THE EFFECTS OF A 16-WEEK INDIVIDUALIZED, INTENSIVE STRENGTH TRAINING PROGRAM FOR PATIENTS WITH RHEUMATOID ARTHRITIS

By

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ABSTRACT

Objective. This study was designed to test the hypotheses that a 16-week individualized, intensive strength training program in rheumatoid arthritis (RA) patients taking Remicade™ (Infliximab) would improve strength, body composition, disease activity, physical function, pain and quality of life outcomes, as compared to RA patients on Remicade™ with no strength training program.

Methods. Twenty-four patients with RA taking Remicade™, participated in a randomized, controlled trial. The exercise group carried out a three time a week strength training program, with the control group continuing standard of care. Assessments were completed at baseline, 8-week, and 16-week time points. Maximal strength, physical function, disease activity, body composition, quality of life, and pain were measured with active tests and via questionnaires. Patients also completed exit evaluations on their satisfaction with the study.

Results. Highly significant strength gains were seen in the exercise group according to 3 repetition maximums (3RMs) ($p<.01$), as well as in all 8 exercises performed in the gym ($p<.01$). The mean exercise attendance for the 16 weeks was 82.0±10.6%. Compared to the control group, there was a significant increase in right hand grip strength ($p<.1$), and lean tissue in the trunk ($p<.01$). Significant improvements were also seen in physical function according to 50-foot walk time ($p<.01$), the Arthritis Impact Measurement Scale 2 (AIMS2) hand and arm function subscales ($p<.05$), and the Medical Outcomes Study Short Form 36 (MOS SF-36) ($p<.1$), as compared to controls. The exercise group showed clinically important differences via the Health Assessment Questionnaire

Disability Index (HAQ DI), with a mean change of -0.41±0.42. Significant reductions in pain, as measured by the Pain Visual Analogue Scale (VAS), also occurred ($p<.1$). The individualization of the strength training program and personal attention received by the patients was critical to the success of the study. Patient satisfaction with the study was high, with limitations due primarily to funding constraints.

Conclusion. This 16-week high intensity strength training program led to statistically significant improvements in strength, lean soft tissue, disease activity, function, pain and quality of life in this RA population. No detrimental effects on the disease were seen in this study.

CHAPTER 1- INTRODUCTION

EXPLANATION OF THE PROBLEM, ITS CONTEXT AND REVIEW OF THE LITERATURE

Impact of RA

Rheumatoid Arthritis (RA) is an autoimmune disease of unknown etiology that causes pain, stiffness, swelling and loss of function in the joints and inflammation in other body organs. A systemic disease, manifestations such as pericarditis, pleuritis (inflammation of the pericardium and pleura, respectively) and Sjogren's Syndrome can often occur. RA affects more than two million Americans, the majority of whom are Caucasian and female (> 75%).(1) RA affects people in their most productive years, with the peak onset of the disease occurring between 20-45 years of age (during peak child-bearing years).(2-6)

Most people with RA exhibit a chronic fluctuating course of disease that, if left untreated, results in progressive joint destruction, deformity, disability and premature death. The Centers for Disease Control and Prevention classified arthritis or rheumatism as the leading cause of disability in the US in 1999, with RA specifically listed as the second leading cause of chronic disability. (2, 4, 6-8) Reductions in body function generally occur early in the disease, leading to limitations such as lost joint range of motion (ROM). Fifty percent of patients with RA display decreased hand ROM at their first rheumatology visit. Two years later, reduced ROM can be found in large joints; the decreased ROM varying between 25-35% in different joints. Due to disability, up to two thirds of persons with RA have a reduced work capacity and substantial income loss as many persons cannot function in their job within 10 years of disease onset.(4)

Loss of functional capacity often leads to depression and reduced or non-participation in valued life activities, increasing the risk of further physical decline and mortality. Katz et al (2001) reports that over a 5 year period, individuals with RA stopped performing activities they had valued at baseline, with greatest losses seen in work-related, service, nurturant, entertainment and social events. This social stress leads to isolation, deepening the anxiety and depression often found in RA patients.(9-11) The impact of the disease affects their overall quality of life and the ability to maintain family roles, social activities and fitness for work.(12, 13)

Physical and psychological impacts translate into greater economic costs with patients utilizing health care services more frequently. The direct costs of treating a person with RA is 3 times more than the costs associated with treating a person who does not have this disease. Direct and indirect costs (medical care and loss of productivity) of RA exceeded $82 billion in 1995, with the greatest percentage of costs due to income lost and hospital charges.(1, 4, 7, 14)

Life expectancy in RA is reduced by an average of 3 to 18 years, with a mortality rate two-fold that of the healthy US population.(1) Deaths from infection occur 20 times more frequently in people with RA and the most frequent causes of death in RA, cardiovascular disease and cancer, mirror the leading causes of death in the general population, suggesting, in effect, that people with RA are physiologically “older” than their healthy counterparts.(15) For those with aggressive disease or extra-articular manifestations, the mortality is comparable to that of people with three vessel coronary arteriosclerosis, or late stage Hodgkin's disease.(16)

Traditional treatment for RA

The impact of RA on a person's life is substantial, affecting one's physical and emotional status, financial stability and independence. Disease modifying anti-rheumatic drugs (DMARDs) have the potential to reduce or prevent joint damage, preserve joint integrity and function, and ultimately, to reduce the total costs of health care and maintain the economic productivity of the patient with RA.(2) Standard pharmaceutical therapies for RA include traditional DMARDs such as sulfasalazine, plaquinel and methotrexate (MTX). Other pharmacotherapies used often in conjunction with DMARDs include anti-inflammatory medications such as glucocorticoids (i.e. prednisone), non-steroidal anti-inflammatory drugs (NSAIDs) (i.e. Bextra, aspirin) and intra-articular corticosteroid injections. Beyond pharmaceuticals, other forms of disease management include splinting the affected joints to immobilize or support and protect the joint; deep heat therapy; physical and/or occupational therapy for the affected joints, such as range of motion exercises; and self-management techniques such as coping skills. Sometimes surgical therapy is required.(17)

Current pharmaceutical treatment for RA

More recently, biologic response modifiers (BRMs), including tumor necrosis factor (TNF) antagonists, have come to the forefront of pharmacotherapy, stemming from the current understanding that disproportionate levels of proinflammatory cytokines (including TNF) are present in the synovial tissues of patients with RA and contribute to the joint inflammation and cartilage destruction characteristic of the disease.(18) These BRMs have been replacing existing DMARDs which only partially controlled the inflammation and did not appear to prevent joint damage.

In 1999, Remicade, a TNF antagonist DMARD was approved for RA treatment in combination with another traditional DMARD, MTX.(19) This new BRM, Remicade, and similar drugs, have revolutionalized the management of RA. These drugs have proven to be superior to conventional drug therapy not only in their ability to control inflammation and other symptoms of RA, but have been shown to prevent disease progression and bony erosions, with treated patients obtaining levels of physical function not previously experienced.(6)

Remicade binds to and neutralizes TNF-α, a pro-inflammatory cytokine that plays a pivotal role in initiation and perpetuation of many inflammatory diseases. Peak response occurs in as little as 3 weeks. Remicade is safe, largely without subjective side effects, and evidence shows it can be used repeatedly over time. Remicade’s success is described in the well-known ATTRACT trial. ATTRACT results showed that in 428 active RA patients, symptoms and signs of RA decreased more in patients in the groups that received Remicade plus MTX than in the group which received MTX alone.(6, 16, 20)

<u>History of physical activity and RA</u>

Smith and Polley stated in their 1978 article, *Rest therapy for rheumatoid arthritis*: “We have been unable to find any evidence that active exercise beneficially affects the inflammatory processes of rheumatoid arthritis.”(21) Historically, dynamic exercises of an intensity adequate to improve muscle strength and aerobic capacity have been avoided in RA patients because of concern of exacerbating joint inflammation, or rupturing tendons, popliteal cysts, or joint capsules.(22, 23) High intensity exercise was thought to exaggerate pain and disease activity and to provoke joint damage by possibly overloading a weak joint and increasing intra-articular temperature, thus destroying cartilage.(24, 25)

In the late 1980's health professionals examined more closely the benefits of physical activity for RA, and the "era of physical inactivity" began to be challenged. Studies were published regarding the possible benefit of physical activity for RA patients, but were mostly limited to low-intensity and non or low-impact aerobic exercise, isometric exercises and physical therapy.

In the 1990's health care professionals acknowledged that regular physical activity was important as an RA treatment and should include strengthening exercises for RA patients.(26) In 1995, dynamic strength training studies began to be published, although the intensity levels recommended were still only of low to moderate intensity. Despite positive findings, regular dynamic strength training continued to be conservatively recommended, with cautions against exercising during acute flare-ups or above moderate intensity levels. Only in the last few years have a handful of moderate to high intensity dynamic strength training studies been conducted. Moderate or high intensity strength training is cited as being "well tolerated", with no side effects reported. (27)

Unfortunately, the two large organizations which provide professional and lay person information on the treatment of RA (the American College of Rheumatology (ACR) and the National Arthritis Foundation (AF), are in a fledgling state as far as clearly defining guidelines and recommendations on strength training exercise programs for RA patients.

In the ACR's Work Group Recommendations from the Exercise and Physical Activity Conference in 2002, one of the recommendations was to create a position statement in favor of strength training and aerobic exercise (distinct from symptom-directed physical and occupational therapy) as routine, comprehensive care for all patients with inflammatory disease.(28) They also recommended further research on exercise and arthritis, with programs focusing on: 1) strengthening muscle and improving BMD, 2) programs specific to the type of arthritis, and 3) long-term outcomes on function and body weight status (muscle and fat mass).(29, 30) Although the ACR now generally recommends strengthening and aerobic conditioning regimens in its revised 2002 Guidelines for the Management of RA, to date, no position statement which could enact movement toward additional strength training research and programs has been created.(14, 31) Additionally, the Guidelines do not address the intensity of strength training necessary to reverse loss of function, bone mineral density (BMD) and other conditions.

The AF focuses its efforts on supporting national programs such as PACE (People with Arthritis Can Exercise), a low-impact land-based exercise program designed for people with arthritis that uses gentle activities to help increase joint flexibility, range of motion, and possibly maintain muscle strength. Although such programs encourage physical activity in RA patients, the focus is to put little stress on the joints. Generally, ROM, non weight-bearing or minimal weight bearing exercises, and isometric exercises are advocated. Once again, building muscle strength is encouraged, but no national programs have been created to encourage and endorse strength training, and certainly no educational materials on intensive strength training programs which provide the crucial type of exercise necessary to preserve integrity of the muscle, joint, cartilage, and bone has been published.

This conservative approach and the unclear recommendations are troubling, since the fear associated with RA patients engaging in properly performed high-intensity strength training is based on scant data. The benefits of participation in a regular, intensive strength training program seems to outweigh any potential risks in RA patients.

Significance of the present study

Although Remicade and other similar BRMs have had tremendous success in curtailing the progression of the disease, they cannot replace the loss of lean tissue and BMD due to the disease. Successful Remicade treatment alleviates symptoms, allowing patients to achieve levels of function not previously experienced, giving them the opportunity to engage in strength training exercise, which can, among other things, replace the loss of lean tissue and BMD.

Unfortunately, the strength training studies that have been conducted thus far have been limited because of small sample sizes, non-generalizable populations (hospital-based) and non-randomized designs. Different approaches to strength training exercise have involved low-moderate intensity isokinetic training, low-intensity physical therapy, low-intensity isometric training, moderate-intensity circuit training, low-moderate isotonic training, with few high intensity strength training programs.(32) Individualization of programs has only consisted of decreasing the intensity during flare-ups without separate exercise options available. Very few studies have had the patients keep exercise logs which could provide valuable dose-response information and provide the patients with feedback opportunities. Also, outcomes have been difficult to compare between studies as the length of the training periods have varied from 3 weeks to 2 years, samples have included patients with other peripheral arthritis and varying durations and severity of RA, and there have been differences in test protocols and equipment.(27) There is also considerable variability among the frequency, intensity (ranging from unknown to 80% of 1 RM) and type of exercise (some have used mixed training methods), with many poorly described exercise protocols. Exercises have been carried out using isokinetic dynamometers, pneumatic equipment, weight machines, cycle ergometers, elastic bands, dumbbells, water, or body weight as resistance.(22, 25) Additionally, no study has looked at the possible synergism between Remicade and strength training.

Despite differences in design, the consistency among studies published about safety of strength training for RA is remarkable, indicating that intensive strength training is safe and feasible for people with RA without exacerbating disease activity.(27) The overall objective of this study was to design and test an individualized program of high enough intensity and sufficient duration to produce results on key physical and psychological outcomes crucial to the quality of life of individuals with RA. As the life expectancy in the United States increases, a greater number of people will be living longer with chronic diseases such as RA. Given the fluctuating course of disease and the long-term management issues people with RA must face, it is imperative that the scientific community develop and disseminate appropriate therapies (such as strength training exercise) to supplement currently available pharmaceutical treatments to help the person with RA regain their loss of functional status and sustain a good quality of life.

Our study is the first continually supervised, facility-based, intensive, randomized, individualized strength training program, and has the largest sample size yet published.

Embracing strength training for patients with RA

Although rest therapy may initially help with pain and fatigue and joint protection as stated by Smith and Polley (1978), the prolonged rest they advocate does have detrimental effects on the cardiovascular/skeletomuscular system. Conservative management of RA, including bed rest and immobilization, can cause loss of muscle strength up to 1-2% a day. A decline of cardiorespiratory function occurs even in healthy subjects during voluntary bed rest, and the time to recover exceeds the time of immobilization.(21, 33) After only 5 weeks of immobilization in a cast, as much as 40% of a healthy person’s muscle strength is lost and it takes 5 months to regain normal strength.(34) With prolonged rest, there is a decrease in stroke volume, muscle strength, blood volume, muscle mass and strength, endurance and osteoporosis and orthostatic intolerance.(35, 36) Given the already limited function and fitness level of RA patients, and the stiffness that can occur without daily ROM movement in RA, we can assume an RA patient's time to recover would be even longer. A large number of persons with RA live just above the muscle strength threshold needed for activities of daily living such as walking or rising from a seated position. A small additional decline in strength may lead to conditions that make some everyday activities or independent living impossible, as there is a direct correlation between decreased strength and decreased functional capacity.(27, 37)

Some researchers have suggested that even in the acute stage of RA, a more intensive, dynamic exercise program has greater benefit than the current standard without deleterious effects, and the dangers of over-resting arthritic patients is as great or greater than those of over-exercise, and that almost any type of properly executed exercise is superior to physical inactivity.(24, 26, 38, 39)

The expense of treating co-morbidities such as osteoporosis, hypercholesterolemia, hypertension, arthroplasties and depression far outweigh any potential aggravation of disease due to an exercise program.(22, 23) Strength training is an essential form of training that has, in addition to strength, demonstrated improvements in several areas such as pain, disease activity, quality of life, BMD, and function, with no detrimental effects on disease activity.(22) With the multitude of issues RA patients face, strength training should be a mainstay of treatment to counter the loss of physical and psychological vitality, a result of years of disease and disability.(32)

Although we have entered the 21st century and the era of "early and aggressive treatment" (with pharmaceuticals), we lag behind in realizing the importance of other cotherapies such as exercise; strength training, in particular. It is known that radiographic progression occurs early in the disease process and results in tremendous functional decline. Those patients who are treated early and aggressively with pharmaceutical therapies have better outcomes than those treated later in the disease course and with less aggressive therapies.(40-42) Regular exercise can be prescribed early in the disease to help the patient cope with symptoms of disease (pain, stiffness, depression, fatigue) and avoid the detrimental results of disease early on, such as loss of muscle mass and BMD. In 2003, Roubenoff wrote: "Exercise is an explosively powerful stimulus to the human body, and failure to harness it in the service of anti-rheumatic treatment would be a great disservice to our patients".(32, 41)

Key factors necessitating strength training for the treatment of RA

RA is associated with increased morbidity and mortality rates that far exceed those of the healthy US population. Only 5% of deaths in RA patients are attributed to the disease itself.(43) Many of the co-morbid conditions leading to this increased morbidity and mortality, such as severe muscle atrophy,loss of functional capacity, loss of BMD, overweight and obesity, and cardiovascular disease, are all conditions thatcan be improved with regular exercise and strength training programs. An overview of these key conditions follows.

Muscle atrophy

Fat-free mass (FFM) consists of body cell mass (BCM), extra-cellular fluid (ECF) and extra-cellular solids (ECS) (i.e. collagen and bone mineral). Reduced FFM contributes to co-morbidity and reduced life expectancy in RA, as muscle is a primary store of body protein and depletion of body protein impairs adaptation to metabolic stress and the ability of patients to cope with secondary infection and concurrent illness. Declining BCM in RA patients is of great significance, as a loss of more than ~40% of baseline BCM severely compromises immune function and is associated with a loss of independence, clinical depression, reduced quality of life, and can ultimately be fatal.(15, 22)

FFM erosion is accelerated in disease states such as RA, with reduced FFM reported among patients with RA despite adequate protein and energy intake. It is estimated that nearly two-thirds of all RA patients experience this muscle wasting, or "rheumatoid cachexia", which occurs without a loss of body fat or body weight.(15, 22, 44) The significant loss of lean tissue is primarily due to elevated levels of pro-inflammatory cytokines (i.e. TNF-α and interleukin 1 beta (IL-1β)), which contribute to increased protein catabolism, anorexia, and elevated resting energy expenditure. The degree of cachexia is correlated with synovial burden, suggesting that these proinflammatory cytokines play a driving role in muscle wasting. In fact, elevated serum TNF was found in cachectic subjects with a RA flare, but not in those with a RA flare and normal lean body mass.(15, 22, 44-46) Decreased physical activity levels and steroid use (i.e. prednisone), nerve function impairment, changes in blood flow and dietary intake that is inadequate to meet increased energy needs, also contribute to loss of lean tissue. Loss of FFM in RA patients results in loss of range of motion of the joints, decreased strength and joint instability, and ultimately leads to an overall decline in functional capacity and higher disability rates.(27)

In a study completed by Munro et al (1997), 50% of those in the study group with RA, fell into the lowest 10^{th} percentile for muscle mass compared to an age, race, and sex-matched healthy reference population.(46) A dose-response relationship has been demonstrated between loss of FFM and RA severity. Roubenoff et al (1996) found BCM was 13% lower in subjects with RA compared to age, race, sex, and weight- matched healthy controls.(45, 47) Rall et al (1996) also found that REE was 12% higher, leading him to believe hypermetabolism contributes to metabolic changes resulting in rheumatoid cachexia. Also by studying whole-body protein turnover by ^{13}C-leucine infusion, he found that the rate of protein breakdown was significantly higher among subjects with RA compared to young and elderly subjects- with protein breakdown rates 17% higher than those in young subjects and 43% higher than those in elderly individuals. Growth hormone (GH) levels were also studied as they influence protein and energy metabolism (stimulates protein synthesis). They found that unrelated to chronological age, GH production among subjects with RA was significantly decreased compared to healthy young and elderly subjects.(47, 48)

The majority of RA patients have a 25-50% reduction in muscular strength compared with age-matched healthy controls, and a 55% deficit (or 45% of normal) in muscular endurance. In patients with more serious RA, (> Functional Class II), reductions of muscular strength up to 70% have been reported. Patients taking long-term steroids had even more pronounced loss of muscle strength.(3, 47)

Ekdahl et al (1992) evaluated isometric/isokinetic muscle strength and isokinetic endurance of the lower extremities as well as aerobic capacity in 67 RA patients (mean age 53 years) with Functional Class II RA and compared them with a healthy reference group matched for age and sex. Isometric hip and knee muscle strength of the RA group was reduced to about 75% normal function, isokinetic knee muscle strength to about 65-75% of normal function, and isokinetic endurance of knee muscle groups was reduced to about 45% of the reference group.(49)

Functional decline

Despite important developments in medical treatment of RA, the functional capacity or performance of activities of daily living and participation in society are seriously hampered in people with RA.(50) The duration of disease has been found to be more highly correlated with poor physical function than age. Reduced muscle strength, muscle atrophy, and a decline in functional capacity are often observed early in the course of RA, forcing patients to perform daily activities and paid work at a higher percentage of their maximum physiologic reserve.(22, 27, 51) The ability to carry out functional tests such as walking on even, level ground, walking on stairs, or the ability to step-up on a foot stool was approximately 40-60% less in RA patients with Functional Class II or III as compared with age-matched controls.(36)

Bone loss

In healthy adult populations, genetic factors, sex, hormonal status, lifestyle, and nutrition, are considered important risk factors for osteoporosis. In patients with RA, the duration of joint disease, immobilization, sex hormone disturbances, corticosteriod therapy, physical inactivity, and the inflammatory process, are additional risk factors for this complication. The incidence of osteoporosis in RA patients taking corticosteriods alone is estimated at 30-50%.(25, 51-55) This problem is so widespread that the ACR published position statements on the important role of rheumatologists in the diagnosis, treatment and continuous monitoring of BMD in RA patients.(56, 57) Decreased bone density puts the patient at increased risk of axial and appendicular fractures.(58)

Obesity

Reaching and maintaining a healthy weight is an important factor in RA patients, as research indicates that those with RA tend to be overweight and/or overfat. "Cachectic obesity", increased fat mass with a decline in FFM, commonly occurs in RA due to physical inactivity and disease mechanisms.(32) Obesity in RA may impair joint function by placing undue stress on the joints and further contributes to concomitant morbidities such as insulin resistance, Type 2 diabetes and heart disease, the latter being the number one co-morbidity associated with RA, accounting for one half to one-third of all RA related deaths.(59) Cachectic obesity is a vicious cycle, as increased TNF-α levels are found with increased adiposity, furthering FFM erosion through inflammatory mechanisms, thereby limiting activity and function, and predisposing one to fat gain.(32)

Cardiovascular disease

The risk of heart disease in people with RA is elevated due to several reasons. An interaction between systemic inflammation and traditional risk factors leads to accelerated damage of vessel walls and thus to a greater lethality of atherosclerosis in the presence of RA.(43) Increased C-reactive protein (CRP) levels (an inflammatory marker), for example, has been associated with accelerated atherosclerosis.(60) Additionally, fat distribution patterns in RA patients, which tend to be more abdominally distributed due to steroid treatment, also contribute to the risk of heart disease. The major contributor, however, is physical inactivity due to symptoms (e.g. pain, fatigue and stiffness), muscle contractures making exercise technically difficult, medication side-effects, decreased self-efficacy, and depression. Wang et al report significantly lower participation rates in leisure time physical activity in those with arthritis compared to healthy controls.(54, 61) Walsmith et al (2002) found habitual physical activity accounted for 77% of the difference in total daily energy expenditure (EE) between RA patients and healthy controls, indicating that low physical activity is an important determinant of low total daily EE in RA.(15)

Treatment goals for RA

Successful management of RA should be multifaceted and targeted to manage the fluctuating course of disease, alleviate symptoms, prevent disability, and maintain ultimate quality of life. The treatment goals may include the rheumatologist's mastering drug therapy to reduce inflammation and prevent structural damage, occupational and physical therapists to improve functional performance and teach self-help techniques, dietitians to help with weight management and overall nutrition, psychologists to support the patient and provide coping mechanisms, and physiologists to create individualized strength training programs and overall exercise programs for the patient.

THESIS FORMAT

The manuscripts within this dissertation will reportthe effects of a n intensive, individualized strength training exercise program on strength and body composition; function, disease activity, pain and quality of life; and discuss the development of, lessons learned, limitations and satisfaction with an individualized program for RA patients. These manuscripts are presented in Appendix A.

Origin of the study

The idea for this study was conceived in April 2002. After several months of research and writing, a grant proposal was submitted to Centocor, Inc., the manufacturer of Remicade™. The detailed planning and developmental work for this project began in the Summer of 2003, by researching methods used for assessing body composition, fatigue, disease activity, pain, self-efficacy, functional capacity, depression, body image, quality of life, physical activity and diet. Several types of assessments (methods used within and outside of the rheumatoid population) were researched for use in this study. In addition, a new method to measure function (box-carrying test) was created by the author in an attempt to fill a void in this area of rheumatologic research. Laboratory protocols were then created and compiled, and staff members were hired and trained.

Because only a limited number of studies have been completed in this area, all with various exercise program designs, durations, and intensities, the author also drew on her personal strength training experiences, the expertise of her doctoral committee, and outside experts. A great deal of time was committed to searching for qualified exercise trainers and creating the detailed, illustrated exercise manual used in the study.

The study then shifted from the development and training stage to recruitment. Due to the small eligible population for this study, and the less than ideal timing of the study implementation (during the summer months) recruitment efforts were intense and multiple strategies were employed, ranging from local media advertisements to one-on-one visits with patients.

Throughout the study, I served as Co-Principal Investigator, Project Director, recruiter, lab manager, lab technician, exercise trainer, motivational and event program coordinator, process evaluator, data manager and statistician.

CHAPTER 2- PRESENT STUDY

Study aims

The present study was designed to test the hypotheses that a 16-week progressive, individualized, intensive strength training program in RA patients taking Remicade™ would improve strength, body composition, disease activity, physical function, pain and quality of life outcomes, as compared to RA patients on Remicade™ with no strength training program. Twenty-four patients, aged 29-75, with a diagnosis of RA according to the ACR Functional Class I and II, participated in this randomized, controlled trial. The exercise group engaged in a three time a week strength training program at a local exercise facility, with the control group continuing standard of care as delivered by their rheumatologist. Assessments were completed at baseline, 8-week, and 16-week time points. Maximal strength, physical function, disease activity, body composition, quality of life, and pain, were measured with active tests and via questionnaires. Patients also completed exit evaluations on their satisfaction with the study.

METHODS

Study design

This randomized, controlled trial included 24 male and female RA patients recruited in one cohort. Patients were randomized near the end of a run-in phase in a 2:1 ratio to exercise or control (standard of care). This allowed for a greater sample size in the exercise group to better characterize the exercise effect. The exercise subjects participated in a strength training program three times per week, and the control group continued with standard of care, as overseen by their rheumatologist. The control group also had the opportunity to attend social events to foster a sense of belonging to the study. At the end of the study, they attended orientation sessions to learn the study's strength training program which they could begin on their own. All patients continued to receive regular medical care and Remicade therapy from their personal physicians. There was no attempt to change their therapy by the study team.

Recruitment and study entry

Patients were recruited via local media, materials in rheumatologists' offices, mailings to patients, and in- person recruitment by the Project Director and participating rheumatologists. The patients were screened over a 4- month period through phone interviews and medical history questionnaires. Eligible patients were invited to complete run-in and baseline testing lasting approximately 5 weeks. Financial compensation was not offered to the subjects. This project was approved by the University of Arizona's Human Subject's Review Committee and written informed consent was obtained from all subjects prior to study entry.

<u>Subject eligibility</u>

Patients >18 years (no upper age limit) with a diagnosis of RA according to the American College of Rheumatology (ACR) 1987 criteria, and American Rheumatology Association (ARA)(now ACR) Functional Class I and II, participated. The patients were on a stable dosage of Remicade (≥4 months) and taking no other biologic therapies. Patients did not have serious concomitant conditions such as heart disease, uncontrolled blood pressure, cancer, or severe osteoporosis (T score of ≤ -3.0 or ≤ -2.5 without treatment) and had no evidence of previous non-traumatic fractures. Patients were excluded for participation in strength training exercise or ≥ 150 minutes a week of aerobic exercise within the past 3 months, or if they had a body mass index (BMI) ≥ 40 kg/m^2. Other exclusions included the need for assistive devices (i.e. cane), plans to discontinue Remicade, or to leave Tucson for an extended period of time. All patients had to obtain written consent from their rheumatologist or primary care physician to participate.

Of the 100 people who were screened, 33 were eligible and began baseline run-in assessments; 32 were randomized (1 person did not pass the physical exam); and 30 began the study (2 people did not complete baseline assessments: 1 due to family commitments and 1 due to an eye infection preventing her from driving to the testing site). The main reasons patients did not meet eligibility criteria were due to 1) transportation difficulties, 2) being part-time residents, and 3) not being on Remicade or not on Remicade for ≥4 months.

<u>Study population</u>

Twenty-four patients (19 women and 5 men) completed the study (sixteen were randomized to exercise and 8 to control). Patients were between the ages of 29 and 75 years (mean 51±12.8 years) and exhibited mild to severe joint deformity. The majority of patients were Caucasian (95.8%), 16.7% were Hispanic, and 75% of the patients were employed (41.7% full time, 29.2% part time, 4.2% self-employed). Several of the patients were also regular care-takers of family members. Sixty seven percent of the patients were married, and the remaining single, divorced, or widowed (8.3%). The majority of patients had incomes >$60,000 or between $20-30,000, with 41.7% completing college. The mean duration of disease was 14.0±10.2 years (range 2.4-39 years) with the main joints affected stated as being the hands, wrists and fingers. One person had arthroplasties (both weight bearing and non-weight bearing joints). Based on the baseline DXA scan, 10 patients (6 were exercisers) had osteoporosis or osteopenia and were subsequently notified of these conditions. Three of the ten patients were currently being treated with bisphosphonates by their physician. Seven patients in the exercise group were currently taking a calcium supplement (5 of them included in the above 10 with osteopenia/osteoporosis). Seven of the twenty-four patients had been on Remicade for ≤12 months, 8 had been on Remicade 13-24 months, and 9 had been on it for 25-60 months. Four of the 24 patients were also taking prednisone, 21 were taking Methotrexate, 13 were taking non-steroidal anti-inflammatory drugs (NSAIDs), and 3 were taking other disease-modifying anti-rheumatic drugs (DMARDs). If the patient had engaged in exercise prior to entry into the study, the primary form of exercise was walking.

Assessments

The baseline and 16-week follow-up assessments took approximately 6 hours over 4 separate visits, with two month testing consisting of a reduced battery of questionnaires (no active tests) which took approximately 60 minutes. For all assessments, the technician gave standard verbal instructions from written protocol and explained the purpose of the assessment. Rigorous quality control procedures were followed with equipment calibrated on a regular basis.

The following assessments were completed in both groups at baseline and 16 weeks. All questionnaires, with the exception of the 7 Day Physical Activity Recall at baseline and 16-week timepoints, were self-administered. A staff member was available during all testing periods to answer subjects' questions.

Muscle Strength

Dynamic muscle strength (peak torque) of the elbow and knee flexors and extensors was measured using a Biodex Isokinetic Dynamometer (Biodex System, Shirley, NY). Subjects were seated comfortably and joint ROM was assessed via the computer interface. Both knee and elbow ROM was 90° to 180°, allowing for modest inter-subject variability based on joint status and pain. Care was taken to not go below 90˚ or above 180˚ (hyperextension) which could aggravate disease. Limb weights were measured during the knee extension exercise as a correction factor via the computer interface and used to correct computations of torque. The patient was seated in a fixed position for the arm extension (seat and dynamometer orientation 15') and leg extension (seat and dynamometer orientation 90'). Both chest and lap belts were used to prohibit excessive movement of the body unless the subject's size prohibited their use. In addition, upper leg and upper arm belts were used on the measured limbs during the knee extension and arm extension tests, respectively. The dynamometer, chair, and attachments were positioned laterally and vertically such that the axis of motion was aligned with the tested joint. The chair position settings (i.e. chair height, extension attachment position) and grip style (thumb wrapped around or thumb on top of handle) were recorded to ensure identical positioning at follow-up assessments. All tests were performed bilaterally unless a subject's injury or dysfunction prohibited such testing. The same technician completed all testing.

After a warm-up of 2-3 trial movements through full range of motion (90-180˚) two sets of 5 maximal contractions were performed at a velocity of 60°/sec (results expressed in newtons). Three minutes of rest was allowed between set one and two of the knee extension. Approximately 3 minutes of rest was allowed between leg sides. Ninety seconds of rest was allowed between sets one and two for the elbow extension and three minutes of rest between arm sides. No verbal encouragement was given during the trials, however, the subject was allowed to look at the computer screen during the test and try to "beat" their previous attempt. Additionally, there was a computer image which cheered the participant at the end of each trial. Before and after the test, patients rated their pain on a Pain VAS and rated their perceived exertion (RPE) at the conclusion of the test.

Peak torques across trials, within a set, were averaged. The highest average peak torque was used as the criterion score.

Three repetition maximums (3RMs) (the highest weight lifted three times through full range of motion with proper technique) were completed only by the exercise group in the gym where they performed their exercise routine. The 3RM was employed rather than the commonly used 1RM due to potential risk of injury and reported difficulty of RA subjects in performing maximal effort.(3, 62)

The first 3RM test was conducted 1 week into the exercise program. This timing allowed the exerciser to practice proper form and familiarize themselves with the weights prior to completing the 3RM. The machine leg press (Med-X, Gainesville, FL), incline dumbbell press (back rest at 55˚), and dumbbell hammer curl were the selected exercises for the 3RMs. For the upper body exercises, each arm was tested separately. No other exercise was completed on the 3RM testing days. The same exercise trainer completed 3RMs on all but two participants, using the same equipment. On test day, the subject walked to warm-up and then performed a light warm-up of 3-5 repetitions at 40% to 60% of perceived maximum. Following a 2 minute rest with light stretching, the subject performed 3-5 repetitions at 60-80% of perceived maximum. At this point, the subject was close to perceived maximum. Following a three minute rest, weight was added in small increments until the subject could not complete three maximal repetitions in proper form. The 3RM and isokinetic dynamometer assessments were done on opposite days than the grip dynamometer and FOCUS® function test to avoid fatigue.

A grip dynamometer assessed isometric grip strength using (Baseline, Irvington, NY) the hand dynamometer used on the FOCUS® System. All scoring was done electronically, generating easy to interpret reports. Subjects gripped the handle perpendicular to the longitudinal axis of the forearm, with the hand and forearm positioned in front of the body and the dynamometer resting on the shelf (not the forearm). The subject stood a comfortable distance away from the shelf with their arm extended but without locking the elbow. The subject was allowed to gently rest the opposite hand on the top of the dynamometer to help stabilize it while testing. The shelf height was set by aligning the shelf with the top of the subject's forearm while standing in a normal, relaxed posture with the elbow bent at 90˚. The dynamometer handle was set at position two. The subject was told to grip and squeeze the handle until the technician instructed them to stop. The subject completed 3 maximal voluntary contractions (MVC) lasting 3 seconds, with 5 seconds of rest in-between each trial (subject alternated from right to left hand). No verbal encouragement was given during the trials, however, the subject was allowed to look at the computer screen during the test to try to "beat" their previous attempt. The average of the 3 trials was used to obtain absolute grip force values (reported in pounds) for each hand. The dominant hand and shelf height was recorded for future reference. These values can be compared to a healthy reference population and work functional capacity.(63) The same technician completed all testing.

Functional performance

The 50-foot walk (the number of seconds it takes a subject to walk 50 feet at a normal pace) was used to assess function, as walk time often increases with more disease activity.(8) A distance of fifty feet was measured on a flat, straight walking surface and marked with masking tape. Each subject was instructed to start walking 10 feet prior to the marked area (also marked by tape) so that stride was established prior to the subject reaching the designated 50 foot starting point. The time used for initial acceleration and the number of steps in the first 10 feet were subtracted from the total. Time used to walk 50 feet was determined by use of a stopwatch and recorded in seconds. The number of strides taken during the 50 feet was recorded (measured by a pedometer) in order to determine stride length (and used in combination with the exercise logs to calculate aerobic intensity).

Because, to our knowledge, no upper body function test for the rheumatoid population currently exists, a test was designed to mimic activities of daily living including lifting, carrying, and setting down items of different loads.(64) The "box-carrying test" was designed as a timed circuit test which required the subject to lift a box off of a shelf (shelf height was determined by aligning the shelf with the top of the subject's forearm while standing in a normal, relaxed posture with the elbow bent at 90˚), carry it 25 feet to a marked point, turn, and carry it back 25 feet to the starting point where they returned the box to the shelf. Even though the test was timed, subjects were asked to carry the box while walking at a normal, relaxed pace. The purpose was to see if the subject walked slower or faster than their usual pace when carrying heavier loads, indicating some difficulty or discomfort and the desire to set the box down quickly. The time began when they lifted the weighted box off of the shelf, with finish time recorded when the box was set down on the shelf. Each circuit time was recorded individually. The box was 9 x 23 x5 inches , designed specifically for this test so that the box was carried in front of their body, with the weight resting on their forearms and against their upper arms, so that neither the wrists or hands had to engage to support the weight, but merely helped stabilize the box. The length of the box made it easy to lift and set down on the shelf by wrapping the arms under the ends of the box. The test had six individual circuits, with first circuit weight consisting of the weight of the box (6.2 lbs), the second circuit adding another 5 lbs (11.2 lbs total weight), and the third through sixth circuits adding 2.5 lbs (13.7 lbs), 2.5 lbs (16.2 lbs), 5 lbs (21.2 lbs), and 5 lbs (26.2 lbs), respectively. The subjects had a 15 second rest period in-between each circuit while additional weight was being added to the box. The subject continued with additional circuits until the subject could not complete a circuit due to pain or fatigue in the upper or lower body, or due to excessive weight (these reasons were recorded).(65) The test was also stopped if the patient leaned backwards or otherwise altered their posture to facilitate carrying the weight. A pre and post test Pain Visual Analogue Scale (VAS) was given. The same technician completed all tests.

The Arthritis Impact Measurement Scale 2 (AIMS2), a revised and expanded version of the original AIMS, is a more comprehensive and sensitive instrument than AIMS, including 3 new scales and 3 new sections to assess health status satisfaction, attribution of health status problems to arthritis, and designation of patient-selected priority areas for improvement.(66) It was selected for use in this population because of the diversity of function and fitness levels. It includes 57 items that may be broken into 12 scales, representing 12 areas of health: mobility, 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 scales may be combined into a 5 component model of health dimensions.(67, 68)

The Health Assessment Questionnaire (HAQ) measures health status and outcome and considers the effects of a disease in terms of death, disability, discomfort, the side effects of treatment and medical costs. The HAQ disability index (DI) which scores 20 questions (in 8 categories) on daily functioning on a scale of 0 (no difficulty- no functional limitations) to 3 (unable to do- serious functional limitations) was used.(69) The HAQ DI also asks questions about assistive aids or devices needed to perform these 20 daily functions. The change score can vary from -3 (maximal improvement) to +3 (maximal deterioration). The patient and physician’s global assessments were also obtained with a 100 mm VAS.

The HAQ R628 (Pincus) was also used, which includesitems from the HAQ, MDHAQ, and HAQII. The HAQ R628 was developed to include more complex or higher functioning activities, but was kept to two pages to minimize patient response burden. (70)

Medical History/Disease Status

A comprehensive medical history questionnaire which recorded medications, disease duration, lifestyle habits, family illness, pastsurgeries and hospitalizations was used to assess health status and monitor changes in disease activity. This questionnaire also provided a background for the rheumatologist who examined the subject at baseline. Additionally, medication information was collected from subjects via a telephone interview, to obtain current medications, dosage, start dates (and end dates) and was entered directly into a database by two different interviewers. The interview was conducted to improve the accuracy of medication reporting since the patient was interviewed at home and had access to their medicine cabinet to report accurate dosages.

One of two rheumatologists (JL and LS), conducted a comprehensive exam on each patient, completing 68-count joint counts (recording tender and swollen joints separately), a physician global assessment, determining ACR functional status, overall health status and gave clearance to subjects to participate in the study. The patient completed a self-report joint count (recording tender OR swollen joints and not differentiating), a Pain VAS, and patient global assessment. The exercise group also completed a Flare-Up VAS weekly, which asked how their arthritis flare-ups affected their ability to complete the study's exercise program that week. This form was used to help decipher any changes in compliance that may have occurred due to their disease status. The higher the score, the greater effect flare-ups had on their exercise regimen.

Quality of Life

The Medical Outcomes Study Short Form 36 (MOS SF-36) measured role limitations due to physical and emotionalrole limitations, physical function, pain, social function, vitality, mental health and general health perceptions.(71, 72) Patients were asked about their views of their health and how well they were able to do usual activities. Scores for each of the 8 subcales (scores for questions within a subscale) can be tallied, with higher scores indicating better health status. A Quality of Life (QOL) VAS also monitored changes in overall well-being and QOL. A 0 to 100 mm VAS format was used for the QOL scale, with the lower score representing a better quality of life.

Anthropometry

Standing height was measured to the nearest 0.1 cm with a Shorr stadiometer and weight was measured to the nearest 0.1 kg with a Secca model 880 digital scale following standard protocols. The average of two trials was used as the criterion measures. The recorded values for each trial had to be within 15% of each other or the measurements were repeated. The body mass index (kg/m^2) was derived from height and weight.

Physical activity

Subject physical activity history was assessed by the Aerobic Center Longitudinal Survey (ACLS) and 7 Day Physical Activity Recall. These tools are used to assess all physical activity including occupational and leisure time activity. The ACLS obtained information on physical activities performed at least once per week over the last 3 months and was self- administered. The Recall recorded time spent sleeping and doing physical activity for the past 7 days and was interview-guided to obtain the duration and intensity of activities. This information, in combination with established estimates of energy cost of various activities and body weight, can be used to estimate total energy cost of activity in control and experimental subjects.(73, 74)

Exercise logs collected from the exercise subjects allowed further description of physical activity at each training session which included a summary section completed once a week to record how many minutes of moderate physical activity they had in the past week in addition to the study regimen.

Exercise dose was quantified from exercise log records on weight lifted, exercise option selected, the number of sets and repetitions completed for each exercise (strength and abdominal), and the type, duration and intensity of their aerobic exercise. RPE was also recorded for the aerobic portions of their workout (including warm up and cool-down.)

Information on ROM exercises was recorded on a separate ROM log which the patients took home with them and returned each week to the facility.

Dietary intake

All subjects completed an optically scanned food frequency questionnaire (FFQ) based on the Block Model (Block et al, 1986) and modified to include southwestern foods (Arizona FFQ or AFFQ). The AAFQ consists of a semi-quantitative 159-item FFQ, which asks respondents to report how often they usually consume each particular food over the prior 12 month period as a number of times per day, week, or month and to indicate whether their usual portion size of that food was small, medium, or large. Although modifications have been made to the food lists, this FFQ is similar to the Block questionnaire with respect to portion size and food composition databases. Modification questions are added to assess dietary behavioral practices related to fat consumption to each line item in the food list. Age-sex specific portion size assumptions are used in the calculations. Daily nutrient totals, nutrients per individual foods, vitamin/mineral supplement intake, number of servings of specific foods, and food groups can be analyzed. Vitamin and mineral supplement intakes are also assessed, reporting nutrient estimates both including and excluding these supplements. The AFFQ demonstrated reliability and validity.(75, 76)

Self-efficacy

Self-efficacy was measured by the Arthritis Self-Efficacy Scale (ASES), Self-Efficacy 1, and Self-Efficacy 2 Questionnaires. The ASES is a 20 item self-efficacy measure developed specifically for individuals with arthritis. “Self efficacy” refers to the belief that one can perform a specific behavior or task in the future. The ASES yields 3 scores: self-efficacy for physical function, for pain management, and for controlling other arthritis symptoms.(77) Self-efficacy 1 assessed on a 10 point scale, how confident the patient was that they could exercise under several different conditions (when tired, during bad weather, or when schedule is hectic). (78) The Self-efficacy 2 questionnaire assessed how confident they were in completing certain physical activities. This was modified to fit our program (e.g. strength training exercises three times per week; aerobic exercise such as walking or bicycling three to four times per week; exercise without making symptoms worse). (79)

Stages of Change, Exercise Decisional Balance

The Exercise Stages of Change Short Form and Exercise Decisional Balance Questionnaires provided information regarding the subject’s ability to manage disease and adopt self-management techniques such as exercise to improve their outcomes. By profiling individuals with the Stages of Change Questionnaire, one may be able to identify sub-groups to predict patients’ participation in and responsiveness to intervention or enhance the outcomes of the intervention by tailoring treatment to the patient's particular stage. We chose to use the short form (1 question) format.(80) The Exercise Decisional Balance questionnaire represents both the cognitive and motivational aspects of decision making. Incentives for and against a particular decision are weighed in a balance sheet format. The 10 question format we used looks at positive and negative aspects of exercise and how important certain opinions are in the patient's decision to exercise or not exercise.(81) Research supports the integration of the decisional balance construct with the Transtheoretical Model (Stages of Change) in many problem behaviors.(82)

Body Image

Body image was assessed using the Body- Self Cathexis Questionnaire which reflects feelings of individuals have toward their bodies. This questionnaire asks which best represents their feelings (strong negative – strong positive feelings) about their moods, self-confidence, intelligence, sex appeal (self-cathexis) and their hands, hips, coordination, weight (body cathexis). The body cathexis asks about the degree of feeling of satisfaction or dissatisfaction with the various parts or processes of the body. The self-cathexis represents the various conceptual aspects of the self. The body-cathexis is believed to be integrally related to the self-concept. The scale contains 40 items with possible scores of 40-200. The body cathexis has well established validity with exercise and resistance training in both men and women.(83)

Depression

The Center for Epidemiologic Studies Depression Scale (CES-D) is a 20 item self-report depression scale developed to identify depression in the general population. The items refer to the frequency of symptoms during the past week, and covers components of depression such as feelings of guilt and worthlessness and feelings of helplessness and hopelessness. The CES-D is scored by reverse-scoring indicated items and summing all item scores. The lowest possible score is 0, indicating absence of depressive symptoms, and the highest possible score is 60, indicating severe depression.(66, 84)

Fatigue

The Multidimensional Assessment of Fatigue (MAF) and the Sleep Questionnaire was administered to determine the effect of exercise on fatigue. The MAF (Tack 1991) has 16 items that measure four dimensions of fatigue for the previous week: severity (2 items), distress (1 item), timing (2 items), and degree of interference in activities of daily living (11 items).(85-87) The 4 question Sleep Questionnaire was designed to assess regular sleeping patterns, hours of sleep, and restfulness of sleep (did they feel they required more sleep or needed help sleeping (medications)).

Pain

Pain was assessed with a VAS 100 mm scale with the end descriptions of “no pain” (0) or “pain as bad as could be” (100). The pain VAS provides a continuous scale for magnitude estimation and consists of a straight line, with the ends defined in terms of the extreme limits of pain experience. The absolute type of VAS was used which seems to be less sensitve to bias than a comparative one and is the refore preferable for general clinical use.(72)

Bone density and muscle mass

Dual-energy x-ray absorptiometry (DXA) is now recognized as a preferred approach (more valid and accurate) for body composition assessment since DXA is based on a three component model of composition. Whole body and regional fat, total FFM and total and regional lean soft tissue were measured by DXA. Appendicular skeletal muscle is derived from arm and leg lean soft tissue which recent studies have shown provides valid estimates of appendicular muscle mass in comparison to cadaver analysis and computed tomography**.** Whole body bone mineral content and density (BMD) (g/cm^2) and lumbar spine, proximal femur (neck, trochanter and Ward's triangle) and forearm BMD were also be measured by DXA.

The scans were conducted with a Hologic QDR 4500W (Hologic, Inc., Bedford, MA) with software version 9.09D. The total body scan was completed on medium (150 speed), the forearm on medium (150 speed), the AP spine on medium (750 speed) if the subjects chest or abdominal area (at thickest point) was ≤ 24 cm. The AP spine was done on slow (750 speed) if the area was >24 cm, and the femur on medium speed (750 speed) if depth of patient's hip measured at greater trochanter was ≤ 24 cm. The femur was scanned on slow speed (750) if the patient's hip depth >24 cm. The left leg was scanned for the femur and hip measurements. All scan analyses were done by two trained technicians with > 10 years of experience. The first technician completed all baseline measures, and the second technician completed all 16 week follow-up assessments (the first DXA technician moved out of state). At each time point, the technician who completed the measurements also completed the analysis.

Exercise program

The exercise intervention included progressive strength training exercise and weight-bearing aerobic activity supported by a program of social activities to promote adherence and compliance to the study protocol. Exercise participants trained three times per week on non-consecutive days (M, W, F). The order of the exercises alternated between upper and lower body and were completed in an order which used the larger muscle groups first in order to help minimize fatigue. Exercise sessions lasted ~75 minutes and included a warm-up (walking) (5-10 minutes), eight resistance exercises (40 minutes), aerobic exercise (15-20 minutes) (combined with the aerobics done during warm-up and cool-down, patients reached a total of 30 minutes), abdominal exercises, and a cool-down period (5 minutes) with walking and static stretching of the muscles. The patients were trained to complete selected range of motion (ROM) exercises 2-3 times per week on their own.

Certified exercise leaders supervised all exercise training sessions (trainer to patient ratio of 1:4). Prior to beginning the program, all patients attended a 2-hour classroom program overview and received a pedometer, weight gloves, a Theraband, and a detailed, illustrated exercise manual . They also completed a one-on-one assessment to determine individual needs and the initial option for each exercise; and a hands-on orientation in the gym with the trainers.

There were 8 strength training exercises: leg press, leg curl, hip abduction, hip adduction, calf raise, incline press, row, and hammer curl. For each exercise, three options were available, engaging the same muscle groups but through different modes. The patients completed 2 sets of 6-8 repetitions. Thirty to sixty seconds of rest was advised between sets, with slow 2-3 second contractions and extensions.

ROM exercises were selected from the Arthritis Foundation's recommended ROM exercises, focusing on the joints most commonly affected by RA, and complemented our strength program. Additional stretching exercises were done for each major body part during the cool-down phase of the exercise session.

Three options were given for the abdominal exercises, focusing on exercises involving pelvic tilts and utilizing leg movements (hip extensors) to work the abdominals to minimize neck and back involvement. Abdominal exercise options included those that could be performed on a floor mat, raised mat, and standing.

Walking, as a low-impact, weight-bearing activity was emphasized as the preferred aerobic activity. Walking also allowed the participant to focus on proper gait mechanics, which was important for many patients who had muscle imbalances and diminished proprioceptive acuity because of their RA. Walking was something the participants could engage in outside of the program with others, and they gained immediate feedback and motivation via their pedometers.

Progression of program

Patients progressed in the aerobic component (i.e. greater intensity or duration) when they could complete the exercises with a level of difficulty as rated on the RPE scale of ≤3. Patients also advanced to more difficult abdominal exercise options or had the choice of continuing the same exercise and holding the static position for a longer period of time.

For the strength training component, the patients progressed to additional weight when they could complete their current regimen in proper form for 2 sessions in a row, with an RPE of ≤4, with no joint pain, and at the trainer's discretion. Continuous progression was facilitated by the patient working with the trainer to set and record weight goals on the exercise log at the beginning of each week, with the aim of reaching the goal by the end of the week. Although the 3RM was primarily used as an assessment tool, along with weekly goal setting, the 3RMs helped to guide patients' progression, and maintained the patients' loads at approximately 70-85% of their maximum.

Individualization and options for the strength training program

The three options for each of the strength training exercises allowed the patient to begin at the appropriate level according to their fitness and functional ability, and advance as appropriate. The options allowed flexibility, giving the patient the means to continue to exercise the same muscle groups and exercise (at a lower intensity or via different mechanism) even in times of disease flare.

Option1, the easiest option, requiring only a Theraband, was generally reserved for severe flare-up days and as an option that could be completed when the patient was not able to make it to the gym due to vacation or gym closure on holidays. Option 2 incorporated Therabands and the use of some weight machines. Option 3, the preferred option, required dumbbells or other resistance equipment for all exercises. With the flexibility of the program, a patient who had problems with balance, for example, might complete option 1 for the calf raise (using both feet flat on the floor), but then could complete the other 7 exercises at option 3, or at a level (option) deemed appropriate by their function and fitness level.

Several types of assistive devices for weight lifting (weight gloves with hooks, wrist guards/supports) were also available to assist the patient in completing a successful exercise session. In addition, some patients used wrist cuff weights rather than dumbbells in times of flare-ups, or added wrist cuff weights to the dumbbell weight when their grip strength did not allow them to increase dumbbell weight.

Intervention Support Program

The intervention support program made use of a variety of social and personal reinforcement strategies, incentives, and awards, including both internal and external motivators for patient retention that have been shown to increase adherence and compliance with physical activity programs.(88-92)

The motivational program encouraged and fostered mechanisms for the inclusion of friends and family as exercisers or active supporters of exercise and addressed such issues as lack of motivation and anxiety that contribute to drop-out. These mechanisms of support are crucial to long term compliance and preventing detraining. The constructs addressed by the program include 1) education and skill development (classroom orientations, training manuals), 2) self-efficacy (personal contracts, goal setting, 3RM strength testing, exercise logs), 3) social support (participant recognition, motivational meals, personal notes of encouragement from trainers), 4) modeling (exercise challenges), and 5) incentive programs (gift cards and other rewards). The role of the trainer was crucial in this support process, providing encouragement, promoting good form, and assisting with both the intensiveness and progressiveness of the regimen, at least initially. The trainers' continuous supervision was important for compliance, as most untrained persons will not exercise at such an intense level or increase their weight without prompting.(93) Examples of events conducted for motivational purposes and to introduce patients to recreational activities for encouragement of lifestyle physical activities included: king/queen of the weight room, breakfast with the trainers, motivational meals, pedometer challenge, dance night, and olympics at the park.

Exercise Compliance and Follow-up

Rigorous compliance procedures were followed by recording problems related to attendance, motivation, barriers and any modifications to a patient's program; discussing them at weekly trainer meetings; and creating a solution with the patient. When a participant failed to attend a training session, their absence was noted in the trainer's notes and on the attendance check off sheet. If the participant failed to show up at the next scheduled exercise session, they were called to see why they did not attend and what we could do to get them back to the gym. If the participant received two calls from the trainers without a response or a negative response, the Project Director called the participant to follow up.

Trainers' notebook

The trainers' notes consisted of notes written on subjects every session. Problems with compliance, injuries, problems with motivation or outside barriers, reasons for absence, modifications to the exercise program and change in exercise options or any potential concern was noted. These notes provided qualitative information to supplement the exercise logs. Any concerns were discussed at weekly trainer meetings.

Adverse events

If an adverse event occurred, additional protocols were in place for tracking and resolution. Adverse events (AE) and serious adverse events (SAE) were recorded by the trainers on the respective forms. These events were discussed, monitored, and a plan of action was created at weekly trainer meetings. AEs and SAEs were recorded whether or not they were the result of participation in the study. They were recorded in order to ensure modifications were made, as necessary, to the exercise regimen, and if needed, medical attention was obtained. If the participant required immediate attention from a health care professional, the "Physical Therapy and Physician Referral Notes" form was also completed by the trainer. This form reported the date of the incident and description of the problem. The participants first were sent to a rheumatologist for evaluation (their notes being recorded on the same form, along with their recommendations for modification of exercises), and then, if necessary, to the study physical therapist. Notes were also made in the study participant's folder and in the trainers' notebook.

Intervention Type and Dose

Exercise dose was quantified from exercise log records on weight lifted, exercise option selected, the number of sets and repetitions completed for each exercise (strength and abdominal), and the type, duration and intensity of their aerobic exercise. RPE was also recorded for the aerobic portions of their workout (including warm up and cool-down.) Information on ROM exercises were recorded on a separate ROM log which the patients took home with them and returned each week to the facility.

Exercise logs collected from the exercise subjects allowed further description of physical activity at each training session which included a summary section completed once a week to record how many minutes of moderate physical activity they had in the past week in addition to the study regimen.

Exit evaluations

The exit evaluations completed by the patients consisted of two separate forms: 1) a 22-item questionnaire on the overall administration and satisfaction with the study (i.e. laboratory assessments, what the patients would change about the study, if anything; and 2) (only for those in the exercise group) a 38-item questionnaire obtaining information on their satisfaction with the exercise program (i.e. rating the knowledge of exercise trainers, their favorite exercises, exercises the patients found challenging). The evaluations were confidential and rated study areas from a score of 1 (strongly disagree) to 5 (strongly agree).

RESULTS

Drop-outs

A total of 6 participants dropped from the study, with co-morbid conditions unrelated to the study responsible for all drop-outs in the exercise program (n=4). Five exercise subjects had an illness or infection and had to delay their Remicade treatment, subsequently causing theirdisease to flare. In 4 of 5 of these cases, the delay was prolonged and the patient was excluded from the study: 1 had pneumonia, 1 had a staph infection, 1 had an infection due to a spider bite (patient completed exercise program but could not do 16- week testing), and 1 had severe gastrointestinal difficulties. In the control group, 2 people dropped: one due to a family crisis and one due to discontinuation of Remicade as per her rheumatologist.

Strength and body composition

As measured by 3RM, the mean % change in strength for the exercise group from baseline to 16 weeks was 46.1± 31.6% ($p<.01$). Significant strength changes were also seen for all 8 exercises performed in they gym ($p<.01$). Subjects continued to increase in strength at every follow-up timepoint (8 and 16 weeks). The mean exercise attendance for the 16 weeks was 82.0±10.6%. Attendance was strongly correlated with total weight lifted by the exercise group ($p<.01$) as reported by the exercise logs. Compared to the control group, there was a significant increase in right hand grip strength in the exercise group with a mean increase of 2.9 ± 4.0 kg, compared to a -1.2± 3.0 kg loss in controls ($p<.1$) over the 16 weeks. The exercise group gained lean tissue in the trunk, with a mean of 0.9 ± 1.0 kg for exercisers, versus 0.2 ± 1.3 kg for controls ($p<.01$). BMD did not differ significantly between the exercisers and controls, although the exercisers lost less BMD at the total hip and trochanter.

Function, disease activity and quality of life

Compared to the control group, there was a significant improvement in 50-foot walk time in the exercise group, with a mean reduction of -1.2±1.6 seconds and increase of 0.8±1.0 seconds in controls ($p=.01$) over the 16 weeks. Results from the AIMS2 also showed significant improvements in the exercise group in both the hand ($p=.04$) and arm ($p=.00$) function subscales. Although not statistically significant, there was a clinically important difference in the HAQ DI, with a mean change of -0.4±0.4 in the exercisers and -0.1±0.4 in the controls. According to the MOS SF-36 Questionnaire, exercisers improved more than controls in 7 of the 8 subscales, with significant improvement in mean physical function, (18.3±11.6) compared to controls (2.1±10.4) ($p=.09$). The exercisers also had a significant decrease in pain, as measured by a Pain VAS of -0.4±0.6, compared to controls who had a mean score of -0.0±0.6 ($p=.07$). Results of the QOL VAS indicated the exercisers improved more than the controls, -0.3±61 versus -0.02±1.2, though this difference was not significant ($p=.62$).

Design and development of the program, lessons learned, limitations and satisfaction with the study

The individualization of the strength training program and personal attention received from the exercise trainers was critical to the success of many of the patients. Because of the exercises included in the program and the program's flexibility, patients could continue with the strength training regimen in times of flare-ups as well as times of good disease control. Although the variety of options available in the strength training program were successful, minor alterations were still needed in the calf raise exercise to further individualize it and meet the needs of some patients. Limitations of the study focused on service-oriented issues that were driven by limited funding. Greater equipment availability (larger gym) and a study of longer duration would have improved the study's implementation. The compliance and satisfaction with the program was high, with all of the patients continuing strength training at the conclusion of the study. Future recommendations from patients included continuing the study for longer, and providing further opportunities to socialize for long-term motivation and support.

CONCLUSIONS

High-intensity strength training in RA patients with low to severe disease activity and joint damage was found to be feasible and led to overall positive impacts on many physical and psychosocial variables. No detrimental effects on disease activity were seen in this study. Other intensive strength training studies have found similar results.(22, 25, 27, 94) With the revolution of BRMs such as Remicade, patients are better able to complete exercise regimens and should be prescribed regular, intensive, individualized strength training exercise just as they would be expected to receive the latest pharmaceutical treatment. Strength training exercise is an essential part of their therapy, serving to regain and maintain muscle mass, BMD, functional capacity and an improved psychological outlook and a good quality of life. An individualized, intensive, strength training program is an essential component of the era of “early and aggressive” treatment for the RA patient.

Implications

It is my hope that the rheumatologic community will soon embrace the importance of intensive strength training, and by accepting its tremendous benefits, will mobilize ACR and AF to educate all health professionals and therefore patients. To gain their acceptance will require more research in RA populations of varying disease status, with studies of larger sample sizes, longer duration, assessments of radiologic impact, and well designed, detailed, randomized studies. This is a monumental task, as historically RA patients have been told not to exercise. Even in the healthy population, fewer than 20% of persons meet current recommendations for exercise or physical activity. The rheumatologist's role is crucial in this effort, as they significantly influence the content of exercise discussions and the likelihood of an exercise prescription for the patient. They are viewed as experts and are most likely to motivate patients to attend to their suggestions, engage in discussion about exercise, and influence patients' attitudes toward exercise.(26) Failure to further research and embrace intensive strength training as a first line therapy for the RA patient will only hinder our advancements in creating essential multi-disciplinary venues for the RA patient to help them achieve a more independent and rewarding quality of life.

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APPENDIX A- MANUSCRIPTS

THE EFFECTS OF A 16-WEEK INDIVIDUALIZED, INTENSIVE STRENGTH TRAINING PROGRAM ON STRENGTH AND BODY COMPOSITION IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Key words: rheumatoid arthritis, strength training, body composition

ABSTRACT

Objective. To assess the effects of a 16-week progressive, individualized, intensive strength training program on strength and body composition in patients with rheumatoid arthritis (RA).

Methods. Twenty-four male and female RA patients taking Remicade™ (Infliximab), with varying levels of disease activity and joint damage, participated in a randomized, controlled trial. The exercise subjects participated in a supervised strength training program three times a week and the control group continued with standard of care as overseen by their rheumatologist. Assessments for strength and body composition were completed at baseline, 8-week, and 16-week (end of study) time points.

Results. As measured by 3 repetition maximum (3RM), the mean % increase in strength for the exercise group from baseline to 16 weeks was 46.1± 31.6% ($p<.01$). The mean

attendance for the 16 weeks was 82.0±10.6%. Attendance was strongly correlated with total weight lifted by the exercise group ($p<.01$) as reported by the exercise logs. Compared to the control group, there was a significant increase in right hand grip strength in the exercise group with a mean increase of 2.9 ± 4.0 kg, compared to a -1.2± 3.0 kg loss in controls ($p<.1$) over the 16 weeks. The exercise group also gained more lean tissue in the trunk, with a mean of 0.9 ± 1.0 kg for exercisers, versus 0.2 ± 1.3 kg for controls ($p<.01$). The exercisers lost less bone mineral density (BMD) in the hip than controls, but the changes were not significant.

Conclusion. High-intensity strength training in RA patients with low to high disease activity and joint damage produces overall positive impacts on strength, BMD and soft tissue, with no detrimental effects on disease activity.

INTRODUCTION

Few intensive strength training studies have been completed in RA populations. The majority of strength training studies have been of low to moderate intensity (≤65% of maximal effort), have been home-based or minimally supervised programs, had small sample sizes, were not generalizable (inpatient populations) or had non-randomized designs.(1-4) Individualization of the programs has only consisted of decreasing the intensity during flare-ups without separate exercise options available. Very few studies have had the patients keep exercise logs which could provide valuable dose-response information and provide the patients with feedback opportunities. Also, outcomes have been difficult to compare between studies as the length of the training periods have varied from 3 weeks to 2 years, samples have included patients with other peripheral arthritis and varying durations and severity of RA, and there have been differences in test protocols and equipment.(5) There is also considerable variability among the frequency, intensity (ranging from unknown to 80% of 1 RM) and type of exercise (some have used mixed training methods), with many insufficiently described exercise protocols. Exercises have been carried out using dynamometers, pneumatic equipment, cycle ergometers, elastic bands, weight machines, dumbbells, water, or body weight as resistance.(4, 6) Additionally, no study has looked at the possible synergism between Remicade and strength training.

Despite these differences in design, the consistency among the studies regarding the benefits of intensive dynamic exercises for patients with RA is remarkable. Results to date seem to indicate that high-intensity strength training is feasible and safe for the majority of patients with RA, and leads to significant improvements in many health outcomes such as strength, function, quality of life, psychosocial factors, and fatigue, without exacerbating disease activity or joint pain.(6, 7) The strength training studies showing the greatest strength improvements were those with high-intensity programs, as compared to lower intensity. Unfortunately, high intensity strength training exercise programs have not yet become a regular part of the management of RA patients due to perceived risks.(5, 8, 9)

The multitude of comorbid conditions RA patients face (i.e. cardiovascular disease, osteoporosis, muscle wasting) may far outweigh the potential risk of injury to RA patients during a properly executed strength training program.(9) Strength training may counter the loss of lean tissue and BMD attributed to corticosteroid use, hypermetabolism, inhibition of muscle contraction due to joint effusions, reduced capillary density, increased levels of proinflammatory cytokines, and steroid myopathy.(1, 5, 10-13)

In a study completed by Munro et al (1997), 50% of subjects with RA fell into the lowest 10^{th} percentile for muscle mass compared to an age, race, and sex-matched healthy reference population.(14) Up to two-thirds of RA patients may experience “rheumatoid cachexia”, or reduced fat free mass (FFM), and this loss of muscle and strength is seen even in RA patients who are very functional.(15, 16) Compared with age-matched healthy controls, RA patients are reported to have a 25-55% deficit in muscular strength.(6, 17)

The disease duration, physical inactivity, impaired function and the inflammatory process itself contribute to bone loss in RA. The incidence of osteoporosis in RA patients taking corticosteriods alone is estimated at 30-50%.(18) Decreased bone density places the RA patient at greater risk of appendicular and peripheral fractures.(19) Compston et al (1988) studied non-steroid treated RA patients compared to healthy controls and found that the mean BMD in the patient group was significantly lower than in the controls. The reduction in BMD was most marked in the youngest age group (21-40 years) and even lower in those treated with steroids.(20)

The present study was designed to investigate the effects of a 16-week high-intensity dynamic, progressive, individualized strength training exercise program in patients with RA currently taking Remicade. Our study is the first continually supervised, facility-based, intensive, randomized, individualized strength training program with the largest sample size yet published.

METHODS

Study design

This randomized, controlled trial included 24 male and female RA patients recruited in one cohort. Patients were randomized near the end of a run-in phase in a 2:1 ratio to exercise or control (standard of care). This allowed for a greater sample size in the exercise group to better characterize the exercise effect. The exercise subjects participated in a strength training program three times per week, and the control group continued with standard of care, as overseen by their rheumatologist. The control group also had the opportunity to attend social events to facilitate a sense of belonging to the study; and, at the end of the study, could attend orientation sessions to learn the study's strength training program, which they could begin on their own. All patients continued to receive regular medical care and Remicade therapy from their personal physicians. There was no attempt to change their therapy by the study team.

Recruitment and study entry

Patients were recruited via local media, materials in rheumatologists' offices, mailings to patients, and in-person recruitment by the Project Director and participating rheumatologists. The patients were screened over a 4-month period through phone interviews and medical history questionnaires. Eligible patients were invited to complete run-in and baseline testing lasting approximately 5 weeks. Financial compensation was not offered to the subjects. This project was approved by the University of Arizona's

Human Subject's Review Committee and written informed consent was obtained from all subjects prior to study entry.

Subject eligibility

Patients >18 years (no upper age limit) with a diagnosis of RA according to the American College of Rheumatology (ACR) 1987 criteria, and American Rheumatology Association (ARA)(now ACR) Functional Class I and II, participated. The patients were on a stable dosage of Remicade (≥4 months) and taking no other biologic therapies. Patients did not have serious concomitant conditions such as heart disease, uncontrolled blood pressure, cancer, or severe osteoporosis (T score of ≤ -3.0 or ≤ -2.5 without treatment) and had no evidence of previous non-traumatic fractures. Patients were excluded from the study for participation in strength training exercise or ≥ 150 minutes a week of aerobic exercise within the past 3 months, or if they had a body mass index (BMI) ≥ 40 kg/m^2. Other exclusions included the need for assistive devices (i.e. cane), plans to discontinue Remicade, or to leave Tucson for an extended period of time. All patients had to obtain written consent from their rheumatologist or primary care physician to participate.

Of the 100 people who were screened, 33 were eligible and began baseline run-in assessments; 32 were randomized (1 person did not pass the physical exam); and 30 began the study (2 people did not complete baseline assessments: 1 due to family commitments and 1 due to an eye infection preventing her from driving to the testing site). The main reasons patients did not meet eligibility criteria were due to 1) transportation difficulties, 2) being part-time Tucson residents, and 3) not being on Remicade or not on Remicade for ≥4 months.

Study population

Twenty-four patients (19 women and 5 men) completed the study (sixteen were randomized to exercise and 8 to control). Patients were between the ages of 29 and 75 years (mean 51±12.8 years) and exhibited mild to severe joint deformity. The majority of patients were Caucasian (95.8%), 16.7% were Hispanic, and 75% of the patients were employed (41.7% full time, 29.2% part time, 4.2% self-employed). Several of the patients were also regular care-takers of family members. The mean duration of disease was 14.0±10.2 years (range 2.4-39 years) with the main joints affected stated as being the hands, wrists and fingers. One person had arthroplasties (both weight bearing and non-weight bearing joints). Based on the baseline dual-energy x-ray absorptiometry (DXA) scan, 10 patients (6 were exercisers) had osteoporosis or osteopenia and were subsequently notified of these conditions. Three of the ten patients were currently being treated with bisphosphonates by their physician. Seven patients in the exercise group were currently taking a calcium supplement (5 of them included in the above 10 with osteopenia/osteoporosis). Seven of the twenty-four patients had been on Remicade for ≤12 months, 8 had been on Remicade 13-24 months, and 9 had been on it for 25-60 months. Four of the 24 patients were also taking prednisone, 21 were taking Methotrexate, 13 were taking non-steroidal anti-inflammatory drugs (NSAIDs), and 3 were taking other disease-modifying anti-rheumatic drugs (DMARDs). If the patient had engaged in exercise prior to entry into the study, the primary form of exercise was walking.

<u>Assessments</u>

The following assessments were completed in both groups at baseline and 16 weeks. Eight week testing consisted only of a reduced battery of questionnaires. Standard quality control procedures were followed and equipment calibration was completed throughout the study.

Muscle strength

Dynamic muscle strength (peak torque) of the elbow and knee flexors and extensors was measured using a Biodex Isokinetic Dynamometer (Biodex System, Shirley, NY). The dynamometer, chair, and attachments were positioned such that the axis of motion was aligned with the tested joint. After a warm-up of 2-3 trials through the full range of motion (90-180˚), two sets of 5 maximal contractions were performed at a velocity of 60°/sec. Short rest periods were allowed between sets and between limb sides as the equipment was repositioned. Before and after the test, patients rated their pain on a Pain Visual Analogue Scale (VAS) and rated their perceived exertion (RPE) at the conclusion of the test. Peak torques across trials within a set were averaged and the highest average peak torque was used as the criterion score.

Muscle strength, estimated by 3RMs (highest weight lifted three times through full range of motion with proper technique) was also measured in the exercise group in the gym where they performed their exercise routine. The first 3RM test was conducted one week into the exercise program. The machine leg press (Med-X, Gainesville, FL), incline dumbbell press (back rest at 55˚), and dumbbell hammer curl were the selected exercises for the 3RMs. For the upper body exercises, each arm was tested separately.

A grip dynamometer assessed isometric grip strength using the hand dynamometer of the FOCUS® System (Baseline, Irvington, NY). The dynamometer handle was set at position two. The patient completed 3 maximal voluntary contractions (MVC) lasting 3 seconds, with 5 seconds of rest in-between each trial (patient alternated from right to left hand). The average of the 3 trials was used to obtain absolute grip force values for each hand.

Bone density and muscle mass

Whole body and regional fat, total fat free mass (FFM) and total and regional lean soft tissue (LST) were measured by DXA. Appendicular skeletal muscle was derived from arm and leg lean soft tissue**.** Whole body lumbar spine, proximal femur (neck, trochanter and Ward's triangle), total hip and forearm BMD were also measured by DXA. The scans were conducted with a Hologic QDR 4500W (Hologic, Inc., Bedford, MA) with software version 9.09D. The left leg was scanned for the femur and hip measurements.

Exercise program

The exercise intervention included progressive strength training exercise and weight-bearing aerobic activity supported by a program of social activities to promote adherence and compliance to the study protocol. Exercise participants trained three times per week on non-consecutive days (M, W, F). The order of the exercises alternated between upper and lower body and were completed in an order which used the larger muscle groups first in order to help minimize fatigue. Exercise sessions lasted ~75 minutes and included a warm-up (walking) (5-10 minutes), eight resistance exercises (40 minutes), aerobic exercise (15-20 minutes) (combined with the aerobics done during warm-up and cool-down, patients reached a minimum of 30 minutes), abdominal exercises, and a cool-down period (5 minutes) with walking and static stretching of the muscles. The patients were trained to complete selected range of motion (ROM) exercises 2-3 times per week on their own.

Certified exercise leaders supervised all exercise training sessions (trainer to patient ratio of 1:4). Prior to beginning the program, all patients attended a 2 hour classroom program overview and received a pedometer, weight gloves, a Theraband, and a detailed, illustrated exercise manual. They also completed a one-on-one assessment to determine individual needs and the initial option for each exercise; and a hands-on orientation in the gym with the trainers.

There were 8 strength training exercises: leg press, leg curl, hip abduction, hip adduction, calf raise, incline press, row, and hammer curl. For each exercise, three options were available, engaging the same muscle groups but through different modes. The patients completed 2 sets of 6-8 repetitions. Thirty to sixty seconds of rest was advised between sets, with slow 2-3 second contractions and extensions.

ROM exercises were selected from the Arthritis Foundation’s recommended ROM exercises, focusing on the joints most commonly affected by RA, and complemented our strength program. Additional stretching exercises were done for each major body part during the cool-down phase of the exercise session.

Three options were given for the abdominal exercises, focusing on exercises involving pelvic tilts and utilizing leg movements (hip extensors) to work the abdominals and minimize neck and back involvement. Abdominal exercise options included those that could be performed on a floor mat, raised mat, and standing.

Walking, as a low-impact, weight-bearing activity was emphasized as the preferred aerobic activity. Walking also allowed the participant to focus on proper gait mechanics, which was important for many patients who had muscle imbalances and diminished proprioceptive acuity because of their RA. Walking was something the participants could engage in outside of the program with others, and they gained immediate feedback and motivation via their pedometers.

Progression of program

Patients progressed in the aerobic component (i.e. greater intensity or duration) when they could complete the exercises with a level of difficulty as rated on the RPE scale of ≤3. Patients also advanced to more difficult abdominal exercise options or had the choice of continuing the same exercise and holding the static position for a longer period of time.

For the strength training component, the patients progressed to additional weight when they could complete their current regimen in proper form for 2 sessions in a row, with an RPE of ≤4, with no joint pain, and at the trainer's discretion. Continuous progression was facilitated by the patient working with the trainer to set and record weight goals on the exercise log at the beginning of each week, with the aim of reaching the goal by the end of the week. Although the 3RM was primarily used as an assessment tool, along with weekly goal setting, the 3RMs helped to guide patients' progression, and maintained the patients' loads at approximately 70-85% of their maximum.

Individualization and options for the strength training program

Three options were available for each of the 8 key strength training exercises, which allowed the patient to begin at the appropriate level according to their fitness level and functional ability. Option1, the easiest option, requiring only a Theraband, was generally reserved for severe flare-up days and as an option that could be completed when the patient was not able to make it to the gym due to vacation or holiday (gym closure). Option 2 incorporated Therabands and the use of some weight machines. Option 3, the preferred option, required dumbbells or other resistance equipment for all exercises. With the flexibility of the program, a patient who had problems with balance, for example, might complete option 1 for the calf raise (using both feet flat on the floor), but then could complete the other 7 exercises at option 3, or at a level (option) deemed appropriate by their function and fitness level.

Several types of assistive devices for weight lifting (weight gloves with hooks, wrist guards/supports) were also available to assist the patient in completing a successful exercise session despite disfigurement or limited mobility. In addition, some patients used wrist cuff weights rather than dumbbells in times of flare ups, or added wrist cuff weights to the dumbbell weight when their grip strength did not allow them to increase dumbbell weight.

Intervention support program

The intervention support program made use of a variety of social and personal reinforcement strategies, incentives, and awards, including both internal and external motivators for patient retention that have been shown to increase adherence and compliance with physical activity programs.(21-25)

Exercise compliance and follow-up

Rigorous compliance procedures were followed by recording problems related to attendance, motivation, barriers and any modifications to a patient's program; discussing them at weekly trainer meetings; and creating a solution with the patient. If an adverse event occurred, additional protocols were in place for tracking and resolution.

Intervention type and dose

Exercise dose was quantified from exercise log records on weight lifted, exercise option selected, the number of sets and repetitions completed for each exercise (strength and abdominal), and the type, duration and intensity of their aerobic exercise. RPE was recorded for the aerobic portions of their workout (including warm up and cool-down.) Information on ROM exercises were recorded on a separate ROM log which the patients took home with them and returned each week to the facility.

Data analysis

Statistical analyses were completed using the Statistical Package for the Social Sciences, (SPSS, version 12.0).(26) Measures of central tendency and distribution were examined to describe the sample, to test for normality and homoscedasticity, and to describe outcomes. The baseline characteristics of those who completed the study were compared to drop-outs using independent t-tests. Possible baseline mean differences in strength and other characteristics between the exercise and control groups were tested using independent t-tests. Paired t-tests were used to test for significant changes in strength within the exercise group and independent t-tests were used to assess differences in mean group changes between exercisers and controls. The general linear model (ANCOVA) was used to study the effects of exercise on strength and body composition outcomes, adjusting for age, sex and baseline values. Because of unequal numbers of men and women, we weighted the sex variable so that the sum of coefficients equaled zero for each contrast. Analysis was repeated without the 5 male patients to examine any differences between an all female sample and a mixed sample. There were no significant differences encountered in this repeat analysis. Attendance was calculated as the percent of sessions attended out of the total possible sessions (48, including holidays). Total weight lifted (Table 3) was calculated from the sum of all weights lifted from eight individual exercises. The weight lifted (kg) was multiplied by number of repetitions, and by 2 sets for each exercise session (3 days). The mean percent change in strength (from 3RM) was calculated as the mean percent change of all 3RM exercises. The mean change in strength (from exercise logs) as calculated for Figures 1 and 2 used the average of weeks 1-3, 8-10, and 14-16 to obtain baseline, mid-point, and end of study timepoint values. The last observation was carried forward when there was one missing value in any of these selected timepoints (due to absence, flare-up, etc.). If two out of the three values were missing at any timepoint, no values were imputed.

RESULTS

Baseline characteristics

Baseline characteristics for the patients who completed baseline and 16 week assessments are shown in Table 1. The mean age was 51± 12.8 years, with an average disease duration of 14.0±10.2 years (Table 1). With the exception of peak torque for both legs, and left hand grip strength, there were no significant differences between exercise and control groups ($p<.05$). The control group had greater baseline leg peak torque and left hand grip strength.

Table 1. Baseline characteristics

Baseline Characteristics	*Control group (n=8)*	*Exercise group (n=16)*
Age, years	49.0±12.6	52.2±13
BMI, kg/m^2	26.0±3.6	26.7±5.4
Duration of RA, years	11.2±8.9	15.4±10.8
Length on Remicade, months	21.8±10.6	24.4±13.7
Pain Visual Analogue Scale (VAS)†	20.6±13	26.4±21.5
Health Assessment Questionnaire Disability Index (HAQ DI)	.53±.43	.84±.63
50 foot walk time, seconds	11.7±2.0	13.2±2.5
BMD L2-L4, g/cm^2	1.03±.16	1.00±.11
BMD total hip, g/cm^2	.98±.16	.89±.19
Lean soft tissue total, kg	50.2±11.0	42.1±8.6
BMD Ultradistal, g/cm^2	.73±.11	.66±.08
Peak Torque Left Leg, Newtons*	127.1±61.3	73.9±21.8
Peak Torque Left Arm, Newtons	43.9±21.2	29.5±13.3
Peak Torque Right Leg, Newtons*	119.8±49.0	74.7±27.5
Peak Torque Right Arm, Newtons	42.8±20.3	30.0±12
Grip dynamometer (Left), kg*	26.8±15	15.1±8.3
Grip dynamometer (Right), kg	26.4±16.4	16±9.6

† n=15 in the exercise group for this variable
*Significant difference (p<.05)

Drop-outs

A total of 6 participants dropped from the study, with comorbid conditions unrelated to the study responsible for all drop-outs in the exercise program (n=4). Five exercise subjects had an illness or infection and had to delay their Remicade treatment, subsequently causing their disease to flare. In 4 of 5 of these cases, the delay was prolonged and the patient was excluded from the study: one had pneumonia, one had a staph infection, one had an infection due to a spider bite (patient completed exercise program but could not do 16-week testing), and one had severe gastrointestinal difficulties. In the control group, 2 people dropped: one due to a family crisis and one due to discontinuation of Remicade as per her rheumatologist. There were no significant baseline value differences between those who completed the study and those who were non-completers.

Attendance

The mean attendance at exercise sessions for the 16 weeks was 82.0±10.6%. Attendance was strongly correlated with total weight lifted by the exercise group ($p<.01$) as reported by the exercise logs. Using the mean of day 2 (Wednesday) as a measure, patients completed option 3, the most advanced option, for 7 of the 8 exercises ≥92.0% of the time. The exception was the calf raise, for which patients completed option 3 an average of 74.0% of the time. Several patients had foot pain due to disfigurement of their toes/feet, had fused toes, or neuropathy, which made the calf-raise exercise challenging, and this accounted for fewer patients completing option 3 for this exercise.

Attendance was positively correlated with changes in grip strength, total weight lifted, and change in weight lifted from baseline to 16 weeks ($p<.05$).

Strength

Significant increases in strength were seen in all 3RM exercises from baseline to 16 weeks (Table 2), with continuous gains in strength at each follow-up timepoint (8 and 16 weeks).

Table 2. Mean strength changes in percent from 3RMs for exercise group

Exercises	Baseline to 8 week n=16	p	8-week to 16 week n=16	p	Baseline to 16-week n=16	p
Leg press	25.1±22.4%	.001	20.8±14%	.000	46.4±35.2%	.000
Hammer curl, Right	19±20.3%	.000	15.4±23.7%	.005	34.1±20.6%	.000
Hammer Curl, Left	32.6±46.5%	.000	12.1±17.2%	.002	43.1±19.3%	.000
Incline dumbbell press, Right	38.8±22.7%	.000	16±17.7%	.021	55.6±38.3%	.000
Incline dumbbell press, Left	36.4±25.6%	.005	15.3±20.7%	.059	48.1±32.7%	.000
Total change	28.9±18.9%	.000	21±11%	.000	46.1±31.6%	.000

The mean % increase in strength from the three 3RM exercises from baseline to 16 weeks was 46.09±31.6% ($p < .01$). Mean percent change ranged from 34.1±20.6% for the hammer curl (right) to 55.6±38.3% for the incline dumbbell press (right). The mean percent increase for the leg press is in actuality slightly higher than reported. Four of the exercisers pressed the entire leg stack (500 lbs) during their 16-week 3RM and were able to complete more than 3 repetitions. As we were unable to increase the weight any further due to equipment limitations, we could not obtain their true 3RM, and thus recorded only the 500 pounds (226.80 kg). The average total weight lifted for each exercise (as recorded on the exercise logs) over the 16 weeks is shown in Table 3, ranging from 4,431 kg for the one arm incline dumbbell press, to 58,310 kg for the leg press. The exercisers also had highly significant increases ($p< .05$) in strength on all 8 exercises performed in the gym (Figures 1 and 2), with a mean increase in strength of up to four times that of baseline values.

The exercisers gained more strength in both hands compared to controls, with a significant increase in right hand mean grip strength in the exercise group of 2.9 ±4.0 kg versus controls who lost strength, -1.2±3.0 kg ($p= .06$). (Table 4) When measured by isokinetic dynamometer, the exercisers did increase their peak torque more than the controls in both legs and the right arm, but the differences were not statistically significant. The controls, however, had a greater increase in left arm peak torque ($p=.09$).

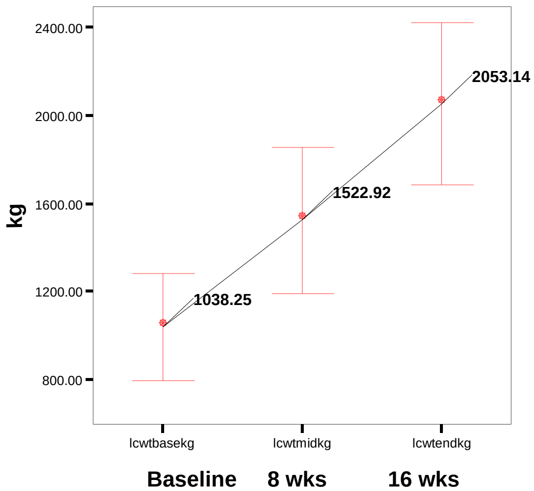
Additionally, there was a positive correlation between time on Remicade and increases in both upper and lower body strength, although this was not significant.

Body composition

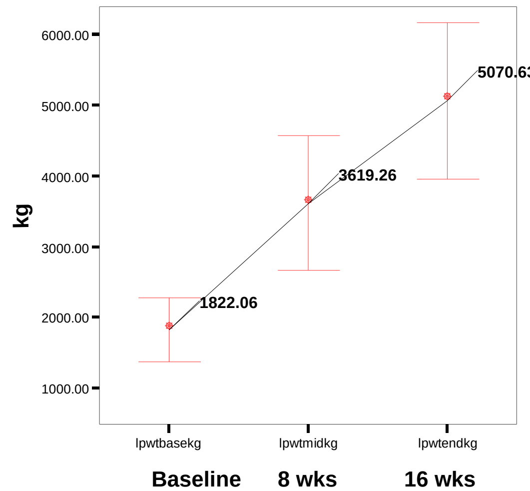
As reported by DXA, both exercisers and controls had above average T-scores for their age, with a collective baseline mean score of -.38±1.4 for the total hip and -.54±1.2 for the spine (L1-L4). However, 8 of the study patients were osteopenic and 2 were osteoporotic.

The exercisers lost less BMD at the total hip and trochanter, lost more fat, and gained significantly more lean tissue in the trunk (mean 0.9kg±1.0 versus controls 0.26kg±1.3) ($p<.01$). The exercisers lost less lean tissue in the total body, with a mean of -0.6kg ±4.2, compared to controls who lost -3.3kg±8.5; and lost more fat in both legs (exercise group losing a mean of -0.5kg±0.9, compared to -0.2kg ±0.6 for controls), but neither were significant. (Table 5) The exercisers had a decrease in body weight of -0.7±1.7 kg, while the controls experienced -0.4±2.6 kg decrease (difference was not significant).

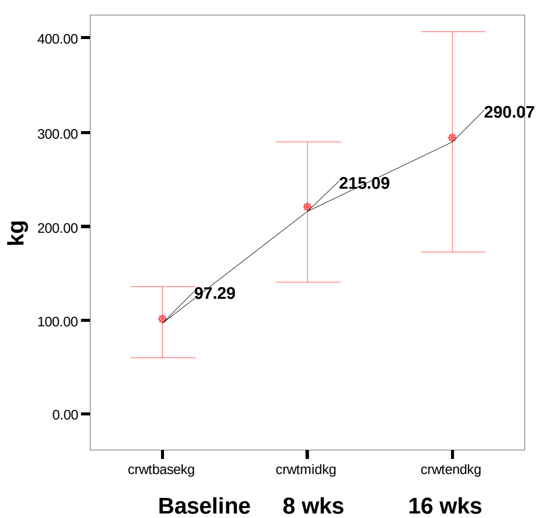
Figure 1. Mean change in strength (kg) in lower body strength training exercises at baseline, 8 weeks and 16 weeks; from exercise logs (n=14-16)



Leg curl



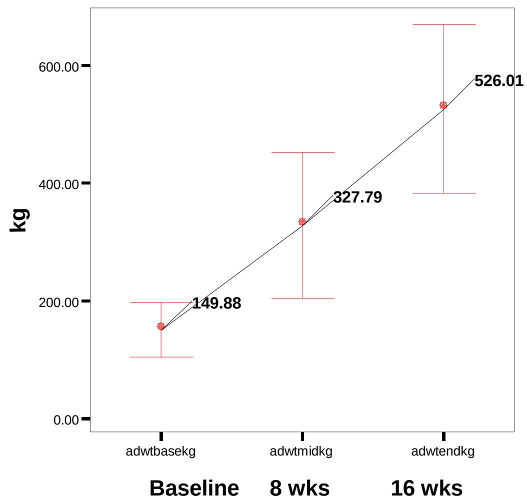
Leg press



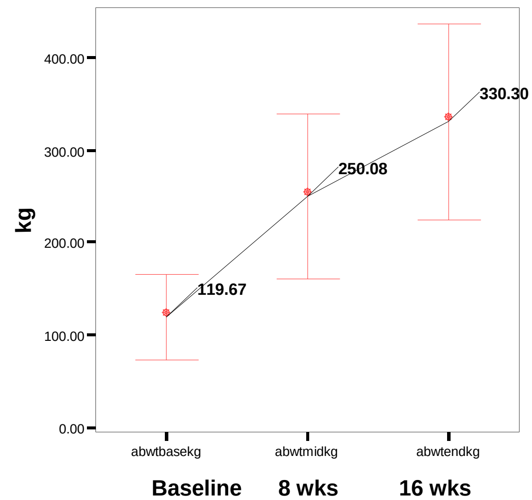
Calf raise

$p<.05$

Figure 1 (Continued). Mean change in strength (kg) in lower body strength training exercises at baseline, 8 weeks and 16 weeks; from exercise logs (n=15-16)



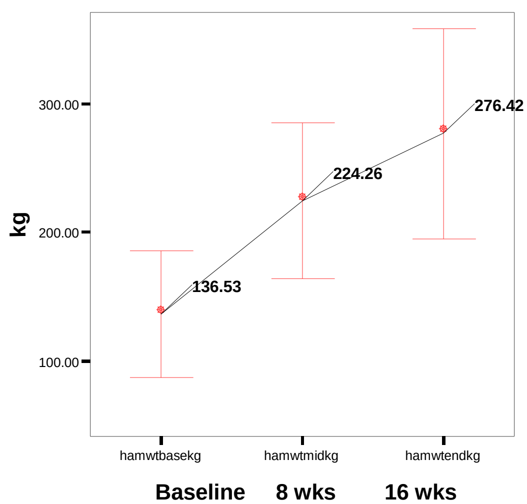
Hip adduction



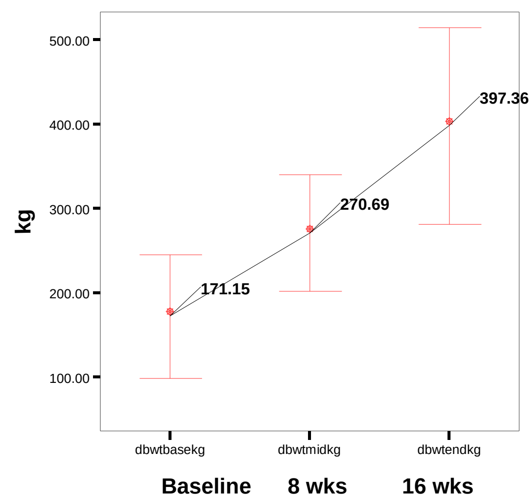
Hip abduction

$p<.05$

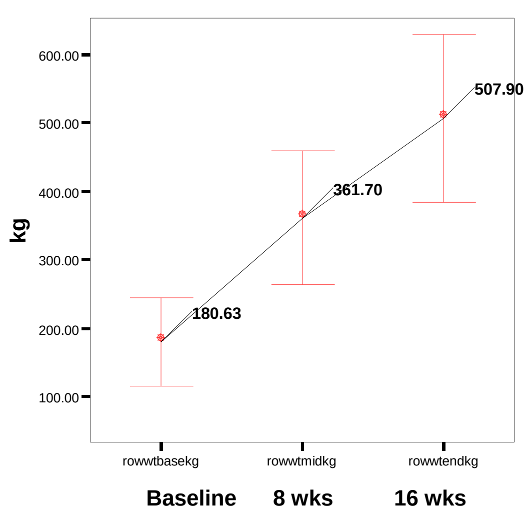
Figure 2. Mean change in strength (kg) in upper body strength training exercises at baseline, 8 weeks and 16 weeks; from exercise logs (n=14-16)



Hammer curl



Incline press



Row

p<.05

Table 3. Total weight lifted from exercise logs for exercise group, n=16

Exercise	*Total weight lifted, kg*
Incline press	4,431±1,982
Dumbbell row	5,437±3,090
Hip abduction	3,796±2,471
Hip adduction	5,326±3,134
Hammer curl	3,460±1,876
Leg press	58,311±25,699
Leg curl	23,242±10,271
Calf raise	3,022±1,964

Table 4. Mean strength changes from grip dynamometer from baseline to 16 weeks

Side	**Control n=6**	**Exercise n=16**	**p**
Right grip, kg	-1.2±3.0	2.9±4.0	.06
Left grip, kg	.45±3.4	3.6±3.2	.20

Table 5. Change in BMD and soft tissue from baseline to 16 weeks

Site	**Controls n=6**	**Exercise n=11**	**p**
Total hip, g/cm^2	-0.04±.04	-0.03±.02	.40
Trochanter, g/cm^2	-0.05±.05	-0.01±.02	.71
L2-L4, g/cm^2	0.02±.04	0.01±.04	.42
Forearm ultradistal, g/cm^2	0.01±.01	0.01±.02	.54
Lean total body, kg	-3.3±8.5	-0.61±4.2	.45
Trunk lean, kg	0.16±1.31	0.86±.97	.01
Fat legs, kg	-0.16±.57	-0.53±.88	.78

DISCUSSION

Strength

This study demonstrated a large increase in strength at all 3RM sites and in all eight exercises that were a part of the exercise regimen. Other studies have demonstrated similar findings of increased strength.(1, 6) Although some patients have been reported to plateau in strength after their body adjusts to the exercise regimen (around 12 weeks), our patients did not plateau, but continued to increase in strength over the entire study.(7) We believe this continued improvement is due in part to the short-term (weekly) and long-term (end of study) goals that were set by the patients and reviewed regularly with the exercise trainers. In contrast to these significant increases in strength, there were no significant strength gains reflected in the isokinetic dynamometer assessments. Komatireddy et al (1997) also reports nonsignificant changes after a 12-week program.(9) Because of the smaller sample size, the chance of a disproportionate number of flare-ups in either group was possible, and may have affected the results. Additionally, there was no correlation between weight lifted in the gym and the isokinetic dynamometer.

As demonstrated by others, significant improvements were also found in grip strength.(27) In our study, this increase may be due to the primary use of dumbbells in our exercises (option 3). The regular use of dumbbells worked small “gripping” muscle groups (the forearm and hand) while stabilizing the weights during the exercises and also allowed individual training of the limbs to correct muscle imbalances.

BMD and body composition

Although the BMD changes between the groups were not statistically significant, the exercise group lost less bone than the control group. Although Rall et al (1996) did not find changes in body composition or significant changes in BMD after a 12 week high-intensity strength training program, de Jong et al (2004) found that after a 2 year high intensity weight bearing exercise program RA patients slowed down the loss of BMD at the hip.(6, 28) In general, significant BMD changes may not occur until after 5 or 6 months of intensive strength training due to the duration of the bone remodeling cycle, thus our study duration was too short to detect significant bone effects.

The preservation of lean tissue seen in the exercise group was to be expected, confirming that normal activities of daily living (control group) are not adequate to prevent the loss of lean tissue in RA patients, which can lead to reduced activity and greater functional decline.(14) With a longer intervention, we would have expected to see an increase in lean tissue evident in the arms and legs, separately.

Compliance with the strength training program

Although we had high attendance and compliance rates, we found that especially during flare-ups, the reinforcement and support of the supervising exercise trainers was crucial to keep the patient in the gym. Some patients reported they did not have enough self-discipline to exercise on their own, but felt better, even during flare-ups, after they exercised. The ability to reinforce the skills patients learned in the gym assured maximum benefit and maintained the consistency of the patients. This may be an advantage a continuously supervised program has over home programs.(16, 29) The personal attention and motivation the patients received helped them understand what they could achieve safely, how to do it properly, and strengthened their beliefs in exercise and self-efficacy(30) This keeps exercise therapy attractive and embedded in their daily life and encourages them to keep exercising long-term.(30, 31) We attribute good compliance to the individualized regimens which allowed patients to complete a regimen which was beneficial and tolerable during flare-ups, and motivated them on days that were challenging to get to the gym.

Some health care professionals do not support continuing exercise in times of disease flare, although this is when joints become more stiff and painful without movement.(32) During acute periods of disease, the rate of joint destruction is increased, and thus the need to counter these effects is even more important.(33)

CONCLUSION AND FUTURE DIRECTIONS

RA is associated with increased morbidity and mortality rates that far exceed those of the healthy US population. Many of the comorbid conditions leading to this increased morbidity and mortality, such as severe muscle atrophy, loss of functional capacity, loss of BMD, overweight and obesity, and cardiovascular disease, are all conditions that can be improved with regular exercise and strength training programs.

The strength training program designed and implemented in this study demonstrated positive effects on both strength and body composition. As measured by 3RM, strength changes from baseline to end of study showed a mean total increase of 46%. This increase was continuous throughout the 16 week intervention. The participants had a highly significant increase in all 8 study exercises with a mean increase in strength of up to four times that of baseline. Grip strength also improved in the exercise group over the control group. The exercisers lost less BMD, lost more fat and gained significantly more lean tissue in the trunk. These results provide support for continued research in individualized, intensive strength training programs for the RA patient.

The multitude of comorbid conditions RA patients face may far outweigh the potential risk of injury to RA patients during a properly executed strength training program. With the revolution of biologic response modifiers (BRMs) such as Remicade, patients are better able to complete exercise regimens and should be prescribed regular, intensive, individualized strength training exercise just as they would be expected to receive the latest pharmaceutical treatment to improve their prognosis. No detrimental effects were seen in disease status due to the strength training program, and in fact, as will be discussed in a subsequent paper, improvements in function, quality of life and other variables were seen.

The continued development and evaluation of individual programs and strategies to promote long-term strength training programs in community-based settings is essential. Although future research can provide guidelines regarding the optimal type and dose of exercise, programs must be individualized as per the function and fitness levels of the RA patients. This will help them successfully maintain a regimen and manage their own disease, while gaining the maximum benefit in times of disease flare as well as good disease control. A larger sample size and a study of longer duration are warranted to further quantify the exercise effects.

Acknowledgements

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THE EFFECTS OF A 16-WEEK INDIVIDUALIZED, INTENSIVE STRENGTH TRAINING PROGRAM ON FUNCTION, DISEASE ACTIVITY, PAIN AND QUALITY OF LIFE IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Key words: rheumatoid arthritis, disease activity, strength training, function, pain, quality of life

ABSTRACT

Objective. To assess the effects of a 16-week progressive, individualized, intensive stength training program on function, disease activity, pain and quality of life in patients with rheumatoid arthritis (RA).

Methods. Twenty-four male and female RA patients taking Remicade™ (Infliximab), with varying levels of disease activity and joint damage, participated in a randomized, controlled trial. The exercise subjects participated in a strength training program three times a week and the control group continued with standard of care as overseen by their rheumatologist. Assessments for function, disease activity, pain and quality of life were completed at baseline, 8 week, and 16 week (end of study) time points.

Results. Compared to the control group, there was a significant improvement in 50-foot walk time in the exercise group, with a mean reduction of -1.2±1.6 seconds and an increase of 0.8±1.0 seconds in controls (p=.01) over the 16 weeks. Results from the

Arthritis Impact Measurement Scale 2 (AIMS2) also showed significant improvements in the exercise group in both the hand -2.3± 3.3 (p=.04) and arm -1.3±1.2 (p=.00) function subscales. Although not statistically significant, there was a clinically important difference (as set at ±.25) in the Health Assessment Questionnaire (HAQ) Disability Index (DI), with a mean change of -0.4±0.4 in the exercisers and -0.1±0.4 in the controls. According to the Medical Outcomes Study Short Form (MOS SF-36) Questionnaire, exercisers improved significantly in physical function (mean 18.3±11.6) compared to controls (mean 2.1±10.4) (p=.09). The exercisers also had a significant decrease in pain of -14.8±19.2 as measured by a Pain Visual Analogue Scale (VAS), compared to controls who did not see a change in pain (p=.07).

Conclusion. High-intensity strength training in RA patients with low to high disease activity and joint damage produces overall positive impacts on function, quality of life, pain and disease activity.

INTRODUCTION

Most people with RA exhibit a chronic, fluctuating course of disease that, if left untreated, results in progressive joint destruction, deformity, disability and premature death. RA is the second leading cause of chronic disability in the United States, with reductions in body function generally occurring early in the disease. (1) Due to disability, up to two thirds of persons with RA have a reduced work capacity, with substantial income losses, and many persons cannot fully function in their job within 10 years of disease onset. (2) Loss of functional capacity leads to loss of independence, depression, social isolation and reduced or non-participation in valued life activities, increasing the risk of further physical decline and mortality. Katz et al (2001) reports that over a 5 year period, individuals with RA stopped performing activities they had valued at baseline, with greatest losses seen in work-related, service, nurturant, entertainment and social events.(1, 3-5) The impact of the disease affects their overall quality of life and the ability to maintain family roles, social activities and fitness for work.(6, 7) These physical and psychological impacts of RA translate into greater economic costs as patients utilize health care services more frequently. The direct costs of treating a person with RA is three times more than the costs associated with treating a person who does not have this disease.(8)

Strength training is an essential form of exercise that has demonstrated improvements not only in strength, but also in several other areas such as pain, disease activity, quality of life, and function, with no detrimental effects on disease activity. With the multitude of issues RA patients face, strength training should be a mainstay of treatment to counter the loss of physical and psychological vitality, a result of years of disease and disability.(9-13)

The present study was designed to investigate the effects of a 16-week high-intensity, isotonic, progressive, individualized strength training exercise program on function, disease activity, pain and quality of life in patients with RA currently taking Remicade. Our study is the first continually supervised, facility-based, intensive, randomized, individualized strength training program, and has the largest sample size yet published.

METHODS

Study design

This randomized, controlled intervention trial included 24 male and female RA patients recruited in one cohort. Patients were randomized near the end of the run-in phase in a 2:1 ratio to exercise or control (standard of care). This allowed for a greater sample size in the exercise group to better characterize the exercise effect. The exercise subjects participated in a strength training program three times a week and the control group continued with standard of care as overseen by their rheumatologist. The control group members also had the opportunity to attend social events to facilitate a sense of belonging to the study; and, at the end of the study, could attend orientation sessions to learn the study's strength training program, which they could begin on their own. All patients continued to receive regular medical care and Remicade therapy from their personal physicians. There was no attempt to change their therapy by the study team.

Recruitment and study entry

Patients were recruited via local media, materials in rheumatologists' offices, mailings to patients, and in-person recruitmentby the Project Director and participating rheumatologists. The patients were recruited over a 4-month period through phone interviews and medical history questionnaires. Eligible patients were invited to complete a run-in, baseline testing phase lasting approximately 5 weeks. No financial compensation was offered to the subjects. This project was approved by the University of Arizona's Human Subject's Review Committee and written informed consent was obtained from all subjects prior to study entry.

Subject eligibility

Patients >18 years (no upper age limit) with a diagnosis of RA according to the American College of Rheumatology (ACR) 1987 criteria, and American Rheumatology Association (ARA)(now ACR) Functional Class I and II, participated. The patients were on a stable dosage of Remicade (≥4 months) and taking no other biologic therapies. Patients did not have serious concomitant conditions such as heart disease, uncontrolled blood pressure, cancer, or severe osteoporosis (T score of ≤ -3.0 or ≤ -2.5 without treatment) and had no evidence of previous non-traumatic fractures. Patients were excluded for participation in strength training exercise or ≥ 150 minutes a week of aerobic exercise within the past 3 months, or if they had a body mass index (BMI) ≥ 40 kg/m^2. Other exclusions included the need for assistive devices (i.e. cane), plans to discontinue Remicade, or to leave Tucson for an extended period of time. All patients had to obtain written consent from their rheumatologist or primary care physician to participate.

Of the 100 people who were screened for eligibility over the phone, 33 were eligible and began baseline run-in assessments; 32 were randomized (1 person did not pass the physical exam), and 30 began the study (2 people did not complete baseline assessments: 1 due to family commitments and 1 due to an eye infection preventing her from driving to the testing site). The main reasons patients did not meet eligibility criteria were due to 1) transportation difficulties, 2) being part-time Tucson residents, and 3) not being on Remicade or not on Remicade for ≥4 months.

Study population

Twenty-four patients (19 women and 5 men) completed the study (16 were randomized to exercise and 8 to control). Patients were between the ages of 29 and 75 years (mean 51±12.8 years) and exhibited mild to severe joint deformity. (See Table 1) The majority of patients were Caucasian (95.8%), 16.7% were Hispanic, and 75% of the patients were employed (41.7% full time, 29.2% part time, 4.2% self-employed). Several of the patients were also regular care-takers of family members. Sixty-seven percent of the patients were married, and the remaining single, divorced, or widowed (8.3%). The majority of patients had incomes >$60,000 or between $20-30,000, with 41.7% completing college. The mean duration of disease was 14.0±10.2 years (range 2.4-39 years) with the main joints affected stated as being the hands, wrists and fingers. One person had arthroplasties (both weight bearing and non-weight bearing joints). Seven of the twenty-four patients had been on Remicade for ≤12 months, 8 had been on Remicade 13-24 months, and 9 had been taking it for 25-60 months. Four of the 24 patients were also taking prednisone, 21 were taking Methotrexate, 13 were taking non-steroidal anti-inflammatory drugs (NSAIDs) and 3 were taking other disease-modifying anti-rheumatic drugs (DMARDs). If the patient engaged in exercise prior to entry into the study, the primary form of exercise was walking.

Assessments

The following assessments were completed in both groups at baseline and 16 weeks. Eight week testing consisted of a reduced battery of questionnaires. Standard quality control procedures were followed and equipment calibrations were completed throughout the study.

Functional performance

The timed 50- foot walk (the number of seconds it takes a subject to walk 50 feet at a normal pace) was used to assess function, as walk time often increases with more disease activity.(1) A distance of fifty feet was measured on a flat, straight walking surface and marked with masking tape. Each subject was instructed to start walking 10 feet prior to the marked area (also marked by tape) so that stride was established prior to the subject reaching the designated 50- foot startingpoint. The time used for initial acceleration was subtracted from the total. Time used to walk 50 feet was determined by use of a stopwatch and recorded in seconds.

The AIMS2 is a more comprehensive and sensitive instrument than the original AIMS, including 3 new scales and 3 new sections to assess health status satisfaction, attribution of health status problems to arthritis, and designation of patient-selected priority areas for improvement. A higher score indicates greater disease activity and disability.(14)

The HAQ DI was also used which scores 20 questions (in 8 categories) on daily functioning on a scale of 0 (no difficulty- no functional limitations) to 3 (unable to do- serious functional limitations).(15) The use of personal assistance or assistive aids or devices needed to perform the 20 functions is also taken into account in the score The HAQ R628 (Pincus) was also used, which includes items from the HAQ, MDHAQ, and

HAQII. The HAQ R628 was developed to include more complex or higher functioning activities, but was kept to two pages to minimize patient response burden. (16)

Medical history and disease status

A comprehensive medical history questionnaire was used to record information such as family medical history, lifestyle habits and past surgeries; and a telephone interview collected current medication information (i.e. dosages, start dates). One of two rheumatologists (JL and LS), conducted a comprehensive exam on each patient, completing 68-count joint counts (recording tender and swollen joints separately). They completed a physician global assessment, determined ACR functional status, overall health status and gave clearance to subjects to participate in the study. The patient completed a self-report joint count (recording tender OR swollen joints and not differentiating), a Pain VAS, and a patient global assessment. The patient and physician's global assessments were obtained with a 100 mm VAS. The exercise group also completed a Flare-Up VAS weekly, which asked how their arthritis flare-ups affected their ability to complete the study's exercise program that week. This form was used to help decipher any changes in compliance that may have occurred due to their disease status.

Quality of life

The MOS SF-36 measured role limitations due to physical and emotional status, physical function, pain, social function, vitality, mental health, and general health perceptions. Patients were asked about their views of their health and how well they were able to do usual activities. Scores for each of the 8 subcales (scores for questions within a subscale) were tallied, with higher scores indicatingbetter health status .(17) A Quality of Life (QOL) VASalso monitored changes in overall well-being and QOL. A 0 to 100 mm VAS format was used for the QOL scale, with a lower score representing a better quality of life.(18, 19)

Pain

Pain was assessed with a VAS 100 mm scale with the end descriptions of “no pain” (0) or “pain as bad as could be”, taken from the HAQ R628.(18, 20)

<u>Exercise program</u>

The exercise intervention included progressive strength training exercise and weight-bearing aerobic activity supported by a program of activities to promote adherence and compliance to the study protocol. Exercise participants trained three times per week on non-consecutive days (M, W, F). The order of the exercises alternated between upper and lower body and were completed in an order which used the larger muscle groups first in order to help avoid fatigue. Exercise sessions lasted ~75 minutes and included a warm-up (walking) (5-10 minutes), eight resistance exercises (40 minutes), aerobic exercise (15-20 minutes) (combined with the aerobics done during warm-up and cool-down, patients reached a minimum of 30 minutes), abdominal exercises, and a cool-down period (5 minutes) with walking and static stretching of the muscles. The patients were trained to complete selected range of motion (ROM) exercises 2-3 times per week on their own. The patients were continually supervised at the exercise facility and had to participate in orientation sessions with the certified trainers prior to beginning the program.

There were 8 strength training exercises: leg press, leg curl, cable hip abduction, hip adduction, calf raise, incline press, row, and hammer curl. For each exercise three options were available, working the same muscle groups but through different modes. The patients completed 2 sets of 6-8 repetitions. Continuous weight progression was facilitated by the patient working with the trainer to set and record weight goals on the exercise log at the beginning of each week, with the aim of reaching the goal by the end of the week. Patients maintained loads of approximately 70-85% of their maximum.

Data analysis

Statistical analyses were completed using the Statistical Package for the Social Sciences, (SPSS, version 12.0).(21) Measures of central tendency and distribution were examined to describe the sample, to test for normality and homoscedasticity, and to describe outcomes. The baseline characteristics of those who completed the study were compared to drop-outs using independent t-tests. Possible baseline mean differences in function and other characteristics between patients in the exercise and control group were tested using independent t-tests. Paired t-tests were used to test for significant changes within the exercise group and independent t-tests were used to assess differences in mean group changes between exercisers and controls. The general linear model (ANCOVA) was used to study the effects of exercise on function, disease activity, pain and quality of life outcomes, adjusting for age, sex and baseline values. Because of unequal numbers of men and women, the sex variable was weighted so that the sum of coefficients equaled zero for each contrast. Analysis was repeated without the 5 male patients to examine any differences between an all female sample and a mixed sample. There were no significant differences encountered in this repeat analysis. The HAQ DI is composed of 20 items in 8 categories with two to three questions in each category. These individual questions are coded from 0 (without any difficulty) to 3 (unable to do). (16). All 24 subjects had answered at least one question in all 8 HAQ component categories. Missing values for individual questions on the HAQ questionnaire were imputed with the mean of the control group. Each category score was determined by the highest score within the category items. These category scores were then modified up to a possible highest score of 3 to take into account the use of personal assistance or assistive aids or devices needed to perform the 20 functions. To obtain a final HAQ DI score, the sum of the modified category scores was divided by 8, yielding an average score of between 0 and 3. In some research, the HAQ score was computed differently- as the sum of the raw values of all questions, and without assistive devices taken into account.(1) In the present study, both methods were used to assess the exercise effect on the change in level of disability after 16 weeks.

RESULTS

Baseline characteristics for the patients who completed baseline and 16-week assessments are shown in Table 1. There were no significant differences between the exercise and control group, or between patients who completed the study and drop-outs.

Table 1. Baseline characteristics for exercise and control groups; drop outs (mean and standard deviation)

Baseline Characteristics	Control group n=8	Exercise group n=16	Drop-outs n=6
Age, years	49.0±12.6	52.2±13	54.7±20.7
BMI, kg/m^2	26.0±3.6	26.7±5.4	29.3±7.8
Duration of RA, years	11.2±8.9	15.4±10.8	12.3±9.3
Length on Remicade, months	21.8±10.6	24.4±13.7	19.3±9.9
Patient joint count†	21.6±16	20.7±10.3	9.5±6.3
Physician joint count	5.4±6.5	7.7±10.8	17.5±12.8
Pain VAS‡	20.6±13	26.4±21.5	45.8±25
HAQ DI	0.5±0.4	0.8±0.6	1.1±.50
50 foot walk time, seconds	11.7±2.0	13.2±2.5	12.2±1.2
Global VAS	12.6±10.1	27±26.6	45.7±25.8
Physician's Global VAS‡	16±13.8	19.2±21.1	25.8±12
SF-36 physical function†	80.7±16.2	58.4±18	51±17.1
Quality of Life VAS†	23.3±32.6	30±25.4	36.4±26
AIMS2 hand†	8.0±2.9	9.6±4.6	12.6±7.2
AIMS2 arm†	5.6±1.5	6.8±1.7	10.2±4.5

† n=7 in the control group for this variable
‡ n=15 in the exercise group for this variable

Drop-outs

A total of 6 participants dropped from the study, with comorbid conditions unrelated to the study responsible for all drop-outs in the exercise program (n=4). Five exercise subjects had an illness or infection and had to delay their Remicade treatment, subsequently causing their disease to flare. In 4 of 5 of these cases, the delay was prolonged and the patient was excluded from the study: one had pneumonia, one had a staph infection, one had an infection due to a spider bite (patient completed exercise program but could not do 16- week testing), and one had severe gastrointestinal difficulties. In the control group, 2 people dropped: one due to a family crisis and one due to discontinuation of Remicade as per her rheumatologist. There were no significant baseline value differences between those who completed the study and non-completers.

Function

As compared to controls, exercisers decreased their 50-foot walk time significantly, (mean -1.2 ± 1.6 seconds); controls increased their walk time by 0.8 ± 1.0 seconds (Table 2). Additionally, the exercisers had greater improvement in the hand and arm function subscales of the AIMS2, with a mean change of -2.3 ± 3.3 (versus 0.9 ± 2.9 in controls) for the hand ($p<.05$), and a mean change of -1.3 ± 1.2 in the exercise group (versus 0.7 ± 1.3 in controls) for the arm ($p<.01$). Additional AIMS2 subscales (mobility, walking and bending, household tasks, arthritis pain, work and level of tension) showed improvement in the exercise group over the control group, but none were statistically significant. The change in HAQ DI was not statistically significant, however, there was a minimal clinically important difference (MCID) with a decrease of -0.4 ± 0.4 in the exercise group. There was no MCID in the controls (as set at ±.25). Alternatively, when calculated as the sum of the raw values of all questions, a change in score of -4.2±5.0 was found in the exercise group.

Table 2. Mean change in function as per 50-foot walk, AIMS2, and HAQ from baseline to 16 weeks

	Control group n=7	Exercise group n=15	p
50 foot walk, seconds	0.8±1.0	-1.2±1.6	.01
AIMS2 (hand subscale)	0.9±2.9	-2.3±3.3	.04
AIMS2 (arm subscale)	0.7±1.3	-1.3±1.2	.00
HAQ DI†	-0.1±.40	-0.4±0.4	.17

† n=8 in the control group for this variable

Quality of life

The exercise group improved more than the controls in 7 out of the 8 MOS SF-36 subscales, with the physical function subscale statisticllysignificant, with a mean change of 18.3±11.6 in exercisers compared to 2.1±10.4 for controls (p<.1). Results of the QOL VAS indicated the exercisers improved more than the controls, -9.4±20.3 versus -.50±40, though this difference was not significant (p=.62) (Table 3).

Disease activity

The patient and physician's global assessments, nor the patient or physician joint counts in the exercise group improved significantly over the controls.

Table 3. Mean change in quality of life baseline to 16 weeks

	Control group (n=7)	Exercise group (n=15)	p
QOL VAS†‡	-0.5±40	-9.4±20.3	.62
SF-36 (physical function)	2.1±10.4	18.3±11.6	.09
SF-36 (emotional, role limitations)	-14.3±42.4	6.7±44.0	.57
SF-36 (social function)	-2.5±11.0	8.8±25.5	.87
SF-36 (pain)	2.1±15.2	9.1±23	.89
SF-36 (general health perceptions)	-0.71±6.1	11±19.1	.29
SF-36 (vitality)	7.9±11.1	7.3±19.5	.69
SF-36 (mental health)	0.0±14.2	3.5±16.0	.93
SF-36 (physical, role limitations)	-14.3±31.8	11.7±41.0	.16

† n=8 in the control group for this variable
‡ n=14 in the exercise group for this variable

Pain

The Pain VAS decreased significantly for exercisers (mean -14.8±19.2) compared to controls (-0.13±20.1) (p=.07) (Table 4).

Table 4. Mean change in disease activity baseline to 16 weeks

	Control n=8	Exercise n=14	p
Pain VAS	-0.13±20.1	-14.8±19.2	.07

DISCUSSION

Function

We found an improvement in 50-ft walk time of 1.2 seconds or a 9% decrease in the exercise group in walk time. Both Rall et al (1996) and Van den Ende et al (1996) demonstrated similar reductions in walk time in their intensive strength training regimens. Regarding the HAQ DI, however, there seems to be more variation in findings across strength training studies. Our MCID change in HAQ in this study is similar to Hakkinen et al (1999 and 2004) who found a difference of -3.2 and -0.5 in the exercisers (as calculated both ways described in the statistical analysis section), but after longer (1 and 2 year) moderate intensity interventions.(22, 23) Two other high-intensity programs (12 weeks and 2 years), did not find statistically significant or clinically significant changes in HAQ scores in their patient populations.(11, 24)

The significant difference in the hand and arm subscales of the AIMS2 may be attributed to the use of dumbbells in our program, strengthening the hand and forearm muscles and increasing grip strength. Komatireddy et al (1997) also saw significant improvements in AIMS dexterity, but Van den ende (1996) did not see significant improvements using the Dutch AIMS.(1, 11, 24) There are no strength training studies that have used the AIMS2 version to look at the effect of such a program on functional capacity in the RA population.

The change in the AIMS2 arm subscale was negatively correlated with the Flare-Up VAS sum and mean scores ($p<.05$) in exercise subjects, such that as the number of flare-ups lessened or had less of an impact on the patient's ability to perform the exercise regimen, the AIMS2 subscale score improved. Additionally, the AIMS2 social subscale was negatively correlated with the Flare-up mean score ($p < .01$).

Pain

The reduction in pain was expected as per the positive verbal feedback from the patients. A reduction in pain has been seen in several studies, with Rall et al (1996) reporting a 21% reduction in pain in subjects after participating in a 12 week strength training intervention. We found a 53% reduction in pain in the exercise group, compared to no change in the control group.(10, 22)

Disease activity

We expected to see changes in patient and physician global assessments given the improvements noted above. No significant reductions in physician or patient joint count were seen due to the exercise program. However non-significant changes have been reported elsewhere.(24) Interestingly, there was also no correlation between the patient joint count and the physician joint count. In general, the patients reported lower joint count scores than the physician, which we hypothesize is attributed to two things: 1) the patients have not been professionally trained to perform joint counts, to identify tender and swollen joints; and 2) due to the chronic nature of the disease, the patient may be accustomed to potentially swollen and tender joints and so the idea of what is "normal" or not swollen varies from the rheumatologist's diagnosis. There was a negative correlation between length of time on Remicade and change in patient global assessment ($p<.05$), indicating that those who have been on Remicade for a longer period of time were experiencing less disease symptoms.

Quality of life

Although the MOS SF-36 has been used to assess QOL in musculoskeletal disease in general, to our knowledge, it has not been used to look at the effect of strength training on QOL in this population. Although not statistically significant, there were greater improvements in 7 out of 8 SF-36 subscales (physical function, role limitations (physical), pain, social function, mental health, role limitations (emotional), and general health perceptions). These results indicate it may be worth further exploring this assessment in this population (Table 3).

There was a strong negative correlation with the QOL VAS score and the Flare-up VAS mean score and sum, indicating that as flare-ups increased, quality of life decreased ($p<.05$). An even stronger negative correlation ($p<.01$) was seen between the physical function score of the SF-36 and change in 50-foot walk time. Additionally, as arm and hand function decreased (according to AIMS2) so did overall physical function according to the SF-36 ($p<.05$). Moderate negative correlations between AIMS2 arm and hand subscales and SF-36 were also found in a previous study with RA patients.(25)

Correlates with strength

There were significant correlations ($p<.05$) found between changes in pain and function; and changes in strength. A negative correlation was seen between change in Pain VAS Scores and weight lifted for the incline dumbbell press (right arm) ($p<.01$) and dumbbell hammer curl (right and left arms) ($p<.05$) from baseline to 16 weeks. A negative correlation was also seen between change in right hand grip strength and change in HAQ DI ($p<.05$) from baseline to 16 weeks.

CONCLUSION AND FUTURE DIRECTIONS

As the first facility-based, continually supervised, intensive, randomized, individualized, strength training study yet conducted, both the design and results of this study should provide impetus for further research, and encouragement for multi-faceted approaches to the treatment of RA.   Increases in strength during this study were associated with decreased pain, disease activity and function. The study showed statistically significant improvements in function and pain. The exercise group also improved more than the controls in 7 out of 8 quality of life sub-scales.

There was a negative correlation between the length of time on Remicade and change in the patient global assessment of disease activity. Those on Remicade longer reported experiencing less disease symptoms. With the revolution of biologic response modifiers (BRMs) such as Remicade, patients are better able to complete exercise regimens and should be prescribed regular, intensive, individualized strength training exercise just as they would be expected to receive the latest pharmaceutical treatment.

Again, significant correlations were found between changes in pain and function; and changes in strength. Strength training exercise should be an essential part of the RA patient's therapy, allowing them to regain and maintain muscle mass, BMD, functional capacity, an improved psychological outlook and a good quality of life. An individualized, intensive, strength training program should be "standard of care" in the era of "early and aggressive" treatment for the RA patient.

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DESIGN AND DEVELOPMENT OF THE PROGRAM, LESSONS LEARNED, LIMITATIONS, AND SATISFACTION WITH AN INDIVIDUALIZED, INTENSIVE STRENGTH TRAINING PROGRAM FOR PATIENTS WITH RHEUMATOID ARTHRITIS

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Key words: strength training, program development, satisfaction, rheumatoid arthritis

ABSTRACT

Objective. This paper explores the design and development of the program, lessons learned, limitations, and satisfaction with a 16-week progressive, individualized, intensive strength training program for patients with rheumatoid arthritis (RA).

Methods. Twenty-four male and female RA patients taking Remicade™ (infliximab), with varying levels of disease activity and joint damage, participated in a randomized, controlled trial. The exercise subjects participated in a supervised strength training program three times a week and the control group continued with standard of care as overseen by their rheumatologist. Information presented in this paper came from written and verbal communications with study staff and subjects, and exit evaluations completed by the subjects.

Results. The individualization of the strength training program and the social support offered throughout the program, including the personal attention and motivation provided

by the exercise trainers, was critical to the success of many of the patients. The exercises selected for the program and the program's flexibility allowed patients to continue with a strength training regimen in times of flare-ups as well as in times of good disease control. Modifications were made to address such issues as limited mobility or accommodate disfigurement of joints. For example, minor alterations were needed in the calf raise exercise to meet the needs of some patients who had disfigurement of toes/feet, fused toes or neuropathy. Limitations of the study focused on service-oriented issues that were driven by limited funding. Gym location, trainer hours, equipment availability, and a study of longer duration, would have improved the study's implementation. RA patients are willing to engage in a high-intensity strength training program and desire continued support to integrate strength training regimens into their daily life.

Conclusion. The individualization of the strength training program, continuous trainer supervision, and the program's social support components were key to its success. Improvements necessary to increase satisfaction with the program could have been resolved with additional funding. The compliance and satisfaction with the program was high, with all of the patients continuing strength training at the conclusion of the study. This information should provide valuable insight for researchers and clinicians as they approach the challenges of developing and implementing strength training studies for RA patients.

INTRODUCTION

Given the alarming rates of disability, increased morbidity and mortality rates, and the gross economic impact associated with RA, it is important for RA patients to engage in regular exercise, and in particular, strength training, to counter the detrimental effects of the disease. Strength training studies completed thus far have proven to be safe and efficacious demonstrating positive results on disease status.(1-4) However, the translation of this research into practical recommendations for the RA population is lagging. In general, high-intensity strength training programs are seldom recommended by health professionals. Multi-faceted approaches are necessary to deal with RA, a disease which continues to grow in scope as a public health issue. Strength training should be a regularly prescribed component since it can contribute to both the treatment of disease symptoms, and prevention of comorbid conditions associated with the disease.

The purpose of this paper is to discuss: 1) the design and development of a strength training program for RA patients; 2) lessons learned in design and implementation of the study; 3) limitations of the study; and 4) satisfaction with the program.

METHODS

Study design

This randomized, controlled intervention trial included 24 male and female RA patients recruited in one cohort. Patients were randomized near the end of the run-in phase in a 2:1 ratio to exercise or control (standard of care). This allowed for a greater sample size in the exercise group to better characterize the exercise effect. The exercise subjects participated in a strength training program three times a week and the control group continued with standard of care as overseen by their rheumatologist. The control group members also had the opportunity to attend social events to foster a sense of belonging to the study. At the end of the study, they could attend orientation sessions to learn the study's strength training program, which they could begin on their own. All patients continued to receive regular medical care and Remicade therapy from their personal physicians. There was no attempt to change their therapy by the study team.

Recruitment and study entry

Patients were recruited via local media, materials in rheumatologists' offices, mailings to patients, and in-person recruitment by the Project Director and participating rheumatologists. The patients were recruited over a 4-month period through phone interviews and medical history questionnaires. Eligible patients were invited to complete a run-in, baseline testing phase lasting approximately 5 weeks. No financial compensation was offered to the subjects. This project was approved by the University of Arizona's Human Subject's Review Committee and written informed consent was obtained from all subjects prior to study entry.

Subject eligibility

Patients >18 years (no upper age limit) with a diagnosis of RA according to the American College of Rheumatology (ACR) 1987 criteria, and American Rheumatology Association (ARA)(now ACR) Functional Class I and II, participated. The patients were on a stable dosage of Remicade (≥4 months) and taking no other biologic therapies. Patients did not have serious concomitant conditions such as heart disease, uncontrolled blood pressure, cancer, or severe osteoporosis (T score of ≤ -3.0 or ≤ -2.5 without treatment) and had no evidence of previous non-traumatic fractures. Patients were excluded for participation in strength training exercise or ≥ 150 minutes a week of aerobic exercise within the past 3 months, orif they had a body mass index (BMI) ≥ 40 kg/m^2. Other exclusions included the need for assistive devices (i.e. cane), plans to discontinue Remicade, or to leave Tucson for an extended period of time. All patients had to obtain written consent from their rheumatologist or primary care physician to participate.

Study population

Twenty-four patients (19 women and 5 men) completed the study (16 were randomized to exercise and 8 to control). Patients were between the ages of 29 and 75 years (mean 51±12.8 years) and exhibited mild to severe joint deformity. The majority of patients were Caucasian (95.8%), 16.7% were Hispanic, and 75% of the patients were employed (41.7% full time, 29.2% part time, 4.2% self-employed). Several of the patients were also regular care-takers of family members. Sixty seven percent of the patients were married, and the remaining single, divorced, or widowed (8.3%). The majority of patients had incomes >$60,000 or between $20-30,000, with 41.7% completing college. The mean duration of disease was 14.0±10.2 years (range 2.4-39 years) with the main joints affected stated as being the hands, wrists and fingers. One person had arthroplasties (both weight bearing and non-weight bearing joints).

Drop-outs

A total of 6 participants were dropped from the study, with comorbid conditions unrelated to the study responsible for all drop-outs in the exercise program (n=4). Five exercise subjects had an illness or infection and had to delay their Remicade treatment, subsequently causing their disease to flare. In 4 of 5 of these cases, the delay was prolonged and the patient was excluded from the study: 1 had pneumonia, 1 had a staph infection, 1 had an infection due to a spider bite (patient completed exercise program but could not do 16- week testing), and 1 had severe gastrointestinal difficulties. In the control group, 2 people were dropped: one due to a family crisis and one due to discontinuation of Remicade as per her rheumatologist.

Assessments

Exit evaluations

The exit evaluations completed by the patients consisted of two separate forms: 1) a 22-item evaluation on the overall administration and satisfaction with the study (i.e. laboratory assessments and what the patients would change about the study, if anything; and 2) (only for those in the exercise group) a 38-item evaluation obtaining information on their satisfaction with the exercise program (i.e. rating the knowledge of exercise trainers, their favorite exercises, exercises they found challenging). The evaluations were confidential and rated study areas from a score of 1 (strongly disagree) to 5 (strongly agree).

Exercise program

The exercise intervention included progressive strength training exercises and weight-bearing aerobic activity supported by a program of social activities to promote adherence and compliance to the study protocol. Exercise participants trained three times per week on non-consecutive days (M, W, F). The order of the exercises alternated between upper and lower body and were completed in an order which used the larger muscle groups first in order to help minimize fatigue. Exercise sessions lasted ~75 minutes and included a warm-up (walking) (5-10 minutes), eight resistance exercises (40 minutes), aerobic exercise (15-20 minutes) (combined with the aerobics done during warm-up and cool-down, patients reached a minimum of 30 minutes), abdominal exercises, and a cool-down period (5 minutes) with walking and static stretching of the muscles. The patients were trained to complete selected range of motion (ROM) exercises 2-3 times per week on their own.

Certified exercise leaders supervised all exercise training sessions (trainer to patient ratio of 1:4). Prior to beginning the program, all patients attended a 2-hour classroom program overview and received a pedometer, weight gloves, a Theraband, and a detailed, illustrated exercise manual. They also completed a one-on-one assessment to determine individual needs and the initial option for each exercise; and a hands-on orientation in the gym with the trainers.

There were 8 strength training exercises used in the study: leg press, leg curl, hip abduction, hip adduction, calf raise, incline press, row, and hammer curl. For each exercise, three options were available, engaging the same muscle groups but through different modes. The patients completed 2 sets of 6-8 repetitions. Thirty to sixty seconds of rest was advised between sets, with slow 2-3 second contractions and extensions.

Individualization of the program

The three options for each of the strength training exercises allowed the patient to begin at the appropriate level according to their fitness and functional abilities, and advance as appropriate. The options allowed flexibility, giving the patient the means to continue to exercise the same muscle groups and exercise (at a lower level of intensity or via different mechanism) even in times of disease flare. This gave the patients confidence in knowing the study trainers were willing to work with them, and their arthritis, and allowed optimal progression and promotion of long-term compliance in spite of changes in their health status. (5-7)

Option1, the easiest option, requiring only a Theraband, was generally reserved for severe flare-up days and was an option that could be completed when the patient was not able to make it to the gym due to vacation or gym closure on holidays. Option 2 incorporated Therabands and the use of some weight machines. Option 3, the preferred option, required dumbbells or other resistance equipment for all exercises. With the flexibility of the program, a patient who had problems with balance, might, for example, complete option 1 for the calf raise (using both feet flat on the floor), and complete the other 7 exercises at option 3, or at a level (option) deemed appropriate by their function and fitness level.

Progression of the program

For the strength training component, the patients progressed to additional weight when they could complete their current regimen in proper form for 2 sessions in a row, with an RPE of ≤4, with no joint pain, and at the trainer's discretion. Continuous progression was facilitated by the patient working with the trainer to set and record weight goals on the exercise log at the beginning of each week, with the aim of reaching the goal by the end of the week. Although thethree repetition maximum (3RM) was primarily used as an assessment tool, along with weekly goal setting, the 3RMs helped to guide patients' progression, and maintained the patients' loads at approximately 70-85% of their maximum.

DISCUSSION

Design and development of the program

A great deal of research went into the design and development of the exercise program. The type of strength training exercise, the intensity of the program, the specific exercises, and the individualization of the regimen to meet the patients' needs were all considered. A discussion of the decisions made, and the rationale for making those decisions, is presented in this section.

Type of strength training

Free weights vs. machine weights

Free weights were used as the preferred method (option 3 exercises) in all of our upper body exercises and for some lower body exercises as well. Free weights require plenty of concentration to perform an exercise, as one must focus not just on the targeted muscles, but also on stabilizing the weight in order to complete the maneuver in proper form. This helps to improve RA patients' balance and coordination, engaging small as well as larger muscles. The one arm incline dumbbell press, for example, focuses on the deltoid, pectoral and tricep muscles. However, it also aids in increasing hand, wrist and forearm strength. Using dumbbells also allows the patient to work each arm separately, which is not always possible with other types of equipment. Working the arms separately allows for a maximum workout as the dominant side of the body does not compensate for the weaker side. We found discrepancies in strength between the limb sides in our population (which may be due to weakness on one side of the body from frequent flare-ups or preferential use of a limb because of a joint replacement). Free weights were successful in dealing with these imbalances, and depending on the severity of the imbalance, patients sometimes completed extra repetitions to increase the strength in the weaker limb.

The use of free weights also allowed more flexibility in positioning of the body. Certain weight machines may be difficult for persons with joint stiffness to maneuver (i.e. setting pins, adjusting the back or seat positions) and can confine the patient to potentially uncomfortable positions. For example, we chose the use of free weights to perform calf raises. This allowed the patient to progress from using two feet to one foot (working on balance) and additionally increased their grip strength through increasing dumbbell weight. Using dumbbells did not put undo pressure on other areas of the body which may cause discomfort, such as is the case with the seated calf raise or donkey calf raise (where the weight and pads are placed above the knees and back, respectively).

In some circumstances, however, weight machines were the only option available for a certain exercise (i.e. leg press). The weight machines do not require as much balance or coordination, but do allow isolation of a muscle group, challenging the muscles throughout the entire motion of an exercise. For some people, weight machines may serve as a learning tool to understand the basic motion of the exercise, assisting with proper form through the guidance provided by the machine. Our option 2 included some machine weights.

Isometric vs. isotonic vs. isokinetic

Isometric exercises are often used in physical therapy. An isometric contraction is a contraction against resistance without movement, in which the muscle maintains a constant length and the joint involved maintains the same position. Maximal strength gained via isometric training is very specific to the joint angle at which the training is performed- requiring training at several points in the ROM of the joint if maximal strength gains are desired throughout ROM.(8) Both isokinetic and isotonic exercises utilize dynamic contractions, in which the muscle lengthens or shortens. Dynamic exercises are more efficient than isometric exercises in building functional strength, cardiovascular function and increasing motor performance. Isokinetic exercise is performed with a specialized apparatus that provides variable resistance to a movement, so that no matter how much effort is exerted, the movement takes place at a constant speed. Such exercise is used to test and improve muscular strength and endurance, especially after injury. A disadvantage of isokinetic exercise is that it controls the rate of maximal contraction throughout the ROM movement.(8)

Isotonic exercise, however, most closely mimics the reality of biomechanical movement and activities of daily living, and involves muscular contractions that increase joint mobility through movement of the joint during resistance. Isotonic exercises were chosen because they introduce movement to the joint, and restore ROM and flexibility, which is essential for the RA patient. This type of exercise influences aspects of disability and function while static (isometric) training does not.(3, 8-10) Additionally, unlike isokinetic and isometric training, visible feedback is available with isotonic exercises (seeing movement of the weight (dumbbell or stack)).(8)

Intensity of the program

Only when the training loads exceed those of the normal daily loading levels will training affect both the structure and function of the muscles trained. The strength training studies demonstrating the most strength improvement have been those of high-intensity, compared with lower intensity.(11) Our program consistently worked on keeping patients at approximately 75-85% of their maximum, with their load evaluated on a weekly basis and reset as needed. Our program encouraged the patients to max out at 5 or 6 repetitions (at a higher weight), rather than to max out at 8 or more reps (at a lower weight).

In addition to the sufficient intensity of loading, the frequency, and a progressive increase in the overall amount (volume) of each training session are important variables to optimize training stimuli.(1) The strength training portion of the exercise regimen was ~40 minutes three times per week. The frequency of the program allowed maximal strength gains in a short period of time, providing positive reinforcement for the patients. Researchers have found that participation in a strength training program less than 3 times per week is sufficient to build strength, however, we were also trying to establish a habit of exercising regularly and encouraging increased physical activity in general.(2) With the three time per week strength training regimen, patients also participated in at least three days a week of aerobic activity, increasing caloric expenditure and fat loss so they could observe their muscle gains more readily.

Performing a greater number of repetitions (i.e. 12) with low weight achieves a more moderate increase in strength than doing fewer repetitions (i.e. 4) with higher weight. A greater number of repetitions also provides muscular endurance, and there is less chance of injury than when lifting very heavy weight to perform a few repetitions. Our study subjects completed 6-8 repetitions to balance the gains in strength with endurance and safety for arthritic joints.

Specific exercises chosen

As the location as well as the severity of joint inflammation in RA is likely to vary from time to time, we created as comprehensive a program as possible and trained all major muscle groups.(1) Our program worked the muscles around the most affected joints (wrists, fingers, ankle and toes), through selecting exercises thatindirectly work ed these areas, and more directly worked those joints or areas less frequently affected by the disease (elbows, hips).(12) For example, although we did not include wrist curls, the patients indirectly worked on strengthening and stabilizing their wrist and forearm muscles and increasing their grip strength as they lifted dumbbells and performed exercises such as the hammer curl and one arm dumbbell row. Additionally, to strengthen the muscles surrounding the knee joint (the most affected lower limb joint), calf raises were employed to strengthen the gastrocnemius and soleus muscles of the lower leg and the leg press was used to strengthen the quadriceps muscles of the upper leg.

Our program avoided certain exercises such as the leg extension, an open-chain exercise. “Chains” are the links of body parts, such as the foot, ankle, knee, and hip. In open chain exercises, the end is free, such as your feet and ankles in the seated leg extension. The leg extension exercise does not engage the vastus medialis obliquus to help track and stabilize the patella, causing wear and tear of the patella, eventually leading to joint degeneration. In a closed chain exercise, the end of the chain farthest from the body is fixed, such as in the leg press, where your feet are fixed on the foot pad and the rest of the leg chain moves. Closed chain exercises tend to involve co-contraction of a greater number of muscles surrounding the joints (such as the hip adductor, abductor and hamstring muscles in the leg press), leading to better co-contraction around the joint structure, which improves overall joint stability. Additionally, in a close chain exercise, the joint proprioceptors are fired which also help to stabilize the joint. The leg press was selected to work the quadriceps instead of the leg extension, with patients placing a ball between their knees to maintain proper form (and to help keep the patella in alignment).

Option 3 included the cable abduction and adduction exercises which proved to be very important for many of our patients who had weak upper leg muscles, impaired balance and coordination, and poor posture.(13) These exercises required them to use their core muscles for stabilization to prevent them from leaning forward or backward during the exercise. Also, while working the targeted leg, their stabilizing leg muscles had to contract to prevent their torso from moving from side to side. Balance poles were available to aid patients until they were confident in performing the exercise. Through this exercise, we strengthened the adductors, gracilis pectineus, gluteus maximus and medius; abductors, rectus femoris, sartorius, tensor fascia latae, gluteus medius and maximus muscles, which proved important in advancing many patients' ability to walk without hindrance.

The hammer curl was selected instead of the bicep curl to place less force on the wrist and reduce extension movement, since the hand and wrists were reported as the most affected joints by our RA patients.

The three options for the abdominal exercises focused on exercises involving pelvic tilts and ultilizing leg movements (hip extensors) to work the abdominals, thus minimizing neck and back involvement. This strategy, along with the development of abdominal exercises that could be performed on a raised mat, or standing, proved beneficial to our patients who had back pain or difficulty rising from the floor mats, respectively.

Individualization of the program

Several types of assistive devices for weight lifting (padded weight gloves, weight gloves with hooks, wrist guards/supports) were available to assist the patient in completing a successful exercise session. These tools allowed those patients with hand disfigurement or those with flare-ups to complete the regimen. Some patients also added wrist cuff weights to the dumbbell weight when their grip strength did not allow them to increase dumbbell weight.

Even with the individualization of the program, slight modifications were necessary to accommodate characteristics of individuals.(14) For example, the option 3 one arm dumbbell row could be performed with the patient's hand and knee on a flat bench; with just the patient's hand on the flat bench and both feet on the floor (if their knees were tender); or with the patient's forearm on an elevated incline bench to avoid having their hand and wrist bear the weight of their body. Some patients with limited wrist mobility (i.e. fused wrists) preferred yet another approach using the flat bench. Instead of placing their palm flat on the bench, they placed a dumbbell on the bench and gripped its center, thereby avoiding the need to flex their wrist.

Lessons Learned

The experience of the author in previous studies, the experience of the entire study team, and the author's personal experience with RA and strength training, all contributed to a largely successful program. However, there was one adjustment made necessary by patients' disabilities that was notable.

Several patients had foot pain due to disfigurement of their toes/feet, fused toes, or neuropathy. This made rising onto their toes difficult and thus the calf-raise exercise challenging. Many patients could not perform the dumbbell calf raise correctly in general, and many could not perform it only using only one leg (option 3) because of these limitations (keeping them at options 1 and 2, at least initially). Through the use of the Airex pad which was a part of the original design, and incorporating the use of a raised block to allow a greater angle of movement (by the patients dropping their heels) we resolved these issues. The patients did progress from performing option 3 for the calf raise from an average of only 70% of the time at baseline, to 81% of the time at 16 weeks.

Limitations of the study

There were three areas where circumstances or funding limited the potential of this study. They were: 1) the intervention support program, 2) facility and staffing, and 3) length and timing of the study.

Intervention support program

The intervention support program made use of a variety of social and personal reinforcement strategies, incentives, and awards, including both internal and external motivators for patient retention that have been shown to increase adherence and compliance with physical activity programs.(15-19) The motivational program encouraged and fostered mechanisms for the inclusion of friends and family as exercisers or active supporters of exercise and addressed such issues as lack of motivation and anxiety that contribute to drop-out. These mechanisms of support are crucial to long-term compliance and preventing detraining. The constructs addressed by the program included: 1) education and skill development (classroom orientations, training manuals), 2) self-efficacy (personal contracts, goal setting, 3RM strength testing, exercise logs), 3) social support (participant recognition, motivational meals; personal notes of encouragement from trainers), 4) modeling (exercise challenges), and 5) incentive programs (gift cards and other rewards). The role of the trainer was crucial in this support process, providing encouragement, promoting good form, and assisting with both the intensity and progression of the regimen. As also discovered in previous studies, the trainers' continuous supervision was important for compliance, as most untrained persons will not exercise at such an intense level or increase their weight without prompting. .(20)

The patients' relationship with the exercise trainers and the bonds that were developed between participants proved essential for the patient in helping them understand what they could achieve safely and strengthening their belief in their ability to perform strength training exercise, therebyobtaining maximum benefit from their work out. (See Table 1.)

Table 1. Satisfaction (mean score) with the exercise trainers from exit evaluations completed by the exercise group (n=14)

Focus Area/Question	**Score (1: Strongly disagree, 5: Strongly agree)** **Comments**
EXERCISE TRAINERS	
The exercise trainers motivate me to do each workout safely, correctly and completely.	4.9 "I couldn't or wouldn't have been able to have done it without them"
The exercise trainers are friendly to work with.	5.0 "Great sense of humor-always" "They understood the process of the disease and trained accordingly"
The exercise trainers conduct themselves in a professional manner.	5.0 "Always willing to help and/or modify exercise for me"
The exercise trainers are knowledgeable and able to answer questions regarding the exercise program.	5.0 "I am thankful for everything I have learned and my progress in the study"

Study incentive programs and events also proved critical to the motivation of patients and also served as an introduction to recreational physical activities, encouraging a lifestyle of physical activity. Examples of events and motivational programs conducted throughout the study included: breakfast with the trainers, dance night, olympics at the park, motivational meals, the pedometer challenge and king/queen of the weight room. (See Table 2)

Table 2. Satisfaction (mean score) with social/motivational program from exit evaluations completed by the exercise group (n=14)

Focus Area/Question	**Score (1: Strongly disagree, 5: Strongly agree)** **Comments**
SOCIAL PROGRAMS	
I enjoyed the motivational events.	4.8 "I think we had a great bunch of people and it was fun to get together"
The motivational events provided a good opportunity to socialize with other study members.	4.8 "Good to get to know everyone else on the study"
I feel there was useful information shared at these events.	4.8 (no comments)
I enjoyed participating in the motivational programs in the gym.	4.7 "They made it fun to work harder" "Great ways to motivate your guinea pigs"
The awards at the events motivated me to continue to improve.	4.7 (no comments)

As confirmed in another study, our patients seemed to benefit emotionally as well as physically from the study.(14) The events gave patients an outlet to discuss their disease with others who understood their experiences. Not only did this provide a support mechanism, but also provided a forum for sharing knowledge. However, despite our efforts to provide social programs, as outlined in the exit evaluations, patients asked for additional social support to help them continue to build their strength training skills and to deal with barriers to continuing their exercise program long-term (See Table 3). We were able to provide the awards and activities we did through donations from community businesses. However, we could not provide additional social support or follow-up as requested due to limited funding.

Table 3. Issues surrounding long-term compliance program from exit evaluations completed by the exercise group (n=14)

Focus Area/Question	
LONG-TERM COMPLIANCE	
How else might we support or motivate you to continue our exercise program?	“Keep in touch”; “Get together once in a while”; “Get more money to continue study”; “Give us additional exercises to do for variety”; “I am sufficiently motivated”
Do you plan to continue exercising after the study ends, and where?	100% said yes Majority exercising at private fitness clubs, YMCA’s or city fitness facilities; two purchased equipment to exercise at home
If you could make one change to the exercise program what would it be?	“More one on one with the trainers” “No changes”
What barriers do you see to continuing exercise on your own?	“Demands on time” “Not being motivated or disciplined on my own”
Other	“I am glad I had the opportunity to participate”; “enjoyed working with the staff and getting to know others in the study”; “I can’t say enough that patients are aware of this type of exercise through their doctors –this should go hand in hand with medication. If I had known this since 1994 my life would probably be very different.”

Facility and staffing

Financial constraints limited our selection of an exercise facility and our ability to staff more than one gym, which reduced the convenience factor for the patients. Although the gym was centrally located, it was fairly small and thus occasionally caused the patients to wait to use equipment necessary for their work out (i.e. benches, treadmills). Additionally, some patients would have preferred a greater variety of aerobic equipment, including a swimming pool. (See Table 4)

Table 4. Satisfaction with the exercise facility from exit evaluations completed by the exercise group (mean score) (n=14)

Focus Area/Question	**Score (1: Strongly disagree, 5: Strongly agree)** **Comments**
EXERCISE FACILITY	
The exercise facility I attended was conveniently located.	4.2
I find that pieces of exercise equipment are readily available when I need to use them.	3.3 “Sometimes I find it hard to find enough of the weight benches”
There is plenty of accessible parking.	4.6

Length and timing of the study

A longer study would have allowed us to accomplish two additional things. First, we could have taught patients more exercises to vary their regimen and prevent the long-term risk of boredom. We were, however, trying to standardize the program as much as possible to determine its effectiveness, and so this was not possible in the 16-week time frame. Secondly, if we had funds to recruit patients in two staggered cohorts, we could have established a mentoring buddy system where the patients in cohort one could have helped those who entered later in cohort two. This would have provided additional support beyond that which the trainers could offer.

Due to logistical constraints, the study began in May and continued through the summer months. In Tucson, Arizona, many people leave for the summer (part-time residents) or go on vacations. The timing of the study not only affected our ability to recruit a larger sample, but we may have achieved an even higher attendance rate (>82%) had the study not been conducted during the summer. Many patients also seem to have been adversely affected by the summer weather and monsoon storms in Southern Arizona.

Satisfaction with program

As indicated in Tables 5-7, patients were, as a whole, very satisfied with the strength training program. Although, as we mentioned in a previous section, we had to modify our calf-raise exercise for some patients, it is interesting to note that no one mentioned this exercise as a challenging exercise when completing the evaluations. We believe this indicates the difficulties were resolved with our modifications. (See Table 5.)

In this study, 100% of the exercisers said they would continue the program and the majority of patients had already signed up at a local gym or purchased strength training equipment before the end of the 16-week study.

Table 5. Satisfaction (mean score) with the strength training exercises from exit evaluations completed by the exercise group (n=14)

Focus Area/Question	**Score (1: Strongly disagree, 5: Strongly agree)** **Comments**
ABILITY AND ENJOYMENT	
I feel that I was able to safely and effectively complete the strength training exercises.	4.8 (no comments)
I enjoyed the strength training exercises.	4.6 (no comments)
Which specific exercises did you find the most challenging?	Upper body: Hammer curls, incline dumbbell press Lower body: Hip abduction and adduction, Leg press

Satisfaction with the overall exercise program was high, and provided valuable qualitative data. Physical, mental and emotional improvements were seen and reinforced by the patients' family and friends.(Table 6)

In Table 7, we report the satisfaction with the overall program from both the exercise and the control group.

Table 6. Satisfaction with overall exercise program from exit evaluations completed by the exercise group (n=14)

Focus Area/Question	**Comments**
OVERALL SATISFACTION WITH EXERCISE	
How has the study affected your quality of life (physically and mentally/emotionally):	
Physically	"Stronger"; "I can open new joints"; "Less fatigued and more energy for daily tasks"; "I have muscles!"; "More confident"; "Less pain"; "Lost some weight"; "More flexible"
Mentally/emotionally	"Feeling better about myself"; "My focus has increased with the change in my strength"; "I have more confidence"; "I am uplifted"; "I feel good about exercising"
What have your family or friends said to you about changes they have observed?	"Husband has noticed attitude change"; "I have a bounce in my step"; "I look better and have more energy"; "I have trimmed down and look healthier"; "They are impressed"; "Comments on how well I'm able to walk"

Table 7. Satisfaction with overall program from exit evaluations completed by the exercise group and control group (mean score) (n=21)

Focus Area/Question	**Score (1: Strongly disagree, 5: Strongly agree)** **Comments**
OVERALL SATISFACTION	
I feel that the requirements for me to be a participant in the study were reasonable and manageable	4.8 "Sometimes exercising three times per week was difficult because of time commitments"
If I had to do it over again, I would still be a participant in the study.	4.7 "It's the best thing I've done for myself in years"
If I could make one change to improve the study for future participants it would be…	"Nothing" "Have all activities in one building" "Have more trainers and more flexible hours and add Saturdays" 'Provide more variety in exercises over the 4 months' "Have less questionnaires to complete"
What could we have done to make the study more valuable to you?	"Everyone did an excellent job" "Post the findings of the study" "Would have liked to participate longer"

Table 7 (Continued). Satisfaction with overall program from exit evaluations completed by the exercise group and control group (mean score) (n=21)

What did you like best about the study?	"Meeting the staff and the participants"; "knowing this study may be helping future RA patients"; "knowing someone was there to motivate and encourage me"; "gaining the knowledge about how to continue with strength training"; "developing confidence in my physical abilities"; "the outcome: I can now walk and even write and play the piano"; "one-on- one training with trainers"; "improving myself physically and emotionally"
What did you like least about the study?	"The paperwork"; "not being randomized to exercise"; "having to commit the time (getting out of work on time)"; "driving to facility"; "would like more weekend exercise times"

CONCLUSION

The success of this study was primarily determined by key decisions made in the design and development of the program. The individualization of the strength training program, personal attention received from the exercise trainers and a comprehensive intervention support program provided the necessary reinforcement for participant compliance and retention. In addition, exercise selection allowed participants to begin at an appropriate level, advance as appropriate, and most importantly, continue during flare-ups. For example, the use of free weights required concentration on proper form, improved balance and coordination, engaged small as well as large muscles, and served to strengthen limbs weakened by disease. The progressive nature of the program and frequency of exercise served as a positive reinforcement and encouraged “habit formation”. The exercises were selected to strengthen muscle groups around the most affected joints and the completion of 6-8 repetitions balanced the gains in strength with endurance and safety for arthritic joints. The use of assistive devices allowed patients to complete their regimen despite disfigurement or flare-ups, and modifications were designed to address such issues as limited wrist mobility or accommodate disfigurement of toes/feet, fused toes or neuropathy. The strong rating (4.8 out of 5.0) on patients’ “confidence in their ability to safely and effectively complete the strength training exercises” is as strong a result as the significant improvements in function, quality of life, disease improvement and pain reduction. It argues well for the inclusion of an intensive strength training program as a part of the multi-faceted treatment of rheumatoid arthritis.

Limitations of the study focused on service-oriented issues that were driven by limited funding. The compliance and satisfaction with the program was high, with 100% of the patients continuing strength training at the conclusion of the study. Future recommendations from patients included continuing the study for longer and providing further opportunities to socialize for long-term motivation and support. While the intervention support program was very comprehensive, including: 1) education and skill development, 2) self-efficacy, 3) social support, 4) modeling, and 5) incentive programs; it was this area that participants wisely acknowledged they could use additional assistance in integrating strength training regimens into their daily lives.

It is our hope that the strong results observed in this study will give impetus to broader use of strength training as a primary intervention and serve as a significant first step toward providing practical recommendations to assist those living with RA on a daily basis.

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APPENDIX A- STUDY EXERCISE MANUAL

The Strength Training and Remicade Exercise Manual that follows has not been reproduced in its entirety, but has been modified and transferred to a Microsoft Word document to meet the University of Arizona's guidelines. Therefore, due to formatting limitations, the illustrations, graphics, and pictures are not included in this dissertation format. The manual's table of contents provide an overview of what was included in the manual, although the page numbers do not correspond due to the continuous pagination of the dissertation.

Strength Training and Remicade Study

Exercise Program Manual

Sponsored by:
Arizona Arthritis Center
and
Departments of Physiology and Nutritional Sciences
Colleges of Medicine and
Agriculture and Life Sciences
University of Arizona
and
Centocor, Inc.

January 2004

Acknowledgments

Many people have donated their time and expertise to the development and implementation of the Strength Training and Remicade Study, with countless hours spent specifically on developing the Strength Training and Remicade Study Exercise Program Manual. I would like to express my gratitude to the following people: Scott Going, who graciously helped me with the detailed design of the exercise program and provided unconditional support; Tim Lohman, who has provided unyielding support of my dreams; David Yocum, whose generosity and vision has made this study a reality; Jeff Lisse, whose caring and professional encouragement is greatly appreciated; and Linda Houtkooper, whose leadership and focus enhanced this project. You have all been extraordinary mentors.

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I am also incredibly grateful to my family and friends. I thank my mom and dad for their unending support of my endeavors. And most of all, I thank my husband, Pete, for the love, patience, perspective and support which has enabled me to accomplish what I have today.

Thank You,
Hilary

An additional thank you goes to the many community businesses who have donated to the Strength Training and Remicade Study, providing subject incentives and study supplies throughout the study.

Thomas & King (Applebee's)
UA Athletics
Arizona Ballroom Company
PF Chang's
Gateway Ice Center
Bruegger's Bagels
Bookman's
Arizona Inn
Target
Westward Look Resort
Beyond Bread
Reid Park Zoo
Omni Hotels
HILTON
Performance Footwear
Marie Calenders
Foster's Shoes

Contents

Welcome to the Strength Training and Remicade Study

We welcome all of you to the Study! Over the next four to five months, we will learn together, sweat together, overcome obstacles together, laugh together and grow strong together. We hope that you will take away something special from this experience and share what you have learned with others to continue the fight against Rheumatoid Arthritis.

Thank you.

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Co-Principal Investigator

Hilary Flint-Wagner, M.P.H.
Co-Principal Investigator

History of the Study

The idea for this Study was born in April, 2002. After three months of research and writing, a grant proposal was submitted to Centocor, Inc., the drug manufacturer of Remicade™ (Infliximab).

Several new "biologic" drug therapies are now available to treat Rheumatoid Arthritis (RA) (i.e. Remicade™). These disease modifying drugs have proven to be very effective in reducing the painful symptoms of RA and in slowing the progressive joint degradation, thereby improving the quality of life for a person with RA. However, there is still a tremendous need to counter other detrimental physical effects that occur, such as the loss of muscle mass and impaired joint range of motion. RA's chronic and fluctuating disease course necessitates the development of additional non-pharmaceutical therapies to further improve and maintain both the physical and psychological well-being of persons with RA.

This study was developed to examine the effects of a progressive and individualized strength training and aerobic exercise program in RA patients taking Remicade. The Study comes at an important time in RA research as health professionals have begun to recognize that exercise, in particular strength training and weight bearing exercise, is not only beneficial but imperative for the health of the RA patient. RA patients should be prescribed an intensive, individualized and comprehensive exercise program just as they should expect to receive early and aggressive treatment with the latest pharmaceutical therapies.

Although the benefits of exercise for the RA patient are acknowledged, the type and dose (intensity, frequency and duration) of exercise necessary to obtain the maximum results and long-term benefits for the RA patient are not known. Researchers conducting studies such as the Strength Training and Remicade Study are at the cutting edge of Rheumatology and Exercise Science, with the task of proving that previously prescribed non weight-bearing exercise (i.e. water aerobics) at low-intensities and short durations are conservative and inadequate to prevent the decline in physical function, loss of bone mineral density (BMD), muscle wasting, and fat gain faced by RA patients.

You are a part of a landmark study testing the hypothesis that progressive, individualized, high intensity strength training exercise can produce positive results in RA patients without exacerbating disease activity. Very few studies have been conducted investigating such an intervention. The studies that have been completed have been of short duration, have been low intensity, have not been randomized controlled trials, have had relatively few patients, or have not individualized the program to the particular needs of the RA patient. This is the first study conducted with the combination of strength, aerobic and Remicade therapies.

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Who to Contact If…

I have a general question or comment about the overall study:

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Co-Principal Investigator and Program Director
(520) 621-7592
hilary@u.arizona.edu

I need to reschedule one of my laboratory appointments or have a question about how to prepare for an appointment:

Alison Foster of Hilary Flint-Wagner
(520) 621-7592

I have a question about the exercise program or one of the study functions (i.e. motivational meal, weekend social activity):

David Mack, M.S.
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dsmack@cox.net

There are also comment cards that can be filled out and dropped in the envelope found in the front of the exercise log box at the gym. These are collected on a weekly basis.

Research on Physical Activity

Benefits of physical activity

Research shows that becoming more physically active can help people with arthritis. For many years, it was a common belief that people with arthritis should avoid physical activity because it could damage their joints. In fact, just the opposite is true. Recent studies show that moderate physical activity helps people with arthritis feel better. By increasing your physical activity, you receive the following benefits: decreased pain, disability, depression, and anxiety; and increased function, cardiovascular fitness, strength, endurance, joint range of motion, bone mineral density, coordination, balance, and energy levels. Physical activity improves your overall health and reduces your risk of obesity and diseases such as heart disease, osteoarthritis, osteoporosis, diabetes, stroke, and colon cancer.

What is physical activity?

Physical activity includes all types of exercise: leisure time activity, occupational activities, and activities such as household chores. Physical activity is defined as “any bodily movement produced by skeletal muscles that results in energy expenditure”.

How much physical activity do I need?

The recommended goal is at least 30 minutes of moderate intensity physical activity on 5 or more days of the week. Examples of moderate intensity exercise include: swimming, dancing, walking briskly and household chores such as mowing the lawn. You may be surprised to know that if you are active the entire day (i.e. walking briskly for 15 minutes in the morning before work, taking one 5-10 minute exercise break during the day, and a short swim in the evening) you can expend as much cumulative energy (calories) as someone who jogs for 30 minutes on their lunch hour, but is sedentary the rest of the day.

Should I continue to exercise during a general or local joint flare up?

If your joints hurt, you may not feel like being active. However, lack of activity can actually make your joints become even more stiff and painful. Physical activity is recommended to keep muscles, bones, and joints healthy. It is appropriate to put joints through their full range of motion once a day during acute systemic or local joint flares.

You may hurt a little at first as a result of exercise, especially if you are not accustomed to the activity. However, most people who stick with a program of regular physical activity begin to feel better within a few weeks.

Research on Strength Training

People with RA have decreased muscle mass, bone mineral density, functional capacity, and also may experience depression, a negative body image, and increased body weight and fat mass. Research on strength training indicates that this type of exercise can help to improve all of these outcomes. While further studies are needed regarding strength training in the RA population, the following review of research supports the benefits of strength training for the RA patient.

Muscle mass

The immune system in RA is hyperactive, creating chemical signals which change the mix of what the body burns for fuel from predominantly fat and carbohydrates to one that includes much more protein and a lot less fat. The protein that is needed to fuel the hyperactive immune system comes from its storage depot, muscle. Therefore, people with RA experience significant losses of muscle mass which can inhibit ones ability to fight off infection and illness. Decreased muscle mass leads to decreased muscle strength and subsequently a decline in function. Strength training increases muscle mass, which is directly correlated with increases in strength.

Bone mineral density

The inflammatory process, inactivity and medications (i.e. prednisone) can contribute to loss of bone mineral density (BMD). Weight bearing exercise such as strength training is essential to counteract this bone loss, providing ground reaction forces which increase BMD. This is important, knowing that the average woman loses about 1 percent of her bone mass each year after age 35 and significantly more after menopause (20% loss in the first 5-7 years post-menopause). Men also suffer from low bone mineral density, which can lead to osteoporosis and increased risk of fractures. Men have an incredibly high rate of mortality due to fractures (hip fractures, in particular). Having strong bones lowers your risk of fractures and improves function.

Fat mass

Although RA patients experience muscle wasting, they still tend to preserve fat mass. Thus, people with RA tend to become over-fat with poor muscle tone. Inactivity, due to declining muscle strength, perpetuates this cycle, causing further weight and fat gain and leads to other conditions such as Type 2 diabetes. Strength training increases muscle mass, improves muscle strength, and decreases fat mass.

Cardiovascular health

Increased fat mass and body weight and high levels of inactivity are often prevalent in people with RA. Additionally, persons with arthritis tend to retain their fat in the abdominal area, increasing their risk of heart disease. Heart disease is the number one comorbid condition (concurrent disease) associated with RA. Strength training exercise can lower your risk of heart disease by decreasing blood pressure, lowering your low density lipoprotein (LDL) or “bad” cholesterol, and by decreasing your fat mass and body weight.

Fatigue

Fatigue is often reported as the “worst part of having arthritis”. Sleep fragmentation, medications, inactivity and pain contribute to the patient’s problem with fatigue. Strength training will increase your energy level and assist in restful sleeping.

Balance

Poor balance is due in part to weakened muscles. By strengthening your bones and muscles surrounding your joints you increase joint stability. This improves your balance and reduces your risk of falls. Fractures due to falls can cause considerable loss of independence due to disability and have detrimental effects on your long term health.

Range of motion

Range of motion(ROM) (how fully one’s joints or limbs are able to move) is essential in performing activities of daily living such as carrying groceries, gardening, or walking. Strength training helps to increase your ROM by lengthening and softening your muscles and connective tissue (cartilage and bone), making tasks easier to perform.

Depression

Many RA patients suffer from depression and a feeling of “loss of control” over their disease. Those who suffer from depression report increased levels of pain and disease activity. It is well documented that exercise helps relieve depression and anxiety, with regular exercisers reporting improvements in mood and a more positive overall outlook on life. Strength training helps to decrease depression through raising endorphin levels during exercise.

Body image

Due to inflamed and disfigured joints caused by RA, an RA patient may have a negative body image. Strength training exercise helps to control the symptoms, which may allow you to reduce your medications that have negative effects on your appearance (i.e. prednisone –which causes bloating and “moon face”). The increased muscle mass gained during strength training enables your body to burn calories more efficiently, helping with weight management, an important component of body image.

Stress

Stress causes muscles to contract and tighten. The type of strength training used in this study allows the muscles to lengthen and shorten, and can alleviate some of the pain caused by this tightening. Strength training also is a great form of stress relief, improving your mood and alertness during the day.

Preparing to Exercise

Before you go to the gym

Getting the most out of your workout does not start when you enter the gym. There are a few important things you should do outside of the gym to maximize your performance.

- Get a good night's sleep. Following a regular bedtime routine such as reading before bed to relax and going to bed at the same time every night, will assist your body in falling asleep. Avoid caffeine, nicotine and alcohol.

- Drink plenty of water to prevent dehydration. A healthful amount is 8-10 eight ounce glasses per day or more than 2 liters of water. The required amount is even greater when you exercise, as you have to replenish the fluids you lose. If you feel thirsty, you are already dehydrated. Listen to your body to determine your personal needs, following these rough guidelines. Before exercise: drink at least 12 ounces 2 hours prior to exercise and another 4 ounces right before exercise. (NOTE: 8 ounces = ½ glass or one mug/cup of water.) During exercise: drink 6-12 ounces every 15-20 minutes during exercise. After exercise: drink at least 24 ounces of fluid. In hot weather, you need to drink more than usual. To check your hydration status, check your urine. If you have clear, light colored urine, you are well hydrated. (See "Am I Hydrated" Appendix L.)

- Prepare for your workout the night before. Have your gym bag all packed with clothes for the day ironed and bathroom essentials ready to go. Avoid rushing around which only causes stress and interferes with your workout.

- Eating before exercise is important. Eat a minimum of 30 minutes before you exercise. Low-fat items, of small portion sizes, such as a low-fat granola bar or an English muffin with a small amount of peanut butter are recommended.

Gym membership

Please complete the University Medical Center Health and Wellness Center (UMCHWC) membership form (See Appendix J). The study will provide your membership for the duration of the study. Please abide by all gym rules, included in the "weight room etiquette" section that follows.

Preparing the gym bag

Shoes

Wear proper athletic shoes. Good quality athletic shoes should provide cushioning for absorbing shock, ankle support, rubber soles to prevent slipping, and the closed toes help protect your feet from falling weights! Close-toed shoes are mandatory in the gym. (See Appendix G for details on proper footwear)

Clothing
Wear proper workout clothing. Lightweight clothing allows your skin to breathe and does not impede movement. Your clothes should be comfortable but not too large, as extra clothing can cover up mistakes in your posture.

Towel
If you tend to sweat a lot, be sure to bring a small towel to wipe your brow and to wipe down equipment after your use.

Water bottle
Bringing a water bottle is not only necessary to re-hydrate during exercise, but is more convenient than making trips to the water fountain.

Weight gloves
Weight gloves will help to protect the skin from blisters and calluses on the palms and provide a firmer grip when exercising.

Watch
A watch may be helpful when you complete your aerobic activity, particularly walking, on the study-designed course which continues in and outside of the UMC building.

ID Card
Please ensure that you bring your study-issued ID card with you to every work-out at UMC HWC. This will help us and the UMC staff to properly manage Wellness Center memberships.

Pedometers
Your pedometer should be on your person at all times in order to help remind you to stay active! You will be asked to record your steps during the aerobic portion of the exercise session on your exercise log.

Study Exercise Book
You should bring this exercise book at the beginning of the program to ensure you complete the exercises in proper form. There is often a substantial learning curve as you learn a new program, and you may need to reference this book in the gym as you complete your work-out.

Exercise logs
Your exercise logs will be kept at the gym at all times. You may pick them up from the study exercise log box at the front desk as you enter the gym for your work-out.

At the Gym

Hours and session times

UMCHWC's area is divided into two rooms: 1) the UMCHWC gym open to all HWC members (front desk area), and 2) the UMC Cardiac Rehabilitation Unit (at the far end of the HWC, in the back room). The gym's regular hours are Monday through Thursday 5am-9pm, Friday 5am-8pm and Saturday and Sunday 7:30 am-4pm. Please be sure to check with the front desk regarding changes in hours around the holidays. The aerobic equipment in the UMCHWC is available for use during regular operating hours. However, the UMC Cardiac Rehabilitation Unit's aerobic equipment is only available to HWC members 5- 7am, 12-1:30pm and after 4pm Monday-Friday. You may use the raised exercise mat in the Cardiac Rehabilitation Unit to complete your stretching exercises at anytime.

The Study exercise session times, when the study trainers will be available for you to complete your work-out, are Monday, Wednesday, and Friday from 6:30-9:00 am and 4:30-7:00 pm. You will choose a work-out session (morning or evening) and inform the study staff of the approximate time you will arrive at the gym. This will be your work-out time for the duration of the study. It is important that you arrive at the facility on time, so that you can complete your entire work-out when the trainer is present. If you miss a session on Monday, Wednesday, or Friday, it is possible to arrange a make-up session at a different time (i.e. in the evening if you miss your morning session). Variable work-out times have been offered to break up the number of participants in the gym, to provide an appropriate participant to trainer ratio to assure your safety, and to allow time for individual attention.

Weight room etiquette

Workouts should be a time to relieve stress, reflect, socialize, and have fun. In order to keep the gym a healthful, happy place with minimal distractions, respect the gym rules and fellow exercisers.

- Do not talk loudly to your work out buddy and do not talk on a cell phone.
- Do not drop the weights on the floor which can startle or injure someone.
- Do not bang the dumbbells or weight plates together- preserve the equipment.
- Put equipment back where it belongs (including unloading weight plates and replacing pins on machines when finished).
- If someone is using the mirror to observe their training form, do not block their view.
- Do not monopolize the water fountain. Bring your own water bottle (already filled) to avoid waiting in line or keeping someone else waiting.
- Do not monopolize a piece of equipment. During busy gym times, it is only polite to allow another exerciser to rotate in between your sets to complete their

strength-training work-out. If you do use the aerobic equipment, please observe the time limits when others are waiting.

- Wipe your sweat off benches and machines after you use them.
- Leave ample room between you and the people lifting weights nearby.
- Keep the locker room clean. You have been given the privilege of using the locker room and its lockers during the day, but please remember that no overnight storage is allowed.

Maximizing your exercise benefit

Rest intervals

…Between sets

This is the time when you allow your cardiovascular system and muscles to recover before you begin another set of repetitions (reps) or a different exercise. The rest interval usually recommended is between 30-60 seconds.

…Between repetitions

Lifting weights too quickly can cause injury and does not maximize your workout. Slow, controlled movements are characterized by more muscle tension, less momentum and lower risk for injury. Anytime you clang and bang the weights, you are probably lifting too quickly, jerking the weights up by using momentum rather than muscle power. You should take at LEAST two seconds to lift a weight and two seconds to lower it. Count in this fashion: "one- one thousand, two- one thousand..". This is only a guideline to ensure that you slowly lift and lower the weight. Counting out loud may assist you in breathing and in performing the resistance exercise at the appropriate speed.

The right fit

Some machines require adjusting the seat height or leg length. To ensure safety and maximum performance, adjust the machines to your body prior to your exercise. If you need assistance to move the pins or knobs to assure the right fit, ask a trainer or a buddy! After adjusting, jiggle the seat or other respective part to make sure it is securely locked in place.

Breathing

It is important to maintain a constant breathing pattern. Never hold your breath when you are lifting weights. Holding your breath causes your blood pressure to rise drastically. There is no set rule for developing a breathing pattern, although most people find it more natural to exhale during the exertion and inhale during the recovery part of the lift (when returning to starting position). Experiment so that you can discover what is comfortable for you.

Do not lock your joints

Usually in reference to your elbows and knees, this phrase means you should not straighten your joint so that it moves past the point where it normally sits at rest. Locking your joints puts undue stress on your joints, tendons and ligaments, and also causes you to perform your exercises incorrectly.

Head position
Do not tense the muscles in your neck or drop your head to your chest while performing the strength exercises. Look straight ahead.

Focus
Focus on the muscle contracting and completing the full range of movement. You may be able to complete more reps by simply envisioning the entire movement.

Safety in the Gym

Lifting and carrying weights
To lift free weights from the rack, get right up next to the rack. Bend from your knees, not your hips, lifting with your legs, not your back. When carrying weights around, hold heavier plates or dumbbells with two hands, keeping them close to your body. Pay close attention to where you are walking.

Proper exercise technique
You will be trained in proper exercise technique. Keep this in mind and do not try to create new exercises on the machines. Follow all guidelines as stated in this book and any additional directions posted on the machine. If a piece of equipment tells you to use a seat belt, for example, use it!

The spotter

The spotter is the person who assists you in lifting heavier weights, in particular, to ensure safety as the exercise is completed. The spotter can be your buddy, an exercise trainer, or another gym member.

Communicate with your spotter:
Prepare your spotter by explaining how many reps you aim to complete and how many reps you think you can do before you will need their assistance. Tell the spotter if you need help getting the dumbbells into position or if you would like them to count for you. It is important to make it clear what type of assistance you need.

If you are the spotter:
First, if you cannot perform the role because the weight the person is lifting is more than you believe you can handle, do not offer your services.
Second, always pay attention! Your job is not only essential for the safety of you and your buddy, but you also have the important role of motivating your buddy. Motivate them to get the most out of their workout.
Third, listen to what the person needs. They may want you to have your hands right under theirs, offering help immediately, or they may prefer you wait until they ask for

assistance. Where you stand and where you place your hands is very important and can either be helpful or distracting.

Injuries

Some minor discomfort of the muscles is to be expected when you begin a strength training program. Sore muscles indicate that you are challenging your muscles appropriately to adapt and become stronger. However, it is imperative that you pay attention to your body and become familiar with what is minor discomfort from increasing your weight lifted versus what could be considered a strain or sprain. A sprain is an injury to a ligament- a stretching or a tearing- which can occur due to accidents such as falling on an outstretched arm or twisting a knee with the foot firmly planted. A strain is an injury to either a muscle or tendon, which can result from improperly lifting heavy objects. Typically, people with a strain experience pain, muscle spasm, and muscle weakness. Strains and sprains can be prevented by wearing proper footwear, completing proper warm-ups and cool-downs, and maintaining proper exercise form.

If you injure yourself during a workout session, notify the trainer in the facility immediately so that he/she may record the event and assist you in obtaining medical treatment, if necessary. If you injure yourself at another time outside of the Study exercise program, please notify the trainer or the Project Director so that he/she may record the event and determine whether it is safe to continue the Study program. All injuries (whether minor or major) can affect your workout program and long-term health.

Assistive Devices

There are many assistive devices on the market to help you complete your work-out while providing joint stability and protection. These devices may be helpful as you increase your weight, particularly if you have problems with your hands or wrists. Joint protection devices help to reduce joint stress (thus pain and inflammation), improve shock attenuation during exercise, and maintain or improve active joint motion and alignment. Several types of braces and hooks are shown below. You should experiment to see what works best for you. These devices can be found at local businesses such as the Sports Authority, Big 5 Sporting Goods, Wal-Mart, and Tucson Safety and Medical Supply.

Motivation and Consistency

The key to consistency

Select a workout time that you feel confident you can commit to and write your workouts on your calendar as you would any other appointment. Your health is a priority and your exercise needs to become a part of your lifestyle. Make sure your schedule reflects this commitment to your health. Your buddy also depends on you and the exercise trainer will plan on seeing you at your designated work out time.

If an unexpected event occurs, contact your exercise trainer and let them know you will not be at your regularly scheduled work out. Schedule a makeup workout with your trainer as soon as possible.

"On the go" program

If you find that you have to travel and miss a work-out session at the gym, make sure you do not miss working out entirely! You can work out "on the go" with a little bit of research into the hotel/city where you will be staying. Remember, exercise helps to combat jet lag and relieves stress. Continuing your routine will make your return to the Study program much easier. Be sure to meet with your trainer prior to your absence to plan your "on the go" program.

What to look for while you are away:
Hotels with fitness facilities
Hotels with arrangements with a local health club
Areas of the city with planned fitness trails

If a gym is not available:
Walk in a local park or shopping mall
Walk to the restaurant
Work out in your hotel room with a video borrowed from UMCHWC
Use stairs instead of elevators
Take a brisk walk during scheduled breaks
Complete strength exercises that do not require weights (see option #1) (You may increase the number of sets that you perform)

How we will help motivate you

Trainer follow-ups

During the program, if you miss an exercise session, the exercise trainer will contact you to ensure that everything is okay and help you get back to the gym. The trainer will work with you to schedule a make-up session.

Monthly introduction to aerobic activities
Aerobic activity is encouraged not only as a part of our program, but outside of the Study regimen as well. Introductory sessions to a variety of aerobic activities will be offered during the program to help you determine the types of activities you enjoy. A Study trainer is present during these sessions, as they take place once a month in the UMC HWC aerobic room, during the regularly designated work-out times. Examples of aerobic activities that will be introduced include: tai chi, funk aerobics, and jazzercise. See Appendices A and E for information on aerobic activities.

Monthly social events
These are scheduled on a weekend day. These events allow you to build social support networks, participate in exercise with those close to you (i.e. spouse, friend), and have a fun, active weekend. Examples of activities include: hiking, Olympics, and country dancing.

One-on-ones with exercise trainers
One-on-one appointments with an exercise trainer are to review your individual regimen, evaluate your exercise form, answer questions, and recommend exercises/modifications specific to your needs. The appointments will be scheduled on an "as needed" basis.

Pedometers
Everyone will receive pedometers which assess activity level by counting the number of steps you take during the day. We will use these fun gadgets to see how your physical activity levels change throughout the program. Research recommends that you take at least 10,000 steps a day. You may review the pedometer hand out in Appendix B which gives you tips on how you can increase the number of steps you take during the day. See Appendix D & E for more information on where to walk and how to stay motivated.

3 Repetition Maximums
Three repetition maximums (3RMs) will be done in the place of the common 1RMs or one repetition maximum to help prevent injury. A 3RM is the amount of weight that can be lifted 3 times in a row with proper form. A test of your 3 RM's will be conducted by the exercise trainer at the gym to assess your strength gains, overall progress toward your goals and to determine when your weights (load) should be increased. You will complete 3 RM's at baseline, at 2 months, and at the end of the study (final measurement).

Motivational Meals
Motivational Meals are social gatherings at which you and your families have an opportunity to socialize in a "non-workout" environment. Fun games, awards, and motivational topics will be presented. Short educational programs will also be offered with such topics as: re-hydration during exercise and overcoming barriers to exercise. See Appendix H for the Study calendar of events.

Goal setting
Establishing short-term goals is essential to ensure that you get the most out of your exercise program. Refer to Appendix I for your "Contract for Success". Complete the contract and keep a copy in a visible location (i.e. refrigerator door) so that you consistently take steps toward completing your goals. Accomplishment of short-term goals leads to successful completion of long-term goals which will help you maintain a healthy lifestyle

How you can motivate others

Buddy system
Be a buddy (choose a fellow study member as an exercise partner) or form a small group of study members to build new supportive relationships and assist each other in exercises as needed (i.e. helping partner up from the floor after stretching, monitoring partner's exercise form). The buddy serves as a spotter and motivator, and can help make sure that you are at the gym at the crack of dawn! Friendly buddy or group competitions will be conducted throughout the program.

Encouraging others in the gym
We can all use a "way to go!" or "one more rep, you can do it!" every once in a while. Motivating others will boost your spirits as well.

Try writing your fellow exerciser an encouraging note, or nominate her/him for a special study award. Maintaining a positive attitude not only helps you succeed in your work-out but attracts other positive people who will encourage you when you may need it most.

Study Exercise Program Overview

The Study exercise program will target improvement in four areas: muscle strengthening, stretching and balance, range of motion and flexibility, and aerobic capacity.

Each exercise session will include the following four components: 1) 5-10 minute warm-up via walking; 2) 40 minutes of strength training exercises (including abdominal exercises); 3) 15-20 minute aerobics component (combined with the aerobics done during warm-up and cool-down, you will reach a total of 30 minutes); and 4) 5 minutes of cool-down which includes walking and static stretching of the muscles. Range of motion exercises will be done on your own.

The exercise session will be completed 3 x week (Monday, Wednesday, Friday) and will take ~60 minutes each session. The sessions are completed on alternate days in order to allow your muscles time to recover from the strength component. This does not mean that you cannot participate in aerobic activities on your days off.

Additional days of aerobic exercise are encouraged on a weekly basis, with study staff facilitating this by sponsoring activities (i.e. monthly introduction to activities and monthly social events). Information on aerobic and other physical activities currently available in the community are listed in Appendix A and E. Participation in these activities fosters the inclusion of friends and family as exercisers or active supporters of exercise. For example, you may initiate a Saturday walking club at Udall Park or attend a yoga class with friends and family.

Progression of the Program

In following the approach of an individualized exercise program, the program's progression will vary according to your needs and accommodate people entering the program at different levels of fitness and function. If you have a flare–up on an exercise day, you may perform a lower intensity regimen or if your flare-up is severe, you may do an alternative exercise. To assure that individual needs are met, three exercise options are available for each of the eight exercises included in the strength training program. These options should accommodate both different entry levels of fitness and function and flare-up conditions. The MOST important thing is to keep exercising at some level. The progression of the program will allow sufficient time for you to learn proper exercise technique and for your body to adapt to the stress of exercise.

Strength Training

You will begin your strength training exercises at 60% of your 3RM (amount of weight that can be lifted 3 times in a row with proper form) and then progress to 75-80 % of your 3RM. We have outlined below an approximate timeline for you to achieve 75-80% of your 3RM. This timeline will allow time for your body to adapt to the stress of exercise, allow time for you to feel comfortable with completing the exercises, and yet encourage you to continue moving toward the next option (level of performance). These progressions are guidelines, and only you and your exercise trainer can decide what progression is best for you.

In the strength training component, you can progress to additional weight when you are able to complete the reps in proper form (proper body position and joint alignment at the start of and throughout exercise) for two sessions in a row, with an RPE of ≤4

Aerobics

For the aerobic component, you can progress to a greater intensity or duration when you are able to complete the exercise with a Rate of Perceived Exertion (RPE) of ≤3 on the Borg RPE scale (see RPE scale in appendix K). When you are ready to progress to the next level your trainer may, for example, suggest you add 5 minutes to your walking time or increase the speed at which you walk. The RPE scale helps you describe how hard you feel you are working. RPE is the level of difficulty at which you perceive you are exercising. Some people might feel they are at level 10 when they are walking on flat ground, others might feel that way only when they are jogging up a hill. Both are right. Only you know how hard your exercise feels to you. As your body adapts and you become more fit, you will gradually keep making your activities more challenging. You might find, for example, that walking on a flat surface used to feel like you were working at level 10 on the Borg RPE scale, but now you have to walk up a hill to feel like you are working at level 10. You will record your RPE for the aerobic component on your exercise card.

Abdominals

For the abdominal exercises, progression options may include holding the static position for a longer period of time or advancing to a more difficult abdominal exercise option.

Exercise at your own pace

It is important that you know your body's signals, and listen to them, particularly during the first few weeks of your exercise program. Remember that slight fatigue and sore muscles are all common body cues that you will experience at the beginning of your program. However, this will soon change as you begin to have more energy, feel more refreshed in the morning, and have less muscle soreness. If you experience more than muscle soreness and slight fatigue from your increased activity level, you may have done too much too fast. You should not experience pain that lingers for several days and interferes with your activities of daily living. Gradually progressing to your goals by challenging yourself to increase your weight or duration of aerobic activity, will allow you to achieve more benefit in the long run, and will achieve your goals faster than you would if you push too hard and injure yourself, prohibiting you from continuing your work-outs.

Individualization and options
You may individualize your program a variety of ways. You may select from the different core strength training exercise options, during flare-ups, modify the way you grip the exercise bar, change the equipment or props you use for an exercise (i.e. the height of the chair for the chair stand exercise), change the amount of resistance you use or try assistive devices such as those listed previously.

The Four Components

Warm-up
Warming up is important to increase your body temperature and to increase blood flow to your muscles, making them more pliable and therefore less susceptible to injury. To do this, begin with 5-10 minutes of walking. We suggest that you walk in the aerobic room (if unoccupied); or follow the Study walking course around UMC; or you may use the treadmill. If you cannot complete the walking aerobic component, you may try a non-weight bearing or partial weight bearing activity such as a stationary bicycle (with or without arm handles) or elliptical trainer. If you are having difficulty in your lower limbs, you may also choose an alternate aerobic exercise for that day, such as the upper body ergometer. During your warm-up, you should walk briskly enough to increase your heart rate but still be able to perform the “talk test” (i.e. when you can converse comfortably during the activity without getting short of breath).

Strength Training
Although we refer to the Strength-training and Remicade Study as a “strength training” program, you may hear other words used interchangeably to describe this type of activity. Strength training is also called resistance exercise. Resistance is an opposing force, like weight or gravity, used to strengthen your muscles. Therefore, you may also hear “strength training” referred to as resistance training or weight training.

In the strength training component you will complete 2 sets of 6-8 reps for eight different exercises. Three options are available as necessary for each exercise, beginning with the easiest exercise(s) (option #1) and progressing to the most difficult (option #3).

Why we use both free weights (i.e. dumbbell) and machines (i.e. Nautilus)
Free weights are versatile and require plenty of concentration to perform an exercise, as you must focus not just on the core muscles you are contracting, but also must stabilize the weight in order to complete the maneuver in proper form. The one arm incline dumbbell press for example, focuses on the pectorals, however, also aids in increasing your hand, wrist and forearm strength. Using dumbbells also allows you to work each

arm separately. This is not always possible with other types of equipment. Working your arms separately allows for a maximum work out as the dominant side of your body does not compensate for the weaker side, since your muscles are not equally strong throughout a particular motion. Free weights are limited to a weight you can move only at your weakest point. Because of this, it is important to include free weights in your routine in order to maximize the strength of your muscles.

Weight machines do not require as much balance or coordination, but allow you to isolate a muscle group, challenging your muscles throughout the entire motion of an exercise. Weight machines also do not require you to load or unload weight plates off a bar (as in some free weight exercises) and assist you in using proper form because of the guidance provided by the machine.

Number of repetitions

Performing a greater number of reps (i.e. 12) achieves a more moderate increase in strength and size than doing fewer reps (i.e. 4). It also gives you something that a low-rep routine does not – muscular endurance. Performing few reps with more weight can also carry a greater risk of injury. Our study recommends 6-8 reps to balance gains in strength and size with endurance and safety for arthritic joints.

Isometric vs. isotonic strength exercises

Isometric exercises involve contraction of your muscles, but muscle fibers maintain a constant length. These exercises are typically performed against an immovable surface- for example, pressing your palm against a wall. Isometric training can help develop the strength of a particular muscle and is often used in rehabilitation. Isotonic exercise, on the other hand, requires the body part to move with the muscle shortening and lengthening. This Study encourages isotonic exercises over isometric resistance exercises for several reasons. Isotonic exercise, or dynamic exercise, uses weights or resistance. It is more efficient than isometric exercises in building strength and has the added benefit of introducing movement to the joint, which is an important factor in restoring range of motion and flexibility.

Why we chose the exercises we did

RA seems to predominately affect the smaller joints such as the wrists and finger joints (metacarpalphalangeal, proximalinterphalangeal), and ankles (subtalar) and toe joints (metatarpalphalangeals). The frequency of involvement of these joints in established RA is 80-90%, and more often than not, the small joints on both sides of the body are affected. The knee is the most frequently involved large joint in RA (80%). The exercises were selected to indirectly work the muscles most affected by the disease, and directly work to strengthen the muscles supporting the most affected joints. For example, although we do not include wrist curls, you will indirectly work on strengthening and stabilizing your wrist and forearm muscles and increasing your grip strength through lifting the dumbbells and performing such exercises as the hammer curl and incline dumbbell press. Additionally, to strengthen the knee joint, we will work the muscles that surround and support this joint. Calf raises strengthen your lower leg and the leg press strengthens your upper leg- all to help support your knee joint. The shoulder, elbow and hip are the next most likely joints to be affected, but the incidence is not nearly as high. Thus, we have chosen to work those joints more directly in some of the exercises. It is essential to strengthen the muscles surrounding the joints that are affected and to focus on increasing ROM and flexibility while doing so. All of the exercises have also been chosen based on maximizing the strength of the muscles most involved in activities of daily living to ensure improve in function and mobility in these essential areas.

Dividing your strength work out
It is advantageous to work your large muscle groups before your small muscle groups. This way, your small muscle groups will not be fatigued and can help perform the large muscle group exercises to ensure they are challenged. For example, you should do the one arm dumbbell row first, which primarily works your back muscles, but also requires assistance from your biceps. If you were to work these smaller muscles first (i.e. hammer curl), they would be too tired to help out the back.

Dividing your exercise so that you alternate between upper and lower body exercises also helps minimize fatigue. The body can be divided into three zones: upper, middle and lower. The examples below identify the core strength training exercises that work each area.

Upper body	Back (one arm dumbbell row) Shoulder and chest (one arm incline dumbbell press) Arm (hammer curl) Wrists (all upper body exercises)
Middle	Abdominal exercises (abs)
Lower body	Buttocks (leg press) Thighs (seated leg curl and leg press) Calves (calf raise) Hips (hip adduction)

Abdominal exercises
Abdominal exercises are included in the strength-training component. For the abdominal exercises, just as for the rest of the strength exercises, you will complete 2 sets of 6-8 reps for each exercise. The progression of many of the abdominal exercises begins by holding the position for 3-5 seconds, but you should progressively increase the difficulty by holding for up to 10 seconds. Abdominal muscles are crucial in supporting the spine and maintaining proper posture. Strong abs also help to prevent back pain and injury. You will select and complete two exercises from either Option #1, 2, or 3.

Aerobics

Weight training can make your muscles larger and stronger and more “firm”, while aerobic exercise complements your strength routine by reducing your body fat to better see the results. Aerobic exercise (increasing your need for oxygen by working your muscles) strengthens your cardiovascular system (heart, lungs and blood vessels) and reduces your risk of heart disease. Regular aerobic exercise decreases fatigue and improves your stamina or endurance, as your aerobic capacity increases (lungs become more efficient). Aerobic exercise also lowers your blood pressure and the level of “bad” (LDL) cholesterol while increasing your “good” (HDL) cholesterol. Although all types of aerobic exercise are beneficial, we emphasize weight bearing aerobic exercise for its additional benefits to people with RA.

Weight bearing means that you carry the weight of your body as you engage in the activity, as in walking. Weight bearing exercises are required to maintain the integrity of the bone and cartilage in the joint. We emphasize walking, a low-impact activity, as the main type of aerobic activity in this program.

Weight bearing exercises (walking in particular or equivalent to a brisk walk) will be the primary aerobic exercise performed in the study. A total of 30 minutes of aerobic activity per day is the end goal. Accumulating this goal in short bouts throughout the day is acceptable and may be necessary at the beginning of the program in order to achieve 30 minutes of aerobic activity during the day. For example, you may complete 15 minutes of walking at two separate times during the day (for a goal of a total of 30 minutes) and still reap the benefits of a single 30 minute work-out. You are encouraged, however, to complete your aerobic exercise at the gym during your scheduled work-out times, after your strength training work-out. Depending on your entry fitness level, this may not be possible for you until after you have participated in the program for several weeks. If you are experiencing a flare-up, however, you may need to try a non weight-bearing or partial weight-bearing exercise such as the elliptical trainer, returning to walking after the flare-up is over.

The monthly introduction to aerobic activities and monthly social events will provide additional ideas on how to increase your aerobic endurance. At these events you can also learn new skills, spend time with your Study friends, meet new people, have fun, and explore a variety of activities you may not have thought to try previously.

In order to properly record your level of intensity, it is important that you always record your level of perceived exertion (using the RPE scale in appendix K) and pedometer steps on your exercise card. You should complete your main aerobic portion in the moderate to vigorous activity range (equivalent to at least a brisk walk.)

Cool down

The cool down is the part of your work-out in which exercise tapers off so that respiration, body temperature and heart rate gradually return to normal. Just as you would not consider jumping into strenuous exercise without some type of preliminary warm-up, you should never conclude a workout without a proper cool-down. Abruptly stopping your activity can increase the risk of injury to skeletal muscles and can cause dizziness or lightheadedness and an irregular heart beat.

A good cool down will relax you emotionally and ease tension throughout your body. It also increases the flexibility of your muscles and the ROM of your joints.

Make sure you complete the two-part cool-down:

(1) post-cardiovascular cool-down: gradually decreasing intensity from high to low (walking casually for 3-5 minutes) and, 2) static stretching.

Stretching

Staying limber can help ease stiffness, improve performance and optimize functional movement in daily life. Good flexibility can develop and maintain range of motion, decrease tension in muscles, improve posture, provide relief from muscle cramps and soreness and may help prevent and treat injury due to inflexibility. Flexibility training also relieves contractures, which are muscles that remain partially contracted, even when they are not in use. With contractures, the muscle shortens, making it less supple, less strong, and unable to absorb the shock and stress of movements. Contractures also cut off circulation to a muscle, inhibiting its supply of oxygen and essential nutrients and allowing waste products to build up in muscle cells.

The Eight Strength Training Exercises

Understanding the instructions

Each exercise description will begin by listing the targeted muscles, the reason we chose the exercise and the equipment needed for each of the three options (indicated with numbers in parentheses). The specific instructions are then listed detailing how to complete the exercise including: how to set up, execution of the exercise and focus for each of the options. Option #3, includes the “goal exercises”, and we encourage you to strive to achieve option #3. You and your trainer will decide which exercise option is most appropriate during flare-up. You must perform one of the strength exercise options for the eight different areas, each session.

Strength Training Exercises

<u># 1 - Leg press</u>

Target muscles: upper legs (front of thighs), buttocks

Specific muscles worked: Quadricep muscles (vastus medialis, vastus lateralis, and rectus femoris), gluteus maximus

Reason we chose this exercise: Basic leg strength is essential for walking, climbing and rising from a chair. The targeted muscles help extend the knee, flex the thigh (quads) and extend and laterally rotate the thigh (glutes). Strong leg muscles preserve your hip, knee and ankle joints and help avoid injury.

Equipment: (1) chair, (2) step platform, (3) leg press machine

Instructions:

<u>Option 1:</u> Chair stand

Setting up: Place a chair in an out of the way location, assuring it is level on the carpet (or other non-slippery surface). Sit down on the chair about half way back in the seat. Your buttocks should be resting on the chair but your back should not be against the backrest. Your knees should be at slightly less than a 90 degree angle, with your legs hip width apart and your toes pointed forward. Place your arms at your side (not on the armrests).

Execution: With your back straight and sternum up, gently rise from the chair. Concentrate on using only your leg muscles and not momentum. Your knees should not cross over the end of your toes when you stand up. To sit down, bend at the hip, slowly lowering your buttocks back to ward the chair seat, maintaining proper upper body posture. This is one repetition.

If necessary, you may hold your arms straight out in front of you until you can rise from the chair with your arms at your side.
Additionally, you may place a pillow on the chair for additional height.

Focus: Be sure not to move to the side or lean too far forward when rising from the chair. Your back should remain straight (not slumped) throughout the motion.

<u>Option 2:</u> Step up

Setting up: Place the step platform in an out of the way location, assuring it is level on the carpet (or other non-slippery surface).

Execution: Standing in front of the platform, with your arms at your side, step up onto the platform leading with your right foot, following with your left. Step back down to the ground with your right foot, following with your left. Repeat by switching the lead leg. This is one repetition. You may advance by adding another step to the first one, increasing the height of the platform.

Focus: Be sure to step in the middle of the platform. Do not push off of the platform when returning your foot to the ground as this may cause the platform to shift.

Option 3: Seated leg press

Setting up: Notice there are two separate weight stacks (upper and lower). Make sure you place the pin (or pins) in the appropriate slots on both weight stacks. Place your feet parallel to each other in the middle of the foot plate, slightly more than hip width apart, with your toes pointed upward. You may need to adjust the seat in order to ensure your knees are at a 90 degree angle. Place a ball (located in the trunk by cardiac rehab) or both of your fists, side by side, between the knees to stabilize. Variation in your foot placement alters the muscles worked (higher foot placement increases gluteal involvement). Thus, make sure your feet are appropriately placed to work both your quadriceps and glutes.

Execution: Slowly press against the footplate, straightening your legs, pressing on the platform through you heels. Stop short of a full leg extension so that you do not lock your knees. Then, lower the weight slowly until your knee angle reaches 90 degrees. Make sure your knee angle does not drop to less than 90 degrees and that your heels stay on the plate through the full range of motion. This is one repetition.

Focus: Do not arch your back and ensure that the small of your back stays pressed against the back pad and that the buttocks remain in the seat. Also make your head is back against the headrest. Your knees should not rotate inward (use the ball or your fists) to stabilize. When lifting very heavy weights, you may opt to use the shoulder stabilizer, gently resting the pads on the top of your shoulders to help avoid movement in the seat.

 # 2 - Incline dumbbell press

Target muscles: shoulder

Specific Muscles worked: deltoid, pectoralis major, tricep brachii, trapezius, serratus anterior

Reason we chose this exercise: These muscles are necessary for lifting items overhead and for carrying items at your side. Strong shoulders help make most arm movements easier.

Equipment: (1) Theraband, (2) medicine ball or physioball, (3) dumbbell and seat bench with back support

Instructions:

Option 1: Theraband Chest Press

Setting up: Stand or sit with Theraband around the upper back and tucked under the arms. Hold hands shoulder height with elbows bent while grasping both ends of the band.

Execution: Slowly push arms away from the body; keeping the hands level. Hold for a second before slowly bending the elbows and returning to the starting point. This is one repetition.

Focus: Maintain resistance in the band throughout the exercise.

Option 2: Seated incline two arm ball press

Setting up: Tilt the back of the bench to a 50° angle. Straddle the bench. Grasp a light weight medicine ball or physioball. Hold the physioball to your chest with hands on either side of the ball.

Execution: Hold the ball against your body at chest level. Slowly push the ball away from your body, extending your arms over head. Retract the ball toward your chest. This is one repetition.

Focus: Do not arch your back or lean to the side.

Option 3: Seated incline one arm dumbbell press

Setting up: Tilt the back of the bench to a ~55 degree angle. Straddle the bench. Grasp a dumbbell with your right hand with an overhand grip and lift it above your shoulder, palm facing forward (away from body). Lean against the backrest, with your head against the headrest. Plant feet firmly on floor on either side of the bench. Start with your hands at ear level.

Execution: Press the weight over your head until your arm is almost fully extended but without locking your elbow. Be sure to press the weight straight up (it will seem as though you are pressing forward because of the incline). Keep your arm in front of your body. Slowly lower the weight to starting position. This is one repetition. Complete an entire set and then switch to the opposite arm and complete a set.

Focus: Do not arch your back or lean to the side.

<u># 3 - Hip adduction</u>

Target muscles: upper legs (inner thighs)

Specific muscles worked: adductor muscles (adductor longus, brevis and adductor magnus, pectineus, gracilis), gluteus maximus, gluteus medius

Reason we chose this exercise: Strong adductors are important in moving from side to side. The target muscles flex and rotate the thigh and pull the leg away from the body.

Equipment: (1)therabands, (2) hip adduction machine (3) pulleymachine

Instructions:

<u>Option 1:</u> Adduction with therabands

Setting up: Tie a Theraband to the tower or other stable weight machine, placing it a few inches above the ground. Tie the free end around your (right) ankle. If possible, hold onto the frame of the machine for support. Pull the right leg toward your body until the Theraband is taut. Stand up straight, with both legs hip width apart.

Execution: Pull the right leg in toward the left (opposite) leg, slightly touching the left leg. Your knee should remain extended (knees straight) but not locked throughout the motion. Slowly release the tension in the Theraband by moving it back toward the machine. This is one repetition. Complete set and switch legs by turning around 180 degrees.

Focus: Try to achieve a straight line of movement and do not lean forward, backwards, or sideways to compensate for the movement. Do not arch your back and keep your arms at your side if you are not using them for support. Use slow, controlled movements.

<u>Option 1:</u> Lying down

Setting up: Lie on the floor on your back with your knees bent. Raise your legs so that they are perpendicular to the floor, with the bottom of your feet facing the ceiling. Your legs should be straight but not locked.

Execution: Open your legs simultaneously to form a “V”. Open your legs as wide as is comfortable without arching your back or letting your legs drift toward your head. Squeeze your legs together to close the “V”. This is one repetition.

Focus: Keep your legs in a straight plane of movement.

<u>Option 2:</u> Hip adduction machine

Setting up: Notice there are two separate weight stacks (upper and lower). Make sure you place the pin (or pins) in the appropriate slots on both weight stacks. Adjust the backrest to its most upright position. Sit down on the seat with the leg pads on either side of you. Release the leg pads by pressing down on the handlebars on either side of the seat. Then, place your legs on the outside of the pads, straddling the machine. Point your toes up in the air. You may place your hands on the handlebars or let them hang at your sides.

Execution: Slowly move your legs together until the leg pads touch. Release tension and allow your legs to move back to the starting position. This is one repetition. To exit the machine, push down on the handlebars and bring your legs back to the center the machine.

Focus: Concentrate on slow, controlled movements. Keep your back against the back rest.

<u>Option 3:</u> Adduction with cable pulleys

Setting up: Place pin in weight stack at appropriate weight. Fasten the ankle cuff connected to the pulley to the ankle closest to the machine (left leg). Make sure the cuff is snug, but comfortable. If possible, hold onto the frame of the pulley machine for support. Pull the left leg toward your body until the cable is taut. Stand up straight, with both legs hip width apart. Your body should be aligned with the middle of the weight stack.

Execution: Pull the right leg in toward the left (opposite) leg, slightly touching the left leg. Your knee should remain extended (knees straight) but not locked throughout the motion. Slowly lower the weight until the weight plates gently touch. This is one repetition. Complete set and switch legs by turning around 180 degrees.

Focus: Try to achieve a straight line of movement and do not lean forward, backwards, or sideways to compensate for the movement. Do not arch your back and keep your arms at your side if you are not using them for support. Use slow, controlled movements.

#4 - Hip abduction

Target muscles: upper legs (outer thigh)

Specific muscles worked: abductor muscles: gluteus medius, gluteus maximus, tensor fasciae latae; sartorius, rectus femoris

Reason we chose this exercise: Strong abductor muscles are important for moving side to side and pull the leg back toward the body.

Equipment: (1) therabands, (2) hip abduction machine (3) pulley machine

Instructions:

Option 1: Abduction with therabands

Theraband:
Setting up: Tie a Theraband to the tower or other stable weight machine, placing it a few inches above the ground. Tie the free end around your (right) ankle. If possible, hold onto the frame of the machine for support.
Pull your right leg away from your body until the cable is taut. Stand up straight, with the left leg directly underneath you.

Execution: Pull the right leg away from the opposite (left) leg, raising the leg laterally as high as possible. Your knee should always remain extended (knees straight) but not locked throughout the motion. Slowly release the tension in the Theraband by moving it back toward the machine. This is one repetition. Complete set and switch legs by turning around 180 degrees.

Focus: Try to achieve a straight line of movement and do not lean forward, backwards, or sideways to compensate for the movement. Do not arch your back and keep your arms at your side if you are not using them for support. Use slow, controlled movements.

Option 1: Lying down:

Setting up: Lie on the floor mat on your left side. Extend your arm straight above your head with your head resting on your upper arm. Rest your right arm on top of your thigh.

Execution: Slowly raise your right leg into the air as high as you can comfortably go. Your knee should always remain extended (knees straight) but not locked throughout the motion. Lower your leg back down to the starting position. This is one repetition. Complete set and switch legs by turning around 180 degrees.

Focus: Try to achieve a straight line of movement and do not lean forward or backwards to compensate for the movement. Do not arch your back. Use slow, controlled movements.

Option 2: Hip abduction machine

Setting up: Notice there are two separate weight stacks (upper and lower). Make sure you place the pin (or pins) in the appropriate slots on both weight stacks. Adjust the backrest to its most upright position. Sit down on the seat with the leg pads on either side of you. Move the leg pads so that they are snug against your outer thighs. To do this, pull on the pin located on the side of each of the leg pads (you can see it from your sitting position). Once you have appropriately placed the pad, release the pin and ensure it is locked in position. Point your toes up in the air. You may place your hands at your sides.

Execution: Slowly move your legs away from your torso, widening your legs as far as possible and comfortable. Then, bring your legs back to the starting position. This is one repetition.

Focus: Concentrate on slow, controlled movement. Keep your back against the backrest.

Option 3: Abduction with cable pulleys

Setting up: Fasten the ankle cuff (connected to the pulley) to the ankle furthest away from the machine (left leg). Make sure the cuff is snug, but comfortable. If possible, hold onto the frame of the pulley machine for support with the opposite hand (right) from the side of the body that you are working. Pull your left leg away from your body until the cable is taut. Stand up straight, with the right leg directly underneath you. Your body should be aligned with the middle of the weight stack.

Execution: Pull the left leg away from the opposite (right) leg, raising the leg laterally as high as possible. Your knee should always remain extended (knees straight) but not locked throughout the motion. Slowly lower the weight until the weight plates lightly touch. This is one repetition. Complete set and switch legs by turning around 180 degrees.

Focus: Try to achieve a straight line of movement and do not lean forward, backwards, or sideways, to compensate for the movement. Do not arch your back. Keep your arms at your side if you are not using them for support. Use slow and controlled movements.

 # 5 - Row

Target muscles: back

Specific Muscles worked: Latissimus dorsi, teres major, trapezius, rhomboid major, deltoideus, biceps brachii, brachiordiasis, brachilais

Why we selected this exercise:
Strong back muscles assist in pulling actions and general torso stability for strong posture. Target muscles extend and rotate upper arm and movement of the head and neck, clavicle and scapula.

Equipment: (1) Theraband and chair, (2) seated row machine, (3) dumbbells

Instructions:

Option 1: Theraband seated row

Setting up: Sit on edge of chair with legs slightly bent and toes lifted. Loop the middle of the band around bottom of feet and grasp both ends with a firm grip, arms straight.

Execution: Slowly draw the elbows back, close to the sides of the body while squeezing the shoulder blades. Hold for a second before straightening the arms back to the starting point.

Focus: Concentrate on keeping the elbows tucked into your sides and relaxing the shoulders during the pull phase of the lift.

Option 2: Seated row machine

Setting up: Place the pin in the appropriate slot on the weight stack. Attach a V grip bar to the cable. Sit in front of the machine with your feet parallel to each other in the middle of the foot plate, slightly more than hip width apart, with your toes pointed upward. Grab the handle and straighten your legs (without locking your knees), pulling the cable taut. Your back should be straight and your elbows at your side. Keep your chin up with eyes forward.

Execution: While keeping your shoulders down, pull the weight toward your body into your lower rib cage. You should pull with your back muscles, (feeling your shoulder blades moving together) rather than focusing on your arms. The movement will be complete when your elbows just go beyond your torso.

Focus: Keep your arms/elbows at your side. Concentrate on using your back muscles. Do not lean backwards to complete the movement.

Option 3: One arm dumbbell row

Setting up: Stand beside and to the left, of the weight bench. With the dumbbell in your left hand and your palm toward your body. Bend forward from your hips so that your back is naturally arched. Tilt your chin in toward your chest so that your head and neck are in line with the rest of your spine. Your knees should be slightly bent. Place your opposite (right) hand on top of the bench for support and let your left arm (holding the dumbbell) gently hang down at your side. You may also place your right knee on the bench if this feels more comfortable, or place one foot in front of the other to help you stabilize. You may need to start by performing this exercise parallel to a mirror in order to ensure the proper positioning of your back. An alternative for those with wrist trouble is to use the adjustable bench (with backrest at a 60° angle), placing your forearm on the backrest to avoid pressure on your wrist.

Execution: Pull your left arm up, leading with your elbow, with forearm perpendicular to the floor. Lift until your hand brushes against your waist. Lower the weight to the starting position. This is one repetition. Complete the set and switch arms. You will switch to the other side of the bench to complete the exercise with the opposite arm.

Focus: Use your back muscles, do not focus on your arms. Do not allow your back to sag toward the floor or hunch up. Keep your abs pulled in and tight throughout the motion.

 # 6 -Calf raise

Target muscles: lower leg (calf)

Specific muscles worked: gastrocnemius, soleus

Reason we chose this exercise: Strengthening the calf improves your walking ability. The targeted muscles are involved in plantar flexion of the foot (standing on tip toes) and flexion of the knee. Calf raises using the foam board also serves as a great balance exercise.

Equipment: (1) wall or walking sticks for support if standing, or chair if sitting, (2) and (3) dumbbells or ankle weights; foam board

Instructions:

Option 1: Calf raise without weight

Setting up: Sitting: Place a chair in an out of the way location, assuring it is level on the carpet (or other non-slippery surface). Sit down on the chair about half way back in the seat. Your buttocks should be resting on the chair but your back should not be against the backrest. Your knees should be at a 90 degree angle, with your legs hip width apart and your toes pointed forward. Place your arms at your side (not on the armrests).

Standing: Stand near a wall in case you need to reach for support. Stand straight with your feet parallel, hip width apart with toes pointed forward. Arms should be at your side.

Execution: Slowly raise both heels and stand on your tip toes. Hold for a moment and then return to starting position. This is one repetition.
You may advance to performing this exercise with one leg at a time (see instructions for Option #3, without the weight).

Focus: Make sure your foot flexes completely on every repetition. Your knees should remain straight, but not locked (for standing option). Do not lean to the side.

See picture for option 3 and perform with both feet.

Option 2: Two-legged calf raise with dumbbells

Complete the following instructions for option 3, but with both feet on the foam board.

Option 3: One legged calf raise with dumbbell

Setting up: Stand on the middle of the foam board with feet parallel and hip width apart. Raise one leg (left leg) and hold at a 90 degree angle behind your body.

Execution: With either an ankle weight (on left leg) or a dumbbell in hand on the side being worked (left), slowly raise your heel and stand on your tip toes. Hold the position for a moment. If you feel unbalanced, you may use walking sticks or the wall to help maintain your balance. Return to starting position. This is one repetition. Complete set and switch legs.

Focus: Make sure your foot flexes completely on every repetition and that your knees remain straight, but not locked. Do not lean to the side.

 # 7 - Hammer curl

Target muscles: upper arms

Specific muscles worked: biceps (biceps brachii, brachialis, brachioradialis)

Reason we chose this exercise: Strong biceps are important for carrying items in front of your body and help support the elbow. The target muscles flex the elbow and the arm and rotate the forearm.

Equipment: (1) theraband, (2) wrist cuff weights (3) dumbbells

Instructions:

Option 1: Theraband bicep curls

Setting up: Sit on middle to edge of chair with legs 90 degrees and feet flat on the floor. Loop the middle of the band under feet and grasp both ends with a firm grip.

Execution: Keeping the elbows tucked into the sides of the body and the forearms parallel to the floor, curl the band straight up. Hold for a second at the top and slowly lower the hands to the starting position. This is one repetition.

Focus: Emphasis is on the isolation of the elbows into the sides of the body.

Option 2: Hammer curl with wrist cuff weights
Completed following instructions for option 3, but with wrist cuff weights.

Option 3: Hammer curl with dumbbells

Setting up: Stand tall, with knees relaxed. Grasp a dumbbell in each hand with your palms facing inward (toward the body).

Execution: Curl the dumbbell in your right hand up toward your chest, lifting the dumbbell in a straight line with your shoulder. Keep your palms faced inward throughout the entire motion. Slowly return to starting position by lowering the weight to your side. Complete the repetition now with your left arm. This is one repetition. Complete the set by alternately curling the dumbbell in each arm.

Focus: Do not swing your elbows out wide, keep them close to your body. Do not arch your back or rock your upper body to assist your arms in lifting the weight. Keep you shoulders and neck relaxed.

 # 8 - Leg curl

Target muscles: upper legs (back of thigh)

Specific muscles worked: Hamstring muscles (biceps femoris, semimembranous, semitendinous and sartorius)

Reason we chose this exercise: Hamstring muscles are important for bending the knee and walking. The target muscles flex the knee, rotate the thigh and flex and extend the hip.

Equipment: (1) Chair (2) theraband, (3) seated leg curl machine

Instructions:

Option 1: Seated heal drag

Setting up: Sit to the back of the chair. One leg starts out straight while the other remains bent at 90 degrees.

Execution: Slowly drag the heel along the floor towards the chair. When the leg reaches full compression, lift the leg and squeeze the calf or back of the ankle against the edge of the chair. Release and return the leg out straight. Perform all repetitions one leg at a time before switching.

Focus: Press the heel downward while dragging it towards the chair. Lift the knee as high as possible while squeezing.

Option 2: Leg curl with cable pulley (shown) or theraband

Setting up: Theraband: Tie a Theraband to the tower or other stable weight machine, placing it a few inches above the ground. Tie the free end around your (right) ankle. If possible, hold onto the frame of the machine for support. Stand facing the machine, far enough back from the machine so the Theraband is taut. Pulley: Place the pin in weight stack at appropriate weight. Fasten the ankle cuff to your right leg. Hold onto the machine for support. Pull your right leg toward your body until the cable is taut.

Execution: Standing straight, with one arm at your side and one on the machine for support, gently pull your right leg back and raise it up toward your buttocks. Slowly return to starting position. This is one repetition.
Repeat on left leg.

Focus: Do not lean forward or to the side, but rather concentrate on a slow controlled movement with your lower body.

Option 3: Machine seated leg curl

Setting up: Notice there are two separate weight stacks (upper and lower). Make sure you place the pin (or pins) in the appropriate slots on both weight stacks. Sit on the machine with your legs straight and with your ankles resting on the lower roller pad. You may need to use the handle to move the roller pad downward in order to situate your legs. Your back and buttocks should be resting against the back chair pad (you may need to adjust the back of the chair for proper positioning of your ankles on the roller pad.) Grasp the handles provided on each side of your body.

Execution: Starting with your knees at a 0 degree angle (as indicated on the black strip on the machine) bend your knees to move the roller pad downward until you reach 90 degrees (do not go past 90°). Return to starting position. This is one repetition.

Focus: Do not slide forward and keep your back against the pad. Keep your toes pointed upward.

Abdominal exercises

For the abdominal exercises, just as for the rest of the strength exercises, you will complete 2 sets of 6-8 reps for each exercise. The progression of many of the abdominal exercises begins by holding the position for 3-5 seconds, but you should progressively increase the difficulty by holding for up to 10 seconds. From the list below, you will select and complete 2 exercises from either option (1), (2), or (3).

Target muscles: stomach (abdominal muscles)

Specific muscles worked: obliquus externus abdominus, rectus abdominus, tensor fasciae latae, rectus femoris

Reason we chose these exercises: Abdominal muscles are crucial in supporting the spine and maintaining proper posture. Strong abs also help prevent back pain and injury. We avoid the traditional sit ups, because as with any sit up type of movement, your abs are involved only in the first part of the motion and are often done incorrectly. Instead we use pelvic tilts and also utilize leg movements (hip flexion) to work the abs which helps minimize neck and back involvement.

Equipment: (1) theraband (2) floor mat, (3) floor mat, physioball

Instructions:
<u>All options</u>

Setting up: Most of these exercises are performed on a floor mat. If you have difficulty getting up and down from the floor, you should use a chair (or your buddy) to assist you. The raised mat in the Cardiac Rehab Room may also be available for use. If this is not possible, there are 2 abdominal exercises you can choose which are not performed on the floor.

Focus: Focus on using your abs, without using other parts of your body for momentum. The movements should be slow and controlled, without bouncing or wiggling around to complete the movement.

Option 3: *Ball crunch*

Setting up: Center your buttocks on the edge of the physioball, with your feet flat on the floor, hip width apart. Place your hands behind your head so that your thumbs are behind your ears. Do not lace your fingers together. Hold your elbows out to the sides or cross hands across the chest. Slowly lean back on to the ball so that your entire back, from your tailbone to your shoulders, rests on the ball. Your head and arms will be suspended above the ball. Ensure your knees are at a 90°.

Execution: Curl up and forward so that your shoulder blades lift up off the ball. Move slowly and carefully to help maintain your balance and reduce any movement other than the crunch. Hold for a moment at the top of the movement, and then lower slowly back down. This is one repetition.

Focus: Keep your abs pulled in so that you feel more tension in your abs and so you do not overarch your lower back. Keep your feet firmly planted on the floor for support and balance and do not allow your buttocks to drop toward the floor. Do not pull your neck with your hands or draw your elbows in. The physioball may be difficult to balance on at first. You may need to ask a buddy to assist in this exercise.

Option 3: *Lower ab hold*

Setting up: Lie on the mat with your arms at your side or place your hands behind your head so that your thumbs are behind your ears, but do not lace your fingers together. Rest your elbows on the mat. Raise your legs up in the air, maintaining a slight bend in your knees. By contracting your abs, flatten your lower back so it touches the mat.

Execution: Keeping your lower back in contact with the mat, attempt to lower your legs. Once your lower back rises off the floor, stop, and return to the starting position. This is one repetition.

Focus: Focus on bringing your legs as low to the ground as possible. Do not twist your body, and keep your head straight, eyes on the ceiling. Make sure you use your abs to stop the lowering of your legs.

Option 3: Bench Knee Ups

Setting up: Sit lengthwise on a flat bench, with your buttocks at the end of the bench seat. Lean slightly backwards, supporting yourself with your hands on either side of the bench.

Execution: While leaning backwards, raise and extend your legs (allowing for a slight bend in your knees), keeping them at bench height. Keeping your legs in the air at all times, bring your upper body and knees together by slightly leaning forward and bringing your knees to your chest. Pretend you are closing a gap between your torso and upper legs. Then, extend your legs, opening up the gap between your torso and legs. This is one repetition.

Focus: Be sure to complete this movement in a straight line of movement, not leaning to the sides. Use your abs to propel your leg and torso positions.

Option 2: Reverse crunch

Setting up: Lie on the mat on your back with your legs up in the air, knees slightly bent. Rest your arms on the floor beside you.

Execution: Lift your buttocks one or two inches off the floor so that your legs lift up and a few inches backward. The movement feels like the beginning of a backwards somersault. Hold the position for one second, then lower your buttocks slowly. This is one repetition.

Focus: Do not use your hands or the rocking momentum to lift up your body- only your abs!

Option 2: Bicycles

Setting up: Lie on your back on a mat. Raise your legs in the air so they are perpendicular to the floor. Rest your arms at your side and look up at the ceiling.

Execution: With your legs in the air, pretend you are riding a bicycle, moving your feet in a forward pedal motion. Count to 6 while pedaling. This is one repetition. After you count to 36 you have completed 6 repetitions.

Focus: Use your abdominal muscles to keep your legs straight in the air. Make clearly defined circles with your feet.

Option 2: Ab twists

Setting up: Lie on your back on a mat. Bend your knees at a 60 degree angle, placing your feet flat on the floor, hip width apart. Rest your arms at your side.

Execution: Move both knees to the right side of your body (allow them to drop to the side) so that your knees touch the mat. Bring your knees back to the center of your body. Then, move your knees to the left side of your body, and then bring your knees back to the center. This is one repetition. To advance, lift your feet off of the floor and bend your knees at a 90 degree angle. Keeping your knees bent, move them to each side of your body.

Focus: Feel the stretch in your oblique muscles as you perform this exercise. Use your abdominal muscles to slowly lower your legs and to bring them back to the center of your body. Keep your head straight and look up at the ceiling.

Option 1: Theraband abs

Setting up: Wrap the theraband around the tower, and hold the free end. Holding on to one end of the theraband, move several feet away from the tower, maintaining a straight line. Hold both ends of the band over the shoulders and tuck the elbows into the sides of the body.

Execution: Using your ab muscles, lean forward, maintaining the resistance with your ab muscles. Exhale (blow out hard) as you lean forward. Be sure to lean forward at your hips, keeping your back straight and arms extended (but elbows not locked).

Focus: Do not use your arms to pull against the theraband- use your ab muscles for the forward movement. Be sure to blow out as you lean forward.

Option 1: Marching in place

Setting Up: Stand with your back to the wall and your feet slightly away from the wall, hip width apart.

Execution: Contract your abs and raise your right knee to a 90 degree angle. Hold for 3-5 seconds. Return leg to starting position. Repeat exercise with your left knee. This is one repetition.

Focus: Keep your abs tightened the entire time, during the raising, holding, and lowering of your leg.

Option 1: Wall pelvic tilt

Setting Up: Stand with your back to the wall and your feet slightly away from the wall, hip width apart. Place both arms out to your side, placing your palms on the wall.

Execution: Contract your abdominal muscles while pressing the small of your lower back into the wall. Hold for 3-5 seconds. Release the pressure, returning your back to its natural position. Return to starting position and switch position of arms. This is one repetition.

Focus: Remember to breathe.

Aerobic Exercise

Walking is a good form of aerobic exercise for several reasons: 1) it is free; 2) it can be done almost anywhere; 3) it is a social activity, which helps in maintaining exercise compliance; 4) it allows you to focus on proper gait mechanics which become even more essential as you age; 5) as previously mentioned, weight bearing exercise builds bone, essential to rheumatoid arthritis patients, many of whom have low bone mineral density; 6) it is a low impact activity; and 7) you can easily assess your progress by measuring the number of steps you take with your pedometer!

Proper gait mechanics?

Due to the aging and disease process (causing depletion of muscle mass), people have a reduced proprioceptive acuity or a diminished joint position sense. This can cause incorrect foot placement or heel strike while walking, which causes jarring of the leg/knee at the heel strike, perpetuating damage to the joints. Strength training can help to build muscles and reduce muscle fatigue, aiding in proper gait mechanics and improving proprioceptive activity.

How fast should I walk?

Your main aerobic work-out should be in the moderate to vigorous activity range (equivalent to at least a brisk walk).

Walking technique

Posture:
Good walking technique begins with a tall posture – with your head up, eyes straight ahead, shoulders back and relaxed, and chest open. Keep your abdominal muscles contracted so that your back does not pitch forward. Tight abs will also prevent a swayback.

Stride:
The key to walking faster is taking more steps rather than longer steps. A long stride will not only waste energy but will also require less dynamic muscle use. Let your foot land practically beneath you.

Push Off:
The toe push-off can add power to a walking stride but is often difficult to feel. To achieve a dynamic push-off, the toes should be lifted when the heel is planted. From this position, the body's weight can roll through the entire foot – from heel to mid-foot to ball, ending with a powerful push-off.

Arms:
Your arms should move forward and back without crossing the body. For all walking speeds, bend the arms at a 90-degree angle with elbows close to your body to accomplish a powerful swing which helps move the legs and condition the back muscles. Do not clench your fists so tightly that they hurt.

Hips:
Relax the lower back so that your hips roll forward with each step to generate more muscle work. This also allows each step to cover more ground without unwanted bouncing. If you are not completely comfortable with the hip roll, take it slowly. Chances are you will become more comfortable as you progress.

Eyes:
Focus on a spot about 10 feet in front of you. You do not want to look at the ground, because doing so would tip your body forward. Avoid hills and rooted, rocky trails until you have perfected your technique.

Thighs:
Keep your thigh muscles relaxed as you step forward. The result: Your knee will straighten, allowing you to land on your heel.

Knees:
Start your stride with a knee that is straight, but not locked, so that you can land on your heel.

Stretching Exercises

The stretching exercises included in this program are designed to work each major body part. However, as you become familiar with your body, you may notice that you require additional stretching to limber a specific body part. Pay special attention to these tight areas, realizing your own history of injuries or existing imbalances in your muscle groups. Additionally, consider your daily activities (i.e. playing golf, gardening). Specific stretching exercises can improve stability (ability to maintain ideal body alignment during activity) and mobility (the ability to use full joint ROM).

Stretching should not be done before your workout, when muscles are cold and are susceptible to injury. Instead, complete stretching at the end of your workout. The stretching exercises in our program are called static stretches, where you slowly stretch your muscles to the end point of movement and hold the stretch in position for the designated period of time before slowly returning joint and muscle groups to resting length. Avoid ballistic stretching which uses bouncing or jerking movements.

<u>All options:</u>
Instructions:
Complete all four stretches (one spare option given) each exercise session.

Target muscles:
All major muscles worked during the exercise session.

Reason we chose these exercises:
Stretching exercises are often done incorrectly and can cause more harm than good. The exercises below demonstrate proper technique without placing undue stress on the joints.

Equipment:

a wall, floor mat (raised mat for Thomas stretch), and physioball

Focus:

Muscles should be slowly stretched only as far as they can comfortably go- feeling a slight pull on your muscle, but not pain. Be sure not to hold your breath.

<u>Wall calf stretch – lower body stretch</u>

Target muscles: lower leg (calf)

Specific muscles worked: gastrocnemius, soleus

Setting up:
Face the wall, standing approximately one foot away. Cross your arms in front of you, with palms flat and fingers extended. Raise your arms to your forehead, and lean forward to the wall with your head resting on your forearms. Extend your right leg another one foot straight behind you. Both heels should be flat on the ground. Your knees should be relaxed.

Execution:
Slowly move your hips forward (left knee will bend) until you feel a stretch in the calf of your straight (right) leg. Hold for 10-30 seconds.
Return to starting position and switch legs.

Focus:
Be sure to keep your heels on the ground and your toes pointed straight ahead.

<u>Thomas Stretch - lower body stretch</u>

Target muscles: upper leg (thigh)

Specific muscles worked: quadriceps muscles, hamstring muscles, hip abductors, hip adductors

Setting up:
Sit on the raised mat and move backward until your calves are up against the metal frame for the mat. Lie back.

Execution:
Pull one (left) knee toward your chest and hold with both hands placed behind your upper thigh (hamstring). Feel the direction your opposite (right) leg moves. If it moves outward, use your abductor muscles to bring it in toward your body. If your leg moves inward, use your adductor muscles to bring it out, away from your body, until it falls in line with your hip. Hold the right leg in the proper alignment for 5-10 seconds. Return to starting position and repeat with your opposite leg. You will probably need to ask a buddy for assistance to help hold your opposite leg in alignment. Additionally, your buddy can press down gently on the opposite (right) thigh to further stretch your muscles.

Focus:
Concentrate on keeping your leg in alignment.

Wall - upper body stretch

Target muscles: arms, shoulders, back

Specific muscles worked: deltoids, pecs

Setting up:
Stand with your back to the wall, with your heels approximately 6 inches away from the wall so that you can press you back against the wall. Raise one (left) arm out to your side with your hand above your head and elbow at a 90° angle. Lower the right, opposite arm, out to your side with your hand at approximately waist height and elbow at a 90° angle. Try to keep your upper arms parallel with the ground.

Execution:
Press gently against the wall with your arms, lower back and entire upper body. Hold for 10-30 seconds. Return to starting position and switch position of arms.
Note: You may need to complete this exercise with your elbows at a greater angle (arms straighter).

Focus:
Remember to breathe. Be careful not to press your hands/fingers too hard into the wall. Keep your head against the wall.

Physioball stretch – alternative upper body stretch
Target muscles: upper body

Specific muscles worked: abs, pecs, deltoids

Setting up:
Center your buttocks on the edge of the physioball, with your feet flat on the floor and hip width apart. Slowly lean backwards so that your entire back, from your tailbone to your shoulders, is supported by the ball. Your knees should be at a 90 degree angle.

Execution:
While lying back, place your arms straight above your head. Hold for 10-30 seconds. Return to starting position.

Focus:
The physioball may be difficult to balance on at first. Ask a buddy to assist in this exercise and make sure you perform this exercise on a mat. Keep your knees at a 90 degree angle so that your buttocks do not drop toward the floor.

Doorway stretch- alternative upper body stretch exercise

Target muscles: upper body

Specific muscles worked: pecs, deltoids

Setting up:
Stand facing an open doorway. Place your feet approximately one foot from the door, hip width apart. Raise both arms above your head and out to each side. Your elbows should be level with your shoulders, and at a 90 degree angle. Have your palms facing forward.

Execution:
Allow your upper body to lean into the doorway until you feel a comfortable stretch in your arms and chest. Hold for 10-30 seconds. Return to starting position.

Focus:
Keep your head up and knees slightly bent.

Sit and Reach

Setting up: Sit on a mat with your legs extended directly in front of you. Sit up straight.

Execution: Slowly lean forward at your hips, stretching both arms out in front of you over your legs. Reach for your toes with both hands. Hold the position for 30 seconds and then return to starting position.

Focus: Keep your legs extended but do not lock your knees. Lean forward only as far as is comfortable.

Range of Motion Exercises

"Range of motion" means the normal distance your joints can be moved in certain directions. ROM exercises can help in decreasing pain and stiffness and allow you to complete your activities of daily living more efficiently. Range of motion exercises should be completed 3 times a week on your own time. They can be done at home. You should complete two sets of each exercise (the reps will vary). We chose these specific exercises to improve the joint and muscle flexibility in the key joints and muscles worked in our program.

Ankle circles

Target joints: knees, ankles

Equipment: chair

Instructions:

Setting up: Sit up straight in a comfortable, stable chair, with your back against the backrest. Raise your (left) foot approximately 6 inches above the ground. Your arms can rest on your thighs or at your side. Keep your opposite leg firmly planted on the ground.

Execution: While holding your foot in the air, curl your toes down to the ground. Hold for three seconds and then lift your toes up toward the ceiling. Hold this position for three seconds. Return to starting position and complete exercise with opposite (right) foot. This is one repetition. Complete two reps.

Focus: Maintain proper posture in the chair and do not wiggle around in the chair.

Finger curl

Target joints: fingers

Equipment: none

Instructions:

Setting up: While sitting or standing, open your hand and extend your fingers.

Execution: Bend each finger joint slowly to make a loose fist. Hold this position for three seconds and then straighten fingers again. This is one repetition. Complete two reps.

Focus: Feel each of your finger joints as they bend. Do not make too tight of a fist.

<u>*Head tilts*</u>
Target joints: shoulders, neck

Equipment: none

Instructions:

Setting up: Look straight ahead and relax your shoulders.

Execution: Tilt your head sideways toward your right shoulder, hold for three seconds, and then move your head back to the center. Tilt your head toward your left shoulder, hold for three seconds, and then move your head back to the center. This is one repetition. Complete one repetition.

Focus: Do not raise your shoulder toward your ear.

<u>*Shoulder touch and reach*</u>

Target joints:
Shoulders, elbows, wrists

Equipment: none

Instructions:
There are two steps to this exercise.

<u>Step 1:</u>
Setting up:
Stand up straight with your arms at your side, palms facing forward.

Execution: Keeping your arms straight (but without your elbows locked), raise your arms in front of your body to shoulder level. Bend your elbows and then lift your elbows up, raising your arms overhead, as if you are trying to reach your upper back.
Return to starting position. This is one repetition. Complete one repetition.

Focus: Try to keep your elbows pointed straight ahead rather that out to the side. Do not arch your back.

<u>Step 2:</u>
Setting up: Stand up straight with your arms at your side, hands on your waist.

Execution: Raise your arms out to your side so that they are parallel to the floor. Keep your arms straight but do not lock your elbows. Your palms should face the ceiling.

Touch your shoulders by bending your elbows (keep your elbows pointed outward, in line with your torso). Lastly, reach above your head with straight arms. Return to starting position. This is one repetition. Complete one repetition.

Focus: When reaching above your head, stand as tall as you can and really reach into the air. Do not arch your back.

Leg bend and lift

Target joints: knee

Equipment: chair

Instructions:

Setting up:
Sit up straight in a comfortable, stable chair, with your back against the backrest. The leg you are not working should be firmly planted on the ground.

Execution: Bend one knee (left), moving your foot under the chair. Hold for three seconds. Slowly straighten your knee, raising your leg in front of your body. Hold for three seconds. Return to starting position. This is one repetition. Complete two reps.

Note: If you experience any pain while placing your foot under the chair, do not continue. Modify the exercise by starting with your knee at a 90 degree and then straightening your knee.

Focus: Maintain proper positioning in the chair and do not wiggle around in the chair. Do not over extend your knee.

Hip Rotator

Target joints: hips

Equipment: floor mats

Instructions:

Setting up:
Lie on your side, balance yourself by placing one hand in front of your body with the other either outstretched above your head or supporting your head. Your top leg (away from the mat) should be bent at the knee at about 60 degrees. Your lower leg should be extended with only a slight bend in your knee.

Execution:
Slowly roll your top leg (knee) toward the ceiling, stopping when it is perpendicular to the floor. Slowly lower your top knee toward the floor. This is one repetition. Complete 2 repetitions and then switch to the opposite leg by rolling over onto your other side.

Focus:
Perform slow, controlled movements so that you remain balanced on your side.

Exercise logs

You will complete your exercise log every exercise session with a No. 2 pencil. Please be sure to completely fill in the circles and to legibly record any comments. Your diligence in completing these logs is essential for the success of this research program. Please refer to the exercise card example below which explains how to accurately record your exercise session. For easy reference, the Borg scale is posted on the bulletin board as you enter the gym and is also located in Appendix K. Blank exercise cards and pencils can be found in the exercise log box at the gym. Completed exercise logs will be picked up every two weeks.

Exercise logs will be filed by ID number in the exercise log box.
Other things you might find in exercise log box are: flyers on upcoming events, notices from study staff, comment cards and study evaluations to complete.

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Glossary

Abductor- a muscle that moves an extremity away from the axis of the body

Abs- Referring to abdominal (stomach) muscles

Adductor- a muscle that moves an extremity toward the axis of the body

Atrophy- reduction in muscle size

BMD Bone Mineral Density - An indication of the amount of calcium and other minerals deposited in the bones. This measure is used to assess bone strength and fracture risk.

Cardiovascular- concerning the heart and blood vessels (arteries, veins and capillaries)

Cartilage- translucent smooth tissue covering the articular (joint) surfaces of mobile bones

Comorbidity- the occurrence of another condition or disease in the presence of an existing condition

Concentric Muscle Contraction – Development of force as the muscle shortens.
Example: Raising the weight toward the body as in a bicep curl

Eccentric Muscle Contraction – Application of force that overcomes the muscle tension resulting in lengthening of the muscle
Example: Lowering weight away from the body during a bicep curl

Extension- Movement increases the angle between the joints

Femur- Bone of the thigh, which is the longest and strongest of all the bones of the human skeleton. The femur includes the head, neck, greater trochanter, lesser trochanter, condyles, and diaphysis

Flexion- Movement decreases the angle between the joints

Functional capacity - Functional capacity is the degree of ability to perform the normal activities required in day-to-day life.

Glutes- Referring to buttock muscles, short for gluteal (i.e. gluteus maximus)

Hypertrophy – Increase in the size of muscle fiber

Intensity – The relative effort expended during an exercise; also, the amount of resistance or weight used

Lats- Referring to a muscle of the back, latissimus dorsi. It extends from the center of the back to under the arm

Lean Body Mass – Fat-free body mass or muscle mass

Ligament - A band of very resistant fibrous connective tissue linking the osseous components of an articulation or serving to attach an organ

Load – The weight or resistance used

Moderate intensity exercise - Exercise that raises the heart rate to 60-80% of an individual's maximum
heart rate (220 - age = Maximum heart rate in beats/minute)

Muscle Definition – Property where size and shape of a muscle is clearly visible. This is best developed by decreasing surface fat and increasing muscle size

Muscle power- power is the product of force and velocity and represents the amount of work a muscle can produce per unit of time. Power is strongly related to many functional activities that require strength with speed such as lifting boxes or rising from a chair, or golfing

Overload – To subject the body to more than normal stress

Overtraining – A condition caused by training too frequently or too intensely and not providing enough time to recover adequately. Symptoms include lack of energy, decreased physical performance, fatigue, depression, aching muscles and joints, and proneness to injury

Proprioceptive acuity - Proprioception is the sense of where your body and its limbs are in relation to one another and the environment around you. Proprioceptive acuity is the degree of accuracy of that sense - someone who frequently stumbles over
objects they see on the floor or knocks things over when they reach for them on a cluttered desk might have a low degree of proprioceptive acuity.

Quads- referring to quadricep muscles, short for quadricep

Repetition Maximum (RM) – The maximum amount of weight you can lift in one repetition of an exercise

Reps – Referring to reps or the number of times an exercise is done during one set. One rep is a single rendition of an exercise

Resistance – A measure of force that must be exerted by the muscles to perform an exercise

Rest – The period of time between exercises, sets of exercises, or workouts

Set – A group of consecutive reps

Spot – The act of assisting with an exercise. The spotter's main job is to help the lifter with the weight if the exercise movement can't be completed

Strength – The ability to exert force

Tendon- A fibrous unit by which the muscles attach to the skeleton

Tower- the machine that hosts the cable or pulley machine. Several different exercises can be performed using different handles and adjusting the heights of the pulley.

Traps- Referring to trapezius muscle of the back. This muscle covers the back and portions of the neck, reaching to the base of the skull.

Volume – The number of sets and reps in a workout.

Appendix A — aerobic exercises you should try

Yoga

Yoga involves a variety of static postures which include backward and forward bends as well as twisted positions. These movements increase flexibility, range of motion, and muscle strength. Iyengar yoga (a type of hatha yoga) works well for people with physical limitations because it allows for the use of props like blocks, belts, and other supports to help achieve poses more easily and with less risk of injury.

Tai Chi

Tai Chi is an ancient Chinese martial art that has found renewed popularity in the West among all age groups, and can be especially beneficial to those with arthritis. The gentle movements promote flexibility (ROM) and balance, builds muscle strength, and aids in stress release. It also serves as a low intensity aerobic exercise which can help in building stamina.

A study conducted in 1991 evaluated Tai Chi's safety in rheumatoid arthritis patients. It concluded that 10 weeks of tai chi classes did not make joint problems worse, and found that the weight-bearing aspects of this exercise has the potential to stimulate bone growth and strengthen connective tissue.

There are five distinct styles of tai chi and many variations within each style. Most gentle and, therefore, suitable for people with arthritis, are the Sun, Wu and Hao styles. The Sun style is particularly recommended for those with arthritis because it is less combative and does not include deep knee bends. The Chen style should be avoided because it includes jumping in the air and stomping heavily on the ground. The "right" version for you may be a variation on a style or one that combines several styles.

Go to www.taichiforarthrits.com to find instructors who are certified to teach Tai Chi for people with Arthritis.

Golf

Golf is a very adaptable sport that can be tailored to meet the physical capabilities of almost anyone. If you have arthritis, playing golf can keep your body flexible, help maintain hand grip strength, aid in coordination and balance and provide low intensity aerobic exercise as you walk around the golf course. Grips, shoes, balls and clubs can all be adjusted to fit your specific needs and abilities. Here are a few tips that can help you keep up to date on the latest products, and instructions on how to make golfing easier on arthritic joints.

Products

Use a lower compression ball so there's more give to the ball when you hit it hard
Use clubs with lightweight graphite shafts to help absorb shock better
Use a perimeter-weighted head on the club, also for better shock absorption
Build up the grip size on your clubs with epoxy tape to help you hold them easier and to reduce stress and pain on your finger joints
Try wearing wrist braces and gloves on both hands to stabilize your joints
Wear comfortable walking shoes or spikeless golf shoes

Instructions

Always loosen up before you play. Begin by walking for a few minutes.
Use tees whenever you hit the ball-even on the practice range-to avoid striking the ground and jarring your joints
Keep your tension on the shaft consistent to add consistency to your swing and heighten your overall comfort
If you have back pain, you may find that the "classic" swing is more comfortable for you than the modern or reverse-C swing
Always brush through the grass so you will hit the ball solidly and carry your momentum out to the target
Play from the 150-yard markers if you begin to get tired
Consider using energy-saving techniques while you are on the course. Pull your golf bag instead of carrying it or rent a motorized cart instead of walking
Remember it's OK to play less than a full 18 hole round. Look for a nearby 9-hole course.
Listen to your body throughout the round. If you begin to tire, practice your chipping or putting, or play fewer holes. (The Arthritis Foundation, 1997)

For a list of companies that make modified golf equipment and assistive devices, visit http://golfcenterdisabilities.usga.org and click on "equipment".

Walking/Hiking

Hiking is a great way to see city sites, enjoy the wilderness, or just spend time with a friend. Although there are endless trails in and around Tucson, remember that you can also make your own trails! Take a walk at the Reid Park Zoo, a local monument, the University campus, a local mall, botanical garden, city park or winery!

Hiking opportunities are rich in the Tucson area. Contact the below organizations for regularly scheduled events.

Southern Arizona Hiking Club
751-4513
http://www.sahcinfo.org/
(Offers 50+ events a month for all ages and abilities)

Senior Trekkers Club
296-7795
(Offers social hikes for those over 50)

To search for trails of interest to you, check out the National and State Parks and National Forest Service found right here in Arizona.

National Park Service- Arizona
http://data2.itc.nps.gov/parksearch/state/state.cfm?statevar=az

National Forest Service
http://www.fs.fed.us/
Look for trails and maps.

Arizona State Park system
http://www.pr.state.az.us/partnerships/trails/statetrails.html

Do not forget to check out their publication, "A step in the right direction, the health benefits of hiking".

Feldenkrais
The Feldenkrais method involves "Awareness Through Movement," where a practitioner verbally guides a group through a sequence of small, non-stressful movements meant to increase body awareness and reduce pain, and improve flexibility and range of motion. These sessions usually begin with participants lying on floor mats, but exercises are also done standing and sitting as students discover more comfortable ways to move.

For more information:

Phone: 800/775-2118
E-mail: feldngld@peak.org
Web site: www.feldenkrais.com.

Mall Walking
Interest in mall walking has grown in the last few years and now local malls offer incentives to regular walkers. Try walking at a mall near you.

Tucson Mall:

When: 6:30 a.m. daily
Where: Tucson Mall, 4500 N. Oracle Road

Cost: One-time sign-up fee
of $1.

The sign-up fee covers the cost of a newsletter, a punch card and a button identifying the wearer as a mall-walker. Sign up before 9 a.m. Mondays, Wednesdays or Fridays in the food court. When the punch card is completed (after about 200 miles), walkers get a T-shirt.

The Tucson Mall is the only mall with a formal mall-walking program, but service entry doors at the Foothills Mall open by 8 a.m. for mall-walkers. Doors open at Park Place at 6 a.m. Mondays through Saturdays and 8 a.m. on Sundays. El Con Mall opens its doors at 7:30 a.m. daily.

Tucson Orienteering Club
Sharpen your navigational and map-reading skills with different levels of on- and off-trail orienteering. Meets are held the third Sunday of each month.

Cost: $10 a year for individuals, $15 a year for households. Members pay $5 per meet.

Contact club officers through the Web site:
www.tucsonorienteering.org

Tucson Parks and Recreation offers many physical activities for the community at reasonable prices. Call or check out their website to learn more about city golf courses, pools, classes, and special events.

791-4245 ; www.ci.tucson.az.us/parksandrec

Dance instruction/clubs

There are several dance clubs in the Tucson area offering individual and group lessons for country, ballroom, salsa dancing, and much more. Check out your local yellow pages.

The American Volkssporting Association
The American Volkssporting Association (AVA) based in Universal City, Texas, may be walking's best kept secret. The national non-profit association maps out walking trails in cities, towns, parks, forests and rural areas - anywhere there is a pleasant or interesting place to walk - for non-competitive walkers throughout the United States. Selected for beauty and ease, most trails are about six to eight miles long. To find out about walking clubs and events by state, call the AVA at 800/830-WALK (9255) or go to www.ava.org. The Tucson Volkssporting club can be reached at tucsonwalker@mindspring.com

Appendix B — pedometers

Why use a pedometer?

The latest research indicates that 10,000 steps a day is equivalent to the goal of 60 minutes of daily physical activity - the level recommended by the Surgeon General.

By providing you with instant feedback, your pedometer may help you become more physically active and achieve your goals.

Getting started:

This tiny device is attached to your waist and counts the number of steps that you take during the day. To begin, press the reset button and ensure screen reads “000”. When you get dressed in the morning, attach the pedometer to your waist, over your hip bone (on your belt or the waistband of your slacks or skirt) and do not take it off until bedtime (unless, of course, you take a shower somewhere in between). Every step you take throughout your day counts! It is important to attach it so the unit is parallel to the ground and as level as possible. Ensure the device snaps completely closed.

It is advisable to wear your pedometer for a couple of “test days” to determine your beginning level of steps. You may find that your initial daily accumulation of steps totals close to 3,500 or 5,000 steps. A reasonable way to increase your activity level would be to gradually add 500 - 1,000 steps to your daily total.

Ways to increase the number of steps per day:

* Take the stairs instead of the elevator
* Park farther away from entrances
* Walk during commercial breaks
* Deliver messages/items to neighbors or co-workers in person instead of using email, the phone or car
* Walk the perimeter of the field while your children or grandchildren play soccer
* Walk the dog
* Vacuum your house more often
* Walk/talk with a cordless phone

Take the 10,000 step challenge!

Health and fitness researchers are finding that people can achieve health benefits by exercising at a less intense level than previously thought. In other words, someone who is sedentary most of the day but who jogs over the lunch hour may expend as much cumulative energy as someone who is active the entire day. Two recent studies published in the Journal of the American Medical Association have confirmed that this lifestyle approach can be as effective as a traditional exercise program. Many doctors and researchers have found that wearing a pedometer is a great way to track your daily activity — and inspire you to move more on days you have been sedentary.

Appendix C — Therabands explained

Progressive Resistance using the TheraBand

TheraBand use can improve the cooperation of muscle groups and works on increasing strength and range of motion. The TheraBand's unique properties allow it to be stretched and relaxed in a smooth and consistent manner. This prevents the bounce at the end of a range of motion exercise that can cause muscle spasms. These 6" wide latex bands come in different, color-coded resistance levels, distinguished by the thickness of the band.

TheraBand Color	TheraBand Thickness	Comparison: Pounds of pull needed to stretch a 12" band length to 24"
Yellow	Thin	2.5 lb
Red	Medium	4.5 lb
Green	Heavy	5.0 lb
Blue	Extra heavy	7.5 lb
Black	Special heavy	9.0 lb
Silver	Super heavy	15.0 lb

The progressive resistance system makes it easy to measure progress in achieving fitness goals. Start with a TheraBand of comfortable resistance. As you use the band, your muscle strength and endurance improves, with the exercises becoming easier to do. When you are ready for more of a challenge, simply move to a more resistant band (i.e. shift from yellow to red or green to blue). This increases the intensity of the exercise.

TheraBand exercise guidelines

When exercising, keep in mind the following:

Do	Don't
Warm up the muscle groups before exercising.	
Maintain good posture.	
Keep your wrists straight and in line with your elbows.	Don't bend your wrists.
If you start to lose your posture, stop and reposition yourself.	
Breathe normally.	
Exhale during the most difficult phase and inhale during the easiest.	Don't hold your breath.

Do (continued)

Use controlled movements.

Maintain the natural width of the band to keep it from digging into your hands or sliding up your legs.

Don't (continued)

Don't continue exercising if anything hurts while you are training.

Tip: Make a handle by tying a loop in the band or tying two bands together.

TheraBand care

Caring for a TheraBand is simple. Just store it out of direct sunlight. Do not use it together with body oil. Regularly examine it for nicks, tears, or punctures that might cause the band to snap.

Appendix D — Walking's selling points

Okay, so what's walking really going to do for me? Skeptical that strapping on a pair of walking shoes will make any difference? There is only one thing a walking program will try to sell you: a better life.

Walking won't pay your bills, meet your deadlines, repair broken relationships or get rid of your clutter. But it will help your body get to a place where you can function more fully, cope more readily and deal with the stresses your health presents more efficiently. Consider these facts:

Regular walking can decrease:

• Anxiety
• Blood pressure
• Blood triglycerides
• Body fat
• Constipation
• Depression
• Glucose
• Weight
• Mobility limitations
• Pain
• Risk of some cancers
• Risk of heart attack, hypertension and stroke
• Risk of diabetes
• Stress
• Falls & Fractures
• Bone loss

Regular walking helps improve:

• Ability to regulate body temperature
• Aerobic capacity
• Balance
• Blood sugar
• Metabolic rate
• Muscle mass and tone
• Overall general health
• Quality of life and sleep
• Reaction time
• HDL (good) cholesterol
• Heart health
• Strength
• Joint mobility
• Life span
• Mental capacity
• Mood
• Bone density
• Cartilage and joint health
• Circulation
• Energy level and endurance
• Flexibility/range of motion
• Feeling of accomplishment
• Self-esteem

Thinking away doubts

"Why walk?" You ask. You're worth it, darn it. That may seem obvious to many people. But as anyone with a chronic health condition knows, a setback in the way you feel physically can make you fell less vital as a human being, which saps your sense of can-do. If pain or stiffness won't let you forget your arthritis as you go about your daily activities, you may nix the thought of exercise too quickly. People are prone to avoid activities that require extra effort or physical self-discipline, say the experts, particularly if the challenge stems from their health. So if you've got even the tiniest inclination to start a walking program, you need to bolster your confidence and turn your back on your doubts.

Whenever you get that sense of "I can't", or "I just don't want to," Stephen Wegener, PhD, Vice Chairman and Chief of Rehabilitation Psychology at Johns Hopkins University in Baltimore, says to try this simple guided imagery exercise. Sit down and take a deep breath. Visualize yourself walking out the door and down the street, think about how much you'll enjoy it and how much you'll be benefiting your body. Feel how proud you will be of yourself. Then, get up and go do it.

You deserve to make this investment in yourself, for yourself. Believe it or not, the first step to starting a successful walking program may take place in your mind.

Appendix E — Community events

Physical activity events and classes. UMC class information. (See hand-outs)

Combine your exercise with another hobby such as bird-watching. Contact the Tucson Audubon Society for a list of activities. Examples of regularly scheduled outings include walks at the Arizona-Sonora Desert Museum, Catalina State Park, Sabino Canyon, Saguaro National Park, Southern Arizona Bird observatory, Patagonia-Sonoita Creek Preserve, and Ramsey Canyon Preserve.

Tucson Audubon Society
622-5622
www.tucsonaudubon.org

Fitness Plus Magazine, available for free at local restaurants and grocery stores, is published monthly. Check out their "Fitness Event Calendar" located in the back of the magazine. Listings include hiking, bicycling, and miscellaneous special events.

Tucson Parks and Recreation

Tucson Parks and Recreation offers many physical activities for the community at reasonable prices. Call or check out their website to learn more about city golf courses, pools, classes, and special events.

791-4245

www.ci.tucson.az.us/parksandrec

There are many other events available throughout the community. The City of Tucson Parks and Recreation Department has several centers available:

Randolph Recreation Complex
200 South Alvernon Way
791-4560

William M. Clements Center
8155 East Poinciana Drive
791-5787

Morris K. Udall Center
7200 East Tanque Verde
791-4931

Old Pueblo Regional Recreation Campus
101 West Irvington
791-5155

El Rio Center
1390 West Speedway Boulevard
791-4683

Fred Archer Center
1665 South La Cholla Boulevard
791-4353

Northwest Center
2160 North 6th Avenue
791-3247

Pascua Center
785 West Saguaro
791-4609

Quincie Douglas Center
1575 East 36th Street
791-2507

Marty Birdman Center
2536 North Castro Avenue
791-5950

Cherry Avenue Center
5085 South Cherry Avenue
791-4497

Ormsby Center
899 West 24th Street
791-4011

Oury Center
600 West St Mary's Road
791-4788

Santa Rosa Recreation Center
1080 South 10th Avenue

Armory Center
220 South 5th Avenue
791-4865

Therapeutic Recreation
1000 South Randolph Way
791-4504

Appendix F — Scientific articles on strength training (omitted)

Appendix G — Proper footwear

Experts repeatedly say one piece of equipment is essential for walking success: a good pair of shoes. Wearing the right shoe determines how you will feel after your workout; and how you will feel after your workout determines whether or not you will want to do it again.

Buying a shoe labeled for walking is a good start, but among "walking shoes," which stand out? Consumers Union (publishers of Consumer Reports) and other groups do annual evaluations of walking shoes. (Visit www.consumerreports.com) Because every shoe and every foot are different, those ratings should be just a loose guide. Shopping in a specialty store in which sales people are trained to fit shoes is your best bet. Walk around for a while and make sure they feel comfortable. Take your time.

Evaluate your prospective shoes for the following features

Sole: Shoe bottoms need to grip the walking surface for good traction. Avoid sticky, non-skid soles and heavy rubber lugs, the part that curls over the top of the toe area; these tend to cause trips and falls. Likewise, avoid slick, smooth-soled shoes, because they make slips and falls more likely.

Flexion: The shoe should be flexible, giving easily at the forefoot when bent, remaining fairly rigid through the midsole.

Beveled heel: A beveled, or angled, heel will permit a smooth rolling motion when you walk. A heel with no bevel will cause your shoes to "slap" down rapidly, possibly leading to shin splints, tenderness and pain, calluses and swelling of leg muscles.

Breathability: The upper portion of the shoe will keep your feet drier if moisture can escape.

Cushioning: A well-cushioned heel absorbs the impact as you walk.

Support: Rear-foot support and stability along with good arch support will help limit inward roll ("pronation").

Proper Fit: Shoes should be comfortable and have a snug fit so your heels do not slip, and provide your toes room to spread out; with a thumb's width between the end of your big toe and the shoe.

Closures: Shoes with laces let you adjust tightness well, but Velcro closures or elastic shoelaces make for easy in and out.

Extra Support: If you like the way a shoe fits, except for the insole (or the shoe's original insole has worn out), try switching to the replacement insoles sold at most shoe stores. Good replacement insoles have a pre-formed heel cup and arch support that help improve fit and stability.

Even after you have bought good shoes and have "bonded" with them over many miles, don't forget to give them a once-over every now and then, because shoes wear out faster than most people expect. A walker who takes 30-minute walks three times a week might need replacements after about 9 to 12 months.

Appendix H — Study calendar (omitted)

Appendix I — Goal setting

Establishing short-term goals is essential to ensure that you get the most out of your exercise program. Keep this "Contract for Success" in a visible location (i.e. refrigerator door) so that you consistently take steps toward completing your goals. Accomplishment of short-term goals leads to successful completion of long-term goals which will help you maintain a healthy lifestyle. Be sure to cross off your goals as you attain them to remind yourself of what you have already achieved. You can complete a second goal setting sheet after you achieve your first goals.

Contract for success

I, ____________________________________ , do hereby commit myself to diligently work toward the following goals:

My short-term goals: To accomplish by (date):

1.____

2.____

3.____

My long-term goals: To accomplish by (date):

1.____

2.____

3.____

In order to achieve my goals I may have to change certain aspects of my lifestyle. I hereby commit to make my health a priority and will strive to successfully complete my goals and improve my quality of life.

____

Signature Date

Appendix J — UMC forms (omitted)

Appendix K — Borg RPE scale (omitted)

Appendix L — Am I hydrated? (omitted)

APPENDIX B- HUMAN SUBJECT'S APPROVAL

THE UNIVERSITY OF
ARIZONA®
TUCSON ARIZONA

Human Subjects Protection Program
http://www.irb.arizona.edu

1350 N. Vine Avenue
P.O. Box 245137
Tucson, AZ 85724–5137
(520) 626-6721

4 May 2004

David Yocum, M.D.
Department of Medicine
Arizona Arthritis Center
PO BOX 245031

RE: **HSC #03-112** STRENGTH TRAINING AND REMICADE STUDY

Dear Dr. Yocum:

We received your 14 April 2004 letter and accompanying revised Consent Form dated for the above referenced project. The protocol has been modified to change definition of "stable dosage of Remicade" to "as determined by duration & number of changes in dosage/frequency of infusions" vs. "greater than 4 months", to extend upper BMI limit to 40 from 35 kg/m^2, to include patients with Lupus/RA overlap syndromes, and to increase the upper limit of aerobic exercise to 150 from 90 minutes/week [a revised Consent Form has been provided for review]. Approval for these changes is granted effective 4 May 2004.

The Institutional Review Board (IRB) of the University of Arizona has a current ***Federalwide Assurance*** of compliance, ***FWA00004218***, which is on file with the Department of Health and Human Services and covers this activity.

Approval is granted with the understanding that no further changes or additions will be made either to the procedures followed or to the consent form(s) used (copies of which we have on file) without the knowledge and approval of the Human Subjects Committee (IRB) and your College or Departmental Review Committee. Any research related physical or psychological harm to any subject must also be reported to each committee.

A university policy requires that all signed subject consent forms be kept in a permanent file in an area designated for that purpose by the Department Head or comparable authority. This will assure their accessibility in the event that university officials require the information and the principal investigator is unavailable for some reason.

Sincerely yours,

David G. Johnson, M.D.

David G. Johnson, M.D.
Chairman
Biomedical Committee
UA Institutional Review Board (IRB)

DGJ:jpm
cc: Departmental/College Review Committee