EFFECTS OF A COMMUNITY-BASED WATER EXERCISE PROGRAMME ON ELDERLY PATIENTS WITH OSTEOARTHRITIS OF THE KNEE OR HIP

BY

YU-CHEN LIN
MPH

Sheffield Centre of Sports Medicine
(Sheffield Institute of Sports Medicine and Exercise Science)

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SUMMARY OF THESIS

This study examines the effects of a community-based water exercise programme on measures of self-reported health and on physical function in patients with knee/hip osteoarthritis (OA) aged over 60 years old. 106 community-dwelling sedentary elderly, with confirmed knee/hip OA, enrolled in an experimental controlled trial for 12 months. 66 subjects in the treatment group exercised in a local community swimming pool for 60 minutes, twice a week. 40 age-matched control subjects received monthly education material and quarterly telephone calls enquiring about changes in medication or exercise behaviour.

Adherence to exercise averaged 70.0% (± 14.4%) over the twelve months. 77.3% treatment subjects and 89.4% control subjects completed both pre and post-intervention assessments. After one year participants in the exercise group experienced a significant improvement in physical function (3.66 ± 8.75 vs. -0.41 ± 7.24 units; $P < 0.05$) and reduction in the perception of pain (1.20 ± 3.53 vs. 0.15 ± 2.51 units; $P < 0.05$) than the control group, as measured by the Western Ontario and McMaster University Osteoarthritis Index. In addition, the exercise group also performed significantly better in the ascending and descending stairs tests ($P < 0.05$), and had significantly greater improvements in knee range of movement ($P < 0.05$) and hip range of movement ($P < 0.05$) than the control group. There were no significant differences in the two groups for quadriceps muscle strength and psychosocial well-being (Arthritis Impact Measurement Scales 2 questionnaire).

Elderly patients with knee/hip OA had modest improvements in measures of physical disability, pain, general mobility and flexibility, after participating in a community-based water exercise programme. The findings from the present investigation support the feasibility and efficacy of a community-based water exercise programme as a public health initiative for the rehabilitation of OA patients.

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CHAPTER ONE

INTRODUCTION

1.1 Osteoarthritis and Its Consequences

Osteoarthritis (OA) is a joint disorder characterised by specific changes in articular cartilage and subchondral bone, leading to varying degrees of pain, stiffness and limited movement. There is no universal agreement on the definition of OA but pathologically it can be described as " a condition of synovial joints characterised by focal cartilage loss (chondropathy) and evidence of accompanying periarticular bone response " (Doherty et al., 1998).

Osteoarthritis is reported to be the primary cause of locomotor pain, the most significant rheumatological cause of disability and handicap (Doherty et al., 1998) and the main indication of joint replacement surgery (Symmons, 1997; Dieppe, 1999). The vast majority of patients suffering from osteoarthritis are those who are aged 65 years or more (Messier, 1994). It has been estimated that 66% of those aged over 65 in the UK had moderate or severe OA in at least one joint (Symmons, 1997). Women have higher prevalence rates of OA (March & Bachmeier, 1997) and experience greater disability compared with their male counterparts (Spencer et al., 1998).

Although osteoarthritis can affect any synovial joints, the most troublesome symptoms often occur in the weight-bearing joints of the lower extremity (Puett et al., 1994) and result in the greatest disability (Minor, 1994). Patients with knee or hip OA often have difficulties with activities requiring ambulation and transfer. The condition restricts activity more often than cardiovascular disease, cancer or diabetes. With progression of the disease, severe OA in the knee(s) and/or hip(s) can prohibit daily activities such as: walking, ascending and descending stairs, rising from a chair, bending down and picking up clothes, getting in and out of a car/bath and doing household chores. This can become a major problem in terms of maintaining independence in later life (Ettinger & Afable, 1994; Spencer et al., 1998). As support for this position, a longitudinal study examining the arthritis-related disability among the elderly in the USA found that 78% of those with arthritis reported a limitation in physical activity and 36% indicated a limitation in activities of daily living (Yelin, 1992).

The chronic progressive nature of OA also poses a life stress to many suffers. As patients become more dysfunctional, a feeling of frustration and helplessness may develop, thus the normal coping mechanism may fail (Rejeski & Shumaker, 1994). Previous studies have shown that patients with knee and/or hip OA have higher levels of depression and anxiety, and have more tension in their family life than the general population (March & Bachmeier, 1997).

The incurred health, social and psychological costs associated with OA are significant. Hip replacement, for example, cost the NHS an estimated £231 millions in 1992 (Office of Health Economics, 1992), and the number of hip replacements carried out in Britain is predicted to increase by 40% over the next 30 years (Birrell et al., 1999). In addition, the direct and indirect costs of OA have risen in recent years and are estimated to account for up to 1 - 2.5% of the gross national product for the USA, the UK, Canada, France and Australia (March & Bachmeier, 1997). The prevalence of OA is strongly age-related and ageing is associated with decreased physical function. Such a combination has become an increasing economic burden on and an important public health issue in many ageing society (Hamerman, 1995) thus cost-effective interventions need to be identified.

1.2 Etiology and Pathogenesis of Osteoarthritis

The causes of OA are unclear. Various theories have been proposed to explain the possible etiology and pathogenesis of OA. Some of these theories suggest that the trigger is mechanical, others that it is genetic or biochemical. OA is, thus, the result of the response of an affected synovial joint to various etiologic factors. This response is a slow but dynamic process and is influenced by many factors such as the specific cause, age, affected joint sites and individual's reaction to injury. Results from current research have suggested that OA is not a single disease entity but an inherent repair process of synovial joints. In most patients the process is non-progressive, while in some, the joints is consequently unable to recover from the inflicted damage, resulting in perceived symptoms and disability (Doherty et al., 1998).

Osteoarthritis can be classified as either primary (or termed idiopathic) or secondary. In most cases, where there is no apparent cause, the condition is called primary OA. The primary form of OA may be localised in particular joints such as knees or hips, or generalised with three or more joints affected. The secondary form of OA may follow trauma, congenital or developmental disease, calcium deposition disease, other bone and joint disorders, metabolic or endocrine disease or other miscellaneous disorders (Panush & Holtz, 1994).

1.2.1 Structure and function of synovial joint

Synovial joints are those in which the articulating bones are separated by a fluid-containing joint cavity. There are a number of structures that distinguish synovial joints from other joints and are described as follows. The articular surfaces of the bones are covered and cushioned with articular (hyaline) cartilage. A joint cavity is present and filled with synovial fluid. The joint cavity is enclosed by a double-layered articular capsule. The exterior portion of the articular capsule, the fibrous capsule, is continuous with the periostea of the bones. Internally, the fibrous capsule is lined with a smooth synovial membrane that secretes synovial fluid. Synovial joints are strengthened and reinforced by a number of ligaments. Most often, the ligaments are thickened parts of the fibrous capsule (intrinsic). In other cases, they remain distinct and found outside the capsule (extracapsule ligaments) or deep to it (intracapsular ligaments).

Articular cartilage

The articular cartilage is composed mainly of extracelluar matrix with very few cells. The chondrocytes are mature cartilage cells whose main function is to generate and maintain the health of the matrix. The articular cartilage is aneural, avascular and alymphatic. Nutrients from the perichondrium must first diffuse across the synovial membrane into the synovial fluid and then through the dense matrix of the cartilage to reach the chondrocyte (Mankin & Radin, 1996). Because of this inefficient delivery of nutrients, cartilage heals slowly when injured. The extracelluar matrix is composed of 65 to 80% water and its major structure components are type II collagen and a large proteoglycan, now commonly referred to as aggrecan. The collagen fibres in cartilage form a framework much like the steel girders supporting a bridge. The aggrecan is a multi-domain proteoglycan with a core protein and is hydrophilic due to the glycosaminoglycan chains. The two glycosaminoglycan types in aggrecan are chondroitin sulfate and O-linked keratan sulfate (Sandy et al., 1996). The sugars and negative charges of these polymers attract the polar water molecular, which form interacting "water shells" around them. When pressure is applied to cartilage, water is forced away from the negative charged areas. When the pressure is released, water molecular rush back to its original sites, causing the cartilage to spring back forcefully to its original shape. The hydrostatic pressure of the water-logged proteoglycans enable the cartilage to withstand compressive loads and give the cartilage its tremendous resilience (Bland & Cooper, 1984). During the alternative compression-releasing cycle, the flow of liquids also carries nutrients to the cartilage cells. Thus, normal weight-bearing physical activity is essential to maintaining the health of the cartilage.

Synovial membrane and fluid

The synovial membrane is a vascular connective tissue but endowed with a rich plexus of blood vessels in the subsynovial layers. The synovial cell synthesises and secretes hyaluronate, an "additive" to the plasma constituents that form the synovial fluid. Normal synovial fluid is clear, pale yellow and viscous. The viscosity of the synovial fluid is due to the presence of the hyaluronate and proteinaceous materials that are important in lubrication (Mankin & Radin, 1996). Synovial fluid that is found within the articular cartilage provides a slippery weight-bearing film that reduces friction between the cartilage. A mechanism called "weeping lubrication" squeezes synovial fluid into and out of the cartilage during normal movements, lubricating their free surfaces and nourishing their cells. When a joint is compressed, the synovial fluid is forced from the cartilage; when the pressure is released, synovial fluid seeps back into the articular cartilage, ready to be squeezed out again. The synovial fluid also contains phagocytes cells that remove the debris and microbes resulting from wear and tear in the joint (Marieb, 1998).

Ligaments and tendons

Ligaments and tendons are composed of dense regular connective tissue with primary components of collagen and elastin. Tendons attach muscles to bones and transmit muscle tension to the mobile part. Because of the highly organised longitudinal arrangement of their collagen structure, tendons have enormous tensile strength, flexibility, resistance to compression and perfect elasticity (Bland & Cooper, 1984). For most joints, the muscle tendons that cross the joint are the most important stabilising factor. Ligaments are very similar to tendons but contain more elastins such that they are more stretchy. Ligaments bind bone together at joints, help to direct bone movement, and prevent excessive motion.

Subchondral bone

The function of the articular cartilage is that of a load-bearing and contact surface. However, it exists in too thin a layer to be physiologically effective as a shock absorber. In fact, it is the subchondral bone that deforms under physiologic load. Deformation of subchondral bone is important in achieving an effective distribution of stress within a joint (Mankins & Radin, 1996). It has been suggested that when microfractures in subchondral bone heal they do so with formation of a callus, which causes stiffening and loss of compliance leading to more microfractures and more stiffening, which ultimately damages the overlying articular cartilage (Bland & Cooper, 1984).

1.2.2 Pathological development of osteoarthritic joints

The precise sequence of the pathological changes of OA joints and their relative relationship is unclear. Changes in the articular cartilage include reduction in proteoglycan content and state of aggregation, fibrillation, increased water content, collagen crimping, chondrocyte multiplication or migration (cloning) and loss of cartilage. Coincident with, preceding, or following the cartilage changes, new bone formation occurs in subchondral bone and at the joint margins (central and marginal osteophyte), and occasionally beneath adjacent periosteum. The bony proliferation has an defective effect of decreasing compliance and increasing the stiffness of the subchondral bone (Bland & Cooper, 1984). With progress cartilage loss repeated motion may polish the bone, the surface bone additionally may undergo focal pressure necrosis as a result of increased local stress. Subarticular cysts (pseudocysts) predominate where overlying cartilage is thinned or absent. The synovium becomes both hypertrophic and hyperplastic, and the capsule thickens and contracts. In many OA joints, calcium crystal deposition can be found in cartilage however, the relationship between calcium crystal formation and OA is unclear (Doherty et al., 1998). Narrowing of joint space (loss of cartilage), subchondral bone sclerosis, osteophyte formation, and pseudocyst formation are the key radiological signs of OA.

Most experimental work on OA has focused on understanding the normal control of articular cartilage in the hope that appropriate pharmacological treatments can be found to cure OA. However, OA is a disorder of the whole synovial joint, not just the articular cartilage. Some evidence has suggested the disease process of OA is centred more in bone than in cartilage (Dieppe, 1999). The relative importance of cartilage and bone changes in the initiation and progression of OA is still subject to debate (Doherty et al., 1998).

1.2.3 Clinical features

The primary clinical features of OA are symptoms (pain, stiffness), functional impairment, and signs (primarily anatomical change). These clinical features do not always correlate with each other and each affected joint has its own unique clinical consequences (Ettinger & Afable, 1994).

Symptoms

Pain is the most common complaint of OA suffers. It is thought to be caused primarily by the irritation of pain receptors located in and around the affected tissues. Raised intra-osseous pressure, bone healing, abnormal stretching of capsule and ligaments insertions, inflammation and muscle spasm may all contribute to the production of pain (Dieppe, 1989). In addition, psychological stress, depression, anxiety, individual personality and sleep disturbance may magnify the pain experience (Marks, 1992). Correlation between pain and radiographic changes varies according to joint sites, with the best at the hip and the poorest in the hands and spine (Doherty et al., 1998). Patients with OA of the knee experience pain in and around the knee while patients with OA of the hip have pain localised to the groin and anterior or lateral thigh (Hochberg et al., 1995 a & b).

Stiffness is another chief complaint and is often described as 'gelling' of the affected joint after sitting or lying in one position for a long period. The limitation in the range of movement of affected joints and pain on movement may contribute to patients' subjective sense of stiffness (World Health Organisation, 1992). Morning stiffness is the common complaint of patients with knee and/or hip OA. Prolonged morning or inactivity stiffness is uncommon but may occur in patients with other diseases (Doherty et al., 1998). Some patients may complain of a crunching noise as they move. This sound, called crepitus, results as the roughened articular surfaces rub together. Others may experience joint swelling or deformity even with the absence of other symptoms.

Functional impairment

Functional impairment/disability resulting from OA, such as difficulty in walking or stair climbing, occurs as a result of pain, muscle weakness, joint instability and the limitation of range of movement of affected joints (World Health Organisation, 1992). The degree of physical disability is associated with the severity of OA and the severity of pain. The disease, pain and disability pathway is complex and is modified by other factors such as comorbid medical conditions, psychological and social factors (Ettinger & Afable, 1994; Dieppe, 1999). Obesity, cardiopulmonary disease, diabetes mellitus, and depression are important chronic comorbidities in patients with knee or hip OA. Significant correlation between these comorbid medical illnesses and both pain and physical disability have been reported in elderly osteoarthritic patients (Ettinger & Afable, 1994; Hopman-Rock et al., 1996). Psychosocial factors may ameliorate the effects of the joint disorder on physical functioning. For example, a coping mechanism named "learned resourcefulness" (or use of adaptive coping processes) was found to be negatively correlated to a significant level with the measures of functional impairment in 68 older men and women with knee or hip OA (Summers et al., 1988). Furthermore, support from family, friends and other community resources may strongly influence the perception of pain and physical disability in OA patients (Ettinger & Afable, 1994).

Signs

The main physical signs include crepitus, bony enlargement, deformity, instability, a reduced range of movement and stress pain (Doherty et al., 1998). On physical examination, patients with knee OA often have tenderness under palpation (Hochberg et al., 1995b). Varying degrees of synovitis may accompany joint line tenderness. In addition, periarticular sources of pain (point tenderness away from the joint line) are often found at the knee and hip (Doherty et al., 1998).

1.2.4 Diagnosis

The diagnosis of OA is predominately made based on radiological data and clinical examination. Radiological evidence can be used both for the diagnosis and evaluation of OA progress. Of the various radiographic criteria, the most widely employed are those of Kellgren and Lawrence (1957) who grade OA into four categories depending on the presence and degrees of various features (Table 1.1). A rating of grade 2 or more changes (definite osteophytes and possible joint space narrowing) on Kellgren and Lawrence's 0-4 graded radiographic scales has been used as the gold standard for diagnosis of OA in many published reports.

Table 1.1 Kellgren-Lawrence grading system for OA (Doherty et al., 1998).

Grade	Criteria
0	Normal
1	Doubtful narrowing of joint space, possible osteophytes
2	Definite osteophytes, absent or questionable narrowing of joint space
3	Moderate osteophytes, definite narrowing, some sclerosis, possible deformity
4	Large osteophytes, marked narrowing, severe sclerosis, definite deformity

Standard radiographs have remained as the main technique for the diagnosis of OA because they are relatively convenient, inexpensive and reflect the major pathological process (Jacobsson, 1996). However, there are considerable discrepancies between the radiographic findings and joint symptoms. Some cross-sectional studies have shown that with increasing severity of the disease process, there is increasing pain and self-reported disability. Other studies, however, have found no significant association between the radiographic severity and the degree of disability (Ettinger & Afable, 1994). In knee OA, muscle weakness and pain are reported to be more explanatory of functional loss than radiographic findings (Minor, 1994). In addition, little is known about the validity and reproducibility of radiographic diagnosis in OA. Thus, several other methods have been introduced to assist in detecting early pathological changes and progress of OA. These techniques include magnetic resonance imaging (MRI), scintingraphy, ultrasound and various biochemical and immunological measurements of changes in cartilage and bone (World Health Organisation, 1992).

Some people with other forms of joint disorder may have pain referred to the knee or the hip. Thus, it is important to identify whether the symptom is exactly attributable to OA (Hochberg et al., 1995 a, b). The American College of Rheumatology had set standard criteria for classification of symptomatic OA of knee and hip, as displayed in Table 1.2 (Hochberg et al., 1995 a, b). These criteria will distinguish OA from other painful joint conditions, but has been criticised for being insensitive in population studies and being not able to detect asymptomatic cases (Doherty et al., 1998).

Table 1.2 American College of Rheumatology classification criteria for osteoarthritis of the knee and hip (Hochberg et al., 1995 a, b).

Knee OA

Traditional format
Knee pain and radiographic osteophytes
and at least 1 of the following 3 items:
age > 50 years
Morning stiffness ≤ 30 minutes in duration
Crepitus on motion
Classification tree
Knee pain and radiographic osteophytes
or
Knee pain and age ≥ 40 years and morning stiffness ≤ 30 minutes in duration and crepitus on motion

Hip OA

Traditional format
Hip pain and at least 2 of the following 3 items:
Erythrocyte sedimentation rate < 20 mm/hour
Radiographic femoral or acetabular osteophytes
Radiographic joint space narrowing
Classification tree
Hip pain and radiographic femoral or acetabular osteophyes
or
Hip pain and radiographic joint space narrowing and erythrocyte sedimentation rate < 20 mm/hour

1.3 The Epidemiolgy of Osteoarthritis

Estimates of the prevalence rate of OA depend on how it is defined, which specific joint is involved and which age group is studied. Most epidemiological studies rely on radiological evidence for definition and assessment of OA. However, there are known inconsistencies between radiological findings and clinical symptoms. For example, it was reported that about 20 ~ 40% of people over the age of 70 have radiological evidence of knee OA, but only 30% of them have clinical symptoms, with small proportion significantly disabled (World Health Organisation, 1992). In an early study of radiographic OA conducted by Kellgren and Lawrence (1958), the prevalence of knee OA at 55 - 64 years was 40.7% in females and 29.8% in males. The prevalence rate for radiological OA of the hip at 55 years and above was less than for the knee, about 8.4% in males and 3.1% in females (Kellgren & Lawrence 1958). Nevertheless, the associated hip OA symptoms were reported to be more frequent and the disabilities were more severe (World Health Organisation, 1992). The occurrence of OA rarely happens before the age of 30 years, but the prevalence rate increases considerably up to age 65, with at least 50 % of the population having at least one joint affected (Doherty et al., 1998). Sex and race also play important roles in the prevalence figures. After age of 50, women have a higher prevalence rate of OA, report more joint symptoms of knee OA, and have more rapid progression of hip OA than men (Nevitt & Felson, 1996). Although OA is considered as a world-wide joint disorder, some discrepancies exist in the age - specific prevalence by joint site among different races. For instance, it was reported that the prevalence rate of hip OA was significantly lower among black and Oriental populations than among whites (Doherty et al., 1998). All of these important determinants need to be taken into consideration when comparing the prevalence rates of OA.

1.3.1 Risk factors

Risk factors for OA can be intrinsic, such as age, sex and race, or extrinsic, such as trauma and occupation stress. Recent studies indicate that the initiation and progression of OA may be controlled by different factors with different associated risks (Dieppe, 1999). In the following discussion the focus will be on the potential risk factors for the initiation and/or progression of OA at knee joints and hip joints.

Age

The prevalence of OA knee is strongly related to age. Age is a risk factor for the development of hip OA, but it is less strongly associated than it is with knee condition. The declining ability of chondrocytes to respond to a variety of stimuli with ageing could limit the ability of the cells to remodel or even maintain the tissue and may be a possible explanation for this relationship (Buckwalter & Lane, 1997). However, ageing alone does not automatically predispose to OA. Other local factors such as high body weight, meniscal injury, crystal deposition and lesser degrees of exercise and joint use may add to the risk of joint degeneration (Hamerman, 1995).

Sex

The prevalence of knee OA has been reported to be higher in women than men after the age of 45. With increasing age, the relative risk of knee OA for women compared with men increased from 1.57 at 45-54 years to 2.14 at 65-74 years (Davis et al., 1988). Older women also complained of more joint symptoms for the same level of radiological severity of knee OA than older men (Nevitt & Felson, 1996). The sex difference in the prevalence rate of knee OA may be partly explained by the higher prevalence of obesity in older women than older men (Davis et al., 1988). In addition, changes in sex hormone status during a women's life cycle, primarily oestrogen, might influence the risk of OA. In premenopausal women, high oestrogen levels may increase the risk of OA, either directly or through a higher bone mass. Conversely, high levels of oestrogen may stabilise OA by slowing subchondral bone remodelling in postmenopausal and elderly women (Nevitt & Felson, 1996). Hip OA is more prevalent in older men than older women (Kellgren & Lawrence 1958), but older women have more rapid progression of hip OA than men (Nevitt & Felson, 1996). Sex hormones also play important roles in the systematic predisposition to hip OA in older women.

Genetic predisposition

The nature of the genetic influence in OA is speculative and may involve either a structure defect in collagen, alteration in cartilage or bone metabolism, or alternatively a known risk factor for OA such as obesity (Cicuttini & Spector, 1996). Previous studies have shown that mutations in the collagen II were associated with some rare, familial forms of OA (Cicuttini & Spector, 1996). In a recent classic female twin study examining the contribution of genetic factors to OA, Spector et al. (1996 a) reported that the influence of genetic factors on radiographic hand and knee OA ranged from 39-65%.

Deformity/developmental problems

Developmental disorders causing anatomical abnormalities are thought to be particularly related to hip OA. Hip deformity such as congenital dislocation of the hip and Perthes disease (avascular necrosis of part of femoral head) account for 40 - 90% of OA hip in adults (Harris, 1986).

Obesity

Epidemiological studies have consistently demonstrated an association between obesity and knee OA. There is a roughly linear relationship between increasing weight and the increased risk of knee OA, and this association is stronger for women than for men (Davis et al., 1988; Felson et al., 1988). In data from the Framingham Heart Study conducted in the Unites States, women in the heaviest quintile of weight had two times the risk of knee OA 36 years later as women in the lightest quintile. At the same time, men in the highest quintile of weight had the age adjusted relative risk of 1.51 (Felson et al., 1988). Studies which used symptomatic hip OA as a disease definition, in general, showed an association between obesity and hip OA, whereas those studies using radiological evidence as a disease definition reported inconsistent findings (Felson, 1996). The biological mechanism relating obesity to OA is not clear. Some possible explanations are that obesity may directly lead to increased mechanical stress across the joint thus accelerating deterioration on cartilage or increasing subchondral bony stiffness; or be indirectly associated with some metabolic conditions that accelerate cartilage degeneration such as diabetes and hypercholesterolemia (Davis et al., 1988; Felson et al., 1988).

Trauma/injuries

Trauma can occur accidentally as in sports related injuries, or it can result from occupational demands. Direct damage occurs through cartilage damage, while indirect damage may occur if the underlying subchondral bone is traumatised or if joint biomechanics are altered in any way. Soccer players have a high incidence of meniscal tears and cruciate ligament tears. Both meniscal and ligamentous injuries have been reported to be followed by osteoarthritic changes of the knee joints (Kujala et al., 1994). Trauma is less commonly associated with OA of the hip.

Occupational activities

A number of epidemiological studies have shown some associations between strenuous occupational physical loading and the occurrence of OA. Heavy manual labourers such as coal miners (Kellgren & Lawrence, 1952) and dock workers (Partridge & Duthie, 1968) have been shown to have a greater prevalence of knee OA than office workers. Those in other occupations which involve a lot of knee bending such as carpet and floor laying were also found to be at increased risk of knee degeneration and later development of OA (Vingård, 1996). As for the occupational activity and the risk of hip OA, several studies have reported that farmers had higher risk of developing hip OA (Cooper et al., 1996). Whether other occupational activities which require regular heavy lifting, such as construction work and fire-fighting might lead to increased risk of hip OA is less certain.

Sports and recreational activities

Certain sports and recreation activities have been reported to be associated with the increased risk of OA, with variation depending on the particular joints being overstressed (McDermott & Freyne, 1983). Soccer players and weight lifters were reported to have an increased incidence of OA in knee joints (Kujala et al., 1995); elite long distance runners in the knees (Spector et al., 1996 b); cyclists in the patella; crickets in the fingers; baseball pitchers in the shoulder and elbow and American football players in knees, feet and ankles (Panush & Holtz, 1994). The current literature suggests that a low to moderate amount of running does not lead to OA in individuals with biomechanically normal weight-bearing joints (Lane, 1996).

However, those individuals with abnormal weight-bearing joints who continue long-term running may have increased risk for subsequent development of OA (Panush & Holtz, 1994).

1.4 Treatment Modalities for the Management of Osteoarthritis

OA has previously been considered to be a 'wear and tear', 'degenerative' disease that is the inevitable consequence of trauma and ageing (Doherty et al., 1998). Although there is no cure for OA of the knee and/or hip at the moment, intervention programmes which help to reduce pain, maintain and or improve joint mobility, and minimise the functional disability of those affected are beneficial both to the individual and society.

Most people with knee/hip OA only have mild to moderate symptoms. Thus, treatments should be tailored to the severity of disease and symptoms. In individual with minor symptomatic OA, non-pharmacological therapy including patient education, social support, physical and occupational therapy and aerobic exercise programmes have been reported to be effective approaches (Hochberg et al., 1995 a, b; Dieppe 1999). Nonsteroidal anti-inflammatory drugs (NSAIDs) may be used for those patients who are unresponsive to these treatments. However, the efficacy of NSAIDs therapy has been questioned because of its deleterious effects on articular cartilage metabolism and its potential risk of toxicity in elderly OA patients from long-term use (Puett & Griffin, 1994; Hochberg et al., 1995 a). Surgical treatments such as total hip/knee replacement and osteotomy may help to relieve pain and improve physical function in patients with severe symptomatic OA, but they are expensive and also associated with risk (Puett & Griffin, 1994).

1.4.1 Exercise in osteoarthritis management

The role of exercise in the management of OA is controversial. The myth of 'wear and tear' has made some patients think that exercise might further damage their impaired joints. Others avoid it because of experiencing more pain after doing certain types of exercise. In the past, doctors have often advised their patients with OA not to do exercise for fear that exercise will worsen their symptoms or accelerate the disease process. However, the skeletal system needs regular movement to maintain its normal function, and long-term immobility causes more pain and stiffness, muscle atrophy and joint instability. Inactivity also contributes to patients' feelings of weakness and fatigue, as well as their impaired functional capacity. It is now clear that exercise therapy is an important approach to the treatment of OA in all stages of the joint disorder. Exercise forms that put little stress on the affected joints like ROM exercise and non weight-bearing exercise are generally advocated and are the basis of traditional physical therapy programmes. Moreover, the use of exercise has some advantages over other treatment approaches; its effects are generally beneficial to all aspects of health, it is possibly less costly; and for some, more enjoyable. The benefits of exercise to OA patients are discussed as follows.

Maintaining physical integrity of synovial joints and surrounding tissues

The intra-articular diffusion of nutrients and removal of metabolic wastes require a pumping action caused by joint compression and decompression during normal physical motion. Regular rhythmic exercise which alternatively compress and decompress joints provide a good biomechanical environment for the maintenance and repair of articular cartilage (Marks, 1992). On the other hand, immobilisation and non-weight-bearing are reported to have adverse effects on the articular cartilage (Ytterberg et al., 1994). Regular exercise also helps to improve the strength, size, and resilience of surrounding ligaments, muscles and tendons, which then are associated with an increase in stability and support to the joint (Marks, 1992).

Alleviating pains, counteracting some of the pathological changes associated with OA

The available evidence indicates that exercise treatment for OA of the knee or hip have small to moderate beneficial effects on pain relief (Van Baar et al., 1999; Petrella, 2000). How exercise achieves the effects of pain relief is not clear. Thorén et al. (1990) proposed that prolonged rhythmic exercise may increase the release of β-endorphin, a neurotransmitter inhibitory to the pain signal, leading to the experience of pain reduction in OA patients. The beneficial effects of exercises in increasing blood flow and cartilage nutrition, improving muscle strength and joint stability, and relieving anxiety and emotional stresses may all contribute to the relief of pain (Marks, 1992). Stretching exercises that increase the range of motion of affected joints could reduce the development of contracture, and also control joint swelling by facilitating venous and lymphatic return (Gerber, 1990). A study investigating the relationship between regular joint motion and the development of osteophyte has suggested that regular weight-bearing exercise might decrease osteophyte formation at the knee joints (Michel et al., 1992).

Improving physical and psychological function

Therapeutic exercises, including stretching, strengthening and aerobic exercises, have been shown to have beneficial effects in improving physical function of OA patients (Minor et al., 1989; Fisher et al., 1991; Kovar et al., 1992; Ettinger et al., 1997). These improvements are associated with improved joint function (range of motion, stability, etc), muscle strength and aerobic capacity resulting from exercise training. The ability to cope with chronic pain and disability varies greatly between individuals and is modified by multiple factors (Summers et al., 1988). There is some evidence suggesting that strong beliefs in internal or personal pain control (Hall et al., 1996), and high self-efficacy in coping with daily activity and disease (Rejeski and Shumaker, 1994) are associated with better physical and psychological health in arthritis patients. Therapeutic exercises (individual or group) may improve the perception of self-efficacy or self-control in coping with chronic pain and disability (Ettinger et al., 1997), and thus reduce levels of anxiety and depression and enhance quality of life (Minor et al., 1989; O'Reilly et al., 1998).

Weight management

Obesity has been identified as a major risk factor in the development and progression of knee OA in several epidemiological studies (Felson, 1996). In the Framingham Study, Felson et al. (1992) reported that loss of weight was associated with a reduced risk of symptomatic knee OA in middle-aged and elderly women. OA patients who are overweight/obese are often advised to lose weight to reduce the weight load on impaired joint(s) and thus alleviate symptoms of OA. Recently, a combined dietary and exercise intervention has been reported to result in significant weight loss and improvements in perceived symptoms of knee pain, disability, physical performance and gait in 13 obese older adults (aged ≥ 60) with knee OA (Messier et al., 2000). However, it is not clear how much weight loss is necessary to relieve symptoms and prevent further progression of knee OA.

1.4.2 Community-based water exercise programme as a therapeutic modality

Water therapy has been used for the treatment of arthritis since ancient times and is still used by physiotherapists worldwide today. Previous studies have shown that water therapy can help to reduce pain (Minor et al., 1989; Sylvester, 1989), increase muscle strength (Minor et al., 1989; Lord et al., 1993; Suomi & Lindauer, 1997), increase aerobic capacity (Minor et al., 1989), increase joint range of movement (Suomi & Lindauer, 1997), improve psychological health (Sylvester, 1989; Minor et al., 1989) and improve physical function (Sylvester, 1989; Minor et al., 1989) in OA patients. Subjects with OA find exercise in the water less painful than other forms of activities. Exercising in water provides an alternative for people who are unable to participate in land-based exercise programmes because of pain or disabilities (Lord et al., 1993). In addition, the fun, enjoyment and social aspects of water exercise provides motivation for some sedentary elderly to become physically active (Rissel, 1987).

Osteoarthritis is a chronic disease and thus a long period of rehabilitation is usually needed. The National Health Service currently provides six free sessions of hydrotherapy for those OA patients referred by their consultants. Patients access to hydrotherapy treatment, however, is limited partly due to the high costs of providing hydrotherapy in the hospital environment and also because of the limitations in pool size. Water exercise can be given to relatively large number of patients in a community setting with the potential to be a more cost-effective method of treatment. Far more people can access public swimming facilities at a reasonable cost than obtain specialised physiotherapy treatment. Furthermore, it might help patients gain confidence to exercise independently and to take more responsibility for their rehabilitation and health.

CHAPTER TWO

LITERATURE REVIEW

2.1 Exercise/Sport Participation to Osteoarthritis

A wealth of studies have shown that regular exercise is of great benefit to the reduction of cardiovascular disease, the improvement of mood and emotional well-being, the assistance of weight control, and the prevention of physical disability (Pate et al., 1995). Recreational walking, running, swimming, etc., have become increasingly popular in recent years. However, the long-term consequences of recreational exercise or sport activities on the musculoskeletal system are uncertain. Radin et al. (1972) hypothesised that repetitive impulsive loading of certain joints may predispose to OA. The available evidence suggests that the increased joint use and impact loading resulting from participating in exercise or sport activities produces different results on normal joints and abnormal joints (Buckwalter & Lane, 1997). In addition, the type, intensity, frequency and duration of participation in exercise and sport may also influence the pathogenesis of OA.

2.1.1 Normal joints

Studies in laboratory animals have inconsistent findings in relation to exercise and degenerative joint changes. In an earlier study by Radin et al. (1979), eight adult sheep were subjected to four hours' daily slow walking on concrete. By nine months, the sheep limped. These sheep were killed after 12 to 30 months and mild to moderate cartilage fibrillation was found in the sheep's knees and elbows. In a recent randomised controlled study, Newton et al. (1997) examined the effect of long term exercise on canine knees. 11 dogs were randomly assigned to exercise on a treadmill at 3km/hr for 75 minutes, five days per week for 527 weeks while carrying jackets weighing 130% of their body weight. At the same time, 10 control dogs were allowed unrestricted activity in cages for the 550 weeks. After 10 years of study, these dogs were sacrificed and their hind limbs were disarticulated. There were no ligament or meniscal injuries, cartilage erosions, or osteophytes observed in any joint of the studied dogs. In addition, there were no significant differences in the tibial articular cartilage thickness and mechanical properties between the two groups. The authors concluded that a lifetime of regular weight bearing exercise in dogs with normal joints did not increase the probability of joint degeneration (Newton et al., 1997).

As recreational running achieved great popularity in recent years, increasing interest has focused on the effects of running on the development of OA. Panush et al. (1986) compared 17 male runners (mean age 56 years) with 18 age and weight matched controls, no significant differences in radiographic and clinical examinations were found between runners and non-runners. At the eight year follow up, a subgroup of the original cohort was examined. Results showed that both runners and controls had some radiographic changes in joints examined but with similar radiographic scores (Panush et al., 1995). Similar observations were reported by Lane et al. (1986). The researchers examined the association of running with the development of OA in 41 runners and 41 controls, over 50 years old. The initial cross-sectional results showed that there were no differences between groups in terms of joint space narrowing, crepitation, joint stability, or complaints of symptomatic OA. Female runners, but not male runners, had significantly more spur formation and sclerosis in their spine and knee x-ray films than controls. A nine-year follow up of a subgroup of the original cohort found that the presence of radiographic hip OA and the progression of radiographic knee OA were similar for those still running, those who had stopped running, and those who had never run (Lane, 1998). In the same running study, the runners had significantly lower mortality rate and slower development of disability than nonrunners (Fries et al., 1994). It was suggested that normal joint cartilage can adapt to progressive, low impact loading (Kujala et al., 1995), and the increased aerobic capacity and muscle strength resulting from engaging in low impact exercise such as recreational running may help to build up and protect the normal joints from deterioration (Fries et al., 1994).

Other studies have different results for normal joints. Spector et al. (1996 b) evaluated the risk of hip and knee OA in 977 women aged over 50 years old from Chingford, England. They reported that a small subgroup of 22 women who reported long-term vigorous sport activity (≥ four units per week) had a two- to threefold increased risk of radiographic OA (particularly osteophytes). In another cross-sectional study Lane et al. (1999) examined the relationship between regular recreational physical activity in young and middle ages and the risk of developing hip OA in 5,818 women aged 65 years and over. The results showed that the risk of radiographic (osteophytes) and symptomatic (self-reported hip pain) OA of the hip joint increased two-fold with high levels of recreational activities (> four times per week) before the age of 50 years. It is not clear how recreational physical activity may increase the risk of knee/hip OA. One possible explanation is that increased duration of exercise periods (Spector et al., 1996 b) or increased exercise intensity (Newton et al., 1997) may generate excessive forces at the weight bearing joints that stimulate abnormal bone remodelling, resulting in osteophyte formation and stiffening of the subchondral bone, thus accelerating cartilage degeneration and leading to radiographic OA (Lane et al., 1999).

Participating in high intensity, high impact competitive sports has been reported to result in increased risk for the development of OA. Spector et al. (1996 b) who examined the risk of knee and hip OA in 81 ex-elite female British long distance runners and tennis players, found that both runners and tennis players had a two to threefold increased risk of radiological knee or hip OA (osteophytes formation). Kajula et al. (1994) carried out a retrospective study examining the 21 years incidence of hospital care for OA of the weight bearing joints in 2,049 former Finnish male athletes and 1,403 matched controls. Athletes from all types of competitive sports had a slightly increased need for hospital treatments for OA of the hip, knee, and ankle. In particular, mixed sports (soccer, ice hockey, basketball, track and field) and power sports (boxing, wrestling, weight lifting, throwing) athletes might have increased incidence of premature OA, while for endurance athletes the hospital admission for treatment of OA occurred at an old age (Kujala et al., 1994). In a following study, the relationship between lifetime physical loading and radiographic/clinical evidence of knee OA was examined in a subgroup of 117 former top-level male runners, soccer players, weight lifters and shooters (Kujala et al., 1995). The results showed that soccer players had the highest prevalence of tibiofemoral OA (26%) and weight lifters had the highest prevalence of patellofemoral OA (28%). The investigators suggested that the increased risk of knee OA in soccer players may be largely due to previous injuries, and that high body mass as well as high-impact loads of weight training may explain part of the high prevalence of knee OA in weight lifters (Kujala et al., 1995). The mechanism by which sports participation could lead to OA in normal joints may be that the competitive sports which expose normal joints to repetitive high levels of impact and torsional loading increase the possibility of cartilage degeneration, or increase the risk of joint injury that could lead to joint degeneration and the resulting clinical symptoms of OA (Buckwalter & Lane, 1997).

2.1.2 Abnormal joints

A moderate amount of low impact weight-bearing exercise does not appear to increase the risk of developing OA in normal joints. However, individuals who have unstable joints, muscle weakness or imbalance, abnormal joint anatomy or alignment, above-average body weight, or have injured their joints or supporting structures of joints (i.e. tendons, ligaments, menisci), participating in physical activities which involve prolonged weight-bearing movement might have increased their risk of developing knee/hip OA (Panush & Holtz, 1994; Buckwalter & Lane, 1997). McDermott and Freyne (1983) examined the factors that may be associated with the development of knee OA in 20 middle-aged long distance runners suffering from knee pain for at least three months. Six out of the 20 runners were found to have radiological and clinical evidence of OA, and all six runners had either anatomical variances or a history of knee injuries (McDermott & Freyne, 1983). Similar results were reported by Neyret et al. (1994) who studied 77 soccer players 20-30 years after anterior cruciate ligament rupture and partial meniscetomy. In this investigation, 25% of players who had an intact anterior cruciate ligament had knee OA and 71% of players who had a ruptured anterior cruciate ligament had radiographic OA. These studies supported the concept that joint abnormalities or injuries may lead to the development of or accelerate the progression of OA.

A major consideration for both OA patients and health professionals is whether weight-bearing exercise, such as recreational running or walking, will worsen OA symptoms. To date, no prospective studies have been specifically designed to investigate this issue in humans. With the lack of sufficient data, OA patients are often advised to reduce or avoid recreational running if they have OA of the knee secondary to ligamentous instability or meniscal damage, or if they have worsened symptoms after participation (Semble et al., 1990). Patients with mild to moderate symptoms of OA and those who have no mechanical instability may tolerate recreational walking, given that they start slowly and gradually increase the walking time to about 30 minutes per day, three times per week (Semble et al., 1990). Recent studies have shown that participation in a small to moderate amount, low intensity weight-bearing walking programme can improve aerobic fitness without worsening pain or OA-related symptoms of the knee joints (Minor et al., 1989; Kovar et al., Ettinger et al., 1997).

2.2 Exercise Therapy for Patients with Osteoarthritis

Like other medical management of OA, the primary goals of exercise treatment are to reduce pain and minimise disability. Decreased muscle strength, range of motion and aerobic capacity in OA patients, may contribute to their symptoms of pain and physical disability (Van Baar et al., 1999). Thus, the objectives of exercise programmes are to preserve or restore range of movement and flexibility of affected joints, improve muscle strength and endurance, and increase cardiovascular fitness (Ytterberg et al., 1994; Van Baar et al., 1999). To achieve these objectives, three main types of exercise are commonly prescribed to OA patients; stretching/range of motion exercise, muscular strengthening exercise and aerobic exercise.

2.2.1 ROM & stretching exercises

Restriction of range of motion (ROM) is typical in patients with arthritic joints. Decreased range of motion may occur as a result of pain, tightening of tendons and soft tissues around affected joints, poor posture and improper positioning, and muscle weakness (Semble et al., 1990). ROM or stretching exercises are frequently prescribed as the first step of traditional therapeutic exercise, or as a warm-up or cool down activity in the strengthening exercise or aerobic exercise programmes for the rehabilitation of OA patients. Studies have not been specifically designed to examine the sole effects of the ROM/stretching exercises on OA patients. However, in a study examining the effect of ultrasound on mobility in 69 patients with knee OA, Falconer et al. (1992) reported increased ROM and gait velocity, and reduced pain after four weeks of stretching exercises, with or without adjunctive ultrasound.

2.2.2 Strengthening exercises

Patients with OA have been found to have decreased muscle strength and selective type II fibre atrophy in the periarticular muscles of the involved joints (Semble et al., 1990). Isometric knee extension strength in 14 elderly men (age over 60 years old) was found to be 30% to 40% of normal (Fisher et al., 1991). The decreased muscle strength might result from several factors including, inactivity, myositis, corticosteroids, and inhibition of muscle contraction due to joint effusion (Semble et al., 1990). Muscles play an important role in shock absorption and joint stabilisation, thus weakness in the para-articular muscles could result in further progression of OA (Semble et al., 1990). Quadriceps weakness is common in patients with knee OA (Fisher et al., 1991; Minor, 1994; Slemenda et al., 1997). Disuse atrophy secondary to pain in the involved joints was thought to contribute to the quadriceps weakness (Slemenda et al., 1997). However, there is evidence suggesting that quadriceps weakness may precede the development of knee OA and is associated with knee pain and subsequent functional impairment (Slemenda et al., 1997; O'Reilly et al., 1998). Exercises to strengthen the quadriceps were widely prescribed for people with knee OA and significant improvements in muscle strength, pain relief as well as physical function have been reported (Fisher et al., 1991; Schilke et al., 1996; O'Reilly et al., 1999). Most studies reported the use of isometric and /or isotonic exercises (Fisher et al., 1991; O'Reilly et al., 1998), which involve less joint motion. This is probably less likely to aggravate OA symptoms (Semble et al., 1990). Isokinetics exercises have been reported to be more efficient in increasing muscle strength, but require the use of expensive, specialised equipment and may cause further damage of arthritic joints (Ytterberg et al., 1994). Only a few studies examined the usefulness of isokinetic exercises in OA patients (Schilke et al., 1996).

A traditional exercise prescription for OA patients usually begins with stretching/ROM exercises, proceeds to isometric exercises and then progresses to resistance isotonic exercises. Fisher et al. (1991) subjected 15 men, average age 67.6 ± 6.1 years, with grade 2 or 3 knee OA (Kellgren and Lawrence grading system) to a four-month rehabilitation programme. Participants exercised on a specifically designed bench to perform isometric and isotonic leg extension exercises for one hour per session, three times per week. 11 out of 15 subjects finished the entire rehabilitation programme, with two dropouts due to other medical conditions (i.e. surgery, stroke). The average attendance rate of the exercise programme was 80%. After rehabilitation, patients had 23% to 47% increased muscle strength (maximal isometric quadriceps force), and experienced a significant decrease in the time taken to walk 50 feet (12%). A decrease on the Jette Functional Status Index scale of dependency (10%), difficulty (30%), and pain (40%) was also reported. This study provided a quantitative value on the effectiveness of a traditional exercise prescription for OA patients. However, a control group of nonexercisers was not included.

Schilke et al. (1996) investigated the effects of an eight-week isokinetic muscle-strength-training programme on the functional status of patients with knee OA. Twenty adult patients, aged over 50 years old, were randomly assigned to either an exercise group (n = 10) or to a routine care control group (n = 10). The treatment group completed six sets of five maximal contractions three times per week for eight weeks on a Cybex II Dynamometer at 90 degrees per second. None of the subjects in either exercise or control groups dropped out from the study. After eight weeks of intervention, subjects in the treatment group had 28% to 49% increase in their leg extension and leg flexion strength (measured with the same Cybex II Dynamometer), compared to a 22% increase in right leg flexion strength and a 7% increase in left leg extension strength of the control subjects. Patients in the treatment group had significant improvements over the control group in the Osteoarthritis Screening Index (OASI) based pain scale (39% decrease vs. 4% increase), stiffness scale (24% decrease vs. 0% change) and mobility scale (32% decrease vs. 4% decrease). There were significant improvements in the knee ROM in both treatment and control groups for the right knee (9^0 vs. 9.1^0) and the left knee (5.4^0 vs. 6.2^0), with no significant difference between groups. No significant within groups or between groups difference was found in the AIMS based measures and in the 50-foot walk time. The control group also had significant improvement in their leg strength, knee ROM and general mobility which may relate to the "placebo effect" (O'Reilley et al., 1999).

In the previous two studies, the evaluation and exercise programmes were conducted on the same equipment, in well-controlled hospital settings. O'Reilly et al. (1999) assessed the effect of a home-based, quadriceps strengthening exercise programme on knee pain and disability. 191 adults with knee pain, aged 40 to 80 years old, were randomly assigned to either an exercise group (n = 113) or to a no intervention control group (n = 78). The exercise group performed daily graded strengthening exercises including isometric quadriceps contraction in full extension for five seconds, isotonic quadriceps contraction held in mid flexion for five seconds, isotonic hamstring contraction, isotonic quadriceps contraction with resistance band held for five seconds and a dynamic stepping exercise, with up to 20 repetitions on each leg, for six months. Subjects in the exercise group also received home visits at two weeks, six weeks, and three months by the exercise instructors. 96% of treatment subjects and 92% of control subjects completed the pre-post assessment. Over 70% of subjects in the exercise group completed 75% of the home exercise programme. After six months of intervention, participants in the exercise group reported 22.5% pain reduction in the Western Ontario and McMaster University (WOMAC) pain scale, compared to 6.2% in the control group ($P = 0.02$). The exercise group also had more improvements over the control group on self-reported WOMAC scale for physical function (17.4% compared with 0.1% , $P = 0.01$). Isometric quadriceps strength (measured by a modified Tornvall chair) increased 4.7% in the right leg and 4.0% in the left leg of the treatment subjects, compared to 4.9% and 7.1% reductions (right leg, left leg; respectively) in the control group ($P < 0.05$). The exercise group demonstrated improvements in general health status (assessed by Short-Form-36 health status dimensions), anxiety and depression (assessed by Hospital Anxiety and Depression scale), compared with no change or deterioration in the control group ($P > 0.05$). Analysis of the level of adherence indicated that improvements in pain and muscle strength were most marked in the most compliant subjects. This study was a low-cost, minimal supervised home exercise programme. It was not clear whether participants actually did these daily quadriceps strengthening exercises to a recommended level (e.g. 20 repetitions on each leg for each set of exercises).

2.2.3 Aerobic exercises

Patients with OA have been shown to have poorer aerobic fitness than age-matched controls (Fisher & Pendergast, 1994), due to reduced physical activity and muscle function as well as pathological development accompanying the disease. Traditionally, people with OA have been excluded from aerobic conditioning exercises because of specific health problems. Recently, several well-designed randomised controlled trials have shown that patients with OA can safely tolerate low to moderate intensity (60% to 80% of maximum heart rate) of weight-bearing and partial-weight-bearing aerobic exercise without exacerbation of symptoms of OA or dropouts due to joint pain (Minor et al., 1989; Kovar et al., 1992; Ettinger et al., 1997).

Minor et al. (1989) investigated the effects of exercise in a group of 120 patients with RA (n = 40) or OA (n = 80), who were randomly assigned into one of three groups: an exercise programme of aerobic walking, aerobic aquatics or a non-aerobic range of motion exercises (control) for 12 weeks. All patients met three times per week for one hour, and all performed supervised flexibility and isometric strengthening exercises. The two aerobic exercise groups also performed walking or did pool activities (jogging and modified callisthenics), up to 30 minutes per session to increase their heart rates to the 60% to 80% of maximum heart rate achieved on the baseline. After 12 weeks of supervised exercise, seven patients (6%) who participated in either exercise group dropped out for arthritis-related reasons. The average attendance of subjects who completed the 12-week exercise class was 85%. 83% of study participants were available for the 12-week re-assessment. The pool group and walking group increased aerobic capacity (maximum oxygen uptake) to 20% and 19% respectively, compared with no changes in the control group ($P = 0.009$). Both aerobic groups also had significant improvements over the control group in AIMS based physical activity scale ($P = 0.009$), anxiety scale ($P = 0.004$), and depression scale ($P = 0.007$). Both aerobic groups decreased the time taken to walk 50 feet by 12%, compared with a 3% change for control group ($P = 0.009$). There was no significant difference between groups in the AIMS pain scale (12%, 24%, and 13% reduction in the pool, walk, and control groups, respectively; $P = 0.216$), trunk flexibility (21%, 25%, and 33% increase in the pool, walk, and control groups, respectively; $P = 0.216$), or grip strength (16%, 25%, and 6% increase in the pool, walk, and control groups, respectively; $P = 0.377$). Re-testing at one year showed maintenance of improved aerobic capacity in the aerobic exercise groups as well as the ROM control group ($P = 0.68$). This study was not designed to analyse the effects of aerobic exercise on OA alone and was not able to detect the difference (Puett & Griffin, 1994).

Kovar et al. (1992) examined the effects of a supervised fitness walking and patient education programme on functional status and pain in patients with stable, primary knee OA. 102 patients aged over 40 years old were randomly assigned to either an eight-week walking exercise group or to a routine care control group. The treatment group received three sessions per week of supervised, light stretching and strengthening exercises followed by up to 30 minutes of indoor walking, and an education session which included lectures and group discussions. The control group received routine care and weekly telephone follow-ups within the corresponding study period. Forty-seven out of the fifty-two patients (92%) who initially started the exercise programme finished the eight-week walking classes, with only one patient dropping out owing to arthritis-related reasons (i.e. underwent total knee replacement). The average attendance of the exercise programme was 21 ± 6 sessions (ranging from 3 to 28 classes). 92% of treatment subjects and 88% of control subjects completed both pre and post-intervention assessments. Participants in the treatment group had a 70-meter increase (18%) in their 6-minute walking distance compared with a 17-meter decrease in the control group ($P < 0.001$). The treatment group also had more improvements than the control group on the self-reported AIMS subscales for physical activity (39% compared with -2%; $P < 0.001$), arthritis pain (27% compared with 2%; $P = 0.003$), arthritis impact (38% compared with 20%; $P = 0.09$), and use of medication (30% compared with 10%, $P = 0.08$). The generalizability of this study, however, was limited by the fact that the independent effects of the walking exercise could not be separated from other co-interventions such as health education and social support from the group format (Kovar et al., 1992).

In the Fitness and Arthritis in Seniors Trial (FAST), Ettinger et al. (1997) compared the effects of random assignment to either aerobic exercise or resistance exercise with a health education programme on self-reported disability in 439 elderly patients, aged over 60 years old, with documentary knee OA. The two exercise groups both started with three sessions per week, a three-month facility based exercise programme, which was then followed by a 15-month home-based exercise programme. The aerobic session lasted one hour, and consisted of walking on a treadmill at 50% to 70% of baseline heart rate as well as some stretching exercises (warm-up and cool down). The resistance exercise session also lasted one hour and consisted of two sets of repetitions of nine strengthening exercises on major muscle groups as well as some stretching exercises (warm-up and cool down). At the same time, subjects assigned to the education group received a monthly 11/2- hour education session for the first three months, then biweekly telephone contacts in the following 15 months. 81% of subjects in the aerobic group, 84% of subjects in the resistance group and 88% of subjects in the health education group completed the final assessments. The average adherence rate to the aerobic exercise was 68%, and 70% for the resistance exercise. After 18 months of interventions, the aerobic exercise group had a 10% lower score on the self-reported physical disability questionnaire ($P < 0.001$), a 12% lower score on the knee pain questionnaire ($P = 0.001$), performed better on the six-minute walk test ($P < 0.001$), Peak VO_2 test ($P = 0.03$, Treadmill Test), isokinetic knee flexion strength test ($P = 0.004$; Kim-Com 125E) than the health education group. They also took a shorter time to climb and descend stairs ($P = 0.05$), lift and carry 10 pounds ($P < 0.001$) and get in and out of a car ($P < 0.001$) than the control group. The resistance group also had significant improvements over the health education group in terms of an 8% lower score on the physical disability questionnaire ($P = 0.003$), an 8% lower score on the knee pain questionnaire ($P = 0.02$), performed better on the six-minute walk test ($P = 0.02$), took a shorter time to lift and carry 10 pounds ($P = 0.001$) and to get in and out of a car ($P = 0.003$). There were no significant differences in the x-ray score or isokinetic knee extension strength between the exercise groups and the health education group. Analysis of the dose-response data suggested that there was a significant improvement in disability, pain, and 6-minute walk distance scores with increasing adherence to either exercise group (Ettinger et al., 1997). It appeared that there was no significant difference on the effects of pain relief and self-reported disability between aerobic exercise and resistance exercise in this study.

It should be noted that the above aerobic exercise programmes were conducted in the supervised, well-controlled settings and were instructed on appropriate ways to avoid/minimise worsening arthritis symptoms. Researchers in previous studies have indicated that patients with OA might experience pain, physical discomfort and a sense of personal failure when they try to meet the demands of many community-held, non-specialised exercise programmes (Minor et al., 1989). In addition, these exercise programmes used some sort of aerobic activities such as walking and were combined with stretching exercises and/or strengthening exercises to obtain the maximum benefits.

2.3 Water Therapy in the Management of Osteoarthritis

Water has been used as a treatment medium for individuals with musculoskeletal diseases for centuries. The buoyancy effect of water helps to reduce weight-bearing stress on the lower limbs at rest, while the resistive effect of water provides exercise loading on movements, which helps build muscle strength (Ruoti et al., 1994). There are three major types of water therapy which are commonly practised including balneotherapy, hydrotherapy and water exercise. Balneotherapy (or spa-therapy) involves having patients bath in thermal or mineral water. Some researchers suggested that immersion in spa water may induce increased diuresis and natriuresis, and the trace elements from mineral water such as zinc and copper may adjust for the disease activity of RA (Elkayam et al., 1991). Others have postulated that the effectiveness of balneotherapy may contribute to changes in individual biomechanical environments such as joint unloading, relaxation, increased muscle function, and increased general health (Verhagen et al., 1997). Hydrotherapy is the specific use of water as a medium of treatment in physiotherapy and may be defined in terms of two important components: warm water immersion (usually around 34^0 C) and physical exercise. The combined effects of hydrotherapy produced greater therapeutic benefits than either of these components used separately (Hall et al., 1996). Finally, water exercise refers to non-swimming exercises in water for the general promotion of health. While water therapy is a recommended therapeutic approach in the treatment of arthritis, its effectiveness is subject to debate due to a lack of well-designed controlled studies.

2.3.1 Balneotherapy and hydrotherapy

The terms “balneotherapy” and “hydrotherapy” have been used interchangeably for all forms of treatment with water over the last century (Verhagen et al., 1997). The majority of literature on the efficacy of hydrotherapy or balneotherapy focuses on the treatment of RA, with only a few studying OA patients. Elkayam et al. (1991) evaluated the effectiveness of a two-week mud packs and mineral baths at the

Tiberial springs (hot mineral water) on patients with RA (n = 41) and OA (n = 12) of the knee. The 12 OA patients, with radiographic (moderate or severe) and symptomatic evidence (pain for at least six months), were treated with a combination of daily mineral water baths at 38^0 C for 20 minutes and mud packs applied to the knees every other day for 20 minutes at 45^0 C initially. After intervention, significant improvements were found in night pain, pain on passive motion, tenderness on palpation and in the index of severity of OA of the knee. Moreover, these beneficial effects were sustained for a period of six months and cannot be attributed to the effect of rest alone (Elkayam et al., 1991). However, a control group was absent and the independent effect of balneotherapy can not be separated from the co-intervention of mud packs.

In a pilot study conducted by Sylvester (1989), 14 patients with hip OA were randomly assigned to either a hydrotherapy group or a routine physiotherapy (control) group for six weeks. The treatment group received supervised aerobic exercise in a hydrotherapy pool for 30 minutes, for two sessions per week. At the same time, the control group received short wave diathermy and supervised exercise in a physiotherapy gym for 30 minutes, twice per week. The same basic exercise protocol was used for both treatment and control groups. After six weeks of intervention, both groups experienced significant pain relief (47% vs. 38%). Patients who received hydrotherapy treatment had a significant improvement in their functional ability (assessed by Oswestry Low Back Pain Disability Questionnaire) over the control group (44% vs. 13%). The hydrotherapy group also reported a better score on the life satisfaction scale (Philadelphia questionnaire, $P > 0.05$), compared to no change in the control group. With the limitation of small sample sizes, this study was not able to detect significant changes in gait and range of motion.

2.3.2 Water exercise

Water exercise is recommended by many clinicians and physiotherapists as a beneficial leisure time activity for those with arthritic-related conditions. In recent years, water exercise or aqua-aerobics has become a popular mode of exercise and is already used by many people who suffer from muscle and/or joint problems. In a matched controlled study, Lord et al. (1993) reported a 'one hour per week for nine weeks' trial of water exercise had significant effects on the quadriceps strength (12.9% increase) and body sway (17% to 26% decrease in the tests of reaction time) in 15 elderly participants (60% have OA). In a randomised controlled trial, Ruoti et al. (1994) found that a 12 weeks trial of three times weekly water exercise significantly increased aerobic capacity (15% increase in VO_2 max) and muscular endurance (as measured by joint actions of shoulders) in 12 older adults, aged over 50 years old. Bravo et al. (1997) conducted a longitudinal study to examine the effects of a weight-bearing water-based exercise programme on bone, functional fitness and well-being of 86 osteopenic women, aged 50 to 70 years old. Subjects exercised in a pool with waist-high water for 60 minutes, at an intensity of 50% to 60% of the heart rate reserve for three sessions per week, over a 12-month period. After one year of intervention, 58 women maintained the exercise participation with an average attendance of 75% (± 14%). An intention-to-treat analysis revealed that participants had significant improvements in their functional fitness (assessed by AAHPERD battery) and psychological well-being (assessed by Dupuy's General Well-being Schedule), despite a lack of effect on the femoral neck bone mineral density.

Most of the water exercise intervention studies employed conditioning protocols designed by individual researchers which make them difficult to compare. In 1983, The Arthritis Foundation in America set up standardised aquatic exercise programmes for people with arthritis. The Arthritis Foundation Aquatic Programme (AFAP) is a non-clinical programme (one that will not replace a prescribed regimen of therapeutic exercises) consisting of 68 aquatic exercises designed to improve range of motion, strength and mobility for arthritic patients. Aquatic exercise classes are designed to be conducted in warm water (83-89^0 F) in 45 to 60 minutes periods, two to three times per week in sessions varying in length from six to 12 weeks. In 1995, over 84,000 participants joined these AFAP programmes in their local indoor pools (Suomi & Lindauer, 1997).

A self-assessment survey by 201 participants revealed that the AFAP water exercise had great benefits on participants' joint flexibility and activity of daily living (Tork & Douglas, 1989). Suomi & Lindauer (1997) reported that 17 women (8 OA, 9 RA) who were randomly assigned to participate in the AFAP classes three times a week for six weeks had significant improvements in their hip abduction isometric strength and range of motion (13% to 17%) over the control group. However, the investigators did not assess the effects of pain relief, an important indicator of the effectiveness of exercise interventions in the management of OA (Van Baar et al., 1999). In a state-wide aquatic exercise study, Patrick et al. (2001) randomised 249 OA patients, aged 55 to 75 years old, to either a twice per week for 20 weeks AFAP aquatic exercise group (n = 125) or a control group which was asked to wait for five months (n = 124). After 20 weeks of intervention, 21 participants (16.8%) in the treatment group and 2 (3%) in the control group dropped out from the study. 36 (29%) exercise participants attended classes a minimum of twice per week for at least 16 weeks. Participants in the treatment group had significant improvements in the disability scores of the Health Assessment Questionnaire (HAQ) and physical domain scores of the Perceived Quality of Life Scale over the control group ($P < 0.05$). The HAQ-based pain score for the treatment group improved between baseline and post-test, while the main score remained the same for the control group. Treatment group scores were also lower (improved) for the Centre for Epidemiological Studies Depression (CES-D) Scale in the post-test, while the mean scores for the control group increased. However, the between-group differences in perceived pain and level of depression were not significant ($P > 0.05$). This study provided supporting evidence of the benefits of the AFAP's community-based aquatic exercises on physical function and functional ability of OA patients, despite a lack of significant effects on pain relief and mental health.

2.3.3 Comparisons of land-based exercise with water-based exercise

The debate has been not whether exercise benefits persons with osteoarthritis but rather what mode of exercise is the most appropriate. Researchers have suggested that water-based exercise may be a preferred mode of exercise for the elderly, as it reduces weight-bearing stresses on the skeletal joints and thus allows free movement without pain (Ruoti et al., 1994). So far there is no single study specifically designed to compare the relative effectiveness of water-based exercise versus land-based exercise in the management of OA. Research into the actual physical effects of the water exercise, in comparison with land-based exercise, has inconsistent findings. In Minor's physical conditioning exercise studies (Minor et al., 1989), there was no significant difference between the aerobic walking group (land-based) and the aerobic aquatics group (water-based) in any of the outcome measurements after 12 weeks of intervention. In another study comparing the effectiveness of a generalised water-based exercise programme with a land-based exercise programme, 41 healthy, sedentary women, aged 70 ± 3.2 years, were randomly assigned to either of the exercise groups (Taunton et al., 1996). The two groups exercised for 45 minutes per session, three sessions per week for 12 weeks. After 12 weeks of intervention, both groups had significant improvements in their aerobic capacity (VO_2 peak), with no significant between and within group difference in the trunk flexibility, muscle strength or body composition. On the other hand, in an evaluation of a hydrotherapy programme for RA patients, Hall et al. (1996) randomly assigned 139 subjects to hydrotherapy (n = 35), seated immersion (n = 35), land exercise (n = 34), or progressive relaxation (n = 35). All participants attended 30-minute sessions twice per week for four weeks. After four weeks of intervention, patients in the hydrotherapy had the greatest reduction in joint stiffness (Ritchie index) and improvement in knee ROM (6.6^0 in women) over other modes of exercise.

It should be noted, however, that the type of exercise that can be done in water versus on land may modify the effect the programme will have on function capacity (Taunton et al., 1996). It may be that the objective treatment outcome is similar in both land-based and water-based exercise, while water-based exercise would appear to be more socially therapeutic (Sylvester, 1989) which makes it a more appropriate starting point for older OA patients to improve their physical fitness (Rissel, 1987).

2.4 Aims of Study

Previous works on water therapy for patients with OA have focused on the effectiveness of hospital-based hydrotherapy treatment. However, hydrotherapy in the hospital environment is an expensive service with limited access to patients in need. A well-designed, supervised water exercise programme held in a community pool might be an alternative treatment, with fewer facility and staff requirements, and might be more widely accessible to the local community. To date, only a few studies have examined the effectiveness of community-based water exercise for OA patients and none of them has been carried out in the UK. In addition, among the few available studies on the effects of water therapy for OA patients, all are of less than six months duration. It is not clear whether OA patients, especially the elderly, will adhere to long term water therapy. The benefits of exercise are only maintained and subsequently retained if performed regularly, however dropout rates were high in previous community-based exercise programmes and average attendance rate declined as time went by (Ettinger et al., 1997).

The purpose of the present study is to 1) test the effects of a community-based water exercise programme on self-reported health and on physical function in elderly patients with OA of the knee(s) and/or hip(s); 2) test patients' adherence to a community-based water exercise programme over a 12-month period.

The hypotheses to be examined in the study are :
Research Hypothesis (H1): There are significant differences in perceived health status and in physical function in subjects who participate in water-based exercise when compared with age-matched subjects not participating in any exercise.

Null Hypothesis (H0): There are no significant differences in perceived health status and in physical function in subjects who participate in water-based exercise when compared with age-matched subjects not participating in any exercise.

2.5 Outcome Measurements

2.5.1 Health status questionnaires

One increasingly-used approach in the arthritic and geriatric literature is to ask patients to self-report their own perceptions of their health. Self-reported health status questionnaires are relatively low cost. They can be administered by mail or phone, thus reducing the investment of professional time and increasing their comparability with various study designs. In addition, questionnaire-based health status parameters, such as pain, mood and depression assess the important disease-related outcomes that most concern OA patients (Meenan et al., 1992).

Pain and physical disability

Pain and physical disability are the major complaints of OA patients. Their measurements play an important role in evaluating the efficacy of therapeutic interventions. Most of the exercise trials for OA patients employed existing well-validated, disease-specific health status questionnaires to assess the effects of pain relief and functional improvement following exercise intervention (Minor et al., 1989; Kovar et al., 1992; Schilke et al., 1996; O'Reilly et al., 1999; Patrick et al., 2001). These include the use of the WOMAC OA Index (Bellamy et al., 1988), the use of the AIMS scales (Meenan et al., 1980) or the revised AIMS 2 scales (Meenan et al., 1992), and the use of the HAQ (Fries et al., 1982). Many patients with OA also have comorbidities. Thus a more holistic view of health related quality of life in this patient group through the use of generic measures (not-disease specific) such as SF-36 (Hayes et al., 1995) may have a greater ability to assess side-effects or complications of treatments which are unrelated to the disease itself (Brazier et al., 1999). Research has provided some evidence of validity for the use of SF-36 in OA patients (Brazier et al., 1999) and the responsiveness to health changes in relation to exercise treatments (O'Reilly et al., 1999).

Psychosocial functioning

As a chronic disorder, OA frequently produces significant stress and a limitation of social life. However, most available disease-specific instruments for evaluating the health status of individuals with arthritis focus exclusively on physical aspects of health. The AIMS (or the revised AIMS 2) is one of the few instruments which also investigates the impact of arthritis on the psychological and social aspects of health, and has been widely used in OA exercise trials (Minor et al., 1989; Schilke et al., 1996). On the other hand, generic health status measure such as SF-36, and the mental health oriented measures of the CES-D scale and the Hospital Anxiety and Depression scale have been increasingly used in OA exercise studies to assess the psychological and/or social benefits of exercise interventions (Ettinger et al., 1997; O'Reilly et al., 1999; Patrick et al., 2001).

2.5.2 Physical function tests

Patients with knee/hip OA have been found to have reduced general mobility, range of motion of affected joints and muscle strength, when compared to normal age-matched control subjects (Fisher & Pendergast, 1994, Ettinger & Afable, 1994). Measures of these physical capacities are important determinants of physical impairment/disability in patients with lower limb OA. Although measures of self-reported physical function have been increasingly used in recent years, objective clinical measures have provided valuable information about the functional status of OA patients (Rejeski et al., 1995). This especially applies to the physical parameters such as range of motion of joints and muscle strength which are hard to estimate accurately from questionnaires.

Physical performance tests

A wealth of assessment techniques for evaluating the physical capacity of patients with OA have been introduced over the past two decades. One of which has been the use of performance-based measures. Daily physical activities such as walking, stair climbing and chair sitting, which typically cause difficulty for patients with lower limb OA (Rejeski et al., 1995), have been chosen as indicators to evaluate the therapeutic use of different therapies. These tests do not require special technology or equipment and are relatively easy to administer in most clinical or community settings. Fisher and his colleagues have used walking (50 ft), stair climbing and chair sitting tests to demonstrate the efficacy of a physical therapy programme in patients with knee OA (Fisher et al., 1993). Rejeski and associates (1995) designed a test battery which includes six-minute walking, ascending and descending five stairs, lifting and carrying ten pounds and getting in and out of a car to evaluate physical activity restriction in patients with knee OA. This battery showed an acceptable test-retest reliability ($r \geq 0.85$), evidence supported construct and convergent validly (Rejeski et al., 1995), and sensitivity to changes in individual physical function in response to exercise programmes (Ettinger et al., 1997).

Flexibility tests

The limitation of ROM is an important clinical criteria for classification of knee and hip OA. (Altman et al., 1986; 1991). In addition, many OA related studies have reported the changes of ROM as important outcomes of treatment (McGrory et al., 1996; Templeton et al., 1996; Van Baar et al., 1998). The ROM of knee and hip joints is often measured by the goniometers. With appropriate training and standardised position, high level of reliability can be achieved (Bellamy & Buchnan, 1993). Good to excellent intertester reliability ($r = 0.98$; ICC = 0.99) and high validity ($r = 0.97 - 0.98$; ICC = 0.98 - 0.99; in comparison with roentgenograms) has been reported with the use of the goniometer in the knee joint (Gogia et al., 1987).

Muscular strength tests

Traditionally, muscular strength is measured by manual muscle testing which has been criticised on account of its qualitative nature and its lack of sensitivity in detecting early muscle weakness (Fisher et al., 1990). The hand-held dynometers provide more subjective assessment of strength but are limited by the strength of the tester who holds the instrument and stabilises the subject (Bohannon, 1995). Recently, quantitative measurements of muscle strength such as methods of isokinetic (Rejeski et al., 1995; Schilke et al., 1996; Slemenda et al., 1997) and isometric (Fisher et al., 1991; O'Reilly et al., 1998) techniques have been recommended and widely used in the measurement of quadriceps strength. The application of isokinetic testing to elderly patients and patients with joint disease has been questioned (Fisher et al., 1990). It is argued that the use of isometric techniques would be more appropriate to the elderly patients with OA, given that they are less likely to aggravate OA symptoms (Semble et al., 1990), and are less expensive (Fisher et al., 1990).

2.6 Determinants of Exercise Behaviour

Individuals with chronic conditions such as OA of the knee/hip are found to be less physically fit than their age- and sex -matched norms (Neuberger et al., 1994) and are less likely to engage in regular exercise (Gecht et al., 1996). However, regular exercise activity is especially important for patients with OA in terms of preserving flexibility of affected joints, strengthening the surrounding muscles, tendons and ligaments and increasing cardiovascular conditioning; thus decreasing accompanying pain and physical disability. Determinants of exercise behaviour have been studied across a wide range of groups, but research into the exercise behaviour of the elderly with OA as a distinct sub-group has been limited. The available research has selected variables derived from the Health Belief Model (Rosenstock, 1974) and/or the Social Cognitive Theory (Bandura, 1986) to explain and/or predict exercise behaviour in patients with arthritis. This included the examining of the cognitive-perceptual variables such as self-efficacy for exercise, perceived benefits of and barriers to exercise, and perceived seriousness of disease. Modifying factors such as the socialpsychological variables (e.g. social support, level of depression) and behavioural variables (e.g. previous participation in exercise) were also examined. Inconsistent results about the determinants of exercise behaviour have been suggested. Some researchers reported that the determinants of exercise behaviour in patients with arthritis are similar to those of the general population (Minor & Brown, 1993). Others, however, claimed that people with arthritis may have different attitudes from others and the factors which usually deter people from taking exercise may not be important for them (Gecht et al., 1996).

Perceived benefits of exercise and perceived ability in carrying out exercise activity have been shown to be important determinants of exercise participation in the general older population (Shephard, 1994; Dishman, 1994). In a study examining the relationship between exercise beliefs and participation in exercise activities among 81 patients with RA or OA, Gecht and colleagues (1996) found that people with arthritis did not participate in exercise programmes due to low self-efficacy and the absence of positive beliefs about the benefits of exercise. Jensen & Lorish (1994) surveyed 791 RA outpatients and reported that those who complied with the prescribed exercise therapy mentioned positive benefits of doing exercise while those who did not comply stressed perceived negative consequences. Moreover, Neuberger and colleagues (1994) studied the determinants of exercise in 100 outpatients with arthritis and confirmed that strong perceived benefits of exercise were a significant predictor of continued exercise participation.

Perceived barriers to exercise such as time, convenience of setting, transportation and family obligations were found to be the strongest predictor of exercise adherence in patients with coronary artery disease (Robertson & Keller, 1994). However, only a weak association between perceived barriers and exercise participation was reported in Neuberger's study (Neuberger et al., 1994), and no relationship was found in Gecht's study (Gecht et al., 1996) in which lack of time and lack of interest were tested as perceived barriers to exercise.

Pain and physical disability accompanying the disease are likely deterrents to the adoption of exercise activity in patients with OA (Ytterberg et al., 1995). OA of the knee/hip involves a process of continued readjustment to fluctuating symptomotology of the disease. Thus, perceived ability to perform prescribed exercise may be influenced by disease-related pain and physical disability (Barlow, 1998). In addition, severity of the disease appears to play a more important role in determining exercise adoption in patients with arthritis than perceived benefits of exercise or self-efficacy for exercise (Gecht et al., 1996). However, once people involved in a positive exercise experience, the intensity or frequency of pain and physical difficulty, might have less influence in the continuance of exercise behaviour. In the FAST study, pain and physical disability were found to have weak relationship with the exercise maintenance across different assessment period (Rejeski et al., 1997).

Psychosocial factors such as depression and lack of social support have been shown to be deterrents to exercise adherence in patients with arthritis. Minor and Brown (1993) reported that mood disturbance and social support were important determinants of exercise maintenance among 120 adults with RA or OA. However, in the FAST study, depression (assessed by CES-D short form) and social support (assessed by the Sherbourne and Stewart MOS Social Support Survey) measures did not predict adherence to the exercise programmes with any consistency across the three, nine, and 16 months of the study periods (Rejeski et al., 1997).

Another important determinant of exercise maintenance is past exercise participation. In the FAST trial, Rejeski et al. (1997) found that the prior exercise behaviour was the strongest predictor of exercise adherence. The same finding was supported by Minor and Brown's study (1993), in which that the previous participation in a supervised exercise class was the most explanatory factor for continued exercise behaviour. It appeared that having the experience of exercise and consequently feeling good motivated people to maintain the exercise habit (Rissel, 1987).

CHAPTER THREE

MATERIALS AND METHODS

3.1 Study Design

In recent years, the randomised controlled trial (RCT) has been accepted as the gold standard for evaluating the efficacy of therapeutic interventions. Randomisation is regarded as the best method to reduce selection bias and thus increase the comparability of two groups of patients at outbreak (Torgerson & Roberts, 1999). However, the RCT designs are not without potential biases, one of which exists when patients have strong preferences for one treatment (Brewin & Bradley, 1989; Black, 1996; Torgerson et al., 1996; Cooper et al., 1997). Some eligible participants may refuse to be randomised and this may lead to a poor recruitment rate (Black, 1996) or a non-representative sample which could restrict the generalisability of the results (Torgerson et al., 1996; Cooper et al., 1997). On the other hand, some patients may agree to be randomised in the hope that they can receive the preferred treatment. While those who receive their preferred treatment are likely to be satisfied, those who do not, may feel disappointed. If those disappointed with the assigned treatment tend to comply poorly or drop out early, this will also result in selection bias (Cooper et al., 1997) and influence the outcome of the treatment (Torgerson & Sibbald, 1998). Brewin and Bradley (1989) argued that the simple RCT may not be appropriate for evaluating "participative" interventions in situation where it is impossible to blind the patients to the nature of the treatment, and when the patients prefer one of the treatments.

The use of the partial randomisation patient preference (PRPP) design has been proposed to cope with the problem of patient preferences (Brewin & Bradley, 1989). However, introduction of the preference arm may require extra size and cost of trials (Torgerson & Sibbald, 1998). In addition, a recent preference trial using the PRPP design to evaluate the alternative management for heavy menstrual bleeding showed that there was no difference in the outcome measurements between those who received their preferred treatment and those who were randomised (Cooper et al., 1997). Therefore, non-RCT studies which allow patients to receive their preferred treatment may provide as important information as the RCT studies (Black, 1996).

A quasi-experimental design consisting of an exercise group and a matched-control group was used in this study. The purpose of this design was to evaluate how the treatment works in every day practice (where patients receive their preferred treatment) while still controlling as many of the threats to internal validity as possible (Thomas & Nelson, 1996). This study was approved by the South Yorkshire Research Committee (Appendix A). All study participants gave their written informed consent.

3.2 Subject and Sample Size

The eligibility criteria for participation in the study were (1) minimum age of 60 years; (2) current symptoms of pain and joint stiffness in knee(s) and/or hip(s); (3) X-ray evidence or written confirmation of knee and/or hip OA from the GP, rheumatologist or orthopaedic surgeon; (4) no knee or hip surgery in the past three months; (5) no knee or hip surgery arrangement during the study period and (6) access to a telephone. Subjects were excluded if they (1) were currently receiving hydrotherapy, physiotherapy or currently regularly participating in an exercise class (defined as any exercise more than once a week for twenty minutes or longer); or (2) had a medical condition that precluded water-based exercise (acute intermittent illness, unstable cardiac failure, myocardial infarction in the last three months, urinary infection or incontinence, open wounds or skin disease, advanced chronic obstructive pulmonary disease, paralysis or dementia).

In order to estimate the sample size, data from a previous pilot study (Davey, 1996, unpublished study) was used. The mean pre-to post difference and standard deviation for the WOMAC physical function scale (4.3 ± 6.1 units), together with alpha set at 0.05 (two-sided) and power at 0.8, showed that 32 patients would be required in both the exercise and control groups. To compensate for an expected 20% attrition rate (Bravo et al., 1997), the goal was to recruit at least 40 patients for each group.

3.2.1 Recruitment

Patients in both the treatment and control groups were recruited from the local community in the Sheffield area through articles in the same local newspaper (Appendix B). Every respondent was sent a letter explaining the purpose of the study (Appendix C). A questionnaire booklet and a pre-paid reply envelope were enclosed together with the letter, patient information sheet (Appendix D) and consent form (Appendix E). The questionnaire booklet contained a screening questionnaire (Appendix F) and two self-completed health status questionnaires (Appendix G); namely the Western Ontario and McMaster University Osteoarthritis Index (WOMAC, Bellamy et al., 1988) and the Arthritis Impact Measurement Scale 2 (AIMS 2, Meenan et al., 1992).

Initial screening for eligibility was carried out through the screening questionnaire and the WOMAC questionnaire (indicating symptoms of pain and stiffness). People who met the inclusion criteria were invited by letter (Appendix H) to have a face to face interview with the researcher at which their eligibility was determined and, if eligible, the baseline data were collected. Potential participants for the control group were further matched to the treatment group by age and self-reported physical disability (assessed by the physical disability dimension of the WOMAC questionnaire). Those volunteers (exercise and control groups) who were not eligible to participate in the study were informed by letter and thanked for their interest (Appendix I). All study participants were asked to continue their medication (where possible) and treatment prescribed by their physician through the one-year study period.

3.3 Instruments and Data Collection Procedures

Changes in the perception of physical disability, pain, joint range of motion, muscle strength, physical mobility, and psycho-social status are important outcomes of any therapeutic intervention for patients with knee and/hip OA (Finch et al., 1998). In the present investigation, the WOMAC questionnaire was used as the primary outcome measurement to assess perceived functional status, pain and stiffness. A physical function test battery, including three physical performance measures (i.e. eight-foot walk, chair rise, ascending and descending stairs), a flexibility measure (range of motion of knee and hip joints) and a strength measure (quadriceps muscle), was used to evaluate changes in participants' gait, mobility, joint flexibility and muscle strength before and after the study. Selected questions from AIMS 2 were included to evaluate the social and psychological aspects of health of OA patients.

Data were collected immediately prior to the trial and immediately after the 12-month study period (Appendix J). The physical function tests and demographic and clinical data were conducted and collected in the Sheffield Institute of Sports Medicine Laboratory in the Physiotherapy Department of the Royal Hallamshire Hospital. The information was entered into a specifically designed data collection sheet (Appendix K). The WOMAC and AIMS 2 questionnaires were post to each participant two weeks before physical function tests.

In order to monitor the progressive changes of physical function in response to the exercise treatment, patients in the exercise group were invited by letter (Appendix L) to have interim physical function tests at sixth months. The acceptability of the water exercise programme was evaluated by a semi-structured questionnaire - the 'participant opinion survey' (Appendix M). To get a realistic picture about how participants complied with the exercise class without close monitoring or other external reinforcements, the questionnaire was sent to each participant in the exercise group six months after the completion of the one year exercise trial.

All data were collected by the same project investigator under the supervision of the project advisor who was blind to the group allocations.

3.3.1 Anthropometric measures

The screening questionnaire contains questions about demographic information, history of OA, recent use of medication, current exercise or leisure time physical activities, other major health problems (i.e. comorbidities[1]). Information on injury, sickness, hospitalisation and concerns of general health were obtained by self-report from the participants during face to face interview. Weight and height were measured by a standard protocol. Body mass index (BMI) was calculated as weight in kilograms divided by the square of height in meters.

3.3.2 WOMAC OA Index

The WOMAC OA index is a tri-dimensional, disease-specific health status measure which consists of 24 questions and probes clinically-important, patient-relevant symptoms in the areas of pain, stiffness and physical function in patients with OA of the hip and/or knee (Bellamy et al., 1988). It is available in both Likert (WOMAC LK 3.0) and Visual Analogue (WOMAC VA 3.0) scaled formats. The LK scaled version allows patients to make their responses on a five-point adjectival scale (0 = none, 1 = mild, 2 = moderate, 3 = severe, 4= extreme) and was used in this study. The pain dimension contains five questions regarding the severity of pain during various activities. Subjects were asked to grade the level of pain in their affected knee and/or hip joints. The stiffness dimension has two questions asking about the degree of stiffness when first waking up in the morning and after periods of rest. Finally, the physical dimension has 17 questions assessing difficulty in performing various physical activities. For each WOMAC dimension, a subscale score was calculated by

[1] A concomitant but unrelated pathologic or disease process which indicates the coexistence of two or more disease processes.

summation of the assigned values scored on component items. Each dimension was kept separate and the analysis was conducted on a subscale-by-subscale basis.

The internal consistency of the WOMAC index has been reported as 0.88 to 0.93 for the pain scale; as 0.73 to 0.96 for the stiffness scale; and as 0.88 to 0.94 for physical function scale (Bellamy et al., 1988). Content validity has been shown to have a strong correlation between pain and physical function (r = 0.74) in subjects with OA of the hip or knee; however, the dimension of stiffness was reported to have weak correlation with pain (r = 0.21) and physical function (r = 0.22, Bellamy et al., 1988).

3.3.3 Physical function test battery

Test-retest reliability of the battery

To assess the test-retest reliability of the battery of physical function tests, 10 volunteers from the water exercise research project (Nine women, One man) with knee or hip OA, aged 61 to 75 years (mean age 68) were asked to come to the Sports Medicine Laboratory on two non-consecutive days (e.g. Monday and Wednesday) to complete the physical function tests. This pilot work provided the data on instrument reliability. In addition, it also helped the researcher to become familiar with each instrument and measurement, and determine the approximate times require to complete the tests and make the necessary adjustments for the testing procedure.

Physical performance measure

Physical performance measures for this study were adapted from previously used measures to assess lower-limb physiological function. Two of the measures were the same as those used by Guralnik et al. (1994), namely the eight foot walk and chair rise. In the eight foot walk test, a distance of eight feet, with an additional two feet at either end, were set to test natural walking speed. Each patient was asked to "walk to the other end of the pre-set distance at natural walking speed, just as walking down the street to go shopping ". Each participant was timed for two repeated walks and the faster of the two times was recorded. For the chair rise, a plastic moulded straight-backed chair 44.5 cm high and 38 cm deep was placed next to a wall. Each participant was instructed to fold their arms across their chest and to stand up from the chair one time. If successful, participants were asked to stand up and sit down five times as fast as possible. Patients were timed from the initial sitting position to the final standing position.

The timed stair climb involved ascending and descending a set of four standard type steps. The stairs, which have wooden handrails, have a rise of 15.2 cm, a run of 26.5 cm by 76 cm wide and an 76.5 × 76 cm platform at the top, and are commonly available in physical therapy departments. Each participant was asked to go up to the top of the steps with/without using the handrails and, without resting, to turn around and climb back down. Subjects were asked to do the task as fast as possible and repeated it twice. The task was timed as the time to go up and the time to come down the four stairs separately. The faster of the two times was used for analysis.

Flexibility test

Flexibility of the knee and hip joints was assessed using a standard goniometer. The reliability of goniometric measurements can be influenced by body mass. In obese people, hip flexion is limited by the opposition of the thigh and abdomen (Roach et al., 1991), however, the joint pathology itself may account more for the substantial loss of joint ROM. OA of the hip commonly results in decreased range of motion of the hip, particularly in internal rotation and extension (Minor, 1994). In our pilot test, some of the subjects had difficulty in performing these two movements because of pain and/or powerlessness. Thus, knee flexion and hip flexion were selected and recorded for their relative convenience and ease to administer (both are measured in the supine position).

The great trochanter, lateral femoral condyle, head of fibula, and lateral malleolus were used as landmarks for the measurement of knee flexion. The central pivot of an international standard goniometer dial was placed over the midpoint of the lateral joint margin, with the stationary arm of the goniometer aligned with the great trochanter. The moving arm of the goniometer was then aligned with the lateral malleolus. The neutral position was taken as zero. Measurements were taken with the patient's knee actively extended, after which the knee was actively fully flexed (Bellamy, 1993). To measure hip flexion, the patient was asked to lie in a supine position, and the stationary arm of the international standard goniometer was placed along a line through the crest of the illium, femur and great trochanter. The moving arm was placed in line with the femur, pointing toward the lateral condyle of the femur. Measurements were taken with the patient's hip actively flexed toward the chest (Bates & Hanson, 1996). Data from the flexibility test were recorded for right and left legs separately, giving two independent scores. Each knee flexion and each hip flexion task were measured twice and the higher angle was recorded.

Strength test

Maximal isometric quadriceps force was measured by placing a strap around the subject's leg. The strap was connected to a fixed point behind a standard physiotherapy couch so that when the subject (seated at the edge of the couch with hip and knee flexed to 90 degrees) was instructed to extend the leg, a strain gauge was extended (Fisher & Pendergast, 1994), giving a measure of maximal quadriceps strength on a myometer (MIE, Medical Research Ltd, UK). Subjects were encouraged to breathe out on exertion (thus avoiding a Valsalva manoeuvre). Each maximal isometric contraction was performed for two to three seconds. Three trials with each leg and a rest period of one minute between each contraction was given. Torque was calculated by multiplying the force by the level arm (distance between the lateral joint line and the point of application) for each subject.

Categories of performance were created for each set of physical function tests for analysis, including patients who could not perform a test. Those who could not complete any one of the physical function tests were assigned a score of five in that particular performance measure. For the performance measures of the eight foot walk, time to ascend and time to descend four stairs and the repeat chair rise, those completing the test were assigned a score of one to four; corresponding to the quartiles of time needed to complete the test, with the fastest times scored as one. For the tests of joint flexibility and quadriceps strength, those completing the test were assigned a score of one to four, according to the quartiles of degrees extended and force pushed, with the highest degree and force scored as one. This ended a lower score indicating a better physical function. Totalling the category scores for the five tests created a summary physical function scale (SPF).

3.3.4 AIMS 2 Questionnaire

The AIMS 2 is a revised and expanded version of the original AIMS questionnaire. It contains 12 subscales: mobility level, walking and bending, hand and finger function, arm function, self-care tasks, household tasks, social activity, support from family and friends, arthritis pain, work, level of tension, and mood. The AIMS 2 questionnaire is designed to evaluate the physical, social and psychological well-being in the outcome measurement of rheumatic clinical trials (Meenan et al., 1992). To avoid overlap with items in the WOMAC questionnaire and to assess the social and mental aspects of the outcome of exercise treatment in patients with OA, only sub-scales of social activity, support from family and friends, level of tension and mood are incorporated from the AIMS 2 questionnaire. The social activity scale consists of five questions and has a raw score ranging from 5 to 25. The scale of support from family and friends is a new added scale which contains four questions and the recorded raw scores range from 4 to 20. The scale of level of tension (anxiety) includes five questions and has a raw score ranging from 5 to 25. Finally, the mood (depression) scale consists of five questions with a raw score ranging from 5 to 25. After recording the raw scores, the scores of each question within the scale were summed up to produce a total score for each particular scale. A normalisation transformation was then used so that all the scale scores could be expressed in the range of 0 to 10, with 0 indicating the best health status and 10 indicating the poorest (Meenan et al., 1992).

Meenan and his colleagues (1992) used the AIMS 2 scale to test 109 subjects with OA and found that the internal consistency coefficients for the sub-scale of social activity, support from family and friends, level of tension and mood were : 0.78, 0.85, 0.96, 0.80, respectively. Test-retest reliability (45 patients with RA or OA) for the four subscales were : 0.91, 0.92, 0.87, 0.80, respectively. In addition, the validity analysis of the four selected AIMS 2 scales showed that there were significant associations ($P < 0.001$) between patients who indicated problems in an area and a poorer AIMS 2 scale score in that area (Meenan et al., 1992).

3.3.5 Participant Opinion Survey

The survey was constructed using semi-structured questions allowing in-depth exploration of attitudes and/or opinions towards the water exercise programme. Structured questions were formed by analysing the results from interviews with some participants in the exercise group. The purpose of this research was to investigate participants' reasons for not continuing the exercise programme; to evaluate participants' general attitudes towards the exercise activity, the exercise instructors and the swimming pool; to assess participants' perceived physical and psychological benefits from participation, and to evaluate overall opinions about the community-based water exercise programme as a public health initiative.

3.4 Treatment of the Groups

3.4.1 The exercise group

The intention of the study was to set up a specifically designed water exercise programme for elderly patients with knee/hip OA, which would improve the physical and psychosocial health of the participants, without increasing potential injury and risk. The water exercise programme consisted of one hour sessions and conducted twice a week for 12 months. Participants were advised to attend at least once a week. The exercises were undertaken in a community swimming pool where the air temperature was about 29.5 ^{0}C, the water temperature was about 29 ^{0}C and the water depth was kept at 135-145 cm. Major aims of the programme were to; build up water confidence, increase flexibility and joint range of motion (especially of the lower limbs), increase muscle strength and muscle endurance, improve postural balance and co-ordination skills, improve general aerobic fitness and to maximise enjoyment. The exercise facilitators were qualified water exercise instructors who used a standard exercise warm-up, conditioning and cool-down period modified for the target group and the medium of water. Each exercise class was built into an exercise-to-music format. Participants of different physical disabilities were advised to work at their own pace and to avoid certain exercise that made them feel uncomfortable. To help participants maintain or gradually improve their functional status, a progressive five-phase plan was used (Koury, 1996; Bates & Hanson, 1996). Each phase included the five components; warm-up, stretching, muscular strength, aerobic endurance, and free to do their own exercise period (Table 3.1, details in Appendix N). Unlike many other exercise interventions that are implemented solely for the purpose of research, this water exercise programme will continue to exist after the evaluation is complete, thus enabling participants to receive the benefits of water exercise, both physical and social, after the research has ended.

Five phase plan

Phase I - The initial conditioning phase

In this phase, the major goal was to help participants become familiar with the water environment. Gentle ROM, strengthening exercises and mild stretching were introduced to help participants build their water confidence and improve joint range of motion.

Phase II - The early exercise phase

In this phase, specific stretching exercises were included. Moderate muscle strength and endurance exercises were also introduced, using the resistance of the water only.

Phase III - The intermediate exercise phase

By phase three, participants began full-joint range movement (where possible). In addition, moderate progressive resistance exercise was introduced using water-floats to improve strength and the speed of movement was increased.

Phase IV - The advanced exercise phase

The objective of this phase was to maximise muscular strength, endurance, balance and co-ordination to prepare patients for more complex movement patterns in the water.

Phase V - The maintenance phase

The major goal of this phase was to help subjects maintain or improve the functional level achieved. The aquatic skills and fitness concepts that were taught in phase I through phase IV were reinforced and subjects were encouraged to continue water exercise and develop their own exercise plans independently.

Attendance at the exercise sessions was recorded each week by the project investigator (Appendix O). The average monthly adherence rate across the 12-month period was calculated as the number of exercise sessions completed divided by the total number of exercise sessions provided for that month. If a participant became ill or missed the exercise class for two weeks in a month, the researcher would telephone the participants to check the reasons for absence. A letter of encouragement appropriate to different reasons of absence was sent to those who were absent from the exercise sessions for more than one month (Appendix P). For those who dropped out from the exercise programme because of factors out of the researcher's control (water temperature, pool facility, etc.), specific advise about available exercise programme was given to encourage them to maintain the exercise habits if possible (Appendix Q). These subjects were monitored to the end of the study (Appendix R).

At the end of six months and twelve months, participants who continued to participate in the water exercise were given certificates (Appendix S) and those who had the best attendance records were given small gifts as a reward. Studies on adherence to exercise programmes have suggested that strategies of relapse prevention and incentives such as telephone follow-up, positive verbal reinforcement and rewards may improve the adherence rate (Robison & Rogers, 1994). Finally, after the finish of the one year exercise project, participants were sent letters to thank for their participating and were encouraged to continue exercising (Appendix T).

Table 3.1 OA Water Exercise Plan

Phase	I	II	III	IV
Duration	**4 weeks**	**4 to 8 weeks**	**8 to 10 weeks**	**10 to 12 weeks**
Warm-Up	**Perform each exercise for 2 minutes.** Forward Walking Backward Walking Side Stepping	**Perform each exercise for 2 minutes.** Forward Walking Backward Walking Sideways walking	**Perform each exercise for 2 minutes.** Marching Backward Walking Sideways walking	**Perform each exercise for 2 minutes.** Marching Backward Walking Sideways walking Leg Exchange Gentle jogging
Stretch	**Perform five repetitions of each exercise, holding for 10 seconds.** Passive Quadriceps Stretch Hamstring Stretch Calf Stretch	**Perform five repetitions of each exercise, holding for 20 seconds.** Quadriceps Stretch Hip Flexor Stretch Adduction Stretch Calf Stretch	**Perform five repetitions of each exercise, holding for 30 seconds.** Quadriceps Stretch Hip Flexor Stretch Calf Stretch	**Perform five repetitions of each exercise, holding for 30 seconds.** Quadriceps Stretch Hip Flexor Stretch Calf Stretch
Strengthen	**Perform one set of 8 to 12 repetitions.** Hip Flexion Hip Extension Hip Abduction and Adduction Single-Leg Bicycle Hamstring Pull-Back	**Perform two set of 8 to 12 repetitions.** Hip Flexion Hip Extension Hip Abduction and Adduction Hip Circumduction Thigh Extension Hamstring Pull-Back Heel Raises Side- to- Side Weight Shifting Single-Leg Bicycle	**Perform three set of 8 to 12 repetitions.** Hip Flexion Hip Extension Hip Abduction and Adduction Hip Circumduction Heel Raises Lunges Straight Leg Kick Stroke Stand Single-Leg Bicycle	**Perform four set of 8 to 12 repetitions.** Hip Flexion Hip Extension Hip Abduction and Adduction Hip Circumduction Heel Raises Lunges Straight Leg Kick Single-Leg Bicycle Shallow knee bends/squats
Conditioning	Aerobic exercise	Aerobic exercise	Aerobic exercise	Aerobic exercise
Cool-down	Exercise on own	Exercise on own	Exercise on own	Exercise on own

3.4.2 The control group

Control subjects were not participating in any organised exercise or recreational programme that would affect the outcome variables examined in the study. In order to increase their continued participation, pre-printed education materials from the Arthritis Rheumatism Council (UK) and the Arthritis Foundation (USA) were sent by post to each participant monthly (Appendix U). Previous studies have shown that the provision of structured health education is an effective intervention in managing pain and disability from OA (Superio-Cabusley et al., 1997; Ettinger et al., 1997). Seasonal greeting cards (Easter, Christmas, etc.) and reminder letters (Appendix V) were sent to all participants and quarterly telephone calls (Appendix W) were made to maintain contact with the participants. At the end of the one year project, participants were asked about their opinions on the health education programme. The following questions were used to guide data collection during face to face interviews: 1) How helpful were these health education materials in the self-management of OA? 2) What type(s) of physical activities/exercise did participants do and how frequently did they do it (them) in a typical week over the past year ? 3) What kind of information related to OA would participants like to receive? Finally, participants were given feedback about the changes of their physical function after one year, and were provided with information about the exercise activities available in their local areas.

3.5 Statistical Analysis

Statistical analysis was performed using SPSS for Windows 6.0 (SPSS Inc.). Mean and standard deviation were calculated for all demographic and measurement variables. 95% confidence interval was also provided for reference. An alpha level of 0.05 was used to test for statistical significant difference and all tests were two-tailed. The reliability of each of the physical function tests was established by calculating the intraclass correlation coefficients (ICC) and the standard error of measurement (SEM). The ICC was calculated from repeated measures of analysis of variance (ANOVA: Thomas & Nelson, 1996). The standard error of measurement (SEM) was calculated as follows: SD $\times \sqrt{1-ICC}$ (Atkinson & Nevill, 1998). Internal consistency of the summary performance scale was assessed using Cronbach's alpha. Correlations were examined using Spearman's Rank correlation coefficient to evaluate relationships between tests in the physical function test battery as well as the relationships between the physical function test battery and the health status questionnaires (WOMAC, AIMS 2). Correlations were judged to be high if there were between 0.71 and 0.90; moderate if they were between 0.41 and 0.70; and low if they were between 0.21 and 0.40 (Finch et al., 1998).

Every attempt was made to follow-up all patients in the study. Outcome analyses were done, initially on intention-to-treat analysis (where baseline data has been input for any missing follow-up data). Baseline difference between the treatment and control groups were compared using either the independent t-test or the Mann-Whitney test for continuous variables as appropriate. The chi-square test was used for categorical data. The within group difference were investigated using paired t-test for parametric data and Wilcoxon matched-pairs test for non-parametric data. Two way repeated-measures ANOVA was used to analyse the significance of before-after changes for parametric data; the Kruskal-Wallis test was used to analyse the difference in exercise and control group regarding the changes from baseline for non-parametric data. Effect sizes were used to give an estimate of the clinical significance. The effect size was calculated as the changes in the exercise group minus the changes in the control group, divided by the pooled pre-treatment standard deviation (Kazis et al., 1989). The judgement criterion was using Cohen's (1977) definition that an effect size of 0.20 as small, one of 0.50 as moderate, and > 0.80 as large.

To assess the on-going changes of physical function in response to the exercise intervention , a subgroup analysis was done using only the outcomes of exercise group participants who completed all the physical function tests at baseline, six months and one year. One way repeated-measures ANOVA was used to analyse the significance of changes for parametric data, and the Friedman test was used to analyse the difference for non-parametric data.

Finally, to determine if there was a dose response between exercise adherence and effects on outcome measures, the change in scores between pre-and-post study health status questionnaires and physical function tests were compared with percentages of exercise adherence. Exercise adherence was divided into three groups based on the average adherence rate over the study period. A group × time (3 × 2) repeated-measures ANOVA was used to analyse the significance of before-after changes between different adherence groups.

CHAPTER FOUR

RESULTS

4.1 Subject Recruitment

Over a two-month recruitment period (January to February, 1998), 125 patients inquired about the water exercise study, of whom 94 returned their screening questionnaires. At the same time, 74 older patients responded to the advertisement asking for volunteers to participate in a study of OA, of whom 60 returned their screening questionnaires. Figure 4.1 shows the recruitment of participants in the exercise group and the control group.

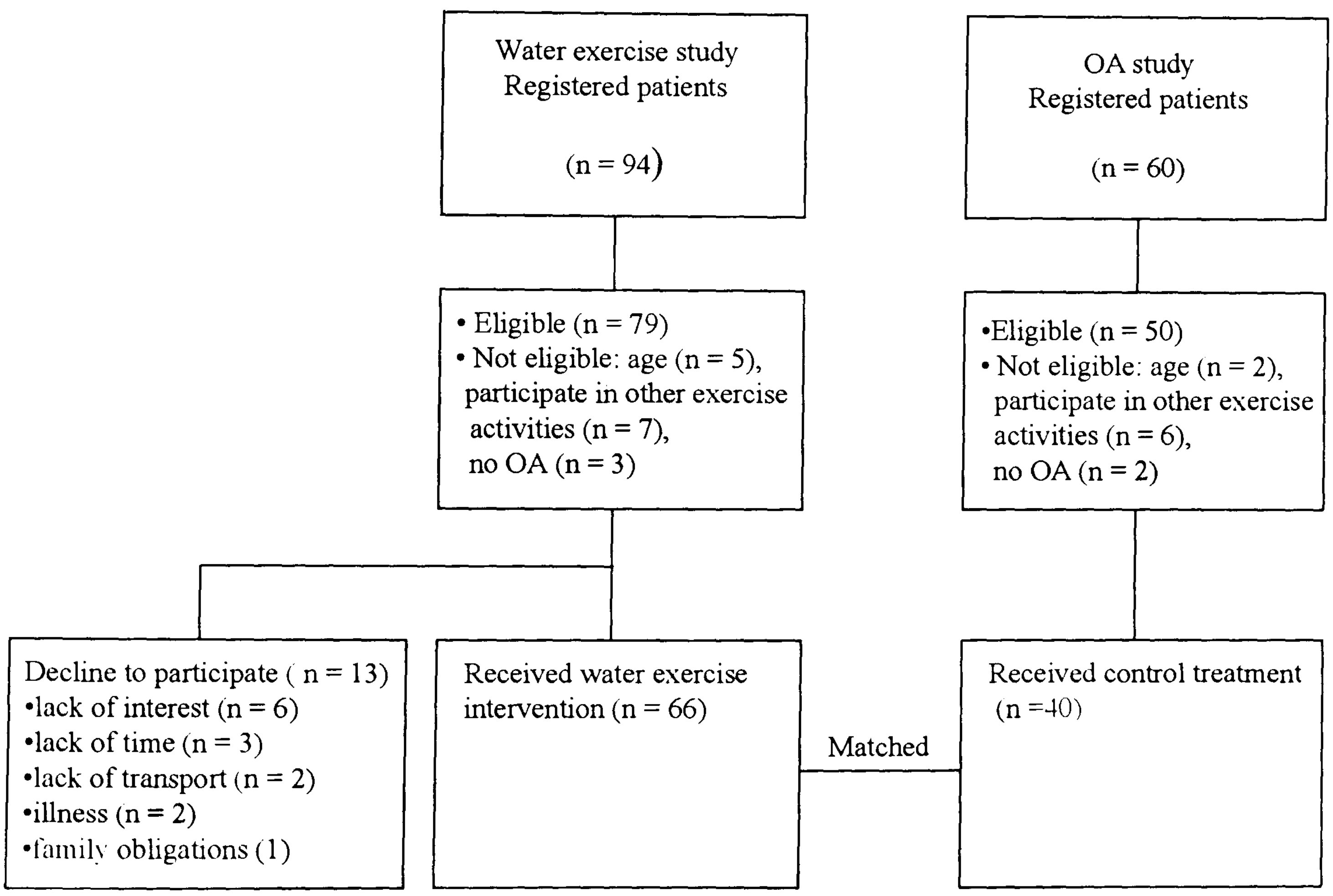

Figure 4.1. Participant allocation in the exercise group and control group at baseline.

Of the 94 in the water exercise arm, 79 (13 male, 66 female) were deemed eligible and 66 (6 male, 60 female) of them agreed to participate. The uptake rate is approximately 84% (male: 46%, female: 91%). The six female non-participants declined for various reasons (Figure 4.1) while six out of seven male non-participants declined because the exercise was conducted in a mixed-group (men and women together). Using the same selection criteria and procedure, 50 older patients were deemed eligible for the control group and were matched according to age and self-reported physical disability (WOMAC OA Index) with the water exercise group. Finally, 40 matched patients agreed to participate in a study of OA, without knowing they were in a "control" group.

4.2 Baseline Measures

4.2.1 Demographic variables and anthropometric measures

The mean (± SD) age for all 106 subjects was 69.2 years (± 5.9). The mean disease duration of OA (i.e., symptomatology) was 12.2 years (S.D. = 11.0). The study subjects had an average body mass index (BMI) of 28.9 kg/m^2 (± 5.3). Baseline demographic and clinical characteristics, including age, sex, disease duration of OA, BMI and medication use for the exercise group and the control group are detailed in Table 4.1. There were no significant differences between the exercise and the control groups in any of the demographic and clinical variables.

Table 4.1 Demographic and clinical characteristics of the participants in the exercise and control groups

Characteristics	Exercise N = 66	Control N = 40	95% CI of the difference	*P* value
Age, mean ± SD, yr.	68.8 ± 6.37	69.9 ± 5.16	-3.31, 1.18	0.35
Sex, Male/Female, No (%),	6 (9.1)/ 60 (90.9)	7 (17.5)/33 (82.5)	NA	0.20
Disease duration, mean± SD, yr.	11.3 ± 10.89	13.6 ± 11.18	-6.83 , 2.16	0.12
BMI, mean± SD	29.0 ± 5.03	28.8 ± 5.74	-1.94 , 2.30	0.72
Medication use, No (%)				
NSAIDs†	23 (35)	20 (50)	NA	0.12
CNS drugs‡	43 (65)	23 (58)	NA	0.43

NB. Statistic comparisons of continuous means were performed using independent t-test or Mann-Whitney test as appropriate; comparison of categorical variables was performed using Chi-Square test.

† NSAIDs: Nonsteroidal antiinflammatory drugs (e.g. naproxen, piroxicam, ibuprofen, surgam, diclofenac sodium, voltarol retard, arthrotec).

‡ CNS drugs: Central nervous system drugs (e.g. paracetamol, co-codamol, co-dydramol, co-proxamol, tramadol, dihydocodeine, codeine).

For comparison of the proportion of obesity in the two groups, threshold cut-offs of 28.6 and 30.0 were used to define obesity in women and men respectively (Royal College of Physicians, 1983). The distribution of the values for BMI classification is shown in Table 4.2.

Table 4.2 Women and men in exercise and control groups classified into weight categories based on BMI

Women

Weight classification	BMI value	Exercise N	Control N
Underweight	18.6 or less	0	0
Acceptable	18.7 - 23.8	9	6
Mildly overweight	23.9 - 28.5	21	13
Obese	28.6 or more	30	14
Total		60	33

Men

Weight classification	BMI value	Exercise N	Control N
Underweight	20.0 or less	0	0
Acceptable	20.1 - 25.0	1	2
Mildly overweight	25.1 - 29.9	1	3
Obese	30.0 or more	4	2
Total		6	7

The knee was selected as the affected OA joint by 53 patients (50%), compared with the hip in 17 patients (16%) and 36 patients (34%) were equally affected with both knee and hip. As shown in Figure 4.2, approximately 48.5% of people in the exercise group and 52.5% in the control group had knee(s) OA only ($P = 0.69$). The proportion of people with hip(s) OA only was less in the control group (10%) than in the exercise group (19.7%, $P = 0.28$). The percentage of people with OA in both knee and hip is 31.8% in the exercise group and 37.5% in the control group ($P = 0.55$). The detailed distribution of affected joint sites (unilateral or bilateral) is presented in Table 4.3. Participants with knee and/or hip OA were treated as a single group for all statistical analysis.

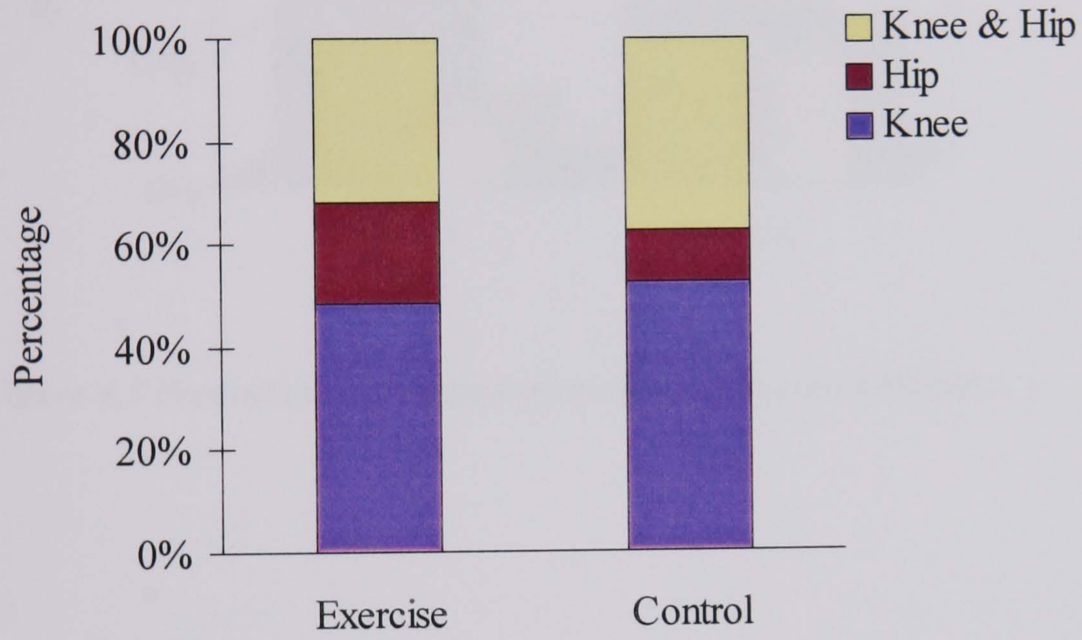

Figure 4.2 Frequency distribution of affected joint side.

Table 4.3 The distribution of affected joint sites (unilateral or bilateral)

	Exercise group			Control group		
	Knee	Hip	Knee&Hip	Knee	Hip	Knee&Hip
Unilateral	11	10	5	6	2	1
Bilateral	21	3	16	15	2	14
Total	32	13	21	21	4	15

As seen in Figure 4.3, hypertension is the most common comorbidity in both the exercise (38%) and the control groups (28%). No significant difference was found between groups in the prevalence of major comorbid conditions ($P = 0.53$).

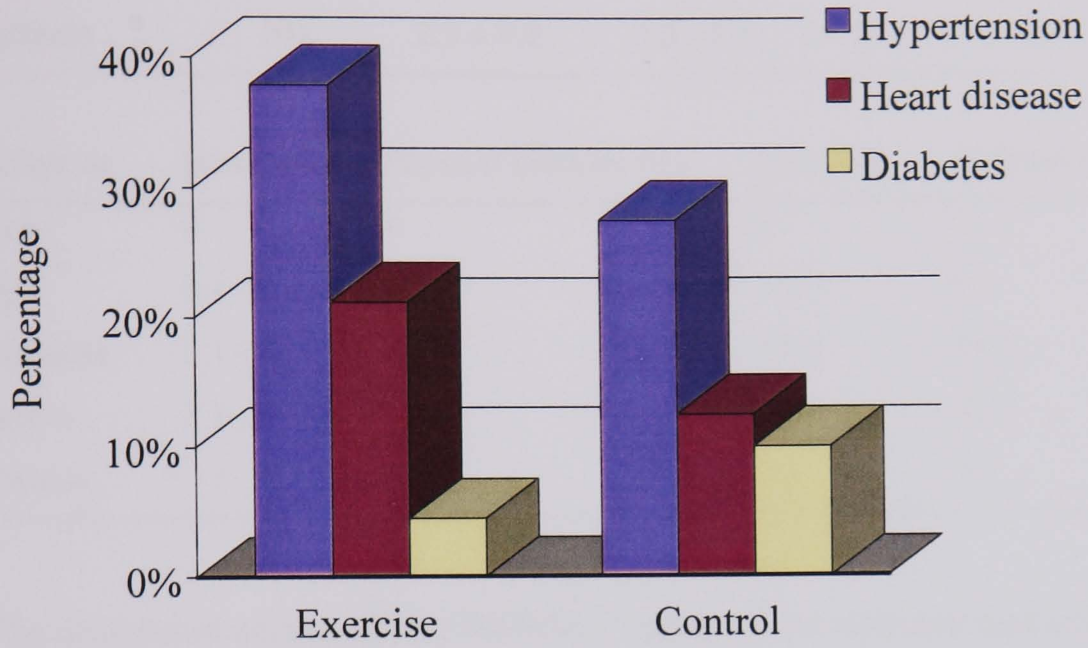

Figure 4.3 Frequency distribution of most common comorbidities.

4.2.2 WOMAC OA Index

The score distribution of each dimension for all subjects, using the WOMAC OA index is shown in Table 4.4. Scores were generated for the three dimensions of physical function, pain and stiffness by summing the coded responses and then diving by the number of items to provide a score range of 0 - 4 (Brazier et al., 1999). More than 80 % of the participants in this study perceived their difficulty in performing daily physical activities and symptoms of pain and stiffness as 'moderate' to 'severe'.

Table 4.4 Score distributions of the WOMAC OA Index

Dimensions	Number	Mean ± SD	95% CI	Possible score range	Actual score range
Physical function	103	2.0 ± 0.6	1.9 - 2.2	0 - 4	0.6 - 3.4
Pain	104	2.0 ± 0.7	1.8 - 2.1	0 - 4	0.4 - 3.2
Stiffness	104	2.3 ± 0.8	2.2 - 2.5	0 - 4	0.5 - 4

Symptom	Score value	Physical function (%)	Pain (%)	Stiffness (%)
None	0	0	0	0
Mild	0.1 - 1	5.8	12.5	9.6
Moderate	1.1 - 2	38.8	37.5	34.6
Severe	2.1 - 3	51.5	49.0	47.1
Extreme	3.1- 4	3.9	1.0	8.7

The dimension scores of the WOMAC index of the exercise and control groups at baseline are shown in Table 4.5. The 'responsiveness' or 'sensitivity' of an instrument can be assessed in terms of the proportion of patients at the floor (i.e. the worst score) or the ceiling (the best score) of each scale. "If many patients score at either extreme of a scale, the instrument will have limited ability to register deterioration or improvement, respectively" (Brazier et al., 1999). Subjects in neither the exercise nor the control group demonstrate substantial (> 10% of responses) 'floor' or 'ceiling' effects. Statistical analysis indicates that there were no significant differences between the exercise group and the control group in any of the WOMAC dimensions at baseline.

Table 4.5 Comparison of the exercise and control group WOMAC questionnaire results at baseline

WOMAC	Exercise (N = 66)			Control (N = 40)			95% CI of the difference	*P* value
	Mean ± SD	% floor	% ceiling	Mean ± SD	% floor	% ceiling		
Physical function	2.02 ± 0.57	0	0	2.06 ± 0.62	0	0	-0.27 - 0.21	0.78
Pain	2.00 ± 0.61	0	0	1.91 ± 0.75	0	0	-0.17 - 0.36	0.48
Stiffness	2.37 ± 0.81	7.6	0	2.23 ± 0.78	2.5	0	-0.18 - 0.46	0.58

For the perception of difficulty in physical activity, Figure 4.4 shows that by far the largest proportion of patients choose the 'severe' category in both exercise group (50%) and control group (52.6%). There is very little variation in the proportion of 'mild' and 'moderate' perceptions and no statistical significance in score distribution is indicated ($P > 0.05$).

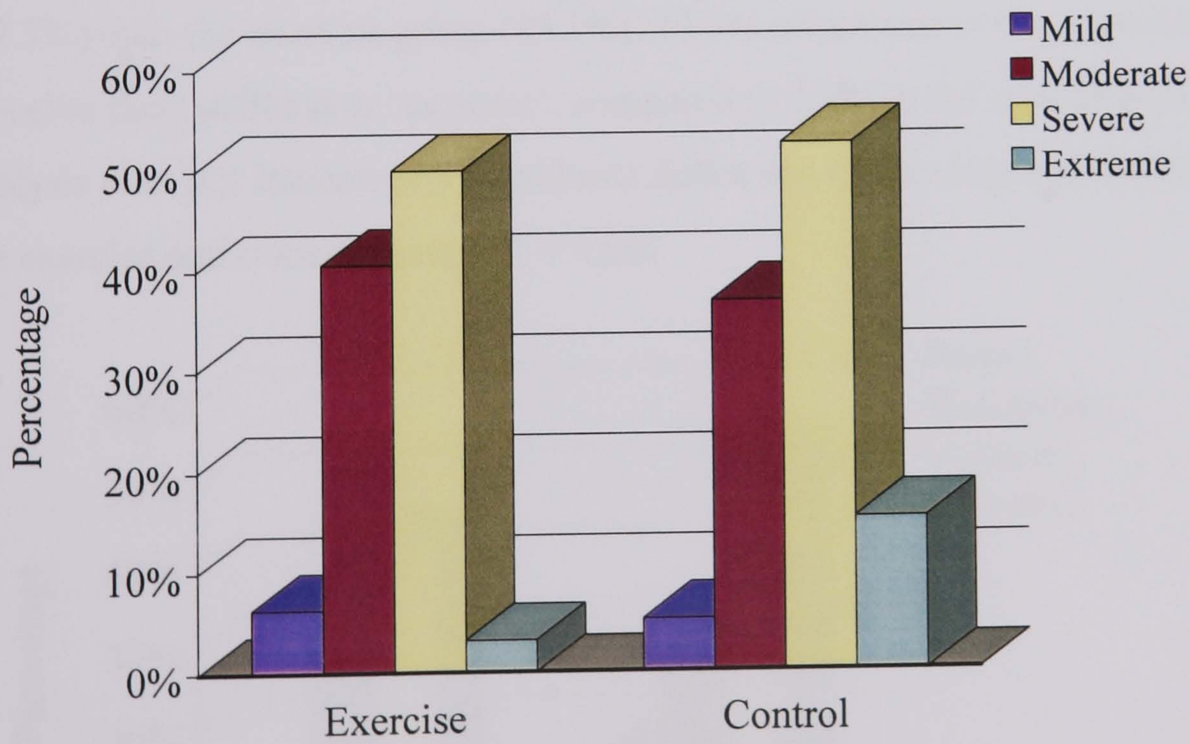

Figure 4.4 Frequency distribution of physical function perception of the WOMAC OA Index.

As can be seen in Figure 4.5, the largest proportion of patients in the exercise group (49.2%) and the control group (47.4%) perceive their degree of pain as 'severe'. The variations of the score distribution between these two groups does not reach any statistical significance ($P > 0.05$).

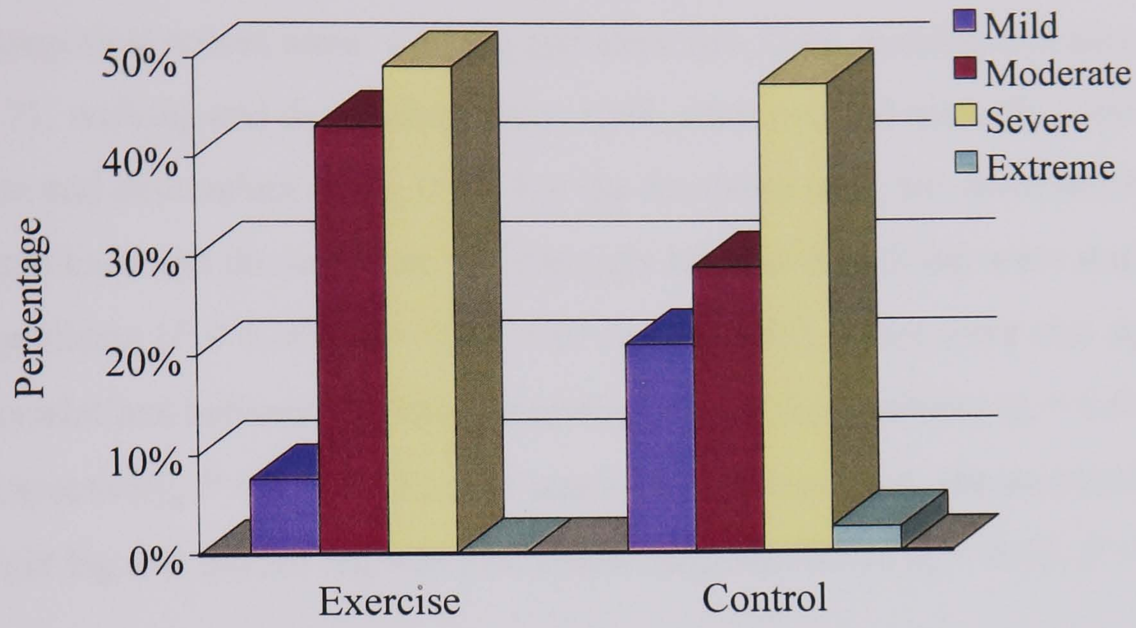

Figure 4.5 Frequency distribution of pain perception of WOMAC OA Index.

Most of the subjects in the exercise group and the control group perceive their degree of stiffness as 'severe' (Figure 4.6), but the proportion is higher in the control group (52.7%) than the exercise group (43.1%). 12.3% of patients in the exercise group perceive their stiffness as 'extreme', compared to 2.6% in the control group. Statistical analysis does not indicate any significant difference in the score distribution between the exercise and control groups ($P > 0.05$).

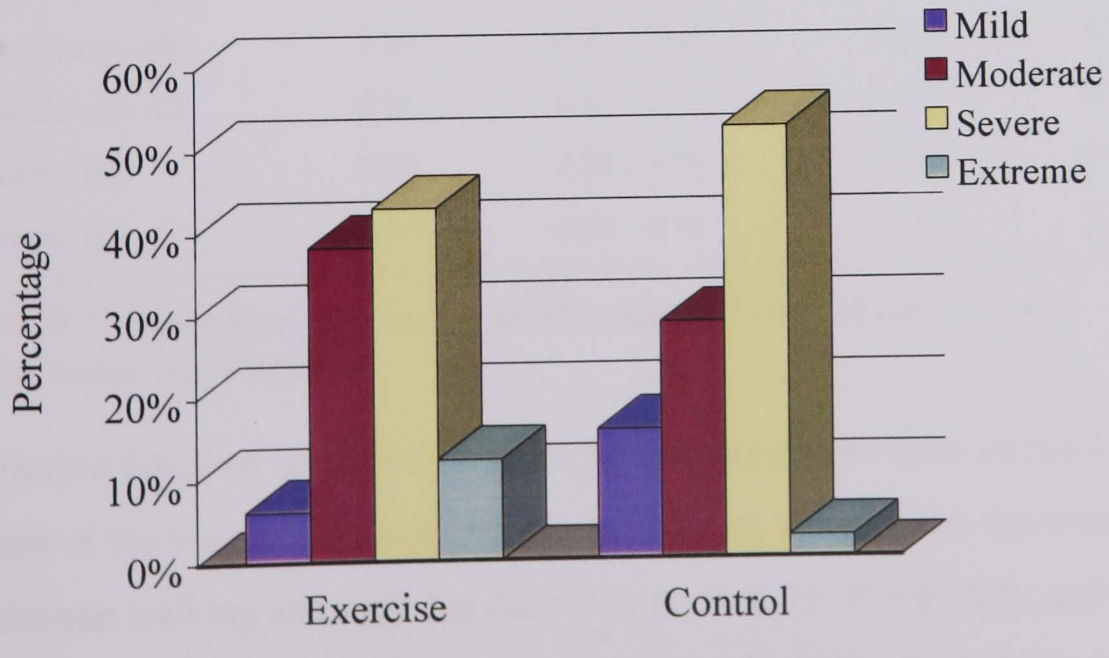

Figure 4.6 Frequency distribution of stiffness perception of the WOMAC OA Index.

4.2.3 Reliability and validity of the battery of physical function tests

Results of the test-retest reliability of each physical function test are presented in Table 4.6. Using data from all subjects, scores on the three physical performance tests were significantly correlated ($P < 0.001$). Spearman correlation coefficients for the categorical scores were: walking and chair rise, 0.44; walking and ascending stairs, 0.71; walking and descending stairs, 0.68; chair rise and ascending stairs, 0.61; chair rise and descending stairs, 0.57. For the flexibility tests, the associations between the right knee and the left knee, and the right hip and the left hip were statistically significant ($P < 0.001$, $r_s = 0.61$; 0.67 respectively). There were also significant correlations between the knee flexibility and the hip flexibility ($r_s = 0.60$ for both legs respectively; $P < 0.001$). For the quadriceps strength test, the association between the right leg and the left leg was also statistically significant ($r_s = 0.67$, $P < 0.001$).

Table 4.6 Reliability of the physical function test battery

Test	ICC		SEM	
	R	95% CI		% of mean
Eight foot walk	0.96	0.83 - 0.99	0.10 s	3.51%
Ascending stairs	0.94	0.75 - 0.98	0.28 s	8.78%
Descending stairs	0.96	0.82 - 0.99	0.25 s	7.77%
Chair rise	0.96	0.84 - 0.99	1.44 s	8.01%
Knee flexion (R)	0.97	0.87 - 0.99	1.60°	1.30%
Knee flexion (L)	0.98	0.91 - 0.99	1.79°	1.40%
Hip flexion (R)	0.82	0.26 - 0.95	4.34°	4.72%
Hip flexion (L)	0.83	0.33 - 0.96	3.64°	3.58%
Torque (R)	0.95	0.79 - 0.99	4.83 Nm	10.16%
Torque (L)	0.97	0.94 - 0.99	3.58 Nm	7.29%

NB. ICC = intraclass correlation; SEM = standard error of measurement.
% of mean: SEM/Mean

Physical function scores in the three performance tests were inversely associated with each of the knee/hip flexibility tests. The lowest value of the correlation was seen between walking and right hip flexibility ($r_s = -0.19$, $P = 0.054$), and the highest was in the correlation between chair rise and left hip flexibility ($r_s = -0.50$, $P < 0.001$). Of the three performance measures, only the chair rise test correlated significantly with the quadriceps strength test (r_s = -0.25 for the right leg, -0.23 for the left leg, $P < 0.05$). Of the associations between the flexibility and the quadriceps strength, only the association between left hip flexibility and left quadriceps torque was statistically significant (r_s = 0.22, $P < 0.05$). The summary physical function scale ranged from 11 to 39, with a mean of 25.4, a median of 25, and an interquartile range of 10 (difference between 25th and 75th percentile). The internal consistency of the summary physical function scale, assessed as Cronbach's alpha, was 0.84.

4.2.4 Physical function tests

Summary of the performance of the five physical function tests for the 106 participants are shown in Table 4.7. The cut-off points for classification into categories of physical function for each test have been provided in the Appendix X (Table A1 to A3). All subjects were able to complete the physical function tests with the exception of the chair rise and the quadriceps strength tests. Twenty-five subjects (24%) were unable to complete the chair rise due to pain in their knee/hip joints (15.1%) or insufficient strength (9.4%). Four patients (3.8%) did not complete the strength tests because of pain in the knee joints (2.8%) or temporary breathlessness (1.9%). In general, it took about 40 minutes per participant to complete the five tests. Although some patients developed pain or cramp after the chair rise, joint flexibility and quadriceps strength tests, there were no serious injuries resulting from the administration of any of the physical function tests.

Comparisons between the exercise and control groups for physical function at baseline are shown in Table 4.8. Although there were small variations, there were no statistically significant differences between exercise and control subjects in any of the physical function test measures or the summary physical function scores.

Table 4.7 Characteristics of the physical function test battery

Characteristics	Number	Mean ± SD	95% CI	Scores range
Eight foot walk (s)	106	2.93 ± 0.94	2.75 - 3.11	1.69 - 7.25
Ascending stairs (s)	106	4.17 ± 2.80	3.63 - 4.71	1.91 - 23.03
Descending stairs (s)	106	4.07 ± 2.12	3.66 - 4.48	1.68 - 13.75
Chair rise (s)	81	26.59 ± 11.15	24.10 - 29.07	11.84 - 63.37
Knee flexion (R) (^{0})	106	117.98 ± 16.01	114.90 - 121.06	49 - 140
Knee flexion (L) (^{0})	106	119.71 ± 19.55	115.94 - 123.47	45 - 145
Hip flexion (R) (^{0})	106	85.77 ± 17.95	82.32 - 89.23	40 - 120
Hip flexion (L) (^{0})	106	89.83 ± 19.59	86.06 - 93.60	40 - 125
Torque (R) (Nm)	103	40.82 ± 23.31	36.25 - 45.40	6.12 - 120.51
Torque (L) (Nm)	102	39.68 ± 24.06	34.97 -44.38	6.12 - 147.60
SPF†	102	25.30 ± 7.10	23.91 - 26.70	11-39

†: Summary physical function score (SPF)

Table 4.8 Comparison of the exercise and control group physical function at baseline

Characteristics	Exercise N= 66	Control N= 40	95% CI of the difference	*P* value
Eight foot walk (s)	2.85 ± 0.87	3.05 ± 1.05	-0.57 - 0.18	0.35
Ascending stairs (s)	3.94 ± 2.26	4.52 ± 3.51	-1.69 - 0.53	0.50
Descending stairs (s)	3.91 ± 2.0	4.27 ± 2.29	-1.20 - 0.48	0.45
Chair rise*	2.98 ± 1.49	3.25 ± 1.37	-0.84 - 0.31	0.37
Knee flexion (R) (^{0})	118.7 ± 13.63	116.6 ± 19.33	-4.24 - 8.48	0.86
Knee flexion (L) (^{0})	119.7 ± 20.90	119.7 ± 17.33	-7.80 - 7.81	0.57
Hip flexion (R) (^{0})	86.3 ± 18.50	84.6 ± 17.23	-5.42 - 8.91	0.38
Hip flexion (L) (^{0})	89.2 ± 21.31	91.4 ± 16.70	-9.62 - 5.15	0.87
Torque (R) (Nm)	40.8 ± 23.19	39.8 ± 23.67	-8.58 - 10.62	0.71
Torque (L) (Nm)	39.6 ± 25.46	41.7 ± 23.56	-12.23 - 7.98	0.46
SPF†	25.6 ± 7.31	25.2 ± 6.58	-2.51- 3.31	0.78

NB. Mean (SD) is given for each parameter.
*: Comparison was performed based on ordinal scores including those who were unable to complete the chair-rise test. Actual score range: (1 = best, 5 = worst).
†: Summary physical function score (SPF)

4.2.5 AIMS 2 questionnaire

The scores for the AIMS 2 subscales for all participants at baseline are shown in Table 4.9. There were no 'floor' effects in any of the AIMS 2 subscales. 'Ceiling' effects of > 10% of responses were observed for the support from family and friends dimension (27% for the exercise group, 13.2% for the control group).

Table 4.9 Score distributions of the AIMS2 questionnaire results

AIMS 2 Scale	Number	Mean (SD)	Possible score range	Actual score range
Social activity	103	5.48 (1.44)	0-10	2-9.5
Support from family and friends	102	2.65 (2.25)	0-10	0-8.75
Level of tension	102	4.94 (1.69)	0-10	0.5-9
Mood	102	3.67 (1.68)	0-10	0-9

The dimension scores of the AIMS 2 questionnaire of the exercise and control groups at baseline are presented in Table 4.10. The exercise group had better scores in the four psycho-social dimensions of the AIMS 2 questionnaire than the control group, but only the differences in the dimension of "support from family and friends" reached statistical significance (P = 0.007).

Table 4.10 Comparison of the exercise and control group AIMS 2 questionnaire results at baseline

AIMS 2 Scale	Exercise (N= 66)			Control (N=40)			95% CI of the difference	P value
	Mean ± SD	% floor	% ceiling	Mean ± SD	% floor	% ceiling		
Social activity	5.31 ± 1.48	0	0	5.76 ± 1.33	0	0	-1.03 - 0.12	0.12
Support from family and friends	2.18 ± 2.03	0	27	3.42 ± 2.40	0	13.2	-2.13 - -0.35	0.007*
Level of tension	4.73 ± 1.48	0	0	5.29 ± 1.96	0	0	-1.24 - 0.12	0.11
Mood	3.42 ± 1.61	0	1.5	4.08 ± 1.74	0	2.6	-1.33 - 0.02	0.056

* P <0.01

The frequency distribution of the dimension of "support from family and friends is depicted in Figure 4.7. The proportion of subjects who responded as 'always' or 'very often' receiving support from their family or friends was higher in the exercise group (65.1%) than the control group (39.5%). A significant proportion of patients who responded as 'almost never' or 'never' receiving support from their family or friends was observed in the control group (23.1%), compared to only 7.9% in the exercise group.

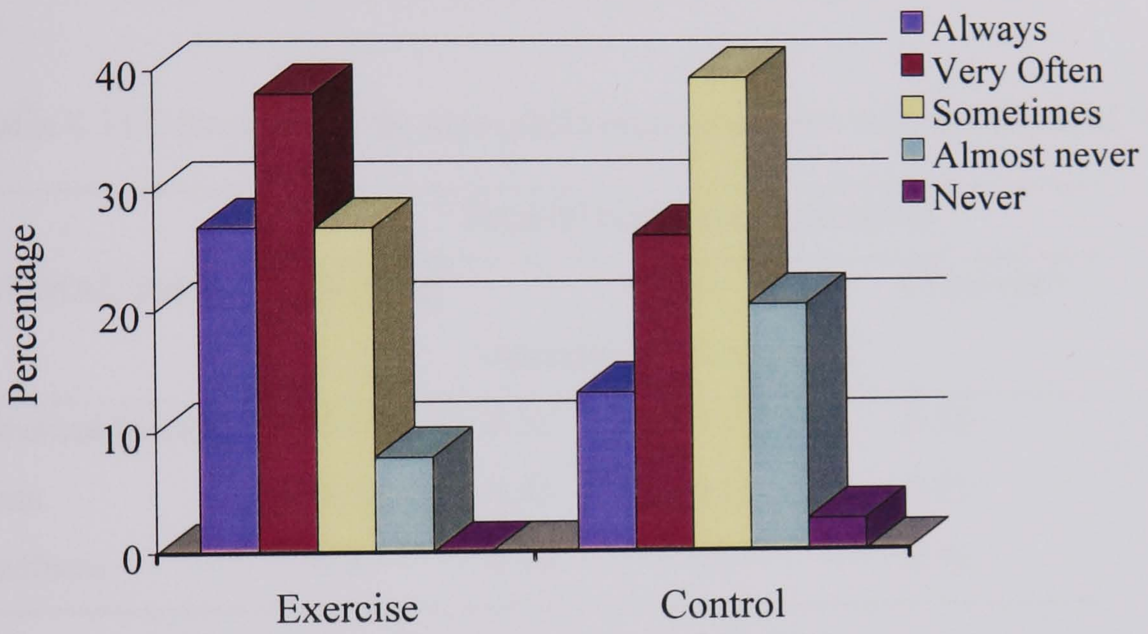

Figure 4.7 Frequency distribution of perception of support from family and friends of the AIMS 2 questionnaire.

4.3 Correlation between the Battery of Physical Function Tests and the Health Status Measures

4.3.1 The battery of physical function tests and the WOMAC OA index

Statistically significant associations ($P < 0.005$) were observed between the three performance measures and each of the WOMAC dimensions, using data from all participants at baseline. The strength of the associations between the three performance measures and the physical function dimension were stronger than the associations with the pain dimension or the associations with the stiffness dimension (Table 4.11). In particular, scores in the three performance measures showed significant associations (*P* < 0.001) with questions of the WOMAC dimension probing the same physical activities. These questions included ' pain in walking on a flat surface' ($r_s = 0.49$), 'pain in going up or down stairs' ($r_s = 0.39$), 'difficulty in ascending stairs' ($r_s = 0.40$), 'difficulty in descending stairs' ($r_s = 0.43$), 'difficulty in rising from sitting' ($r_s = 0.48$) and 'difficulty in walking on a flat surface' ($r_s = 0.42$).

Table 4.11 Correlation of the three performance measures with the WOMAC OA Index

	Physical performance measures			
WOMAC Index	Walking	Stairs		Chair rise*
		Ascending	Descending	
Physical function	0.48	0.53	0.52	0.54
Pain	0.38	0.45	0.38	0.33
Stiffness	0.33	0.38	0.37	0.36

NB. Spearman rho is given as the correlation coefficient.

*: Statistical analysis was based on the ordinal scores including those who were unable to complete the chair-rise test.

Physical function scores on the tests of knee flexibility and hip flexibility were inversely correlated with the three WOMAC index items (*P* < 0.01), except the association between the knee flexibility (left leg) and the pain dimension (*P* > 0.05, Table 4.12). Of the WOMAC questions that were individually tested, 'the stiffness after first waking in the morning', difficulty when 'rising from the sitting', 'getting in/out of car', 'getting in/out of bath' and 'getting on/off toilet' correlated significantly with the knee flexibility and the hip flexibility (*P* < 0.01; r_s ranged from -0.30 to -0.44). In particular, individual questions including: difficulty when 'bending to floor', 'putting on socks/stockings' and 'taking off socks/stockings' significantly correlated with the test of hip flexibility only (*P* < 0.01; r_s ranged from -0.32 to -0.37).

Table 4.12 Correlation of the knee and hip flexibility tests with the WOMAC OA Index

WOMAC Index	Flexibility test			
	Knee (R)	Knee (L)	Hip (R)	Hip (L)
Physical function	-0.39	-0.35	-0.37	-0.45
Pain	-0.26	NS	-0.26	-0.31
Stiffness	-0.30	-0.21	-0.27	-0.22

NB. Spearman rho is given as the correlation coefficient.

NS: Not significant at $P \leq 0.05$ level

Physical function scores on torque of the quadriceps (right leg) were inversely associated with the pain dimension and stiffness dimension of the WOMAC index ($P < 0.05$). The physical function global scores did not correlate significantly with the scores of the quadriceps strength. However, some questions of the physical function dimension were associated with the torque of the quadriceps ($P < 0.05$). These relevant questions included 'getting in/out of a car', 'lying in bed', 'getting in/out of a bath'. 'sitting', 'getting on/off a toilet, and 'heavy domestic duties' (r_s ranged from -0.22 to -0.32).

The summary physical function scores (SPF) were positively associated with global scores on each of the WOMAC OA index dimensions. That is, lower scores on the summary physical function scale (better physical function performance) were associated with lower scores on all the WOMAC index dimensions (better perceived health status). Spearman rank correlation coefficients for the association between the SPF scores and the three dimensions of the WOMAC index were: physical function and summary physical function scale, 0.61 (Figure 4.8), pain and summary physical function scale, 0.44; stiffness and summary physical function scale, 0.43.

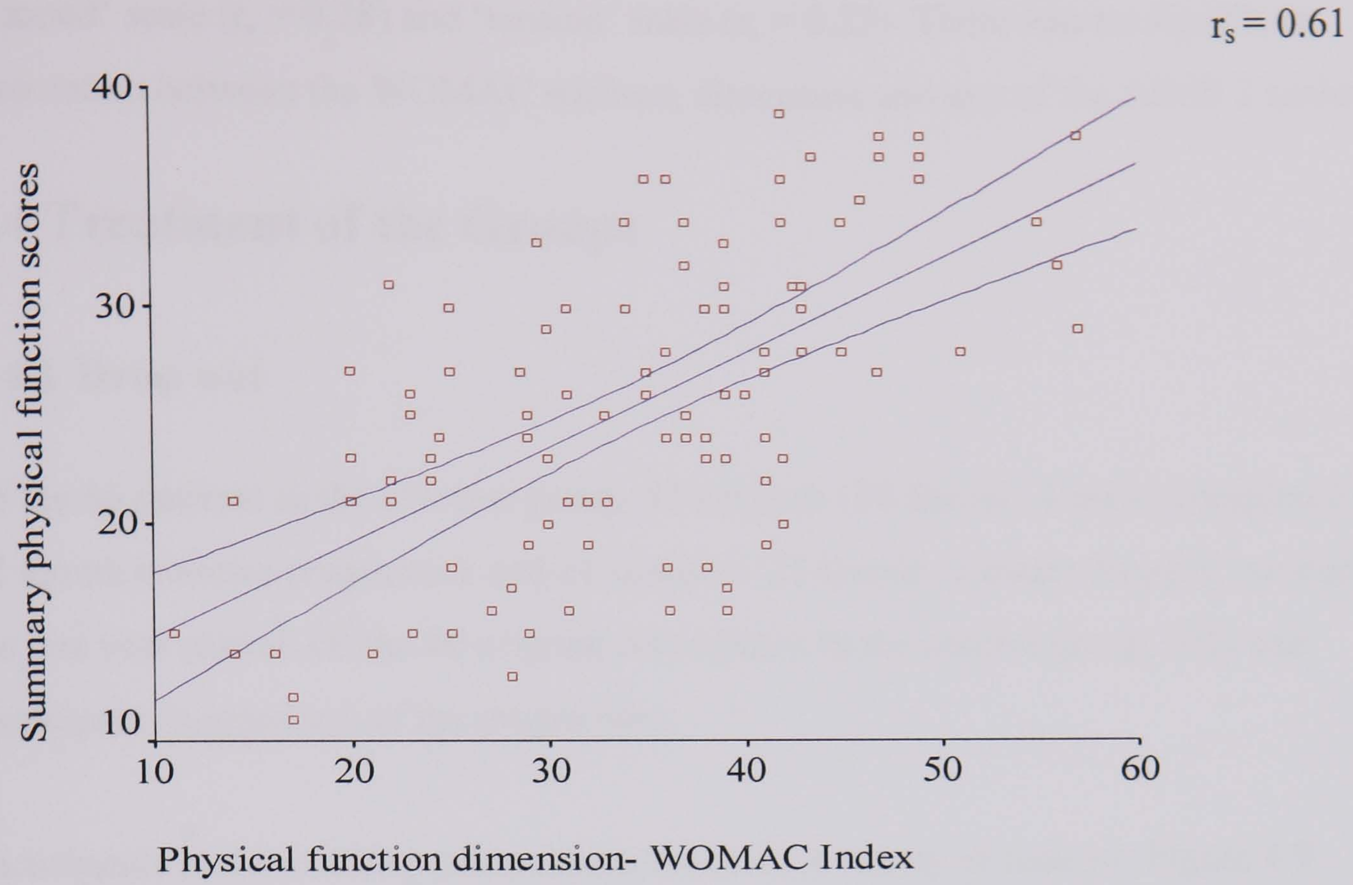

Figure 4.8 Association between the summary physical function scores and the physical function dimension of WOMAC index. The Mean and 95% confidence interval are shown.

4.3.2 The battery of physical function tests and the AIMS 2 scales

Physical function scores in the eight foot walking test, ascending/descending stairs tests and the quadriceps strength tests were not significantly associated with the four selected AIMS 2 scales. Statistically significant associations (*P* < 0.05) were observed between the chair rise test and the social activity dimension, the level of tension dimension and the mood dimension. There was no significant association between the flexibility tests and the AIMS 2 subscales, except the test of hip flexion and the dimension of social activity (r_s = -0.20 for both right and left legs). Finally, the summary physical function score was only significantly associated with the social activity dimension of the AIMS 2 scales (r_s = 0.21).

As for the correlation between the WOMAC OA Index and the AIMS 2 scales, the WOMAC pain dimension was significantly associated with the AIMS 2 'level of tension' scale ($r_s = 0.21$) and 'support from family and friends' scale (r_s = -0.20); and the WOMAC physical function dimension was significantly associated with the AIMS

2 'mood' scale (r_s = 0.28) and 'tension' scale (r_s = 0.23). There was no significant association between the WOMAC stiffness dimension and any of the AIMS 2 scales.

4.4 Treatment of the Groups

4.4.1 Drop out

Of the 66 patients in the exercise group, 42 subjects (38 female, 4 male) completed the 12 month exercise programme and 24 subjects (22 female, 2 male) dropped out during the one year period. Of the 40 original participants in the control group, only one participant dropped out of the programme.

Participants in the exercise group dropped out for a variety of reasons. Figure 4.9 summarises the reasons given for dropping out. The "programme" category refers to water temperature (5), time inconvenience (3), location inconvenience (1), and access to the pool (1). The "medical" category includes surgery (5), illness (3) and physical weakness (1). The "psychosocial" category includes family obligations (e.g. looking after grandchildren, sick partner or relatives) (4). The "unavoidable" category refers to change of residence (1). For the only participant who dropped out from the control group, "undergoing a hip replacement" was the reason given for discontinuing.

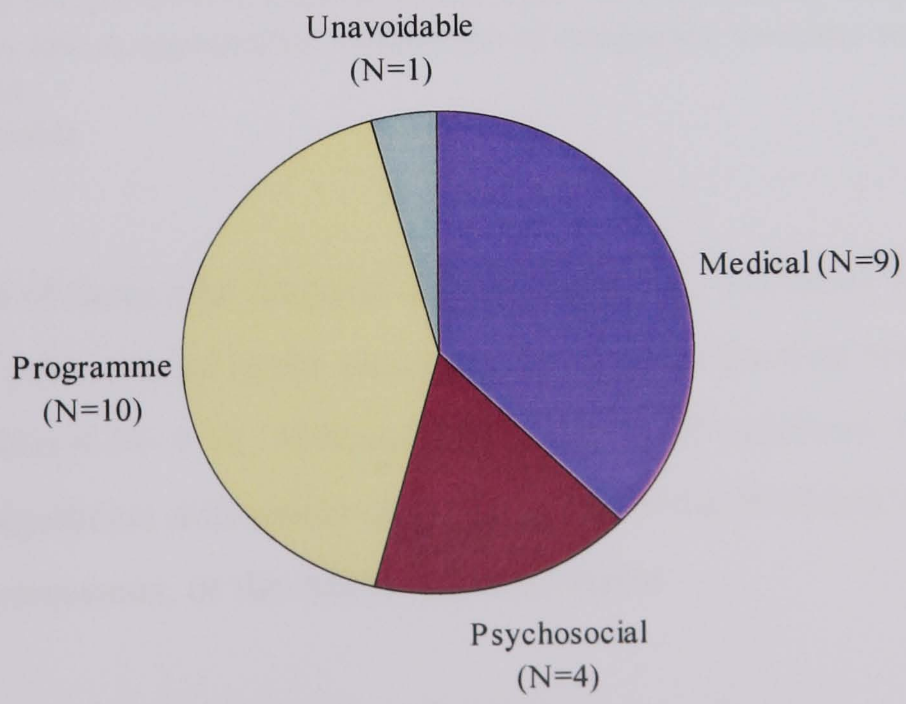

Figure 4.9 Reasons for dropping out from the exercise programme.

As can be seen from Table 4.13, those who dropped out of the exercise class were younger, had less disease duration of OA and lower BMI, but the differences were not statistically significant ($P > 0.05$). As for the number of those with chronic conditions, a greater number of subjects in the exercise group who had other comorbid illness remained in the exercise programme compared with the number who dropped out. The only significant difference ($P = 0.03$) was observed in those also suffering from hypertension.

Table 4.13. Demographic and clinical characteristics of adherers and drop-outs in the exercise group at baseline

Characteristics	Adherers N = 42	Drop-outs N = 24	95% CI of the difference	*P* value
Age, mean ± SD, yr.	69.2 ± 6.81	68.3 ± 5.61	-2.36 - 4.19	0.58
Disease duration, mean± SD, yr.	11.5 ± 12.19	11.0 ± 8.48	-5.37 - 6.18	0.89
BMI, mean± SD	29.3 ± 5.12	28.3 ± 4.90	-1.55 - 3.61	0.43
Comorbid illness, No (%)				
Hypertension	20 (47.62)	5 (20.83)	NA	0.03
Heart disease	11 (26.2)	3 (12.5)	NA	0.19
Diabetes	2 (4.8)	1 (4.2)	NA	0.70

NB. Statistical comparisons of interval means were performed using independent t-test or Mann-Whitney test as appropriate; comparison of categorical variables was performed using Chi-Square test.
NA: not applicable

Comparisons of those who dropped out and those who continued with the exercise class for the self-reported health status and the physical function tests at baseline are shown in Tables 4.14- 4.16. Although there were small variations, there were no statistically significant differences observed in any of the WOMAC OA Index, physical function test measures, or the AIMS 2 questionnaire.

Table 4.14 Comparison of the results of WOMAC OA index between adherers and drop-outs at baseline

WOMAC Index	Adherers N= 42	Drop-outs N= 22 - 23	95% CI of the difference	*P* value
Physical function	34.20 ± 9.69	34.79 ± 9.99	-5.73 – 4.57	0.82
Pain	10.06 ± 2.78	10.00 ± 3.57	-1.63 - 1.84	0.91
Stiffness	4.81 ± 1.61	4.61 ± 1.67	-0.65 - 1.05	0.64

NB. Mean (SD) is given for each parameter.

Table 4.15 Comparison of the performance of the physical function tests between adherers and drop-outs at baseline

Characteristics	Adherers N= 41	Drop-outs N= 25	95% CI of the difference	*P* value
Eight foot walk (s)	2.76 ± 0.70	3.02 ± 1.10	-0.7 - 0.19	0.25
Ascending stairs (s)	3.94 ± 2.35	3.94 ±2.16	-1.16 - 1.17	0.99
Descending stairs (s)	3.85 ± 2.00	4.02 ± 2.03	-1.20 - 0.86	0.51
Chair rise*	3.00 ± 1.53	2.96 ± 1.46	-0.73 - 0.81	0.92
Knee flexion (R) (^{0})	117.43 ± 14.28	120.83 ± 12.40	-10.37 - 3.57	0.33
Knee flexion (L) (^{0})	118.52 ± 21.02	121.71 ± 20.98	-13.92 - 7.56	0.56
Hip flexion (R) (^{0})	84.71 ± 19.27	89.13 ± 17.08	-13.88 - 5.06	0.36
Hip flexion (L) (^{0})	86.95 ± 22.68	93.04 ± 18.46	-16.96 - 4.78	0.27
Torque (R) (Nm)	40.10 ± 20.76	42.10 ± 27.36	-13.93 - 9.95	0.74
Torque (L) (Nm)	41.79 ± 22.08	35.67 ± 30.64	-6.91- 19.15	0.35
SPF†	25.62 ± 7.31	24.96 ± 7.74	- 3.16 - 4.48	0.73

NB. Mean (SD) is given for each parameter.

*: Comparison was performed based on ordinal scores including those who were unable to complete the chair-rise test. Actual score range: 1= best, 5 = worst.

†: Summary physical function score

Table 4.16 Comparison of the results of AIMS 2 questionnaires between adherers and drop-outs at baseline

Characteristics	Adherers N= 42	Drop-outs N= 22 - 23	95% CI of the difference	*P* value
Social activity	5.18 ± 1.33	5.54 ± 1.73	-1.13 - 0.40	0.35
Support from family and friends	2.10 ± 2.06	2.33 ± 2.00	-1.30 - 0.85	0.68
Level of tension	4.66 ± 1.64	4.86 ± 1.16	-0.99 - 0.58	0.60
Mood	3.37 ± 1.46	3.52 ± 1.90	-1.0 - 0.69	0.72

NB. Mean (SD) is given for each parameter.

4.4.2 Injury/Accidents

Some of the participants in the exercise group had an increase of pain and/or muscle soreness after the exercise sessions, but most of them were very positive about the exercise programme and still continued to participate. Six minor injuries possibly related to participation in the exercise classes occurred during the study: two people slipped on the pool side; two people slipped in the pool entrance; one person slipped in the locker room and one person slipped on the pool floor. Five out of these six injured people remained and finished the exercise programme after first aid care and rest. As for illness related directly to the OA, five people had hip replacements and only two of them returned to the exercise class three months post-operation. Three people had knee replacement surgery and only one of them re-joined the exercise class. At the same time, one female subject in the control group had knee and shoulder operations but remained in the project.

4.5 Pre/Post Measurements

Of the 66 participants in the exercise group, 59 (89.4%), including 19 drop-outs returned their follow-up health status questionnaires and 51 (77.3%), including 14 drop-outs, completed their post-test physical function measures. The control group had higher response rates than the exercise group in which 38 (95%) out of 40 original participants returned their follow-up health status questionnaires, and 35 (87.5%) of them completed their post-test physical function evaluation. These differences in response rates between the exercise group and the control group, however, were not statistically significant (P = 0.32, 0.19; for the health status questionnaire and the physical function tests; respectively).

4.5.1 Comparisons of baseline and one-year WOMAC results

Analysis of the results of baseline and one year WOMAC OA index are shown in Table 4.17. Scores on the WOMAC physical function dimension decreased significantly, with an average of 3.66 ± 8.75 units (10.6%) in the exercise group, compared to an average 0.41 ± 7.24 units (1.2%) of increase in the control group (P = 0.025). On the pain dimension, a significant decrease of an average of 1.20 ± 3.53 units (12.0%) was found in the exercise group, compared to an average of only 0.15 ± 2.51 units (1.6%) of decrease in the control group (P = 0.047). Scores on the stiffness dimension decreased by an average of 0.54 ± 1.56 units (11.4%) in the exercise group compared to an average of 0.21 ± 1.20 units (4.7%) in the control group (P = 0.34).

Table 4.17. Results of WOMAC OA index: changes between exercise and control groups

Measure	Exercise group N = 66		Control group N = 44		*P* Value‡	Effect Size
	Baseline	One year	Baseline	One year		
Physical function	34.40 (9.71)	30.75 (13.68)**	34.97 (10.52)	35.37 (10.07)	0.025	0.41
Pain	10.02 (3.05)	8.83 (4.22)**	9.54 (3.74)	9.39 (2.84)	0.047	0.32
Stiffness	4.74 (1.62)	4.20 (1.78)*	4.46 (1.55)	4.26 (1.37)	0.34	0.21

NB. Mean (SD) is given for each parameter

†: P values are for between-group comparisons of pre-post changes

** $P \leq 0.01$ versus baseline.

* $P \leq 0.05$ versus baseline.

Figure 4.10 summarises the percentage changes in scores on the WOMAC OA index before and after the intervention for the exercise and the control group. The effect sizes indicate that the exercise intervention was associated with a small to moderate effect on self-reported physical disability, and a small effect on the relief of pain and stiffness.

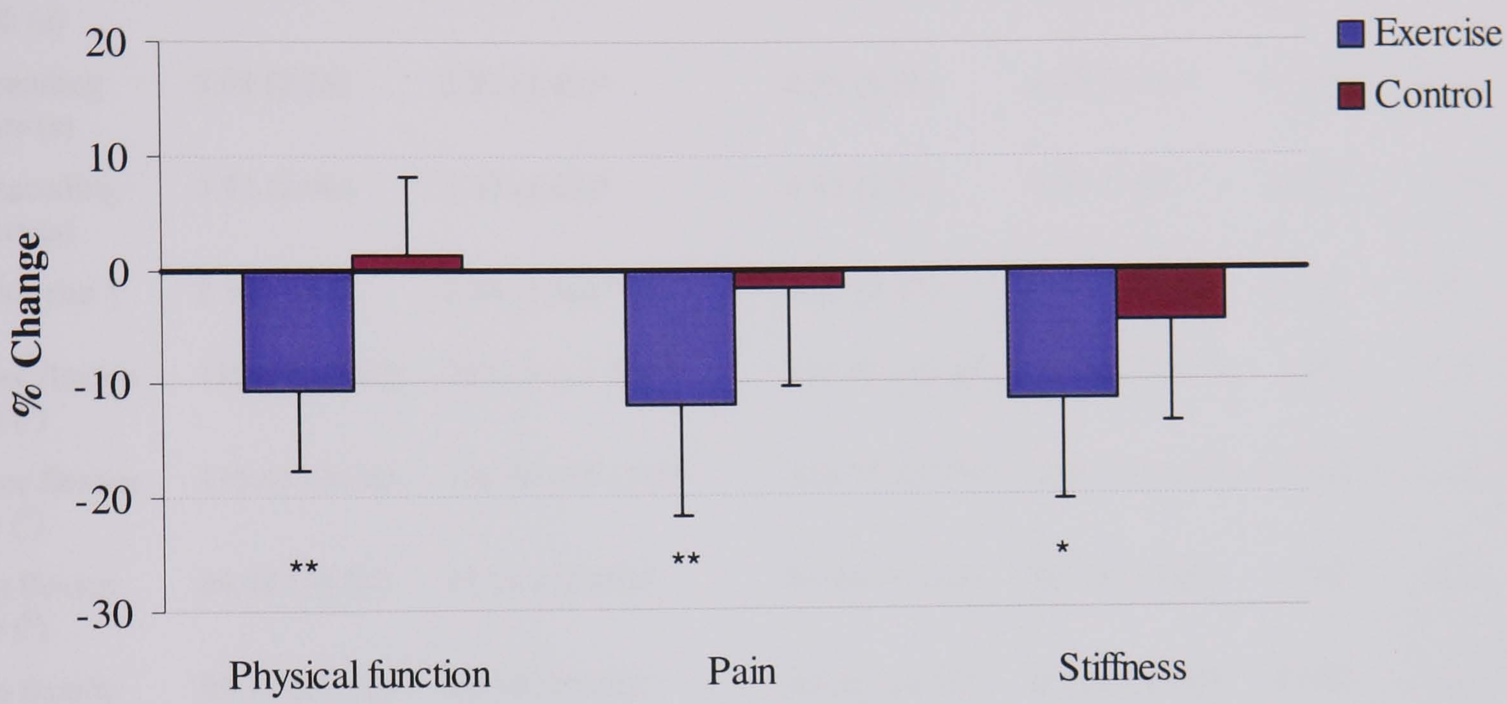

*Figure 4.10 Percentage changes for physical function, pain and stiffness by the WOMAC OA Index for exercise and control groups after one year of intervention. Error bars indicate 95% CI. A negative change signifies improvement (** P< 0.01, * P < 0.05 compared with the baseline values).*

4.5.2 Comparisons of baseline and one-year physical function tests

After one year of intervention, no significant change in body weight from baseline was observed either in the exercise group (0.67 ± 4.02 kg loss, $P = 0.18$) or in the control group (0.73 ± 5.07 kg loss, $P = 0.37$). Analysis of the results of baseline and one-year physical function measures are shown in Table 4.18.

Table 4.18. Physical function test measures: changes between exercise and control groups.

Measure	Exercise group N =66		Control group N = 40		P Value‡	Effect Size
	Baseline	One year	Baseline	One year		
Eight foot walk (s)	2.85 (0.87)	2.96 (0.79)**	3.05 (1.05)	3.62 (1.37)**	0.007	0.47
Ascending stairs (s)	3.94 (2.26)	3.53 (1.43)*	4.55 (3.51)	4.85 (3.53)*	0.008	0.26
Descending stairs (s)	3.91 (2.00)	3.57 (1.63)*	4.33 (2.31)	4.59 (2.49)	0.023	0.28
Chair rise †	2.98 (1.49)	2.44 (1.40)**	3.25 (1.37)	3.00 (1.57)*	0.35	0.20
Knee flexion (R) (^{0})	118.67 (13.63)	123.29 (11.51)**	116.85 (19.45)	116.48 (18.91)	0.005	0.31
Knee flexion (L) (^{0})	119.68 (20.90)	126.30 (15.13)**	119.75 (17.36)	120.32 (13.11)	0.021	0.31
Hip flexion (R) (^{0})	86.32 (18.50)	91.23 (12.89)*	84.88 (17.22)	86.08 (17.22)	0.381	0.21
Hip flexion (L) (^{0})	89.17 (21.31)	94.50 (13.45)*	90.93 (16.57)	87.25 (15.06)	0.022	0.46
Torque (R) (Nm)	40.41 (23.28)	42.80 (27.39)	40.82 (23.85)	38.04 (21.15)	0.82	0.22
Torque (L) (Nm)	39.87 (25.68)	40.31 (25.86)	39.87 (21.65)	37.56 (23.32)	0.52	0.11
SPF†	25.48 (7.37)	23.66 (6.76)**	25.17 (6.58)	26.88 (7.08)*	0.005	0.50

NB. Mean (SD) is given for each parameter

†: Comparisons calculated based on ordinal score including those who were unable to complete the chair-rise test. Actual score range :1 = best, 5 = worst.

‡ P values are for between-group comparisons of pre-post mean changes.

** $P \leq 0.01$ versus baseline.

* $P \leq 0.05$ versus baseline.

Subjects in the exercise group performed better in the ascending and descending stairs tests, the knee flexibility tests and the hip flexibility tests than the control group ($P < 0.05$). The effect sizes indicate that the exercise intervention was associated with a small effect on general mobility, and a small beneficial effect on knee and hip flexibility. Both the exercise and control group performed better in the chair rise test, with no significant between group difference ($P > 0.05$). The exercise group maintained quadriceps strength, compared with the deterioration in the control group. However, the between-group difference is not statistically significant ($P > 0.05$). It took longer for the exercise group to complete the eight-foot walking test, but the deterioration was more marked in the control group ($P < 0.01$). Finally, the exercise group had an average of (1.82 ± 5.18) units of improvement in the summary physical function score, compared to an average of (1.71 ± 4.36) units of deterioration in the control group ($P < 0.01$; Figure 4.11).

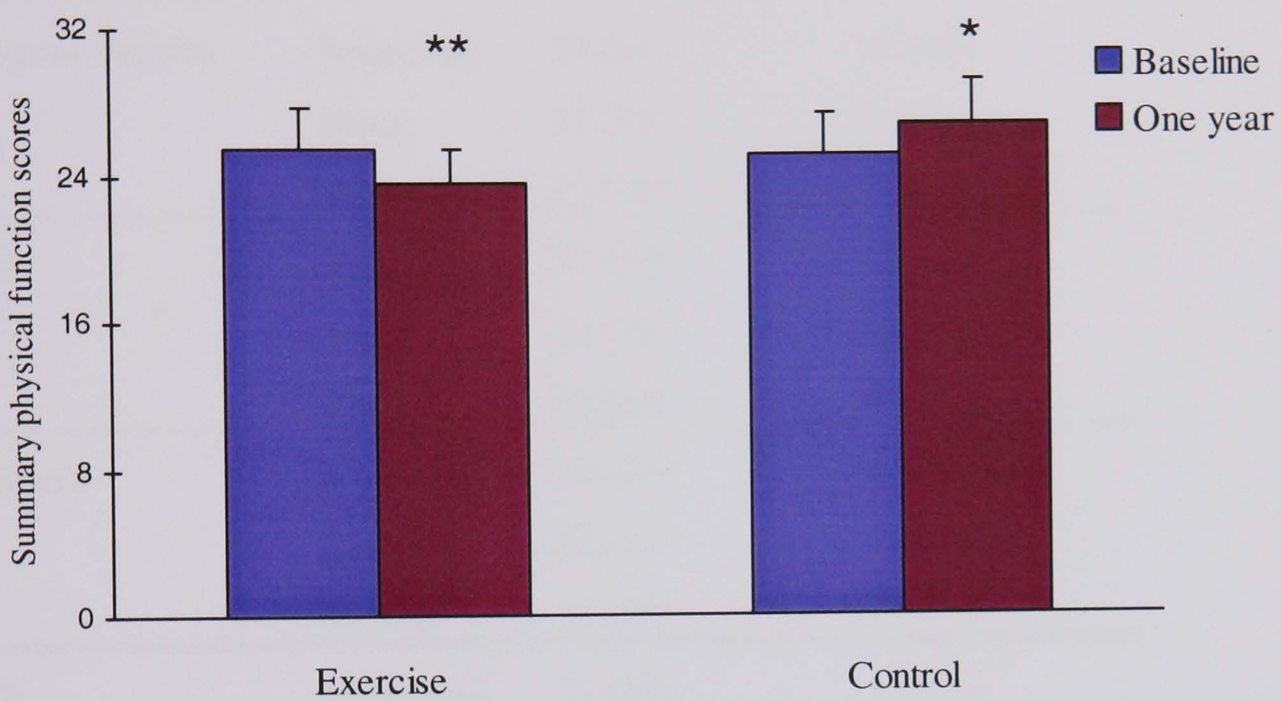

*Figure 4.11 Baseline and one year mean summary physical function scores (SPF) for exercise and control groups. Error bars indicate 95% CI. A fall in SPF indicates improvement. ** P< 0.01, * P < 0.05 compared with the baseline values.*

The number of patients who improved, stayed the same and got worse, for the WOMAC OA Index and the Summary Physical Function scores (SPF) is presented in Table 4.19.

Table 4.19 Numbers of patients who improved, stayed the same and got worse for the WOMAC OA Index and the Summary Physical Function scores (SPF)

Outcome Measure	Changes	Exercise (N = 66) N (%)	Control (N = 40) N (%)
WOMAC OA Index			
Physical function	Improved	37 (56)	19 (47)
	Same	12 (18)	4 (10)
	Worse	17 (26)	17 (43)
Pain	Improved	39 (59)	16 (40)
	Same	12 (18)	7 (18)
	Worse	15 (23)	17 (43)
Stiffness	Improved	29 (44)	14 (35)
	Same	22 (33)	16 (40)
	Worse	15 (23)	10 (25)
SPF	Improved	31 (47)	12 (30)
	Same	13 (17)	8 (20)
	Worse	22 (33)	20 (50)

† improved: post-test score < pre-test score; stayed the same: post-test score = pre-test score; got worse: post-test score> pre-test score.

4.5.3 Comparisons of physical function test at baseline, six months and one year

Forty-four of the sixty-six subjects (67%), including eight people who dropped out of the exercise programme, completed all the baseline, six-month and one year assessments of physical function. Mean scores for the physical function tests at baseline, six months, and one year are shown in Table 4.20. Statistical analysis revealed a significant time effect in all tests, with the exception of the quadriceps strength test. Compared with baseline scores, the study subjects who received exercise treatment improved significantly when performing the chair rise test ($P = 0.001$) and the knee flexibility tests ($P < 0.001$ for both knees) at the six month interim test. These improvements were maintained throughout the intervention as indicated by similar test scores at six months and one year. A trend towards improvements were apparent in the ascending and descending stairs tests, and in the hip flexibility test over the one year period ($P < 0.05$). No significant changes were observed in the quadriceps strength test in different time periods ($P > 0.05$).

Table 4.20 Mean values (SD) for the physical function tests at baseline, six months and one year (N = 44)

Measure	Time		
	Baseline	Six months	One year
Eight foot walk (s)	2.71 (0.75)	2.83 (0.93)	2.90 (0.80)*
Ascending stairs (s)	3.77 (2.34)	3.65 (1.73)	3.31 (1.30)*
Descending stairs (s)	3.70 (2.02)	3.54 (1.67)	3.27 (1.50)*
Chair rise † (s)	2.91 (1.51)	2.34 (1.45)**	2.27 (1.35)**
Knee flexion (R) (^{0})	116.93 (13.44)	124.52 (9.61)**	124.39 (10.12)**
Knee flexion (L) (^{0})	118.20 (19.62)	126.80 (10.62)**	128.52 (10.74)**
Hip flexion (R) (^{0})	85.73 (20.03)	87.36 (15.27)	92.36 (12.50)*
Hip flexion (L) (^{0})	86.14 (21.38)	88.28 (13.34)	95.14 (12.78)*
Torque (R) (Nm)	37.77 (19.18)	43.11 (26.75)	41.77 (25.95)
Torque (L) (Nm)	39.06 (19.53)	40.57 (22.92)	38.87 (20.60)

NB. Statistical comparisons of means were performed using one way repeated-measures ANOVA or Friedman test as appropriate, for the exercise group only.

†: Comparison was performed based on ordinal scores including those who were unable to complete the chair-rise test. Actual score range: 1= best, 5 = worst.

** $P \leq 0.01$ versus baseline.

* $P \leq 0.05$ versus baseline.

4.5.4 Comparisons of baseline and one year AIMS 2 questionnaire results

As seen in Table 4.21, both exercise and control groups had a significant decrease in their AIMS 2 tension score between baseline and one year ($P < 0.05$); however, the mean changes in tension score were not statistically significant (0.30 ± 1.17 vs. 0.36 ± 0.92 units; $P > 0.05$). On the other three selected AIMS 2 dimensions, no significant changes within groups and between groups were observed. No effect of exercise intervention was found on the subscale of social activity, support from family and friends, level of tension, and mood.

Table 4.21. Results of AIMS 2 questionnaire: changes between exercise and control groups

Measure	Exercise group		Control group		*P* Value‡	Effect Size
	Baseline	One year	Baseline	One year		
AIMS 2						
Social activity	5.36 (1.43)	5.19 (1.40)	5.81 (1.35)	5.86 (1.92)	0.25	0.17
Support from family and friends	2.15 (2.02)	1.96 (1.97)	3.42 (2.40)	3.29 (2.29)	0.806	0.03
Tension	4.70 (1.49)	4.41 (1.67)*	5.29 (1.96)	4.93 (2.08)*	0.84	-0.04
Mood	3.42 (1.62)	3.15 (1.47)	4.08 (1.74)	3.96 (2.08)	0.46	0.09

NB. Mean (SD) is given for each parameter

†: P values are for between-group comparisons of pre-post mean change.

* $P \leq 0.05$ versus baseline.

4.6 Exercise Adherence

Table 4.22 provides descriptive data on the exercise adherence of the treatment group over the 12 months. The percentage of those who dropped out increased from 21% at six months to almost 40% at the end of the 12 months. The average attendance of the 42 participants who continued to participate in the exercise class was 70.0% ± 14.4% (range, 40.8% to 96.3%). At the same time, the twenty-four subjects who dropped out of the exercise programme had average adherence rate of 27.8% ± 11.3% (range, 12.1% to 52.5%). There were marked decreases in the adherence rate of adherers in the last two months due to an unavoidable change in venue (closure of the original swimming facility for major maintenance work).

Table 4.22. Descriptive data on adherence to the exercise group.

Assessment time interval (months)	Adherers (N)	Drop-outs (N)	Drop-outs (%)	% Attendance for Adherers (%)
3	66	0	0	74.12%
6	52	14	21.21%	69.38%
9	44	22	33.33%	70.34%
12	42	24	37.88%	62.44%

In order to examine a possible dose-response between exercise adherence and effects on self-reported health status and physical function tests, subjects in the exercise groups were divided into three groups according to their average adherence rates. At baseline, no significant differences were found in the three adherence group for any of the WOMAC OA Index, the physical function test measures, or the AIMS 2 questionnaire ($P > 0.05$).

As shown in Table 4.23, significant Group × Time interactions were obtained for the WOMAC based physical function scale $F(2, 56) = 6.25$, $P = 0.004$; pain scale, $F(2, 56) = 3.26$, $P = 0.046$; and stiffness scale, $F(2, 56) = 5.86$, $P = 0.005$. Results of the simple main effects for time within group analyses indicated that the most compliant subjects had a significant decrease in the scores on the physical function scale, with an average of 8.52 ± 8.60 (24%) units, $P < 0.001$; a significant decrease in their perception of pain, with an average of 2.73 ± 3.74 (26%) units, $P = 0.002$; and a significant decrease in their perception of stiffness, with an average of 1.43 ± 1.56 (29%) units, $P < 0.001$. For those participants who had average exercise adherence rate of less than 71%, time within-group analyses demonstrated no significant changes on either of the WOMAC dimensions ($P > 0.05$).

Table 4.23 Mean changes in the WOMAC OA index in the exercise group by tertile of exercise adherence

Measure	Exercise adherence		
	Tertile I (0% - 40%) N = 16-17	Tertile II (41% - 70%) N = 19	Tertile III (71% - 100%) N = 23
Physical function	0.85 (7.76)	-2.72 (8.58)	-8.52 (8.60)**
Pain	0.06 (3.99)	-0.84 (2.83)	-2.73 (3.74)**
Stiffness	-0.06 (1.56)	-0.05 (1.39)	-1.43 (1.56)**

NB. Mean (SD) is given for each parameter.
Statistical comparisons made using repeated measures analysis of variance.
** $P < 0.01$.

As seen in Table 4.24, significant Group × Time interactions were also obtained for right knee flexion, $F(2, 48) = 6.14$, $P = 0.004$, and left knee flexion, $F(2, 45) = 9.10$, $P < 0.001$, knee flexibility tests. Results of the simple main effects for time within group analyses indicated that the most compliant subjects (adherence rate > 70%) had significant increases in their right knee flexion (11.3 ± 12.0 degrees, $P < 0.001$), and left knee flexion (15.7 ± 16.5 degrees, $P < 0.001$). Participants who had average exercise adherence rate of 41% to 70% (tertile II group) also experienced improvements in their right knee flexion (5.3 ± 9.8 degrees, $P = 0.048$). For those least compliant subjects (average exercise adherence rate < 40%), time within-group analyses demonstrated no significant change on either limb for knee flexibility scores (*P* > 0.05).

Table 4.24 Mean changes in the physical function tests in the exercise group by tertile of exercise adherence

Measure	Exercise adherence		
	Tertile I (0% - 40%) N = 12-14	Tertile II (41% - 70%) N = 16	Tertile III (71% - 100%) N = 21
Eight foot walk (s)	-0.01 (0.46)	0.27 (0.44)	0.18 (0.48)
Ascending stairs (s)	-0.08 (0.85)	-0.66 (1.88)	-0.46 (1.14)
Descending stairs (s)	-0.26 (0.88)	-0.41 (1.25)	-0.58 (1.28)
Chair rise †	-0.64 (0.93)	-0.50 (1.03)	-0.95 (1.75)
Knee flexion (R) (^{0})	-1.07 (7.55)	5.25 (9.75)*	11.29 (12.03)**
Knee flexion (L) (^{0})	2.29 (21.13)	4.13 (15.68)	15.67 (16.51)**
Hip flexion (R) (^{0})	0.57 (13.81)	7.31 (15.48)	9.71 (15.07)
Hip flexion (L) (^{0})	1.00 (12.18)	6.75 (20.68)	13.14 (21.40)
Torque (R) (Nm)	3.13 (13.94)	3.61 (17.26)	3.06 (19.08)
Torque (L) (Nm)	1.27 (19.31)	-3.35 (13.18)	0.90 (14.67)

NB. Mean (SD) is given for each parameter.

†: Comparisons calculated based on ordinal score including those who were unable to complete the chair-rise test. Actual score range : 1 = best, 5 = worst.

Statistical comparisons made using repeated measures analysis of variance.

** $P < 0.01$; * $P < 0.05$.

No significant Group × Time interactions were found for the eight-foot walking test, ascending/descending stairs tests, chair rise test, hip flexibility test, quadriceps strength test and any of the AIMS 2 scales (Table 4.25).

Table 4.25 Mean changes in the AIMS 2 questionnaire in the exercise group by tertile of exercise adherence

Measure	Exercise adherence		
	Tertile I (0% - 40%)	Tertile II (41% - 70%)	Tertile III (71% - 100%)
Social activity	-0.47 (1.14)	-0.11 (1.39)	-0.08 (1.38)
Support from family and friends	0.17 (1.43)	-0.44 (1.12)	-0.31 (1.43)
Tension	-0.07 (1.32)	-0.12 (0.99)	-0.71 (1.34)
Mood	-0.31 (1.68)	-0.5 (1.00)	-0.17 (1.85)

NB. Mean (SD) is given for each parameter.

Statistical comparisons made using repeated measures analysis of variance.

The average attendance of the exercise class was 25 sessions (SD = 11.4), of the 49 prescribed. The range was 6-47 exercise sessions, with 17 subjects (26%) attending at least 75% of the sessions. Table 4.26 shows the mean differences in WOMAC OA Index and the Summary Physical Function in terms of adherence to the exercise programme. Improvements were most marked in the most compliant subjects.

Table 4.26 Mean difference (SD) in WOMAC OA Index and the Summary Physical Function (SPF) in the exercise group by level of adherence

	Total exercise sessions attended			
	≤ 3 months (≤ 13 sessions)	≤ 6 Months (14 -24 sessions)	≤ 9 Months (25 -35 sessions)	> 9 months (≥ 36 sessions)
WOMAC Index				
Physical Function	-1.05 (11.08)	-2.73 (7.01)	-2.29 (8.69)	-7.97 (7.39)
Pain	0.14 (4.40)	-1.31 (2.30)	-1.50 (3.96)	-1.87 (3.22)
Stiffness	-0.50 (2.10)	-0.19 (0.98)	-0.50 (1.83)	-0.94 (1.20)
SPF	1.08 (2.88)	-3.72 (4.76)	-0.28 (4.74)	-4.18 (5.99)

4.7 Feedback from the Study Participants

4.7.1 The exercise group

Fifty out of sixty-six 'Participant Opinion Survey' questionnaires were completed and returned (76%), with 27 people indicating that they were still participating in the water exercise class once (18) or twice (9) per week; 23 subjects were not continuing with the exercise class. Of those who stopped attending the exercise class, ten of them were taking part in other physical activities such as swimming, local age group activities and walking. However, 13 of them were not following any alternative exercise activities.

Reasons for not continuing with the water exercise are summarised in Table 4.27. Compared to the reasons given for dropping out six months ago (Figure 4.9), there were at least seven more people who were not continuing with the exercise classes because of the inconvenience of swimming pool location (i.e. tired of travelling long distance to the swimming pool). Other major barriers to continue with the exercise programme include physical illness/weakness, operation and family obligations.

Table 4.27 Reasons for dropping out of the water exercise classes (N = 23)

Category	Reasons	Number
Programme		
	Location not convenient	8
	Water temperature	6
	Pool facility	3
	Time not convenient	3
	Exercise activity	2
Medical		
	Illness	9
	Operations	7
Social		
	Family obligations	7
Individual		
	Lack of confidence with water	1
	Allergy to water	1
	Lack of benefits	1

Overall satisfaction with the water exercise class was high, with 47 out of 50 (94%) satisfied with the exercise class. High praise was given to the exercise instructors. Forty-eight out of 50 (96%) scoring the exercise instructors as "excellent", and only two people were not happy because of the change of instructors. Although some people complained about the pool facility in terms of its water temperature, location, changing space, access point and wet floor, 42 out of 50 (84%) were satisfied with the swimming pool as a venue.

The majority of participants (80%) thought that they had benefited from the exercise programme; two people were not sure about the benefits and another two people perceived no benefits from participation. As can be seen from Table 4.28, the most significant perceived benefits/rewards for participating in the exercise programme was social. Ninety-eight percent of participants had benefited from meeting new people with the same condition (osteoarthritis) and maintaining friendships. In addition, the sense of self-achievement through being able to exercise again also played an important part in motivating some to exercise. These psycho-social rewards increased in priority to the extent that the physical benefits of the exercise element became less significant.

Table 4.28. Perceived benefits from the exercise programme (N = 40)

Category	Benefits	Number
Psychological		
	Self-achievement (e.g. be able to exercise again)	36
	Cheer them up	33
	Reduced the stress	26
	Increase self-confidence	23
	Increase self-independence	19
Social		
	Meet people with the same condition, make new friends	39
Physical		
	Reduce pain	28
	Increase mobility	30

Forty-two out of 50 participants (84%) thought the community-based water exercise programme was a good public health initiative for people with OA. The sorts of suggestions given fell into;

Exercise activity

- "The exercise activities need to be tailored to each person ."
- "Don't mix fit and unfit people in the same group."
- "Numbers of participants for each class should be less than 30 people."
- "Recruit more men to cheer the ladies up!"
- "Need more exercise classes at more convenient time."

Swimming Pool facility

- "Prefer the water to be warmer."
- "Access down the vertical steps was too steep and very difficult for very big size ladies."
- "Floor around pool is very slippery."
- "Changing facilities are too small for big ladies."
- "Lockers were difficult to use for people with OA in the hands."
- "Steps need to have a hand rail for disabled people."
- "It is better to have exercise classes in local swimming pools or in the city centre "

4.7.2 The control group

No changes in medication or level of physical activity were reported from the telephone interviews. Qualitative information gathering from the face to face interviews with control subjects in their one year evaluation revealed the following:

How helpful were these health education materials in the self-management of OA?

Thirty out of thirty-five patients thought that these health education materials were helpful in terms of understanding the development of OA (14), giving hints and advice on living with OA (10), offering guidance on diet and exercise (5), and providing information on organisations that offer further help (2). Three patients thought, however, that only surgical treatments can ease their pain of OA. Finally, two patients were not sure about the effects of these health education materials.

What types of physical activities/exercise did participants do and how frequently did they do it in a typical week over the past year?

Approximately 34% of patients in the control group took part in some form of moderate level physical activity (activities which made you breath a bit harder, or made you feel warm) for at least 30 minutes per time during a typical week in the past year. These physical activities included gardening (4), easy swimming (3), heavy housework (3), social dancing (2), golf (2) and cycling on a stationary bike (1). In addition, seventeen patients reported that they walked at normal pace for about a mile when the weather was fine. None of these physical activities were performed more than once a week for twenty minutes or longer. Finally, five subjects reported that they were too weak to do even a light level of physical activity due to illness and physical disability

What kind of information related to OA would participants like to receive?

Ten patients in the control group would like to know more about diet and OA. In particular, they would like to receive professional advice on weight control or participate in weight management programme. Eight patients would like to know about exercise opportunities in their local areas. Finally, five people expressed a strong desire to find out about new medical treatments (pharmaceutical or surgical) of knee/hip OA.

CHAPTER FIVE

DISCUSSION

5.1 Subject Recruitment

It is challenging work to recruit sedentary older patients with chronic conditions such as OA from the general community (Spencer et al., 1998). Previous studies indicated that advertisements in the local newspaper are one of the most effective strategies for reaching older adults at the community level (Anderson et al., 1995; Stead et al., 1997). The use of newspaper advertisements in this study has been shown to be a successful approach to recruit sufficient numbers of patients. The enrolment ratio for this study was near 53% for both the water exercise group and the control group (final number recruited as percentage of total enquiries). Compared with prior RCT studies that recruited OA patients from the general community and achieved enrolment rates of about 10% (Ettinger et al., 1997) and 24% (Spencer et al., 1998), this study required a relatively small sample of participants. It should be noted, however, that this study had more liberal eligibility criteria (i.e. no commitments to the one year study period, no strict clinical examination) than the two studies mentioned above. In addition, this study was designed to allow patients to receive their preferred treatment, which may also contribute to the higher rate of enrolment.

The uptake rate of the exercise programme was significantly higher for female patients than in their male counterparts. The present study revealed that most male nonparticipants mentioned lack of interest in mixed-sex style exercise as a barrier to enrolling in the exercise class. This may correspond to the literature indicating that older women would attend exercise classes for social interaction (Shephard, 1994), while special encouragement or strategies (e.g. wife accompanying in exercise programme) might be needed for attracting older men into the exercise programmes (Dunn, 1996).

5.2 Baseline Measures

5.2.1 Demographic variables and anthropometric measures

The distributions of values of BMI classification showed that many in both the exercise group and the control group were overweight or obese. Comparisons with other studies support the finding that obesity is common in patients with lower limb OA. Other research has classified both men and women with a BMI > 30 as obese. Using this criterion, approximately 40.9% of those in the exercise group and 40% of those in the control group were classified as 'obese'. Data is available from the Fitness and Arthritis in Seniors Trial (Ettinger et al., 1997) where over 50% of study subjects were classified as 'obese' (BMI > 30 kg/m^2).

More than one third of participants in both the exercise and control groups had at least one kind of chronic illness, which is consistent with the findings of previous research indicating that many people with OA also have comorbidities (Ettinger et al., 1997). The existence of these comorbid medical illnesses may result in the decrease of patients' aerobic capacity thus increasing the degree of their physical disability from OA (Ettinger & Afable, 1994).

5.2.2 WOMAC OA Index

The mean scores for each dimension of the WOMAC OA index obtained in this investigation were close to values obtained by Brazier and colleagues (1999), who reported a mean physical function score of 2.0, a pain score of 2.0 and a stiffness score of 2.3 using the WOMAC questionnaire on 105 rheumatology clinic patients with a primary diagnosis of OA. No significant 'floor' or 'ceiling' effects were found, indicating a potential sensitivity in detecting any improvement or deterioration over a period of time. In addition, the majority of patients in this study perceived their difficulty of performing daily physical activities, and their severity of pain and stiffness as 'moderate' to 'severe', which were similar to those perceived by most of the OA outpatients living in the community.

5.2.3 Reliability and validity of the battery of physical function tests

The battery of physical function tests employed here showed an acceptable test-retest reliability (ICC of all tasks ≥ 0.80) and internal consistency (Cronbach's alpha ≥ 0.80). Upon closer examination of the reliability data, the hip flexibility test and the quadriceps strength test had great variations between repeated measurements which may be a consequence of the measurement errors and/or the small sample size. For the quadriceps strength test, the testing position and the muscle fatigue engendered during the tests may have contributed to this variability.

The correlation between the performance of walking and chair rise ($r_s = 0.44$) was close to the value ($r_s = 0.48$) reported by Guralnik and associates (1994), using the same protocol. In addition, the strength of the association between chair rise and stair climbing ($r_s > 0.57$) was similar to that found in patients with end-stage renal disease ($r_s > 0.56$) (Bohannon, 1995). Decreased ROM of knee and/or hip joints was shown to be strongly associated with decreased walking speed, and also with prolonged time in ascending/descending stairs and in chair rising. These findings are not surprising in that these basic activities of daily living require the minimum amount of knee and hip ROM (Minor, 1994). Moreover, results of this study supported the findings of past studies reporting that chair-rise performance correlated significantly with lower extremity muscle strength (Newcomer et al., 1993; Rikli & Jones, 1999). The correlation between quadriceps muscle strength and the chair rise indicates the importance of good muscle function in the lower extremity for this activity. Subjects with low strength in the quadriceps probably compensate by using their arms in daily life.

5.2.4 Physical function tests

The battery of physical function tests administered in this study was selected specifically to assess mobility, joint flexibility and lower body strength of older people with lower limb OA. It is recognised that significant "floor" or "ceiling" effects (> 10% of response) might influence the test's ability to monitor the deterioration or improvement of functional capacity over a period of time. Approximately 24% of the 106 patients in this study could not complete the chair rise. Therefore, its ability to detect deterioration of lower body strength among older patients with knee/hip OA was limited. The repeat chair rise test (or sit-to-stand test) is a commonly used field test for assessing lower body strength in older adults. The performance of this test requires a person to tolerate a relatively high degree of mechanical loads and stresses (Pai et al., 1994). Individuals who are very frail, or who have lower limb joint disease may not be able to complete the prescribed number of repetitions (Bohannon, 1995). However, some researchers suggest that counting the number of full stands completed over a period of time may be more appropriate than measuring times taken to complete the test (Rikli & Jones, 1999). As the major barrier preventing patients with lower limb OA from completing the chair rise task is pain in/around the affected joints, the applicability of the modified chair rise test (the number of repetitions completed in a given period of time) to this specific population needs further examination.

Research has demonstrated that physical function tests contain potential risks. The eight foot walk and the stair climbing could potentially have led to falls (Guralnik et al., 1994), the repeat chair rise task could have caused some muscle injury, and the quadriceps strength task could have led to the risk of extremely high blood pressure (Fisher et al., 1993). However, in practice the battery of physical function tests was found to be safe, practical and relatively easy to administer. A few minor incidents (pain and cramps) occurred during the administration of the tests but no serious injuries were encountered and the general patient compliance was high. Before testing, a standardised warm-up with stretching activities using the muscle to be tested might be helpful for the prevention of test-related injury in future studies.

Results from the present investigation were consistent with the previous studies reporting that patients with knee/hip OA had limited range of motion in affected joints (Ettinger & Afable, 1994), reduced knee extension strength (Slemenda et al., 1997) and prolonged time in performing the chair rise tests (Pai et al., 1994). Approximately 84% of participants had limited range of motion of the knee joint, and 87% of them were limited in their range of motion of the hip joint, when compared to the published norms (Roach & Miles, 1991). The quadriceps muscle strength was significantly lower in 88% of the participants than that in the age- and sex- matched norms (Fisher et al., 1990). Moreover, 67% of participants needed more time to complete the chair rise test than age- matched norm (Guralnik et al., 1994).

Results of the eight foot walking time were above normal in the present study when compared to other published studies. Approximately 90% of the participants were faster in completing the eight foot walk test than Guralnik's subjects (Guralnik et al., 1994). A possible reason for this result could be that the participants in the study were younger (age ≥ 60 yr.) than Guralnik's population (age ≥ 71 yr.), and the performance of eight foot walk has been shown to decline significantly with increasing age (Guralnik et al., 1994). Finally, it is hard to make comparisons between performance in the stair climbing task and results in other studies because of the different testing protocols and equipment being used. Nevertheless, difficulties in performing the stair climbing (pain accompanying the movements) and changes in the normal pattern of movements (descending stairs backwards or sideways) were observed in some extremely disabled people.

5.2.5 AIMS 2 questionnaire

The mean scores for each dimension of the AIMS 2 questionnaire obtained in the baseline investigation for the 106 patients were higher than values obtained by Meenan and colleagues (1992), who reported a mean social activities score of 4.88, a support from family and friends score of 1.83, a level of tension score of 4.19 and a mood score of 2.48 using the AIMS 2 questionnaire on 109 patients with OA. One dimension of the AIMS 2 instrument, Support from family and friends, demonstrated significant 'ceiling' effects in both the exercise and control groups, thus its ability to detect changes over a period of time may be limited.

5.2.6 Comparisons of baseline differences between the exercise and the control groups

After matching, the exercise and the control groups were comparable in terms of age and self-perceived physical disability (WOMAC OA index). In addition, there were no significant differences in any of the demographic, anthropometric, physical function and health status parameters, except the dimension of the 'support from family and friends' of the AIMS 2 instrument. Participants in the exercise group demonstrated better scores in the dimension of 'support from family and friends' than the control group ($P < 0.05$). It should be noted, however, that the 'support from family and friends' dimension was not the main outcome measure and its sensibility to changes was questionable due to the significant 'ceiling effects'. In addition, there was no statistically significant association between the dimension of 'support from family and friends' and any of the physical function measures but a low association ($r_s = -0.20$) with the WOMAC pain scale. Thus, this baseline difference should not have great influences on the treatment effects and could be adjusted by ANCOVA

5.3 Correlation between the Battery of Physical Function Tests and the Health Status Questionnaires

5.3.1 The battery of physical function tests and the WOMAC OA Index

The physical performance measures employed in this research were not selected to examine objectively the same tasks as assessed by the WOMAC OA Index. As expected, low to moderate correlation was found between the three performance tests and the dimensions of the WOMAC Index. These results are consistent with those reported by Rejeski et al. (1995), who studied 440 people with knee OA, and found that self-reported disability from a functional performance questionnaire correlated with measures of physical performance at a low to moderate level. In a recent study, Finch et al. (1998) reported that the WOMAC scores were moderately correlated with self-paced walking speed ($r = -0.53$ to -0.65) and stair performance time ($r = 0.68$ to 0.73) in 15 men who had total knee arthroplasty (TKA) twelve months previously. However, there were no significant associations (P values ≥ 0.05) found in 14 women who had TKA, when the same tests were used.

Estimates of the range of motion of joints are difficult to obtain without a clinical examination. McGrory et al. (1996) examined the correlation of measured range of hip motion and response to the WOMAC Index in 28 patients who had total hip arthroplasty a year before the study. They found that the WOMAC pain and stiffness scores did not correlate with range of motion of hip joints, and the WOMAC physical function score correlated significantly only with the hip flexion ($r = 0.42$). Our investigation demonstrates a similar association between the WOMAC physical function score and the joint flexibility tests. In contrast to previous studies, a low correlation was observed between the WOMAC stiffness dimension and the flexibility tests. Joint stiffness increases with age due to diminished flexibility of the connective tissue and with OA and other musculoskeletal disorders.

Considerable attention has recently been focused on the relation between the quadriceps strength and knee pain and physical disability. Slemenda and colleagues (1997) suggested that quadriceps weakness is a primary risk factor for knee pain and disability in those suffering from OA. O'Reilly et al. (1998) reported that quadriceps strength is strongly associated with knee pain and disability (assessed by WOMAC Index) in an older population recruited from the community. A relatively lower correlation was observed between the quadriceps strength and the WOMAC pain scores, and between the quadriceps strength and the WOMAC physical function scores in the present study. This discrepancy may, in part, be explained by the slightly different method of strength assessment, the sample being studied (all older patients), the various diagnoses of the present cohort, and the pain and muscle fatigue generated during the strength testing which could influence the performance of quadriceps strength.

Spearman's Rank correlation coefficient with the summary physical function score (SPF) and the three dimensions of the WOMAC Index ranged from 0.44 to 0.61. Factors that might explain the discordance between the SPF and the self-reported measures may include inaccuracies in reporting, measurement errors (Guralnik et al., 1994) and the constantly fluctuating symptomatology of OA (Bellamy, 1993). These physical function measures are objective assessments of functional limitations, while the health status measures will reflect patient's perceived disability, and thus a perfect correlation would not be expected. In addition, some subjects may perform relatively well on the physical function tests because of their desire to please the researcher but self-report relatively poor functioning in their daily activities, or vice versa. Thus, the physical function test battery on its own would not be recommended as a "gold standard" in characterising disability, but rather, in conjunction with an appropriate disease-specific health status questionnaire.

Results from the present investigation demonstrate that there is some association between the physical function tests and the WOMAC OA Index. It should be noted, however, that this study is not a validation of these physical function tests but a study of their correlation to the WOMAC Index. A more thorough examination of the construct and convergent validity of the physical function test battery is needed.

5.3.2 The battery of physical function test and the AIMS 2 scales

The association between psychosocial factors (i.e. depression, anxiety, social interaction) and pain and functional impairment has been described previously in a hospital referred outpatient sample (Summers et al., 1988) and in a community sample (Hopman-Rock et al., 1996) with knee and/or hip OA. While the strength of associations was weaker in the present study, the results showed that subjects with more pain in the knee and/or hip had higher level of tension and perceived less support from family and friends; and patients who perceived higher physical disability, also reported higher level of tension and disturbance of mood. Conversely, subjects who reported more social activities tended to have less physical limitations, in that a low association was observed between the social activity dimension and the scores of the summary physical function.

5.4 Intervention

5.4.1 Drop out

The benefits from the exercise activity are initially obtained and subsequently retained only if individuals maintain appropriate exercise habits over the long term (American College of Sports Medicine, 1990). In a four-month muscle rehabilitation programme for OA patients, Fisher et al. (1991) reported that significant improvements in muscle strength and functional performance were sustained at four months, but declined at eight months after the programme. However, exercise requiring sustained effort over a long period is often associated with a high dropout rate. It has been reported that about 50% of the individuals who begin an exercise programme discontinue it within the first 6 months (Robison & Roger 1994) and there is a further decline to about 25% at the end of one year (Minor et al., 1989). The dropout rate over the one year period for this community-based study (38%), however, was better than that reported above. The possible reasons for this result could be that: 1) the water exercise class was specially designed for patients with knee and/or hip OA; 2) the exercise classes were run by instructors trained in teaching such programmes for the elderly; 3) the exercise class will continue to exist after the intervention has ended, thus participants can continue their exercise activities; and 4) the telephone follow-up, letter reinforcements and rewards provided motivational incentives to the participants.

On the other hand, the results showed that the control group had a better retention rate (97.5%) than the exercise group (64%). These findings are not surprising in that there was no time commitment for the control group; there were no transport problems for the control group to worry about and, most importantly, the control group received free health education materials on a regular basis.

5.4.2 Determinants of exercise maintenance

Results of the present study showed that perceived barriers to exercise played a predominant role in determining exercise maintenance for patients with knee/hip OA receiving structured water exercise treatment. These findings are in accord with those reported for patients with coronary heart disease (Robertson & Keller, 1994), but are contrary to those reported for other arthritic patients where weak or no association was found between perceived barriers and exercise participation (Neuberger et al., 1994; Gecht et al., 1996). When the exercise project was finished, the influence of these perceived barriers to exercise seemed to be more significant (Table 4.27). Although the structured exercise classes and peer support from other participants may have acted as incentives for continued participation, the perceived barriers to exercise may have had more weight than these perceived benefits and some participants might, therefore, have relapsed at the end of the programmes.

Consistent with results from other research on individuals with OA (Minor et al., 1989; Ettinger et al., 1997), the study participants who dropped out of the exercise programmes were not significantly different from those who remained, in terms of age, disease duration, physical disability scores, joint pain, or psychosocial health measures. Some previous research on determinants of exercise has suggested that those with greater body weight and body fat tended to drop out more from exercise programmes (Robison & Roger, 1994). However, there was no such relationship in the present study. Finally, an atypical finding of the study was that a great number of those who had other comorbid illness remained in the exercise programme compared with the number who dropped out. It appears that having other chronic conditions did not discourage subjects from continuing with the exercise class.

5.4.3 Injury/Accidents

The water exercise programme in this study was designed to be safe, easy to follow and make progress in, and modifiable for the OA study population. In general, the exercise was well tolerated and most participants could follow the instructions without difficulty. It should be noted, however, that about 9% of participants in the exercise group had minor accidents related to participation in the exercise programme. Many elderly with lower limb OA have problems in mobility, balance and co-ordination which put them at high risk of falling. Unfortunately, the pool setting selected for this programme has its own limitation and risks for any group of users, such as slipping on the pool deck, problems with getting into and out of the pool, etc. Although accidents are inevitable, and however well the pool is designed and constructed, they will occur, it is the responsibility of the researchers to make every effort to prevent and minimise the occurrence of accidents. Safety management strategies may include: 1) having sign posted at the entrance to locker rooms and in the pool area about the slippery floors; 2) provision of close monitoring before, during and after the exercise from the exercise facilitator and lifeguards; 3) advising participants to wear aqua shoes to prevent them from slipping; 4) providing health education about the prevention of exercise related injury and pool safety; 5) providing thorough orientation in order to review facilities and safety procedures prior to or during participants ' initial visit to the pool (Van Norman 1995; Koury 1996).

5.5 Comparisons of Pre/Post Measurements

5.5.1 Comparisons of baseline and one year WOMAC OA Index

A significant improvement in self-perceived physical function has been reported from previous studies on water-based exercise for patients with arthritis (Minor et al., 1989; Sylvester, 1989; Hall et al., 1996; Patrick et al., 2001). Consistent with previous findings, patients with knee/hip OA who participated in this community-based water exercise programme also reported significant reduction in self-perceived physical disability. In addition, the magnitude of change (3.66 units) is comparable to that reported from one home-based, randomised controlled study of daily strengthening exercise in knee OA patients (3.55 units), using the same WOMAC physical function scale (O'Reilly et al., 1999).

While some hospital-based exercise studies have documented significant pain relief in patients with arthritis following hydrotherapy treatments (Sylvester 1989; Hall et al., 1996), the few community-based water exercise programmes have reported only small, non-significant improvements (Patrick et al., 2001). A similar reduction in pain perception to this study (1.20 units) was documented in O'Reilly's strengthening exercise study (1.45 units), using the same WOMAC pain scale (O'Reilly et al., 1999). It should be noted however, that subjects in O'Reilly's study had average pain (6.45 ± 3.50 units) lower than those in the current study (10.02 ± 3.05units) at baseline, thus the magnitude of pain relief following this water exercise programme might be more clinically significant. Moreover, the results from the present study confirm previous findings that people with OA can perform aerobic exercise, either land-based or water-based, to improve their physical function, without experiencing exacerbation of their symptoms (Minor et al, 1989; Kovar et al, 1992; Ettinger et al, 1997).

The measurement of stiffness is considered to be both difficult and problematic (Bellamy & Buchanan, 1997). Thus this aspect of OA symptoms has rarely been reported as an outcome measurement in previous OA exercise studies. A trend towards reduction in perceived stiffness in the exercise group was apparent though the level of statistical significance reached was small. This may in part be due to a "placebo effect", as stiffness scores were also reduced in the control group, an effect that was apparent in other OA trials (O'Reilly et al., 1999).

5.5.2 Comparisons of baseline and one year physical function tests

Consistent with results from previous studies on OA patients (Messier et al, 2000), exercise treatment without specific dietary intervention resulted in only a small weight loss (0.7 Kg) in the present study. Although it is unknown how much weight loss is necessary to be of clinical benefit for OA patients, Felson and colleagues (1992) suggested that an average weight loss of 5.1 kg could result in a 50% decrease in the odds of developing knee OA 10 years later. As more than 40% of participants in the exercise group were obese, it is possible that the predominant factor of obesity might well influence the magnitude of treatment effects of the water exercise intervention.

Subjects who participated in this community-based water exercise programme showed significant improvements over control subjects in the physical performance tests of ascending and descending stairs. This finding is consistent with results from previous studies of aerobic or resistance exercise programmes in patients with knee OA (Ettinger et al., 1997). In addition, exercise participants also had significant gains in their ROM measures (i.e. 6.6 degrees in knee flexion and 5.3 degrees in hip flexion, left leg), which are comparable to previous water-based studies for patients with arthritis (Hall et al., 1996), and can be considered as clinically important (Falconer et al., 1992). These improvements in general mobility and joint flexibility are essential for the elderly to perform normal daily tasks (Rissel, 1987).

All subjects, both in the exercise and control groups, had significantly better performance in the chair rise test over the one year period, though the improvement was more marked in the exercise group. It should be noted that those subjects who could not complete the five times full chair rise were scored as "0", even those who managed four completions. Some subjects managed to complete one or two successful chair rises, despite being able to complete none at all at baseline. However, these small improvements were not shown in the change scores but may be clinically important. Moreover, some subjects in the control group may have increased their physical activities as a result of being recruited into the study and receiving the health education materials. These may all contribute to the small difference between the exercise and control group in performing the chair rise test.

One year of community-based water exercise programme had no significant effects on the measure of isometric quadriceps strength, although a small improvement (5.9%) was observed in the exercise group (right leg), compared to a reduction (6.8%) in the control group (right leg). Other researchers have shown that specific quadriceps strength training programmes result in between 14 and 49% significant gains in the quadriceps strength of OA patients (Fisher et al., 1991; Schilke et al., 1996). As a general water-based aerobic exercise programme, there were few specific quadriceps strengthening exercises (i.e. shallow knee squats, etc.) performed in the exercise class. Thus a significant improvement in the measure of quadriceps strength was less expected. In addition, this exercise programme was relatively low intensity and frequency. In general, higher -intensity training programmes lead to greater improvements in measures of muscle strength (Ettinger et al., 1997).

Decreased walking speed is common in patients with knee/hip OA, and increased walking speed following therapeutic interventions is generally considered a meaningful indicator of functional improvement (Minor, 1994). An unexpected finding in this study was that subjects in the exercise group took more time (0.11 sec) to walk the distance of eight feet than one year earlier, although there was more marked deterioration (0.57 sec) in the control group. No specific explanation for this result can be suggested at present.

A statistically significant change may or may not have clinical relevance. One approach to assess the clinical relevance of the results from the present investigation is to calculate the effect sizes. The effect sizes indicate that this water exercise intervention was associated with a small to moderate effect on self-reported physical disability, a small effect on pain relief, a small effect on general mobility, and a small effect on the flexibility of affected joints. These beneficial effects are comparable to previous randomised controlled exercise studies. A systematic review of available RCT in patients with OA of the hip or knee has documented small beneficial effects of exercise therapy on both clinical and self-reported disability outcome measures, and small-to-moderate beneficial effects on pain relief (Van Baar et al., 1999; Petrella, 2000).

5.5.3 Comparisons of physical function tests at baseline, six months and one year

In measurements of knee flexibility and chair rise, the improved performance found in the tests at the study mid-point in the exercisers was maintained at 12 months. The hip flexion measures showed significant improvement in the second half of the study year. Performance in stair ascending and descending tests showed a steady improvement over the one year period. Performances in quadriceps strength test, however, were improved after six months, but declined slightly at the one year test. Progressive functional decline in general mobility, flexibility and strength was reported to be associated with increasing age (Lord et al., 1995). It appears that the water exercise may help to reduce or delay age-related declines in some of these parameters. However, a non-exercise control group with the physical function tests done at the same measurement time is needed to support this assumption.

5.5.4 Comparisons of baseline and one year AIMS 2 results

One major argument about water-based exercise being a preferred mode of exercise for the elderly is that it is more enjoyable and socially therapeutic (Rissel, 1987; Sylvester, 1989). Previous studies have documented that arthritis patients reported improved psychological and social well-being from participating in water-based exercise (Minor et al., 1989; Sylvester, 1989; Hall et al., 1996). A trend towards reduction in perceived level of tension was observed in both the exercise and control groups with no significant differences between groups. The reduction in level of tension in the control group may be due to the receiving of health education materials. Previous studies have shown that the provision of health information can improve psychological health in OA patients (Weinberger et al., 1989). Another factor that may have influenced the present findings is that the exercise group had better scores in the level of tension at pre-test and thus had less potential for improvement.

5.6 Exercise Adherence

To improve or maintain fitness, exercise must be performed regularly and appropriate exercise habits must be maintained (Minor et al., 1989). As with other long-term studies of exercise interventions (Minor et al., 1989; Rejeski et al., 1997), a downtrend in adherence to the exercise classes across the duration of the trial was found in the present study. Also, the adherence rates for those who remained active in the exercise classes were similar to those reported for older participants with knee OA participating in aerobic exercise or resistance exercise in the same measurement period (Rejeski et al., 1997). These findings indicate the difficulty of getting people, especially the elderly who were previously sedentary as a result of chronic disease, to exercise regularly over a long term period (Rejeski et al., 1997). Strategies focused on relapse prevention (i.e. training that teaches patients how to cope with situations that lead to discontinuation of exercise activities and prevent a return to previous sedentary status) might help to maintain habitual exercise behaviour (Hillsdon et al., 1999).

Analysis of the level of adherence indicated that reduction in self-perceived physical function, pain and stiffness, and improvements in knee ROM were most marked in the most compliant subjects. The direct relationship between adherence to the exercise programmes and benefits in terms of reduced physical disability and pain are concordant with results from previous studies of aerobic or strengthening exercise programmes for patients with knee OA (Ettinger et al., 1997; O'Reilly et al., 1999). In addition, this finding supports the hypothesis that the decrease in exercise adherence over time may contribute to the small differences between the exercise and control groups, as observed with the 'intention to treat analysis'. It should be noted, however, that the exact dose-response relationship between frequency, intensity and duration of exercise and improvement in physical function and pain for patients with OA is not clear. This merits future studies to better define an exercise protocol that may have the potential for a public health intervention.

5.7 Feedback from the Study Participants

5.7.1 Exercise group

About 40% of the original participants in the exercise group still participated in the water exercise classes once or twice per week, six months after the end of the project. For those who discontinued with the water exercise classes, approximately 40% have started other forms of exercise activities. These figures may indicate that exercise behaviour has been well maintained in half of the participants who were non-exercisers before intervention. In addition, as patients are not likely to continue water exercise throughout their lifetime, it may be more important that they can develop the exercise habits and find the appropriate exercise activities for their own health.

Previous studies have suggested that exercise programmes improve self-efficacy and enhance social support (Ettinger et al., 1997). These psychosocial variables might well influence the individual's coping strategy and play as important roles as disease and pain in determining quality of life of OA patients. Results from the participants' opinion survey revealed that the vast majority of participants experienced an enhancement of physical, psychological and social well-being following the water exercise programme. In particular, participants valued the social and psychological benefits, such as the increase in social contact and self-achievement, as the major rewards. These results confirm findings from previous qualitative studies that older people participated in exercise activities because they enjoyed the regular social contact and felt better about themselves as a result of exercise participation (Stead et al., 1997). However, these results are in contrast to our findings that no significant improvements in the psychosocial aspects of health (measured by the AIMS 2 questionnaire) were found within the exercise group after one year of intervention. The discrepancy between the patients' appreciation of the exercise class and our inability to measure it, indicates the difficulty in studying the influence of exercise interventions on the complicated psychosocial aspects of health. The quantitative instrument used in the present study may be too crude to capture the psychosocial issues that most concern OA participants.

To the extent that the qualitative survey was valid, it suggests that the community-based water exercise programme may be an effective health promotion activity for older patients with OA. To keep the exercise programme of this nature operating on a regular basis and make it more accessible and affordable to the general public, a partnership set up between the local leisure authority, health authority and health care professionals is necessary. Exercise referral schemes have become popular in many General Practices throughout Britain. Such schemes fit well into the Government's new agenda for health improvement, and provide an opportunity to address inequalities in health care, disease prevention and quality of life. At the same time, exercise referral schemes also give the leisure industry an opportunity to provide their service to a wider region of the community and maximise their profits. However, the elderly are not the targeted customers for the leisure industry because of the relatively lower profits generated from those senior exercise classes. Water-based exercise for patients with lower limb OA could be incorporated into the exercise referral schemes where partnership between health and leisure/water facility providers is established. A General Practitioner or practice nurse could refer patients to appropriate centres offering water-exercise programmes. The local health authority or the General Medical Practitioners may be able to subsidise some of the operation fees. This may thus encourage more leisure centres to deliver exercise classes tailored for the need of the elderly and offer more exercise sessions in convenient time. Recently published guidelines for exercise referral schemes have been published with the aim of improving standards among existing schemes and helping in the development of new ones (Department of Health, 2001). The community-based water exercise programme can be considered on a sliding scale, from hydrotherapy to general water exercise to land-based exercise, thus allowing patients to find their own level of physical activity with potential for progression (Rissel, 1987).

5.7.2 Control group

The major purpose of provision of health education materials to the control group was to motivate their continued participation in the study. Researchers have suggested that if patients with chronic illness are better informed about their disease, its treatment and its prognosis, they will be better able to manage their illness (Superio-Calbuslay et al., 1996). Responses from participants' feedback indicated that the majority of participants thought these health education materials were helpful in the self-management of OA. As expected, the educational strategies that only provided information had little effect on changing individual's exercise behaviour. Though these health education materials recommended exercise as an effective approach to cope with OA, it seemed that some behavioural strategies might be needed to motivate sedentary elderly to become more physically active. But that is beyond the scope of the current discussion.

5.8 Methodological Issues and Limitation of the Study

5.8.1 Study design and subject recruitment

The randomised controlled trial (RCT) is seen by many as the "gold standard" for evaluating health interventions. The main strength of the RCT is its potential for reducing selection bias. This research design allocates the participants on a random basis in that all participants have the same opportunity of being assigned to each of the study groups. If the randomisation is done properly, the characteristics of the participants are likely to be similar across groups at baseline. Thus the researchers might be more able to isolate and quantify the effects of the interventions they are studying, and control for other unknown but important factors that could influence the outcomes of the study. No other study design allows researchers to adjust these unknown factors at baseline (Jadad, 1998). However, there are some situations in which the RCT are unnecessary, inappropriate, impossible and inadequate to help solve important health problems (Black, 1996). A recognised difficulty in employing A recognised difficulty in employing randomised controlled trials in studies of therapeutic interventions is that patients have strong preferences for a particular treatment. A potential source of selection bias may arise when some eligible patients refuse randomisation and thus the recruited participants are not representative. A further potential selection bias exists when those who receive the non-preferred treatment feel disappointed. A "resentful demoralisation" may occur within those disappointed patients (Torgerson et al., 1996) in which they may be less motivated to comply with the allocated treatment or tend to drop out in the early stages. In clinical practice one can hardly train patients other than those who are interested in attending a certain programme (Stenström et al., 1991).). In this study, a quasi-experimental, matched-control group design was used. A major strength of this design is its suitability for use in a natural setting (where participants were allowed to receive their preferred treatment). Provided that initial comparability is established, this design is considered to be as rigorous as the before-and-after RCT (Reid, 1993). However, the fact that the matched-pairs do not differ on the selected characteristics at baseline does not mean that they are not different on any unknown confounding factors which may affect the outcomes of the research. Thus, this study complements rather than replaces the randomised controlled trials in that it may provide more pragmatic estimates of the impact of treatments in real practice.

Patients volunteering for the study were asked to provide X-ray evidence or written confirmation from their GP, rheumatologist or orthopaedic surgeon. Radiographs were obtained on 40 out of the 66 subjects in the exercise group and 26 out of the 40 subjects in the control group. These radiographs were not further examined by qualified rheumatologists because of limited research funding. All subjects had written confirmed diagnosis of OA from their GP. The exact method of clinical diagnosis was not recorded (i.e. whether from radiological evidence or clinical examination or both). It was assumed that the GP involved was competent in diagnosing OA. However, some patients with other forms of muscular or joint disorders might have clinical symptoms similar to knee or hip OA (Hochberg et al, 1995 a,b), and might be misdiagnosed as suffering from OA. Future studies selecting patients on the basis of GP clinical judgement will need to collect more information about the exact method of diagnosis (e.g. radiographic ratings, presence of physical signs, etc.) from the participating GP.

It was not feasible to bring control patients to certain groups to provide some sort of social support during the one year period. Instead, the researchers provided the control patients with quarterly telephone contacts and seasonal greeting cards to compensate. However, the weekly group-style water exercise may provide some kind of social support which itself improved the physical and psychological health of the participants. It is possible that water exercise alone would not have produced the same improvements that were observed in the study. Previous studies have shown the beneficial effect of social support in patients with arthritis (Kovar et. al, 1992). Therefore, the importance of the psychosocial benefit derived from the informal supportive group format of the exercise programme should not be underestimated.

Another inherent limitation in a study of this type is that the subjects in the exercise group cannot be "blinded" to their "treatment" condition. Thus, the participants in the exercise group were aware that they were receiving the intervention, and it is possible that part of the improvement at retest in this group may have been caused by increased motivation and effort expended in performing outcome tests.

5.8.2 Water exercise programme

The intention of the study was to set up a progressive water exercise programme allowing older patients with knee or hip OA to gradually improve their functional status. In practice, most participants adapted progressively to the training demands but some less-fit participants did not. It will be ideal to have two separate exercise classes for both fit and less fit patients. However, this planning was not feasible because of the limitation of available exercise sessions at the time of investigation. The exercise adherence rate might be higher than it was, if participants could work on their own level of fitness.

It is a challenging task to find a community-based pool that offers a comfortable water temperature for patients with arthritis. Many public pools cater for lap swimmers who prefer a temperature ranging from 82 to 85 degrees F (27.8 to 29.4 degrees C), which is not warm enough for some arthritis patients. The only available swimming pool at the time of investigation had the water temperature close to 29 degrees C, which had caused discomfort and stiffness in some participants during or after the exercise classes. Because of limited research funding and the practicalities of doing so, the swimming centre was not able to raise the water temperature. Alternatively, the exercise facilitators adjusted the exercise activities by instructing more vigorous warm-up exercises such as water-walking forwards, sideways, and backwards which seemed to help some participants work better at that temperature. Another operational problem may arise because many community-based swimming pools are not designed to cater for the needs of disabled people. Several participants in the exercise classes had trouble in getting in and out of the swimming pool. Thus exercise facilitators had to stand in the pool side to assist participants with entry and exit. Future practice may consider adding portable ramps and stainless handrails to facilitate entry and exit for disabled OA patients (Koury, 1996).

The direct cost of the water-exercise intervention per session was £15 for the exercise facilitator and £40 for the pool hire. Patients paid £1.05 for each exercise session attended and the transportation fee (£1.20 - 2.50 by public transport). The average attendance per session was 35 patients. No other costs were analysed as it was not the intention of the study to examine cost-effectiveness. No other health economic data was collected, therefore comparisons with the cost-effectiveness of water exercise and other pharmaceutical interventions has not been discussed.

5.8.3 Outcome measurement

It was not possible to "blind" the project investigator who conducted all outcome assessments and assisted the water exercise class. Although this constitutes a bias of this study, this limitation does not compromise the validity of the results. The perceived health status measures of the WOMAC and AIMS 2 were self-administered by the patients and thus were relatively uninfluenced by the individual conducting the assessments.

Previous studies have found no significant differences in the effectiveness of exercise therapy between knee and hip OA patients (Minor et al., 1989; Van Baar et al., 1998). The effectiveness of water exercise in patients with OA of the knee(s) and patients with OA of the hip(s) can not be analysed separately because of the small sample size of hip OA only patients in the control group (N = 4). Nevertheless, most of the objective physical outcome measurements (i.e. walking, stair climbing, chair rise and quadriceps strength tests) employed in the present study are mainly used for testing knee function and may not be suitable for measuring outcome effects of exercise therapy in patients with hip OA. This drawback, however, may be compensated for by the use of the WOMAC OA Index. This test has been shown to be a reliable and valid multidimensional outcome measure for evaluation of patients with OA of the hip or knee (Bellamy et al., 1988). Increasing usage of the WOMAC OA Index in the evaluation of therapeutic interventions in hip or knee OA patients has often been reported in the arthritis literature (McGrory et al., 1996; O'Reilly et al., 1998; Deyle et al., 2000; Peloso et al., 2000).

The walking test is the most frequently used outcome parameter for observing disability in arthritic and geriatric studies (Guralnik et al., 1994; Van Baar et al, 1998; Rikli & Jones, 1999; Petrella, 2000). The eight-foot walking test employed in the present study has been shown in some studies to be a valid performance measure which can be used to characterise older people across a broad spectrum of lower extremity function. It is a practical task which can be administered in the home setting (Guralnik et al., 1994). However, results from the present investigation indicate that the eight-foot walking test may not be appropriate for the detection of functional change in response to the exercise intervention in a group of older patients with knee and/or hip OA, when measurements are spaced a long time apart (one year). Other walking tests frequently used in assessing the functional capacity of patients with knee/hip OA included the 50-foot-walking test (Minor et al, 1988) and the six-minute walking distance test (Kovar et al, 1992; Ettinger et al, 1997; Deyle et al., 2000). The 50-foot-walking test is a recommended functional performance test for arthritis patients (Bellamy 1993). However, a lack of responsiveness to intervention was found in some OA exercise trials (Schilke et al, 1996). In Minor's study of aerobic conditioning exercise for patients with knee/hip OA, the actual change in the 50-foot walk time was just over 1 second (Minor et al., 1988). Some researchers suggested that the 50-foot walking test may be a useful outcome measure in assessing functional performance but the test is insensitive in measuring disease activity in arthritis because it may not be affected significantly by the disease (Spiegel et al, 1987; Fisher et al, 1991). The six-minute test of walking distance (Guytt et al., 1985) has been demonstrated to be a reliable measure of aerobic endurance (Rikli & Jones, 1999), and has been shown to have a moderate correlation with tests using a treadmill ergometer (Rejeski et al, 1995). This test can be considered to be a more relevant indicator of aerobic capacity than other high workload exercise tests (Kovar et al, 1992). However, one drawback is that this test requires a distance of at least 60-foot free from distractions and obstacles (Rikli & Jones, 1999), which might not be applicable in some clinical settings with limited space.

Despite these limitations, results from this study of a community-based water exercise programme can be considered as clinically relevant. These included improvements in self-reported physical disability and pain on the well established WOMAC OA index, as well as improvements on clinical measures of general mobility and joint flexibility. This conclusion may apply to elderly patients, especially elderly women, with mild to moderate knee or hip OA who are living in the community. However, these results may not be generalisable to patients with severe OA of knee and/or hip. One study comparing participants in community-based water exercise programmes with patients from a rheumatic disease clinic has suggested that most severely affected people attending arthritis clinics are underrepresented in community-based water exercise programmes (Meyer & Hawley, 1994).

5.9 Conclusions

The results of this study show that, over a 12 month period, elderly patients with knee/hip OA who participated in a community-based water exercise programme experienced small to moderate improvements in measures of self-perceived physical disability, pain, general mobility and flexibility, when compared with the control group. These findings provide empirical support for the hypothesis that a programme of supervised water exercise programme in the community-based swimming pool setting can be an important function-enhancing intervention in the clinical management of knee/hip OA. Moreover, these beneficial effects are comparable to those reported in other water-based or land-based exercise programmes for OA patients and are achieved without worsening pain or exacerbating arthritis-related symptoms.

The programme period of one year is relatively long compared to previously published studies of exercise trials among elderly patients with knee/hip OA. Thus, this study may offer a realistic picture of participation, attrition, adherence and health changes possible in a community setting. The high adoption rates and moderate adherence rates may indicate that exercise intervention of this nature could offer an effective public health initiative for the rehabilitation of OA patients, with potential for improving their quality of life.

Health promotion interventions are suggested, by some researchers, to be useful methods in reducing health care utilisation and thus, reducing overall health care expenditures (Sevick et al, 1999). It is not clear whether an exercise programme of this nature can reduce the medical costs in elderly patients with knee and/hip OA over the long term. Given that such a programme is likely to be effective, but costly, economic appraisals are necessary to convince cost-conscious policy-makers. Future studies are needed to evaluate the cost-effectiveness of the community-based water exercise programme.

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APPENDICES

SOUTH SHEFFIELD RESEARCH ETHICS COMMITTEE
Ethics Office: 8 Beech Hill Road
Tel & Fax No: (0114) 271 2394
E-mail: External: Kate.Khoaz@csuh-tr.trent.nhs.uk
Chairman: Dr P R Jackson
(Please quote the Ethics Reference No in your reply)

THE Central Sheffield University Hospitals
Glossop Road, Sheffield S10 2JF • Telephone 0114 271 1900

Ref: PRJ/IH

21 September 1998

Ms Y C Lin
Research Student
Institute of Sports Medicine & Exercise Science
University of Sheffield

Dear Ms Lin,

SS 98/177 - The efficacy of Water Exercises in Patients with Lower Limb Osteoarthritis

Thank you for your letter of 14 September 1998 answering the queries raised by the Ethics Committee and enclosing a revised information sheet.

I can now confirm Ethics Committee unreserved approval for the above study subject to the following terms and conditions.

1. It is understood that approval of the investigation does not absolve you from total responsibility for the safety and well-being of the subjects.
2. If any substantial change is made to the protocol it will be necessary for you to obtain approval from the Ethics Committee.
3. That should any untoward event occur during the conduct of the study the Chairman of the Committee or failing this the Administrator should be informed immediately.
4. Reports of progress shall be submitted at yearly intervals. A follow-up form will be sent to you annually to keep the Ethics Committee informed of the progress of the project.
5. The Ethics Committee is to be advised if the project has not commenced within six months.
6. No deviations from or changes of the protocol will be initiated without prior written approval of an appropriate amendment, except when necessary to eliminate immediate hazards to the subjects or when the change(s) involve only logistical or administrative aspects of the trial.
7. That you should promptly report any changes increasing the risk to subjects; adverse drug reactions or new information that may affect adversely the safety of the subjects or conduct of the trial.
8. That you familiarise yourself with the ICH Guidelines laid down for the conduct of human experiments.
9. The Ethics Committee is to be advised when the project is completed.

Yours sincerely

Peter Jackson
Chairman

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21/09/98

OSTEOARTHRITIS OF THE KNEE(S) AND/OR HIP(S)

VOLUNTEERS REQUIRED FOR A 12 MONTH RESEARCH STUDY

Are you over 60 years old,
have got osteoarthritis of the knee(s) and/or hip(s), and
are <u>not</u> currently participating in any exercise?

Researchers at the Sheffield Institute of Sports Medicine and Exercise Science, University of Sheffield are running a 12 month study examining the effects of water exercise on osteoarthritis of the knee(s) and/or hip(s).

Volunteers are required to participate in a weekly water-exercise class at Hillsborough Leisure Centre, Sheffield.

Subjects will be asked to visit the Physiotherapy Department at the Royal Hallamshire Hospital before the programme begins and at 6 and 12 months after starting the programme to have their knee and hip function assessed.

If you are interested in more information about the project or would like to volunteer, please contact Sophia Lin, The University of Sheffield, Tel: (0114) 2220985.

OSTEOARTHRITIS OF THE KNEE(S) AND/OR HIP(S)

VOLUNTEERS REQUIRED FOR A 12 MONTH RESEARCH STUDY

Are you over 60 years old,
have got osteoarthritis of the knee(s) and/or hip(s), and
are <u>not</u> currently participating in any exercise?

Researchers at the Sheffield Institute of Sports Medicine and Exercise Science, University of Sheffield are running a 12 month study examining the benefits of health education on osteoarthritis of the knee(s) and/or hip(s).

Volunteers will be sent information in the post with regard to exercise opportunity on local leisure centres and health clubs along with information on appropriate exercise, weight control, suggestions on how to cope with pain and advice on how to improve general mobility. A researcher will also contact you by telephone every three month to answer any questions or to help with any problems you may have

Subjects will be asked to visit the Physiotherapy Department at the Royal Hallamshire Hospital before the programme begins and at 6 and 12 months after starting the programme to have their knee and hip function assessed.

If you are interested in more information about the project or would like to volunteer, please contact Sophia Lin, Sheffield Institute of Sports Medicine and Exercise Science, The University of Sheffield, Tel: (0114) 2220985.

The University of Sheffield

SHEFFIELD

SISMES

Institute of Sports Medicine and Exercise Science

11th February 1998

«Title»
«Address1»
«City»
«PostalCode»

Water Exercise Programme for Osteoarthritis

Dear «Title»,

I am writing to thank you for taking an interest in our water exercise programme for people with osteoarthritis in the hip or knee. This water exercise programme is specially designed to improve your joint flexibility, muscle strength and help relieve pain. The exercise session will take place in the Hillsborough Leisure Centre on Fridays, from 1:15 to 2:30 p.m. Enclosed please find a research study information sheet explaining more details about the study.

To help us know more about your current health status, please fill in the enclosed questionnaire and send it back using the enclosed pre-stamped envelope. If you have any queries regarding this study, please feel free to contact Sophia at (0114) 2220985 or Dr. Davey at (0114) 2220983.

Thank you for your interest and co-operation.

Yours sincerely

Sophia Lin, MPH, PhD Research Student
Tel: (0114)2220985

Dr. Rachel Davey
Tel: (0114)2220983

The University of Sheffield
SHEFFIELD
SISMES
Institute of Sports Medicine and Exercise Science

16th March 1998

«Title»
«Address1»
«City»
«PostalCode»

Health Education Programme for Osteoarthritis

Dear «Title»,

I am writing to thank you for taking an interest in our health education programme for people with osteoarthritis in the hip or knee. This programme is designed to increase your self-management skills of Osteoarthritis. You will be sent 12 health leaflets throughout 1999, each one dealing with different topics. Enclosed please find a research study information sheet explaining more details about the study.

To help us know more about your current health status, please fill in the enclosed questionnaire and send it back using the enclosed pre-stamped envelope. If you have any queries regarding this study, please feel free to contact Sophia at (0114) 2220985 or Dr. Davey at (0114) 2220983.

Thank you for your interest and co-operation.

Yours sincerely

P.p.

Sophia Lin, MPH, PhD Research Student
Tel: (0114)2220985

Dr. Rachel Davey
Tel: (0114)2220983

Sheffield Institute of Sports Medicine and Exercise Science, University of Sheffield.

RESEARCH STUDY INFORMATION SHEET

Water exercise for patients with lower limb osteoarthritis

What is the purpose of this study?

Osteoarthritis (OA) of the knee(s) and/or hip(s) is a very common chronic joint disease which often causes pain and stiffness. With more severe OA, joint movement may be restricted, daily activities such as walking and climbing can become a major problem. This study aims to find out whether a community-based, water exercise programme can help reduce pain, increase joint mobility and muscle strength and enhance quality of life for patients with osteoarthritis of the knee(s) and/or hip(s).

What will be involved if I agree to take part in the study?

If you agree to participate in this study, we will ask you to take part in a 12 month, community-based, recreational water exercise programme. The water exercise programme will be run by specialist instructors twice a week. The price for the water exercise class per session is £1.05 and you have to bring your own towel and swimming costume. Exercise classes will consist of a warm-up (10 to 15 minutes), conditioning (40 to 50 minutes) and stretching phase (10 to 15 minutes). The class will last for about one hour and you will be asked to attend each week. The exercise sessions will be designed to improve your joint flexibility, muscle strength and help relieve pain.

What other information will be collected in the study?

A number of simple tests will be done before you begin the exercise programme, at 6 months, and at 12 months of the study to see if there are any changes in pain or joint function. These measurements will be done in the Sports Medicine Laboratory, in the Physiotherapy department on 'B' floor of the Royal Hallamshire Hospital. These tests will include walking a short distance, going up and down a few steps, getting up from a chair and sitting down and flexibility measures.

What information will the study yield?

Changes in the physical tests and your health will be measured before, during and after the exercise programme to determine whether the water exercise has any effect on your pain level, physical mobility and quality of life.

Where will the study take place?

You will be required to visit the Sports Medicine Laboratory on 'B' floor in the Royal Hallamshire Hospital at the beginning of the study, and at 6 and 12 months to complete some simple physical tests. The water exercise programme will take place in the Hillsborough Leisure centre on Fridays, from 1:15 to 2:30 p.m. each week.

Can I withdraw from the study at any time?

You are under no obligation to take part in this study and you may withdraw at any time. You will receive the same quality of care at the hospital whether you participate in the study or not.

Will the information obtained in the study be confidential?

All experimental data and information will be confidential and will be used only for the purpose of this study. No names will be mentioned in any reports and care will be taken so that individuals cannot be identified from details in reports of the study.

Can I ask further question about the study?

Yes. The information sheet is intended to give you the information about why this study is being done and what commitment will be asked of you. If you have any future questions then please ask the researchers who, will answer any queries you have.

What if I am harmed?

If you are harmed by your participation in this study, there are no *special* compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action.

What if I wish to complain about the way in which this study has been conducted?

If you have *any* cause of complain about *any* aspect of the way in which you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you and are not compromised in any way because you have taken part in a research study.

If you have any complaints or concerns please contact either the project co-ordinator:

Yu-Chen Lin
Tel: (0114) 2220985
Sheffield Institute of Sports Medicine and Exercise Science
23 Claremont Crescent
Sheffield S10 2TA

or Dr. Rachel Davey
Tel: (0114) 2220983
Sheffield Institute of Sports Medicine and Exercise Science
23 Claremont Crescent
Sheffield S10 2TA

Otherwise you can use the normal hospital complaints procedure and contact the following person:

Janet Wainwright (Patient Representative)
Department of Nursing
Royal Hallamshire Hospital
Glossop Road
Sheffield S10 2JF
Tel: (0114) 2712450

Sheffield Institute of Sports Medicine and Exercise Science, University of Sheffield

RESEARCH STUDY INFORMATION SHEET

Health education programme for patients with lower limb osteoarthritis

What is the purpose of this study?

Osteoarthritis (OA) of the knee(s) and/or hip(s) is a very common chronic joint disease which often causes pain and stiffness. With more severe OA, joint movement may be restricted, daily activities such as walking and climbing can become a major problem. This study aims to find out whether a specially designed patient education/information leaflet can help reduce pain, increase joint mobility and muscle strength and enhance quality of life for patients with osteoarthritis of the knee(s) and/or hip(s).

What will be involved if I agree to take part in the study?

If you agree to participate in this study, we will ask you to take part in a 12 month health education programme. A health education leaflet/booklet will be sent to you each month. The health education leaflet/booklets are specially designed and aimed at increasing the self-management skills of OA in the lower limb(s). We will contact you every three months by telephone to monitor any changes in circumstances which may affect the study, e.g. changes in health status, medicine, hospitalisation, lifestyle etc.

What other information will be collected in the study?

A number of simple tests will be done before you begin the health education programme and again in 12 months time to see if there are any changes in pain or joint function. These measurements will be done in the Sports Medicine Laboratory, in the Physiotherapy department on 'B' floor of the Royal Hallamshire Hospital. These tests will include walking a short distance, going up and down a few steps, getting up from a chair and sitting down and flexibility measures. This will take about 30 minutes. In addition, you will be asked to complete a questionnaire before your first visit and again after 12 months.

What information will the study yield?

Changes in the physical tests and your health will be measured before and after the programme.

What will the study take place?

You will be required to visit the Sports Medicine Laboratory on 'B' floor in the Royal Hallamshire Hospital at the beginning of the study and at 12 months to complete some simple physical tests.

Can I withdraw from the study at any time?

You are under no obligation to take part in this study and you may withdraw at any time. You will receive the same quality of care at the hospital whether you participate in the study or not.

Will the information obtained in the study be confidential?

All experimental data and information will be confidential and will be used only for the purpose of this study. No names will be mentioned in any reports and care will be taken so that individuals cannot be identified from details in reports of the study.

Can I ask further question about the study?

Yes. The information sheet is intended to give you the information about why this study is being done and what commitment will be asked of you. If you have any further questions then please ask the researchers who, will answer any queries you have.

What if I am harmed?

If you are harmed by your participation in this study, there are no *special* compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action.

What if I wish to complain about the way in which this study has been conducted?

If you have *any* cause of complain about *any* aspect of the way in which you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you and are not compromised in any way because you have taken part in a research study.

If you have any complaints or concerns please contact either the project co-ordinator:
Sophia Lin
Tel: (0114) 2220985
Sheffield Institute of Sports Medicine and Exercise Science
23 Claremont Crescent
Sheffield S10 2TA

or Dr. Rachel Davey
Tel: (0114) 2220983
Sheffield Institute of Sports Medicine and Exercise Science
23 Claremont Crescent
Sheffield S10 2TA

Otherwise you can use the normal hospital complaints procedure and contact the following person:
Janet Wainwright (Patient Representative)
Department of Nursing
Royal Hallamshire Hospital
Glossop Road
Sheffield S10 2JF
Tel: (0114) 2712450

RESEARCH CONSENT FORM	
TITLE OF PROJECT: Water exercise for patients with lower limb osteoarthritis	
Each subject should complete the whole of this sheet him/herself	Please circle YES or NO as approprtiate
Have you read the Research Study Information sheet?	YES/NO
Have you had an opportunity to ask questions and discuss this study?	YES/NO
Have you received satisfactory answers to all of your questions?	YES/NO
Have you received enough information about this study?	YES/NO
Who have you spoken to ? Dr/Mr/Mrs/Miss Do you understand that you are free to withdraw from the study: • at any time; • without having to give a reason for withdrawing; • and without affecting your future medical care.	YES/NO
Do you agree to take part in the study?	YES/NO
Signed	Date ....
Name: (in block capitals)	

RESEARCH CONSENT FORM	
TITLE OF PROJECT: Health education programme for patients with lower limb osteoarthritis	
Each subject should complete the whole of this sheet him/herself	Please circle YES or NO as approprtiate
Have you read the Research Study Information sheet?	YES/NO
Have you had an opportunity to ask questions and discuss this study?	YES/NO
Have you received satisfactory answers to all of your questions?	YES/NO
Have you received enough information about this study?	YES/NO
Who have you spoken to ? Dr/Mr/Mrs/Miss Do you understand that you are free to withdraw from the study: • at any time; • without having to give a reason for withdrawing; • and without affecting your future medical care.	YES/NO
Do you agree to take part in the study?	YES/NO
Signed	Date ....
Name: (in block capitals)	

NO:

SHEFFIELD INSTITUTE OF SPORTS MEDICINE AND EXERCISE SCIENCE

LOWER LIMB OSTEOARTHRITIS SUBJECTS SURVEYS

I. Please answer the following questions about yourself.

Age : ____________ years old
Sex : male ☐ female ☐

II. Please tick the appropriate boxes below to tell us about your osteoarthritis.

1. How do you know that you have osteoarthritis?

Diagnosed by my doctor	☐please go to Question 2
Showed at X-ray	☐please go to Question 2
Not sure about having osteoarthritis	☐Finish the questionnaire. Thank you for your help

2. How many **years** have you had osteoarthritis? ____________ years

3. Which part of your **joint**(s) is (are) affected by osteoarthritis?

Hip: right ☐ left ☐
Knee: right ☐ left ☐
Others: ______________________________ (please specify)

4. Do you currently take any **medication** for the **treatment of osteoarthritis** ?

Yes ☐ No ☐
If yes, which kind(s) of medication do you take and how often?
e.g. ibuprofen, twice every day

____

____

____

5. Have you had any **surgical treatment** (e.g., total hip replacement) for your osteoarthritis?

Yes ☐ No ☐
If yes, which kind(s) of surgery and when was your operation?

____

____

____

6. Are you on the waiting list for any surgical treatment for your osteoarthritis?

Yes ☐ No ☐
If yes, which kind of surgery is going to be done and when it may happen?

____

____

____

III. Please answer the following questions about your current physical activity.

1. Are you currently participating in any exercise activities?

Yes ☐ No ☐
If yes, which kind(s) of exercise are you doing and how often?
e.g. keep fit, 30 minutes a day, 3 times a week

____

____

____

IV. Please tick the appropriate boxes below to tell us about your health condition.

1. Is your health currently affected by any of the following medical problems other than osteoarthritis?

High blood pressure ☐
Heart problem ☐
Diabetes ☐
Lung problem ☐
Cancer ☐
Kidney problem ☐
Ulcer/Stomach problem ☐
Liver problem ☐
Anaemia/blood disease ☐
Others ______________________________________(please specify)

Thank you for your help

Please continue to fill in the attached questionnaire

CONFIDENTIAL

_ _ _

Date:

University of Sheffield

Sheffield Institute of Sports Medicine and Exercise Science

A study of the quality of life of people with lower limb osteoarthritis

Please send the completed questionnaire back using the pre-stamped envelope.

THANK YOU FOR YOUR HELP

WOMAC OSTEOARTHRITIS INDEX

A. PAIN:

The following questions concern the amount of pain you are experiencing now due to arthritis in your knee/ knees/hip/hips. For each situation please enter the amount of pain experienced now.

(Please mark your answers with a tick).

How much pain do you have?

1. Walking on a flat surface:

   None ☐ *Mild* ☐ *Moderate* ☐ *Severe* ☐ *Extreme* ☐

2. Going up or down stairs:

   None ☐ *Mild* ☐ *Moderate* ☐ *Severe* ☐ *Extreme* ☐

3. At night while in bed:

   None ☐ *Mild* ☐ *Moderate* ☐ *Severe* ☐ *Extreme* ☐

4. Sitting or lying:

   None ☐ *Mild* ☐ *Moderate* ☐ *Severe* ☐ *Extreme* ☐

5. Standing upright:

   None ☐ *Mild* ☐ *Moderate* ☐ *Severe* ☐ *Extreme* ☐

B. STIFFNESS

The following questions concern the amount of joint stiffness (not pain) you are experiencing now in your knee/knees/hip/hips. Stiffness is a sensation of restriction or slowness in the ease with which you move your joints.

(Please mark your answers with a tick).

1. How severe is your stiffness **after first waking** in the morning?

   None ☐ *Mild* ☐ *Moderate* ☐ *Severe* ☐ *Extreme* ☐

2. How severe is your stiffness after sitting, lying, or resting **later in the day**?

   None ☐ *Mild* ☐ *Moderate* ☐ *Severe* ☐ *Extreme* ☐

C. PHYSICAL FUNCTION

The following questions concern your physical function. By this we mean your ability to move around and look after yourself. For each of the following activities, please indicate the degree of difficulty you are experiencing now due to arthritis in your knee/knees/hip/hips.

(Please mark your answers with a tick).

What degree of difficulty do you have with

1. Descending stairs

None ☐ *Mild* ☐ *Moderate* ☐ *Severe* ☐ *Extreme* ☐

2. Ascending stairs

None ☐ *Mild* ☐ *Moderate* ☐ *Severe* ☐ *Extreme* ☐

3. Rising from sitting

None ☐ *Mild* ☐ *Moderate* ☐ *Severe* ☐ *Extreme* ☐

4. Standing

None ☐ *Mild* ☐ *Moderate* ☐ *Severe* ☐ *Extreme* ☐

5. Bending to floor

None ☐ *Mild* ☐ *Moderate* ☐ *Severe* ☐ *Extreme* ☐

6. Walking on flat

None ☐ *Mild* ☐ *Moderate* ☐ *Severe* ☐ *Extreme* ☐

7. Getting in/out of car

None ☐ *Mild* ☐ *Moderate* ☐ *Severe* ☐ *Extreme* ☐

8. Going shopping

None ☐ *Mild* ☐ *Moderate* ☐ *Severe* ☐ *Extreme* ☐

9. Putting on socks/stockings

None ☐ *Mild* ☐ *Moderate* ☐ *Severe* ☐ *Extreme* ☐

10. Rising from the bed

None	*Mild*	*Moderate*	*Severe*	*Extreme*
☐	☐	☐	☐	☐

11. Taking off socks/stockings

None	*Mild*	*Moderate*	*Severe*	*Extreme*
☐	☐	☐	☐	☐

12. Lying in bed

None	*Mild*	*Moderate*	*Severe*	*Extreme*
☐	☐	☐	☐	☐

13. Getting in/out of bath

None	*Mild*	*Moderate*	*Severe*	*Extreme*
☐	☐	☐	☐	☐

14. Sitting

None	*Mild*	*Moderate*	*Severe*	*Extreme*
☐	☐	☐	☐	☐

15. Getting on/off toilet

None	*Mild*	*Moderate*	*Severe*	*Extreme*
☐	☐	☐	☐	☐

16. Heavy domestic duties

None	*Mild*	*Moderate*	*Severe*	*Extreme*
☐	☐	☐	☐	☐

17. Light domestic duties

None	*Mild*	*Moderate*	*Severe*	*Extreme*
☐	☐	☐	☐	☐

ARTHRITIS IMPACT MEASUREMENT SCALES 2 (AIMS2)

The following questions refer to SOCIAL ACTIVITY

(Please tick the most appropriate answer for each question).

DURING THE PAST MONTH...

1. How often did you get together with friends or relatives?

   All Days ☐ *Most Days* ☐ *Some Days* ☐ *Few Days* ☐ *No Days* ☐

2. How often did you have friends or relatives over to your home?

   All Days ☐ *Most Days* ☐ *Some Days* ☐ *Few Days* ☐ *No Days* ☐

3. How often did you visit friends or relative at their home ?

   All Days ☐ *Most Days* ☐ *Some Days* ☐ *Few Days* ☐ *No Days* ☐

4. How often were you on the telephone with close friends or relatives?

   All Days ☐ *Most Days* ☐ *Some Days* ☐ *Few Days* ☐ *No Days* ☐

5. How often did you go to a meeting of a church, club, team or other group?

   All Days ☐ *Most Days* ☐ *Some Days* ☐ *Few Days* ☐ *No Days* ☐

The following questions refer to SUPPORT FROM FAMILY AND FRIENDS

(Please tick the most appropriate answer for each question).

DURING THE PAST MONTH...

1. Did you feel that your family or friends would be around if you needed assistance ?

   Always ☐ *Very often* ☐ *Sometimes* ☐ *Almost Never* ☐ *Never* ☐

2. Did you feel that your family or friends were sensitive to your personal needs?

   Always ☐ *Very often* ☐ *Sometimes* ☐ *Almost Never* ☐ *Never* ☐

3. Did you feel that your family or friends were interested in helping you solve problems?

Always	*Very often*	*Sometimes*	*Almost Never*	*Never*
☐	☐	☐	☐	☐

4. Did you feel that your family or friends understood the effects of your arthritis?

Always	*Very often*	*Sometimes*	*Almost Never*	*Never*
☐	☐	☐	☐	☐

The following questions refer to LEVEL OF TENSION

(*Please tick the most appropriate answer for each question*).

DURING THE PAST MONTH...

1. How often have you felt tense or high strung?

Always	*Very often*	*Sometimes*	*Almost Never*	*Never*
☐	☐	☐	☐	☐

2. How often have you been bothered by nervousness or your nerves?

Always	*Very often*	*Sometimes*	*Almost Never*	*Never*
☐	☐	☐	☐	☐

3. How often were you able to relax without difficulty?

Always	*Very often*	*Sometimes*	*Almost Never*	*Never*
☐	☐	☐	☐	☐

4. How often have you felt relaxed and free of tension?

Always	*Very often*	*Sometimes*	*Almost Never*	*Never*
☐	☐	☐	☐	☐

5. How often have you felt calm and peaceful?

Always	*Very often*	*Sometimes*	*Almost Never*	*Never*
☐	☐	☐	☐	☐

The following questions refer to MOOD

(Please tick the most appropriate answer for each question).

DURING THE PAST MONTH...

1. How often have you enjoyed the things you do?

Always	*Very often*	*Sometimes*	*Almost Never*	*Never*
☐	☐	☐	☐	☐

2. How often have you been in low or very low spirits?

Always	*Very often*	*Sometimes*	*Almost Never*	*Never*
☐	☐	☐	☐	☐

3. How often did you feel that nothing turned out the way you wanted it to?

Always	*Very often*	*Sometimes*	*Almost Never*	*Never*
☐	☐	☐	☐	☐

4. How often did you feel that others would be better off if you were dead?

Always	*Very often*	*Sometimes*	*Almost Never*	*Never*
☐	☐	☐	☐	☐

5. How often did you feel so down in the dumps that nothing would cheer up?

Always	*Very often*	*Sometimes*	*Almost Never*	*Never*
☐	☐	☐	☐	☐

The University of Sheffield
SHEFFIELD
SISMES
Institute of Sports Medicine and Exercise Science

27th February 1998
«Title»
«Address1»
«City»
«PostalCode»

Water Exercise Programme for Osteoarthritis

Dear «Name»,

I am writing to thank you for taking an interest in our water exercise programme for people with osteoarthritis in the hip or knee. This water exercise programme is specially designed to improve your joint flexibility, muscle strength and help relieve pain. Before you begin the water exercise programme, we would like you to come to the Hallamshire Hospital for some simple tests. These simple measures will include, for example; height, weight, walking a short distance, ability to get up from a chair. It will also give you an opportunity to find out more about your health and help us to know about the effects of water exercise on the management of osteoarthritis.

Please come for your appointment at:

SISMES Laboratory which is situated in the **Physiotherapy Department on B-Floor** in the **Royal Hallamshire Hospital** (buses numbers and the hospital map are attached) on **«appointment»** .

Please **wear loose, comfortable clothing**. If you cannot make the appointment, would you please ring Sophia on **Tel: 2220985 (Work), 2679396 (Home)** or the General Office on **2220980** to arrange a convenient time.
Thank you for your interest and co-operation, I look forward to meeting you soon,

---

Yours sincerely

P.p.

Sophia Lin, MPH, PhD Research Student
Tel: (0114)2220985

Dr. Rachel Davey
Tel: (0114)2220983

The University of Sheffield
SHEFFIELD
SISMES
Institute of Sports Medicine and Exercise Science

19th April 1998

«Title»
«Address1»
«City»
«PostalCode»

Health Education Programme for Osteoarthritis

Dear «Name»,

I am writing to thank you for taking an interest in our health education programme for people with osteoarthritis in the hip or knee. This programme is designed to increase your self-management skills of Osteoarthritis. Before you begin the health education programme, we would like you to come to the Hallamshire Hospital for some simple tests. These simple measures will include, for example; height, weight, walking a short distance, ability to get up from a chair. It will also give you an opportunity to find out more about your health and help us to know about the effects of health education on the management of osteoarthritis.

Please come for your appointment at:

SISMES Laboratory which is situated in the **Physiotherapy Department on B-Floor** in the **Royal Hallamshire Hospital** (buses numbers and the hospital map are attached) on **«appointment»** .

Please **wear loose, comfortable clothing**. If you cannot make the appointment, would you please ring Sophia on **Tel: 2220985 (Work), 2679396 (Home)** or the General Office on **2220980** to arrange a convenient time.
Thank you for your interest and co-operation, I look forward to meeting you soon,

---

Yours sincerely

P.p.

Sophia Lin, MPH, PhD Research Student
Tel: (0114)2220985

Dr. Rachel Davey
Tel: (0114)2220983

The University of Sheffield
SHEFFIELD
SISMES
Institute of Sports Medicine and Exercise Science

16 April 1998

Dear patient,

I am writing to thank you for taking an interest in our water exercise programme for people with osteoarthritis in the hip or knee. There are strict criteria in selecting participants for the water exercise programme based on current exercise habits and present medical history. We are very sorry that you do not meet all of these criteria and as such will not be eligible to participate. However, I enclose information about other exercise opportunities available which may be of interest.

Thank you again for your interest and your time.

Yours sincerely

Sophia Lin, MPH, PhD Research Student
Tel: (0114)2220985

Dr. Rachel Davey
Tel: (0114)2220983

The University of Sheffield
SHEFFIELD
SISMES
Institute of Sports Medicine and Exercise Science

20 May 1998

Dear patient,

I am writing to thank you for taking an interest in our health education programme for people with osteoarthritis in the hip or knee. There are strict criteria in selecting participants for the health education programme based on current exercise habits and present medical history. We are very sorry that you do not meet all of these criteria and as such will not be eligible to participate. However, I enclose information about other exercise opportunities available which may be of interest.

Thank you again for your interest and your time.

Yours sincerely

Sophia Lin, MPH, PhD Research Student
Tel: (0114)2220985

Dr. Rachel Davey
Tel: (0114)2220983

The University of Sheffield
SHEFFIELD
SISMES
Institute of Sports Medicine and Exercise Science

11th February 1999

«Title»
«Address1»
«City»
«PostalCode»

Water Exercise Programme

Dear «Name»,

I am writing to ask you to help us finish our one year research study : "water exercise for people with osteoarthritis in the hip or knee". If you remember, you were kind enough to come for some simple tests and fill in a questionnaire about one year ago.

Please fill in the enclosed questionnaire and send it back using the enclosed pre-stamped envelope. In addition, it will be highly appreciated that you can come back for your one year check up.

Please come for your appointment at:

SISMES Laboratory which is situated in the **Physiotherapy Department on B-Floor** in the **Royal Hallamshire Hospital** on **«appointment»** .

Please **wear loose, comfortable clothing**. If you cannot make the appointment, would you please ring Sophia on **Tel: 2220985** or Dr. Davey on **Tel: 2220983** to arrange a convenient time.
Thank you for your interest and co-operation. I look forward to meeting you soon.

Yours Sincerely,

Pp.

Sophia Lin, MPH, PhD Research Student
Tel: (0114)2220985

Dr. Rachel Davey
Tel: (0114)2220983

The University of Sheffield
SHEFFIELD
SISMES
Institute of Sports Medicine and Exercise Science

15th March 1999

«Title»
«Address1»
«City»
«PostalCode»

Health Education Programme for Osteoarthritis

Dear «Name»,

We are writing to ask you to attend for your one year follow-up health evaluation. If you remember, you were kind enough to come for some simple tests and fill in a questionnaire a year ago.

Please fill in the enclosed questionnaire and return using the enclosed pre-stamped envelope. If you require any help with transport, please indicate on the front page of the questionnaire.

This one year evaluation will give you an opportunity to find out about the changes in your health and osteoarthritis. In addition, you may be able to join some exercise classes we are currently running or simply get some useful information about the recreational activities available in your local area.

Please come for your appointment at:

SISMES Laboratory which is situated in the **Physiotherapy Department on B-Floor** in the **Royal Hallamshire Hospital** (please wait in the reception area) on **«appointment»** .

Please **wear loose, comfortable clothing**. If you cannot make the appointment, would you please ring Sophia on **Tel: 2220985 (Work), 2679396 (Home)** or the General Office on **2220980** to arrange a convenient time.
Thank you for your interest and co-operation, I look forward to meeting you soon,

---

Yours sincerely

P.p.

Sophia Lin, MPH, PhD Research Student
Tel: (0114) 2220985

Dr. Rachel Davey
Tel: (0114) 2220983

Appendix K – Data collection sheet

Lower Limb OA Physical Performance Data Collection Sheet

Date:____

Name	Ht (cm)	Wt (kg)	8'W (S)	Stair (S)		Chair (S)	Knee flex		Hip flex		Leg Length		Quadriceps		
				UP	Dn		R	L	R	L	R	L	1	2	3
													R	R	R
													L	L	L
													R	R	R
													L	L	L
													R	R	R
													L	L	L
													R	R	R
													L	L	L
													R	R	R
													L	L	L

The University of Sheffield
SHEFFIELD
SISMES
Institute of Sports Medicine and Exercise Science

24 November 1998

«Title»
«Address1»
«City»
«PostalCode»

Water Exercise Programme

Dear «Name»,

I am writing to thank you for taking an interest in our water exercise programme for people with osteoarthritis in the hip or knee. If you remember, you were kind enough to come for some simple tests about six months ago.

We are asking you to come back for your repeat six months check up. I do hope that you will be able to help us with this important study which will hopefully be of benefit to people with osteoarthritis. It will also give you an opportunity to find out more about your health.

Please come for your appointment to:

SISMES Laboratory which is situated in the **Physiotherapy Department on B-Floor** in the **Royal Hallamshire Hospital** on **«appointment»** .

Please **wear loose, comfortable clothing**. If you cannot make the appointment, would you please ring Sophia on **Tel: 2220985** or Dr. Davey on **Tel: 2220983** to arrange a convenient time.
Thank you for your interest and co-operation. I look forward to meeting you soon.

Yours sincerely

Sophia Lin, MPH, PhD Research Student
Tel: (0114)2220985

Dr. Rachel Davey
Tel: (0114)2220983

The University of Sheffield

SISMES

Institute of Sports Medicine and Exercise Science

23 Claremont Crescent

24th November 1999

Water Exercise Programme

Dear Participant,

I am writing to inform you of the results of your physical function tests and health status questionnaire. The results showed that most of you, especially those who went to the exercise classes twice per week, had better mobility and joint flexibility, suffered less pain and stiffness, had less difficulty in performing daily activities, and felt less tense than one year ago. So it is encouraging to know that the exercise is good for you!

The water exercise class at Hillsborough Leisure Centre re-started at the end of September and some of you have re-joined the exercise class. Although our 12 month study has now finished, I hope you will continue your participation. Please remember that, the beneficial effects of water exercise will only be maintained by regularly attending the exercise class.
The dates and times for the water exercise classes are listed below;

Wednesday: 9:15 a.m. to 10:15 a.m.
Wednesday: 10:30 a.m. to 11:30 a.m.
Friday: 1:15 p.m. to 2:30 p.m.

As this water exercise programme is new to the Sheffield area, your opinions about the programme are invaluable and can help us to improve our service. We would be very grateful if you could fill in the enclosed '**participants opinion survey**' and send it back using the enclosed pre-stamped envelope.

If you require your individual results for the tests or have any queries regarding exercise and osteoarthritis, please feel free to contact Sophia on Tel: 2220985 (Office) or 2679396 (Home). We would like to take this opportunity to wish you a Merry Christmas and a Happy Millennium New Year.

Yours sincerely

Pp.

Sophia Lin, MPH, PhD Research Student

Dr. Rachel Davey

CONFIDENTIAL

University of Sheffield

Sheffield Institute of Sports Medicine and Exercise Science

Participants opinion survey

Enclosed are some questions asking you what you think and feel about participating in the water exercise class. These questions apply to your participation in the water exercise class (current or past). Please try to answer all the questions.

The replies will be anonymous so please answer as honestly as possible.

Please return the questionnaire using the enclosed pre-stamped envelope.

THANK YOU FOR YOUR HELP

1. Do you currently attend the water exercise class?

Yes ☐ (Go to question 2)

No ☐ (Go to question 3)

2. If yes, on average, how often do you attend the exercise class?

One time ☐ Two times ☐ (Go to question 5)

3. If no, what was the main reason? (please tick the appropriate box (es)

Illness	☐
Operation	☐
Couldn't tolerate the water temperature	☐
Family obligations	☐
Times were not convenient	☐
Pool facility was inappropriate (e.g. access into the pool was too steep, a wet floor was too slippery)	☐
Didn't enjoy it	☐
Lack of transport	☐
Didn't feel you were getting anything from it	☐
There was no body to go with	☐
Exercise was too much for you	☐
Didn't feel comfortable with the other people	☐
Other	☐(please specify)

____

____

____

____

4. If you do not go to the water exercise class any more, have you carried on taking other leisure or exercise activities?

Yes ☐ No ☐

If yes, what activity(ies) ____________________________

and how often__________________________________

5. In general, were you happy with the exercise activities themselves?

Yes ☐ Uncertain/ No view ☐ No ☐

If you were unhappy with the exercise activities, please say why.

____

____

____

6. In general, were you happy with the exercise instructors?

Yes ☐ Uncertain/ No view ☐ No ☐

If you were unhappy with the exercise instructors, please say why.

____

____

____

7. In general, were you happy with the swimming pool ? (Hillsborough Leisure Centre)

Yes ☐ Uncertain/ No view ☐ No ☐

If you were unhappy with the swimming pool, please say why.

____

____

____

8. Do you think the community-based water exercise programme for people with osteoarthritis was a good idea?

Yes ☐ Not sure/no opinion ☐ No ☐

9. Do you think the programme was beneficial to you in any way?

Yes ☐ Not sure/no opinion ☐ No ☐

If you feel the water exercise class did help you, what was the main benefits? (please tick the appropriate box(es).

Cheered me up ☐

Eased my physical pain ☐

Increased my mobility ☐

Reduced my stress ☐

I enjoyed meeting with other people ☐

Gave me a sense of achievement ☐

Increased my self-confidence ☐

Helped me to feel more independent ☐

Being able to exercise again made me feel good ☐

Other ☐ (please specify)

___

___

___

10. Can you suggest any ways in which we could make the programme better?

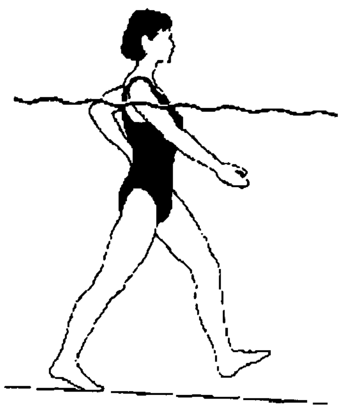
___

___

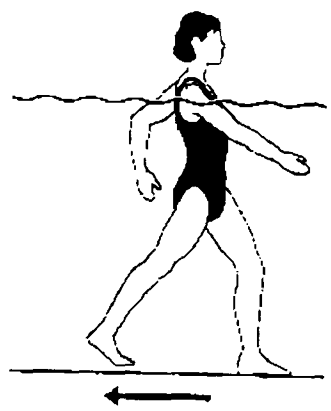
___

___

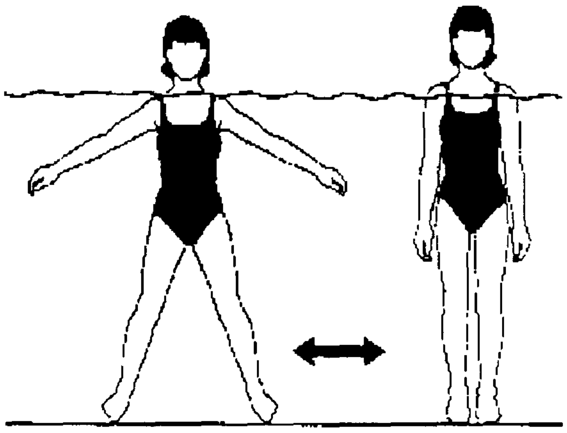
Thank you for your time and co-operation!



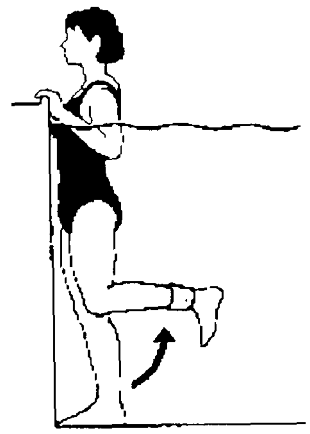
Forward walking



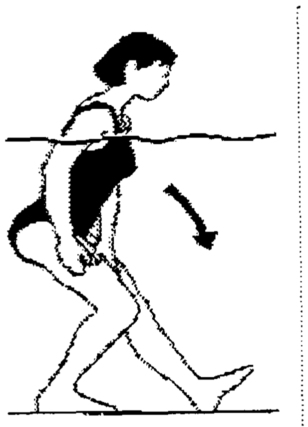
Backward walking



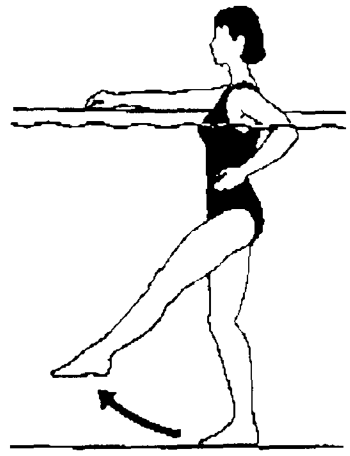
Side stepping



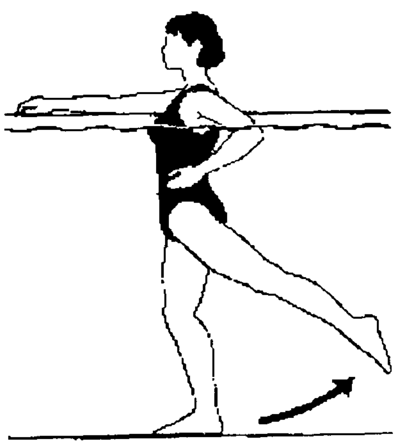
Passive quadriceps stretch



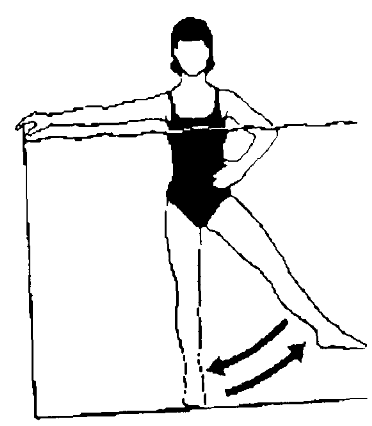
Hamstring stretch



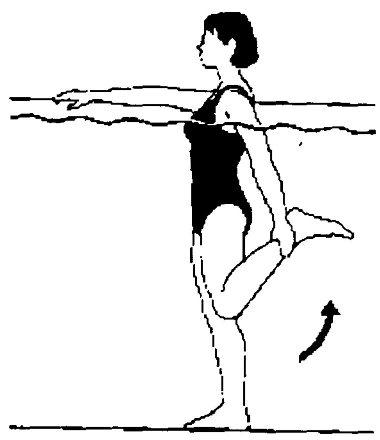
Hip flexion



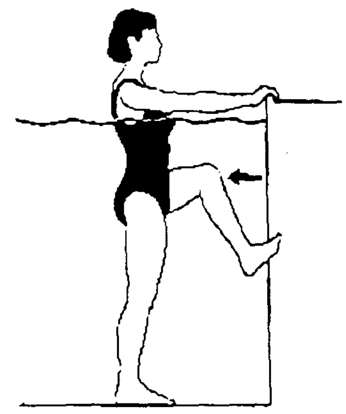
Hip extension



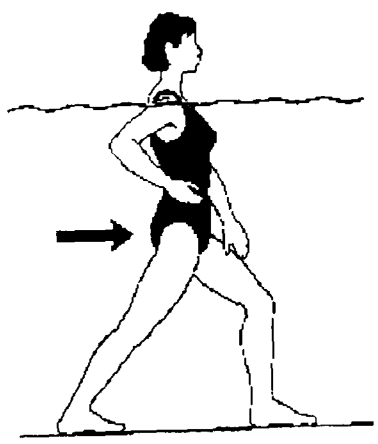
Hip abduction and adduction



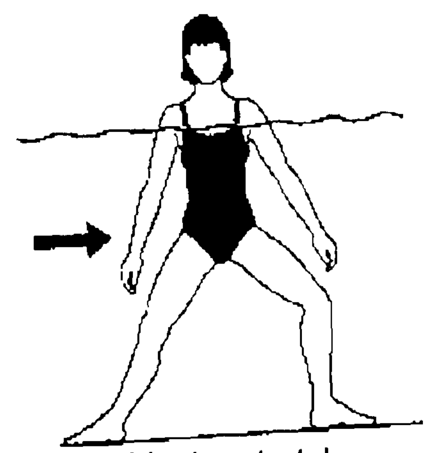
Quadriceps stretch



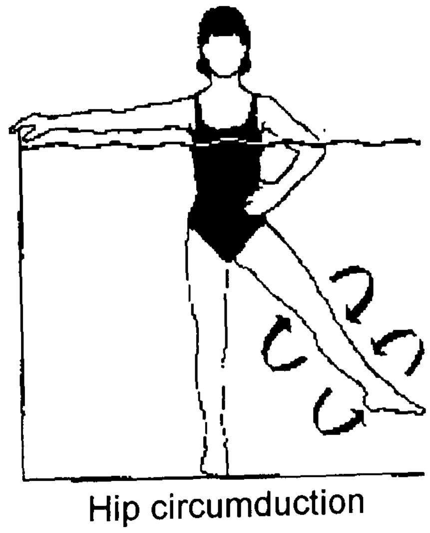
Active hamstring stretch



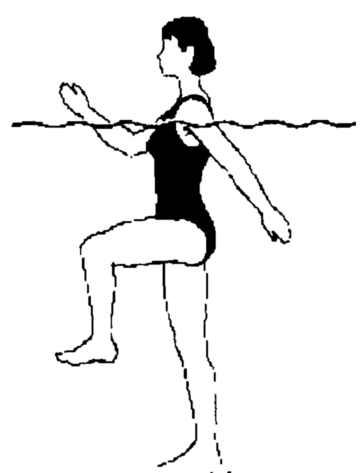
Hip flexor stretch



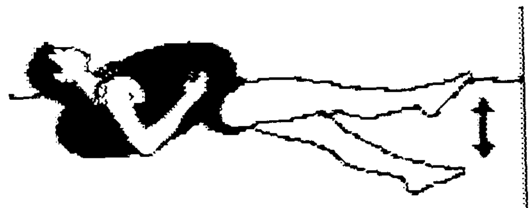
Adductor stretch



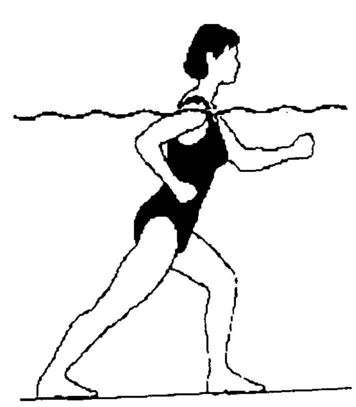
Hip circumduction



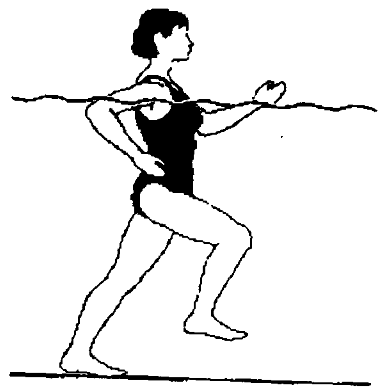
Marching



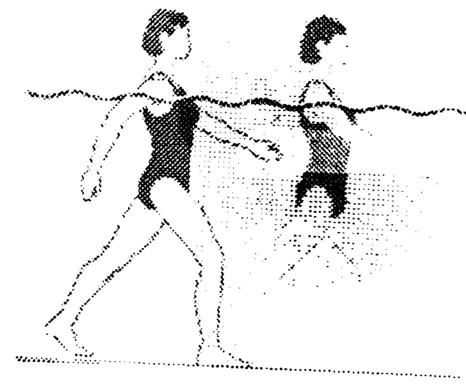
Straight leg kick



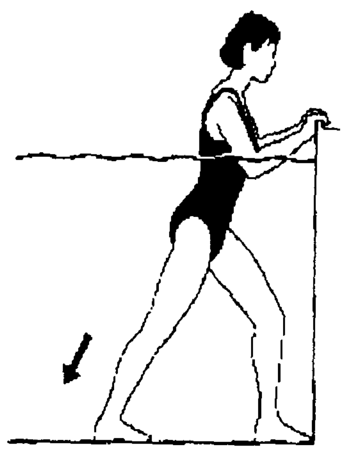
Lunges



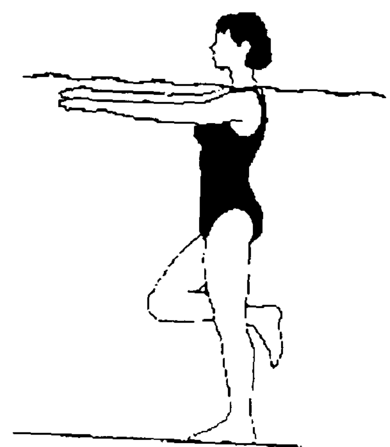
Jogging



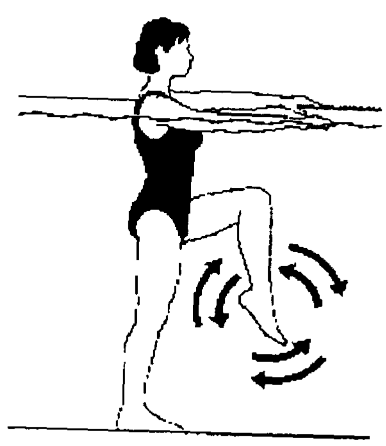
Leg exchange



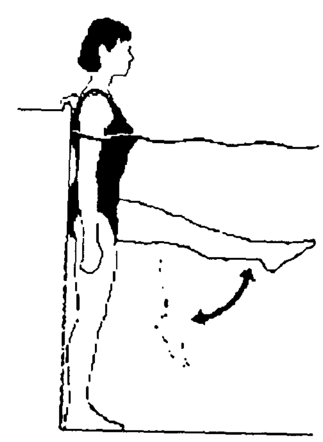
Calf stretch



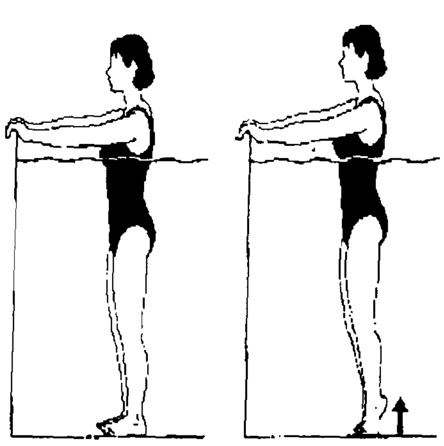
Stork stand



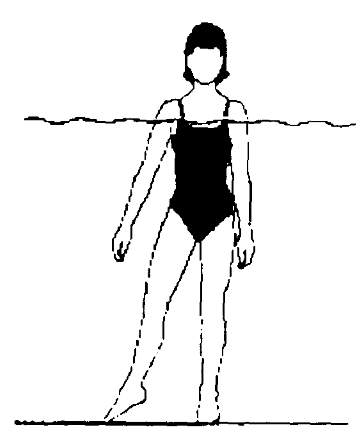
Single-leg bicycle



Hamstring pull-back



Heel raises



Side-to-side weight shifting

Exercise on own- using floating device

Aerobic exercise

SISMES OA Water Exercise Name List-January, 1999

Name	8/1	15/1	22/1	29/1		Note

The University of Sheffield
SHEFFIELD
SISMES
Institute of Sports Medicine and Exercise Science

November 1998

Water Exercise Programme

:ar patient,

e have noticed that you have not been to the water exercise class for some time w and are writing as we are concerned that you have been ill and unable to attend. e now have two extra exercise sessions alongside the original Friday class at llsborough Leisure Centre at the following times:-

Wednesdays: 9:15 a.m. to 10:15 a.m.

Wednesdays: 10:30 a.m. to 11:30 a.m.

Fridays: 1:15 p.m. to 2:30 p.m.

e would like to encourage you to participate since exercise makes you fitter and althier. It helps keep your bones and muscles strong, your joints healthy and gives u more energy to keep up with daily activities. This is especially important if you ve osteoarthritis. As you may be aware, lack of exercise can lead to joints coming even more stiff and painful, muscles becoming smaller and weaker, and nes becoming more brittle and prone to breaking. Water exercise is especially good stiff, sore joints and is a low stress way for people with osteoarthritis to start an ercise plan. In addition, it is worth noting that a programme of gentle exercise such this can help to speed up recovery after an operation or a period of illness.

e would like to emphasis, however, that the beneficial effects of water exercise will y be maintained by regularly attending the class. While improvements may not be bvious during the early stages, long-term benefits can be gained by continuing this ind of programme over a period of time.

/e look forward to seeing you at the classes in the near future. If you have any ıeries regarding the water exercise programme, please feel free to contact Sophia at)114)2220985 or Dr. Davey at (0114)2220983. We would like to take this pportunity to wish you a Merry Christmas and a Happy New Year.

ours sincerely

pp.

ɔphia Lin, MPH, PhD Research Student
el: (0114)2220985

Dr.Rachel Davey
Tel: (0114)2220983

The University of Sheffield
SHEFFIELD
SISMES
Institute of Sports Medicine and Exercise Science

5 November 1998

Water Exercise Programme

Dear patient,

I am writing to thank you for participating in our water exercise programme for people with osteoarthritis in the hip or knee. The Hillsborough Leisure Centre are not able to increase the water temperature due to financial reasons. Therefore, we would like to give you some information about alternative swimming/water exercise classes in other swimming pools where the water temperature is much warmer. The **King Edwards Swimming Pool** offers an "Over 50's Swim" on Monday and Tuesday morning with water temperature at 33°C. The **Upperthorpe Swimming Pool** offers a "Disabled Swimming" on Tuesday, Thursday and Saturday and a "Over 50's Swim" on Wednesday and Thursday with water temperature at 30°C. If you are interested in joining these sessions please see Sophia, or you can just turn up on the day.

Please find enclosed the leaflets explaining more detail about the swimming programmes held in the two swimming pools. If you have any query regarding the water exercise programme, please feel free to contact Sophia at (0114)2220985 or Dr. Davey at (0114)2220983.

Yours sincerely

pp.

Sophia Lin, MPH, PhD Research Student
Tel: (0114)2220985

Dr. Rachel Davey
Tel: (0114)2220983

The University of Sheffield
SHEFFIELD
SISMES
Institute of Sports Medicine and Exercise Science

11th February 1999

«Title»
«Address1»
«City»
«PostalCode»

Water Exercise Programme

Dear «Name»,

I am writing to ask you to help us finish our one year research study : "water exercise for people with osteoarthritis in the hip or knee". If you remember, you were kind enough to come for some simple tests and fill in a questionnaire about one year ago.

Although you have not been to the water exercise class for some time now, we do hope that you will be able to come back and complete our study.

Please fill in the enclosed questionnaire and send it back using the enclosed pre-stamped envelope. In addition, it will be highly appreciated that you can come back for your one year check up.

Please come for your appointment at:

SISMES Laboratory which is situated in the **Physiotherapy Department on B-Floor** in the **Royal Hallamshire Hospital** on **«appointment»** .

Please **wear loose, comfortable clothing**. If you cannot make the appointment, would you please ring Sophia on **Tel: 2220985** or Dr. Davey on **Tel: 2220983** to arrange a convenient time.
Thank you for your interest and co-operation. I look forward to meeting you soon.

Yours Sincerely,

Pp.

Sophia Lin, MPH, PhD Research Student
Tel: (0114)2220985

Dr. Rachel Davey
Tel: (0114)2220983

This certificate records that

Mary Tobin

Has successfully participated in the Osteoarthritis Water Exercise Class for six months

Congratulations!

Sophia Lin
Research Investigator

Sheffield Institute of Sports Medicine and Exercise Science
October 1998

This certificate is awarded to

Mary Tobin

for your successful completion of the Osteoarthritis Water Exercise Programme

Congratulation!

Sophia Lin
Research Investigator

Sheffield Institute of Sports Medicine and Exercise Science
April 1999

The University of Sheffield

SHEFFIELD

SISMES

Institute of Sports Medicine and Exercise Science

26 March 1999

Water Exercise Programme

Dear Participant,

Thank you for participating in our water exercise programme. Our 12 month study is now completed and we are currently collecting the results. Once we have analysed the results, you will be sent a brief summary.

We hope you have found the water exercise of benefit and would encourage you to continue exercising.

We have enjoyed working with you and have made many friends.
Thank you for your support and co-operation.
With best wishes

Yours sincerely

pp.

Sophia Lin, MPH, PhD Research Student | Dr. Rachel Davey

Health Education Materials for Osteoarthritis

No: ___________

1. General introduction to Osteoarthritis
2. Diet and Arthritis
3. Exercise and Arthritis
4. Are You Sitting Comfortably?
5. Choosing Shoes
6. Your Home and Your Rheumatism
7. Managing Your Activities
8. Managing Your Pain
9. Managing Your Fatigue
10. Managing Your Stress

Bonus (Please choose two)

1. Walking and Arthritis
2. Gardening with Arthritis
3. Rheumatism and the Weather
4. Stair lifts and Home lifts
5. Backache
6. Arthritis and the Feet
7. A New Hip Joint
8. A New Knee Joint
9. Pain in the Neck
10. The Painful Shoulder

Special Requirements

____

The University of Sheffield
SHEFFIELD
SISMES
Institute of Sports Medicine and Exercise Science

4th August 1999

Health Education Programme for Osteoarthritis

Dear Patient,

It is seven months since you started to participate in our health education programme. I hope you have found the information to be of interest. In the next five months, you will receive some articles on self-management of osteoarthritis and some information relating to the specific topics you chose at the beginning of the project. At the end of the year, we will invite you to come back for your one year evaluation. The same tests will be done as six months ago.

If you have not received any of the following materials in the past seven months, please ring Sophia on **Tel: 2220985 (O)** or **2679396 (H)**. We will send you any of the missing issues as soon as possible.

1. Osteoarthritis- An Information Booklet
2. Choosing Shoes
3. Diet and Arthritis
4. Are You Sitting Comfortably?
5. Your Home and Your Rheumatism
6. Exercise and Arthritis
7. Managing Your Fatigue

May I take this opportunity of wishing you a good summer, and thanking you for your support.

Yours sincerely

P.p.

Sophia Lin, MPH, PhD Research Student
Tel: (0114) 2220985

Dr. Rachel Davey
Tel: (0114) 2220983

SHEFFIELD INSTITUTE OF SPORTS MEDICINE AND EXERCISE SCIENCE

HEALTH EDUCATION PROGRAMME FOR PATIENTS WITH OSTEOARTHRITIS

TELEPHONE FOLLOW-UPS

Name: ______________________

NO: ________________________

I. During the past three months, has there been any change in your medication?

No: ________

Yes:________ please give detail

____

____

II. During the past three months, have you been admitted to the hospital because of sickness or surgery?

No: ________

Yes:________ please give detail

____

____

III. In the last three months, have you begun any new exercise classes or increased your physical activity levels? If so, please give detail.

____

____

Table A1. Performance of the eight-foot walk, ascending/descending stairs and chair rise tasks: Percentage unable to complete and percentile for those complete the task

Measure	Eight-foot walk[a]	Ascending stairs[b]	Descending stairs[c]	Chair rise[d]
Number	106	106	106	81
Unable to complete (%)	0	0	0	24%
25th * percentile	2.35	2.68	2.53	18.25
50th * percentile	2.65	3.42	3.52	24.03
75th * percentile	3.16	4.93	4.89	31.63
99th percentile	7.18	22.60	13.67	NA

* Used to define categories of performance.

[a] Category 1: ≤ 2.35 sec, Category 2: 2.36 - 2.65 sec, Category 3: 2.66 - 3.16 sec, Category 4: ≥ 3.17 sec.

[b] Category 1: ≤ 2.68 sec, Category 2: 2.69 - 3.42 sec, Category 3: 3.43 - 4.93 sec, Category 4: ≥ 4.94 sec.

[c] Category 1: ≤ 2.53 sec, Category 2: 2.54 - 3.52 sec, Category 3: 3.53 - 4.89 sec, Category 4: ≥ 4.90 sec.

[d] Category 1: ≤ 18.25 sec, Category 2: 18.26 - 24.03 sec, Category 3: 24.04 - 31.63 sec, Category 4: ≥ 31.64 sec. Category 5: unable to complete.

NA: not available.

Table A2. Performance of the flexibility tests: Percentage unable to complete and percentile for those complete the task

Measure	Knee flexion		Hip flexion	
	Right leg [a]	Left leg [b]	Right leg [c]	Left leg [d]
Number	106	106	106	106
Unable to complete (%)	0	0	0	0
25th * percentile	111	111	75	79
50th * percentile	122	128	89	94
75th * percentile	129	131	97	105
99th percentile	140	145	119	124

* Used to define categories of performance.

[a] Category 1: ≥ 129 degrees, Category 2: 122-128 degrees, Category 3: 111-121 degrees, Category 4: ≤ 110 degrees.

[b] Category 1: ≥ 131 degrees, Category 2: 128-130 degrees, Category 3: 111-127 degrees, Category 4: ≤ 110 degrees.

[c] Category 1: ≥ 97 degrees, Category 2: 89-98 degrees, Category 3: 75-88 degrees, Category 4: ≤ 74 degrees.

[d] Category 1: ≥ 105 degrees, Category 2: 94-104 degrees, Category 3: 79-93 degrees, Category 4: ≤ 78 degrees.

Table A3. Performance of the quadriceps strength tests: Percentage unable to complete and percentile for those complete the task.

Measure	Quadriceps	
	Right leg	Left leg
Number	102	103
Unable to complete (%)	3.8%	2.8%
25th * percentile	23.25	24.48
50th * percentile	34.49	33.68
75th * percentile	50.91	52.26
99th percentile	120.15	146.18

* Used to define categories of performance.

[a] Category 1: ≥ 50.91 Nm, Category 2: 34.49-50.90 Nm, Category 3: 23.25-34.48 Nm, Category 4: ≤ 23.24 Nm, Category 5: unable to complete.

[b] Category 1: ≥ 52.26 Nm, Category 2: 33.68-52.25 Nm, Category 3: 24.48-33.67 Nm, Category 4: ≤ 24.47 Nm, Category 5: unable to complete.