment has social consequences, I may not report this situation as health problems interfering with social activity because my understanding of social activity no longer includes the possibility of attending church.

Limited changes in physical and social function scores of the SF-36 may indicate that although participants in the intervention groups travelled to the city weekly for ten weeks to meet with student therapists, they possibly did not view these activities as social or physical functions. It is likely that participants maintained ordered social and physical activity habits (e.g., golf on Wednesdays, Probus club on Fridays) that, other than the addition of a weekly visit to a manual therapist, did not change over the course of the study.

Clinical Implications

Joint mobilisation appears justified as an adjunctive therapy to improve HRQOL for people with OA. Massage may also be a useful adjunctive therapy for people with OA, and is likely to have positive effects on sensory pain. In this study, manual therapies were tested in isolation, but the separation of treatments is unlikely in the clinical setting. Massage therapists may offer single therapies (i.e., massage), but most manual therapists (e.g., physiotherapists, chiropractors, osteopaths) are trained in a range of manual therapy procedures and combine these treatment approaches in clinical practice (APA, n.d.; AOA, n.d.; CAA, n.d.). The manual therapies used in this study are generic, and would be readily

recognised by Australian physiotherapists, chiropractors, and osteopaths as part of their usual practice. Also practitioners may combine manual therapies with exercise and other procedures (e.g, nutritional advice, see CAA).

Clinically, there is no reason to separate manual therapies, but the multifaceted and often idiosyncratically delivered quality of clinical practice is difficult to test. Because massage and joint mobilisation were tested separately, it is not possible to make recommendations regarding the effect of combined therapies. Future studies could be directed at determining the effects of the pragmatic application of manual therapies, in single and combined forms, and in conjunction with other therapies (e.g., exercise).

Cost and Benefits

In this study, a 10-week program of manual therapy cost $250 (Australian) to deliver. The usual cost of a standard consultation at the Osteopathic Medicine Clinic at Victoria University is $25, but this figure is low because the student clinic does not charge professional rates. Manual therapy is likely to be available to clients at $25 per consultation only if they use services offered at a teaching clinic. Private consultation fees for manual therapy are commonly double, or more, the rates charged at teaching clinics.

Although it not possible to ascribe monetary values to the gains in HRQOL observed in this study, it is important to acknowledge that manual therapy can be financially costly. Individuals with OA need to be fully informed of the costs of an intervention, particularly one that is delivered on a regular and ongoing basis, as well as the benefits of that intervention, in order to make a personal decision about costs and benefits.

Kaplan (1993), as part of a general health policy model, proposed the Quality of Well-being Scale (QWB) as a generic HRQOL outcome measure that could be used to calculate the cost/utility ratio of interventions, and allow comparison between interventions of different types and for different diseases. In the QWB scale, functionality and symptoms

are given a weight, derived from community surveys regarding utility, ranging from 0 (dead) to 1.0 (optimum function). A score of .64 suggests that an individual was in an observable state 64% of the way between optimum functioning and death. A person remaining in that state for one year would have lost .36 (1 - .64) well-years (or quality adjusted life years: QALYs). Using the QWB scale it is possible to estimate the number of well-years an intervention produces. Dividing the cost of the intervention by the well-years produced by that intervention gives a cost/utility ratio that permits comparison between interventions and across diagnoses.

Kaplan et al. (1996) estimated the public health impact of OA (in the USA) via a survey of people with self-reported arthritis. Kaplan et al. estimated the mean expected QALYs lost because of arthritis to be 1.86. Measures of QALYs lost to arthritis were greater among men than women.

Comparison of the cost/utility of interventions across the breadth of health care is of great interest and importance to health policy makers and legislators (Kaplan, 1998). Despite this obvious advantage of the QWB scale, it has not become widely adopted as a HRQOL outcome measure. The general health policy model, comprising the QWB scale, was trialed in the US State of Oregon between 1987 and 1990. The policy model failed in Oregon due to several methodological and analytical flaws associated with departure from the original design (Kaplan, 1993). Other generic health outcome measures, including the SF-36 (Ware & Sherbourne, 1992), are used more commonly than the QWB scale in HRQOL research. Kaplan et al. (1998) presented evidence supporting the validity of the QWB scale for population monitoring, descriptive studies, and clinical trials. Although the QWB scale is a valid tool for HRQOL research, Kaplan et al. (1998) concluded that the more widely used SF-36 is a comparable, comprehensive, alternative tool.

Clinical Cautions and Limitations

In this study participants were asked to provide verbal feedback to therapists regarding the level of pressure applied during massage, the comfort of joints and skin contacts during mobilisation, and to report immediately any discomfort. There are many disciplines of massage, and not all are comfortable to receive (e.g., Rolfing). The results of this study may not apply to the more vigorous forms. Furthermore, Ernst (2003) cautioned that vigorous massage styles are most frequently associated with adverse reactions to therapy.

Physical and manual therapies are generally associated with a low risk of physical harm to clients, but the Australian Physiotherapy Association's (APA, n.d.) claim that "unlike pharmaceuticals physiotherapy has no side effects and no contraindications" (p. 1) may somewhat overstate the safety profile. Some manual treatments, including massage, and particularly spinal manipulation, have been associated, albeit rarely, with adverse outcomes including stroke and death (Ernst, 2003; Rothwell, Bondy, & Williams, 2001; Gross et al., 2004). Although these potentially more dangerous forms of manual therapy were not used in the studies that constitute this thesis, they are widely practiced, and a caution is necessary. The improvements in HRQOL observed in this study, and Study 3, cannot automatically be expected with other forms of manual therapy.

In delivering manual therapy, a therapist's hands make contact with the body of the client in joint mobilisation to move joint structures through passive ranges of motion, and in massage to apply pressure to muscles, tendons, and other soft tissues. Because of the way these treatments are delivered, manual therapies are not likely to be attractive therapeutic options for people who dislike being touched, or who have painful or embarrassing skin conditions.

For information regarding a client's comfort during manual therapy a therapist gathers data via: (a) palpatory sensation, and (b) feedback from the client. Palpation,

particularly of spinal joints, has been repeatedly demonstrated to have poor inter-rater reliability (Troyanovich, Harrison, & Harrison, 1998), and the validity of joint motion palpation has not been established (Najm et al., 2003). What therapists can feel (palpate) is probably unreliable, may have no clinical meaning, and is clearly inadequate as a measure of client comfort.

Some studies have demonstrated that joint motion palpation has higher reliability, and some clinical validity, when used with other criteria (e.g., client's feedback regarding tenderness) as is usual in clinical practice. Perhaps the most celebrated of these studies is Jull, Bogduk, and Marsland's (1988) work, in which a manual therapist identified symptomatic cervical zygapophysial joints, as confirmed with diagnostic joint blocks, with 100% accuracy. The criteria used to diagnose symptomatic joints in Jull et al.'s study were abnormal end-feel, abnormal quality of resistance to motion, and reproduction of pain as reported by the participants. A caution, however, is necessary: given the poor reliability and unknown validity of joint motion palpation as a method of obtaining information regarding the comfort of joint mobilisation, it is wise to reserve this therapy for clients with intact joint sensation (e.g., not neuropathic osteoarthropathy) and the capacity to give verbal feedback to the therapist. Also, it would be judicious for a therapist to seek the client's perception of the comfort of an intervention regularly during treatment.

The small sample size in this research limits the generalisability of the results. Additionally, because the participants in this study were ambulatory and able to self-care fully (e.g., dress, undress, shower), the positive results might not be applicable to people with more severe mobility impairments. Additional research is needed to explore the influence of joint mobilisation on people with OA over a range of impairment levels. At present, however, joint mobilisation, and to some extent massage, appear to be effective adjunctive therapies in OA, at least for those people with stable joint structures, moderate ambulatory capacity, and low AIMS2 self-care scores.

Recommendations for Future Research and Conclusions

How this Study Informed Study 3

In this study, participants in the joint mobilisation group reported improvements in more HRQOL domains than did participants in either the control or massage groups. Many of these improvements were in medium to large effect size ranges. Because the improvements associated with massage were moderate by comparison, joint mobilisation was the only manual therapy employed in Study 3. Considerations of time and the financial cost of conducting this research on an extremely limited budget also entered into this decision. The design of Study 3 was expanded to include short- and medium-term follow-up of participants after completion of the 10-week intervention in order to explore further how the HRQOL improvements associated with joint mobilisation changed over time.

The small sample size compromised the statistical power of this study, and the changes observed and the associated effect sizes should be considered as suggestions of effectiveness. Mobilisation and usual care groups were repeated in Study 3 to test for replicability and allow comparison across the studies.

Future Research

Future research might be directed towards longitudinal studies of one to two years, with larger samples. It is particularly important to determine whether the HRQOL gains identified in this study are: (a) consistently and repeatedly observed, (b) maintained with ongoing treatment, and (c) maintained after conclusion of the interventions. Also, if reliable, sensitive, and valid disease monitoring techniques become established, it would be useful to correlate quality of life measures with concurrent disease markers to determine if manual therapy interventions alter the progression of osteoarthritis.

Conclusions

Joint mobilisation appears to be effective in bringing about improvements in many aspects of quality of life in people with OA. Joint mobilisation is consistently more

effective than either massage or usual care in bringing about HRQOL improvements across a range of domains, particularly general health, social function, and pain. Massage may also be useful in relieving some components of pain, and improving mood, tension, and satisfaction over time. Clinically, there is no reason to use single manual therapies in isolation: massage and joint moblisation may be used together.

The joint mobilisation and massage programs used in this study were generic interventions, not specific to any discipline, and can be readily adopted into the diversity of manual therapy practices. These interventions are likely to be easy to teach to trainee therapists, and might reasonably be incorporated into existing student training programs. Also, a useful future project might be to adapt these manual therapies for clients' home use.

CHAPTER 5

A CAUTIONARY TALE: WHEN RESEARCH FAILS

Introduction

There is a tendency in medicine and social sciences to report only successful studies. Studies with few participants (low *N*s), inconclusive (non-significant) results, or low power, are unlikely to be accepted for publication. Journal editors might prefer to fill their pages with reports of scientific success stories, but it is my contention that the reporting of failed studies is important because lessons arise from mistakes.

If a study failed because participants became worse, or were injured, then to repeat such a study would be unethical. When such failed studies are not published or discussed then, in ignorance, researchers may repeat mistakes with ethical implications. Exploration of a failed study may unearth suggestions about how to do research better. As Sparkes (2002) put it: "an experience that might initially be viewed as a researcher's nightmare is redefined as a useful resource for raising questions about ethical practice" (p. 58). Sparkes was writing about qualitative research, but his observation holds equally well for quantitative studies.

Admission of failure is painful. It is easy to understand why failed studies are rarely published. I would like to be the author of successful, ground-breaking research. I would like to be known and respected for my scientific achievements. I would prefer to keep my failures to myself, but if there is something to be learned from them, perhaps I should swallow my academic pride. In the wisdom of Aesop: "Better be wise by the misfortunes of others than by your own." In this case, the mistakes are mine, and I hope that future researchers (Aesop's "others") might learn from them.

Failed research has consumed time, money, and resources, expenses that would be wasted if repeated in future studies. Research grants are never infinite, and it is important that research funds are allocated for the studies most likely to succeed. If reports of failed

studies were accessible to researchers during the design and development stages of new projects, then pitfalls might be avoided. When a failed study is disregarded, and the lessons that arise from it are overlooked, then any research grant awarded has returned less, educationally and scientifically, than the value of the investment.

Cost-benefit or cost-utility analyses are included in many clinical studies, and provide important data that allow consumers to make informed choices about whether the benefits of a therapy are worth paying for. Is it not at least as important to know when a therapy produces no benefits, or is not worth paying for?

Sechrest et al. (1996) argued that clinical outcomes should be calibrated against "real life" measures in order to be made inherently meaningful to therapists and consumers. This line of reasoning applies equally to failed as to successful studies. A failed study may be useful if the failure can be reported in a meaningful metric. For example, it is more useful to know that participants doubled their analgesic drug use during a therapy than it is to know that visual analogue scale pain scores increased by one and a half standard deviations. Not only did this (hypothetical) therapy increase participants' pain (by whatever 1.5 *SD* means in real life), it cost them twice as much as normal (i.e., compared with usual care) in drug expenses.

Method

I had planned that Study 2 would be a four-group comparison of the effects of manual therapies (massage or joint mobilisation), warm-water exercise, and ordinary medical care on the HRQOL of people with rheumatoid arthritis (RA). Study 2 was conducted at the same time as Study 1, and used an almost identical design, but with participants with a different type of arthritis (RA not OA). Study 2 failed because of the composite influences of mistakes in design, participant withdrawal, and incomplete data. To discuss each of these issues, I have modified a traditional study report.

Participants

Fourteen adults (13 females, 1 male) previously diagnosed with rheumatoid arthritis were recruited via an invitational flyer (see Appendix A) and volunteered to participate in this study. Participants had a mean age of 56.8 years (range 29-72) and a mean time since diagnosis of RA of 12.9 years (range 1.5-35).

Eligibility criteria for this study were similar to those in Study 1 (see Chapter 4). Participants needed to be able to walk unassisted for 20 meters, climb in and out of a swimming pool safely, and undress to their underwear unaided. In order to complete the questionnaires used as data collection tools, participants needed to be literate in English. Participants were excluded from this study if they: (a) attended fewer than eight manual therapy or exercise sessions, or (b) were diagnosed during the study with disorders other than those attributable to RA. Participation in this study was voluntary, and participants were free to withdraw from the study at any time.

Measures

Three questionnaires assessing generic and disease-related physical and psychological function, and pain, were used to determine the influence of the exercise and manual therapy programs on dimensions of HRQOL and well-being. The individual scales were the Australian / New Zealand adaptation of the Medical Outcomes Study 36-Item Short Form Health Survey Version 1 (SF-36; Ware & Sherbourne, 1992), the Short-Form McGill Pain Questionnaire (SF-MPQ; Melzack, 1987), and the Arthritis Impact Measurement Scales Version 2 (AIMS2; Meenan et al., 1992). These measures were described in the Method section of Chapter 3 (Pilot Study).

Statistical controls were built into this study. The Medical Outcomes Study Social Support Survey (MOS-SS; Sherbourne & Stewart, 1991) was used as a statistical control for the potential positive effect of an increased social support network associated with exercising in a group or attending consultations with a therapist. The Medication Use

Survey developed for this thesis was used to account for altered medication regimes, the influence of medication, particularly analgesics, on pain scores. These measures were also described in the Method section of Chapter 3.

Compliance data. Participants' attendance at intervention sessions was documented by either exercise instructors or osteopathic students. Attendance at an exercise session was assumed to mean participation, to the level of the participant's ability, in that session. Drop-out rates were recorded for all studies.

Procedures

The standardised manual therapy regimes (joint mobilisation and massage) used in this study were the same as those in Study 1. Prior to use with participants, these manual therapy regimes were reviewed by practitioners of relevant disciplines (i.e., manual therapists, rheumatologists, representatives from Arthritis Victoria) to determine that the procedures were: (a) safe for use with people with rheumatoid arthritis, and (b) not specific to any particular discipline. Manual therapy regimes were modified according to feedback received from experts in the field prior to use with participants.

Recruitment and randomisation procedures were also the same as those used in Study 1. There were three intervention groups and one non-intervention control group in this study. Participants were randomly allocated to: (a) warm-water exercise (n = 2), (b) joint mobilisation (n = 3), massage (n = 4), or (d) usual care (n = 5) groups. All participants remained in the care of their usual practitioners throughout this study. With participants' permission, medical practitioners (specialists and general practitioners) were notified of their clients' involvement in the study, provided with a copy of the information sheet distributed to participants, and invited to contact me if they had any concerns or queries regarding the study. No existing care regimes (i.e., medication, exercise, alternative therapies) were altered during the study. Participants in the intervention groups undertook adjunct therapies (manual therapy or warm-water exercise) in addition to their usual care.

Participants in the control group continued with all usual care but commenced no new therapies.

All interventions were undertaken once a week for ten consecutive weeks. Data on HRQOL, including functionality and pain perception of participants in the four groups were collected for comparison. All measures were recorded before any therapy was administered at week 1 (baseline), and repeated at weeks 5 and 9. Final measures were taken at week 9 instead of the last week of the 10-week program because, according to Petajan et al. (1996), anticipation of the end of a regime of therapy, and the associated removal of social support, may negatively influence psychological aspects of health.

All intervention sessions were 40 minutes in duration. As in Study 1, all manual therapy interventions were conducted at the Victoria University Osteopathic Medicine Clinic and provided by Masters level osteopathic students. Osteopathic student therapists taking part in this study were enrolled in 4th or 5th year clinical practica as part of their full time enrolment in the Master of Health Science (Osteopathy) course at Victoria University. Students were allocated to participants according to availability (i.e., students met with research participants during the students' usual clinical shifts). Because of the interest in social support and other psychosocial factors influencing HRQOL, continuity of care was maintained as far as was reasonably possible.

Participants joined established water-exercises classes conducted under the auspices of Arthritis Victoria (AV) at various heated public, and hospital swimming pools in suburban Melbourne. The 10-week timeframe was chosen for this study because that is the length of one Victorian school term, and AV offers warm-water exercise classes during term time only. Participants contacted AV to enrol in warm-water exercise classes at convenient locations. All classes comprised groups of 10-15 adults, led by an AV trained adult volunteer, and met at the same time and place each week for 10 weeks.

All interventions in this study were provided at no charge to participants. AV invoiced Victoria University for the warm-water exercise classes, and was paid from doctoral research funds. Students are not paid for consultations at the Osteopathic Medicine Clinic because these consultations form part of the students' clinical training. Participants paid for their usual care exactly as they did prior to the study. No participant was paid for involvement in the study or offered any inducement, other than free therapy, for participation.

Issues Arising from the Research Design

It is a standard proviso for the ethical conduct of the study that participants are free to withdraw at any time (Victoria University, n.d.a., n.d.b). Three participants withdrew from the study (one at each of weeks 4, 5, and 7) and reported that they had experienced worsening symptoms, particularly increased pain. Participants were not required to give any explanation for withdrawal from the study. That they chose to do so is useful because it highlights two important aspects of living with RA: (a) the priority given to pain, and (b) the fluctuating symptoms of the disease.

In designing the study I did not fully account for the episodic nature of rheumatoid arthritis. I attributed too much weight to scientific literature reporting that RA is a relatively stable disease over short to medium periods of time (Meenan, Kazis, & Anderson, 1988; Roche et al., 2003), and placed inadequate weight on lay literature advising people with RA to abstain from exercise or manual therapies during disease flares (Lam & Horstman, 2002). Such lay literature is developed out of the experience of clinicians and people with arthritis, and is a "real world" account of what people with RA feel able and confident to do during disease peaks.

Retrospectively, I can see that my own disease and career history subconsciously influenced my design of this study. I experience clinical symptoms and signs that satisfy the ACR criteria for the diagnosis of RA. Up to this time I have experienced non-erosive

disease, with only mild disability during flares. I may have expected that my participants would be like me, overestimated how much many people with RA feel able to do, and designed a study suited to either rather healthy or very determined individuals.

I am also an osteopath, and have both administered and received manual therapy. As a client, I find manual therapy pleasant, comforting, and therapeutic. My bias in favour of manual therapy led me to design a clinical trial that was somewhat prolonged. Because of the episodic and unpredictable nature of RA, a pilot study of simple pre-post design over a very short course (e.g., 1 or 2 sessions) of manual therapy may have been a more appropriate first study.

Meenan et al. (1988) used the Arthritis Impact Measurement Scales (AIMS) to assess the stability of health status in people with RA over 5 years and reported no "clinically important deteriorations" on any subscales (p. 1484). It is worth noting that 111 people of the original cohort of 410 were lost to follow-up. Any clinically important deteriorations of RA in the people who withdrew from Meenan et al.'s study could not be determined. In those people completing the study, brief fluctuations in health status, such as flares, may have been overlooked because data were collected at the beginning and end of the five-year period only. Because the sample size was large (n = 299) variance in health status scores due to a few participants having flares at either data collection point is likely to have been: (a) small, and (b) approximately equal in both data sets. On the basis of the data gathered, it was reasonable for Meenan et al. to conclude that RA may be "more stable than previously thought," but that picture of stability over time belies the clinical flux experienced by people with RA (p. 1484).

In contrast, Lam and Horstman (2002), in *Overcoming Arthritis*, a book for people with arthritides, wrote that:

> It can be frustrating and depressing to cope with RA because it is so unpredictable and so painful. Symptoms can come and go without warning and vary from

person to person. ...Most people suffer through cycles of flares and remissions. (p. 18).

Lam and Horstman (2002) also advised that people with RA reduce the difficulty of their exercise regimes during flares. They suggested that massage, and by implication, other manual therapies, should be avoided during disease flares: "hot, swollen joints should not be massaged" (p. 66). There is no scientific evidence, but common wisdom, that massage or joint mobilisation aggravate symptoms during RA flares. Participants who withdrew from this study at times of increased pain acted in keeping with common sense advice.

Guthlin and Walach (cited in Ernst, 2002) conducted an unblinded, randomised comparison of Swedish massage and drug therapy (analgesia) for the management of non-inflamatory rheumatic pain. Participants ($N = 29$) were randomised to two groups, and received either ten 20-minute massages or oral analgesic medication for five weeks. Outcome measures of pain (visual analogue scale), depressed mood, and fearfulness were recorded pre- and post intervention, and at a follow-up period of three months. At the end of the intervention period, improvements in all outcome measures were seen in both groups. At the end of the 3-month follow-up, pain was reduced in the massage group only. Guthlin and Walach concluded that massage is at least as effective as oral analgesic medication for management of rheumatic pain. Guthlin and Walach's findings must be considered with some caution in relation to Study 2. Participants in this study had been diagnosed with RA, and those participants with erosive polyarthropathy were likely to be experiencing both rheumatic pain and inflammatory pain.

Because RA flares are unpredictable, modifications to the Study 2 design may not have altered the study results. Regardless, I believe that it may have been prudent to attempt to recruit participants with relatively stable RA. For example, people with a history of only one or two flares per year, or people with non-erosive disease, more like Guthlin

and Walach's (cited in Ernst, 2000) cohort of people with rheumatic, non-inflammatory, pain. It may also have been sensible to collect baseline data over several weeks to demonstrate disease stability within individuals.

The recruitment strategy for this study, a flyer in a magazine for people with arthritis, used a medium directed at the population, yet yielded only 19 expressions of interest and 14 participants from a mailing of more than 6000 flyers. Because small sample size was an important factor contributing to the failure of this study, I have some reservations recommending any changes to study design, such as recruiting only participants with non-erosive disease, which might reduce the pool of available participants.

In the UK and Norway, large samples of people with RA have been recruited for clinical trials and longitudinal studies from central databases; the Norfolk Arthritis Register and the Oslo Rheumatoid Arthritis Register respectively (Harrison et al., 1998; Brekke et al., 2001a, 2001b). The development of an Australian Rheumatoid Arthritis Database (ARAD) began during 2003, for the purpose of determining the incidence and prevalence of RA in Australia. At this time, the ARAD is not available to researchers for participant recruitment, and is unlikely to become so (R. Buchbinder, personal communication, May 5, 2004).

A panel of experts, including rheumatologists, approved the manual therapy programs developed for use in this study, prior to use with participants. Rheumatologists and general practitioners were informed of their patients' involvement in the study, and invited to raise comments, queries, or concerns. No medical practitioner relayed to me an opinion that manual therapy should be avoided during RA flares, but given the clear statement in the study information sheet that participants could withdraw at any time, it is possible that clients who developed flares were advised by their doctors to leave the study. I recommend that if future studies of manual therapies in people with RA are proposed,

researchers develop manual therapy programs that are approved by rheumatologists for use during flares as well as remissions, and clearly state as much in any study information.

It is possible that manual therapy might have provoked RA flares in three of the 14 participants. The ethical principle of *Primum non Nocere* (First do no harm) has its roots in the Hippocratic Oath: "I will follow that system of regimen which, according to my ability and judgement, I consider for the benefit of my patients, and abstain from whatever is deleterious..." and is the first principle of ethical health care delivery (Hippocrates, trans 1949. Works, Volume 1). In order to prevent possible harm to participants, recruitment of people with RA was discontinued for Study 3. There is inadequate data arising from Study 1 to determine whether manual therapy has harmful effects on people with RA, neither is it an hypothesis that can be ethically tested.

Data Analysis and Results

Due to the small sample size, further reduced by participant withdrawal, the intended data analysis was discarded. All results from Study 2 are presented in Appendix F. My planned data analysis is described below.

Data Analysis

Repeated measures analyses of covariance (ANCOVA) were used to assess group (treatment groups versus control) differences for the SF-36, the AIMS2, and the MPQ measures. Social support was used as a covariate, along with pre-intervention (i.e., week 1, baseline) measures of HRQOL, disability, and pain, to control for initial differences between-groups. Statistical significance (alpha) was set at $p < .05$. Change in medication use and social support over time were each analysed using one way ANCOVA to determine whether week 5 and week 9 scores differed significantly from baseline.

Omnibus effect sizes were calculated as η^2. Eta squared (η^2) represents the amount of variance in a variable accounted for by group membership (i.e., being in an intervention group or the control group), and is therefore a relevant measure of effect size because it

explains the strength of association between treatments and the variables measured. Univariate effect sizes for within- and between-groups analyses were calculated as Cohen's *d*s.

Issues Arising from Data Analysis and Results

From a statistical point of view, the study failed because three of the 14 participants withdrew, and one participant did not return the week 5 or week 9 questionnaires, making the sample size too small ($N = 10$) to achieve acceptable statistical power for any variable (HRQOL domain). Missing data further reduced the power of the study. As anticipated from the Pilot Study (see Chapter 3), some participants omitted sections of the questionnaires, particularly the VAS of the SF-MPQ. Missing data are represented as two en dashes (--) in the data table of Appendix F.

Data from Study 2 are useful for what they reveal about the usual care (control) group. By way of example, means and standard deviations of the SF-MPQ scores for the control group over time are presented in Table 5.1. Clearly participants in the usual care group experienced generally worsening pain over the ten weeks of the clinical trial, but that worsening pain cannot be attributed to manual therapy. Because control group participants continued with all usual care, neither can their increased pain scores be explained by the removal of an intervention.

Table 5.1 *Means and Standard Deviations for SF-MPQ scores in the Usual Care Group*

SF-MPQ subscales	Baseline		Week 5		Week 9	
	M	*SD*	*M*	*SD*	*M*	*SD*
Sensory pain	9.8	2.7	15.0	6.6	14.0	5.1
Affective pain	2.4	1.1	4.4	2.5	4.4	3.5
Total pain	12.2	3.1	19.4	9.0	18.4	8.0
Present Pain Index	2.2	0.8	2.4	0.9	2.4	0.9

Note. Lower scores denote less intense pain.

The sample size of the usual care group is small ($n = 5$), and a non-normal distribution of data, with substantial variance, is to be expected, however, the pattern of highly variable, and somewhat worsening, pain scores over time is worthy of comment. One possible explanation is that there may be considerable pain variation over time in people with RA. Participants in the manual therapy groups may have attributed their worsening pain to manual therapy, when such pain increase might have occurred in any case. Of course, this explanation is conjecture–the question of how much variability in pain scores is due to an intervention, and how much is background "noise" from the disease process, could only be answered satisfactorily with larger sample sizes and participants who remain in the study until its conclusion.

Over two decades ago, Kazis, Meenan, and Anderson (1983) documented the importance of pain as a key component of health status in people with rheumatic disease. Kazis et al. used a regression model to explore the contributions of pain, physical disability, and psychological status as components in explaining physicians' and clients' assessments of health, medication use, and changes in health status (including pain) over time. They found that pain made a highly significant contribution to explaining both clients' and physicians' assessments of health status, and the largest explanatory contribution to participants' medication use. Using prospective data, Kazis et al. also demonstrated "that current pain, rather than current physical or psychological disability, is the best predictor of subsequent pain ($p < .001$)." (p. 1017). Pain is an important component in driving health behaviour (e.g., medication use). With this understanding, it is not surprising that participants in the manual therapy groups who experienced increased pain might: (a) attribute their pain to the intervention, and (b) seek to withdraw from the perceived painful stimulus.

Recommendations for Future Research and Conclusions

It is easy to draw the simple conclusions that this study might have succeeded if I had been able to recruit more people, recruit a more homogenous group of people, gather baseline data over a longer period, and trial the manual therapy interventions over a very short course. The logistics of such changes to research design are not always straightforward.

I chose to report this failed study in order to share my experience of what it was really like to conduct a clinical trial. Because I am an osteopath, and a person with RA, as well as a researcher, the failure of this study presented considerable role conflicts for me. I had to consider the possibility that a therapy I practice, and personally find useful, might be harmful to the people I wish to serve. In response, I ceased recruitment of people with RA for Study 3.

> The reporting of failed studies is not common practice. Much more commonly: "...by the time the research is presented or written up, all the perils and pitfalls of the research experience have been omitted or smoothed out in a tidy report outlining what went right rather than what went wrong in the research endeavor." (Boman & Jevne, 2000, p. 547).

Some of the questions raised by this study lend themselves to qualitative inquiry. In following up this study, I would like to interview the participants who withdrew from the manual therapy groups, to gain an insight into their motivations for withdrawal. In particular, I would like to explore participants' health loci of control, and whether participants felt that manual therapy worsened their pain. From questions such as these, I could also ascertain whether participants' withdrew from the study upon the advice of other people, such as their doctors, or acted of their own volition. Consistent with the Australian National Health and Medical Research Council (NHMRC) guidelines for conducting research with consumers (NHMRC, 2002), I could also seek the advice of

those who withdrew from this study on how to improve the design of future studies of manual therapies in RA.

CHAPTER 6

STUDY 3: IS MORE BETTER?

EFFECTS OF SINGLE AND COMBINED INTERVENTIONS

Introduction

In Sobel and Klein's (1989) survey of 1,051 people with arthritis (all types), exercise was consistently reported as the intervention individuals found "worked best" to manage arthritis, and water exercise received particularly strong endorsement. Clinical trials have demonstrated that water exercise is comparable to land-based exercise, and significantly better than no treatment controls, for improving physical function (a component of HRQOL) in people with OA, (Green, McKenna, Redfern, & Chamberlain, 1993; Foley, Halbert, Hewitt, & Crotty, 2003). Water exercise is now commonly used as a part of the Arthritis Self-Management Program (ASMP; Lorig & Fries, 2000), which has been shown to improve HRQOL in people with OA (Lorig et al., 1989, 1993). Therapists and client advocacy groups also recommend water exercise for people with OA (APA, n.d.; Arthritis Victoria, 2002; Sobel & Klein, 1993).

In Study 1 of this thesis, joint mobilisation was shown to have positive effects on the HRQOL of people with OA, both over time, and compared with other therapies (i.e., massage and usual care). Some of the associated effect sizes were very large, particularly for the general health and well-being aspects of HRQOL (see Chapter 4).

The second study in this thesis was an investigation of the effectiveness of manual therapies and warm-water exercise in improving health-related quality of life in people with rheumatoid arthritis. Study 2 became problematic because three participants withdrew from the study reporting worsening pain, and one participant did not complete the questionnaires. The resulting sample size ($N = 10$) was quite small. Each of the non-completing participants was in a manual therapy group, either massage or joint mobilisation, and their withdrawals raised important questions about the safety of manual

therapies in RA (see Chapter 5 for a detailed discussion). Consistent with the ethical principle of *do no harm*, recruitment of people with RA ceased after Study 2.

An underlying tenet of this study (Study 3) is that both joint mobilisation and warm-water exercise may be effective for improving HRQOL in people with OA. In real life, some people with arthritis engage in water exercise; others consult manual therapists; some people do both, and some people do neither. What remains unknown at this stage is whether these therapies: (a) are equally effective, (b) influence the same aspects of HRQOL, and (c) act conjunctively (or disjunctively). In this study, the effectiveness of joint mobilisation and water exercise for improving HRQOL in people with OA was tested in isolation (disjunctive), and as a combined therapy (conjunctive), in comparison to usual care.

Method

Study 3 was a comparison of joint mobilisation, water exercise, combined joint mobilisation and water exercise, and usual care in people with osteoarthritis (OA). The methodology of Study 3 was partly dependent upon the results of Studies 1 and 2. Because the outcomes of Studies 1 and 2 differed markedly, and these differences might be attributed to participants' illness profiles (i.e., OA versus RA), Study 3 was designed to include only participants with OA. Because the joint mobilisation group in Study 1 demonstrated more consistent, and often larger, effects than the massage group for most HRQOL domains, joint mobilisation was the only manual therapy tested in Study 3.

Participants

Adults ($N = 22$; 16 females, 6 males) previously diagnosed with OA were recruited via an invitational flyer (see Appendix A) distributed in a normal mailing of Arthritis Victoria's members' magazine *Update*. Participants had a mean age of 56.8 years (range 29-72) and a mean time since diagnosis of OA of 12.9 years (range 1.5-35.0).

Eligibility criteria were the same as in Study 1 (see Chapter 4). Participants also needed to be able to climb in and out of a swimming pool safely using a ramp or steps with rails (not a ladder). Participation in this study was voluntary, and participants were free to withdraw from the study at any time.

Measures

All the measures in this study had been used in Studies 1 and 2. Consistent with the HRQOL emphasis of the previous studies, the outcomes of primary interest were the physical function and well-being of participants. Questionnaires assessing generic and disease-related physical and psychological function, and pain, were used to determine the influence of the exercise and manual therapy programs on dimensions of HRQOL and well-being. The individual scales were the Australian / New Zealand adaptation of the Medical Outcomes Study 36-Item Short Form Health Survey Version 1 (SF-36; Ware & Sherbourne, 1992), the Short-Form McGill Pain Questionnaire (SF-MPQ; Melzack, 1987), and the Arthritis Impact Measurement Scales Version 2 (AIMS2; Meenan et al., 1992). These measures were described in the Method section in the Pilot Study (see Chapter 3).

Social support and medication use measures were not primary outcomes. These data were used as covariates. The Medical Outcomes Study Social Support Survey (MOS-SS; Sherbourne & Stewart, 1991) was used as a statistical control for the potential positive effect of an increased social support network associated with exercising in a group or attending treatments with a therapist. This measure was also described in Chapter 3. Change in medication use over time was not recorded in this study because no significant changes in medication use over time were identified in Study 1.

Compliance data. Participants' attendance at intervention sessions was documented by either exercise instructors, or osteopathic students, as appropriate. Attendance at a session was assumed to mean participation in that session.

Procedures

Recruitment, informed consent, and randomisation procedures were the same as those applied in Study 1 (see Chapter 4). There were three intervention groups and one non-intervention control group in this study. Participants were allocated to: (a) water exercise (n = 7), (b) joint mobilisation (n = 4), combined water exercise and joint mobilisation (n = 6), or (d) usual care (control; n = 4) groups. All participants remained under the care of their rheumatologists and general medical practitioners throughout this study. No existing care regimes (i.e., medication, exercise, alternative therapies) were altered during the study. Participants in the intervention groups undertook these therapies in addition to their usual care. Participants in the control group continued with all existing care but commenced no new therapies.

Participants in the joint mobilisation and water exercise groups attended intervention sessions once a week for ten consecutive weeks. Participants in the combined water exercise and joint mobilisation group attended one session of each intervention per week for ten weeks, thus receiving twice the amount of time in intervention compared to the participants in the other treatment groups.

All intervention were 40 minutes in duration. Water-based exercise classes were conducted under the auspices of Arthritis Victoria (AV) at various heated public and hospital swimming pools in suburban Melbourne. The 10-week timeframe was chosen for this study because that is the length of one Victorian school term, and AV conduct water exercise classes during term time only. Participants contacted AV to enrol in already established water exercise classes in convenient locations. All classes comprised groups of 10-15 adults, led by an AV trained adult volunteer, and met at the same time and place each week for 10 weeks.

As in Studies 1 and 2, all manual therapy interventions were conducted at the Victoria University Osteopathic Medicine Clinic, and were provided by Master's level

osteopathic student volunteers. All osteopathic student therapists taking part in this study were in 4th or 5th year clinical practica as part of their full time enrolment in the Master of Health Science (Osteopathy) course at Victoria University. Students were allocated to participants according to availability (i.e., students met with research participants during the students' usual clinical shifts) and continuity of care was maintained as far as was reasonably possible throughout the study.

Participants were requested to refrain from commencing any new therapy, other than that being trialed, during the course of the study. Upon completion of the intervention phase of this study, all participants returned to usual care only for a further 14 weeks.

HRQOL outcomes were measured using the above questionnaires. All measures were recorded before any therapy was administered at week 1, at weeks 5 and 9 during the intervention phase of the study, and again at weeks 12 and 24 (i.e., 2 and 14 weeks post-intervention). As in Studies 1 and 2, final intervention phase measures were be taken at week 9 of the 10-week program. The addition of two new data collection times (weeks 12 and 24) allowed investigation of whether the gains of therapy were maintained in the short and medium term.

All interventions in this study were provided at no charge to participants. AV invoiced Victoria University for the water exercise classes, and was paid from allocated research funds. Students are not paid for consultations at the Osteopathic Medicine Clinic because these consultations form part of the students' clinical training. Participants paid for their usual arthritis care exactly as they did prior to the study. No participant was paid for involvement in the study.

Data Analysis

As in the preceding studies, all questionnaires were scored by hand, according to the developers' instructions. Composite data (means and standard deviations) for each group on each subscale, at each data collection time, are presented in Appendix G.

The data analyses applied in this study were the same as in Study 1 (see Chapter 4). Week-5 data were used to monitor participants' safe progress in the study. Analyses of covariance (ANCOVA) were used to assess group (treatment groups versus control) differences for the SF-36, the AIMS2, and the MPQ measures. Social support was used as a covariate, along with pre-intervention (i.e., week 1, baseline) measures of HRQOL, disability, and pain, to control for initial differences between groups. Week-12 and week-24 data were used for within-group comparisons only, to determine whether any gains within treatment groups observed at week 9 were maintained at the short- and medium-term follow-up times. Also consistent with Study 1, no Bonferroni adjustment was made for the alpha slippage associated with multiple tests of significance because such adjustments increase the probability of Type II errors. The results are interpreted primarily in terms of effect sizes and clinically meaningful changes rather than statistical significance (Speed & Andersen, 2000).

Omnibus effect sizes were calculated as η^2. Univariate effect sizes were calculated as two forms of Cohen's *d*. Cohen's *d* for dependent means was used as the measure of effect size for the within-groups analyses (i.e., change over time, week 1 to week 9), and Cohen's *d* for independent means, with pooled standard deviations to account for unequal sample sizes, was the measure of effect size for the between-groups analyses (i.e., comparison of groups at week 9).

Participants' priorities for health status improvement at baseline and at week 9, as recorded using the AIMS2, are reported in Appendix H. These categorical data were not subject to any inferential analyses.

Results

Missing Data

All participants in intervention groups completed at least eight sessions of manual therapy or water exercise, or both. All participants completed the study and returned most

questionnaires for analysis. Five participants did not complete or return one of their week 5, 9, or 12 questionnaires, and scores for these questionnaires were replaced with the means of the two scores from the participant's questionnaires immediately preceding and following the missing one.

Consistent with the questionnaire completion patterns observed in the previous studies, 12 participants omitted the VAS on at least one occasion, and twelve participants identified themselves as *retired, unemployed,* or *disabled*, and consequently, did not complete the work subscale of the AIMS2. These subscales (i.e., AIMS2-work, SF-MPQ-VAS) were excluded from the analyses because of inadequate sample size.

Missing data in the remaining subscales were replaced according to scoring instructions from the questionnaire developers. Where participants had omitted single items from multi-item subscales, scores for these subscales were calculated by assigning the mean score for the subscale to the missing item. If a score for a subscale could not be calculated in this way, then the mean score for the corresponding group on that subscale at that time was assigned instead.

Data replacement was required for approximately 1% of data points (342 out of 3080 data points; 28 subscales x 5 administrations x 22 participants), and was distributed across subscales and data collection times. The benefits of retaining these data points for analysis outweigh the lowered participant *n*s that would occur if these data points were excluded from the analyses. Week-5 data, including 93 missing data points, were used only as checks that there were no problems arising from interventions. Week-5 descriptive statistics are reported in Appendix G, but were not used in any inferential analyses.

Floor effect. Consistent with the previous studies, a floor effect was observed on the self-care subscale of the AIMS2 at each data collection time. Because all participants completed this subscale, it was included in the analyses, but the results are probably not interpretable. No ceiling effects were identified.

Covariate Measure

Total social support scores are out of 100, and oriented so that a higher score indicates more social support. Social support scores at week 9 were $M = 81.0$, $SD = 14.0$ for the control group; $M = 55.8$, $SD = 20.1$ for the mobilisation group; $M = 77.9$, $SD = 18.5$ for the water exercise group, and $M = 77.3$, $SD = 15.3$ for the combined therapies group (see Appendix G).

Differences in social support among the groups at baseline were statistically significant ($p < .01$). The amount of variance in social support associated with group membership (treatment or control group allocation) at week 9, once baseline measures were accounted for, was large ($\eta^2 = .17$) but not statistically significant ($p = .36$). These results indicate that the groups were dissimilar in terms of social support at baseline. The lack of statistical significance is probably due to small *n*s, and should not be interpreted as "no real difference" between groups (Speed & Andersen, 2000). Although a large increase in social support was associated with being in a treatment group, the largest proportion of the variance in social support at the end of the trial was accounted for by social support at baseline ($\eta^2 = .94$).

These social support differences were accounted for in the ANCOVAs for the dependant variables. Even though there were differences in social support at week 9, those differences reflected social support at baseline.

Changes Within and Between Groups

As with Study 1, the mixed design of this study allows comparison of results both between and within groups. Group means and standard deviations for each HRQOL subscale, at each data collection time, are reported in Appendix G. Within-group comparisons (baseline to week 9 differences for each groups) are expressed as Cohen's *d* for dependent means (see Table 6.1). Between-group comparisons at week 9 are expressed as *F* values and η^2 (see Table 6.2), and as Cohen's *d* for independent means (see Table

6.3). The SF-36 subscales, except health transition, are oriented so that a higher score denotes better health-related quality of life, and subscales of the SF-MPQ and AIMS2 are oriented so that a lower score denotes better health-related quality of life. For ease of interpretation of these results, however, all Cohen's *d* are oriented such that a positive sign indicates an improvement in health status and a negative sign indicates health status decline. Cohen's (1988) conventions for *d* as a measure of effect size for dependent and independent means are that a small effect is identified if $d = .20$, a medium effect if $d = .50$, a large effect if $d = .80$ or greater.

Within-Groups Analyses

In effect size terms, moderate to large positive effects over time (Cohen's *d* of .5 or greater) were identified on some subscales in each of the groups. The control group demonstrated improvements on nine subscales, including some medium to large effects, however, no change ($d = .00$) was reported on two subscales, and declines in HRQOL (negative effect sizes) recorded on the remaining 16 subscales.

Improvements in the mobilisation group were largely consistent with the results of Study 1. Particularly, greater improvements were observed on the disease-specific scales (AIMS2) than the general HRQOL scale (SF-36). Positive effect sizes were found for 13 of the 27 subscales. Nine of these subscales were from the AIMS2. Of note were the large to very large effect sizes for the walking and bending ($d = .87$), tension ($d = .88$), and mood ($d = 1.10$) subscales of the AIMS2, and the affective pain ($d = 1.02$) subscale of the SF-MPQ.

The water exercise group demonstrated improvements (positive effect sizes) on 19 of the 27 subscales. Each of these effects was small to medium. Improvements ranging from $d = .23$ to $d = .39$ were identified on all pain scales in all HRQOL instruments.

In the combined therapies group improvements were identified on 20 subscales across general and disease-specific HRQOL instruments. The largest improvements were

found in the physical role limitations (d = 1.09) and bodily pain (d = 1.44) subscales of the SF-36, and the arthritis pain (d = .95) and walking and bending (d = .85) subscales of the AIMS2, and the sensory pain (d = .85) subscale of the SF-MPQ. Medium to large effect sizes were also noted in most other subscales. Small to medium negative effect sizes (ds from -.18 to -.46), indicating health status decline, were found in 5 subscales of the AIMS 2.

Table 6.1 *Within-Group Effects: Effect Sizes (d) for the Change Over Time (Baseline-Week 9) in Each Group for Each HRQOL Domain*

	Group			
AIMS2 Subscale	Control	Mobilisation	Water Ex	Combined
Mobility	.00	.10	- .18	- .18
Walk & Bend	- .40	.87	.37	.85
Hand Function	- .58	.13	.20	- .30
Arm Function	- .20	- .50	.47	- .36
Self-care	- .50	.00	- .18	.00
Household Tasks	- .86	.00	.01	.00
Social Activity	- .86	- .63	.54	- .46
Family Support	- .12	.25	.36	- .34
Arthritis Pain	.18	.50	.31	.95
Tension	- .04	.88	- .01	.18
Mood	- .56	1.10	- .34	.79
Satisfaction	- .36	.61	- .01	.44
Health Perceptions	.50	.60	.35	.60
Arthritis Impact	.78	.00	- .16	.00
	Group			
SF-MPQ Subscale	Control	Mobilisation	Water Ex	Combined
Sensory Pain	- .50	.52	.32	.85
Affective Pain	- .50	1.02	.23	.55
Total Pain	- .50	.60	.29	.83
Present Pain Index	.50	- .50	.12	.65

Table 6.1 continues overleaf

Table 6.1 continued

	Group			
SF-36 Subscale	Control	Mobilisation	Water Ex	Combined
Physical Function	.29	.40	.50	.35
Role: Physical	.71	- .44	.43	1.09
Bodily Pain	.50	- .10	.39	1.44
General Health	- .50	- .10	.02	.60
Vitality	- .50	- .25	.44	.71
Social Function	.50	.00	.23	.73
Role: Emotional	.00	- .71	.35	.09
Mental Health	.71	- .78	.40	.37
Health Transition	- .50	- .50	.41	.71

Between-Group Analyses

Omnibus between-groups effect sizes (η^2) are reported in Table 6.2. Cohen's (1988) conventions for η^2 as a measure of effect size in analysis of variance are that a small effect is identified if $\eta^2 = .01$, a medium effect if $\eta^2 = .06$, a large effect if $\eta^2 = .14$ or greater. Analyses of covariance (ANCOVAs), using the relevant baseline measures and week-9 social support scores as covariates, revealed that at week 9 of the 10-week trial, group membership accounted for a large portion of improvements (η^2 of .14 or greater) on each of the same subscales where large effect sizes were identified in Study 1 (see Chapter 4), as well as in some other aspects of HRQOL. This repetition of large effect sizes on key subscales across Studies 1 and 3 suggests that, despite low statistical power and lack of statistical significance, these results are robust.

Particularly large effect sizes were found for walking and bending ($\eta^2 = .23$,

$p = .24$), hand function ($\eta^2 = .18$, $p = .36$), social activity ($\eta^2 = .30$, $p = .12$), arthritis pain ($\eta^2 = .30$, $p = .12$), mood ($\eta^2 = .18$, $p = .36$), and the overall impact of arthritis on health ($\eta^2 = .25$, $p = .19$) subscales of the AIMS2. The same pattern was evident for each of the subscales of the SF-MPQ: sensory pain ($\eta^2 = .18$, $p = .34$), affective pain ($\eta^2 = .24$, $p = .21$), total pain ($\eta^2 = .21$, $p = .29$), and present pain index ($\eta^2 = .27$, $p = .19$); and also the physical role limitations ($\eta^2 = .19$, $p = .32$), bodily pain ($\eta^2 = .27$, $p = .16$), general health ($\eta^2 = .16$, $p = .40$), social function ($\eta^2 = .23$, $p = .23$), and health transition ($\eta^2 = .40$, $p = .07$) subscales of the SF-36. Univariate effect sizes, presented in Table 6.3 clarify between which groups, these differences occurred.

Table 6.2 *Between-Group Comparisons: F-values, Significance Levels, and Effect Sizes (η^2) for HRQOL Domains, using Social Support at Week 9, and Appropriate Baseline Scores as Covariates.*

Scale	Subscale	F-value	*p*	η^2	Power
AIMS2	Mobility	.06	.98	.01	.06
	Walking & Bending	1.55	.24	.23	.33
	Hand Function	1.15	.36	.18	.25
	Arm Function	.75	.54	.12	.18
	Self-care	.36	.79	.06	.11
	Household Tasks	1.05	.40	.17	.23
	Social Activity	2.27	.12	.30	.47
	Family Support	.37	.77	.07	.11
	Arthritis Pain	2.24	.12	.30	.46
	Tension	.19	.91	.03	.08
	Mood	1.14	.36	.18	.25
	Satisfaction	.72	.56	.12	.17
	Health Perceptions	.88	.48	.14	.20
	Arthritis Impact	1.78	.19	.25	.38
MPQ	Sensory Pain	1.19	.34	.18	.26
	Affective Pain	1.70	.21	.24	.36
	Total Pain	1.37	.29	.21	.29
	Present Pain Index	1.80	.19	.27	.38

Table 6.2 continues overleaf

Table 6.2 continued

Scale	Subscale	F-value	p	η^2	Power
SF-36	Physical Function	.26	.86	.05	.09
	Role: Physical	1.27	.32	.19	.28
	Bodily Pain	1.94	.16	.27	.41
	General Health	1.04	.40	.16	.23
	Vitality	.55	.66	.09	.14
	Social Function	1.58	.23	.23	.34
	Role: Emotional	.48	.70	.08	.13
	Mental Health	.31	.82	.05	.10
	Health Transition	2.80	.07	.34	.56

Univariate effect sizes (Cohen's *d* for independent means) were calculated for all possible comparisons between groups at week 9, and are presented in Table 6.3. These effect sizes represent the magnitude of the differences between the groups at a point in time. Baseline differences are not accounted for in these analyses, and so the results are best understood when interpreted in conjunction with the within-groups effect sizes reported previously. Between-group comparisons, in order of presentation in Table 6.3, are: 1 = usual care compared with mobilisation, 2 = usual care compared with water exercise, 3 = usual care compared with combined therapies, 4 = mobilisation compared with water exercise, 5 = mobilisation compared with combined therapies, and 6 = water exercise compared with combined therapies. These between-group effect sizes are oriented such that a positive effect size indicates improvement in the second group compared with the first, and a negative effect size indicates a decline in the second group compared with the first. Cohen's (1988) conventions for *d* as a measure of effect size for independent

means are that a small effect is identified if $d = .20$, a medium effect if $d = .50$, a large effect if $d = .80$ or greater.

Participants in the intervention groups reported better HRQOL across most subscales than participants in the control (usual care) group. Mobilisation was superior to control on 15 subscales (see comparison 1), and largely consistent with Study 1; positive effect sizes were reported predominantly on the arthritis-specific domains of the AIMS2. Water exercise outperformed usual care on 17 subscales (see comparison 2), but notably, not on any of the pain subscales of the SF-MPQ (sensory pain, $d = -.21$; affective pain, $d = -.54$; total pain, $d = -.31$; present pain index, $d = -.14$). Combined therapies returned positive effect sizes in comparison with usual care on 23 subscales across each of the HRQOL instruments (see comparison 3). Large to very large effect sizes were noted for each of the intervention groups over the control group on the walking and bending subscale of the AIMS2 (mobilisation, $d = 1.69$; water exercise, $d = 1.01$; combined therapies, $d = 1.08$) and the physical function scale of the SF-36 (mobilisation, $d = 1.17$; water exercise, $d = .82$; combined therapies, $d = 1.03$). These results suggest that across a wide variety of domains, adjunctive interventions are more effective than usual care for improving HRQOL.

Comparison 4 revealed that the water exercise group outperformed the mobilisation group on 15 subscales. Very large effect sizes in favour of water exercise were identified on the hand function ($d = 1.01$) and health perceptions ($d = 1.27$) subscales of the AIMS2, and on the general health ($d = 1.38$) subscale of the SF-36. Conversely, negative effect sizes, indicating that mobilisation was superior to water exercise, were identified on all the subscales of the SF-MPQ, with a large effect size reported for affective pain ($d = -.93$). The same pattern, of mobilisation outperforming water exercise was evident on six subscales of the AIMS2, and two subscales of the SF-36.

Overall these results suggest that each of the adjunctive therapies trialed afforded some improvements in HRQOL over usual care. On only the family support subscale of the AIMS2 did usual care outperform all adjunctive therapies (compared with: mobilisation, d = -.1.02; water exercise, d = -.41; combined therapies, d = -.67). These results are clarified by the omnibus between-groups effect size for this subscale reported in Table 6.2 (η^2 = .04). That is, only 4% of the variance in family support was accounted for by being in a treatment or control group. Family support at baseline, and social support at week 9 (i.e., the covariates) accounted for much larger proportions of the variance on this subscale (η^2 = .48 and η^2 = .17, respectively).

Furthermore, these results indicate that combined therapies largely outperformed single therapies. In direct comparisons between therapies at the end of the intervention period (week 9), combined therapies were associated with more, and often larger, improvements in HRQOL than were single therapies. The combined therapies group outperformed all other groups on 14 of the 27 subscales: mobility, household tasks, arthritis pain, mood, and satisfaction subscales of the AIMS2; sensory pain, total pain, and present pain index (PPI) subscales of the SF-MPQ; and physical role limitations, bodily pain, general health, vitality, social function, and health transition subscales of the SF-36. Large to very large effect sizes were reported for combined therapies over usual care and single therapies on the present pain index of the SF-MPQ (compared with: control, d = 1.03; mobilisation, d = .77; water exercise, d = 1.24), and the bodily pain (compared with: control, d = 1.64; mobilisation, d = 2.84; water exercise, d = 1.37) and social function (compared with: control, d = 1.35; mobilisation, d = 1.98; water exercise, d = 1.11) subscales of the SF-36.

Table 6.3 *Between-Group Comparisons: Effect sizes (d) for the Difference Between Groups at Week 9 for Each HRQOL Subscale*

Note. Comparison types: 1 = usual care compared with mobilisation, 2 = usual care compared with water exercise, 3 = usual care compared with combined therapies, 4 = mobilisation compared with water exercise, 5 = mobilisation compared with combined therapies, 6 = water exercise compared with combined therapies.

	Comparison type					
AIMS2 subscale	1	2	3	4	5	6
Mobility	.32	.22	.59	- .26	.40	.69
Walk & Bend	1.69	1.01	1.08	- .78	- .35	.29
Hand Function	- .15	.62	.19	1.01	.46	- .83
Arm Function	.28	.40	.10	.10	- .28	- .41
Self-care	.71	- .32	.82	- .52	.00	.57
Household Tasks	.76	.48	.88	- .45	.06	.51
Social Activity	.35	.63	.67	.20	.03	- .24
Family Support	-1.02	- .41	- .67	.45	.43	- .10
Arthritis Pain	.75	.58	1.12	- .16	.35	.51
Tension	.30	.02	- .66	- .33	-1.14	- .77
Mood	- .76	- .25	.26	.75	1.04	.53
Satisfaction	.00	.42	.46	.43	.46	.01
Health Perceptions	- .60	.50	.27	1.27	.87	- .16
Arthritis Impact	- .40	- .26	- .14	.17	.34	.14

	Comparison type					
SF-MPQ subscale	1	2	3	4	5	6
Sensory Pain	.11	- .21	.64	- .31	.68	.68
Affective Pain	.71	- .54	.00	- .93	- .55	.55
Total Pain	.22	- .31	.50	- .48	.31	.68
Present Pain Index	.35	- .14	1.03	- .54	.77	1.24

Table 6.3 continues overleaf

Table 6.3 continued

	Comparison type					
SF-36 subscale	1	2	3	4	5	6
Physical Function	1.17	.82	1.03	- .46	- .01	.40
Role: Physical	- .71	- .74	.43	.05	1.33	1.34
Bodily Pain	- .46	.07	1.64	.50	2.84	1.37
General Health	- .77	.76	.66	1.38	1.20	.01
Vitality	- .23	- .24	.13	.05	.35	.36
Social Function	.54	.53	1.35	- .05	1.98	1.11
Role: Emotional	- .66	.15	.06	.95	.82	- .09
Mental Health	- .54	.11	- .30	.65	.41	- .40
Health Transition	1.96	1.44	2.20	.22	.58	.15

Follow-up Data: Changes Within Groups Over Time

Week-12 and week-24 data were used to determine whether any gains within treatment groups observed at week 9 were maintained at the short- and medium-term follow-up times. Means and standard deviations of each group's scores on each HRQOL subscale are reported in Table 6.4, 6.5, and 6.6. Note that the AIMS2 and SF-MPQ are oriented such that a lower score indicated better HRQOL, whereas on the SF-36 a higher score indicates better HRQOL.

Mobilisation group. Generally, the improvements in HRQOL reported at week 9 were maintained at week 12 (2 weeks post intervention), and some improvements persisted to week 24. On a few subscales, better HRQOL was reported at week 24 than at the end of the intervention period. Subscales on which large between- and within-group effect sizes were found during the intervention period are of particular interest in the follow-up period. For example, in the mobilisation group, large improvements in the walking and bending

subscale of the AIMS2 were followed by a further small improvement on this subscale at week 12, and a decline on this subscale at week 24 (see Table 6.4).

Table 6.4 *Mean Follow-up Scores on Each HRQOL Subscale in the Mobilisation Group*

Scale	Week 9		Week 12		Week 24	
AIMS2	*M*	*SD*	*M*	*SD*	*M*	*SD*
Mobility	0.83	0.89	0.58	0.51	1.63	1.11
Walk & bend	2.13	1.93	2.03	2.10	3.08	2.98
Hand function	2.63	3.01	2.75	3.20	3.88	4.84
Arm function	0.63	0.75	0.50	1.00	1.13	1.44
Self-care	0.00	0.00	0.00	0.00	0.00	0.00
Household tasks	0.48	0.62	0.33	0.65	0.80	0.96
Social activity	5.38	2.06	5.08	1.27	5.50	0.91
Family support	3.30	2.51	3.05	2.14	4.08	2.54
Arthritis pain	3.63	1.93	2.75	0.87	5.53	3.74
Tension	2.60	1.68	2.63	2.14	3.88	2.17
Mood	3.63	3.09	1.50	0.91	2.50	1.83
Satisfaction	3.68	2.57	2.78	2.35	2.85	2.96
Health perceptions	5.85	1.70	5.00	1.96	6.68	2.74
Arthritis impact	3.75	2.50	3.75	1.44	4.38	3.15

Note. AIMS2 is scored out of 10. Lower score denotes better health status.

Scale	Week 9		Week 12		Week 24	
SF-MPQ	*M*	*SD*	*M*	*SD*	*M*	*SD*
Sensory pain	5.8	3.8	5.8	5.2	15.3	14.8
Affective pain	0.3	0.5	1.3	1.5	3.3	3.9
Total pain	6.0	4.2	7.0	6.6	18.5	18.7
Present Pain Index	1.8	0.6	1.5	0.0	2.0	1.2

Note. Lower scores denote less intense pain.

Table 6.4 continues overleaf

Table 6.4 continued

Scale	Week 9		Week 12		Week 24	
SF-36	*M*	*SD*	*M*	*SD*	*M*	*SD*
Physical Function	61.3	26.6	66.3	16.0	50.0	28.0
Role: Physical	25.0	35.4	31.3	37.5	25.0	50.0
Bodily Pain	39.3	12.5	54.3	10.0	47.5	31.8
General Health	40.5	23.6	39.8	21.5	40.5	32.8
Vitality	46.3	25.6	46.3	28.7	51.3	38.4
Social Function	78.5	12.0	72.0	15.9	75.0	28.9
Role: Emotional	41.8	50.1	75.0	50.0	50.0	57.7
Mental Health	70.0	19.7	69.0	23.6	73.0	25.6
Health Transition	2.8	0.5	2.8	0.5	2.8	1.5

Note. All SF-36 domains except health transition are scaled to scores out of 100, and a higher score denotes better health-related quality of life. Health transition is scored from 1-5. A score of 3 denotes stable health status, a score from 1-2.9 denotes health improvement, and a score from 3.1-5 denotes health decline.

Water exercise group. Follow-up data in the water exercise group show much the patterns as in the mobilisation group. On many subscales, week 9 improvements are maintained at week 12, and from week 12 to week 24, small reductions in HRQOL are evident on most subscales. Some key HRQOL domains, including the pain subscales of the SF-MPQ, show a different pattern. Pain scores decline at week 12 (indicating less pain), and return to the week 9 level by week 24. Although the effect sizes for changes in pain over time were medium, and other therapies (joint mobilisation and combined therapies) outperformed water exercise on most pain subscales, the positive effects of water exercise on pain persisted well beyond the intervention period of the study.

Table 6.5 *Follow-up Scores on Each HRQOL Subscale in the Water Exercise Group*

Scale	Week 9		Week 12		Week 24	
AIMS2	*M*	*SD*	*M*	*SD*	*M*	*SD*
Mobility	1.04	0.79	1.01	0.61	0.94	0.68
Walk & bend	3.69	2.03	3.73	1.94	3.88	2.17
Hand function	0.81	0.84	0.66	0.81	0.69	1.00
Arm function	0.56	0.56	0.50	0.60	0.44	0.56
Self-care	0.20	0.46	0.10	0.28	0.11	0.22
Household tasks	1.01	1.37	0.69	0.83	0.95	1.16
Social activity	5.04	1.55	4.83	1.46	5.04	1.30
Family support	2.19	2.43	1.18	1.93	2.34	2.47
Arthritis pain	3.94	1.95	3.53	1.84	3.66	1.86
Tension	3.20	1.91	2.76	1.67	3.01	2.30
Mood	2.14	1.26	1.80	1.37	1.83	1.48
Satisfaction	2.76	1.90	2.30	1.48	2.26	1.43
Health perceptions	3.53	1.89	3.38	0.90	3.70	1.97
Arthritis impact	3.29	2.92	2.88	2.47	2.98	2.84

Note. AIMS2 is scored out of 10. Lower score denotes better health status.

SF-MPQ	*M*	*SD*	*M*	*SD*	*M*	*SD*
Sensory pain	7.7	7.2	6.0	5.6	7.1	6.1
Affective pain	2.2	2.5	1.3	1.4	2.3	2.2
Total pain	9.9	9.3	7.3	6.7	9.4	8.1
Present Pain Index	2.1	0.7	1.7	0.6	2.1	1.0

Note. Lower scores denote less intense pain.

Table 6.5 continues overleaf

Table 6.5 continued

Scale	Week 9		Week 12		Week 24	
SF-36	*M*	*SD*	*M*	*SD*	*M*	*SD*
Physical Function	50.6	21.8	54.9	25.6	56.3	26.6
Role: Physical	26.6	34.3	45.4	37.7	32.9	33.3
Bodily Pain	48.0	19.0	56.4	16.3	55.4	20.1
General Health	68.3	18.3	72.6	16.4	72.0	20.2
Vitality	47.3	17.0	49.8	17.5	41.0	22.3
Social Function	77.5	21.1	77.9	11.7	72.8	22.6
Role: Emotional	81.3	37.2	90.9	25.8	81.3	37.2
Mental Health	82.0	17.7	86.3	12.0	82.0	17.9
Health Transition	2.5	1.3	2.4	1.3	2.8	1.2

Note. All SF-36 domains except health transition are scaled to scores out of 100, and a higher score denotes better health-related quality of life. Health transition is scored from 1-5. A score of 3 denotes stable health status, a score from 1-2.9 denotes health improvement, and a score from 3.1-5 denotes health decline.

Combined therapies group. In the combined therapies group improvements at week 9 persisted through week 12 until week 24. For example, on the health perceptions subscale of the AIMS 2, the combined therapies group reported improvement from the week 9 mean score of 3.88 to 3.33 at week 12. At week 24, the mean score for this group had returned to 3.88.

On other subscales, participants in the combined therapies group reported further HRQOL improvements at both 2 and 12 weeks after the end of the intervention. This pattern was observed on the notably household tasks, social activity, tension, mood, and arthritis impact subscales of the AIMS2, and the sensory pain and total pain subscales of the SF-MPQ. In general, for the combined therapies group, many of the improvements over baseline at week 9 were maintained or even showed further gains by week 14. This pattern contrasts meaningfully over the results for usual care and single therapies.

Table 6.6 *Follow-up Scores on Each HRQOL Subscale in the Combined Group*

Scale	Week 9		Week 12		Week 24	
AIMS2	*M*	*SD*	*M*	*SD*	*M*	*SD*
Mobility	0.50	0.77	1.00	1.05	0.92	0.97
Walk & bend	3.00	2.77	3.33	3.53	4.00	3.45
Hand function	1.67	1.25	0.92	0.92	1.83	2.40
Arm function	0.92	1.16	0.58	0.49	0.75	0.69
Self-care	0.00	0.00	0.00	0.00	0.00	0.00
Household tasks	0.43	0.67	0.22	0.53	0.22	0.53
Social activity	5.33	0.52	5.33	1.08	4.75	2.44
Family support	2.40	1.84	1.98	1.83	1.67	1.53
Arthritis pain	2.97	1.83	2.82	1.38	3.15	1.38
Tension	4.67	1.89	4.42	1.32	4.00	1.70
Mood	1.58	0.66	1.58	0.58	1.33	0.82
Satisfaction	2.75	1.57	2.67	0.86	2.28	0.93
Health perceptions	3.88	2.53	3.33	3.00	3.88	2.53
Arthritis impact	2.92	2.46	2.08	2.46	2.08	2.46

Note. AIMS2 is scored out of 10. Lower score denotes better health status.

SF-MPQ	*M*	*SD*	*M*	*SD*	*M*	*SD*
Sensory pain	3.8	2.0	3.5	3.3	3.3	1.6
Affective pain	1.0	1.7	1.3	2.0	1.0	1.3
Total pain	4.8	3.4	4.8	3.8	4.3	2.7
Present Pain Index	1.3	0.5	1.3	0.5	1.5	0.8

Note. Lower scores denote less intense pain.

Table 6.6 continues overleaf

therapies also have longer lasting effects, and in several cases, further improvements 14 weeks after cessation of treatment.

More intervention, however, comes at higher cost. The costs of diseases and interventions are not always easily measured (Kaplan et al., 1992). Furthermore, the economics of healthcare differ from other industries. In healthcare service delivery, price is governed, in part by supply and demand, and by the type and quality of a service (Cronan, Groessl, & Kaplan, 1997), but other substantial influences include third party payers, public policies, national culture, and legislation (Kaplan, 1993). In this discussion section, I consider the results of this study by comparing usual care with single and multiple therapies, in terms of the benefits and costs of these configurations of interventions.

Health-Related Quality of Life

Impact of Arthritis: AIMS2

Participants in the mobilisation and water exercise groups reported improvements over time on most of the 14 AIMS2 subscales, but the effect sizes varied considerably (see Table 6.1). By contrast, the control group reported health status declines on most subscales. Between-groups comparisons indicated that at week 9 of the study, very large effect sizes (η^2) could be attributed to intervention groups membership on six subscales. In head to head comparisons, at least one of the intervention groups outperformed the usual care on each of these subscales. Considering the within- and between-groups results together, it appears that each of the interventions is generally more effective than usual care for improving HRQOL, and that the various interventions influence different aspects of arthritis-specific health status.

As explained in Chapter 3, the first 12 subscales of the AIMS2 may be combined to form a five-component model of arthritis-specific health status, comprising physical, affect, symptom, social interaction, and role components (Meenan, n.d.). The role

Table 6.6 continued

Scale	Week 9		Week 12		Week 24	
SF-36	*M*	*SD*	*M*	*SD*	*M*	*SD*
Physical Function	60.8	29.9	58.3	27.7	63.3	22.9
Role: Physical	75.0	38.7	66.7	43.8	70.8	40.1
Bodily Pain	69.5	9.3	65.8	14.7	68.8	21.5
General Health	68.5	23.3	71.5	27.2	68.2	28.5
Vitality	53.3	16.3	45.8	25.8	50.0	27.7
Social Function	96.0	6.2	85.5	12.3	93.8	10.4
Role: Emotional	77.8	40.4	72.2	44.4	77.8	40.4
Mental Health	76.0	10.1	72.0	15.6	77.3	11.8
Health Transition	2.3	0.8	2.7	0.8	2.5	0.8

Note. All SF-36 domains except health transition are scaled to scores out of 100, and a higher score denotes better health-related quality of life. Health transition is scored from 1-5. A score of 3 denotes stable health status, a score from 1-2.9 denotes health improvement, and a score from 3.1-5 denotes health decline.

Priorities for HRQOL Improvement

Participants' priorities for health status improvement, as reported on the AIM2, did not change markedly over the course of the intervention (baseline to week 9; see Appendix H). Pain due to arthritis was the area most commonly reported as a priority for improvement.

Discussion

The overall message of this study might be colloquially summarised as *more is better*. Generally, usual care plus adjunctive therapy was superior to usual care alone. Each of the interventions applied in addition to usual care afforded participants some HRQOL improvements. Also, combinations of therapies often returned greater improvements than single therapies. The increased effectiveness of combined therapies over individual therapies gave rise to the title of this thesis: *Joint Effects*. Combined

component comprises the work subscale only, and because of the large number of retired, disabled, or unemployed participants, is not applicable to this thesis.

Unlike Study 1, the results of this study do not fall so clearly into the five components of the AIMS2. This disparity between studies is probably due to the inclusion of a combined therapies group. In Study 1, mobilisation positively influenced health status predominantly in the physical component. In this study each of the adjunctive therapy groups reported large effects over time or between groups on some of the subscales that constitute the physical component of health status. What is unclear is whether combining mobilisation with water exercise enhanced, or modulated, the effects of mobilisation on the physical component of HRQOL. Using regression analysis the contributions of each intervention (mobilisation, water exercise, combined therapies) to physical HRQOL could be determined, but calculations of this type would be feasible only in a study with more participants per group.

General Health-Related Quality of Life: SF-36

The combined therapies and water exercise groups demonstrated improvements over time on all, and between groups on most, subscales of the SF-36 (see Tables 6.1 and 6.3 respectively). Medium to large omnibus effect sizes were calculated for all general HRQOL subscales (see Table 6.2). Considering these results alongside those on the AIMS2, it appears that water exercise affords improvements in general HRQOL, and joint mobilisation tends to improve the arthritis-specific aspects of HRQOL. The combined therapies group reported improvements across disease-specific and general measures. Because many of the effect sizes associated with the combined therapies are larger than those for either of the single interventions on the same domains, it is possible that the effects of water exercise and joint mobilisation are, at least, somewhat additive.

Pain

Substantial improvements occurred in all intervention groups on the pain scales of the SF-MPQ. When the within- and between-groups effect sizes are considered together with the omnibus effects, it is apparent that the combined therapies group outperformed all other groups in the reduction of pain.

At baseline and at week 9, pain due to arthritis was the HRQOL domain most commonly reported as the area in which participants wanted to experience improvements (see Appendix H). Although many participants made improvements in pain over the course of the interventions, decreases in pain were still desired at the end of the treatment period. Heiberg and Kvien's (2002) found that pain was the domain of greatest priority in people with RA. Participants in this study had been diagnosed with OA, but their priorities for improvement are similar to those of the group surveyed by Heiberg and Kvien.

Heiberg and Kvien (2002) did not report the pain scores of their participants, but they did report a comparison between participants who cited pain as a priority area for health improvement and those who did not. These two groups differed significantly on each of the three pain scales completed (i.e., SF-36, AIMS2, and VAS), but did not differ significantly on any measures of physical function (i.e., disability). It is hardly surprising that if you experience a lot of pain, then in your priorities for health improvement, reduction of pain rates highly.

The large effect sizes for the combination of water exercise and joint mobilisation on pain establish the clinical value of this approach. Given the importance, and ubiquity, of pain in arthritis, therapies that reduce pain are likely to find favour with clients. Participants with high pain scores are likely to prefer therapies that have large effects on pain.

Interventions Affecting Health-Related Quality of Life

Water Exercise

Exercise, of many kinds, is of benefit for people with arthritis. Sobel and Klein (1993) reported that

> exercise helped ninety-five percent of those Arthritis Survey participants who tried it. No other approach to arthritis–no drug, no surgical procedure–matches exercise for high rates of improvement. Nor can any other treatment modality boast exercise's low risk of serious complications or unpleasant side effects. (p. 3).

Despite the enthusiastic tone of Sobel and Klein's statements, there is considerable evidence that exercise improves muscle strength, lessens pain, and reduces joint stiffness in people with OA (Hurley, 1999; Maurer et al., 1999; Thomas et al., 2002; ASG, 2001).

Water exercise was chosen as the exercise intervention for this study because it was: (a) available in a format that was adapted specifically for people with arthritis, (b) administered by trained instructors, (c) provided in doses that were comparable to the length and frequency of manual therapy interventions, and (d) affordable within the research budget. There is little evidence to indicate that water exercise is superior to other forms of exercise for people with OA (ASG, 2001). Foley et al. (2003) compared gym-based and water exercise strength training programs in people with OA, and identified functional gains, particularly increased muscle strength, in both intervention groups compared with a non-intervention control.

In this study the water exercise group reported improvements in HRQOL over time (baseline to week 9) on 19 out of 27 subscales. These improvements were of small to medium effect size, and included subscales from most aspects of HRQOL. As previously discussed, small effects may be clinically important. Speed and Andersen (2000) gave the example of athletes improving race times by half of one percent as a small effect that was meaningful and important for participants. A therapy that induces small to medium effects

across many aspects of health may be "just what the doctor ordered" to improve overall quality of life for people with arthritis. Perhaps Sobel and Klein (1993) were not completely guilty of hyperbole when they described exercise as "the miracle drug you can give yourself" (p. 3).

Using data from the USA 2001 Behavioral Risk Surveillance Survey, Brown et al. (2003) calculated odds ratios for the associations between recommended levels of physical activity in adults (20-90 minutes of moderate intensity activity, 3-5 times per week) and HRQOL. After adjustment for race and sex, the relative odds of 14 or more unhealthy days (physical or mental) in a month (30 days) was 0.67 in adults aged 18-44 years who were active at recommended levels compared with physically inactive adults. Odd ratios lower than 1.0 indicate that people in these categories are likely to have more health days than the population at large. Physical activity appeared to buffer the HRQOL declines expected with increasing age. In adults aged 45-64 years, the odds of unhealthy days dropped to 0.40 for active adults over inactive adults. Similarly, in active adults aged over 65 years, the odds ratio of unhealthy days was 0.41 compared with their inactive counterparts. The results were robust even among adults with chronic illnesses such as arthritis.

The water exercise classes used in this study were of approximately 40 minutes duration. Although participants could vary the intensity of the exercise to suit their fitness levels, these classes are generally considered to require moderate physical exertion (Arthritis Victoria, 2002). The improvements in HRQOL observed in the water exercise group might be partly explained by having moved some previously inactive adults towards recommended levels of physical activity.

Psychosocial benefits, such as improved self-efficacy and improved social functioning, have been attributed to exercise, and posited as an explanation for symptomatic change in people with OA (Bean, Vora, & Frontera, 2004; Lorig et al., 1993; Rejeski et al., 1998). Hurley, Mitchell, and Walsh (2003) claimed that in people with OA

the psychosocial benefits of exercise are at least as important as physiological improvements. They stated:

> Participation in regular exercise, consciously or subconsciously, addresses many deficits in psychosocial traits. Exercise promotes acceptance of appropriate health beliefs by challenging beliefs that activity causes pain and joint damage, thereby disrupting detrimental fear-avoidance behaviors. Regular exercise also helps control the symptoms of OA, providing people with an active coping strategy; through exercise they learn how to implement these strategies, enhancing exercise self-efficacy and enabling them to do more for themselves, thereby reducing helplessness, disability, and social isolation. (p. 142).

Joint Mobilisation and Combined Therapies

The effects of joint mobilisation of HRQOL in this study largely mirrored the results from Study 1, with joint mobilisation improving HRQOL principally in disease-specific domains. The effect sizes were largest in the physical function component of the AIMS2, and on the physical function scale of the SF-36. Participants who undertook water exercise and joint mobilisation each week reported more, larger, and longer lasting improvements in HRQOL than participants in single therapy groups. Improvements were spread across disease-specific, pain, and general health measures, suggesting that the combination of physical exercise and manual therapies is an effective way to improve many facets of health.

There is little other research on joint mobilisation for people with arthritis. Recommendations for the usefulness of manual therapy are commonly based on studies in populations without rheumatic diseases (Fiechtner & Brodeur, 2002a, 2002b). In a clinical trial over six weeks, Hoving et al. (2002) found manual therapy was more effective than physical therapy or general practitioner care for improving pain, disability, physical function, and general health in people with non-specific neck pain. Because Hoving et al.

deliberately excluded people with neck pain due to rheumatic diseases their results should be interpreted with caution, and not necessarily generalised to people with OA or RA.

Hoving et al. (2002) used a pragmatic study design. Although they reported the study as a comparison of three interventions, the treatments were eclectic and not entirely discrete. Manual therapy was performed by physical therapists who had completed formal manual therapy training, and practitioners of all disciplines were permitted to vary treatment regimes according to the participant's presentations. Both manual and physical therapists used a range of active and passive procedures. The frequency and length of interventions varied among groups: 40-minute treatments weekly for the manual therapy group, 30-minute consultations twice per week for the physical therapy group, and a 10-minute appointment, with optional follow-up appointments fortnightly, for the usual care group. All participants were allowed to use over-the-counter analgesics and complete exercises at home. Pragmatic studies have high external validity, and are likely to be well received by practicing therapists who identify the interventions as consistent with their own work. Internal validity, however, is compromised by these designs because the interventions are not truly comparable.

Hoving et al. (2002) argued that "In our study, mobilization, the passive component of the manual therapy strategy, formed the main contrast with physical therapy or continued care and was considered to be the most effective component." (p. 721), but this conclusion is not entirely evident from the study. Hoving et al.'s study may contribute as much to the understanding of combined therapies as of manual therapy. Several participants combined interventions during the study but were not excluded from analyses. For example, seven people in the usual care group received manual therapy, and five people in the manual therapy group and seven people in the physical therapy group consulted with general practitioners. Hoving et al. maintained that joint mobilisation was

the most important independent variable, but clearly, some participants in each group were likely to have received this intervention.

Clinical Implications

Costs and Benefits

Although all interventions in this thesis were provided at no charge to participants, there are usually financial costs associated with the delivery of these services. The increased effectiveness of combined therapies needs to be balanced against these costs. The costs of manual therapy delivery in this study were the same as in Study 1: $25 per consultation. Arthritis Victoria (AV) makes water exercise classes available to members for $4.95 per class, plus an annual AV membership fee of $28. The costs of the interventions in this study are summarised in Table 6.6.

Table 6.7 *Costs of Interventions*

Intervention	Per session	Extras	Total
Mobilisation	$25	--	$250
Water Exercise	$4.95	$28	$77.50
Combined	$29.95	$28	$327.50

Clearly, more intervention is more expensive. Each of the costs shown in Table 6.6 is in addition to the costs of usual care. The usual care costs were unknown because participants in this trial paid for their usual care exactly as they had done prior to the study and were not asked to report these expenses.

Indirect, and some hidden, costs are associated with health care delivery, but are difficult to measure, and may vary between individuals. For example, joint mobilisation sessions were provided in the Victoria University Osteopathic Medicine Clinic, which is located in the central business district (CBD) of Melbourne. Only two participants were residents of the CBD. All other participants travelled to the city, at their own expense, to

take part in the studies. The costs of travel are highly variable, depending upon the distance covered, the mode of transport used, and the eligibility for concession fares. As mentioned in Study 2, it is important that clients are informed of the costs, as well as the benefits, of an intervention, so that they can decide whether it is personally cost-effective.

Longevity of Effects

Follow up data demonstrates that the combined therapies produce longer lasting effects than do single therapies. In each of the single intervention groups, most positive effects on HRQOL were maintained at week 12, but had declined somewhat by week 24. In the combined therapies group, many positive effects persisted until week 24, and on some subscales, participants reported further HRQOL improvements 14 weeks after cessation of the interventions.

Custom and practice in manual therapy is service delivery on a short cycle (e.g., weekly or fortnightly consultations until recovery). Other trials of single manual therapies have demonstrated loss of most gains at medium term follow-up (3-6 months; Hurwitz et al., 2002, Korthals-de Bos et al., 2003). It is likely that the customary practices of manual therapists reflect their empirical observations that the improvements associated with manual therapy persist for a few weeks following intervention.

The longevity of effects apparent with the combined therapies intervention has important implications for clinical practice. Can the HRQOL gains of one therapy be made more persistent via the addition of a second therapy? If so, then it is in the best interests of clients to offer combined therapies. This question is worthy of further investigation. Future researchers might consider studying combinations of physical and manual therapies to determine which combinations produce HRQOL improvements that are most resistant to decline over time.

Participants in the combined therapies group reported further improvement on some HRQOL subscales after the end of the interventions. Participants were asked to return to

their usual care as it had been prior to the study for the duration of the follow up period. It may be considered a limitation of the study that participants' activities were not closely monitored during the follow up period. It is plausible (but unknown) that some participants continued with water exercise or manual therapies in private settings at their own expense.

An alternate explanation of the continued growth of HRQOL improvements after intervention is that participants' perception of "usual care" had altered during the intervention stage. During the intervention stage, participants who received joint mobilisation became more mobile, and participants who undertook water exercise classes probably increased their cardiovascular fitness and endurance. Participants in the combined therapies group are likely to have experienced all these effects, and may have lost touch with what it felt like to be comparatively immobile and unfit. They are also likely to have used their newfound mobility and fitness to do more of the physical activities they enjoy (e.g., gardening, hiking, walking their dogs). Anecdotal reports from participants support these explanations of the enduring and improving effects after combined interventions. For example, at the end of the intervention period, one participant planned and took an overseas trip.

It is consistent with observations in other therapies (e.g., psychotherapy) that clients are not static after their discharge from care. It is a mark of the success of therapy if clients are able to apply, without the ongoing assistance of a therapist, the lessons of the intervention. The results of this study suggest that in the physical and manual therapies the shift to self-driven care may be more likely to be made by clients receiving both physical and manual interventions.

Selection of Therapies

Joint mobilisation is a passive therapy administered by a therapist. Water exercise is an active therapy engaged in by the client, albeit with direction from an exercise leader. Keefe et al. (2000) and Kerns and Rosenberg (2000) demonstrated that approximately 55%

of adults with arthritis are not psychologically ready to engage in an ASMP, and so are likely to drop out of such a program prior to completing it. Keefe et al. and Kerns and Rosenberg based their studies on Prochaska and DiClemente's (1983, 1998) stages of change model, which has also been used to predict the adoption of exercise as a health promoting behaviour (Prochaska & Velicer, 1997). Although the adoption of water exercise by people with OA has not been investigated specifically, it is likely that Keefe et al.'s and Kerns and Rosenberg's findings regarding ASMPs would also apply to the exercise section of those programs.

As discussed in the preceding section, the combination of physical and manual therapies appears to be more useful than either therapy in isolation for moving clients towards self-directed care. One of the limitations of any research with volunteers is that participants enter the trial willing to undertake the interventions. All participants in the combined therapies group undertook at least eight out of ten sessions of each intervention. In day-to-day practice some clients do not participate in active therapies (e.g., exercise) despite ongoing encouragement from the therapist. The way in which physical and manual therapies are delivered means that one or other type may be suitable for different people at different psychological stages. It is plausible that in the "real world," clients self-select these therapies according to their stages of change.

Clinical Cautions and Limitations

Water exercise is generally considered a safe intervention for people with arthritis because in water, ground reaction forces and stresses on joints are lower than if the same exercises were undertaken on land (Arthritis Victoria, 2002). Warm water (approximately 34 degrees centigrade) is comforting for many people, and the buoyancy of the water supports the body, reducing the need for balance, and lowering the difficulty of some exercises (Sobel & Klein, 1993). Despite these benefits, all activities in water have some inherent risks. The risk of drowning is small, and is reduced by conducting classes: (a) in

chest-deep water (i.e., participants can reach the floor of the pool), (b) with trained instructors, and (c) at pools with lifeguards on patrol. Water exercise may be frightening for people who cannot swim, and may pose a health risk for some people (e.g., pregnant women should avoid exercise in situations that might elevate their core temperature).

The cautions and limitations of manual therapies explained in Chapter 4 also apply to this study. When manual therapies are used in conjunction with other interventions, such as water exercise, the safety profiles of both treatments must be considered. Furthermore, although no adverse reactions to therapy were reported in either this study or Study 1, it is possible that multiple therapies might pose unforseen risks when used together.

Despite the evidence in favour of combined therapies, multidisciplinary or multi-therapy care is potentially expensive. Recruitment of each member of a health care team, and the addition of each therapy, should be made with budgetary considerations. In most health care systems, general practitioner care is cheaper than specialist care per consultation (Kaplan, 1993). Additionally, communication within the team is important to ensure that services for clients are neither overlooked nor excessively duplicated (Dexter & Hayes, 1998).

Recommendations for Future Research and Conclusions

Future Research

There remains much scope for research on arthritides, exercise, manual therapies, and quality of life issues. In particular, there exists an opportunity to explore whether participation in long-term, regular exercise and physical or manual therapy decelerates OA progression.

The research model used for this study is particularly suitable for exercise and physical and manual therapy interventions, where single and double blind designs are virtually impossible. In this type of research placebo or sham interventions are difficult to develop, and cessation of usual care treatment controls are unethical. Furthermore, this

design has ecological validity, that is, it is akin to actual practice (Goldfried & Wolfe, 1998). Many complementary therapies, such as those used in this thesis, are promoted as beneficial for people with arthritis, but often lack the evidence base for such claims (Ernst, 2002). The design of this study could be extended to investigate the effectiveness of other complementary, physical, or manual therapies in arthritis care.

The usefulness of combined therapies needs to be balanced against the financial costs. The persistence of many HRQOL improvements at 2 weeks, and, in the combined therapies group, the development of further improvements by 14 weeks post intervention, suggests that less frequent therapy might be adequate. Future research might be directed towards determining which therapeutic combinations, in which doses, afford the most favourable cost:benefit results.

Conclusions

People with OA who undertook programs of joint mobilisation, water exercise, or a combination of these therapies, demonstrated improvements in many aspects of HRQOL. Joint mobilisation appears most useful for improving the physical function components of disease-specific HRQOL. Water exercise group appears more generally useful, moderately improving HRQOL across several domains.

The combination of joint mobilisation and water exercise appears to be more effective than either therapy in isolation for improving quality of life in people with OA. Participants who undertook both interventions in the same week reported more, larger, and more persistent improvements in HRQOL than participants in single intervention groups. Because some participants reported increasing improvements 14 weeks after the end of the intervention period, it is possible that water exercise and joint mobilisation in combination are useful for moving clients towards better HRQOL, possibly through increases in self-directed care (Phillips, Schneider, & Mercer, 2004).

CHAPTER 7

OVERALL DISCUSSION

Comparison and Interpretation of Results

The main aim of this thesis was to investigate the effects of water exercise and manual therapies on the HRQOL of people with RA or OA. Small sample sizes present problems in interpretation of both significant and non-significant results. As discussed in Chapter 5, the sample of people who completed Study 2 was too small to support conclusions regarding effects of these adjunctive therapies on HRQOL in RA.

The effects of massage, joint mobilisation, water exercise, and a combination of the latter two therapies on HRQOL and psychosocial well-being of people with OA were investigated in two independent studies with small sample sizes. The inferential statistics and corresponding effect sizes presented in Chapters 4 and 6 are suggestions of effectiveness in people with OA that need to be confirmed by future studies with larger samples. Comparing the effects across the studies may be confounded by factors both related, and peripheral, to the intervention programs, including participant characteristics, social and environmental factors, and contact with the researcher. Bearing this caveat in mind, comparison of the effects of joint mobilisation across the two studies show similarities; joint mobilisation appears to bring about improvements primarily in arthritis-specific health status. Many of these improvements seem to be large. The other therapies, namely massage and water exercise, show most improvements in pain and general HRQOL domains, respectively.

On most HRQOL domains, the combination of physical and manual therapies, specifically water exercise and joint mobilisation, appear to result in more improvements, often with larger effect sizes than those afforded by either therapy in isolation. These improvements persist and, on some HRQOL domains, increase, up to 14 week after the end of the intervention. From this evidence, I suggest that these therapies might act

additively to improve HRQOL in people with OA, and that the combination of physical exercise and manual therapies may be useful in moving clients towards self-directed care (Phillips, Schneider, & Mercer, 2004).

Reasons for the Observed Effects

The mechanisms by which physical and manual therapies affect HRQOL were not investigated in the studies of this thesis. I have focussed on measures and outcomes that are important to clients. People are generally more concerned with whether they feel better than why they feel better. That said, it is intellectually appealing to consider some explanations for the observed effects.

Hyaluronan. A plausible explanation for some of the observed improvements is that physical and manual therapies that induce joint motion, whether passively or actively, are likely to increase the secretion of hyaluronan into the joint cavities. Hyaluronan is known to decrease the viscosity of synovial fluid (Ogston & Stanier, 1953), and elevated concentrations of it may go some way to explaining improvements in physical function domains affected by the arthritis symptom of stiffness: namely mobility, walking and bending, arm function, and hand function. Intrarticular injections of hyaluronan are used in treatment of OA of the knee, and produce similar results to joint mobilisation and water exercise in reducing joint stiffness and improving mobility-related function (Altman, Akermark, Beaulieu, & Schnitzer, 2004; Lee, Park, & Chmell, 2004).

Hyaluronan is secreted by cells of the synovial membrane. Because the style of massage in this thesis does not involve movement of joints (see Appendix A), synovial membranes are unlikely to have been stimulated during massage, offering some explanation as to why participants in the massage group reported fewer and smaller improvements on the physical function scales than participants in the joint mobilisation, water exercise, and combined therapies groups. Additionally, any improvements in

function explained by increased production of hyaluronan would logically apply only to synovial joints, and not, for example, to the secondary cartilaginous joints of the spine.

Muscle strength. Hurley (1999) suggested that sensorimotor dysfunctions, particularly muscle weakness, fatigue, and proprioceptive deficits, may be contributory factors in the development of OA, and exercise programs that include resistance training are likely to reduce pain in OA due to the muscle hypertrophy and increased strength that results from such training. There is considerable evidence that people with arthritis become stronger in response to resistance training (de Jong et al., 2003; Foley et al., 2003; Philbin et al., 1995; Van den Ende et al., 1998, 2002), but few studies have investigated whether participants experience reduced pain during or after resistance training interventions.

Thomas et al. (2002) conducted a clinical trial of home-based resistance training with 786 adults aged over 45 years who had knee pain. At all measurement points over the two-year study, people in the exercise group were statistically significantly stronger, reported less pain, and scored better on disease-specific measures of physical function (Western Ontario and McMaster Universities Arthritis Index, WOMAC; Bellamy, Buchanan, Goldsmith, & Campbell, 1988) than their non-exercising counterparts. Exercise and non-exercise groups did not differ significantly on general measures of physical function, HRQOL, or well-being (SF-36 and HADS). The effect sizes for all differences were small (*d*s ranged from .05 to .25), and statistical significance may be attributable more to the large sample size than to treatment effects. Thomas et al. calculated the number of clients needed to treat to show an improvement as a clinically relevant measure of effect (Cook & Sackett, 1995), and reported that the likelihood of improvement with exercise was such that in order to achieve a 50% reduction in knee pain in one person, 13 people would need to undergo the intervention. This measure of clinical significance, however, is questionable. For example, why is a 50% reduction in pain the threshold for a meaningful effect? Reductions in pain of less than 50% would most likely be welcomed by

many clients. As previously explained, although OA of the knee is the most common cause of knee pain in adults aged over 45 years, Thomas and colleagues did not distinguish between OA and other causes of knee pain. The benefits of exercise reported by Thomas et al. are moderate, and although possibly due to improvements in muscle strength, may be indicative of a more generalised effect of exercise on pain.

The mechanism proposed by Hurley (1999) does little to explain improvements in HRQOL associated with manual therapies. Manual therapies, as applied in the studies of this thesis, are unlikely to have contributed to the development of muscular strength because no resistance is applied to muscles during contraction. Hurley's opinion also appears to have altered with time. In 2003, Hurley et al. argued that the biomedical model is too simplistic an explanation of improvement in arthritis because it does not explain the disparity between joint damage (e.g., as seen on a radiograph) and symptoms.

Self-efficacy. Several authors have proposed that improvements in self-efficacy may explain many of the functional gains associated with exercise (Bean, Vora, & Frontera, 2004; Hurley et al., 2003; Lorig et al., 1993; Rejeski et al., 1998). Essentially, if an exercise program involves climbing stairs, then as participants undertake that activity, their confidence in their ability to do that activity (i.e., self-efficacy) improves. It is not surprising that at the end of an exercise intervention, participants have improved capacity to do the activities for which they have trained. The effects of exercise, however, appear to reach further than the anticipated functional gains, including reduced pain and improved mental health (Hurley et al., 2003; Keysor, 2003).

Improved self-efficacy does little to explain the improvements in HRQOL observed in the manual therapy groups. Possibly some improvements in social and physical function are accounted for by self-efficacy derived from travelling to and attending appointments with a therapist, but the passive quality of manual therapies suggests that self-efficacy gains arising from these interventions are likely to be small. Social support, particularly

through the development of a working alliance with a therapist, appears a more likely psychosocial mechanism by which manual therapies might afford improvement in HRQOL (Mitchell & Cormack, 1998; Petitpas et al., 1999, Phillips, Schneider, & Mercer, 2004). The quality of the relationship between the therapist and the client, however, was not examined in this thesis, but it is an area that deserves attention in future studies.

Choosing Between Interventions

Fiechtner and Brodeur (2002a, 2002b) reviewed studies of manual therapy treatments in people with musculoskeletal disorders, including back pain, neck pain, and OA. Although the results of many studies were compromised by weaknesses in design, Fiechtner and Brodeur found reasonable evidence in favour of manual therapies over no treatment and placebo controls. Comparative studies of manual therapies with physical therapies, exercise, and education programs were not consistently conclusive in favour of any particular approach. Also, Fiechtner and Brodeur did not report any studies that used combinations of multiple adjunctive therapies.

Study 3 provides some evidence that manual therapies and water exercise used together are more effective in improving HRQOL than either therapy in isolation, and that the effects of combined interventions are robust over time. As mentioned in Studies 1 and 3, there is little justification for isolating interventions clinically. Furthermore, if each of the adjunctive therapies tested is effective in improving HRQOL to some extent, then decisions about which therapy to use should be driven not so much by effectiveness alone, but also by client preferences and the practicalities of service delivery.

Strengths, Weaknesses, and Unexpected Findings in these Studies

Ecological Validity

The studies in this thesis were designed to parallel real-world treatments as much as possible, and the results of these studies are readily applicable to clinical practice. This pragmatic approach to research design affords both strengths and weaknesses. Goldfried

and Wolfe (1998) argued that "research's clinical validity has been compromised by the medicalization of outcome research, use of random assignment of clients without regard to appropriateness of treatment, fixed number of therapy sessions. . . and use of theoretically pure therapies." (p. 143). Goldfried and Wolfe's criticisms were of psychotherapy research, but their comments also apply to manual therapy research. In manual therapy practice, clients are not randomly assigned to interventions. Although practice guidelines have been developed for some common conditions (Australian Acute Musculoskeletal Pain Guidelines Group, 2003), for the most part, practitioners assess clients individually, and tailor interventions to suit, often combining supposed theoretically pure therapies in idiosyncratic ways (McKone, 2001). Goldfried and Wolfe argued that clinical (external) validity is a fundamental criterion of therapy research that should be satisfied even if internal validity, such as blinding to group allocation or rigorous between-groups controls, is compromised. "Although we agree. . . that inferences can be more confidently drawn from controlled research than from surveys involving correlational findings, we maintain that such controlled research is severely limited if it fails to meet the more basic criterion of having clinical validity." (Goldfried & Wolfe, p. 143).

In the studies of this thesis, participants were volunteers recruited through promotional material distributed via Arthritis Victoria. Diagnosis of OA or RA was confirmed through contact with the participants' medical practitioners (usually general practitioners or rheumatologists), but no additional results of diagnostic tests were applied as inclusion criteria. This approach probably contributed to the differences between groups at baseline because there was no attempt to recruit participants at similar stages of disease progress. On the other hand, it is ecologically valid to recruit participants across many stages of a disease because it is consistent with the breadth of client presentations in clinical practice. Sokka and Pincus (2003) reviewed 378 people with RA, 232 with early signs and symptoms, and 146 with late or advanced disease, who presented for clinical

care in 2001. They compared clients' clinical presentations with inclusion criteria for clinical trials run in the same year. All clients had, at some time, met the ACR criteria for a diagnosis of RA, so although the diagnosis was not in doubt, no people with early RA, and only 4.1% of people with late RA, actually met the inclusion criteria for clinical trials. Sokka and Pincus concluded that the inclusion criteria for many arthritis trials were too stringent and likely to exclude people who would receive routine arthritis care in clinical practice.

In allocating participants to groups an attempt was made to balance internal and external validity. Participants were randomly allocated to groups using a table of random numbers, but they were not blind to treatments. Blinding to therapy allocation is almost impossible in most manual and physical therapy research because adequate sham therapies are not available. Some authors have suggested using sham laser acupuncture or sham therapeutic ultrasound (i.e., using a unit that lights up as though active, but emits no therapeutic signal; see Irnich et al., 2001), but these sham therapies are poor mimics of the physical and manual therapies used in this thesis.

For ethical reasons, usual care was the only control that was possible in this thesis. In the Australian healthcare system, the client (patient) has a common law right to be informed about any procedure or therapy before intervention commences. Clients may choose to undertake an intervention voluntarily or refuse it. Therefore, there is always an option of no treatment. In a randomised clinical trial, however, it is unethical to allocate participants to a no treatment control group if there are broadly accepted effective therapies (usual care) in current use by participants and when removing people from usual care is likely to harm them.

The outcome measures used in this thesis are intuitively relevant. Although the AIMS2 is a lengthy questionnaire, and best kept for clinical research, the SF-36 and SF-MPQ are relatively brief and suitable for monitoring ongoing clinical care. The scoring

algorithm of the SF-36, however, is complex, and copyright restrictions apply to clinical use of the questionnaire (MOT, 1997). Davidson and Keating (2002) compared several HRQOL scales commonly used in manual therapy (physiotherapy) practice, and found that the physical function subscale of the SF-36 was reliable and had adequate scale width and responsiveness for use as a stand-alone scale. Although Davidson and Keating's intention was specifically to identify an instrument to assess disability in people with low back pain, their work contributes to the understanding that HRQOL outcome measures such as the SF-36 are useable and meaningful in day-to-day manual therapy practice.

Floor Effects

A floor effect occurs when participants' scores tend to cluster around the minimum possible score on an item or subscale. Conversely, a ceiling effect occurs when participants' scores tend to cluster around the maximum possible score. Floor and ceiling effects across a group or sample demonstrate that the data collection tool, or a subscale within it, is probably not appropriate for the cohort, and is not likely to be sensitive to changes in whatever is being measured because participants are already at the extreme ends of the measurement scale (Aron & Aron, 1999).

When using the AIMS2, a floor effect was observed in the self-care subscale. Most participants in Studies 1, 2, and 3 ($n = 38$) reported that they could complete with ease all of the tasks described in this subscale (bathe/shower, dress, use the toilet, and get in and out of bed). The studies in this thesis were conducted in ambulatory care settings (i.e., Victoria University Osteopathic Medicine Clinic [VU-OMC] and various public and hospital swimming pools). Criteria for recruitment included that participants had to have been able to do a substantial amount of self-care (e.g., dress/undress themselves). It is likely that the inclusion criteria are responsible for this floor effect because people unable to complete self-care tasks would be unlikely to volunteer for a study in which they might be assigned to a water exercise class at a local public swimming pool or required to disrobe

by themselves for manual therapy. Pool attendants and water exercise leaders are usually unavailable to assist others with dressing, showering, or toileting. Neither are osteopathic students usually available to assist clients at the VU-OMC with these tasks.

Social Support

Although exercise is therapeutic in its own right, exercise in a group, as was used in this thesis, may also offer important social support. I anticipated that, consistent with research in psychotherapy (Petitpas et al., 1999), the working alliance between the manual therapist and the client, a type of social support, would be a component of the therapeutic intervention. A measure of total social support (TSS) was administered at each of the data collection points in the clinical studies (MOS-SS). In Studies 1 and 3, this measure at week 9 was used as a covariate in the ANCOVAs performed on each HRQOL variable. Measures of TSS were also compared across time. Social support at week 9 was selected as the measure most likely to have captured any increases in social support due to the development of new relationships, either with a manual therapist, exercise leader, or other members of an exercise group. For the most part, the variance accounted for by social support was smaller than the variance accounted for by group (interventions or control) or by baseline scores on a given variable, but this pattern was not consistent across all HRQOL domains.

In retrospect, the MOS-SS appears not to be appropriate to measure social support derived from practitioner-client relationships or group interventions. Although it is important to have used it as a covariate measure in order to clarify the effects of the interventions, the social support measure used in these studies may not have incorporated many aspects of social support associated with the interventions. Furthermore, other HRQOL domains that might be expected to share variance with social support, such as the satisfaction, tension, and mood subscales of the AIMS2, and the mental health subscale of the SF-36, did not demonstrate significant associations with the MOS-SS.

Unexplored Aspects of HRQOL

The HRQOL tools used in these studies are valid, reliable instruments, covering most aspects of HRQOL important to people with arthritis. Recent studies, however, have demonstrated that the sexual aspects of HRQOL are: (a) of considerable importance to people with arthritis, (b) under-researched, and (c) rarely discussed in clinical settings (Hill & Reay, 2004; Bosworth, 2004). In Hill and Reay's anonymous survey of 76 adults with OA, 30% of participants with partners reported that OA had altered their sexual relationships, and 50% of participants reported that OA limited their sexual activity.

Bosworth's (2004) study of 200 adults with RA used a telephone interview format and covered many social and psychological aspects of living with RA, including the effects on sexual activity and relationships. Because of the sensitive nature of the topic, it is possible that interviews regarding sexual activity might result in under-reporting of any problems. Bearing this caveat in mind, 15% of all participants, and 38% of participants aged 25-34 years, reported that RA made it impossible for them to have a sexual partner or lover. Although Bosworth was unable to compare her data with population norms, it is unlikely that 38% of healthy young adults are also celibate.

Sexual aspects of HRQOL were not considered in the studies that constitute this thesis. Meenan et al. (1982, 1992) did not consider sexual function in the development of the Arthritis Impact Measurement Scales (Versions 1 and 2). Ware and Sherbourne (1992) acknowledged that sexual function is an important health concept, but it was not represented in the SF-36. They justified this omission in the development of the generic health status survey because sexual functioning was included in other sections of the Medical Outcomes Study (MOS). Sixteen years on, the SF-36 is more widely used than most other components of the MOS, and the sexual aspects of HRQOL are rarely measured.

Although some arthritis foundations, such as the Deutsche [German] Rheuma-Liga. (2001), provide thorough, and sensitively written, documentation on sexual relationships for people with arthritis, such printed materials are not readily available in English. The Arthritis Foundation of the USA (2002) website includes a section on sexual relationships, but access to the internet is problematic for some people. Bosworth (2004) recommended that "people with RA have access to support and advice. . . about the issues that RA may raise in terms of relationships and sex." (p. 560). Clearly, there is scope for further research into the intimate lives and sexual functioning of people with arthritis, and for improved English language client resources on the sexual aspects of OA, RA, and HRQOL. More importantly, information and advice may be imparted through printed or virtual literature, but psychosocial support is conveyed person to person. If one takes seriously Bosworth's recommendation, then practitioners need to begin to discuss sexual functioning with clients who have arthritis.

Recommendations for Further Research and Conclusions

Future Research

There is considerable scope for the further investigation of manual therapies and water exercise in arthritis care. I recommend that the positive effects of these therapies on HRQOL in people with arthritis be further investigated. The difficulties arising from Study 2 should be considered when planning a study using manual therapy for people with RA. I recommend a pre-test post-test pilot study of a manual therapy over a short cycle (one to two treatment sessions) in a single group of people with RA as an initial step.

The results of manual therapies for OA are largely consistent across Studies 1 and 3. Large effect sizes were identified on several HRQOL domains in both studies. If the large effect sizes found in these studies were repeated in a study with larger samples, then the results would likely achieve statistical significance. Although what matters in clinical research are the sizes of any clinically meaningful changes (Beaton, Boers, & Wells, 2002;

Stoové & Andersen, 2003), and the interpretation of changes in real-life variables (Kaplan, 1990, 1994; Sechrest et al., 1996); for many readers of research, alpha levels of .05 remain sacred.

Manual and physical therapies are delivered in varying combinations, settings, and by a range of therapists. Most studies of the Arthritis Self-Management Program (ASMP), modelled on Lorig's work, have demonstrated HRQOL benefits for people with arthritis (Lorig et al., 1993; Lorig & Holman, 1989, 2003; Lorig, Kraines, & Holman, 1981), but Solomon et al. (2002) found that people who attended an ASMP received no greater benefits (i.e., reduced pain, decreased disability, use of health resources, increased self-efficacy) than people who received an ASMP program manual from their general practitioner. Solomon et al.'s study was conducted in a managed care general practice network in the USA, and suggests that the method and setting of service delivery might influence outcomes. Future researchers might consider investigating how variations in manual and exercise service delivery alter the costs and benefits of these interventions.

Conclusions

The results of this thesis are directly applicable to physical and manual therapy practice. Manual therapy, particularly joint mobilisation, and water exercise can positively affect HRQOL in people with OA. Improvements may be substantial, and longer lasting, if combinations of therapies are employed. Because improvement in HRQOL is the central aim of much of arthritis care, and the HRQOL domains investigated in this thesis are of importance to people with arthritis, the positive results suggest that manual therapies and water exercise are appropriate therapeutic options for people with OA. The usefulness of these interventions in people with RA is inconclusive, but worthy of further investigation provided some cautions are heeded.

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Appendix A: Recruitment Flyer

Do you have Rheumatoid Arthritis or Osteoarthritis?

You are invited to participate in a series of clinical trials comparing the effects of manual therapy, water-based exercise, and standard medical care, on the health and wellbeing of people with rheumatoid arthritis or osteoarthritis. The trials are being conducted by Melainie Cameron, of Victoria University.

If you are aged between 18 and 80, and have been diagnosed, by a medial practitioner (GP or rheumatologist), with either osteoarthritis or rheumatoid arthritis, then you are invited to participate. Your current rheumatologist will continue to provide medical care for you throughout the research period. Your current medication regime will not be changed.

To participate in this project, you must be able to:

- walk unassisted for 20 meters
- climb in and out of a swimming pool safely
- undress to your underwear unaided
- read and write in English.

No therapy is completely risk free. Concerted effort has been made to reduce the risks associated with the therapies used in this research project, however, it is important that only people who meet **all** the criteria listed above take part in this project.

You will be assigned to either a "therapy" or a "control" group for a ten-week period (the length of one Victorian school term). At three points during this period, you will be asked to complete questionnaires regarding your pain, disability, and general health and well-being.

If you are assigned to a therapy group, then you may be asked to take part in water-based exercise (gentle, aerobic exercise in chest-deep warm water), or to attend manual therapy sessions (to receive either a massage, or passive mobilisation), once a week for the ten weeks. Each exercise / manual therapy session will take approximately 40 minutes. You will be able to adjust the exercise / manual therapy to suit your fitness and personal preferences. In one of the trials (there are three studies in this research project), you may be asked to take part in both water-based exercise and manual therapy. There will be no charge to you for either water-based exercise or manual therapy during the research period.

Manual therapy sessions will be conducted by senior osteopathic students at Victoria University, Osteopathic Medicine Clinic, level 4, 301 Flinders Lane, Melbourne. Water-based exercise sessions will be conducted by Arthritis Victoria at a public, or hospital, heated swimming pool near you.

Please contact Melainie Cameron at Victoria University for further information.
Telephone: (03) 9248 1149 Mobile: 0412 852 956
Email: Melainie.Cameron@vu.edu.au

Appendix B: Information to Participants with Covering Letter and Consent Form

set on VU letterhead

date**

Dear *********,

Thank you for your interest in my research. As per our telephone conversation this morning, I have enclosed a copy of the "Information to Participants" and an "Informed Participant Consent" form. Please read these documents carefully, and if you wish to proceed with participation in the research, please return the consent form to me using the enclosed reply-paid envelope.

Once I have received your completed consent form, I will contact you by telephone.

If you have any questions or concerns about my research, please contact me on (03) 9248 1149, or 0412 852 956.

Yours faithfully,

Melainie Cameron
B.App.Sc (Ost), M.H.Sc.
Osteopath, and Doctoral research student.

INFORMATION TO PARTICIPANTS

Regarding:

The Effectiveness of Manual Therapies and Water Based Exercise in Improving Health-related Quality of Life in People with Rheumatoid or Osteoarthritis.

If you are aged between 18 and 80, and have been diagnosed, by a medical practitioner (GP or rheumatologist), with either osteoarthritis or rheumatoid arthritis, then you are invited to participate in the research project named above. Your current rheumatologist will continue to provide medical care for you throughout the research period. Your current medication regime will not be changed.

To participate in this project, you must be able to:

- walk unassisted for 20 meters
- climb in and out of a swimming pool safely
- undress to your underwear unaided
- read and write in English.

No therapy is completely risk free. Concerted effort has been made to reduce the risks associated with the therapies used in this research project, however, it is important that only people who meet **all** the criteria listed above take part in this project.

You will be assigned to either a "therapy" or a "control" group for a ten-week period (the length of one Victorian school term). At three points during this period, you will be asked to complete questionnaires regarding your pain, disability, and general health and well-being.

If you are assigned to a therapy group, then you may be asked to take part in water based exercise (gentle, aerobic exercise in chest deep warm water), or to attend manual therapy sessions (to receive either a massage, or passive mobilisation), once a week for the ten weeks. Each exercise / manual therapy session will take approximately 40 minutes. You will be able to adjust the exercise / manual therapy to suit your fitness and personal preferences. In one of the studies (there are three studies in this research project), you may be asked to take part in both water based-exercise and manual therapy. There will be no charge to you for either water-based exercise or manual therapy during the research period.

Manual therapy sessions will be conducted by senior osteopathic students at Victoria University, Osteopathic Medicine Clinic, level 4, 301 Flinders Lane, Melbourne. Water-based exercise sessions will be conducted by Arthritis Victoria at a public, or hospital, heated swimming pool near you.

If you are assigned to a control group, then you will be asked to continue with your current arthritis management under the guidance of your rheumatologist. You will be asked not to start any new therapy as part of your arthritis management. You will still be

asked to complete the research questionnaires. At the end of the study, you will be offered the opportunity to take part in one of the therapies.

Each group in this project will be made up of people with arthritic diseases only. The risk of physical injury from therapies or exercise will be minimised by the exclusive use of water-based exercise and manual therapy regimes that are tailored specifically for people with arthritic diseases, and approved by experts in the field to be appropriate for such use. All normal occupational health and safety requirements for public access zones will be observed in both the consulting rooms and the swimming pool areas used in this project. If you perceive that you have been injured during the course of the project, please inform the therapist or exercise leader immediately, and cease the therapy / exercise. Appropriate first aid will be provided for you.

Participation in this project is voluntary. You are free to withdraw from the project at any time, without needing to provide a reason, and without fear of prejudice. If you attend fewer than eight of the ten rostered sessions in a study, you will be considered to have withdrawn from that study.

If you have any questions about this research, please contact me at Victoria University.

Thank you.

Melainie Cameron
PhD student researcher

Telephone: 03 9248 1149
Facsimile: 03 9248 1112
Email: Melainie.Cameron@vu.edu.au

INFORMED PARTICIPANT CONSENT

I,

of

certify that I am at least 18 years old and that I am voluntarily giving my consent to participate in the experiment entitled:

The Effectiveness of Manual Therapies and Water Based Exercise in Improving Health-related Quality of Life in People with Rheumatoid or Osteoarthritis

being conducted at Victoria University of Technology by Melainie Cameron, Dr Mark Andersen, and Dr Harriet Speed.

I certify that the objectives of the experiment, together with any risks to me associated with the procedures to be carried out in the experiment, have been fully explained to me. I freely consent to participating in this experiment and the use of the procedures outlined in the "Information to Participants".

I certify that I have had the opportunity to have any questions answered and that I understand that I can withdraw from this experiment at any time and that this withdrawal will not jeopardise me in any way.

I have been informed that the information I provide will be kept confidential.

Signed:

Date:

Witness (other than the researchers):

Date:

Any queries about your participation in this project may be directed to the researcher (Name: Melainie Cameron, ph. 9248 1149). If you have any queries or complaints about the way you have been treated, you may contact the Secretary, University Human Research Ethics Committee, Victoria University of Technology, PO Box 14428 MC, Melbourne, 8001 (telephone no: 03-9688 4710).

Appendix C: Questionnaire Booklet and Covering Letters for each Group

Letter C.1: Control Group

set on VU letterhead

date**

Dear *********,

Thank you for agreeing to assist me with my research into arthritis. I really appreciate your time and help. You have been allocated to the control group.

I have enclosed a copy of the "questionnaire booklet." As you will notice, it is printed on white paper and quite bulky, but there are few questions per page. The questionnaires have been tested by other people with arthritis, and should take no longer than half an hour to complete.

Please fill out the questionnaire booklet on the morning of Monday **********, at approximately "morning tea" time. The information gathered from these questionnaires gives a measure of how you usually feel. It is important that you continue to do all the things you usually do to manage your arthritis, but commence no new therapy for the next 10 weeks. If you are unable to meet this requirement because your health is at risk, please contact me directly on (03) 9248 1149.

There are 5 questionnaires in the booklet. They are

- **Short-form McGill Pain Questionnaire**: mark each item to describe the sort of pain you feel, and how much of it you feel.
- **SF-36 Health Survey**: asks about you general health and well being.
- **Arthritis Impact Measurement Scales 2 (AIMS2):** asks about health and well being, activity and function in relation to your arthritis.
- **Medication Use**: complete week 1 only
- **Social Support Survey (MOS):** asks if you have people around you who support you.

Unless the questionnaire includes specific instructions, consider that each questionnaire refers to how you feel at the time of completing the questionnaire.

Thank you for your assistance in this study. When you have completed the questionnaire booklet, please return it to me in the envelope provided. I will send you another copy of the questionnaire in 5 weeks time.

Most appreciatively,

Melainie Cameron.

Note. Variations of this letter were used at each data collection time across the studies (e.g., change dates, alter instructions for completion of Medication Use Survey).

Letter C.2: Massage Group

set on VU letterhead

date**

Dear *********,

Thank you for agreeing to assist me with my research into arthritis. I really appreciate your time and help. You have been allocated to the massage group. Massage sessions will commence next week, and continue for 10 weeks. Please telephone me on (03) 9248 1149 to book a massage session time.

Massage sessions will be conducted at Victoria University in the Osteopathic Medicine Clinic, on level 4 of 301 Flinders Lane. I have enclosed a brochure about the clinic. A map and directions are included in the brochure.

I have enclosed a copy of the "questionnaire booklet." As you will notice, it is printed on coloured paper and quite bulky, but there are few questions per page. The questionnaires have been tested by other people with arthritis, and should take no longer than half an hour to complete.

Please fill out the questionnaire booklet on the morning of your first massage session, before you go to the appointment. The information gathered from these questionnaires gives a "baseline" measure of how you usually feel, so it is important to complete it before you start any new therapy.

There are 5 questionnaires in the booklet. They are

- **Short-form McGill Pain Questionnaire**: mark each item to describe the sort of pain you feel, and how much of it you feel.
- **SF-36 Health Survey**: asks about you general health and well being.
- **Arthritis Impact Measurement Scales 2 (AIMS2):** asks about health and well being, activity and function in relation to your arthritis.
- **Medication Use**: complete week 1 only
- **Social Support Survey (MOS):** asks if you have people around you who support you.

Unless the questionnaire includes specific instructions, consider that each questionnaire refers to how you feel at the time of completing the questionnaire.

Thank you for your assistance in this study. When you have completed the questionnaire booklet, please return it to me in the envelope provided. I will send you another copy of the questionnaire in a few weeks, to complete before your 5th massage session.

Most appreciatively,

Melainie Cameron.

Letter C.3: Mobilisation Group

set on VU letterhead

date**

Dear *********,

Thank you for agreeing to assist me with my research into arthritis. I really appreciate your time and help. You have been allocated to the joint mobilisation group. Mobilisation sessions will commence next week, and continue for 10 weeks. Please telephone me on (03) 9248 1149 to book a mobilisation session time.

Mobilisation sessions will be conducted at Victoria University in the Osteopathic Medicine Clinic, on level 4 of 301 Flinders Lane. I have enclosed a brochure about the clinic. A map and directions are included in the brochure.

I have enclosed a copy of the "questionnaire booklet." As you will notice, it is printed on coloured paper and quite bulky, but there are few questions per page. The questionnaires have been tested by other people with arthritis, and should take no longer than half an hour to complete.

Please fill out the questionnaire booklet on the morning of your first mobilisation session, before you go to the appointment. The information gathered from these questionnaires gives a "baseline" measure of how you usually feel, so it is important to complete it before you start any new therapy.

There are 5 questionnaires in the booklet. They are

- **Short-form McGill Pain Questionnaire**: mark each item to describe the sort of pain you feel, and how much of it you feel.
- **SF-36 Health Survey**: asks about you general health and well being.
- **Arthritis Impact Measurement Scales 2 (AIMS2):** asks about health and well being, activity and function in relation to your arthritis.
- **Medication Use**: complete week 1 only
- **Social Support Survey (MOS):** asks if you have people around you who support you.

Unless the questionnaire includes specific instructions, consider that each questionnaire refers to how you feel at the time of completing the questionnaire.

Thank you for your assistance in this study. When you have completed the questionnaire booklet, please return it to me in the envelope provided. I will send you another copy of the questionnaire in a few weeks, to complete before your 5th appointment.

Most appreciatively,

Melainie Cameron.

Letter C.4: Water Exercise Group

set on VU letterhead

date**

Dear *********,

Thank you for agreeing to assist me with my research into arthritis. I really appreciate your time and help. You have been allocated to the warm water exercise group.

Please contact Jane Hawke at Arthritis Victoria on (03) 8531 8009 to identify a warm water exercise class at a time and location that suits your needs. All of Arthritis Victoria's usual requirements and restrictions will apply to these classes, so please follow any instructions you receive from Jane. Jane is usually in her office from 8.30 am to 4.30 pm Monday to Friday, but please leave a message if she is unavailable to answer the phone when you ring.

I have enclosed a copy of the "questionnaire booklet." As you will notice, it is printed on coloured paper and quite bulky, but there are few questions per page. The questionnaires have been tested by other people with arthritis, and should take no longer than half an hour to complete.

Please fill out the questionnaire booklet on the morning of your first water exercise class, before you go to the class. The information gathered from these questionnaires gives a "baseline" measure of how you usually feel, so it is important to complete it before you start any new therapy.

There are 5 questionnaires in the booklet. They are

- **Short-form McGill Pain Questionnaire**: mark each item to describe the sort of pain you feel, and how much of it you feel.
- **SF-36 Health Survey**: asks about you general health and well being.
- **Arthritis Impact Measurement Scales 2 (AIMS2):** asks about health and well being, activity and function in relation to your arthritis.
- **Medication Use**: complete week 1 only
- **Social Support Survey (MOS):** asks if you have people around you who support you.

Unless the questionnaire includes specific instructions, consider that each questionnaire refers to how you feel at the time of completing the questionnaire.

Thank you for your assistance in this study. When you have completed the questionnaire booklet, please return it to me in the envelope provided. I will send you another copy of the questionnaire in a few weeks, to complete before your 5th warm water exercise class.

Most appreciatively,

Melainie Cameron.

Letter C.5: Combined Therapies Group

set on VU letterhead

date**

Dear *********,

Thank you for agreeing to assist me with my research into arthritis. I really appreciate your time and help. You have been allocated to the combined manual therapy and water exercise group. Both manual therapy and water exercise sessions will commence next week, and continue for 10 weeks. Please telephone me on (03) 9248 1149 to book an appointment time for manual therapy.

Manual therapy sessions will be conducted at Victoria University in the Osteopathic Medicine Clinic, on level 4 of 301 Flinders Lane. I have enclosed a brochure about the clinic. A map and directions are included in the brochure.

Please contact Jane Hawke at Arthritis Victoria on (03) 8531 8009 to identify a warm water exercise class at a time and location that suits your needs. All of Arthritis Victoria's usual requirements and restrictions will apply to these classes, so please follow any instructions you receive from Jane. Jane is usually in her office from 8.30 am to 4.30 pm Monday to Friday, but please leave a message if she is unavailable to answer the phone when you ring.

I have enclosed a copy of the "questionnaire booklet." As you will notice, it is printed on coloured paper and quite bulky, but there are few questions per page. The questionnaires have been tested by other people with arthritis, and should take no longer than half an hour to complete.

Please fill out the questionnaire booklet on the morning of your first manual therapy or exercise session, whichever occurs first, before you go to the session. The information gathered from these questionnaires gives a "baseline" measure of how you usually feel, so it is important to complete it before you start any new therapy.

There are 5 questionnaires in the booklet. They are

- **Short-form McGill Pain Questionnaire**: mark each item to describe the sort of pain you feel, and how much of it you feel.
- **SF-36 Health Survey**: asks about you general health and well being.
- **Arthritis Impact Measurement Scales 2 (AIMS2):** asks about health and well being, activity and function in relation to your arthritis.
- **Social Support Survey (MOS):** asks if you have people around you who support you.

Unless the questionnaire includes specific instructions, consider that each questionnaire refers to how you feel at the time of completing the questionnaire.

Thank you for your assistance in this study. When you have completed the questionnaire booklet, please return it to me in the envelope provided. I will send you another copy of the questionnaire in a few weeks, to complete in the 5th week of the study.

Most appreciatively,

Melainie Cameron.

ID _____ 1-4/
Adm# _____ 5-6/
Card #1 7/*

ARTHRITIS IMPACT MEASUREMENT SCALES 2 (AIMS2)

Instructions: Please answer the following questions about your health. Most questions ask about your health during the past month. There are no right or wrong answers to the questions and most can be answered with a simple check (X). Please answer every question.

Please begin by providing the following information about yourself.

NAME: _____

ADDRESS: _____
Number Street Apt#

_____
City State Zip

PHONE: _____ TODAY'S DATE: _____
Area Code Number Month Day Year

AIMS

Please check (X) the most appropriate answer for each question.

These questions refer to **MOBILITY LEVEL**.

DURING THE PAST MONTH...	All Days (1)	Most Days (2)	Some Days (3)	Few Days (4)	No Days (5)	
1. How often were you physically able to drive a car or use public transportation?	____	____	____	____	____	8/
2. How often were you out of the house for at least part of the day?	____	____	____	____	____	9/
3. How often were you able to do errands in the neighborhood?	____	____	____	____	____	10/
4. How often did someone have to assist you to get around outside your home?	____	____	____	____	____	11/
5. How often were you in a bed or chair for most or all of the day?	____	____	____	____	____	12/

. . . . . .

AIMS

These questions refer to **WALKING AND BENDING.**

DURING THE PAST MONTH...	All Days (1)	Most Days (2)	Some Days (3)	Few Days (4)	No Days (5)	
6. Did you have trouble doing vigorous activities such as running, lifting heavy objects, or participating in strenuous sports?	____	____	____	____	____	13/
7. Did you have trouble either walking several blocks or climbing a few flights of stairs?	____	____	____	____	____	14/
8. Did you have trouble bending, lifting or stooping?	____	____	____	____	____	15/
9. Did you have trouble either walking one block or climbing one flight of stairs?	____	____	____	____	____	16/
10. Were you unable to walk unless assisted by another person or by a cane, crutches, or walker?	____	____	____	____	____	17/

AIMS

Please check (X) the most appropriate answer for each question.

These questions refer to **HAND AND FINGER FUNCTION**.

DURING THE PAST MONTH...	All Days (1)	Most Days (2)	Some Days (3)	Few Days (4)	No Days (5)	
11. Could you easily write with a pen or pencil?	____	____	____	____	____	18/
12. Could you easily button a shirt or blouse?	____	____	____	____	____	19/
13. Could you easily turn a key in a lock?	____	____	____	____	____	20/
14. Could you easily tie a knot or a bow?	____	____	____	____	____	21/
15. Could you easily open a new jar of food?	____	____	____	____	____	22/

. . . . . .

AIMS

These questions refer to **ARM FUNCTION**.

DURING THE PAST MONTH...	All Days (1)	Most Days (2)	Some Days (3)	Few Days (4)	No Days (5)	
16. Could you easily wipe your mouth with a napkin?	____	____	____	____	____	23/
17. Could you easily put on a pullover sweater?	____	____	____	____	____	24/
18. Could you easily comb or brush your hair?	____	____	____	____	____	25/
19. Could you easily scratch your low back with your hand?	____	____	____	____	____	26/
20. Could you easily reach shelves that were above your head?	____	____	____	____	____	27/

AIMS

Please check (X) the most appropriate answer for each question.

These questions refer to **SELF-CARE TASKS.**

DURING THE PAST MONTH...	Always (1)	Very Often (2)	Sometimes (3)	Almost Never (4)	Never (5)	
21. Did you need help to take a bath or shower?	____	____	____	____	____	28/
22. Did you need help to get dressed?	____	____	____	____	____	29/
23. Did you need help to use the toilet?	____	____	____	____	____	30/
24. Did you need help to get in or out of bed?	____	____	____	____	____	31/

AIMS

These questions refer to **HOUSEHOLD TASKS.**

DURING THE PAST MONTH...	Always (1)	Very Often (2)	Sometimes (3)	Almost Never (4)	Never (5)	
25. If you had the necessary transportation, could you go shopping for groceries without help?	____	____	____	____	____	32/
26. If you had kitchen facilities, could you prepare your own meals without help?	____	____	____	____	____	33/
27. If you had household tools and appliances, could you do your own housework without help?	____	____	____	____	____	34/
28. If you had laundry facilities, could you do your own laundry without help?	____	____	____	____	____	35/

Please check (X) the most appropriate answer for each question.

These questions refer to **SOCIAL ACTIVITY**.

DURING THE PAST MONTH...	All Days (1)	Most Days (2)	Some Days (3)	Few Days (4)	No Days (5)	
29. How often did you get together with friends or relatives?	____	____	____	____	____	36/
30. How often did you have friends or relatives over to your home?	____	____	____	____	____	37/
31. How often did you visit friends or relatives at their homes?	____	____	____	____	____	38/
32. How often were you on the telephone with close friends or relatives?	____	____	____	____	____	39/
33. How often did you go to a meeting of a church, club, team or other group?	____	____	____	____	____	40/

These questions refer to **SUPPORT FROM FAMILY AND FRIENDS**.

DURING THE PAST MONTH...	Always (1)	Very Often (2)	Sometimes (3)	Almost Never (4)	Never (5)	
34. Did you feel that your family or friends would be around if you needed assistance?	____	____	____	____	____	41/
35. Did you feel that your family or friends were sensitive to your personal needs?	____	____	____	____	____	42/
36. Did you feel that your family or friends were interested in helping you solve problems?	____	____	____	____	____	43/
37. Did you feel that your family or friends understood the effects of your arthritis?	____	____	____	____	____	44/

Please check (X) the most appropriate answer for each question.

These questions refer to **ARTHRITIS PAIN.**

DURING THE PAST MONTH...	Severe (1)	Moderate (2)	Mild (3)	Very Mild (4)	None (5)	
38. How would you describe the arthritis pain you usually had?	____	____	____	____	____	45/

	All Days (1)	Most Days (2)	Some Days (3)	Few Days (4)	No Days (5)	
39. How often did you have severe pain from your arthritis?	____	____	____	____	____	46/
40. How often did you have pain in two or more joints at the same time?	____	____	____	____	____	47/
41. How often did your morning stiffness last more than one hour from the time you woke up?	____	____	____	____	____	48/
42. How often did your pain make it difficult for you to sleep?	____	____	____	____	____	49/

. . . . . .

These questions refer to **WORK.**

DURING THE PAST MONTH...	Paid work (1)	House work (2)	School work (3)	Unemployed (4)	Disabled (5)	Retired (6)	
43. What has been your main form of work?	____	____	____	____	____	____	50/

If you answered unemployed, disabled or retired, please skip the next four questions and go to the next page.

DURING THE PAST MONTH...	All Days (1)	Most Days (2)	Some Days (3)	Few Days (4)	No Days (5)	
44. How often were you unable to do any paid work, housework or school work?	____	____	____	____	____	51/
45. On the days that you did work, how often did you have to work a shorter day?	____	____	____	____	____	52/
46. On the days that you did work, how often were you unable to do your work as carefully and accurately as you would like?	____	____	____	____	____	53/
47. On the days that you did work, how often did you have to change the way your paid work, housework or school work is usually done?	____	____	____	____	____	54/

AIMS

Please check (X) the most appropriate answer for each question.

These questions refer to **LEVEL OF TENSION.**

DURING THE PAST MONTH...	Always (1)	Very Often (2)	Sometimes (3)	Almost Never (4)	Never (5)	
48. How often have you felt tense or high strung?	____	____	____	____	____	55/
49. How often have you been bothered by nervousness or your nerves?	____	____	____	____	____	56/
50. How often were you able to relax without difficulty?	____	____	____	____	____	57/
51. How often have you felt relaxed and free of tension?	____	____	____	____	____	58/
52. How often have you felt calm and peaceful?	____	____	____	____	____	59/

AIMS

These questions refer to **MOOD**.

DURING THE PAST MONTH...	Always (1)	Very Often (2)	Sometimes (3)	Almost Never (4)	Never (5)	
53. How often have you enjoyed the things you do?	____	____	____	____	____	60/
54. How often have you been in low or very low spirits?	____	____	____	____	____	61/
55. How often did you feel that nothing turned out the way you wanted it to?	____	____	____	____	____	62/
56. How often did you feel that others would be better off if you were dead?	____	____	____	____	____	63/
57. How often did you feel so down in the dumps that nothing would cheer you up?	____	____	____	____	____	64/

Please check (X) the most appropriate answer for each question.

These questions refer to **SATISFACTION WITH EACH HEALTH AREA.**

DURING THE PAST MONTH...	Very Satisfied (1)	Somewhat Satisfied (2)	Neither Satisfied Nor Dis-satisfied (3)	Somewhat Dissatisfied (4)	Very Dis-satisfied (5)	
58. How satisfied have you been with each of these areas of your health?						
MOBILITY LEVEL (example: do errands)	____	____	____	____	____	65/
WALKING AND BENDING (example: climb stairs)	____	____	____	____	____	66/
HAND AND FINGER FUNCTION (example: tie a bow)	____	____	____	____	____	67/
ARM FUNCTION (example: comb hair)	____	____	____	____	____	68/
SELF-CARE (example: take bath)	____	____	____	____	____	69/
HOUSEHOLD TASKS (example: housework)	____	____	____	____	____	70/
SOCIAL ACTIVITY (example: visit friends)	____	____	____	____	____	71/
SUPPORT FROM FAMILY (example: help with problems)	____	____	____	____	____	72/
ARTHRITIS PAIN (example: joint pain)	____	____	____	____	____	73/
WORK (example: reduce hours)	____	____	____	____	____	74/
LEVEL OF TENSION (example: felt tense)	____	____	____	____	____	75/
MOOD (example: down in dumps)	____	____	____	____	____	76/

ID 1-4/
ADM# 5-6/
CARD #2 7/
AIMS

Please check (X) the most appropriate answer for each question.

These questions refer to **ARTHRITIS IMPACT ON EACH AREA OF HEALTH.**

DURING THE PAST MONTH...	Not A Problem For Me (0)	Due Entirely To Other Causes (1)	Due Largely To Other Causes (2)	Due Partly To Arthritis And Partly To Other Causes (3)	Due Largely To My Arthritis (4)	Due Entirely To My Arthritis (5)	
59. How much of your problem in each area of health was due to your arthritis?							
MOBILITY LEVEL (example: do errands)	____	____	____	____	____	____	8/
WALKING AND BENDING (example: climb stairs)	____	____	____	____	____	____	9/
HAND AND FINGER FUNCTION (example: tie a bow)	____	____	____	____	____	____	10/
ARM FUNCTION (example: comb hair)	____	____	____	____	____	____	11/
SELF-CARE (example: take bath)	____	____	____	____	____	____	12/
HOUSEHOLD TASKS (example: housework)	____	____	____	____	____	____	13/
SOCIAL ACTIVITY (example: visit friends)	____	____	____	____	____	____	14/
SUPPORT FROM FAMILY (example: help with problems)	____	____	____	____	____	____	15/
ARTHRITIS PAIN (example: joint pain)	____	____	____	____	____	____	16/
WORK (example: reduce hours)	____	____	____	____	____	____	17/
LEVEL OF TENSION (example: felt tense)	____	____	____	____	____	____	18/
MOOD (example: down in dumps)	____	____	____	____	____	____	19/

AIMS

You have now answered questions about different AREAS OF YOUR HEALTH. These areas are listed below. Please check (X) UP to THREE AREAS in which you would **MOST LIKE TO SEE IMPROVEMENT**. Please read all 12 areas of health choices before making your decision:

check = 1
blank = 0

60. AREAS OF HEALTH	THREE AREAS FOR IMPROVEMENT	
MOBILITY LEVEL (example: do errands)	_____	20/
WALKING AND BENDING (example: climb stairs)	_____	21/
HAND AND FINGER FUNCTION (example: tie a bow)	_____	22/
ARM FUNCTION (example: comb hair)	_____	23/
SELF-CARE (example: take bath)	_____	24/
HOUSEHOLD TASKS (example: housework)	_____	25/
SOCIAL ACTIVITY (example: visit friends)	_____	26/
SUPPORT FROM FAMILY (example: help with problems)	_____	27/
ARTHRITIS PAIN (example: joint pain)	_____	28/
WORK (example: reduce hours)	_____	29/
LEVEL OF TENSION (example: felt tense)	_____	30/
MOOD (example: down in dumps)	_____	31/

Please make sure that you have checked no more than THREE AREAS for improvement.

Please check (X) the most appropriate answer for each question.

These questions refer to your **CURRENT** and **FUTURE HEALTH**.

	Excellent (1)	Good (2)	Fair (3)	Poor (4)	
61. In general would you say that your HEALTH NOW is excellent, good, fair or poor?	____	____	____	____	64/

	Very Satisfied (1)	Somewhat Satisfied (2)	Neither Satisfied Nor Dis-satisfied (3)	Somewhat Dissatisfied (4)	Very Dis-satisfied (5)	
62. How satisfied are you with your HEALTH NOW?	____	____	____	____	____	32/

	Not A Problem For Me (0)	Due Entirely To Other Causes (1)	Due Largely To Other Causes (2)	Due Partly To Arthritis And Partly To Other Causes (3)	Due Largely To My Arthritis (4)	Due Entirely To My Arthritis (5)	
63. How much of your problem with your HEALTH NOW is due to your arthritis?	____	____	____	____	____	____	34/

	Excellent (1)	Good (2)	Fair (3)	Poor (4)	
64. In general do you expect that your HEALTH 10 YEARS FROM NOW will be excellent, good, fair or poor?	____	____	____	____	35/

	No Problem At All (1)	Minor Problem (2)	Moderate Problem (3)	Major Problem (4)	
65. How big a problem do you expect your arthritis to be 10 YEARS FROM NOW?	____	____	____	____	36/

Please check (X) the most appropriate answer for each question.

This question refers to **OVERALL ARTHRITIS IMPACT.**

	Very Well (1)	Well (2)	Fair (3)	Poor (4)	Very Poorly (5)	
66. CONSIDERING ALL THE WAYS THAT YOUR ARTHRITIS AFFECTS YOU, how well are you doing compared to other people your age?	____	____	____	____	____	37/

67. What is the main kind of arthritis that you have?

check = 1
blank = 0

Rheumatoid Arthritis	_____	38/
Osteoarthritis/Degenerative Arthritis	_____	39/
Systemic Lupus Erythematosis	_____	40/
Fibromyalgia	_____	41/
Scleroderma	_____	42/
Psoriatic Arthritis	_____	43/
Reiter's Syndrome	_____	44/
Gout	_____	45/
Low Back Pain	_____	46/
Tendonitis/Bursitis	_____	47/
Osteoporosis	_____	48/
Other	_____	49/

68. How many years have you had arthritis? _____ 50–51/

. . . . . .

DURING THE PAST MONTH...	All Days (1)	Most Days (2)	Some Days (3)	Few Days (4)	No Days (5)	
69. How often have you had to take MEDICATION for your arthritis?	____	____	____	____	____	52/

Please check (X) yes or no for each question.

70. Is your health currently affected by any of the following medical problems?

	Yes (1)	No (2)	
High blood pressure	_____	_____	53/
Heart disease	_____	_____	54/
Mental illness	_____	_____	55/
Diabetes	_____	_____	56/
Cancer	_____	_____	57/
Alcohol or drug use	_____	_____	58/
Lung disease	_____	_____	59/
Kidney disease	_____	_____	60/
Liver disease	_____	_____	61/
Ulcer or other stomach disease	_____	_____	62/
Anaemia or other blood disease	_____	_____	63/

	Yes (1)	No (2)	
71. Do you take medicine every day for any problem other than your arthritis?	_____	_____	64/
72. Did you see a doctor more than three times last year for any problem other than arthritis?	_____	_____	65/

Please provide the following information about yourself:

73. What is your age at this time? _____ 66–67/

74. What is your sex?

Male (1) _____ 68/
Female (2) _____

75. What is your racial background?

White (1) _____ 69/
Black (2) _____
Hispanic (3) _____
Asian or Pacific Islander (4) _____
American Indian or Alaskan Native (5) _____
Other (6) _____

76. What is your current marital status?

Married (1) _____ 70/
Separate (2) _____
Divorced (3) _____
Widowed (4) _____
Never married (5) _____

77. What is the highest level of education you received? 71/

Less than seven years of school (1) _____
Grades seven through nine (2) _____
Grades ten through eleven (3) _____
High school graduate (4) _____
One to four years of college (5) _____
College graduate (6) _____
Professional or graduate school (7) _____

78. What is your approximate family income including wages, disability payment, retirement income and welfare? 72/

Less than $10,000 (1) _____
$10,000–$19,999 (2) _____
$20,000–$29,999 (3) _____
$30,000–$39,999 (4) _____
$40,000–$49,999 (5) _____
$50,000–$59,999 (6) _____
$60,000–$69,999 (7) _____
More than $70,000 (8) _____

Thank you for completing this questionnaire.

SHORT-FORM McGILL PAIN QUESTIONNAIRE (SF-MPQ)

RONALD MELZACK

PATIENT'S NAME _____ DATE _____

	NONE	MILD	MODERATE	SEVERE
THROBBING	0) _____	1) _____	2) _____	3) _____
SHOOTING	0) _____	1) _____	2) _____	3) _____
STABBING	0) _____	1) _____	2) _____	3) _____
SHARP	0) _____	1) _____	2) _____	3) _____
CRAMPING	0) _____	1) _____	2) _____	3) _____
GNAWING	0) _____	1) _____	2) _____	3) _____
HOT, BURNING	0) _____	1) _____	2) _____	3) _____
ACHING	0) _____	1) _____	2) _____	3) _____
HEAVY	0) _____	1) _____	2) _____	3) _____
TENDER	0) _____	1) _____	2) _____	3) _____
SPLITTING	0) _____	1) _____	2) _____	3) _____
TIRING, EXHAUSTING	0) _____	1) _____	2) _____	3) _____
SICKENING	0) _____	1) _____	2) _____	3) _____
FEARFUL	0) _____	1) _____	2) _____	3) _____
PUNISHING, CRUEL	0) _____	1) _____	2) _____	3) _____

PPI

0	NO PAIN	_____
1	MILD	_____
2	DISCOMFORTING	_____
3	DISTRESSING	_____
4	HORRIBLE	_____
5	EXCRUCIATING	_____

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Your Health and Well-Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. ***Thank you for completing this survey!***

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐1	☐2	☐3	☐4	☐5

2. <u>Compared to one year ago</u>, how would you rate your health in general <u>now</u>?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
☐1	☐2	☐3	☐4	☐5

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐ 1	☐ 2	☐ 3
b Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
c Lifting or carrying groceries	☐ 1	☐ 2	☐ 3
d Climbing several flights of stairs	☐ 1	☐ 2	☐ 3
e Climbing one flight of stairs	☐ 1	☐ 2	☐ 3
f Bending, kneeling, or stooping	☐ 1	☐ 2	☐ 3
g Walking more than a mile	☐ 1	☐ 2	☐ 3
h Walking several blocks	☐ 1	☐ 2	☐ 3
i Walking one block	☐ 1	☐ 2	☐ 3
j Bathing or dressing yourself	☐ 1	☐ 2	☐ 3

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
a Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2
b Accomplished less than you would like	☐ 1	☐ 2
c Were limited in the kind of work or other activities	☐ 1	☐ 2
d Had difficulty performing the work or other activities (for example, it took extra effort)	☐ 1	☐ 2

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	No
a Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2
b Accomplished less than you would like	☐ 1	☐ 2
c Did work or other activities less carefully than usual	☐ 1	☐ 2

6. **During the <u>past 4 weeks</u>, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?**

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐1	☐2	☐3	☐4	☐5

7. **How much <u>bodily</u> pain have you had during the <u>past 4 weeks</u>?**

None	Very mild	Mild	Moderate	Severe	Very Severe
☐1	☐2	☐3	☐4	☐5	☐6

8. **During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?**

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐1	☐2	☐3	☐4	☐5

9. These questions are about how you feel and how things have been with you during the <u>past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>...

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a Did you feel full of pep?	☐1	☐2	☐3	☐4	☐5	☐6
b Have you been a very nervous person?	☐1	☐2	☐3	☐4	☐5	☐6
c Have you felt so down in the dumps that nothing could cheer you up?	☐1	☐2	☐3	☐4	☐5	☐6
d Have you felt calm and peaceful?	☐1	☐2	☐3	☐4	☐5	☐6
e Did you have a lot of energy?	☐1	☐2	☐3	☐4	☐5	☐6
f Have you felt downhearted and blue?	☐1	☐2	☐3	☐4	☐5	☐6
g Did you feel worn out?	☐1	☐2	☐3	☐4	☐5	☐6
h Have you been a happy person?	☐1	☐2	☐3	☐4	☐5	☐6
i Did you feel tired?	☐1	☐2	☐3	☐4	☐5	☐6

10. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

11. How TRUE or FALSE is <u>each</u> of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a I seem to get sick a little easier than other people	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b I am as healthy as anybody I know	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c I expect my health to get worse	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d My health is excellent	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Thank you for completing these questions!

MEDICATION USE

Week 1

List the medications you currently take for your arthritis. If you know the doses of these medications, please list this information also.

Week 5

Compared with previous weeks, would you say that your current medication use is:

☐ A lot more
☐ A little more
☐ About the same
☐ A little less
☐ A lot less

Week 9

Compared with previous weeks, would you say that your current medication use is:

☐ A lot more
☐ A little more
☐ About the same
☐ A little less
☐ A lot less

Social Support Survey (MOS)

Next are some questions about the support that is available to you.

1. About how many close friends and close relatives do you have (people you feel at ease with and can talk to about what is on your mind)?

Write in number of close friends and close relatives: ☐☐

People sometimes look to others for companionship, assistance, or other types of support. How often is each of the following kinds of support available to you if you need it?

(Circle One Number On Each Line)

	None of the Time	A Little of the Time	Some of the Time	Most of the Time	All of the Time
2. Someone to help you if you were confined to bed	1	2	3	4	5
3. Someone you can count on to listen to you when you need to talk	1	2	3	4	5
4. Someone to give you good advice about a crisis	1	2	3	4	5
5. Someone to take you to the doctor if you needed it	1	2	3	4	5
6. Someone who shows you love and affection	1	2	3	4	5
7. Someone to have a good time with	1	2	3	4	5
8. Someone to give you information to help you understand a situation	1	2	3	4	5
9. Someone to confide in or talk to about yourself or your problems	1	2	3	4	5
10. Someone who hugs you	1	2	3	4	5
11. Someone to get together with for relaxation	1	2	3	4	5
12. Someone to prepare your meals if you were unable to do it yourself	1	2	3	4	5
13. Someone whose advice you really want	1	2	3	4	5
14. Someone to do things with to help you get your mind off things	1	2	3	4	5
15. Someone to help with daily chores if you were sick	1	2	3	4	5
16. Someone to share your most private worries and fears with	1	2	3	4	5
17. Someone to turn to for suggestions about how to deal with a personal problem	1	2	3	4	5
18. Someone to do something enjoyable with	1	2	3	4	5
19. Someone who understands your problems	1	2	3	4	5
20. Someone to love and make you feel wanted	1	2	3	4	5

Appendix D: Standardised Manual Therapy Programs

Massage Program

Instructions to Osteopathic Students

Participant has undressed to underwear, and is lying prone on treatment table in heated room. Participant is draped with towels for warmth and modesty. Practitioner is clean, neatly attired in clinic uniform, and has washed hands thoroughly with chlorhexidine soap and warm water prior to commencing manual therapy.

Massage is conducted with broad hand contacts, comprising the palmar surfaces of the hand/s, and the posterior surface of a flexed elbow. Massage strokes comprise effleurage, long fibre massage, and cross fibre kneading. Strokes are smooth, gentle, and fluid. Initially the massage strokes are very light, but may become firmer as the participant reports tolerance. Massage should not be painful. The entire massage is scheduled to take 32 minutes. 40 minutes is allocated per appointment, allowing time for the participant to undress and re-dress.

Order of Massage

Type of massage	*Region*	*Time allocated*
Effleurage	Whole of right upper limb, commencing distally, and moving proximally.	2.5 minutes
	Whole of left upper limb, commencing distally, and moving proximally.	2.5 minutes
	Whole of right lower limb, commencing distally, and moving proximally.	3 minutes
	Whole of left lower limb, commencing distally, and moving proximally.	3 minutes
	Whole of back, thoracic and lumbar regions, from inferior to superior.	1 minute
	Posterior cervical surface, from occipital margin to thoracic spine junction.	1 minute
Long fibre massage	Posterior right leg, along full length of gastrocnemius muscle.	1 minute
	Posterior left leg, along full length of gastrocnemius muscle.	1 minute

	Lumbar and thoracic regions, along full length of right erector spinae muscle group.	2 minutes
	Lumbar and thoracic regions, along full length of left erector spinae muscle group.	2 minutes
Cross fibre kneading	Posterior right thigh surface, across whole length of hamstring muscle group.	2 minutes
	Posterior left thigh surface, across whole length of hamstring muscle group.	2 minutes
	Right buttock, from greater trochanter to sacroiliac joint.	1 minute
	Left buttock, from greater trochanter to sacroiliac joint.	1 minute
	Lumbar region, across right lumbar erector spinae and quadratus lumborum muscles.	1 minute
	Lumbar region, across left lumbar erector spinae and quadratus lumborum muscles	1 minute
	Thoracic region, across right trapezius muscle, from inferior to superior.	2 minutes
	Thoracic region, across left trapezius muscle, from inferior to superior.	2 minutes
	Cervical region, bilaterally, across full length of cervical erector spinae and sub-occipital muscles	1 minute

Joint Mobilisation Program

Instructions to Osteopathic Students

Participant has undressed to underwear, and is lying supine on treatment table in heated room. Participant is draped with towels for warmth and modesty. Practitioner is clean, neatly attired in clinic uniform, and has washed hands thoroughly with chlorhexidine soap and warm water prior to commencing manual therapy.

Joint mobilisation (articulation) is conducted with broad hand contacts, comprising the palmar surface and finger pads of the hands. In this schedule each limb is used as a lever to move joints of the axial skeleton. Mobilisation repetitions are smooth, gentle, and fluid. Each joint mobilised is moved rhythmically through all ranges of motion, to the pain-free barriers of motion, for three to five repetitions (see times allocated).

The entire joint mobilisation program is scheduled to take 32 minutes. 40 minutes is allocated per appointment, allowing time for the participant to undress and re-dress.

Order of Articulation: Commence on right side of body.

Lever contact	*Lever motion*	*Joints articulated*	*Time allocated*
Posterior surface of calcaneus	Inversion and eversion	Subtalar	30 seconds
	Anterior glide	Talocrural	30 seconds
Anterior surface of tibia	Flex knee over practitioner's forearm	Knee	1 minute
2 hands: Lateral surface of knee and inferior surface of calcaneus	Circumduction	Hip	1.5 minutes
Grasp around flexed knee with forearm and hand	Flexion, then abduction	Sacroiliac, lumbar spine, from inferior to superior	2 minutes
Posterior surface of triceps brachii muscle	Abduction	Ribs, from superior to inferior. Sternoclavicular. Sternocostal, from superior to inferior.	2 minutes
Repeat from beginning on left side.			
Posterior aspect of transverse processes of cervical spine	Translation to left, then to right.	Cervical spine	2 minutes
Ask participant to roll to prone position. Drape lower body.			
Anterior aspect of tibia	Internal and external rotation of femur with knee flexed to 90°	Hip, sacroiliac, lumbar spine.	2 minutes
Anterior surface of biceps brachii muscle	Circumduction	Glenohumeral.	1 minute
	Abduction	Acromioclavicular, scapulothoracic.	1 minute
Anterior surface of glenohumeral joint	Horizontal extension	Thoracic spine, from superior to inferior.	2 minutes
	Abduction	Ribs, from superior to inferior.	1.5 minutes
Repeat prone sequence on left side.			

Appendix E: Composite Data (Means and Standard Deviations) from Study 1

Table E.1 *Group Scores for Covariates (Medication Use and Total Social Support: TSS) Over Time*

Scale and time	Group					
	Control		Mobilisation		Massage	
	M	*SD*	*M*	*SD*	*M*	*SD*
Medication baseline	0.00		0.00		0.00	
Medication week 5	0.50	0.84	0.00	0.00	0.00	0.82
Medication week 9	0.17	0.41	-0.17	0.41	0.00	0.58

Scale and time	Group					
	Control		Mobilisation		Massage	
	M	*SD*	*M*	*SD*	*M*	*SD*
TSS baseline	69.2	23.8	82.8	12.3	62.1	19.9
TSS week 5	63.9	24.1	78.8	7.9	65.0	21.5
TSS week 9	67.0	19.0	81.3	8.2	69.0	20.1

Table E.2 *Week 0 (baseline) Group Scores for Each HRQOL Subscale*

Scale	Group					
	Control		Mobilisation		Massage	
AIMS2	*M*	*SD*	*M*	*SD*	*M*	*SD*
Mobility	0.83	0.75	0.97	0.91	1.57	1.46
Walk & Bend	3.42	1.93	5.05	1.81	4.93	1.92
Hand Function	1.42	2.56	1.72	2.20	3.09	2.50
Arm Function	0.58	0.92	1.25	1.41	2.29	3.67
Self-care	0.20	0.31	0.22	0.53	0.44	0.93
Household Tasks	0.53	0.64	0.62	1.24	0.90	1.46
Social Activity	5.33	1.03	4.33	0.88	5.04	1.37
Family Support	3.73	2.68	1.73	1.20	2.24	1.39
Arthritis Pain	4.63	1.36	4.38	2.07	5.43	2.85
Tension	4.33	1.99	1.90	1.09	4.66	1.79
Mood	2.97	1.46	1.55	0.69	2.87	1.55
Satisfaction	3.67	2.48	2.93	1.39	5.40	1.67
Health Perceptions	3.87	1.39	5.00	1.86	5.47	2.51
Arthritis Impact	3.33	1.29	1.47	1.68	3.21	1.89
Note. AIMS2 is scored out of 10. Lower score denotes better health status.						
SF-MPQ	*M*	*SD*	*M*	*SD*	*M*	*SD*
Sensory Pain	11.8	5.6	8.7	6.5	10.3	4.4
Affective Pain	2.5	2.0	1.2	1.6	1.4	1.5
Total Pain	14.3	6.6	9.8	7.9	11.7	5.4
Present Pain Index	2.2	0.4	1.8	0.7	2.2	0.7
Note. Lower scores denote less intense pain.						
SF-36	*M*	*SD*	*M*	*SD*	*M*	*SD*
Physical Function	51.7	17.2	40.0	4.5	30.0	15.0
Role: Physical	8.3	20.4	25.0	31.6	28.6	30.4
Bodily Pain	41.7	17.9	43.5	12.8	41.6	12.8
General Health	56.7	16.1	59.2	20.2	48.3	13.9
Vitality	42.5	18.4	48.3	16.3	45.0	12.2
Social Function	71.0	23.2	87.7	11.2	69.7	22.6

Role: Emotional	55.7	45.6	100.0	0.0	38.3	35.4
Mental Health	74.7	14.0	84.7	9.3	63.4	11.4
Health Transition	3.2	0.8	2.5	1.2	3.6	0.8

Note. All SF-36 domains except health transition are scaled to scores out of 100, and a higher score denotes better health-related quality of life. Health transition is scored from1-5. A score of 3 denotes stable health status, a score from 1-2.9 denotes health improvement, and a score from 3.1-5 denotes health decline.

Table E.3 *Week 5 Group Scores for Each HRQOL Subscale*

	Group					
Scale	Control		Mobilisation		Massage	
AIMS2	*M*	*SD*	*M*	*SD*	*M*	*SD*
Mobility	1.00	0.95	0.47	0.78	1.43	1.10
Walk & Bend	3.42	1.99	4.25	1.78	4.79	2.38
Hand Function	2.08	3.51	1.67	2.21	2.86	2.39
Arm Function	0.42	0.66	1.00	1.38	0.79	1.25
Self-care	0.20	0.31	0.10	0.24	0.54	0.99
Household Tasks	0.32	0.54	0.42	0.56	1.27	1.58
Social Activity	5.75	1.51	4.47	1.11	5.29	1.19
Family Support	4.05	2.08	2.08	1.86	3.41	1.45
Arthritis Pain	4.88	1.69	3.68	2.20	4.83	2.31
Tension	3.75	1.60	2.78	1.47	5.40	1.06
Mood	2.88	1.46	0.97	0.80	3.11	1.41
Satisfaction	3.52	2.18	2.60	1.11	5.04	1.63
Health Perceptions	3.87	1.39	3.88	2.53	5.96	2.35
Arthritis Impact	4.17	1.29	2.50	2.24	4.11	3.12
Note. AIMS2 is scored out of 10. Lower score denotes better health status.						
SF-MPQ	*M*	*SD*	*M*	*SD*	*M*	*SD*
Sensory Pain	12.2	6.4	4.3	2.9	8.9	4.6
Affective Pain	3.8	1.8	0.5	0.8	2.3	2.6
Total Pain	16.0	7.2	4.8	3.0	11.1	6.9
Present Pain Index	2.3	0.5	1.6	0.7	2.0	0.9
Note. Lower scores denote less intense pain.						
SF-36	*M*	*SD*	*M*	*SD*	*M*	*SD*
Physical Function	55.8	25.8	41.7	9.3	33.6	13.1
Role: Physical	33.3	43.8	41.7	30.3	28.6	36.6
Bodily Pain	43.2	18.1	50.0	15.8	51.7	15.2
General Health	53.3	22.1	63.5	23.6	44.7	11.4
Vitality	48.3	23.6	54.2	24.2	45.7	13.4
Social Function	77.3	21.4	85.5	20.0	71.7	19.9
Role: Emotional	72.2	44.4	100.0	0.0	42.9	46.0
Mental Health	78.0	12.8	84.0	8.4	66.3	11.0
Health Transition	2.7	0.8	2.3	1.0	3.6	0.8

Note. All SF-36 domains except health transition are scaled to scores out of 100, and a higher score denotes better health-related quality of life. Health transition is scored from1-5. A score of 3 denotes stable health status, a score from 1-2.9 denotes health improvement, and a score from 3.1-5 denotes health decline.

Table E.4 *Week 9 Group Scores for Each HRQOL Subscale*

	Group					
Scale	Control		Mobilisation		Massage	
AIMS2	*M*	*SD*	*M*	*SD*	*M*	*SD*
Mobility	1.17	0.98	0.67	0.75	1.30	0.92

Walk & Bend	4.25	2.12	3.58	1.77	4.83	2.58
Hand Function	2.50	3.82	1.42	2.01	2.57	1.79
Arm Function	0.83	0.98	0.50	0.55	1.19	1.61
Self-care	0.10	0.25	0.00	0.00	0.73	1.28
Household Tasks	0.75	0.64	0.35	0.76	0.90	1.02
Social Activity	6.25	0.94	3.82	1.62	4.07	1.69
Family Support	3.23	2.20	1.67	1.93	2.69	1.56
Arthritis Pain	4.80	1.57	3.23	2.26	4.61	1.82
Tension	3.83	1.21	2.68	1.99	4.16	1.52
Mood	2.18	0.93	1.22	0.55	2.30	1.50
Satisfaction	3.23	2.68	2.23	0.83	4.01	1.39
Health Perceptions	5.00	1.86	2.77	2.52	4.76	1.82
Arthritis Impact	4.58	1.88	2.08	1.88	3.93	1.34

Note. AIMS2 is scored out of 10. Lower score denotes better health status.

SF-MPQ	*M*	*SD*	*M*	*SD*	*M*	*SD*
Sensory Pain	12.3	7.5	4.7	2.0	6.1	1.5
Affective Pain	2.8	2.7	1.0	0.9	1.3	1.0
Total Pain	15.2	8.7	5.7	2.4	7.4	1.9
Present Pain Index	2.2	0.8	1.9	0.8	2.2	0.9

Note. Lower scores denote less intense pain.

SF-36	*M*	*SD*	*M*	*SD*	*M*	*SD*
Physical Function	45.8	21.8	43.3	15.1	41.8	16.0
Role: Physical	25.0	31.6	41.7	40.8	37.5	37.5
Bodily Pain	41.3	18.5	50.2	15.7	49.3	14.7
General Health	51.3	20.4	67.7	24.5	43.9	14.1
Vitality	42.5	23.2	58.3	20.4	48.9	13.8
Social Function	68.8	22.0	87.5	25.0	71.4	15.7
Role: Emotional	77.8	27.3	88.8	27.4	52.4	42.5
Mental Health	77.3	19.0	86.7	10.6	66.9	11.2
Health Transition	3.3	1.0	2.7	0.8	3.3	1.3

Note. All SF-36 domains except health transition are scaled to scores out of 100, and a higher score denotes better health-related quality of life. Health transition is scored from1-5. A score of 3 denotes stable health status, a score from 1-2.9 denotes health improvement, and a score from 3.1-5 denotes health decline.

Table E.5 *Within-Group Results: Change of Scores (baseline-week 9) in Each Group for Each HRQOL Subscale*

	Group		
Scale	Control	Mobilisation	Massage
AIMS2			
Mobility	- .33	.30	.27
Walk & Bend	- .83	1.47	.10
Hand Function	-1.08	.30	.51
Arm Function	- .25	.75	1.10
Self-care	.10	.22	- .29
Household Tasks	- .22	.27	.00
Social Activity	- .92	.52	.97
Family Support	.50	.07	- .44
Arthritis Pain	- .17	1.15	.81
Tension	.50	- .78	.50
Mood	.78	.33	.57
Satisfaction	.43	.70	1.39

Health Perceptions	-1.13	2.23	.71
Arthritis Impact	-1.25	- .62	- .71

Note. AIMS2 is scored out of 10. Lower score denotes better health status.

SF-MPQ			
Sensory Pain	- .50	4.00	4.21
Affective Pain	- .33	.17	.14
Total Pain	- .83	4.17	4.36
Present Pain Index	- .02	- .13	- .01

Note. Lower scores denote less intense pain.

SF-36			
Physical Function	- 5.83	3.33	11.86
Role: Physical	16.67	16.67	9.00
Bodily Pain	- .33	6.67	7.71
General Health	- 5.33	8.50	- 4.29
Vitality	.00	5.83	4.00
Social Function	- 1.83	- 2.17	1.86
Role: Emotional	22.17	-11.17	14.14
Mental Health	2.67	2.00	3.43
Health Transition	- .17	.17	.29

Note. All SF-36 domains except health transition are scaled to scores out of 100, and a higher score denotes better health-related quality of life. Health transition is scored from1-5. A score of 3 denotes stable health status, a score from 1-2.9 denotes health improvement, and a score from 3.1-5 denotes health decline.

Appendix F: Raw Data (Scaled Scores) from Study 2

Participant	Group	Disease	MOB0	WALK0	HAND0	ARM0	SELF0	HOUSE0	SOCIAL0	FAMILY0	PAIN0	WORK0
ADBRA	2	1	1.5	3.5	10.0	7.5	0.0	1.3	6.0	1.3	3.5	5.0
ARRA	2	1	2.5	6.5	3.5	1.0	3.1	0.6	4.5	0.5	6.0	2.5
BSRA	2	1	0.5	3.5	0.5	1.5	0.0	0.0	5.5	0.0	2.5	--
DARA	3	1	0.5	3.0	4.5	1.0	1.3	2.5	5.5	0.0	7.0	--
EMcRA	4	1	2.5	5.0	6.5	4.5	0.0	2.5	4.5	5.6	5.5	6.3
GCRA	2	1	6.0	6.5	3.5	4.5	1.3	5.6	6.0	2.5	5.5	--
GGRA	4	1	1.5	7.5	4.5	3.0	0.6	1.9	8.5	7.5	9.5	6.9
JGRA	3	1	3.0	5.0	5.5	5.5	0.0	6.9	4.5	0.0	7.0	--
JHRA	1	1	1.0	6.0	2.5	1.5	0.0	0.0	6.0	3.1	5.0	5.6
KCRA	3	1	1.5	3.0	5.5	3.5	1.3	0.6	4.0	0.6	6.0	2.5
MBRA	1	1	0.0	1.5	0.5	1.5	0.0	0.0	5.5	2.5	4.0	0.0
MJRA	1	1	3.0	7.0	2.5	2.0	1.9	1.3	3.5	2.5	7.5	5.0
NHOA	1	1	2.0	5.5	0.0	3.0	1.9	0.0	7.5	8.1	9.5	--
PRRA	1	1	1.5	4.0	1.5	0.5	0.0	0.0	5.0	5.0	7.5	--

Participant	TENSION0	MOOD0	SATIS0	HEALTH0	IMPACT0	MOB5	WALK5	HAND5	ARM5	SELF5	HOUSE5	SOCIAL5
ADBRA	6.5	6.5	5.2	3.3	5.0	1.5	4.5	8.0	10.0	0.0	2.5	5.5
ARRA	4.5	1.5	5.6	6.7	2.5	1.0	5.5	2.5	1.0	0.6	0.6	2.3
BSRA	2.5	2.5	1.3	3.3	5.0	0.5	3.0	0.0	0.0	0.0	0.0	6.0
DARA	4.0	1.5	3.3	10.0	7.5	1.0	5.0	2.3	1.0	1.3	2.5	5.5
EMcRA	3.5	4.0	8.4	6.7	7.5	2.0	5.0	3.0	1.5	0.0	1.9	5.0
GCRA	4.5	3.5	2.9	6.7	2.5	--	--	--	--	--	--	--
GGRA	3.3	3.8	5.4	10.0	10.0	1.0	6.0	5.0	4.0	1.3	2.5	2.8
JGRA	5.0	3.5	4.0	6.7	7.5	2.0	5.0	6.0	3.0	0.0	5.6	4.5
JHRA	3.5	9.0	5.2	6.7	7.5	0.5	4.0	3.0	0.5	0.0	0.0	6.5

KCRA	4.0	2.0	2.9	6.7	7.5	0.0	1.0	0.5	0.5	0.0	0.0	4.0
MBRA	5.0	2.0	1.3	3.3	0.0	0.0	1.0	0.0	1.0	0.0	0.0	4.5
MJRA	3.5	2.5	5.0	6.7	7.5	3.0	7.5	3.5	3.5	3.8	3.1	4.5
NHOA	7.0	4.0	7.5	6.7	5.0	1.5	6.0	0.0	2.0	0.0	2.5	6.5
PRRA	6.0	3.0	4.2	6.7	2.5	2.0	5.0	2.5	1.5	0.0	0.0	5.0

Participant	FAMILY5	PAIN5	WORK5	TENSION5	MOOD5	SATIS5	HEALTH5	IMPACT5	MOB9	WALK9	HAND9	ARM9
ADBRA	2.5	5.5	*3.4*	5.5	3.0	4.6	3.3	5.0	1.5	4.0	10.0	9.5
ARRA	1.3	4.5	*2.5*	4.5	0.5	1.5	6.7	0.0	0.5	2.0	1.0	0.0
BSRA	0.0	1.5	--	2.0	1.0	0.6	3.3	5.0	0.5	3.5	0.5	0.0
DARA	0.0	7.0	--	4.0	1.5	1.0	6.7	5.0	--	--	--	--
EMcRA	4.4	6.0	5.6	3.5	1.0	8.2	6.7	7.5	0.0	5.5	8.0	3.0
GCRA	--	--	--	--	--	--	--	--	--	--	--	--
GGRA	1.6	9.0	3.8	4.3	1.5	6.7	10.0	10.0	0.5	6.0	3.5	6.5
JGRA	0.0	6.5		5.0	3.5	3.8	6.7	5.0	2.0	4.5	5.5	4.0
JHRA	3.1	6.5	*5.9*	3.5	2.5	5.2	6.7	7.5	0.5	5.0	2.5	1.0
KCRA	0.6	3.5	0.6	1.5	0.5	1.0	3.3	5.0	0.0	0.5	1.0	0.5
MBRA	1.3	2.5	0.0	4.0	2.0	0.8	3.3	0.0	0.0	1.5	0.0	0.0
MJRA	1.3	7.0	4.4	4.5	2.5	4.8	6.7	2.5	3.0	6.0	6.5	3.0
NHOA	8.1	9.0	--	3.0	3.5	5.0	6.7	7.5	2.0	5.5	6.5	4.0
PRRA	5.0	6.0	--	4.0	3.0	5.6	10.0	5.0	1.0	7.5	4.5	2.5

Participant	SELF9	HOUSE9	SOCIAL9	FAMILY9	PAIN9	WORK9	TENSION9	MOOD9	SATIS9	HEALTH9	IMPACT9	SEN0
ADBRA	0.0	2.5	6.0	4.4	4.5	1.9	5.0	3.5	4.2	3.3	5.0	2.0
ARRA	0.0	0.0	4.0	1.9	2.0	2.5	1.5	0.0	0.0	3.3	0.0	13.0
BSRA	0.0	0.0	5.0	0.0	1.0	--	1.5	1.0	1.0	3.3	5.0	5.0
DARA	--	--	--	--	--	--	--	--	--	--	--	--

EMcRA	0.0	3.1	4.5	4.4	2.0	6.9	3.0	1.5	7.1	6.7	5.0	20.0
GCRA	--	--	--	--	--	--	--	--	--	--	--	--
GGRA	0.0	0.6	3.5	0.3	9.0	1.9	2.0	0.5	4.2	10.0	10.0	22.0
JGRA	0.6	5.0	4.0	0.0	7.5	--	5.0	2.5	4.0	6.7	5.0	9.0
JHRA	0.0	0.0	5.5	2.5	6.0	6.3	6.0	2.5	5.6	6.7	7.5	8.0
KCRA	0.0	0.0	3.0	0.6	2.0	0.0	0.5	0.0	0.4	3.3	5.0	10.0
MBRA	0.0	0.0	4.0	1.9	3.0	0.0	2.0	2.0	0.4	6.7	2.5	6.0
MJRA	0.6	0.0	4.0	3.8	3.5	3.8	4.0	3.5	5.2	6.7	5.0	11.0
NHOA	0.0	1.9	6.5	3.4	6.5	--	6.0	3.0	5.4	6.7	2.5	12.0
PRRA	2.5	0.0	6.0	5.0	10.0	--	7.0	2.5	6.3	6.7	7.5	12.0

Participant	AFF0	TPRI0	VAS0	PPI0	SEN5	AFF5	TPRI5	VAS5	PPI5	SEN9	AFF9	TPRI9
ADBRA	0.0	2.0	18.0	2.0	7.0	2.0	9.0	49.0	2.0	6.0	2.0	8.0
ARRA	2.0	15.0	--	2.0	10.0	1.0	11.0	--	2.0	6.0	0.0	6.0
BSRA	1.0	6.0	--	2.0	2.0	0.0	2.0	--	3.0	2.0	1.0	3.0
DARA	--	--	--	--	--	--	--	--	--	--	--	--
EMcRA	11.0	31.0	58.0	3.0	18.0	6.0	24.0	56.0	3.0	11.0	3.0	14.0
GCRA	--	--	--	--	--	--	--	--	--	--	--	--
GGRA	9.0	31.0	6.5	4.0	25.0	7.0	32.0	6.1	2.0	21.0	6.0	27.0
JGRA	3.0	12.0	49.0	2.0	10.0	3.0	13.0	39.0	2.0	8.0	2.0	10.0
JHRA	4.0	12.0	43.0	1.0	18.0	4.0	22.0	44.0	2.0	19.0	5.0	24.0
KCRA	3.0	13.0	37.0	2.0	7.0	4.0	11.0	33.0	2.0	5.0	2.0	7.0
MBRA	1.0	7.0	--	2.0	6.0	1.0	7.0	--	1.0	6.0	1.0	7.0
MJRA	2.0	13.0	68.0	3.0	14.0	4.0	18.0	38.0	3.0	16.0	4.0	20.0
NHOA	3.0	15.0	42.0	2.0	13.0	5.0	18.0	70.0	3.0	12.0	2.0	14.0
PRRA	2.0	14.0	--	3.0	24.0	8.0	32.0	--	3.0	17.0	10.0	27.0

Participant	VAS9	PPI9	PF0	RP0	BP0	GH0	VT0	SF0	RE0	MH0	RHT0	PF5
ADBRA	33.0	2.0	45	0	51	47	50	38	67	52	2	35
ARRA	--	1.0	25	0	22	40	50	75	0	88	4	35
BSRA	--	1.0	50	0	74	42	55	88	100	80	5	55
DARA	--	--	25	0	22	25	45	88	100	92	4	25
EMcRA	49.0	3.0	20	0	22	25	10	50	100	76	4	20
GCRA	--	--	20	0	31	45	0	50	0	60	1	--
GGRA	5.7	2.0	30	0	12	10	10	25	0	36	3	5
JGRA	56.0	2.0	50	0	31	40	45	75	100	72	3	45
JHRA	61.0	2.0	35	0	41	25	25	50	100	68	3	35
KCRA	26.0	2.0	75	75	62	25	15	100	100	84	1	80
MBRA	--	1.0	65	10	72	62	70	75	100	84	3	75
MJRA	55.0	3.0	15	0	22	32	40	38	67	80	4	15
NHOA	32.0	3.0	15	0	22	15	10	75	0	52	4	30
PRRA	--	3.0	70	25	42	30	35	75	33	68	4	40

Participant	RP5	BP5	GH5	VT5	SF5	RE5	MH5	RHT5	PF9	RP9	BP9	GH9
ADBRA	0	32	47	50	75	100	60	3	30	50	41	47
ARRA	75	62	45	85	100	100	88	2	75	100	84	72
BSRA	25	62	57	45	100	100	88	3	55	25	74	52
DARA	0	22	25	45	88	100	92	4	--	--	--	--
EMcRA	25	51	30	10	100	100	84	3	25	75	72	40
GCRA	--	--	--	--	--	--	--	--	--	--	--	--
GGRA	0	10	5	0	0	0	20	4	10	50	22	5
JGRA	0	31	30	45	100	100	76	3	40	0	31	30
JHRA	0	41	20	40	50	100	76	4	30	0	41	25
KCRA	75	74	30	60	88	100	92	2	90	100	84	37
MBRA	100	72	57	55	100	100	68	3	85	100	62	50

MJRA	0	31	30	30	50	100	84	4	25	0	22	25
NHOA	0	31	12	20	63	33	56	4	35	25	22	15
PRRA	0	22	30	35	25	33	64	4	35	0	42	25

Participant	VT9	SF9	RE9	MH9	RHT9	TSS0	TSS5	TSS9	Med0	Med5	Med9
ADBRA	45	38	0	56	3	79	79	61	0	2	1
ARRA	100	100	100	96	1	74	76	95	0	-1	-2
BSRA	60	100	100	92	4	94	95	94	0	0	0
DARA	--	--	--	--	--	*92*	92	--	0	1	--
EMcRA	20	100	100	88	4	75	95	87	0	0	1
GCRA	--	--	--	--	--	70	--	--	0	--	--
GGRA	5	75	67	80	4	47	41	--	0	0	0
JGRA	45	100	0	56	4	95	95	95	0	0	-1
JHRA	25	50	0	72	2	56	69	67	0	0	0
KCRA	60	100	100	92	1	81	86	85	0	-1	0
MBRA	70	63	100	76	4	82	74	75	0	0	1
MJRA	40	63	100	80	4	74	72	67	0	0	0
NHOA	30	50	0	56	3	35	--	38	0	0	--
PRRA	45	63	33	68	4	45	54	51	0	0	0

Appendix G: Composite Data (Means and Standard Deviations) from Study 3

Table G.1 *Group Scores for Covariate (Total Social Support: TSS) Over Time*

Scale and time	Group							
	Control		Mobilisation		Water Exercise		Combined	
	M	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
TSS baseline	80.8	14.4	60.3	16.6	76.9	18.8	78.5	13.9
TSS week 5	81.3	13.9	55.0	24.7	76.5	18.3	76.7	13.6
TSS week 9	81.0	14.0	55.8	20.1	77.9	18.5	77.3	15.3
TSS week 12	82.8	14.4	58.3	17.5	75.5	19.1	75.2	18.9
TSS week 24	84.0	14.2	54.8	19.8	78.1	18.5	80.2	16.6

Table G.2 *Week 0 (baseline) Group Scores for Each HRQOL Subscale*

Scale	Group							
	Control		Mobilisation		Water Exercise		Combined	
AIMS2	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
Mobility	1.33	1.40	0.88	0.85	0.88	0.69	0.33	0.41
Walk & bend	4.50	1.96	2.88	1.93	4.63	2.39	4.25	2.81
Hand function	1.00	1.68	2.75	3.20	0.88	1.09	1.42	0.86
Arm function	0.83	1.09	0.50	0.58	0.81	0.84	0.50	0.32
Self-care	0.00	0.00	0.00	0.00	0.15	0.28	0.00	0.00
Household tasks	1.18	1.97	0.48	0.62	1.03	0.89	0.43	0.67
Social activity	2.98	4.03	4.95	2.09	5.50	1.46	4.83	0.93
Family support	1.28	1.02	3.90	1.29	2.50	2.89	2.00	1.22
Arthritis pain	5.38	1.44	3.88	1.49	4.25	2.19	4.83	2.84
Tension	3.15	2.79	3.33	0.85	3.19	1.93	5.00	1.87
Mood	1.20	0.68	1.63	0.35	1.81	1.53	2.58	1.46
Satisfaction	3.28	1.68	2.65	2.93	2.75	1.69	3.62	1.65
Health perceptions	4.98	3.35	5.00	1.96	4.14	2.37	4.72	3.06
Arthritis impact	3.45	3.13	3.13	2.39	3.13	3.47	2.92	2.46

Note. AIMS2 is scored out of 10. Lower score denotes better health status.

SF-MPQ	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
Sensory pain	6.0	5.2	10.3	8.6	9.0	7.6	7.3	5.0
Affective pain	0.8	1.5	2.0	1.8	2.8	3.9	1.7	2.7
Total pain	6.8	6.1	12.3	10.4	11.8	11.2	9.0	7.6
Present Pain Index	2.3	0.5	1.3	0.6	2.2	1.2	1.7	0.5

Note. Lower scores denote less intense pain.

SF-36	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
Physical Function	30.0	23.5	55.0	14.1	38.1	18.3	54.2	19.3
Role: Physical	31.3	47.3	43.8	51.5	9.4	18.6	37.5	34.5
Bodily Pain	41.5	16.3	41.3	8.6	42.4	20.2	53.3	12.0
General Health	59.0	17.5	41.0	21.2	68.0	19.9	63.0	25.7
Vitality	52.5	17.5	50.0	21.6	38.8	15.3	40.8	21.8
Social Function	59.5	37.1	78.5	27.6	72.3	27.3	81.3	21.9
Role: Emotional	75.0	50.0	75.0	50.0	75.0	46.3	72.2	44.4
Mental Health	76.0	15.0	73.0	17.1	75.5	26.0	68.7	21.1
Health Transition	4.0	0.8	2.5	1.0	2.9	1.3	3.2	1.3

Note. All SF-36 domains except health transition are scaled to scores out of 100, and a higher score denotes better health-related quality of life. Health transition is scored from1-5. A score of 3 denotes stable health status, a score from 1-2.9 denotes health improvement, and a score from 3.1-5 denotes health decline.

Table G.3 *Week 5 Group Scores for Each HRQOL Subscale*

	Group							
Scale	Control		Mobilisation		Water Exercise		Combined	
AIMS2	*M*	*SD*	*M*	*SD*	*M*	*SD*	M	SD
Mobility	1.33	2.04	1.00	1.22	1.88	2.00	0.17	0.41
Walk & bend	5.38	2.95	3.25	2.10	4.13	1.53	4.00	2.88
Hand function	2.13	3.61	2.50	2.80	0.69	1.00	1.67	1.08
Arm function	1.20	2.08	1.00	1.22	0.63	0.64	0.42	0.49
Self-care	0.08	0.15	0.00	0.00	0.19	0.27	0.10	0.24
Household tasks	2.03	2.51	0.48	0.62	0.94	1.11	0.53	0.64
Social activity	5.88	1.38	5.63	0.95	5.06	0.98	4.43	1.74

Family support	1.18	1.04	3.43	2.31	2.31	2.04	1.95	1.43
Arthritis pain	4.33	2.53	4.03	2.80	3.63	1.73	3.13	2.12
Tension	3.58	2.57	3.50	2.38	3.33	1.91	4.47	2.07
Mood	1.58	1.18	2.10	1.92	1.79	1.15	1.72	1.64
Satisfaction	3.53	2.29	3.63	2.71	2.64	1.64	3.27	1.81
Health perceptions	4.60	3.73	5.85	1.70	4.15	1.57	4.57	3.26
Arthritis impact	2.53	3.09	3.13	2.39	3.29	3.21	3.33	2.58

Note. AIMS2 is scored out of 10. Lower score denotes better health status.

SF-MPQ	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
Sensory pain	7.0	6.7	7.8	6.8	6.8	1.3	6.2	3.1
Affective pain	1.0	1.4	1.5	1.3	2.2	2.2	1.8	2.7
Total pain	8.0	7.6	9.3	7.8	8.9	9.2	8.1	5.5
Present Pain Index	2.0	0.8	1.8	0.6	1.9	0.8	1.2	0.4

Note. Lower scores denote less intense pain.

SF-36	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
Physical Function	32.5	25.0	50.0	20.8	47.5	18.5	55.5	24.0
Role: Physical	25.0	35.4	25.0	35.4	28.1	33.9	70.8	36.8
Bodily Pain	49.3	22.3	36.8	19.1	50.0	18.5	60.3	10.3
General Health	54.0	12.9	44.3	15.1	69.8	15.8	67.7	27.1
Vitality	40.0	9.1	51.3	24.6	44.4	19.4	47.2	26.0
Social Function	53.3	35.7	75.3	17.4	78.5	17.0	91.7	12.9
Role: Emotional	66.8	47.1	41.8	50.1	93.8	17.7	77.8	40.4
Mental Health	76.0	13.5	71.0	20.0	80.8	17.8	72.7	25.4
Health Transition	4.3	1.0	2.5	1.0	2.6	1.2	2.6	0.7

Note. All SF-36 domains except health transition are scaled to scores out of 100, and a higher score denotes better health-related quality of life. Health transition is scored from1-5. A score of 3 denotes stable health status, a score from 1-2.9 denotes health improvement, and a score from 3.1-5 denotes health decline.

Table G.4 *Week 9 Group Scores for Each HRQOL Subscale*

	Group							
Scale	Control		Mobilisation		Water Exercise		Combined	
AIMS2	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*

Mobility	1.33	2.04	0.83	0.89	1.04	0.79	0.50	0.77
Walk & bend	5.88	2.46	2.13	1.93	3.69	2.03	3.00	2.77
Hand function	2.13	3.61	2.63	3.01	0.81	0.84	1.67	1.25
Arm function	1.08	2.15	0.63	0.75	0.56	0.56	0.92	1.16
Self-care	0.08	0.15	0.00	0.00	0.20	0.46	0.00	0.00
Household tasks	1.88	2.54	0.48	0.62	1.01	1.37	0.43	0.67
Social activity	6.00	1.47	5.38	2.06	5.04	1.55	5.33	0.52
Family support	1.33	1.10	3.30	2.51	2.19	2.43	2.40	1.84
Arthritis pain	5.08	1.94	3.63	1.93	3.94	1.95	2.97	1.83
Tension	3.25	2.53	2.60	1.68	3.20	1.91	4.67	1.89
Mood	1.83	1.26	3.63	3.09	2.14	1.26	1.58	0.66
Satisfaction	3.60	2.24	3.68	2.57	2.76	1.90	2.75	1.57
Health perceptions	4.58	2.55	5.85	1.70	3.53	1.89	3.88	2.53
Arthritis impact	2.53	3.09	3.75	2.50	3.29	2.92	2.92	2.46

Note. AIMS2 is scored out of 10. Lower score denotes better health status.

SF-MPQ	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
Sensory pain	6.3	5.6	5.8	3.8	7.7	7.2	3.8	2.0
Affective pain	1.0	1.4	0.3	0.5	2.2	2.5	1.0	1.7
Total pain	7.3	6.7	6.0	4.2	9.9	9.3	4.8	3.4
Present Pain Index	2.0	0.8	1.8	0.6	2.1	0.7	1.3	0.5

Note. Lower scores denote less intense pain.

SF-36	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
Physical Function	32.5	22.5	61.3	26.6	50.6	21.8	60.8	29.9
Role: Physical	56.3	51.5	25.0	35.4	26.6	34.3	75.0	38.7
Bodily Pain	46.8	19.2	39.3	12.5	48.0	19.0	69.5	9.3
General Health	55.3	13.5	40.5	23.6	68.3	18.3	68.5	23.3
Vitality	51.3	16.5	46.3	25.6	47.3	17.0	53.3	16.3
Social Function	62.8	39.4	78.5	12.0	77.5	21.1	96.0	6.2
Role: Emotional	75.0	50.0	41.8	50.1	81.3	37.2	77.8	40.4
Mental Health	80.0	17.6	70.0	19.7	82.0	17.7	76.0	10.1
Health Transition	4.4	1.0	2.8	0.5	2.5	1.3	2.3	0.8

Note. All SF-36 domains except health transition are scaled to scores out of 100, and a higher score denotes better health-related quality of life. Health transition is scored from 1-5. A score of 3 denotes stable health status, a score from 1-2.9 denotes health improvement, and a score from 3.1-5 denotes health decline.

Table G.5 *Week 12 (follow-up 1) Group Scores for Each HRQOL Subscale*

	Group							
Scale	Control		Mobilisation		Water Exercise		Combined	
AIMS2	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
Mobility	1.45	2.03	0.58	0.51	1.01	0.61	1.00	1.05
Walk & bend	7.00	1.47	2.03	2.10	3.73	1.94	3.33	3.53
Hand function	2.38	3.54	2.75	3.20	0.66	0.81	0.92	0.92
Arm function	1.20	2.08	0.50	1.00	0.50	0.60	0.58	0.49
Self-care	0.08	0.15	0.00	0.00	0.10	0.28	0.00	0.00
Household tasks	1.73	2.66	0.33	0.65	0.69	0.83	0.22	0.53
Social activity	6.13	1.38	5.08	1.27	4.83	1.46	5.33	1.08
Family support	1.00	1.07	3.05	2.14	1.18	1.93	1.98	1.83
Arthritis pain	5.38	1.65	2.75	0.87	3.53	1.84	2.82	1.38
Tension	3.15	3.28	2.63	2.14	2.76	1.67	4.42	1.32
Mood	1.80	1.92	1.50	0.91	1.80	1.37	1.58	0.58
Satisfaction	3.80	1.97	2.78	2.35	2.30	1.48	2.67	0.86
Health perceptions	5.85	2.19	5.00	1.96	3.38	0.90	3.33	3.00
Arthritis impact	3.78	1.79	3.75	1.44	2.88	2.47	2.08	2.46
Note. AIMS2 is scored out of 10. Lower score denotes better health status.								
SF-MPQ	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
Sensory pain	8.3	2.4	5.8	5.2	6.0	5.6	3.5	3.3
Affective pain	1.5	1.3	1.3	1.5	1.3	1.4	1.3	2.0
Total pain	9.8	3.4	7.0	6.6	7.3	6.7	4.8	3.8
Present Pain Index	2.3	0.5	1.5	0.0	1.7	0.6	1.3	0.5
Note. Lower scores denote less intense pain.								
SF-36	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
Physical Function	25.0	14.1	66.3	16.0	54.9	25.6	58.3	27.7
Role: Physical	18.8	37.5	31.3	37.5	45.4	37.7	66.7	43.8

Bodily Pain	44.0	17.0	54.3	10.0	56.4	16.3	65.8	14.7
General Health	56.5	17.6	39.8	21.5	72.6	16.4	71.5	27.2
Vitality	46.3	13.8	46.3	28.7	49.8	17.5	45.8	25.8
Social Function	47.0	32.7	72.0	15.9	77.9	11.7	85.5	12.3
Role: Emotional	75.0	50.0	75.0	50.0	90.9	25.8	72.2	44.4
Mental Health	75.0	25.6	69.0	23.6	86.3	12.0	72.0	15.6
Health Transition	3.8	1.0	2.8	0.5	2.4	1.3	2.7	0.8

Note. All SF-36 domains except health transition are scaled to scores out of 100, and a higher score denotes better health-related quality of life. Health transition is scored from1-5. A score of 3 denotes stable health status, a score from 1-2.9 denotes health improvement, and a score from 3.1-5 denotes health decline.

Table G.6 *Week 24 (follow-up 2) Group Scores for Each HRQOL Subscale*

	Group							
Scale	Control		Mobilisation		Water Exercise		Combined	
AIMS2	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
Mobility	0.75	0.96	1.63	1.11	0.94	0.68	0.92	0.97
Walk & bend	5.45	3.49	3.08	2.98	3.88	2.17	4.00	3.45
Hand function	2.13	3.92	3.88	4.84	0.69	1.00	1.83	2.40
Arm function	0.50	1.00	1.13	1.44	0.44	0.56	0.75	0.69
Self-care	0.08	0.15	0.00	0.00	0.11	0.22	0.00	0.00
Household tasks	0.68	0.90	0.80	0.96	0.95	1.16	0.22	0.53
Social activity	4.83	1.16	5.50	0.91	5.04	1.30	4.75	2.44
Family support	0.85	1.13	4.08	2.54	2.34	2.47	1.67	1.53
Arthritis pain	5.25	3.18	5.53	3.74	3.66	1.86	3.15	1.38
Tension	2.73	2.78	3.88	2.17	3.01	2.30	4.00	1.70
Mood	1.15	1.01	2.50	1.83	1.83	1.48	1.33	0.82
Satisfaction	3.65	2.32	2.85	2.96	2.26	1.43	2.28	0.93
Health perceptions	4.50	1.71	6.68	2.74	3.70	1.97	3.88	2.53
Arthritis impact	2.50	2.89	4.38	3.15	2.98	2.84	2.08	2.46

Note. AIMS2 is scored out of 10. Lower score denotes better health status.

SF-MPQ	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
Sensory pain	7.8	5.1	15.3	14.8	7.1	6.1	3.3	1.6

Affective pain	0.8	1.0	3.3	3.9	2.3	2.2	1.0	1.3
Total pain	8.5	5.7	18.5	18.7	9.4	8.1	4.3	2.7
Present Pain Index	2.1	0.9	2.0	1.2	2.1	1.0	1.5	0.8

Note. Lower scores denote less intense pain.

SF-36	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
Physical Function	37.5	15.5	50.0	28.0	56.3	26.6	63.3	22.9
Role: Physical	37.5	32.3	25.0	50.0	32.9	33.3	70.8	40.1
Bodily Pain	48.3	19.8	47.5	31.8	55.4	20.1	68.8	21.5
General Health	61.0	9.0	40.5	32.8	72.0	20.2	68.2	28.5
Vitality	48.3	21.9	51.3	38.4	41.0	22.3	50.0	27.7
Social Function	78.5	18.6	75.0	28.9	72.8	22.6	93.8	10.4
Role: Emotional	100.0	0.0	50.0	57.7	81.3	37.2	77.8	40.4
Mental Health	86.0	10.1	73.0	25.6	82.0	17.9	77.3	11.8
Health Transition	3.5	0.6	2.8	1.5	2.8	1.2	2.5	0.8

Note. All SF-36 domains except health transition are scaled to scores out of 100, and a higher score denotes better health-related quality of life. Health transition is scored from1-5. A score of 3 denotes stable health status, a score from 1-2.9 denotes health improvement, and a score from 3.1-5 denotes health decline.

Table G.7 *Between-Group Comparisons: Effect Sizes (d) for the Difference Between Groups at Week 12 for Each HRQOL Subscale*

Note. Comparison types: 1 = usual care compared with mobilisation, 2 = usual care compared with water exercise, 3 = usual care compared with combined therapies, 4 = mobilisation compared with water exercise, 5 = mobilisation compared with combined therapies, 6 = water exercise compared with combined therapies.

	Comparison type					
AIMS2 subscale	1	2	3	4	5	6
Mobility	.59	.36	.30	- .75	.48	.02
Walk & Bend	2.75	1.81	1.25	- .85	.43	.14
Hand Function	- .11	.83	.64	1.11	- .88	- .30
Arm Function	.43	.56	.46	.00	.11	- .15
Self-care	.71	- .10	.82	- .42	.00	.46
Household Tasks	.72	.64	.90	- .47	- .19	.66
Social Activity	.79	.91	.66	.18	.22	- .39
Family Support	-1.21	- .10	- .62	.94	- .55	- .43
Arthritis Pain	1.99	1.04	1.72	- .48	.05	.43
Tension	.19	.17	- .56	- .08	1.07	-1.08

Mood	.20	.00	.17	- .24	.11	.20
Satisfaction	.47	.91	.82	.27	- .07	- .29
Health Perceptions	.41	1.75	.92	1.24	- .63	.02
Arthritis Impact	.20	.39	.76	.39	- .78	.32
	Comparison type					
SF-MPQ subscale	1	2	3	4	5	6
Sensory pain	.62	.46	1.58	- .05	- .55	.52
Affective pain	.18	.14	.10	- .04	.05	- .01
Total pain	.52	.41	1.35	- .05	- .43	.44
Present Pain Index	2.12	1.09	1.80	- .35	- .41	.61
	Comparison type					
SF-36 subscale	1	2	3	4	5	6
Physical Function	2.73	1.31	1.42	- .49	.33	.13
Role: Physical	.33	.71	1.15	.38	- .85	.53
Bodily Pain	.74	.75	1.40	.14	- .88	.60
General Health	- .85	.96	.62	1.82	-1.26	- .05
Vitality	.00	.21	- .02	.16	.02	- .18
Social Function	.97	1.51	1.73	.45	- .98	.64
Role: Emotional	.00	.46	- .06	.46	.06	- .54
Mental Health	.24	.65	- .15	1.05	- .16	-1.05
Health Transition	1.31	1.18	1.22	.36	- .05	- .34

Table G.8 *Between-Group Comparisons: Effect Sizes (d) for the Difference Between Groups at Week 24 for Each HRQOL Subscale*

Note. Comparison types: 1 = usual care compared with mobilisation, 2 = usual care compared with water exercise, 3 = usual care compared with combined therapies, 4 = mobilisation compared with water exercise, 5 = mobilisation compared with combined therapies, 6 = water exercise compared with combined therapies.

	Comparison type					
AIMS2 subscale	1	2	3	4	5	6
Mobility	- .84	- .24	- .17	.83	- .69	.03
Walk & Bend	.73	.60	.42	- .33	.28	- .05

Hand Function-	.40	.62	.10	1.15	- .58	- .66
Arm Function	- .51	.09	- .30	.75	- .36	- .51
Self-care	.71	- .18	.82	- .60	.00	.66
Household Tasks	- .13	- .25	.66	- .14	- .81	.77
Social Activity	- .65	- .17	.04	.39	- .37	.15
Family Support	-1.64	- .69	- .59	.70	-1.22	.32
Arthritis Pain	- .08	.68	.94	.72	- .94	.31
Tension	- .46	- .12	- .59	.38	.07	- .48
Mood	- .91	- .50	- .20	.42	- .90	.40
Satisfaction	.30	.79	.85	.29	- .29	- .02
Health Perceptions	- .95	.42	.27	1.34	-1.07	- .08
Arthritis Impact	- .62	- .17	.16	.48	- .84	.33

	Comparison type					
SF-MPQ subscale	1	2	3	4	5	6
Sensory Pain	- .68	.12	1.32	.85	-1.30	.78
Affective Pain	- .87	- .82	- .22	.35	- .86	.71
Total Pain	- .72	- .12	1.02	.74	-1.12	.79
Present Pain Index	.12	.06	.74	- .06	- .52	.60

	Comparison type					
SF-36 subscale	1	2	3	4	5	6
Physical Function	.55	.79	1.26	.23	- .53	.28
Role: Physical	- .30	- .14	.89	.20	-1.04	1.05
Bodily Pain	- .03	.36	.99	.33	- .82	.65
General Health	- .85	.62	.31	1.28	- .92	- .16
Vitality	.10	- .33	.07	- .36	.04	.36
Social Function	- .14	- .27	1.09	- .09	- .97	1.14
Role: Emotional	-1.22	- .60	- .69	.70	- .58	- .09
Mental Health	- .67	- .25	- .78	.44	- .24	- .30
Health Transition	.66	.73	1.33	.00	- .22	.24

Appendix H: Priorities for Health Status Improvements from Study 1 and Study 3

Table H.1 *Nominated Priority Areas for Health Status Improvement*

	Study 1		Study 3	
HRQOL Domain	Baseline	Week 9	Baseline	Week 9
Mobility	6	4	8	8
Walk & Bend	12	10	12	13
Hand Function	6	7	5	7
Arm Function	2	2	2	1
Self-care	2	1	2	1
Household Tasks	2	5	6	6
Social Activity	1	0	0	0
Family Support	1	1	1	1
Arthritis Pain	15	14	15	16
Work	0	0	1	2
Tension	3	6	7	6
Mood	4	2	6	2

Note. Each participant may nominate up to three areas for health status improvement. No order is attributed to priority areas.