Affectivity, quality of life and health resources utilization in arthritis

AFFECTIVITY, QUALITY OF LIFE AND HEALTH RESOURCES UTILIZATION IN ARTHRITIS

by

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"*To my loving wife, Maria del Mar,*

and to my two beautiful daughters,

Maria del Mar and Victoria"

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ABSTRACT

The main objective of this dissertation was to analyze the role of psychosocial variables, especially positive affect, on health outcomes and health care services utilization (HCSU) in arthritis. The identification of additional psychological variables as predictive or mediating factors is critical for gaining a better understanding of the dynamics of treatment response, especially in the setting of interventions that focus on behavioral changes, and health care seeking behavior. The analyses performed were based on a theoretical model that assumed affective status as a direct effector on the use of specific coping strategies and patients' perception of control over their health, which would, in turn, influence health outcomes and health resources utilization. Using random effects modeling, we found positive affect (PA) to have a negative (β=-4.27; $p<0.001$) and negative affect (NA) a positive (β=5.33; $p<0.001$) longitudinal association with levels of perceived pain, adjusted for other covariates. The final, most parsimonious, model explained 22% of the overall variance and 28% of the between-subjects variance of the level of pain perceived by subjects with osteoarthritis. Subjects with high PA levels were more likely to achieve minimal clinically important differences in pain (OR=7.1; 95% CI, 1.4 to 36.2), global assessment of disease activity (OR=6.1; 95% CI, 1.7 to 21.8), and physical function (OR=13.27; 95% CI, 1.7 to 102.1) than subjects with low PA. Finally, in a multivariate stepwise linear regression model, higher levels of positive affect significantly predicted less HCSU (B=-0.29; p=0.04). The final model also included social support and anxiety and explained slightly over 17% of the variance of long term HCSU (R=0.51; Adjusted R-square=0.217).

CHAPTER 1

INTRODUCTION

EXPLANATION OF THE PROBLEM

Background and Significance

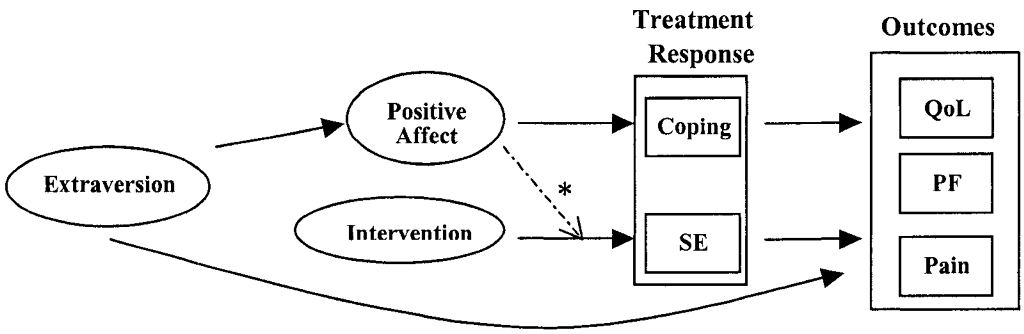
The main objective of this dissertation is to analyze the role of psychosocial variables, especially positive affect (PA), on health outcomes (such as pain, physical function and global assessment of disease activity) and health resources utilization in persons with arthritis. Some psychological dimensions, such as perception of self-efficacy, learned helplessness, and coping, have been proposed as potential determinants of outcomes in arthritis. Nevertheless, these variables have only been shown to explain a small percentage of the variance for different outcomes. The identification of additional psychological variables as predictive or mediating factors is critical for gaining a better understanding of the dynamics of treatment response, especially in the setting of interventions that focus on behavioral changes and health care seeking behavior. There is evidence that, in the context of these interventions, observed changes in outcomes are not necessarily related to behavioral changes. Some of these psychological dimensions, such as self-efficacy, have been proposed as potential mediators that can affect outcomes independently of the acquisition of healthy behaviors.

Targeting additional psychosocial dimensions in the design of self-management programs or cognitive-behavioral interventions could improve outcomes for patients with arthritis and, these relationships could allow the potential for tailoring interventions based on psychosocial characteristics. In this sense, subjects with a specific psychological profile might obtain greater benefits from self-management programs (or other psycho-behavioral interventions), while others might require alternative health interventions to achieve similar levels of improvement.

In prior studies, demand for health care resources in arthritis has been related primarily to the patient's physical condition (i.e., disease status), age, sex, and self-efficacy expectations towards coping with the disease. Little emphasis has been placed on the evaluation of the role of psychosocial profiles as predictive of the amount of contacts with health care providers. This dissertation seeks to further explore the role of psychosocial variables as determinants of health care services utilization in persons with arthritis. The construct of PA as a psychosocial predictor will be targeted. The evidence suggests that positive affective states are not simply the opposite of negative states; for this reason, the role of negative affect (NA) will also be evaluated.

The underlying theoretical model (Figure 1) for the dissertation assumes that affective status has a direct effect on the use of specific coping strategies (i.e., PA will result in higher use of adaptive strategies and lower use of maladaptive ones) and patients' perception of control over their health – self-efficacy – (i.e., higher levels of PA increasing the perception of control). Coping and self-efficacy, in turn, will differentially affect health outcomes (i.e., pain, physical function and global assessment) and health services utilization. Furthermore, in the context of a self-management intervention, affect will moderate the acquisition of better coping strategies and an increased perception of self-efficacy.

Figure 1. Theoretical model



* *Moderation effect; SE=Self-efficacy; QoL=Quality of life; PF Physical function*

Hypothesis and Specific Aims

The working hypothesis for this dissertation is: "Higher levels of PA and lower levels of NA are associated with better outcomes (i.e., less pain, less impairment in physical function and higher quality of life) and lower use of health services for the management of arthritis."

The specific aims include:

- *Specific aim 1.* To longitudinally analyze the relationships between affectivity (i.e., PA and NA) and pain perception in persons with arthritis (Manuscript 1). The null hypothesis in this study is: "Arthritis patients with higher levels of PA (and lower levels of NA) will report same levels of pain in a 12-week followup as compared with subjects reporting lower levels of PA."
- *Specific aim 2.* To determine the role of PA as a predictor of health outcomes in the context of a health intervention for arthritis (Manuscript 2). The null hypothesis in this study is: "Arthritis patients that report high levels of PA will

achieve similar levels of clinically important changes in pain, physical function and global assessment of disease activity as patients reporting lower levels of PA, after their participation in a health intervention."

- *Specific aim 3.* To determine the role of positive affect as a predictive factor for future use of health care services (Manuscript 3). The null hypothesis for this study is: "Arthritis patients with higher levels of PA (and lower levels of NA) will report similar levels of health care services utilization as compared to patients reporting lower levels of PA."

Data from three studies carried out at the University of Arizona Arthritis Center and the Department of Psychology at the Arizona State University were used for the analyses. Human subjects approval was obtained for each of the studies.

DISSERTATION FORMAT

Data from three different studies were used for the analyses presented in this dissertation: 1) Interpersonal Stress and Disease Activity in Arthritis (PI, Alex Zautra, PhD); 2) The Living Healthy with Arthritis Study (PI, David E. Yocum, MD); and 3) The Psychosocial Determinants of Health Care Services Utilization Study (PI, David E. Yocum, MD; Co-PI, Isidro Villanueva, MD).

The Interpersonal Stress and Disease Activity in Arthritis Study was a prospective cohort study funded by NIH (NIAMS; R01 AR41687) that examined the influence of interpersonal stress on arthritis symptoms, affective distress, and disease activity. Data from this study were used to address specific aim 1 and part of specific aim 3. The study was conducted at the Department of Psychology, Arizona State University and the University of Arizona Arthritis Center. I began collaboration with the study team in March 2001. My role in this project was exclusively related to data cleanup and analysis. As a result of this collaboration, we have presented several abstracts in national and international conferences in addition to the analyses presented here.

The Living Healthy with Arthritis Study was a prospective cohort study, with an interventional component. The study sought to examine the impact of a combined exercise and self-management health intervention on patients with arthritis. The study was conducted with funding from the David and Lura Lovell Family Foundation and data were used to target specific aims 2 and 3. The study was conducted at the University of Arizona Arthritis Center, with prior approval of the university's Institutional Review Board (IRB). I joined the study team in January of 1999 and my responsibilities included:

selection of measurement instruments, database management, data cleanup and quality assurance, analysis, and manuscript preparation. Results from this study were used as the foundation for two grants that recently received funds, one from the National Arthritis Foundation (the Affect and Learning in the Management of Arthritis [ALMA] study; PI, David E. Yocum, MD; Co-Investigator and Project Director, Isidro Villanueva, MD) and the other from NIH-NIAMS (the Multidimensional Intervention in Early Osteoarthritis, 1 R01 AR047595-01A1; PI, David E. Yocum, MD; Co-Investigator and Project Director, Isidro Villanueva, MD). These two grant proposals originated as class projects in the context of my course work in the Interdisciplinary Epidemiology PhD program.

The Psychosocial Determinants of Health Care Services Utilization Study (PI, David E. Yocum, MD; Co-PI, Isidro Villanueva, MD) was a follow-up study that examined the role of psychosocial characteristics to determine future health care services utilization. Subjects that participated in either the Interpersonal Stress and Disease Activity in Arthritis Study or the Living Healthy with Arthritis Study were re-contacted and information collected on their health care services utilization during the previous six months. Data from this study were used to target specific aim 3. The study was conducted at the Arizona Arthritis Center, with prior approval of the university's IRB. My responsibilities in this project were extensive, including: study planning and design, protocol development, IRB protocol development, supervision of subjects' recruitment, supervision of data collection and entry, data management, data cleanup, quality assurance, data analysis and manuscript preparation.

The Epidemiology Interdisciplinary Graduate Program at the University of Arizona established that three manuscripts could contribute to the main body of the dissertation. After completion of the three above-mentioned studies, I completed all statistical analyses, summarized results, and drafted manuscripts for journal submission. These three papers were incorporated into the dissertation. Drs. Harris and Sherrill provided assistance on analysis strategies, interpretation of the results and statistical consultation. Drs. Harris, Lebowitz , Sherrill, Coons and Malone provided editing and comments on all three papers. Manuscripts were also submitted to all co-authors for review and comments.

CHAPTER 2

BACKGROUND AND LITERATURE REVIEW

Section 2.1. - ARTHRITIS OVERVIEW

Arthritis Burden

Arthritis is a general term that is used to identify a series of chronic conditions that affect joints as a main feature, but that can also affect many other extraarticular tissues and organs. Virtually any joint of the body anatomy can be affected by arthritis. The main symptoms of arthritis are: joint pain or tenderness, swelling, stiffness, and difficulty or limitation of movement. Some signs suggestive or arthritis are: redness, warmth, tenderness, or crunching sounds or feeling in or around a joint. Arthritis can in many cases induce high levels of disability and impairment of patients' perception of quality of life. The two main arthritis diagnoses are Osteoarthritis (OA) and Rheumatoid arthritis (RA).

Osteoarthritis

Osteoarthritis (OA) is the most common rheumatic disease and most prevalent form of arthritis in the United States.[1-3] OA is described as a degenerative non-inflammatory type of arthritis that mainly affects the joint cartilage; however, in a proportion of subjects, some mild inflammation can occur. OA is characterized by softening and disintegration of articular cartilage, with reactive phenomena such as vascular congestion and osteoblastic activity in the subarticular bone, new growth of cartilage and bone (i.e., osteophytes) at the joint margins, and capsular fibrosis.[4]

Moderate-to-severe OA affects at least 15.8 million American adults between the ages of 25 and 74 years – more than 12% of the population in this age range.[1,3] Estimates of the prevalence of OA based on radiographic evidence range from 30 to 90 percent.[3] In women, for example, OA is currently the most prevalent chronic condition, and the rate of self-reported cases is projected to increase in the next decades. A population-based study showed incident rates for the United States of 2/1000 per year for knee OA.[2]

Table 1. Clinical Features of Osteoarthritis

Symptoms
Joint pain
Morning stiffness lasting less than 30 minutes
Joint instability or buckling
Loss of function
Signs
Bony enlargement at affected joints
Limitation of range of motion
Crepitus on motion
Pain with motion
Malalignment and/or joint deformity
Pattern of joint involvement
Axial: cervical and lumbar spine
Peripheral: distal interphalangeal joint, proximal interphalangeal joint, first carpometacarpal joints, knees, hips

The principal clinical features of OA reported by patients are joint pain, stiffness, decreased function, joint instability, peri-articular muscle weakness, and fatigue (Table 1).[5] Pain typically worsens with use of the affected joint and is alleviated with rest. Pain at rest or nocturnal pain is a feature of severe OA. Morning stiffness lasting less than 30 minutes is common. In contrast, morning stiffness in patients with active rheumatoid arthritis lasts longer than 45 minutes. OA usually does not affect the wrists, elbows or shoulders, which could be affected in RA. However, a less common subtype of the disease is characterized by multiple joint involvement. In advanced stages of arthritis most patients show profound structural articular changes, including the involvement of muscles and other peri-articular elements. These structural changes, accompanied by co-morbidities and age-related regression in physical conditioning, determines further impairment and disability at advanced ages.[6]

Advancing age, female gender, and obesity constitute some of the identified risk factors for OA. Symptomatic OA affects roughly 6% of the adult population, 10% of persons over 65 years of age.[7] However, there are estimations that 30-40% of individuals with radiographic disease remain asymptomatic.[4] For men and women between the ages of 45 and 54, the estimated prevalence of OA is 2.4% and 3.6%, respectively. Among those individuals between the ages of 55-64, the rate is estimated at 7.5% for women and 4.3% for men.[8]

Rheumatoid Arthritis

Rheumatoid arthritis (RA) is a chronic inflammatory arthritis characterized by symmetric, erosive synovitis. RA, which affects approximately 1% of the North American population, is the most common form of inflammatory joint disease.[9] The main feature of RA is joint inflammation that initially affects the synovial tissue and that progresses with cartilage and bone destruction. The principal clinical features of RA reported by patients are joint pain and swelling, prolonged morning stiffness or stiffness after a period of inactivity, decreased function, joint instability, peri-articular muscle weakness, and fatigue.[10]

Table 2. Clinical Features of Rheumatoid Arthritis

Symptoms
- Joint pain and swelling
- Joint instability or buckling
- Loss of function
- Malaise
- Low-grade fever
- Fatigue

Signs
- "Soft" enlargement at affected joints
- Tenderness at palpation
- Limitation of range of motion
- Pain with motion
- Malalignment and/or joint deformity

Pattern of joint involvement
- Polyarticular and symmetrical
- Typically involved joints: proximal interphalangeal, metacarpophalangeal, wrist, elbow, shoulder, knee, ankle, and metatarsophalangeal joints

The mode of onset of RA is highly variable. In the majority of cases, joint pain and/or stiffness develops insidiously over several weeks to months.[11] One or more small joints of the hands, wrists, shoulders, or knees and/or the metatarsophalangeal joints are frequently the first symptomatic areas. [12] Malaise and fatigue, occasionally with low-grade fever, may accompany musculoskeletal discomfort.[13] As the disease progresses, joint swelling, tenderness, and a red or bluish discoloration become apparent. The pattern of joint involvement is typically polyarticular and symmetrical and involves the proximal interphalangeal, metacarpophalangeal, wrist, elbow, shoulder, knee, ankle, and metatarsophalangeal joints.[12] The distal interphalangeal joints of the fingers, commonly affected in OA, are usually spared. Joint stiffness, especially if lasting more than 1 hour in the morning and after inactivity, is prominent.[13] One of the most common consequences of this process and of the use of arthritis medications is an increase in the rate of loss of bone mineral density with its corresponding higher risk for vertebral and hip fractures, which could further impair patients' functional ability or life expectancy.[14]

Although RA can occur at any age, its peak incidence is between the fourth and the sixth decade of life.[15] Estimates of prevalence for this condition are remarkably uniform across studies, even among those with a number of methodological limitations. Prevalence estimates vary between 0.5% and 1% of the adult population, and these estimates seem to be homogeneous across cultures and ethnicities.[16-22] However, population-based studies have shown highly variable estimates for the annual incidence of rheumatoid arthritis (12-1200 per 100,000 population) depending on gender, race/ethnicity, and calendar year.[17,22,23]

RA occurs in women about two to three times as frequently as in men.[22] Several risk factors have been suggested as important in the development or progression of RA. These include genetics,[24,25] infectious agents,[26] oral contraceptives,[27,28] smoking,[29,30] and formal education.[31] RA is considered a disease of the joints, with the synovial membrane of the joint as the seat of the disease process. A number of systemic manifestations can occur, however. Studies have consistently demonstrated an increased mortality in patients with RA when compared with expected rates in the general population.[32-34] The standardized mortality ratios in these studies varied from 1.28 to 2.98.

OA is perceived by many as a milder type of disease as compared to RA, but some researchers have suggested that patient's perception of their respective severity is similar. In this sense, Wolfe and Skevington have found the scores for variables such as pain, perceived global severity of the disease, functional disability, anxiety, depression, sleep disturbance, fatigue, health satisfaction, and health status to be similar for RA and OA groups of patients.[35]

Impact of Arthritis on Physical Function

Arthritis, in general, is a principal cause of disability, as compared to several other chronic health conditions and after adjustment for age, gender, and co-morbidity.[36] Functional tasks, such as ascending stairs, walking, transfer from seated to standing position, and daily activities, are reported to be severely impaired in arthritis patients.[37] There are multiple interrelated biomechanical and psychological factors that have been reported to influence the pathways that lead to physical disability in people with arthritis.[38-43] Quadriceps weakness has often been found to be the greatest single predictor of lower limb functional limitation.[44-46] Neurological deficits, impaired propioception, laxity, restricted range of motion and aerobic deconditioning have all been correlated with worse scores on physical function tests.[47-52] Psychological factors such as self-efficacy, coping, depression and anxiety have also been shown to be independent predictors of disability among individuals with knee OA.[48,50,53-55]

Economic Burden of Arthritis

Joint pain and physical impairment from arthritis are responsible for extensive use of medical and surgical resources in the US. Estimated medical care costs for individuals with arthritis were $15 billion and total costs (medical care and lost productivity) were $65 billion in 1992.[56] It has also been estimated that OA is responsible for 75-80% of the total cost of arthritis.[57] The management of the risks of major gastrointestinal complications (i.e., ulceration, hemorrhage, perforation) of nonsteroidal anti-inflammatory drugs (NSAIDs) use may add a substantial amount to the cost of treatment.[58] Arthritis is a constantly growing source of negative impacts on individuals and socioeconomic situations. There is increasing recognition that arthritis is a public health problem and that there are challenges in addressing this problem.

Management of Arthritis

So far, no single drug has been shown to be able to modify the course of osteoarthritis (OA). The development of new drugs for OA is hampered by, among other factors, the lack of surrogate markers of disease activity.[59] New information on the role of inflammation in OA has increased our awareness of the disease process and suggested potentially valuable new treatment targets; however, a great deal of clinical research remains until effective new treatments for OA are available.[60] Analgesics and NSAIDs are the most commonly used medications in OA, yet they provide only partial improvement in symptoms.[61] Furthermore, the use of analgesics and, especially, NSAIDs results in high incidence of side effects,[62] with increased risk of major gastrointestinal complications (i.e., ulcers, bleeding, perforations).[58] The point prevalence of NSAID-induced ulcers is 10% to 30%, and 15% to 35% of all peptic ulcer complications are caused by NSAIDs.[63]

For rheumatoid arthritis and other types of inflammatory arthritis, it has only been very recently that studies of new therapeutical agents have shown a potential disease modification effect.[64] However, these agents still only achieve partial control of the disease process. Pain and joint inflammation at mild to moderate activity are present for most patients with inflammatory arthritis despite multiple medication use.[65]

Thus, the goals for managing arthritis are reduction of pain, prevention or reduction of disability, and improvement of perceived quality of life.[64,66] The implementation of complementary approaches to medications seems to be imperative when trying to meet these goals, especially considering the increasing prevalence of these conditions as a result of the aging of the general population. As stated above, for many arthritis patients, pain, disability, and reduced quality of life persist in spite of treatment. There is clearly a need to develop new approaches to enhance the effectiveness of therapeutic strategies.

Section 2.2. - HEALTH INTERVENTIONS IN ARTHRITIS

The American College of Rheumatology, in its published guidelines for the treatment of arthritis, strongly recommends the use of patient education strategies (including psycho-behavioral programs) and exercise as complements to medication use (Table 3).[67] Exercise and education are recommended in many other guidelines even as a first-line therapy combined with simple analgesics.[68] Results from interventions that include exercise, education, or a combination of the two, tend to vary across individuals, regardless of disease activity or medication use. Thus, there is a clear need for the identification of factors that predict intervention outcomes, which, if modifiable, could be targeted in the design of interventions.

Table 3. ***ACR*Guidelines: Nonpharmacologic Therapy for Osteoarthritis***

Patient education
Self-management programs (e.g., Arthritis Foundation Self-Management Program)
Personalized social support through telephone contact
Weight loss (if overweight)
Aerobic exercise programs
Physical therapy
Range-of-motion exercises
Muscle-strengthening exercises
Assistive devices for ambulation
Patellar taping
Appropriate footwear
Lateral-wedged insoles (for genu varum)
Bracing
Occupational therapy
Joint protection and energy conservation
Assistive devices for activities of daily living

* *American College of Rheumatology, 2000*

Exercise Therapy

Exercise therapy is defined as a range of activities intended to improve strength, range of motion, endurance, coordination, and motor function. It can be performed actively, passively, or against resistance.[69] The evidence shows that regular physical activity is associated with better health for people of all ages, and that increasing physical activity improves health at any age.[70] People who exercise regularly or maintain higher levels of physical activity live longer and are healthier than people who are sedentary.[70] The challenge for persons with arthritis is how to find and maintain a safe and effective conditioning routine. Whichever activity/exercise program is adopted, it is important that novice exercisers be given a positive outlook regarding their ability to exercise successfully and safely. Current recommendations for the accumulation of 30 minutes of moderate physical activity on most days of the week provide a feasible and effective treatment for persons with arthritis.[71] Many of the factors that lead to disability in arthritis can be improved with exercise (i.e., muscle strength, propioception, range of motion, cardiovascular fitness and comorbidities associated with arthritis, such as diabetes, hypertension and obesity).[71-73]

With respect to OA, indirect evidence suggests that muscle dysfunction may be implicated in the pathogenesis and progression of knee OA.[74] Muscle is an extremely adaptable tissue, and the plasticity of this tissue is demonstrated by the fact that muscle function can be improved in some degree even in very old subjects.[75] Strong quadriceps can decrease impulse loading on the lower limb, which has been identified as a potential factor contributing to onset and progression of knee OA.[76] In established disease, rehabilitation programs that increase muscle strength have shown this outcome to be associated with a decrease in joint pain and disability without exacerbation of arthritis pain.[45,77] However, as soon as exercising stops, the benefits are lost, making it imperative to maintain habitual exercise. Therefore, keeping muscles strong and well conditioned with prophylactic exercises may prevent the onset of OA and retard, or even halt, progression of joint damage, especially if the exercise therapy or the increase in physical activity begins in early stages of the disease and is maintained for longer periods.

Regular exercise can also improve psychological variables such as affect, coping, and self-efficacy, which are also regarded as mediators for the effect of exercise on health outcomes.[78-80] In this sense, Rejeski et al [55] found that aerobic and resistance exercise increased self-efficacy, which in turn mediated the effect that such programs had on disability. Published studies have shown beneficial effects of exercise therapy on relevant outcomes in patients with arthritis,[81-84] however, psychological characteristics, which are shown to be potential mediators, have rarely been measured.

Psycho-Educational Interventions

Patient education, defined as "Any set of planned educational activities designed to improve patients' health behaviors and/or health status," [85] is thought to be beneficial in helping patients to cope and co-operate with their disease and its management. Although improvements in pain, functional ability, psychological well-being, and health status have been shown by some programs,[85-87] analytic reviews of psycho-educational interventions are ambiguous about the effect on these outcomes in arthritis patients.[88-90] A recent review found average effect sizes (i.e., mean difference between baseline and follow-up divided by the standard deviation of the pre-intervention values) to be 0.44 for pain and 0.28 for functional ability for clinical samples and 0.21 and 0.08, respectively, for community samples.[89] Results from psycho-educational interventions tend to vary across individuals, regardless of disease activity or medication use.[80] Thus, there is a clear need for the identification of factors that could be useful in predicting outcomes, which, if modifiable, could be targeted in the design of interventions that could result in the improvement of these outcomes.

One of the most used interventions of this kind is the Arthritis Self-Help Course (ASHC). The ASHC has proven to be effective for patients suffering from arthritis on aspects such as behavior changes, self-efficacy perception, and health status.[85] The intervention focuses on increasing the participant's perception of being able to cope (self-efficacy) with pain and other arthritis symptoms, including functional limitation. The intervention has shown to have a positive effect on the frequency of exercise and relaxation behaviors while reducing pain.[91] It has also been reported that changes in outcomes obtained with this intervention are not related to changes in behaviors,[92,93] and that they are more associated with changes in self-efficacy.[93] The ASHC has been shown to be effective in the long-term with improvements in pain and self- efficacy maintained after four years while reducing physicians' visits, which, in turn, is evidence of cost-effectiveness.[85] The reported data do not, however, support the existence of a strong link between changes in self-efficacy, the proposed mediator, and improvement in health outcomes. Thus, it is important to investigate additional psychological dimensions as potential predictors or mediators of this effect.

The author of this dissertation and his collaborators have proposed a model that will be used to test the hypothesis that supplementing an exercise intervention with a self-management program will enhance the achieved effect of physical activity alone. This model will be tested during the next five years by a study funded by NIH/NIAMS. Even though improvements in function that occur with exercise training would seemingly be due to physiological adaptations, the evidence suggests that psychological factors such as coping efficacy predicts performance-related disability over and above physiologic capacities, an effect that is independent of the role played by knee pain.[48] Affective status (i.e., positive affect) may also influence performance through an effect on the motivational component of physical function. We hypothesize that a self-management program, through its effect on coping efficacy, will enhance the effect of exercise on physical function. An alternative hypothesis is that self-management will moderate the effect of exercise on coping efficacy.

Subjects' Compliance with Health Interventions

In the general medical literature, there are numerous examples of poor treatment compliance with recommendations for health-related behavior change, even when risks of noncompliance are immediately life-threatening.[94,95] Compliance to exercise therapy is no better than for other health behaviors or treatments.[96] In a review of compliance literature,[97] combinations of strategies have been shown to increase compliance with a variety of therapeutic regimens. These include incorporating cognitive strategies as well as behavioral strategies. Cognitively, it is important for subjects to gain practical knowledge and understanding of the principles of exercise and of the effects structured physical activity could have on arthritis. Behaviorally, reinforcement techniques can be initiated at different levels throughout the duration of the health intervention to facilitate and develop the subject commitment and adherence to a long-term program. Incentives provided frequently during the early stages of habit formation, followed by more significant reinforcement awards, as the program progresses, are important tools to assist individuals to achieve predetermined goals.

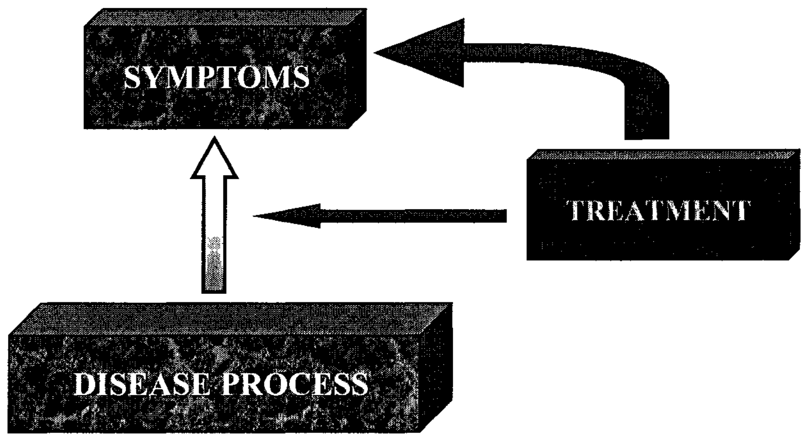
Section 2.3. - PSYCHOLOGICAL DIMENSIONS AND HEALTH STATUS

Traditional Physiopathological vs. Biopsychosocial Model

It has been said that the goals for the management of arthritis are still the reduction of pain, the prevention or reduction of disability and the improvement of perceived quality of life. To meet these goals, the American College of Rheumatology and other national and international organizations strongly recommend the use of complementary strategies, such us education (including psycho-behavioral interventions) as first-line therapy for arthritis.[66,67] However these recommendations have not been always followed by practicing rheumatologists.

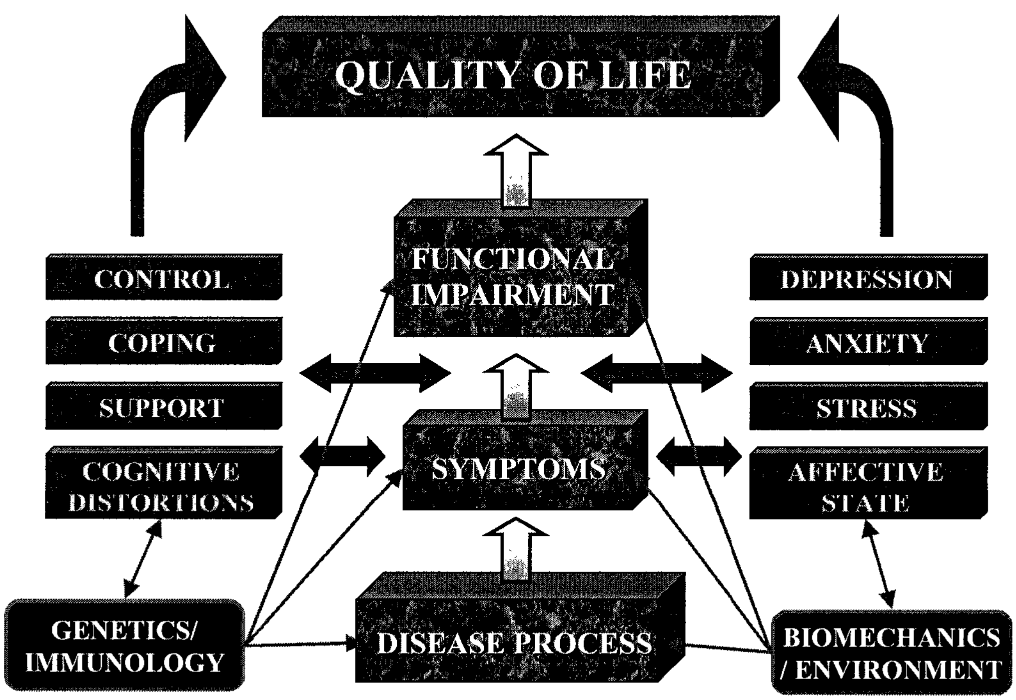
One of the reasons for the lack of adherence to these recommendations – aside from considerations related with the access to and financial coverage for this type of interventions – is that the vast majority of treatment decisions in rheumatology are driven by the traditional physiopathological or biomedical model.[80] This model implies that whatever the initial cause of the disease, this etiologic agent will interact at the tissue and organ levels initiating the disease process. If this process is intense enough, the disease will eventually become clinically manifested. For example, according to the biomedical model, OA is the consequence of a lifetime of mechanical (ab)use that causes joint damage, physiological disfunction, and impairment. These changes lead to greater pain and disability. At this point, treatment (i.e., medications) will be initiated with the goal of controlling these physiopathological mechanisms or, more commonly, trying to control the symptoms directly.

Figure 2. Traditional Physiopathological or Biomedical Model



Clearly, this model is too simplistic to explain the complexities of a chronic condition such as arthritis. For example, the biomedical model cannot explain why people with advanced joint damage frequently report less pain than people with minimal structural damage, whereas others with low levels of damage often report severe pain.[98] Nor can it explain why some people receive considerable benefit from a particular health intervention (i.e., exercise regimen, self-management program, or psychobehavioral intervention), whereas other people with similar disease activity obtain little or no benefit from the same intervention.[80] For these reasons, a more complex model has been proposed: the biopsychosocial model.[99-101] This new model implies the interaction of a series of factors, including: genetical, immunological, biomechanical, environmental and psychosocial dimensions (Figure 3). Under this model, it is the interaction of all these factors with each other that leads to different levels of symptom perception, functional impairment and decreased quality of life. In contrast to the physiopathological model, the biopsychosocial model is concerned not only with disease but with illness, a patient's subjective sense of suffering, feeling unwell, or disability.[80] In the biopsychosocial model, an illness may arise from any one of or a combination of organic disease, functional disorder, psychologic disorder, somatization, failure of relationship between the patient and society, the individual's interpretation of symptoms, and peer or family reactions.[100]

Figure 3. Biopsychosocial Model



In the case of arthritis, the biopsychosocial model accepts that there is a biological cause of nociception that is perceived as painful, but it takes a broader view of pain and disability stating that people's "pain behavior" is a product of their beliefs, understandings, experiences and emotions, which may be modulated by their social environment.[101] Rather than focusing on attempts to cure the underlying pathology, the biopsychosocial model emphasizes the role people's beliefs and use of specific coping strategies play in adjustment to living with arthritis. Consequently, this model views arthritis as the result of complex interactions between joint damage, muscle dysfunction, obesity, pain, disability, psychological profile, social support, and economic resources.[80] This model can then explain the observed individual differences in the impact of health interventions for arthritis, by suggesting that patients have different internal traits (i.e., personality and affectivity traits) and external influences (i.e., social support) that affect their perceptions, beliefs (i.e., perception of self-efficacy or control over the disease), and behaviors (i.e., use of specific coping strategies).

Psychological Dimensions and Arthritis

Using the biopsychosocial model, psychological characteristics have received increased attention as explanations for differences in perceived health, quality of life and well-being among patients with arthritis.[102] As mentioned, these characteristics can be regarded as predictors of the individual's response to health interventions (i.e., exercise training, and self-management and cognitive-behavioral programs). The following dimensions have been identified as possible mediators in affecting health outcome status:

the perception of personal control over the disease – emphasized in three related constructs (i.e., health locus of control,[103] learned helplessness,[104] and self-efficacy [105]); coping;[106,107] optimistic expectations for improvement;[108] and social support.[109] Most studies among arthritis patients have focused in RA, with little attention to OA.[110]

Self-efficacy

According to Bandura, "Perceived self-efficacy refers to the beliefs in one's capacities to mobilize the motivation, cognitive resources, and course of action needed to meet given situational demands." [105] It has been proposed that self-efficacy is a common cognitive mechanism that mediates behavior change, and that influences one's choice of activities, effort expended during the performance of these activities, and the degree of persistence exhibited in the face of adverse stimuli.[111] Patients with low self-efficacy have a high probability of avoiding physical activity in their daily routines.[111] Lorig and Holman report that promoting self-efficacy beliefs specific to coping resulted in an increase in self-reported physical activity.[85] Their data do not, however, support the existence of a strong link between changes in self-efficacy and improvement in health outcomes.

Helplessness

Helplessness refers to a generalized experience of hopelessness that some patients develop and the belief that no effective solutions are available to eliminate or reduce the impact of negative events. High levels of helplessness have been associated with greater pain, depression, and disability.[112,113] The chronic nature of arthritis, our poor understanding of its cause, and our inability to correct inherent health beliefs about the prognosis and management of arthritis foster feelings of helplessness.[42]

Coping

Coping refers to individuals' attempts to limit the effect of a stressor.[114] In general, these attempts can be divided into behavioral (e.g., seeking information, increasing activity level, and relaxing) and cognitive strategies (e.g., positive self-statements, catastrophizing, wishful thinking, and denial). Also, these strategies can be divided into active coping, such as increasing physical activity, diverting attention, and reinterpreting pain, and passive coping strategies, such as resting, avoiding activities, and relinquishing responsibility for pain control to others.[115] Subjects that predominantly use active coping strategies tend to report fewer symptoms, less disability and lower levels of psychological distress; in comparison, those that primarily use passive coping report higher levels of pain, lower physical and social function, and worse general health perception.[79,116,117]

Social Support

Interpersonal relationships with a spouse, family, and friends promote physical, social, and emotional well-being through emotional (i.e., promoting feelings of belonging and being valued) and informational (i.e., providing explanation of medical conditions and treatment) support.[118] Both the size of people's social network and the number and frequency of social contacts is important; however, the quality of support is critical. Consequently people's adjustment to arthritis will be poor if they have a wide circle of support but they are dissatisfied with the support provided.[80]

These psychological dimensions, however, still explain only a small percentage of the variance of different outcomes in studies with arthritis patients.[102] Identifying further predictive or mediating factors may increase understanding of the dynamics of treatment response in the context of different health interventions. Targeting these characteristics in the design of psycho-educational interventions could result in better health outcomes for patients with arthritis or other chronic diseases. Also, the ability to predict outcomes based on psychological profiles may potentially be used for the identification of subjects that could most benefit from psycho-educational or from alternative health interventions. To date, most studies investigating these issues have been cross-sectional and have studied differences between patients instead of changes over time in the same individuals. A longitudinal design will permit a more thorough examination of potential causal relationships between psychological dimensions and health status change.

Personality, Affect and Health Outcomes

Positive Affect

It has been suggested that personality traits, related to positive or negative affect, may constitute general factors that can influence and confound most types of subjective experiences.[119,120] Positive Affect (PA) reflects the extent to which an individual feels enthusiastic, active, and alert. High PA is a state of high energy, full concentration, and pleasurable engagement, whereas low PA is characterized by sadness and lethargy.[121] PA is represented as an affective state dimension but it is also related to the corresponding personality trait of extraversion.[122] Researchers have reported that personality and affect are related over the lifespan and that this relationship is stronger later in life.[123] It has also been postulated that extraversion and neuroticism are directly responsible for regulating individual differences in the experience of positive and negative affect, respectively [124] or, alternatively, that personality traits indirectly influence affect by predisposing individuals to participate in activities that induce positive and negative affect.[125]

PA has been found to be a good indicator of psychological well-being in older adults with chronic arthritis.[120] The presence of higher levels of PA has been related with a more frequent use of adaptive strategies that facilitate psychological adjustment to a chronic illness.[126,127] PA has also been related with increased levels of self-efficacy perception and disease adjustment in cancer patients.[128]

A model has been proposed where lower levels of PA and higher levels of negative affect (NA) are associated with maladaptive coping; which, in turn, is associated with higher pain and limitation.[127] In support of this model, it has recently been reported that positive affect, but not negative affect, predicts improved active coping, and initial active coping predicts, in turn, increased positive affect, but not reductions in negative affect.[129] Further analyses show that positive affect and active coping serially enhanced one another.[129]

PA has also been linked with creative or divergent thinking, which in turn, facilitates creative problem solving.[130] Recently, Erez and Isen have reported that positive affect improves people's performance and affects their perceptions of expectancy and capacity to react to stressful situations.[131] Positive affect interacts with task conditions in influencing motivation, which occurs not through general effects, such as response bias or general activation, but rather through its influence on the cognitive processes involved in motivation.

In a recent study, the authors found that PA was an independent predictor for overall mobility and physical functioning in older adults.[132] Fisher et al, conducted a two-year prospective cohort study using a population-based sample of 1084 non-institutionalized Mexican American subjects aged 65 or older with arthritis residing in five Southwestern states.[133] They reported that higher scores of PA were independently associated with lower incidence of disability over a two-year period. Only one study has suggested the role of PA on treatment efficacy. In that randomized controlled trial, the experimental group focused on individualized and generic problem-solving approaches facing the subject and his/her family. Results demonstrated the contribution of PA to change processes.[134]

Negative Affect

Negative affect (NA) is a general dimension of subjective distress and unpleasurable engagement that comprises a variety of aversive mood states, including anger, contempt, disgust, guilt, fear, and nervousness, with low NA being a state of calmness and serenity.[121] People with high levels of NA, which is highly related to the personality trait of neuroticism, tend to have more negative cognitions, to use less effective coping strategies, and to have exaggerated perception of pain.[119,135] Negative affect appears to inhibit performance on cognitive tasks, especially when the negative mood is intense and the task demands effortful and sustained processing.[136] High NA and low PA are major distinguishing features of depression and anxiety.[137]

PA and NA are the two dominant dimensions in studies of affective structure; the first two factors in factor analyses of self-rated mood; and the two first dimensions in multidimensional scaling of facial expressions or mood terms.[138-140] Although the terms of PA and NA might suggest that these two mood factors are opposites (that is, strongly negatively correlated), they have, in fact, emerged as highly distinctive dimensions.[122] In this sense, considerable evidence shows that these two factors are orthogonal dimensions.[122,141] Indeed, high ratings of perceived quality of life have been found to derive from a mixture PA and the relative absence of NA.[142]

Stress Reactivity and Disease Activity

A study conducted with collaboration of the Department of Psychology at the Arizona State University and the University of Arizona Arthritis Center examined the effects of change in interpersonal stress on disease activity among 41 women with Rheumatoid Arthritis.[143] Measures of everyday stressful events and perceived stress were collected weekly for twelve weeks and related to disease activity in a series of pooled time-series regression analyses. Increases in the number of interpersonal stressors in the same week and one-week prior were associated with increases in disease activity. In addition, pain from joint tenderness was significantly related to a decrease in stressful events one week later. Significant elevations in clinician rating of disease and self-reports of joint tenderness were found during the week of increased interpersonal stress.

This study was the first to describe a procedure for the identification of periods of elevated stress occurring in everyday life that is based on a priori decision rules. Such a procedure added considerable experimental control to the prospective study of naturally occurring events, something that had been lacking in the methods of life event research to date.

Section 2.4. - MEASUREMENT OF HEALTH OUTCOMES IN ARTHRITIS

The assessment of outcomes in arthritis should target, at the very least, some of the main features of this chronic condition. The arthritis researcher should then consider tests or instruments that evaluate pain, tenderness, swelling and dysfunction – for both OA and RA. Also since arthritis is associated with higher levels of disability and impairment of patients' quality of life, it is recommended that these dimensions be regarded also as relevant outcomes. A number of candidate variables and measurement procedures for both OA and RA are identified in Table 4.

Table 4. Outcome Measures for Arthritis

Pain scales

- Visual analogue scale
- Likert scale
- Pain faces scale
- McGill Pain Questionnaire

Stiffness

- Intensity
- Duration

Physical performance

- Grip strength
- 50' walk time
- Ascent time
- Joint range of movement

Swelling

- Arthrocircametry
- Graded

Health status instruments

- Wenstern Ontario and McMasters Universities OA Index (WOMAC OA)
- Lequesne Index (OA)
- Dreiser Index(Hand OA)
- Australian / Canadian hand OA Index
- Health Assessment Questionnaire (HAQ)
- Arthritis Impact Measurement Scales (AIMS)
- AIMS2

Health -related quality of life

- MOS 36-Item Short-Form Health Survey (SF-36)
- EuroQol Group's EQ-5D
- Nottingham Health Profile
- Health Utility Index

Imaging

- Plain radiographs
- MRI
- Scintigraphy
- Ultrasound
- Arthroscopy

Standardization of Outcomes in Arthritis

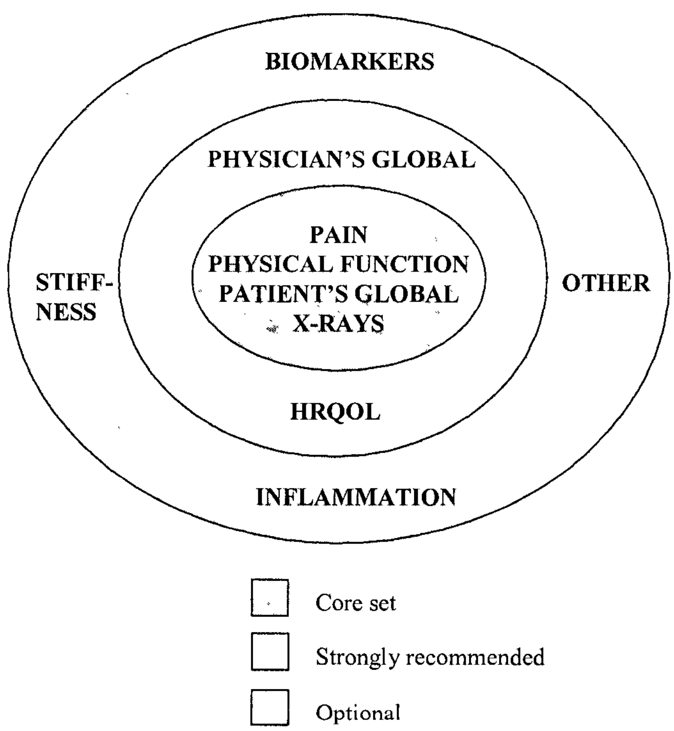
When performing outcomes evaluation, especially in the setting of clinical or interventional trials, the use of instruments with high levels of reliability and discriminative power becomes crucial.[144] If unreliable instruments are used, the obtained statistical estimates can constitute highly attenuated versions of the true population parameters. These attenuated estimates can have a great impact the necessary sample size and study budget. Many studies that have utilized education, exercise, or both, as intervention strategies, have frequently not included all the relevant outcome measures for arthritis clinical trials.[145] In addition, studies have used different instruments for assessment of specific outcomes in arthritis, with some instruments having no tested validity or reliability. This lack of consistency in outcome measurement has complicated the comparison of effect sizes across different studies.[146] The recently published list of candidate instruments provided by Bellamy [147] and the OMERACT (Outcome Measures in Rheumatology; formerly Outcome Measures for Rheumatoid Arthritis Clinical Trials) recommendations for OA and RA studies [147-149] can be seen as a first step in the standardization of assessments.[150]

Recommendations for Outcomes Measurement in Osteoarthritis Studies

It was recommended at the 1996 OMERACT III conference that all OA studies, especially clinical trials, include a core set of measurement targeting the following dimensions: pain, physical function, and patient's global assessment of disease activity (Figure 2).[147] There were no specific recommendations for the instruments to be used for the evaluation of each of these dimensions, although it was suggested that pain and patient's global assessment of disease activity could be measured using a 0 to 100 visual analogue scale and physical function using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC),[151] the Lequesne Algofunctional Index [152] or the Health Assessment Questionnaire (HAQ).[153]

Figure 2.

OMERACT* Recommendations for Outcome Measurement in OA Studies



* *Outcome Measures in Rheumatology conference (1996)*
Recommendations for outcomes measurement in RA studies

The American College of Rheumatology introduced the first standard guidelines for the evaluation of outcomes in RA studies [148] (Table 5). A minimum core set of measurements was proposed for RA clinical trials and other epidemiological studies, including: number of tender joints, number of swollen joints, patient and physician's global assessment of disease activity, pain, physical function or disability, and an acute-phase reactant lab test (i.e., erythrocyte sedimentation rate or C-reactive protein). These measurements were recommended to be used in all RA studies, in addition to other assessments chosen by the particular researcher, depending on the particular goal of the study.

Table 5. Recommendations for Outcome Measurement in OA Studies*

Number of tender joints
Number of swollen joints
Patient's evaluation of pain
Patient's global assessment of disease activity
Physician's global assessment of disease activity
Disability
One measure of acute-phase reactants (i.e., erythrocyte sedimentation rate or C-reactive protein)

* *American College of Rheumatology (1993).*

The Committee on Outcome Measures in Rheumatoid Arthritis Clinical Trials

Evaluation of Questionnaires' Psychometric Properties

The process of selection of questionnaires should rely on the outcomes being measured and the reported measurement properties of each specific instrument (Table 6). One of the first properties that a researcher should consider is the applicability of the instrument in the particular research setting. The feasibility of the instrument may be evaluated, for example, by assessing the number of subjects that can complete the questionnaire, their level of comprehension of the instrument's content, and the required time for completion.[154]

Table 6. Instruments' Psychometric Properties

Feasibility

- Number of subjects completing
- Subjects' comprehension of instrument content
- Time to completion

Discriminative properties

Validity

- Construct validity (convergent and divergent)
- ROC curves (criterion validity)

Reliability

- Internal consistency
- Test-retest

Evaluative properties (Responsiveness)

- Within subjects changes (Sensitivity to change)
- Relative efficiency

Validity

A second property that a researcher needs to evaluate is the validity of the instrument or the extent to which it measures what it attempts to measure.[155] Several types of validity have been described. One of these types is *content validity*, which examines whether the questions are representative of the concepts they are intended to target.[156,157] This property is usually evaluated by expert opinion. Another type is *construct validity* (convergent and divergent – or discriminant), which examines whether and how developed hypotheses (constructs) about the relationship between specific scales are borne out.[158] To test this property, the scores of the scales being evaluated and those from other instruments purported to measure the same and different constructs are correlated with each other. A particular scale is expected to converge with the scores of those instruments or scales targeting the same construct, and to deviate from the scores given by instruments or scales assessing a different one.

Reliability

Reliability reflects the extent to which a score is free of random error. This property can be examined in, at least, two different ways. First, the *internal consistency* of each scale can be assessed by examining whether individual items are consistent with the concept being measured by the scale. It provides a measure of the stability across the items that constitute that particular scale and with the total score of the scale.[159] Internal consistency is commonly reported as a Cronbach's alpha coefficient.[160] Second, *test-retest* reliability can be assessed to evaluate the stability of the measurements at different time points.[161] An instrument is considered reliable if there is a high correspondence between the answers to the same question asked of the same respondent at two points in time. The time period between testing should be short enough to avoid expected changes resulting from the impact of disease or treatment, yet long enough to avoid recall bias. To test this property, intraclass correlation coefficients [161] are usually obtained if continuous variables, or Kappa statistics for categorical data.[162]

Responsiveness

This final property reflects the extent to which a scale detects true improvements or deteriorations resulting from treatment or disease progression.[163] We can test the *sensitivity to change* of the instrument by assessing the ability to detect within-subject changes. The relative responsiveness of two instruments can be determined by means of the evaluation of their *relative efficiency*. This estimates the extent to which one scale is more or less efficient at detecting change over time relative to another scale. Relative efficiency and the significance of change scores are typically computed from paired-samples t-tests as pairwise squared t-values (t2 scale 1/t2 scale 2).[164] However, results generated by this method confound "responsiveness" with the effects of non-normality such that scales with more normally distributed outcomes are favored.[165] Therefore, the significance of change scores can be better examined using Wilcoxon's matched-pairs signed-ranks test and computing relative efficiency as pairwise squared z-values (z2 scale 1/z2 scale 2) generated by this test.[165]

Minimal Clinically Important Differences

Minimal Clinically Important Differences (MCID) was first defined as "the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management." [166] Other definitions for MCID have been proposed, such as "the smallest difference in a score that is considered to be worthwhile or important," [167] the "minimum absolute risk reduction for which patients would take a treatment given their understanding of the risk without that treatment," [168] or "the mean score for patients with an optimal result minus the mean score for a group with a suboptimal result." [169] Each of the definitions stresses a different aspect: some weighing change against potential risks, others weighing the impact on treatment decision-making, others weighing the impact on the magnitude of change alone. But, the common argument is that MCID should be the lower boundary of change that is perceived to be important.

In the past few years, several studies have proposed different, but similar, cut-offs for the definition of MCID corresponding to different outcomes in arthritis. For example, it has been proposed that ~10 units improvement, on a scale of 0 to 100, meets the definition of MCID for pain [170-172] and the MOS 36-item Short-Form Health Survey (SF-36) scales [173-175] in pain or arthritis studies. Similarly, it has been proposed that a ~ 0.2 units improvement on the 0 to 3 scale for physical function as measured by the Health Assessment Questionnaire (HAQ) meets such definition.[174,176]

Section 2.5. - ARTHRITIS AND HEALTH RESOURCES UTILIZATION

Predictors of Health Resources Utilization

In the last 60 years, total health care expenditures in the United States have increased from 4% to almost 14% of the gross national product.[177] Expenditures for personal medical care have risen at a faster pace than expenditures in almost any other good or service in the economy.[177] As can be deduced from what was said in the arthritis overview section, arthritis is responsible for the use of a considerable fraction of the health care resources consumed in the United States.[178] Estimated medical care costs for individuals with arthritis were $15 billion and total costs (medical care and lost productivity) were $65 billion in 1992.[56]

The Centers for Disease Control and Prevention (CDC) reported that arthritis was the first listed hospital discharge diagnosis for 744,000 hospitalizations annually, lasting a total of 3.8 million days, based on 1997 National Hospital Discharge Survey data.[179] The same CDC report also estimated that 44 million ambulatory care visits could be attributed to arthritis, of which almost 39 million were to physician offices, based on the National Hospital Ambulatory Medical Care Survey.[179] Estimates from the 1996 Medical Expenditure Survey showed that adults with musculoskeletal conditions were more likely to use ambulatory (physician and non-physician visits), home health care days, and hospital services.[178] Similarly, cross-sectional findings from the 1990 Ontario Health Survey revealed that musculoskeletal conditions ranked first among chronic conditions for consultations with a health professional.[180]

In a recently published study, data were analyzed from 6,230 participants interviewed in 1993 and 1995 in the Asset and Health Dynamic Survey Among the Oldest Old.[181] Older adults with arthritis were significantly more likely to have had a physician visit (odds ratio [OR]=3.0), hospital admission (OR=1.6), outpatient surgery (OR=1.3), home health care (OR=1.6), and have had out-of-pocket costs of >$5,000 (OR=1.6) compared with contemporaries having similar demographics (age, sex, racial/ethnic group, marital status), comorbid conditions, and economic resources (education, income, wealth, health insurance), but not reporting arthritis.

Furthermore, all these costs are expected to rapidly increase during the next two decades. This is due, in part, to the progressive aging of the US population. It is of primary interest for public health policy makers to optimize health care expenditures. To permit such optimization, it is crucial to identify determinants of health care resources utilization (HCSU) by people with arthritis and other chronic conditions.

A behavioral model, the Andersen Model, has been proposed to relate use of health services with: 1) predisposing factors (i.e., socio-demographic characteristics and health beliefs); 2) enabling factors (i.e., ability to secure health services); and 3) need factors (i.e., illness-related factors).[182] This model was proposed in response to a number of sociological studies indicating that the decision to seek medical care involved cultural, structural, and psychological factors that are independent of the presence and severity of disease.[183] Need factors can be divided between "perceived need" and "evaluated need." Studies predicting HCSU for the elderly population have shown that the most important predictors are the need factors,[184-186] although predisposing and enabling factors have been shown to contribute to the explained variance after adjusting for need factors.[187]

One of the reasons for the substantial economic burden imposed by arthritis, other than its high prevalence in the general population and the long disease duration, is the fact that this condition inflicts great levels of impairment. Arthritis is one of the main causes of disability; as compared with other chronic conditions.[36] In this sense, the amount of demand for health care resources in arthritis has been related primarily to the patient's physical condition (i.e., disease status), and specifically to the patient observed and perceived level of physical function and functional decline.[183,188-191] Poorer function, as evaluated by the Health Assessment Questionnaire (HAQ) disability index, has been shown to be associated with higher direct medical costs in patients with arthritis.[191-194] Other identified factors are age, sex, education, socioeconomic status, prior health care use, costs of services and quality of well-being.[31,195-198]

Ethgen et al [183] recently evaluated the impact of health related quality of life (HRQL) on HCSU in patients with arthritis. They found higher rates of HCSU in those in the worst quartile compared with those in the best quartile of HRQL. Patients with arthritis with a high level of HRQL as measured by the SF-36 (physical component score) reported a decrease of 31% ($p < 0.01$) in general practitioner visits and a decrease of 52% ($p < 0.01$) in hospitalization. They also found a relationship between physical function, as measured by the HAQ, and HCSU; osteoarthritis and rheumatoid arthritis patients in the worst quartile reported a 199% ($p < 0.05$) and 48% ($p < 0.05$) increase in rheumatologists visits, respectively.

Psychosocial Characteristics and Health Care Resources Utilization

HCSU has been found to be related to anxiety and depression scores in arthritis,[199,200] but not much emphasis has been placed on the evaluation of the role of other psychosocial characteristics as predictive of the amount of contacts with the health care system. Psychosocial factors could be categorized as predisposing factors or as need factors (perceived need) under the Andersen Model (see above).

In a study among Health Management Organization (HMO) members 60 years of age or older with arthritis, perceived self-efficacy, arthritis helplessness, perceived emotional support, and depression did not significantly contribute to the variance of utilization rates.[198] The best single predictor of HCSU in this study was prior use of the system. In a follow-up to a randomized trial, where 831 subjects 40 years and older with heart disease, lung disease, stroke, or arthritis participated in the Chronic Disease Self-Management Program, a reduction in the number of emergency room / outpatient visits at 2 years was assumed to be related with an increase in the perception of self-efficacy.[201] Similar results were reported for an arthritis sample with a 4-years follow-up period.[85]

In a recent study, the author of this dissertation and collaborators evaluated determinants of health care utilization in a sample of subjects with arthritis enrolled in a national arthritis registry.[202] A cross-sectional analysis with 2381 subjects and a longitudinal analysis with 461 subjects' responses were performed. The following variables were collected: age, gender, educational level, race, employment status, perception of overall health, pain, physical and mental health status – as measured by the

Modified Health Assessment Questionnaire (MHAQ), health care services utilization – measured as the number of contacts with the health care system during the previous 6 months. Both in the crossectional analysis and the longitudinal analysis, mental health was one of the most significant predictors of health care utilization after adjusting for the rest of the variables in the models. The conclusion was that mental health status is a relevant predictor of health resources utilization in patients with arthritis.

This dissertation seeks to further analyze the role of psychosocial variables as determinants of health care utilization in arthritis. Based on the model that we propose (see Chapter 1), positive affect is hypothesized as one of the main predictor of health services utilization.

Accuracy of Self-Reported Health Care Use in Subjects with Arthritis

Studies assessing HCSU usually rely on self-reported data, since these data are typically convenient and inexpensive to obtain. It is, however, well known that the accuracy of this information is less than ideal.[203-206] Problems related with the validity and reliability of the measurement instruments can compromise the internal validity of the results. Furthermore, even with moderate to high correlations between self-reported and agency-reported HCSU,[207,208] using aggregate numbers can be problematic. Studies have reported patterns of high users underreporting and low users overreporting, potentially making the average discrepancy appear much smaller than it is.[209]

In general, inaccuracy of reported HCSU has been associated with age (older adults and children are less accurate), low income, low education level, poorer health status, having a chronic disease, greater levels of disability and high levels of HCSU.[204-206,210] Because subjects with arthritis are, in general, older and suffer from a chronic disease, it is expected that they would underreport HCSU. A recent study that evaluated the accuracy of self-reported HCSU in patients with arthritis found that the average number of contacts reported by a HMO for a 6-month period was 6.42, while the average number of self-reported contacts was 3.79.[209] More salient contacts (i.e., days in hospital) were more accurately reported than routine doctor visits, but 70% of the participants underreported their total use of the medical care system.

CHAPTER 3

PRESENT STUDY

The methods, results, and conclusions of this dissertation are presented in the appended papers. The following is a summary of methods for each of the studies that were used as a data source and of the analysis strategy used to address the specific aims.

Section 3.1. - DATA SOURCES

Study 1: Interpersonal Stress and Disease Activity in Arthritis (PI, Alex Zautra, PhD; Co-PI, David E. Yocum)

Data from this study were used to target specific aims 1 and 3 (i.e., to longitudinally analyze the relationships between affectivity and pain perception in arthritis, and to determine the role of positive affect as a predictive factor for future use of health care services). This study is a prospective cohort study funded by NIH/NIAMS (R01 AR41687) that examined the influence of interpersonal stress on arthritis symptoms, affective distress and disease activity.

The study consisted of 283 women; who had either rheumatoid arthritis (RA; n = 89), active osteoarthritis (OA; n = 105), or inactive OA (n= 89). The classification between active and inactive OA was based on the self-reported levels of pain (i.e., higher vs. lower than 25 on a 0 to 100 scale) and physical function (i.e., higher vs. lower than 0.5 on the health assessment questionnaire). Participants had been recruited starting in January of 1994 using a variety of ways including newspaper ads, mailings to Arthritis

Foundation members, and through rheumatology clinics. The newspaper ads stated that there was a "paid research opportunity for older women with or without RA" and identified the research as a "study on stress and health in older adult women." The letter to Arthritis Foundation members and the flyers left in rheumatology clinics stated that there was a “paid research opportunity for older women with OA or RA" and identified the research as a "study of stress and health in older women with arthritis.”

Only postmenopausal women were studied to reduce within and between groups heterogeneity in the hormonal profiles that might underlie stress-related inflammatory processes. Patients were required to be on stable dosages of their medications for two months prior to enrollment. If a patient received a steroid injection, her participation in clinician assessments was suspended for one month, to reduce any effects that this medication may have had on immune parameters.

All RA and OA patients had their diagnoses confirmed by their rheumatologists, and then reconfirmed as meeting American College of Rheumatology criteria by one of the study’s principal investigators (Yocum) based on comprehensive reviews of medical history, medication use, and joint tenderness and swelling evaluations made during in home visits. To insure that patients were not asymptomatic, only those RA and OA patients who rated their average pain at least 30 on a scale of 0-100 (0 = no pain to 100 = pain as bad as it could be) and who reported moderate or greater activity limitation on the Health Assessment Questionnaire (a score of 0.5 or higher) were enrolled. All participants were paid $50 initially and another $50 after they completed the study. The

Institutional Review Board at Arizona State University approved the study protocol for the protection of human subjects.

Study 2: The Living Healthy with Arthritis Study (PI, David Yocum, MD)

Data from this study were used to target specific aims 2 and 3 (i.e., to determine the role of positive affect as a predictor of health outcomes in the context of a health intervention for arthritis, and to determine the role of positive affect as a predictive factor for future use of health care services). This second study was a prospective cohort study with an interventional component that examined the impact of a health intervention on patients with arthritis. The study was conducted starting in May 1997 at the University of Arizona Arthritis Center, with prior approval of the university's Institution Review Board.

Individuals with both inflammatory and non-inflammatory arthritis were recruited by printed advertisements and public announcements to participate in a community-based, 12-session program titled the "Living Healthy with Arthritis", developed by the Arizona Arthritis Center. The program was offered through a recreation center in a retirement community (Green Valley; population 26,000) located near the Tucson metropolitan area and implemented through the Arizona Arthritis Center by an integrated team of specialists trained in arthritis and preventive care. It was developed to provide a community-based program that integrates traditional and complementary health practices to promote optimal health for individuals with arthritis. The 12-session intervention incorporated both a comprehensive education/self-management component and an exercise (aquatics) component. Participants met for three hours, three times weekly over a four-week period. Enrollment was limited to a maximum of 20 participants per session.

The 90-minute self-management/education portion addressed an overview of arthritis, osteoporosis, stress management, medications, complementary treatments, and a variety of exercise and relaxation techniques and used both a didactic and interactive approach. The 60-minute aquatic class emphasized stretching, range of motion, and aerobic fitness providing an opportunity to increase endurance over time. The instructor was an American Academy of Family Physicians Certified Medical Exercise Specialist and an Arthritis Foundation Certified Instructor for Aquatics.

Study 3: The Psychosocial Determinants of Health Resources Utilization Study (PI, David Yocum, MD; Co-PI, Isidro Villanueva, MD)

Data from this study were used to target specific aim 3 (i.e., to determine the role of positive affect as a predictive factor for future use of health care services). Subjects that originally participated in the two studies described above were re-contacted from May to August 2003 and data on health services utilization and health outcomes in the previous six months were collected. The average follow-up time between their initial entry in the two studies and re-contact was about seven years. Initially, an Arizona Arthritis Center staff member contacted subjects by telephone. The project was explained and subjects asked if they were willing to complete a short phone interview and to receive and complete a short mailed questionnaire. A stamped envelope for subjects to mail back the completed questionnaire was included in the mailing. The telephone interview took approximately five to ten minutes and included questions about perceived health status (pain, fatigue, global assessment of disease activity) and the number of contacts with different health care services during the previous six months. The mailed questionnaire included an instrument for the evaluation of health-related quality of life, physical function and affective status. See a description of the instruments used for this evaluation in the Data Collection section.

Section 3.2. - SUBJECTS' CHARACTERISTICS

The previous section detailed the general characteristics of the three studies used as data source for the analyses performed in this dissertation; here follows the description of the samples that were recruited in those three studies. First, the sample for the Interpersonal Stress and Disease Activity in Arthritis Study consisted of 283 women who had either RA (n = 89), active OA (n = 105), or inactive OA (n= 89). The Living Healthy with Arthritis Study consisted of 106 subjects with inflammatory and non-inflammatory arthritis recruited in six cohorts. Data from the five initial cohorts were used for the analysis corresponding to specific aim 2 (manuscript 2; Appendix B). The sixth cohort only had baseline data. Data from all six cohorts were used for the analyses in manuscript 3 (Appendix C). Finally, the Psychosocial Determinants of Health Resources Utilization Study enrolled subjects that participated in these two previous studies. The average period of time between the original study entry date and the date of recruitment into the follow-up health services utilization study was about seven years. While this follow-up study is ongoing, to date, a total of 101 subjects with inflammatory and non-inflammatory arthritis were recruited, which is the 25.9% of the original sample that participated in the two source studies. To rule out the possibility of participant bias, a comparison of baseline characteristics between those who were recruited and those tat were not was performed (see results section for details). Table 7 lists baseline characteristics for participants in these three studies.

Table 7. Baseline Characteristics of Participants in the Three Source Studies

	Study 1* n=283	**Study 2*** n=106	**Study 3*** n=101
Age	63.17 (42-76)	69.29 (40-88)	65.8 (40-82)
Gender (male/female)	All women	14/89	4/97
Duration arthritis in years	16.31 (12.54)	14.96 (13.39)	16.9 (11.3)
Marital status:			
• ***Never married***	8 (2.8%)	3 (2.9%)	5 (5.0%)
• ***Married***	168 (58.4%)	78 (75.8%)	67 (66.3%)
• ***Widowed***	44 (15.5%)	15 (14.6%)	15 (14.9%)
• ***Divorced/Separated***	63 (22.3%)	7 (6.8%)	14 (13.9%)
Educational level:			
• ***Up to high school***	75 (26.5%)	20 (19.5%)	31 (30.7%)
• ***Trade school***	46 (16.3%)	18 (17.5%)	17 (16.8%)
• ***1-3 years college***	80 (28.3%)	26 (25.2%)	11 (10.9%)
• ***4 years college***	29 (10.3%)	30 (29.1%)	36 (35.6%)
• ***Post-graduate college***	53 (18.7%)	9 (8.8%)	6 (5.9%)
Race/ethnicity:			
• ***Anglo-American***	265 (93.6%)	100 (97.1%)	100 (99.0%)
• ***Hispanic***	9 (3.2%)	2 (1.9%)	1 (1.0%)
• ***African American***	6 (2.1%)	-	-
• ***other***	3 (1.1%)	1 (1.0%)	-

* Study 1= Interpersonal Stress and Disease Activity in Arthritis Study; Study 2= The Living Healthy with Arthritis Study; Study 3= The Psychosocial Determinants of Health Resources Utilization Study

Section 3.3. - DATA COLLECTION AND MEASUREMENTS

Instruments used for each of the studies, including notes about their reported psychometric properties, are described below. This section will end with a summary of the instruments' reliability coefficients tested in our studies. A copy of the instruments used for data collection is included in Appendix D. Table 8 lists the specific instruments used for data collection.

Table 8. Instruments and Questionnaires Used for Data Collection

Dimensions	**Study 1**	**Study 2**
Pain	0 to 100 Rating Scale	0 to 100 VAS
Physical Function	HAQ[153]	HAQ
Global Assessment of Disease Activity	-	SF-36 GH Scale [211]
Health-Related Quality of Life	SF-36[211]	SF-36
Anxiety	MHI[212]	AIMS
Depression	MHI	BDI[213]
Learned Helplessness	AHI[104]	
Stress	3 Questions	PSS[214]
Social Support	ASI[215]	MOS-SSS[216]
Coping	CPCI[217]	
Affect	PANAS[122]	PANAS
Extraversion	NEO-PI-R[218]	
Neuroticism	NEO-PI-R	

__VAS__= Visual Analogue Scale; __HAQ__= Stanford Health Assessment Questionnaire; __SF-36__= MOS 36-item Short-Form Health Survey; __MHI__= Rand Mental Health Inventory; __AIMS__= Arthritis Impact Measurement Scales; __BDI__= Beck Depression Inventory; __AHI__= Arthritis Helplessness Index; __PSS__= Perceived Stress Scale; __ASI__= Arthritis Support Inventory; __MOS-SSS__= Medical Outcomes Study Social Support Survey; __CPCI__= Chronic Pain Coping Inventory; __PANAS__= Positive and Negative Affect Schedule; __NEO-PI-R__= NEO Personality Inventory

Study 1: The Interpersonal Stress and Disease Activity in Arthritis Study

Data were collected at two in-home visits by nurse clinicians, an initial mailed questionnaire, and 12 to 20 weekly telephone interviews. The weekly interviews were conducted by trained research assistants and included measures of interpersonal stress and self-reported arthritis disease activity (see description below). These measures were used to determine a week of low disease activity and low interpersonal stress (baseline) and a week of high interpersonal stress (stress). In-home visits were conducted within 36 hours of designating the baseline and stress weeks and included a clinician's global assessment of disease activity, a measure of depressive symptoms, and a blood draw used to assess immune function. These assessments were conducted between 8am and 10am for all participants to hold constant the influence of circadian rhythms on immune parameters.

At baseline, data on demographic characteristics, PA, NA, perceived social support, arthritis helplessness, depression, anxiety, extraversion, neuroticism, and level of perceived pain were collected. Then weekly, PA, NA, perceived stress, coping difficulty with week's most stressful event, and perceived change in the amount of stress were evaluated. In addition to the mailed questionnaires, the 307 participants provided a total of 2856 weeks of data. There were a total of 204 weeks of missing data.

Specific Psychosocial Variables and Measures of Disease Activity

Pain. In our survey tools, average level of pain was assessed by using the following numeric pain rating scale: "Please choose a number between 0 and 100 that best describes the average level of pain you have experienced over the past week due to your arthritis. A zero (0) would mean "no pain" and a one hundred would mean "pain as bad as it could be." This type of scale provides a simple way to record subjective estimates of pain intensity. It has been extensively used to rate the overall severity of pain both in arthritis and other pain conditions. This scale, for example, has shown good correlation levels with physician's assessments of disease activity.[219] Pain evaluation is recommended as one of the core set measurement dimension for OA studies by standard guidelines.[147]

Positive and Negative Affect. Positive affect (PA) and negative affect (NA) were measured by the items from the Positive and Negative Affect Schedule.[122] Ten items to assess positive affect are interspersed with ten items that assess negative affect (Table 9). These items were designed to assess the extent to which participants experience positive and negative affective states. The sum of the corresponding ten items results in an individual participant's PA or NA score.

The positive affect items were "interested", "excited", "strong", "enthusiastic", "proud", "alert", "inspired", "determined", "attentive", and "active"; the negative affect items were "distressed", "upset", "guilty", "scared", "hostile", "irritable", "ashamed", "nervous", "jittery", and "afraid". Participants were asked to indicate the extent to which they had different PA and NA affects during the previous week. Participant's responses were rated on a five-point scale ranging from 1 = "very slightly or not at all" to 5 = "extremely." PA and NA were measured during each week of the study.

Table 9. Positive and Negative Affect Schedule

1.	Interested	11.	*Irritable*
2.	*Distressed*	12.	Alert
3.	Excited	13.	*Ashamed*
4.	*Upset*	14.	Inspired
5.	Strong	15.	*Nervous*
6.	*Guilty*	16.	Determined
7.	*Scared*	17.	Attentive
8.	*Hostile*	18.	*Jittery*
9.	Enthusiastic	19.	Active
10.	Proud	20.	*Afraid*

Items in regular font pertain to the Positive Affect scale;
Items in italic font pertain to the Negative Affect scale

PANAS was used in this study because it has shown to be able to produce independent assessments of positive and negative affectivity in diverse populations, and to have well-established reliability and validity across a wide spectrum of healthy and ill samples including arthritis patients.[127] Previous instruments assessing mood lacked adequate levels of reliability and validity.[220] PANAS has shown to be particularly useful for the assessment of mood in diseased samples because it does not include somatic items frequently confounded with medical conditions. Subsequent factor analyses have confirmed the two factors of PA and NA, hypothesized by Watson et al, underlie the Schedule.[221] In those analyses, the PA factor was retained, while the NA factor split into two lower-order factors generally consistent with the described Upset and Afraid factors. The PA and NA scales in the PANAS are sensitive to fluctuations in mood, but they also exhibit trait like stability.[122]

The PA and NA scales included in the Schedule have shown good levels of reliability and validity, in addition to being brief and easy to administer. In the original validation studies, the scales showed high internal consistency (Cronbach's alpha coefficients ranging from 0.84 to 0.90) and appropriate test-retest reliability (coefficients ranging from 0.42 to 0.72, in 8-weeks retest interval).[122] In our study, Cronbach's alpha was 0.81 and 0.83 for the PA and NA scales respectively; and the week-to-week test-retest correlation was 0.72 and 0.51 for the PA and NA scales respectively.

Depressive Symptoms. The measure for depressive symptoms consisted of nine items taken from the RAND Mental Health Inventory (MHI).[212] Five of theses nine items corresponded to the depression scale and four to the "loss of behavioral control" scale. The MHI measures mental health in terms of psychological distress and well-being, focusing on affective states. The items included questions such as "How often have you felt like crying?" and "How much of the time have you felt downhearted and blue?" Participants were asked to respond to each of these items with regard to the previous week. The responses were scored on a six-point scale for all items except for the last that was scored on a five-point scale. Internal consistency for the MHI scales have been reported to range from 0.83 to 0.92. Cronbach's alpha for the depression scale in this study was 0.91.

Anxiety. The measure for anxiety consisted of ten items taken from the RAND Mental Health Inventory.[212] The items included questions such as "During the past week, have you been anxious or worried?" and "How often during the past week did you find yourself having difficulty trying to calm down?" The responses were scored on a three-point scale for all items (i.e., "always," "very often," and "fairly often"). Cronbach's alpha for the scale in this study was 0.86.

Learned Helplessness. Arthritis Helplessness Index (AHI) [104] consisted of a 15-item self-report measure on which respondents rated their perceptions of helplessness in dealing with various aspects of their arthritis. Each item was rated using a four-point scale with labeled categories ranging from "strongly disagree" to "strongly agree." Some individuals confronted with the challenge of coping with persistent arthritis pain develop a strong sense of helplessness, which is defined as a state in which individuals do not belief their efforts will be successful in limiting the effect of stressful events.[104] Arthritis patients who have high levels of perceived helplessness are much more likely to report severe pain, symptoms of depression, and higher levels of functional impairment.[112,113] Nicassio examined the reliability of the AHI and found it to have adequate internal consistency (alpha =0 .69) and a 1-year test-retest reliability of 0.53.[104] In this sample, Cronbach's alpha was 0.65.

Extraversion and Neuroticism. The personality traits of extraversion and neuroticism were assessed using the corresponding scales from the self-report version of the NEO Personality Inventory (NEO-PI-R).[218] Both scales consisted of 48 items and were scored on a five-point scale ranging from "strongly disagree" to "strongly agree." It has also been postulated that extraversion and neuroticism are directly responsible for regulating individual differences in the experience of PA and NA, respectively [124] or, alternatively, that personality traits indirectly influence affect by predisposing individuals to participate in activities that induce PA and NA.[125] Subjects that score high on neuroticism, similar to those that report high levels of NA, tend to have more negative cognitions, to use less effective coping strategies, and to have exaggerated perception of pain.[135] Reliability and validity data for these scales are provided in the NEO manual.[218] In our study, for the OA group, Cronbach's alpha was 0.87 for both the extraversion (0.873) and neuroticism (0.872) scales.

Interpersonal Stress. Interpersonal stress was measured with regard to spouse, family members, and friends [143,222] with three questions: (1) "overall, how stressful were your relations with your spouse (or significant other) this past week?" (2) "Overall, how stressful were your relations with your family members this past week?" And (3) "overall, how stressful were your relations with friends this past week?" If the participant did not have a spouse or a significant other, only the family member and friend categories were used. Each of these questions was asked only after participants were primed to consider stressful events that occurred over the past week. The responses were scored on a four-point scale where 0 = "not stressful at all" to 3 = "extremely stressful." The total interpersonal stress score was computed by taking the mean score of only the items that were relevant for each participant. Interpersonal stress was measured during each week of the study. In this sample, Cronbach's alpha was 0.58 and the week-to-week test-retest correlation was 0.63. Internal consistency was expected to be low because each of the items was designed to measure a different domain of interpersonal relationships.

Arthritis Support Inventory.[215] The ASI asks the patient about perceptions of the negative and helpful social interactions between self and spouse, and the self and friends/family. Supportiveness has been associated with successful coping and less psychological distress in patients with rheumatoid arthritis.[215] The internal consistency coefficient for this instrument in this sample of OA subjects was 0.88.

Disease Activity. Disease activity was assessed each week for RA and OA participants. The measure of disease activity consists of four components: (1) pain, (2) joint tenderness, (3) curtailment of normal activities, and (4) overall arthritis activity. The average level of pain was assessed each week for the RA and OA participants by using the following question: "Please choose a number between 0 and 100 that best describes the average level of pain you have experienced over the past week due to your arthritis. A zero (0) would mean 'no pain' and a one hundred (100) would mean 'pain as bad as it could be."

Joint tenderness was assessed using a scale consisting of eight questions asking about tenderness in each of eight joints (knuckles, wrists, elbows, knees, shoulders, hips, ankles, and toes). The questions were phrased "How tender are your (joint) this week as compared to the week before?" Responses were scored on a five-point scale including 0

= "not tender this week and not tender the week before," 1 = "less tender than the week before," 2 = "just as tender as the week before," 3 = "worse than the week before," and 4 = "much worse than the week before." Totals scores on joint tenderness could range from 0 to 32. Cronbach's alpha for the eight tenderness items was 0.82 for the combined RA and OA groups.

Curtailment of activities was assessed with the question: "Over the past week, how much have you had to curtail normal activities due to your arthritis?" Responses were scored on a four-point scale including 1 = "not at all," 2 = "somewhat more than usual," 3 = "a little more than usual," and 4 = "very much more than usual." Overall arthritis activity was assessed with the question: "During the past week, how active has your arthritis been?" Responses were scored on a four-point scale including 1 = "not active at all," 2 = "mildly active," 3 = "moderately active," and 4 = "very active."

The composite disease activity score was created by giving between one and four points for scores on pain, joint tenderness, curtailment of activities, and overall arthritis activity. A four-point scale was used because the curtailment of activities and overall arthritis activity questions were already on four-point scales and the joint tenderness and pain questions could easily be converted. Joint tenderness scores were weighted as follows: 0-8 = 1 point, 9-16 = 2 points, 17-24 = 3 points, and 25-32 = 4 points. Pain scores were weighted as follows: 0-25 = 1 point, 26-50 = 2 points, 51-75 = 3 points, 76-100 = 4 points. Cronbach's alpha for the four components of disease activity was 0.83 and the week-to-week test-retest correlation was 0.63.

Study 2: The Living Healthy with Arthritis Study

Assessments were made at baseline, right after intervention (four weeks), and three months post-intervention by means of a set of self-administered questionnaires. Participants mailed the completed questionnaire package to the AAC at each follow-up point. Subjects were phoned if the corresponding assessment was not received within two weeks of the corresponding assessments. Even with an expected time for completion of the questionnaire of about 1.5 to 2 hours, the response rate was 96.3% at four weeks and 91.2% at 3 months.

A battery of standard and validated questionnaires was administered at each time point to all participants. The targeted dimensions were: psychological status (positive and negative affect, depression, perceived stress); psychosocial resistance resources (social support, coping); health status (physical function, pain); and health related quality of life. Following standard guidelines (OMERACT), [146] the evaluated outcomes in this study were: pain, as the main outcome, and physical function and patient's global assessment, as secondary outcomes. A description of the specific instruments that were used and the reported validity and reliability coefficients for each of them will be presented below. Here we present literature-reported validity and reliability properties as additional justification for the selection of these specific instruments; in manuscript 2 (Appendix B) we report the actual reliability coefficients – both internal consistency (Cronbach's alpha) and test-retest (intraclass correlation) – that we observed in our sample for each of these instruments.

Measurements

Pain. Pain, the main outcome for this study, was measured on a 0 to 100 visual analogue scale (VAS). This type of scale has shown high levels of reliability (coefficient alphas ~ 0.90) [223] and validity (correlation coefficients with other scales measuring pain ranging from 0.71 to 0.91) [224] in previous studies. One advantage of this type of measurement is that it provides the patient with a robust and sensitive method regardless of language, age or cultural level.[225] Patients were asked to rate their pain answering the following question: How much pain have you had because of your arthritis during the past week? The scale was anchored with the words "No pain" and "Most severe pain possible."

Physical function. Functional status was measured using the Stanford Health Assessment Questionnaire (HAQ).[153] The HAQ consists of 20 items in eight domains: dressing and grooming, arising, eating, walking, hygiene, reach, grip, and activity. Subjects had to evaluate their level of difficulty for each item on a categorical scale where 0 = no difficulty, 1 = some difficulty, 2 = much difficulty, and 3 = unable to do. The sum of the highest response for each dimension was divided by the number of dimensions to form the final score, which ranges from 0 (no/very mild physical dysfunction) to 3 (severe physical dysfunction).

Health-Related Quality of Life. Health-related quality of life was measured by the Medical Outcomes Study 36-item Short-Form Health Survey (SF-36).[211] This is a 36-item measure of overall health status. It includes scales targeting the following eight dimensions: bodily pain, physical functioning, role limitations due to physical health, social functioning, general mental health, role limitations due to emotional problems, vitality, and general health perceptions. Each scale score was re-coded into a 0 to 100 score, oriented so that high values represent more favorable states. All the questions were framed to the previous four weeks. Several studies have reported about the appropriateness and validity of this generic instrument for the evaluation of overall health status in arthritis. Reported psychometric properties are: validity (correlation coefficients ranging from 0.39 to 0.85), internal consistency (Cronbach's alpha 0.73 to 0.96 for the different scales) and test-retest reliability (correlation coefficients ranging from 0.60 to 0.90).[211,226]

The scale of general health perception was used as a measure of *patient's global assessment of disease activity*, which was one of the main outcomes in this study (see analysis section). This scale is comprised of five items that provide an evaluation of the impact of health problems – arthritis in this case – and contains items such as: "I am as healthy as anybody I know" or "I expect my health to get worse" (Table 10). Again, the score for the scale was re-coded into a 0-to-100 scale, oriented so that high values represent more favorable states.

To evaluate if this scale was measuring what it was purported to measure (i.e., global assessment of disease activity, for the purpose of this study), we assessed the construct (predictive) validity of the scale. The hypothesized relationships were tested between the general health scale and other health status measurements using product-moment (Pearson's) correlation coefficients. It was hypothesized that, for the scale to represent the construct of global assessment of disease activity, the general health scale would show negative correlations with pain, disability, and perception of vitality and energy. Table 2 in manuscript 2 (Appendix B) shows the correlation coefficients for the association between the SF-36 general health scale and other health status measurements. All observed correlations were as hypothesized supporting the (construct) validity of this scale as a measure of global assessment of disease activity.

Table 10. SF-36 General Health Perceptions Scale [211]

In general, would you say your health is...
- ☐1. Excellent
- ☐2. Very good
- ☐3. Good
- ☐4. Fair
- ☐5. Poor

How true or false is each of the following statements for you?

	Definitely true 1	Mostly true 2	Don't know 3	Mostly false 4	Definitely false 5
I seem to get sick a little easier than other people.	❍ 1	❍ 2	❍ 3	❍ 4	❍ 5
I am as healthy as anybody I know.	❍ 1	❍ 2	❍ 3	❍ 4	❍ 5
I expect my health to get worse.	❍ 1	❍ 2	❍ 3	❍ 4	❍ 5
My health is excellent.	❍ 1	❍ 2	❍ 3	❍ 4	❍ 5

Positive and Negative Affect. For this study, positive and negative affect was also measured using the Positive and Negative Affect Schedule (PANAS).[122] This is a brief instrument that will be used to assess, by means of two 10-items scales, the primary dimensions of mood – PA and NA (See a more detailed description in the previous section). Participants were asked to rate on a five-point scale (very slightly or not at all, a little, moderately, quite a bit, and very much) the extent to which they experienced each mood state during the previous week. It has demonstrated to have high internal consistency (Cronbach's alpha ranging from 0.84 to 0.90) and appropriate test-retest reliability (coefficients ranging from 0.42 to 0.72, in 8-weeks retest interval).[122]

Depression. Depression was measured using the Beck Depression Inventory (BDI).[213] The BDI is a self- report of depressive symptoms. It is not designed to be used for the actual diagnosis of depression. The test contains 21 items, most of which assess depressive symptoms on a response scale of 0-3. Subjects were asked to report feelings consistent with their own over the past week. Clinical interpretation of scores is accomplished through criterion-referenced procedures utilizing the following interpretive ranges: 0-13 - minimal depression; 14-19 - mild depression; 20-28 -moderate depression; and 29-63 - severe depression.

Coping. Coping was evaluated using the Chronic Pain Coping Inventory (CPCI).[217] The CPCI assesses both cognitive and behavioral coping. The instrument is composed of 64 items distributed in four scales that target functional (adaptive or active) coping (coping self-statements, task persistence, relaxation, and exercise and stretch) and four that target dysfunctional (maladaptive or passive) coping practices (guarding, resting, asking for assistance, and seeking emotional support). These scales have shown good or excellent internal consistency and test-retest stability among patients with long pain duration.[217,227]

Social support. The level of perceived social support was measured using the Medical Outcomes Study Social Support Survey (MOS-SSS).[216] This 20-item instrument offers a brief indicator of the availability of five dimensions of social support: emotional support, informational support, tangible support, positive social interaction, and affection. The questionnaire is self-administered and uses five-point response scales (1=none of the time, 2=a little of the time, 3=some of the time, 4=most of the time, and 5=all of the time). The reported validity and reliability coefficients for this scale are as follows: validity (correlation coefficients with other symptomatological measures, 0.24 – 0.69), internal consistency (Cronbach's alpha, 0.91 to 0.96) and test-retest reliability (correlation coefficient=0.78).[228]

Perceived stress. Perceived stress was measured using the Perceived Stress Scale.[214] This was a ten-item abbreviated version of the instrument was administered to measure general feelings of stress at baseline and follow-up. This scale quantified the perception of situations in one's life as unpredictable, uncontrollable, and taxing. Items asked participants how often in the last month they felt unable to control important things in life, deal with daily hassles, cope with life changes, handle personal problems, control irritations, and overcome difficulties, and also how often they felt that things were going well and when they were "on top of things." Responses were provided on a 5-point scale anchored by 1 (never) and 5 (almost always). The reported validity and reliability coefficients for this scale are as follows: validity (correlation coefficients with other symptomatological measures, 0.52 to 0.76), internal consistency (Cronbach's alpha, 0.84 to 0.86) and test-retest reliability (correlation coefficient, 0.85).[214]

The Psychosocial Determinants of Health Services Utilization Study

Potential participants were contacted over the telephone by a researcher from the Arizona Arthritis Center (AAC) or the Department of Psychology at the Arizona State University (DPASU). The project was explained to subjects who, at the same time, were asked for permission to be mailed a packet with further details about the study, a HIPAA authorization and a consent form. Data collection procedures, which started once the signed consents were returned back, were slightly different for the two participating centers, due to particular logistic arrangements at each center. However, all participants received and answered the same questions using the same instruments.

At the AAC, subjects were asked to answer questions, during a 10 to 15 minute phone interview about their perceived health status (pain, fatigue, global assessment of disease activity) and health care services utilization (HCSU) during the previous six months. Subjects were also asked to complete a short questionnaire that evaluated health-related quality of life, physical function and affective status, and type of insurance. At the DPASU the same information was fully collected during an approximately 25 to 30 minute phone interview.

Measures

Baseline variables

Baseline variables were used as predictors or independent variables. Both original studies measured similar dimensions and, in most cases, with the same instruments. The databases corresponding to each of the studies were pooled and the scores for variables with different instruments were standardized by dividing each particular score by the maximum score possible for the corresponding instrument.

In both studies, subjects had to assess their level of perceived pain during the previous week on a 0 to 100 visual analogue scale (VAS). Functional status was evaluated using the Stanford Health Assessment Questionnaire (HAQ).[153] Positive and negative affects were measured using the Positive and Negative Affect Schedule (PANAS),[122] the construct of Learned Helplessness with the Arthritis Helplessness Index (AHI),[104] and perceived social support with the Medical Outcomes Study Social Support Survey (MOS-SSS).[216] The measure for depression in the SNIF study consisted of nine items taken from the Mental Health Inventory;[212] in the LHWA study depression was assessed using the Beck's Depression Inventory (BDI).[213] Perceived stress in the SNIF study was measured asking three questions: (1) Overall, how stressful were your relations with your spouse (or significant other) this past week? (2) Overall, how stressful were your relations with your family members this past week? And (3) overall, how stressful were your relations with friends this past week?; in the LHWA it was measured using the Perceived Stress Scale.[214]

Followup variables (outcome)

During the interview, HCSU was assessed. Participants were asked to report the number of times they accessed a series of listed health care services during the six months previous to the followup interview. The list of services comprised ten services or providers including: family doctor, specialist physician, nurse practitioner/physician assistant, physical/occupational therapist, lab tests, home care nurse, x-rays/CT scans/MRI scans, hospitalization, emergency room, urgent care and surgery. For the purpose of the analysis presented in this dissertation, a score was derived from the sum of the items referring to outpatient visits (i.e., visits to a family doctor, specialist physician, nurse practitioner/physician assistant, or physical/occupational therapist). This score, referred to as "outpatient visits", was used as a dependent variable. Similar scales have been extensively used for the evaluation of health care utilization in arthritis.[183,188-191]

In addition to the measure of HCSU, subjects rated their current level of pain, fatigue and global assessment of disease activity using 0 to 100 scales. Perceived level of health-related quality of life at follow-up, as referred to the previous four weeks, was measured using the 36-item Short-Form Health Survey (SF-36),[211] physical function using the HAQ and affective status using the PANAS. Finally, participants were asked about their current type of health insurance.

Performance of the Measurement Instruments in our Samples

We evaluated the performance of all the instruments used in each of the data source studies. For this purpose, we obtained internal consistency and test-retest –

whenever the instrument was applied more tan once – reliability coefficients for each of the instruments. Table 11 summarizes these findings. Additionally we evaluated construct validity for the PA and NA scales and the general health subscale of the SF-36 instrument (see details in data collection and analysis sections, and in appendices A and B).

Table 11. Performance of Measurement Instruments: Reliability Coefficients (Internal Consistency and Test-Retest)

Instruments	Internal Consistency (Cronbach's alpha)		Test-retest Reliability (Intraclass Correlation)	
	Study 1	**Study 2**	**Study 1**	**Study 2**
HAQ [153]	–	0.87	–	0.81
SF-36 scales [211]	–	0.74 to 0.86	–	0.67 to 0.88
MHI Depression [212]	0.91	–	–	–
MHI Anxiety [212]	0.86	–	–	–
BDI [213]	–	0.75	–	0.89
AHI [104]	0.65	–	–	–
PSS [214]	–	0.81	–	0.78
ASI [215]	0.88	–	–	–
MOS-SSS scales [228]	–	0.81 to 0.95	–	0.77 to 0.83
CPCI scales [217]	–	0.78 to 0.92	–	0.78 to 0.87
PANAS Positive Affect [122]	0.81	0.90	0.72	0.77
PANAS Negative Affect [122]	0.83	0.83	0.51	0.66
NEO-PI-R Extraversion [218]	0.87	–	–	–
NEO-PI-R Neuroticism [218]	0.87	–	–	–

Study 1= The Interpersonal Stress and Disease Activity in Arthritis Study; Study 2= The Living Healthy with Arthritis Study.

VAS= Visual Analogue Scale; ***HAQ****= Stanford Health Assessment Questionnaire;* ***SF-36****= MOS 36-item Short-Form Health Survey;* ***MHI****= Rand Mental Health Inventory;* ***AIMS****= Arthritis Impact Measurement Scales;* ***BDI****= Beck Depression Inventory;* ***AHI****= Arthritis Helplessness Index;* ***PSS****= Perceived Stress Scale;* ***ASI****= Arthritis Support Inventory;* ***MOS-SSS****= Medical Outcomes Study Social Support Survey;* ***CPCI****= Chronic Pain Coping Inventory;* ***PANAS****= Positive and Negative Affect Schedule;* ***NEO-PI-R****= NEO Personality Inventory*

Section 3.4 - DATA MANAGEMENT

Study 1: The Interpersonal Stress and Disease Activity in Arthritis Study

Data were collected from the weekly phone interviews, the nurses' interviews at weeks of increased stress, and baseline questionnaires. All data were entered by trained personnel using SPSS data templates. As standard quality control procedure, double key entry was performed on 10% of all documents. All files were reviewed by the data management supervisor for errors, and standard protocols were enacted to examine all files for out of range values, shifts in columnar entry, and other common human errors made in keying in data. Crude data were stored in SPSS files and analyses performed from copies of this original source.

Study 2 and 3: The Living Healthy with Arthritis Study and The Psychosocial Determinants of Health Services Utilization Study

Part of the data from "Living Healthy with Arthritis Study" and all the data for "The Psychosocial Determinants of Health Resources Utilization Study" were managed using the Outcomes Research Management Information System (ORMIS) at the Arizona Arthritis Center. ORMIS is a relational database application designed for efficient data collection and analysis. ORMIS allows projects to collect multiple questionnaires for each participant, with each questionnaire containing multiple research instruments. Instruments can then be used systematically for cross-sectional and longitudinal analyses.

Data can be entered into ORMIS in a variety of ways. Subjects can complete and submit questionnaires directly using the online ORMIS interface. Subjects can alternatively fill out paper questionnaires, which can be scanned and verified by research staff before being imported. Staff can supplement questionnaire data with additional information, such as patient medication usage, directly through the online ORMIS interface. Hard copy scanning and verification use TELEform Enterprise 8.0, a network Optical Character Recognition (OCR) software application. All data is stored in a Microsoft Access 2000 database, but can be converted to Oracle 9i and also extracted into outside statistical packages, such as SPSS 11.5 for Windows. The databases are stored and secured within one of the Arizona Arthritis Center network servers. The system is backed up regularly with back-up tapes stored in a secured area with controlled access.

Data for the Living Healthy with Arthritis Study were originally entered by hand with random checks of 10% of the questionnaires searching for data entry errors, inconsistencies and out of range values. Data were stored in a SPSS file and later transferred to a Microsoft Access database using the ORMIS system. Data from the phone interviews in "The Psychosocial Determinants of Health Resources Utilization Study" were directly entered to a Microsoft Access 2000 database using the ORMIS interface. The telephone interviews were conducted following a standard script with the research assistant directly entering data into the database. Mailed questionnaires were scanned and entered using TELEform Enterprise 8.0 software. A research assistant verified all data entry following the cues prompts by TELEform. A project investigator then verified a 20% random sample of the entered questionnaires. Appropriate variables were extracted from the database and converted into SPSS files for analysis.

Section 3.5 - DATA ANALYSES

Analysis Strategy: Specific Aim 1

The first specific aim for this dissertation was to longitudinally analyze the relationships between affectivity (i.e., positive affect [PA] and negative affect [NA]) and pain perception in persons with arthritis. The null hypothesis that was tested stated that arthritis patients with higher levels of PA (and lower levels of NA) would report same levels of pain in a 12-week followup as compared with subjects reporting lower levels of PA.

Longitudinal Data Analysis: Model Selection

Longitudinal data with repeated observations were available for this analysis. Specifically, 12 weeks of repeated observations obtained from 105 subjects with OA. We could have used simple / multiple linear regression to test if there was a linear association between affect and pain perception, but this technique assumes that each of the primary observations that make up the data set is independent of all others [229] (i.e., the errors of different measurements on the same individual must be assumed to be uncorrelated). However, this assumption was inappropriate for our sample of repeated observations, because observations within an individual could be correlated with one another.[230] Table 12 shows the coefficients for the correlation between weekly pain scores in our sample of subjects with OA. As expected, scores closer in time showed stronger correlations. The Intraclass Correlation Coefficient for the series of weekly measurements of pain perception (dependent variable) was 0.72. The same coefficient for our primary predictor (i.e., PA) was 0.66.

Table 12. Correlations between scores of pain perception at each followup week

	Pain 1	Pain 2	Pain 3	Pain 4	Pain 5	Pain 6	Pain 7	Pain 8	Pain 9	Pain 10	Pain 11
Pain 2	0.69										
Pain 3	0.71	0.81									
Pain 4	0.72	0.69	0.76								
Pain 5	0.53	0.65	0.64	0.77							
Pain 6	0.60	0.66	0.66	0.80	0.74						
Pain 7	0.63	0.67	0.70	0.68	0.63	0.65					
Pain 8	0.58	0.68	0.65	0.69	0.63	0.70	0.78				
Pain 9	0.69	0.69	0.68	0.74	0.72	0.78	0.80	0.84			
Pain 10	0.64	0.65	0.62	0.77	0.63	0.79	0.68	0.70	0.85		
Pain 11	0.57	0.63	0.66	0.73	0.70	0.74	0.63	0.77	0.83	0.83	
Pain 12	0.54	0.60	0.67	0.69	0.62	0.72	0.68	0.67	0.74	0.79	0.81

All coefficients were statistically significant at the 0.01 leve (Pearson's coefficients)
Pain 1 = Pain score at week 1, and so on

If we had used a standard statistical analysis technique (i.e., multiple linear regression) on our serially-correlated data, the estimates for the standard errors would have likely been too small.[231] One potential valid approach to analysis would have been to resolve the repeated measurements in each individual by creating a single summary statistic (e.g., mean, difference, or slope);[229] however, such summary statistics only use part of the available information. We sought a statistical technique that could utilize the full information content of the data set without exaggerating the apparent sample size and still maintain the original structure of the data.[229]

Analysis of longitudinal or repeated measures data for balanced study designs, or when all subjects are measured at equal times and there are no missing observations, can be done using repeated measures ANOVA or MANOVA.[232] However, we did not have a balanced design. There was a sizable amount of missing data (i.e., 16.2% for the dependent variable, and 21.1% for PA), which needed to be taken into account for analysis strategies and model selection. In general, we assumed missed data were missing completely at random for all subsequent analyses.

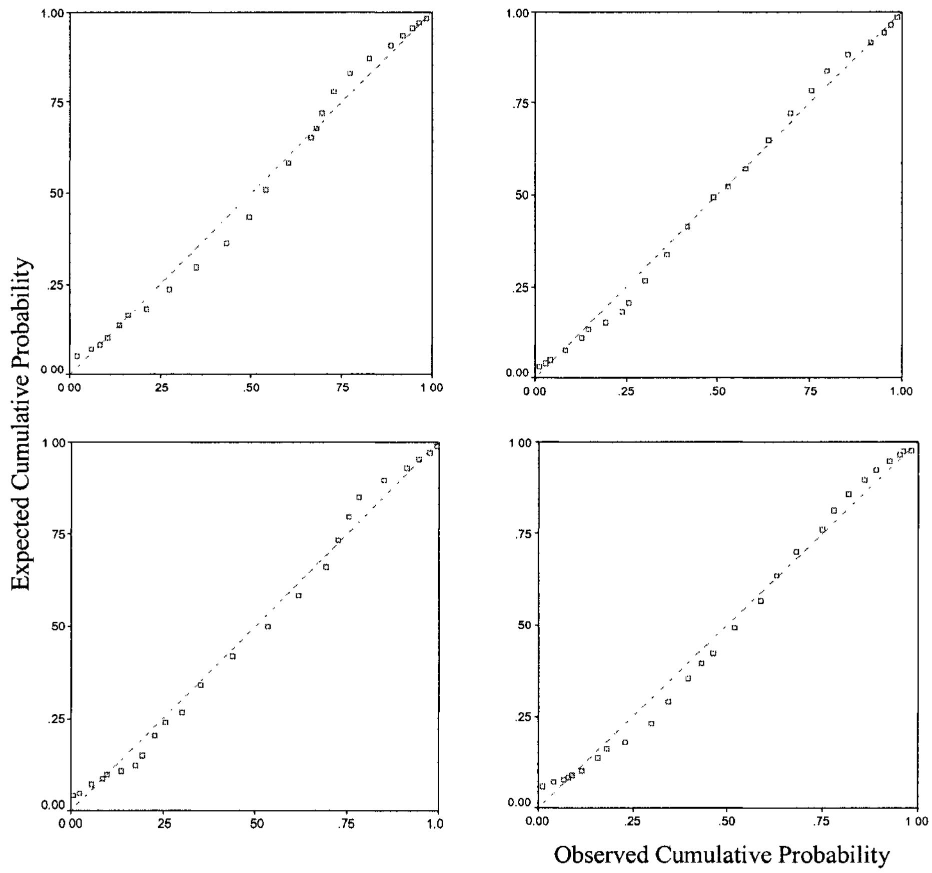
Table 13. Mean, SD, Skewness, and Kurtosis for Pain at Weeks 1 to 12

Pain 0 to 100 scale	Mean	SD	Skewness		Kurtosis	
			Statistic	SE	Statistic	SE
Pain 1	44.91	26.47	0.39	0.24	-0.74	0.47
Pain 2	44.38	26.93	0.27	0.24	-0.90	0.47
Pain 3	44.00	27.85	0.27	0.26	-0.91	0.51
Pain 4	44.93	24.06	0.22	0.26	-0.84	0.51
Pain 5	44.85	25.26	0.25	0.25	-0.81	0.50
Pain 6	44.25	25.49	0.28	0.25	-0.93	0.49
Pain 7	42.98	25.31	0.28	0.25	-0.96	0.50
Pain 8	45.47	24.92	0.10	0.26	-0.82	0.51
Pain 9	42.80	25.66	0.32	0.26	-0.73	0.52
Pain 10	44.58	25.42	0.35	0.25	-0.84	0.50
Pain 11	45.36	27.73	0.28	0.25	-0.95	0.49
Pain 12	39.94	24.57	0.39	0.26	-0.92	0.51

SD= standard deviation; SE= standard error; Pain 1= Pain score at week 1, and so on.

Finally, our dependent variable was fairly normally distributed. Table 13 shows the mean and standard deviation for the pain scores corresponding to each week along with the statistics for skewness and kurtosis with their corresponding standard errors. Tests for normality are complicated by the longitudinal nature of the data, but normal or probability plots at selected intervals can provide insight into the underlying data structure.[232] Figure 5 shows normal probability plots (P-P plots) for the dependent variable at four selected weeks.

Figure 5. Normal probability plots for pain (P-P plots; Selected weeks)



Taking into consideration the longitudinal characteristics of the data, the amount of missing data, and the continuous nature of the outcome, a Random Effects Model procedure was used. This method constitutes an extension of the General Linear Model but allows the serial correlation of outcomes within-subjects to be estimated and taken into appropriate account in the formulae that generates the regression coefficients and their standard errors. We assumed that all subjects had similar slopes with intercepts varying randomly. A first-order random effects was included, which allows subjects' intercepts to be random but not their slopes.[232]

Analysis

Initially, plots showing the relationship of each predictor variable with the dependent variable were generated at each weekly evaluation. To further explore the longitudinal associations between affect and pain at the different weekly evaluations, correlation matrices were obtained, which were also used to check for potential collinearity among predictors. Next, multivariate procedures evaluated the relationship between the predictors of interest (i.e., affect) and the dependent variable (i.e., pain) controlling for demographic variables and other baseline characteristics, including the following psychosocial factors: extraversion, neuroticism, depression, anxiety, helplessness, social support and perceived stress. Pain was evaluated as the "current level of arthritis pain"; PA and NA were evaluated with the time frame being the "previous week." Thus the analyses performed modeled "current" levels of pain to PA and NA perceptions during the "previous week" for the 12 weeks of followup.

A series of interaction terms were entered in the models, including: PA x NA, extraversion x neuroticism, PA x extraversion, PA x neuroticism, NA x neuroticism and NA x extraversion. STATA 6.0 XTREG (STATA Corp., College Station) procedure was used for the longitudinal analysis and SPSS 11.5 (SPSS Inc., Chicago) for the remainder of the analyses.

Validity of the Positive and Negative Affect Schedule (PANAS)

Internal consistency (Cronbach's alpha) and test-retest (intraclass correlation) reliability coefficients were estimated for all the instruments used in the study. Additionally, we evaluated the validity of the PANAS in our sample of subjects with OA. Construct (predictive) validity of the PANAS scales were evaluated using product-moment (Pearson's) correlation coefficients between the scales and the other psychosocial instruments. On the basis of the literature, it was hypothesized that PA would show positive correlations with extraversion and perception of social support and negative correlations with negative affect, perceived stress, neuroticism, anxiety, depression, and perception of helplessness. In turn, it was hypothesized that NA would show positive correlations with perceived stress, neuroticism, anxiety, depression, and helplessness; and negative correlations with extraversion and social support.

Analysis Strategy: Specific Aim 2

The second specific aim for this dissertation was to determine the role of PA as a predictor of health outcomes in the context of a health intervention for arthritis. The null hypothesis that was tested was that "arthritis patients that reported high levels of PA would be as likely to achieve minimal clinically important changes in pain, physical function and global assessment of disease activity as subjects reporting lower levels of PA, after their participation in a health intervention." Data from 89 subjects with arthritis that participated in a prospective cohort study with an interventional component were used for the analyses.

Instruments' Psychometric Properties

Before proceeding with the analyses, we evaluated the reliability of the instruments used in the study. For this purpose, we obtained internal consistency (Cronbach's alpha) and test-retest (Intraclass Correlation) reliability coefficients for all the instruments used in the study. The scale of general health perception was used as a measure of patient's global assessment of disease activity, which was one of the main outcomes in this study (see below). To evaluate if this scale was measuring what it was purported to measure (i.e., global assessment of disease activity, for the purpose of this study), we assessed the construct (predictive) validity of the scale. The hypothesized relationships were tested between the general health scale and other health status measurements using product-moment (Pearson's) correlation coefficients. It was hypothesized that, for the scale to represent the construct of global assessment of disease activity, the general health scale would show negative correlations with pain, disability, and positive with perception of vitality and energy.

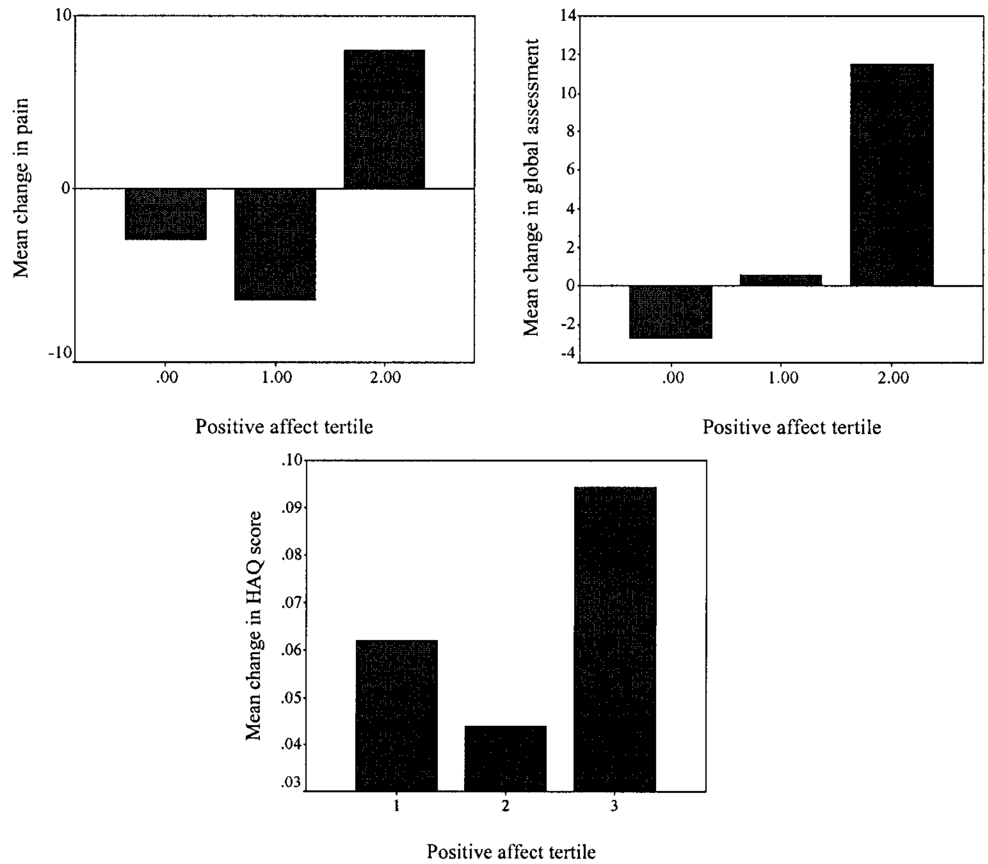
Classification of Outcomes

The goal was to determine whether or not there was a relationship between PA (main predictor) and changes in pain, physical function, or global assessment as measured by the SF-36 general health perceptions scale (dependent variables). We were interested in changes that were not only statistically significant but also clinically meaningful. For this reason, the dependent variables were dichotomized based on definitions for minimal clinically important differences (MCID). Using standard definitions of MCID, we defined a MCID as a ten units improvement on the 0 to 100 scales for pain [170-172] and health-related quality of life (SF-36 scales) [173-175] and 0.2 units improvement on the 0 to 3 scale for physical function (HAQ). [174,176] The outcome was then defined as 1=MCID achieved or 0=no MCID achieved.

Classification of Exposures

The independent predictor variable of interest was PA, which was collected as a continuous variable. Due to the fact that the observed relationships between PA and changes in outcomes (i.e., difference between baseline and three months in pain, global assessment of disease activity, and physical function) were not completely linear (see Figure 6), PA was transformed into tertiles. It was observed that subjects in the low and middle tertile had a similar response (Figure 6). The variable of PA was then dichotomized into: 0=lower plus middle tertile and 1=upper tertile. Subsequently, comparisons were made between subjects in the higher vs. the middle and lower tertiles combined.

Figure 6. Mean Change in Outcomes and Positive Affect Tertiles



Model Selection

We performed univariate and multivariate stepwise logistic regression analyses to test for the hypothesized relationships between PA and the binary outcome variables, adjusted for demographic variables and other psychosocial constructs. Odds ratios (OR) and 95% confidence intervals (CI) were estimated from the logistic model regression coefficients. Different models were fitted for each of the three dependent variables (i.e., MCID in pain, global assessment of disease activity, and physical function). To determine how well the different models fitted the data, we used the Hosmer-Lemeshow goodness-of-fit test.[233] The null hypothesis for this test was that "the model fits the data"; if the null hypothesis could not be rejected – at the 0.05 significance level – it was concluded that the model fitted the data.

Logistic regression is a widely used technique to adjust for confounders, not only in case-control studies but also in cohort studies.[234] However, logistic regression yields an OR rather than a relative risk (RR), even in a cohort study. When the outcome of interest is common in the study population (i.e., > 10%), the adjusted OR from the logistic regression may exaggerate a risk association or a treatment effect.[235] In our sample, the outcomes of interest were present in more than 10% of the sample. To address this issue we could have used the Mantel-Haenszel method,[236] which can adjust for one or two confounders. However, this method becomes inefficient when several factors, especially continuous variables, are being adjusted for simultaneously.[235] For this reason we used the method recently proposed by Zhang and Yu to approximate a RR from the adjusted OR and derive an estimate of an association or treatment effect that better represents the true RR even in multivariate analysis.[235] This method uses the following formula to obtain a corrected estimate of the RR: $RR = \frac{OR}{(1 - P_0) + (P_0 \times OR)}$; Where, P_0 indicates the incidence of the outcome of interest in the nonexposed group. This method can also be used to correct the lower and upper limits of the 95% CI applying this formula to the lower and upper confidence limits of the adjusted OR.

Analyses

Two general strategies were utilized in this study. One treated the outcome variables as continuous measures and the second strategy utilized the definition of MCID to produce binary variables and proceed with logistic regression analyses. First, data at baseline were compared with data obtained at three months post-intervention for the whole sample by means of paired t-tests. As mentioned, the sample was subdivided in two groups based on PA tertiles. T-tests for independent samples (for continuous variables) and Chi-square tests (for categorical variables) were performed to compare baseline characteristics between the two affect subgroups (i.e., upper [high PA group] vs. middle plus lower [low PA group] tertiles). Effect size, which is a measure of treatment effect, was calculated for the different outcome measures by affect subgroup, according to the formula: effect size=mean change/standard deviation of pre-intervention scores;[237] and Mann-Whitney U test performed to test differences in change scores between the "high" and "low" PA subgroup.

Next, product-moment correlation coefficients (Pearson's) were obtained to test for associations between PA and other psychosocial variables at baseline, and to initially evaluate associations between baseline variables and changes in each of the outcomes. Finally, univariate and stepwise multivariate logistic regression procedures were performed to test for the association between PA (dichotomized as mentioned above) and changes in pain and the other outcomes (dichotomized based on the definition of MCID). SPSS 11.5 (SPSS Inc., Chicago) was used for all these analyses.

Analysis Strategy: Specific Aim 3

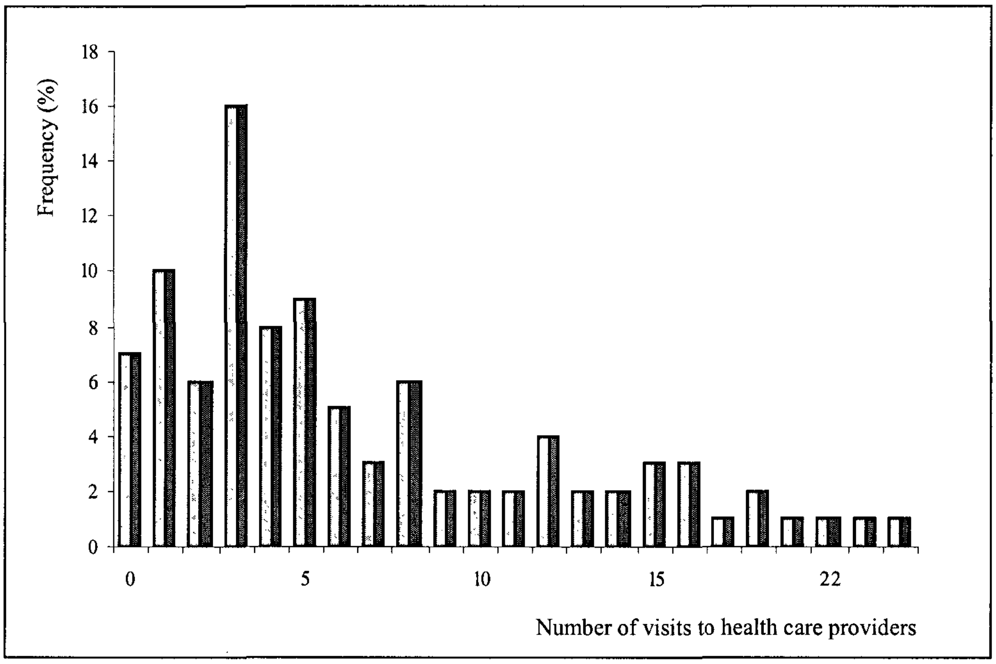
The third specific aim for this dissertation was to determine the role of PA as a predictive factor for future use of health care services. The null hypothesis that was tested stated that arthritis patients with higher levels of PA (and lower levels of NA) would report same levels of health care services utilization as compared to subjects with lower levels of PA (and higher levels of NA). Data from 101 subjects with arthritis surveyed approximately seven years after their participation in two previous studies were used for these analyses.

Definition of Outcome

The goal was to determine whether or not there was a linear relationship between PA (main predictor) and future use of health services (dependent variable). Participants reported the number of times they accessed a series of health care services during the six months previous to the followup survey, including: family doctor, specialist physician, nurse practitioner/physician assistant, physical/occupational therapist, lab tests, home care nurse, x-rays/CT scans/MRI scans, hospitalization, emergency room, urgent care and surgery. A summary score ("outpatient visits") was derived from the sum of the items referring to outpatient visits (i.e., visits to a family doctor, specialist physician, nurse practitioner/physician assistant, or physical/occupational therapist). Figure 7 shows a histogram of the number of outpatient visits in this population. The mean number was 7.63 visits (SD=8.42 visits). Although somewhat skewed to the right, the distribution of the dependent variable was fairly normal (kurtosis=1.41± 0.25 SE; and skewness=1.84±

0.48 SE). While there were no clear outlier observations; there were four subjects with >20 outpatient visits in the previous six months – two of them had a PA score of approximately 20 (low PA), and the other two a PA score of approximately 40 (high PA), on a scale of 10 to 50. Only 7% of the sample reported no outpatient visits in the previous six months.

Figure 7. Histogram for "Number of Visits to Health Care Providers"



Comparability of Participants with Eligible Population

A total of 101 subjects participated in this follow-up study, which constitutes 25.9% of the subjects that participated in the two original studies. To rule out the presence of participant bias, we compared the baseline characteristics of those that were recruited into the study with those that were not recruited. Table 14 compares the two groups for selected demographic and psychosocial characteristics. The scores for those variables measured in the two parent studies with different instruments were standardized by means of dividing each particular score by the maximum score possible for the corresponding instrument.

Table 14. Comparison of recruited vs. non-recruited subjects

	Participants (n=101)		Non-Participants (n=283)		
	Mean	***SD***	***Mean***	***SD***	***p-value ****
Age	65.91	8.60	64.44	7.93	0.125
Disease duration	16.89	11.25	15.66	13.23	0.510
Education(0 to 8)	5.77	1.57	5.52	1.56	0.182
Income (0 to 100)	68.94	26.33	70.07	25.62	0.788
Pain	36.99	23.61	44.14	26.07	0.033
Physical function	0.87	0.58	0.99	0.75	0.184
Positive affect	33.31	8.06	31.84	7.30	0.101
Negative affect	16.59	5.62	16.75	5.99	0.820
Anxiety	44.95	15.32	47.41	16.69	0.269
Depression	37.45	13.28	40.59	17.42	0.154
Perceived stress	33.22	22.36	23.63	22.47	0.001
Social support	74.35	17.14	70.88	18.64	0.110
Helplessness	48.59	19.34	52.29	17.79	0.158

SD = Standard deviation
* *p-value for test of significance using t-test for independent samples*

Predictor Variables

Demographic, health status, and psychosocial variables collected at baseline in the two original studies were used as predictors or independent variables for the analyses. The dependent variable was future "outpatient visits" as defined above. PA was the predictor variable of interest. Correlation matrices among predictors were obtained to initially test for associations and potential collinearity. Additionally, to further test for collinearity, tolerance statistics were obtained with the multivariate procedures.

Linear Regression Modeling

Linear regression and stepwise multivariate procedures were then performed to test for the association between affectivity at baseline and future "outpatient visits" (i.e., number of visits to health care providers reported for the six months previous to the followup survey). The multivariate procedures evaluated the relationship between the predictors of interest (i.e., positive and negative affect) and future "outpatient visits", controlling for demographic, health status, and other psychosocial characteristics at baseline. Variables found in previous research to be significant predictors for services utilization such as: age, education, income level, functional status, anxiety, and depressive symptoms were considered for inclusion. First, a series of models were fitted for each of the predictors adjusted by age, income, and level of education. The final model was obtained using a backwards stepwise procedure. Compared with forward selection, this method provides a better description if two or more variables together provide good prediction but each variable individually is less effective.[238] The stepwise method criteria that were used were based on the probability for the F statistics (from the ANOVA test) with the probability of entry set at 0.05, and the probability of removal set at 0.1.

Different models were fitted with the inclusion and exclusion of variables that were highly correlated to others. When a variable was highly correlated with another, two different models were produced for each of these variables. We evaluated for the presence of a potential effect modification of the association between positive affect and "outpatient visits" due to the different study source (i.e., a potential different relationship between PA and outpatient visits depending on study source) by means of entering an interaction term in the univariate and multivariate models.

A series of plots were generated to test for the appropriateness of the linear regression model. First, plots of residuals versus each of the independent variables in the final model were created to test for linearity, normality, homoscedasticity, independence of residuals (i.e., assumption that the residuals have constant variance), and presence of outliers. Figure 8 shows a plot of residuals vs. PA. Second, histograms and normal probability plots of the residuals were created to test for normality (Figure 9 and 10). SPSS 11.5 (SPSS Inc., Chicago) was used for all these analyses.

Figure 8. Plot of Positive Affect Scores against Regression Residuals

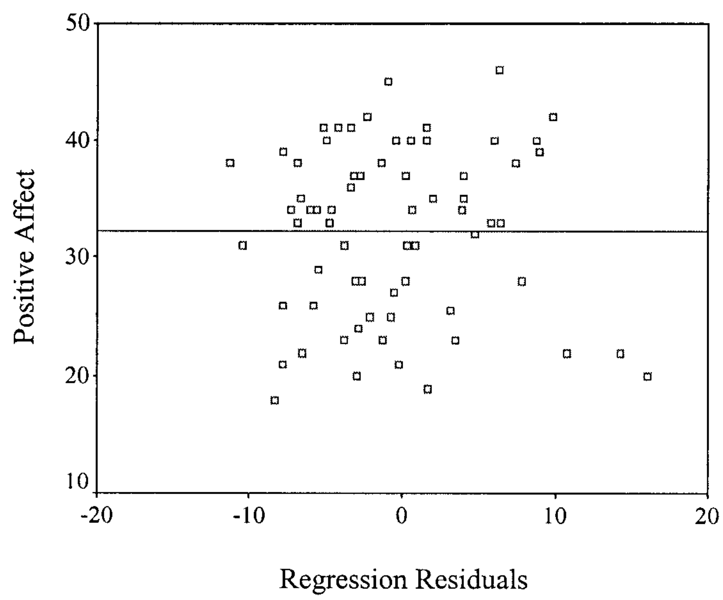


Figure 9. Histogram for Regression Residuals (Final Model)

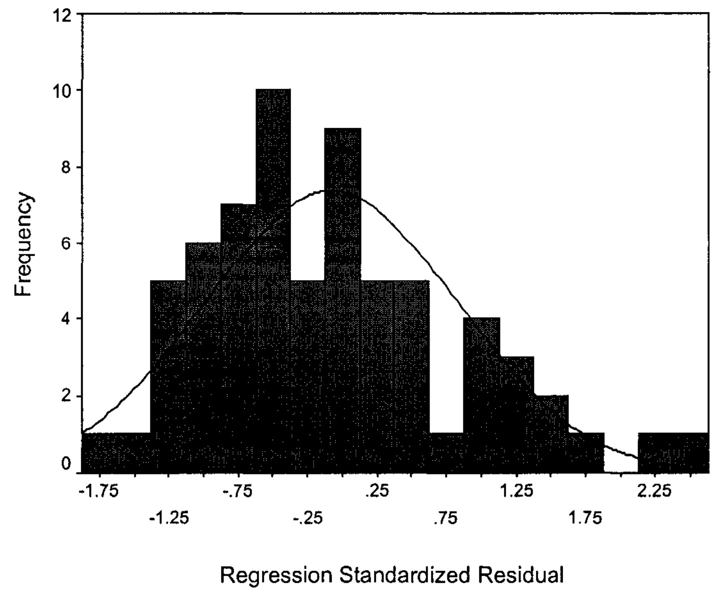
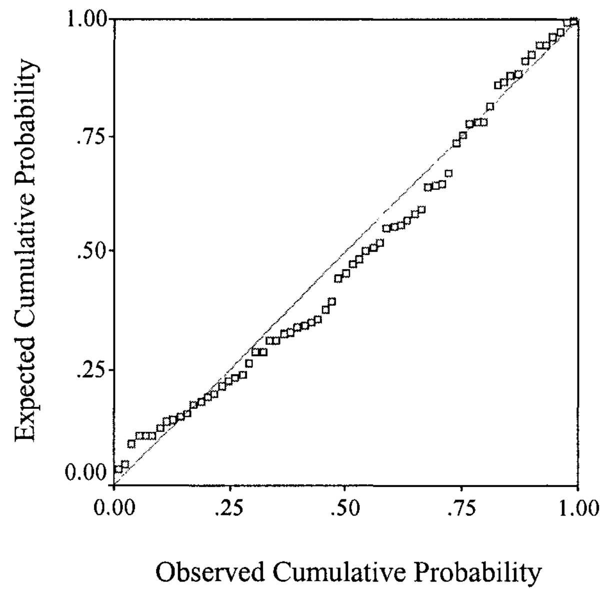


Figure 10. Normal Probability Plot for Regression Residuals



CHAPTER 4

RESULTS

The results and conclusions of this study are fully detailed in the three papers appended to this dissertation (Appendices A, B and C). The following is a summary of the most relevant findings in these papers.

Specific aim 1

The aim was to analyze the predictive role of affectivity (i.e., positive affect [PA] and negative affect [NA]) on level of pain perception in osteoarthritis (OA) patients over a 12-week period. A total of 105 women with OA with a mean age of 65.2 (range, 42 to 75) and mean disease duration of 13.4 years (SD= 11.0 years) were recruited into the study.

Using random effects modeling, baseline level of PA, NA, anxiety, depression, helplessness, and perceived stress were statistically significantly associated with level of self-reported pain (Table 15). In a multivariate random effects model, adjusting for other psychosocial and demographic covariates, both PA and NA were associated with level of perceived pain (see Table 4 in Appendix A); PA showed a negative (β=-4.27; $p<0.001$) and NA a positive (β=5.33; $p<0.001$) association with levels of perceived pain. Level of income was also significantly associated with the perception of pain in this model (i.e., the higher the level of income the lower the amount of pain perceived) (β=-4.21, SE=1.09; $p<0.001$). Additionally, neuroticism, anxiety, perception of helplessness all had statistically significant coefficients (see Table 4 in Appendix A).

Table 15. Univariate Predictors of Pain over a 12-Week Follow-Up of Women with Osteoarthritis

Models	***Coefficient***	***SE***	***p***	***95% CI***	
Positive affect (1 to 6)	-5.69	0.91	<0.001	-7.48	-3.89
Extraversion (1 to 4)	-2.27	6.24	0.716	-14.49	9.95
Negative affect (1 to 6)	6.60	1.01	<0.001	4.62	8.58
Neuroticism (1 to 4)	4.82	5.10	0.345	-5.18	14.81
Anxiety (1 to 5)	10.08	2.36	<0.001	5.44	14.71
Depression (1 to 5)	6.99	2.40	0.004	2.27	11.70
Helplessness (1 to 6)	8.05	1.94	<0.001	4.25	11.84
Social Support (1 to 4)	-4.39	3.14	0.163	-10.54	1.77
Perceived Stress (0 to 3)	2.25	1.07	0.036	0.15	4.35

Random Effects Models. STATA XTREG procedure; SE= Standard Error; CI= Confidence Interval

Table 16 shows the final, most parsimonious, model. In this model 22% of the overall variance were explained and 28% of the between-subjects variance of the level of pain perceived by subjects with OA (Table 16). PA, NA, anxiety, helplessness and income all were statistically significant independent predictors of level of pain reported over the 12 weeks.

Table 16. Predictors of Self-Reported Pain over a 12-Week Follow-up: Most Parsimonious Model

	Coefficient	***SE****	***p***	***95% CI***	
Positive affect	-3.90	0.756	<0.001	-5.38	-2.42
Negative affect	5.49	0.855	<0.001	3.81	7.16
Anxiety	4.81	1.880	0.010	1.13	8.50
Helplessness	5.50	1.458	<0.001	2.64	8.35
Income	-0.71	0.358	0.049	-1.41	0.00

Random Effects Model. STATA XTREG procedure; * Standard Error

Specific aim 2

The objective sought to determine the role of PA to predict clinically relevant outcomes after a four-week participation in a health intervention for arthritis. Eighty-six subjects with arthritis and mean age of 69.2 years (SD=7.0) completed the Living Healthy with Arthritis program. In this study we observed a better short-term response to the health intervention in individuals with higher levels of PA at study entry. Patients in the "high PA" group reported statistically significant and clinically relevant improvements in pain, global assessment of disease activity and physical function at the three months follow-up after a four-week health intervention that included exercise and self-management. In comparison, participants with lower levels of PA did not report statistically significant improvements in any of the evaluated outcomes.

Participants with higher levels of PA were more likely to achieve minimal clinically important differences (MCIDs) for pain, global assessment of disease activity and physical function than subjects with lower levels of PA. The results were specific for PA and not explained by other factors such as age, disease duration, marital status, education, level of NA, perceived stress, depression scores, perceived social support and baseline levels of pain, physical function or global assessment of disease activity.

Subjects in the highest tertile of PA were more than three times as likely to achieve a 10 units improvement in pain than subjects in the low PA group (Odds Ratio [OR]=3.3; 95% CI, 1.0 to 11.0). Adjusted for age, baseline level of pain and physical function, social support, and NA, subjects in the high PA group were six times as likely to achieve MCID in pain than subjects in the low affect group (Table 17).

Table 17. Predictors of Minimal Clinically Important Differences in Pain

	OR	p	95.0% C.I.	
			Lower	**Upper**
Positive affect : lowest + middle tertile	1.00	-	-	-
Positive affect: highest tertile	6.06	0.045	1.04	35.31
Physical function at baseline (0 to 3)	0.13	0.023	0.02	0.75
Pain at baseline (0 to 100 VAS)	1.07	0.000	1.03	1.12

Stepwise multivariate logistic regression adjusted for social support, negative affect and age
p value for Hosmer-Lemeshow goodness-of-fit test =0.898

Subjects in the highest PA tertile were five times as likely to achieve MCID in the global assessment of disease activity than subjects in the low PA group (OR=5.4; 95% CI, 1.6 to 18.4). Adjusted for age, global assessment of disease activity, pain, physical function, NA, perceived stress, and social support, subjects in the highest PA tertile group were almost seven times as likely to achieve a clinically relevant response in the arthritis global assessment of disease activity than subjects in the low affect group (Table 18).

Table 18. Predictors of Minimal Clinically Important Differences in Arthritis Global Assessment of Disease Activity

	OR	p	95.0% C.I.	
			Lower	**Upper**
Positive affect : lowest + middle tertile	1.00	-	-	-
Positive affect: highest tertile	6.91	0.004	1.84	25.92
Age (per unit change)	0.92	0.038	0.86	0.99

Stepwise multivariate logistic regression adjusted for baseline global assessment of disease activity, pain and physical function, negative affect, perceived stress, and social support
p value for Hosmer-Lemeshow goodness-of-fit test =0.708

Adjusted for age, disease duration and baseline physical function scores, subjects in the high PA group were 14 times as likely to achieve MCID than subjects in the low affect group (OR=14.5; 95% CI, 1.6 to 125.8). The multivariate logistic regression procedure including other psychosocial and health status variables showed that participants reporting the highest levels of PA group at baseline were 13 times as likely to report a 0.2 unit improvement in physical function, as measured by the Health Assessment Questionnaire, than subjects with lower levels of PA (OR=13.27; 95% CI, 1.7 to 102.1). This model also showed that older patients were less likely to achieve MCID; per each additional year of age the likelihood of achieving a 0.2 unit improvement in physical function decreased by 11 % (Table 19).

Table 19. Predictors of Minimal Clinically Important Differences in Physical Function

	OR	p	95.0% C.I.	
			Lower	**Upper**
Positive affect : lowest + middle tertile	1.00	-	-	-
Positive affect: highest tertile	13.27	0.013	1.72	102.15
Age (per unit of change)	0.89	0.024	0.81	0.98
Physical function at baseline (HAQ)	3.95	0.118	0.71	22.17

Stepwise multivariate logistic regression adjusted for: disease duration, baseline pain, negative affect, perceived stress, and social support
p value for Hosmer-Lemeshow goodness-of-fit test =0.417

Specific aim 3

The study objective was to determine the role of PA and other psychosocial variables measured at a baseline visit as predictors of outpatient visits after a long-term follow-up. A total of 101 subjects with inflammatory and non-inflammatory arthritis were recruited into this follow-up study. The average number of visits to health care providers over a 6-month period was 7.63 visits (SD 8.42), including visits to family doctors, specialists, nurse practitioners, and physical therapists.

Table 20. Relationship Between Baseline Psychosocial Variables and Number of Outpatient Visits in Last Six Months

	Coefficient	***SE*** ‡	***p***	***95% CI***	
Positive affect	-0.32	0.15	0.048	-0.63	0.00
Negative affect	0.19	0.28	0.505	-0.38	0.76
Anxiety	0.10	0.09	0.301	-0.09	0.28
Helplessness	0.06	0.08	0.419	-0.09	0.22
Social support	-0.12	0.07	0.093	-0.27	0.02
Pain	-0.07	0.06	0.230	-0.19	0.05
Physical function	2.22	1.99	0.273	-1.84	6.28
Disease duration	0.03	0.11	0.795	-0.19	0.25
Age	0.12	0.14	0.400	-0.17	0.40
Income	0.05	0.05	0.383	-0.06	0.15
Education level	-0.36	0.96	0.707	-2.31	1.58

‡ SE=Standard Error

Using multivariate linear regression adjusted for age, income, and education level, PA was the only variable associated with outpatient visits at followup at the $p<0.05$ level (Table 20). Higher levels of PA at baseline were associated with lower number of future contacts with health care providers ($\beta=-0.32$; $p=0.048$). Table 21 shows the final multivariate stepwise linear regression model. Higher levels of positive affect significantly predicted fewer outpatient visits (β=-0.29; p=0.04). Higher perceived social support and lower levels of anxiety were also associated with fewer outpatient visits (Table 21).

Table 21. Independent Predictors of Outpatient Visits at Followup. Final Model *

	Coefficient	***SE* ‡**	***p***	***95% CI***	
Positive affect	-0.29	0.13	0.041	-0.56	-0.01
Social support	-0.16	0.06	0.014	-0.28	-0.03
Anxiety	0.14	0.06	0.033	0.01	0.27

R = 0.51 ; Adjusted R-square = 0.20
* *Final model obtained using backwards stepwise linear regression*
‡ *SE=Standard Error*

CHAPTER 5

SUMMARY AND FUTURE DIRECTIONS

In summary, the analyses performed in the context of this dissertation have shown that the psychological dimension of positive affect (PA) is significantly related to: (1) level of pain perception on a 12-week period of assessment; (2) clinically relevant changes in level of pain, global assessment of disease activity, and physical function in response to a 12-week self-management arthritis intervention; and (3) usage of health care services, as measured by number of outpatient visits several years after the assessment of PA. Furthermore, these associations were consistent across the various study designs employed in this dissertation.

All these results are consistent with the model that we have proposed by which the association between PA, outcomes and health care seeking behavior can be explained by the effect of affective status on the use of specific coping strategies (i.e., PA would determine a higher use of adaptive strategies and lower use of maladaptive or passive strategies) and the perception of control or self-efficacy (i.e., higher levels of PA increasing the perception of control over the course of the disease).[127,239] These effects on coping and self-efficacy may explain the better outcomes and the lower level of interaction with the health care system for subjects with higher levels of PA. This model formed the core for the dissertation research that was undertaken.

Positive Affect and Pain Perception

PA showed a statistically significant inverse association with weekly assessments of pain perception. The relationship remained significant after adjusting for several other psychosocial and demographic variables including negative affect (NA), anxiety, and depression.

There is an extensive body of literature regarding the relationship between measurements of mental distress (i.e., anxiety and depression) and outcomes, not only for arthritis but also for many other chronic diseases. It has been reported that people with high levels of NA, which is highly related with anxiety, depressive symptoms and the personality trait of neuroticism, tend to have more negative cognitions, to use less effective coping strategies, and to have exaggerated perceptions of pain.[119,135] NA appears to inhibit performance on cognitive tasks, especially when the negative mood is intense and the task demands effortful and sustained processing.[136] The results of our study supports that the presence of high levels of NA, a state dimension, is a good indicator for increased pain perception in osteoarthritis (OA).

In recent years, there has been an increasing interest in the role of what it has come to be known as "Positive Mental Health" in symptom perception, other subjective disease experiences and even disease etiopathology and progression. However, not much research in this area has been devoted to arthritis, and even less to OA. PA is an aspect of positive mental health and reflects the extent to which an individual feels enthusiastic, active and alert. PA is represented as an affective state dimension but is also related to the corresponding personality trait dimension of extraversion.[122] PA has been found to be a good indicator of psychological well being in older adults with chronic arthritis.[120] PA has also been related with use of adaptive strategies for psychological adjustment to a chronic illness such as rheumatoid arthritis [126,127] and with patient self-efficacy expectations and disease adjustment in cancer patients.[128] In an earlier publication, we have proposed a model where lower levels of PA and higher levels of NA are associated with maladaptive coping, which, in turn, is associated with higher levels of reported pain and limitation.[127] PA has also been linked with creative, or divergent, thinking, which would facilitate creative problem solving.[130]

One limitation of this first study is its relatively small sample size. This limited the ability to get more precise estimates and to perform subset analyses. Another limitation is the homogeneity of the demographic characteristics of the recruited sample. In general, subjects were older, white, NonHispanic, women with a high educational and socio-economical background. This homogeneity does not invalidate the results, however it can limit their generalizability. Finally, the length of the followup (i.e., 3 months) in this longitudinal design may have been insufficient to fully characterize the hypothesized relationships. However, most prior studies investigating the role of psychosocial constructs in arthritis have used cross-sectional designs. Therefore, researchers studied differences between patients at the same point in time but, failed to explore the longitudinal associations between psychological profiles and subsequent symptoms perception or the changes over time in perception within the same individuals. Longitudinal designs permit a more thorough examination of the relationships between psychological dimensions and health status.

Positive Affect and Minimal Clinically Important Differences in Outcomes

We observed better short-term responses to a health intervention in individuals with higher levels of PA. Patients in the "high PA" group showed significant and clinically relevant improvements in pain, global assessment of disease activity, and physical function at three months follow-up after a four-week health intervention that included exercise and self-management components. In comparison, participants with lower levels of PA did not show significant improvements in any of the evaluated outcomes. Subjects in the highest tertile for PA were more likely to achieve minimal clinically important differences (MCID) for self-reported perception of pain, global assessment of disease activity, and physical function than subjects with lower levels of PA. The results were specific for PA and not explained by other factors such as age, disease duration, marital status, education, level of NA, perceived stress, depression scores, perceived social support, and baseline levels of pain, physical function, or global assessment. As far as we know only one study has previously analyzed the role of PA on treatment efficacy. In that randomized controlled trial, the experimental group focused on individualized and generic problem-solving approaches facing the subject and his/her family.[134]

These findings suggest that people with a favorable affective profile are more likely to benefit from psychobehavioral interventions. It is possible that people with higher levels of PA are more likely to improve or incorporate new health behaviors as a result of a health intervention, which could result in better outcomes. However, it has been shown that, in the context of a self-management intervention, changes in outcomes are not related with its positive effects on health behaviors,[91,92] but more associated with changes in self-efficacy.[93] As mentioned, PA has been shown to be related to adaptive strategies for psychological adjustment to a chronic illness such as rheumatoid arthritis,[126,127] and with patient self-efficacy expectations and disease adjustment in cancer patients.[128]

Limitations of this study are the open pre-post design and the relatively small sample size available for subgroup analyses. We do not believe, however, that having had a control group would have changed the observed results with respect to positive affect, but a larger sample could have helped in increasing the precision for estimates of the differences among subgroups.

Positive Affect and Future Outpatient Visits

We were able to predict a sizable amount of variance (20%) of outpatient visits with a small set of psychosocial variables. Positive affect, perceived social support and anxiety levels all contributed to the prediction of the number of outpatient visits in a long-term follow-up. Health care services utilization has been shown to be related to anxiety and depression scores in arthritis,[199,200] but not much emphasis has been placed on the evaluation of the role of other psychosocial constructs as predictive of the amount of contacts with the health care system.

The demand for health care services in arthritis has been related primarily to the patient's observed and self-perceived level of physical function and functional decline.[183,188-191] In our study, physical function was not related with health care services utilization. It has been reported that psychological factors influence the pathways leading to physical disability in people with arthritis. Psychological factors such as perception of self-efficacy, coping, and depression have been shown to be independent predictors of disability in arthritis.[48,50,53,55] In the model that we have proposed, lower levels of PA and higher levels of NA are associated with maladaptive coping, which, in turn, is associated with higher reported pain and limitation.[127] This association between psychosocial factors and disability can explain, at least in part, the dilution of the effect of physical function on SU when adjusting for psychosocial variables in multivariate models.

A limitation of our study is that the measurement of health care services utilization was based on self-reports. When assessing health care services utilization is common practice to rely on self-reported data, as such data are very convenient and inexpensive to obtain. The accuracy of this information obtained from the patient is less than ideal.[205,206] However, many studies have reported moderate to high correlations between self-reported and agency-reported health care services utilization. [207,208]

Future directions

The same questions addressed in the analyses included in this dissertation are being targeted with two projects that have recently been awarded funds. One of these projects has received a grant from the National Arthritis Foundation (the *Affect and Learning in the Management of Arthritis* [ALMA] study; PI, David E. Yocum, MD; Co-Investigator and Project Director, Isidro Villanueva, MD). The main objective of the proposed study is to study prospectively the predictive role of personality traits and affect on pain, physical function, and global status or quality of life in a sample of patients with knee OA participating in a psycho-educational intervention. The working hypothesis is that: "higher levels of extraversion and PA are associated with better outcomes in terms of pain, physical functioning, and quality of life in patients with knee osteoarthritis who participate in a psycho-educational intervention." This hypothesis will be tested based on a model that assumes that personality traits (i.e., extraversion and neuroticism) would have a direct effect on affective status (i.e., PA and NA). Then, affective status would have a further effect on the use of specific coping strategies (i.e., positive affect would determine a higher use of adaptive or active strategies and lower use of maladaptive or passive ones) and the perception of control or self-efficacy (i.e., higher levels of positive affect increasing the perception of control); being this described effect additive with that induced by the health intervention. Coping and self-efficacy in turn would directly, and probably differentially, affect health outcomes (i.e., pain, physical function and global status or quality of life). An alternative model also supposes a direct effect of personality traits on affective status, but in this case the effect of affect on coping and self-efficacy would be of multiplicative nature with that corresponding to the intervention. Specifically, affect would moderate the acquisition of a better coping profile and increased self-efficacy perception induced by the intervention. A prospective study with a pre-post interventional design is being used to test the proposed model. The plan is to recruit 150 subjects (53 subjects have been recruited to this date) with a definite diagnosis of OA of the knee (as defined by the American College of Rheumatology Criteria) and symptomatic at the time of enrollment, to participate in the study. The estimated four-year long study is being carried out through the Arizona Arthritis Center at the University of Arizona.

The second project has been awarded by NIH-NIAMS (the *Multidimensional Intervention in Early Osteoarthritis* study, 1 R01 AR047595-01A1; PI, David E. Yocum, MD; Co-Investigator and Project Director, Isidro Villanueva, MD). We hypothesize that the implementation of a long-term multidimensional intervention incorporating both an exercise and a self-management program in a sample of subjects with early knee OA will result in a significant improvement in physical function, as compared with each of the two programs alone. We aim to test this hypothesis based on a model that assumes the exercise intervention would have both direct and indirect effects (mediated by coping efficacy and affectivity) on physical function. The addition of a self-management program would have an additive effect on physical function, through its effect on coping efficacy or, alternatively a multiplicative effect moderating the effect of exercise on coping efficacy and affectivity. In conclusion, given that multiple factors are involved in this dynamic model, the use of a multidimensional program, combining exercise training and self-management, should result in a stronger effect on long-term maintenance of physical function and prevention of disability. For this purpose we will randomize 300 early OA patients to: 1) a 24-month intervention combining a multifaceted exercise training plus a self-management program; 2) an exercise program; or 3) a self-management program. As primary and secondary aims for this project we will determine the potential mediator versus moderator role of coping efficacy and affectivity (i.e., PA) on the effect of the interventions; we will evaluate the potential effect of positive and negative emotionality traits on coping efficacy and affectivity, the role of pain as a mediator in the relationship between improvements in coping efficacy and improvements in physical function, and the effects of the interventions on other outcomes such as pain, health-related quality of life and health services utilization.

APPENDIX A

Manuscript 1

AFFECTIVITY AS A PREDICTOR OF PAIN IN OSTEOARTHRITIS: A LONGITUDINAL ANALYSIS

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INTRODUCTION

Psychological characteristics have received increasing attention in explaining differences in perceived health, quality of life and well being.[1] The following dimensions have been identified as possible mediators or moderators of health status in arthritis: perception of personal control over the disease (as assessed through the constructs of health locus of control,[2] learned helplessness,[3] and self-efficacy [4]), coping,[5,6] and optimistic expectations for improvement.[7] These dimensions, however, have explained only a small percentage of the variance of different health outcome variables.[1] The identification of further predictive factors for physical and psychological well-being in arthritis are needed to gain a better understanding of the dynamics of disease processes and treatment response, especially in the framework of health interventions that focus on behavioral changes.

It has been suggested that personality traits, related to positive or negative affect, may constitute general factors that can influence and confound most types of subjective experiences.[8,9] Positive Affect (PA) reflects the extent to which an individual feels enthusiastic, active, and alert. PA is represented as an affective state dimension but is also related to the corresponding personality trait dimension of extraversion.[8] In contrast to PA, people with high levels of negative affect (NA), which is itself highly related with the personality trait of neuroticism, tend to have more negative cognitions, to use less effective coping strategies, and to have exaggerated perception of pain.[8,10] There is a well-established body of evidence linking negative affect, and its related constructs of anxiety and depression, with higher perceptions of pain in arthritis and other chronic conditions. Much less research activity has been devoted to the area of positive mental health, especially in arthritis. Furthermore, most studies investigating the role of these psychosocial constructs in arthritis have used cross-sectional designs.

The analyses presented here explored the relationship between positive affect and related domains (i.e., extraversion) and the perception of pain in a sample of subjects with osteoarthritis (OA) who were assessed over a 12-week period. A longitudinal design was used for these analyses based on the working hypothesis that higher levels of extraversion and positive affect would be associated with lower levels of pain. The analysis strategy incorporated the longitudinal nature of the data and the multiple assessment periods.

SUBJECTS AND METHODS

Data were from a prospective cohort study (i.e., the Interpersonal Stress and Disease Activity in Arthritis; NIH/NIAMS - R01 AR41687) that examined the influence of interpersonal stress on arthritis symptoms, affective distress, and disease activity over a 12 to 20-week period. The study consisted of 283 women; who had either rheumatoid arthritis (RA; n = 89), active osteoarthritis (OA; n = 105), or inactive OA (n= 89). Participants had been recruited starting in January of 1994 through newspaper ads, mailings to Arthritis Foundation members, and through rheumatology clinics. Full details of the study's methodology have been published elsewhere.[11]

Subjects

Data from the 105 women with a diagnosis of OA and symptomatic at enrollment were included in this analysis. The diagnosis of OA was confirmed according to the ACR criteria based on comprehensive reviews of medical history, medication use and joint tenderness and swelling evaluations made during in home visits. Subjects were excluded if they had a diagnosis of inflammatory arthritis or reporting very low level of pain (<25 on a 0 to 100 visual analogue scale). Only postmenopausal women were studied to reduce within and between groups heterogeneity in the hormonal profiles that might underlie stress-related inflammatory processes. All subjects were required to be on stable dosages of their medications for two months prior to enrollment. If a patient received a steroid injection, during the 12 weeks, her participation in clinician assessments was suspended for one month, to reduce any effects that this medication may have had on immune parameters.

Data Collection

The data included in this analysis came from an initial mailed questionnaire and 12 weekly telephone interviews. The weekly interviews were conducted by trained research assistants and included measures of interpersonal stress and self-reported arthritis disease activity. At baseline, data on demographic characteristics (i.e., age, education, marital status, income level, and disease duration), perceived social support, arthritis helplessness, depression, anxiety, perceived stress, extraversion, neuroticism, and level of perceived pain was collected. Then weekly, assessments were taken on perceived stress, coping difficulty with week's most stressful event, perceived change in the amount of stress, PA and NA, and current level of perceived pain.

Instruments

Positive and Negative Affect Schedule (PANAS).[12] PA and NA were measured using the corresponding items from the PANAS. Participants were asked to indicate the extent to which they had experienced different positive and negative affects during the previous week, using a five-point scale from 1 = "very slightly or not at all" to 5 = "extremely." The PA items were "interested," "excited," "strong," "enthusiastic," "proud," "alert," "inspired," "determined," "attentive," and "active"; the NA items were "distressed," "upset," "guilty," "scared," "hostile," "irritable," "ashamed," "nervous," "jittery," and "afraid." Scores for each scale were then summed for each participant assessment. In this study, Cronbach's alpha was 0.81 and 0.83 for the PA and NA scales respectively; and the week-to-week test-retest correlation was 0.72 and 0.51 for the PA and NA scales respectively.

Pain. The current level of pain was assessed by using a 0 to 100 pain rating scale. Subjects had to rate their pain prompted by the statement: "Please choose a number between 0 and 100 that best describes your current level of arthritis pain." A zero (0) would mean 'no pain' and a one hundred (100) would mean 'pain as bad as it could be.' This type of scale has shown good correlation with physician's assessments of disease activity [13] and it is recommended as one of the core set measurements for OA studies by standard guidelines.[14]

RAND Mental Health Inventory (MHI).[15] The measure for depressive symptoms consisted of nine items taken from the MHI. Five of theses nine items corresponded to the depression scale and four to the "loss of behavioral control" scale. The items included questions such as "How often have you felt like crying?" and "How much of the time have you felt downhearted and blue?" Participants were asked to respond to each of these items with regard to the previous week. The responses were scored on a six-point scale for all items except for the last item that was scored on a five-point scale. Cronbach's alpha coefficient for this sample was 0.91.

The measure for anxiety consisted of ten items taken also from the MHI. The items included questions such as “During the past week, have you been anxious or worried?” and “How often during the past week did you find yourself having difficulty trying to calm down?” The responses were scored on a three-point scale for all items (i.e., “always,” “very often,” and “fairly often.” Cronbach’s alpha coefficient was 0.86 for this sample.

Arthritis Helplessness Index (AHI).[3] The AHI is a 15-item self-report measure on which respondents rate their perceptions of helplessness in dealing with various aspects of their arthritis. Arthritis patients who have high levels of perceived helplessness are much more likely to report severe pain, symptoms of depression, and higher levels of functional impairment.[16,17] Each item is rated using a four-point scale with labeled categories ranging from "strongly disagree" to "strongly agree." The internal consistency coefficient (Cronbach’s alpha) for this instrument in this sample of OA subjects was 0.65.

NEO Personality Inventory (NEO-PI-R).[18] Extraversion and neuroticism traits were assessed using the corresponding scales from the self-report version of the *NEO Personality Inventory*. It has been postulated that extraversion and neuroticism are directly responsible for regulating individual differences in the experience of PA and NA, respectively [19] or, alternatively, that personality traits indirectly influence affect by predisposing individuals to participate in activities that induce PA and NA.[20] Subjects that score high on neuroticism, similar to those that report high levels of negative affect, tend to have more negative cognitions, to use less effective coping strategies, and to have exaggerated perception of pain.[10] Both scales consist of 48 items and were scored on a five-point scale ranging from "strongly disagree" to "strongly agree." Cronbach's alpha was 0.87 for both the extraversion (0.873) and neuroticism (0.872) scales.

Perceived stress. Interpersonal stress was measured with regard to three central interpersonal domains: spouse, family members, and friends.[11,21] Three questions were asked: (1) Overall, how stressful were your relations with your spouse (or significant other) this past week? (2) Overall, how stressful were your relations with your family members this past week? and (3) Overall, how stressful were your relations with friends this past week? If the participant did not have a spouse or a significant other, only the family member and friend categories were used. Each of these questions was formulated after participants were first asked to consider stressful events in the given domain that occurred over the past week. The responses were scored on a four-point scale where 0 = "not stressful at all" to 3 = "extremely stressful." The total interpersonal stress score was computed by taking the mean score of the items that were relevant for each participant (i.e., participants without spouses would have no score in that domain). Interpersonal stress was measured during each week of the study. For the combined groups, Cronbach's alpha was 0.58 and the week-to-week test-retest correlation was 0.63. Internal consistency was expected to be low because each of the items was designed to measure a different domain of the general construct of interpersonal stress. The relatively high test-retest reliability attests to the moderate level of stability in these weekly assessments of interpersonal stress.

Arthritis Support Inventory (ASI).[22] The ASI asks the patient about perceptions of the negative and helpful social interactions between self and spouse, and the self and friends/family. Supportiveness has been associated with successful coping and less psychological distress in patients with rheumatoid arthritis.[22] The internal consistency coefficient for this instrument in this sample of OA subjects was 0.88.

Analyses

The primary hypothesis was that "OA patients with higher levels of PA (and lower levels of NA) would report same levels of pain over a 12-week follow-up as compared with subjects reporting lower levels of PA." Pain, the dependent variable, was evaluated as the "current level of arthritis pain" at each weekly assessment; PA and NA, the main predictors, were also evaluated each week of follow-up and measured in reference to the "previous week." Thus the analyses evaluated the association between "current" levels of pain and PA and NA perceptions during the "previous week" over the 12 weeks time period.

Validity of the Positive and Negative Affect Schedule (PANAS)

PA and NA, the main predictors, were measured using the PANAS. The Schedule have shown good levels of reliability and validity.[12] We reported in the measurement section the values for both Internal consistency and test-retest reliability coefficients for this instrument, but we wanted to further explore the validity of this instrument in our sample of subjects with OA. For this purpose we evaluated the construct (predictive) validity of the instrument. The hypothesized relationships were tested between the PANAS scales and the other psychosocial instruments that we applied to our sample using product-moment (Pearson's) correlation coefficients. On the basis of the reports from the literature, it was hypothesized that PA would show positive correlations with extraversion and perception of social support; and negative correlations with negative affect, perceived stress, neuroticism, anxiety, depression, and perception of helplessness. In turn, it was hypothesized that NA would show positive correlations with perceived stress, neuroticism, anxiety, depression, and helplessness; and negative correlations with extraversion and social support.

Analysis Strategy

Plots showing the relationship of each predictor with the dependent variable were generated for each weekly evaluation, as well as correlation matrices also to check for potential collinearity among predictors. Considering the longitudinal characteristics of the data, the amount of missing data (i.e., 16.2% for the dependent variable, and 21.1% for PA) and the continuous nature of the outcome, Random Effects Model (REM) procedures were used.[23] This method constitutes an extension of the General Linear Model but allows the serial correlation of outcomes within-subjects to be estimated and taken into appropriate account in the formulae that generate the regression coefficients and their standard errors.[23] It was assumed that all subjects would have similar slopes, but their intercepts would vary randomly. A first-order random effects was included then, which allows subjects' intercepts to be random but not their slopes.[23]

Both univariate and multivariate analyses were performed using the REM. The multivariate models evaluated the relationship between the predictors of interest (i.e., affect) and the dependent variable (i.e., pain) controlling for demographic variables (i.e., age, marital status, education level, income, and disease duration) and other baseline psychosocial factors (i.e., extraversion, neuroticism, depression, anxiety, helplessness, social support, and perceived stress). A series of models were evaluated and the most parsimonious model obtained using stepwise methods. Finally, interaction terms were forced in the models, including: PA x NA, extraversion x neuroticism, PA x extraversion, PA x neuroticism, NA x neuroticism and NA x extraversion. STATA 6.0 XTREG procedure was used for these longitudinal analyses.

RESULTS

A total of 105 women with osteoarthritis (OA) with a mean age of 65.2 (range, 42 to 75) and mean disease duration of 13.4 years (SD=11.0 years) were included in this analysis. As shown in table 1, about half of the sample (52.4%) was married and 28% had completed college or had some postgraduate college education. Patients entered the study reporting a moderate level of pain, with a mean of 44.9 (SD, 46.5) on a 0 to 100 scale for the average level of pain perceived during the previous week. Scores for other psychosocial variables at baseline are also shown in Table 1.

The observed correlation coefficients among the psychosocial variables at baseline (see Table 2) confirmed most of the hypothesized relationships for both PA and NA. PA was positively correlated with extraversion ($r=0.43$), and negatively correlated with neuroticism ($r=-0.24$), anxiety (-0.18), depression ($r=-0.31$), and helplessness ($r=-0.20$). These relationships support the construct validity of the measurement of these two independent mood dimensions with the use of the PANAS.

Univariate Random Effects Models

PA, NA, anxiety, depression, helplessness, and perceived stress all showed statistically significant associations with perceived pain in univariate analyses (Table 3). PA showed a negative association with pain, i.e., higher levels of positive affect were associated with lower perception of pain ($\beta=-5.69$; $p<0.001$); while higher levels of NA were associated with higher levels of perceived pain ($\beta=6.60$; $p<0.001$). These univariate models, however, assumed that the relationships were linear. Figures 1 and 2 present a series of graphs for the weekly association between level of pain and affectivity (i.e., PA and NA categorized into tertiles) at various time points – these figures suggest that the relationship between affectivity (especially PA) and pain perception was not completely linear.

Multivariate Random Effects Models

Multivariate random effects models were next fitted to evaluate the longitudinal relationship between affect and pain controlling for demographic variables and other baseline characteristics. The level of pain was, in general, stable during the 12 weeks of follow-up as represented by the non-significance of the term corresponding to time (visits). Adjusting for all other baseline covariates, the weekly assessments of both PA and NA continued to show a statistically significant longitudinal association with weekly "current levels of pain" (Table 4 shows the results for the inclusive model; demographic variables are not shown). PA and NA showed statistically significant negative and positive longitudinal associations with perceived levels of pain, respectively (i.e., higher levels of PA and lower of NA during the previous week were associated with lower levels of current pain, during the 12-week follow-up). Baseline levels of anxiety and perception of helplessness also showed a positive statistically significant association with pain perception. Level of income (entered as an ordinal variable) was the only demographic covariate independently significantly associated with the perception of pain – i.e., the higher the level of income the lower the amount of pain perceived (β=-4.21, SE=1.09; $p<0.001$). None of the interaction coefficients terms were statistically significant

Table 5 presents results from the final model that explained the higher amount of variance with the minimum set of variables. In this model, weekly assessments of PA and NA, and baseline assessments of neuroticism, anxiety, perception of helplessness, and income all showed a statistically significant independent association with pain. These variables included in this parsimonious model explained 16% of the overall variance and 22% of the between-subjects variance of pain perceived by subjects with osteoarthritis during a 12-week followup.

We noted that depression showed a statistically significant association with pain in the univariate analysis (β=7.62, SE=1.72; $p<0.001$). However, due to the high correlation between depression and anxiety ($r=0.70$, $p<0.001$), the coefficient for depression did not remain statistically significant in the multivariate models unless anxiety was left out of the model. The final model with anxiety included and depression excluded, offered a slightly better fit than the model with depression included and anxiety excluded (22% vs. 18% of the overall variance and 28% vs. 23% of the between-subjects variance explained, respectively).

As observed in Figure 1, the relationship between PA and pain perception was not completely linear. For this reason, a final model was evaluated with PA coded as a categorical variable (based on tertiles) and two variables entered in the model (i.e., PA2 and PA3). This final model explained a higher proportion of the variance than when positive affect was entered as a continuous variable. As shown in table 6, both the middle (PA2) and higher (PA3) PA tertiles (as compared with the lower tertile) and income level, were inversely and significantly associated with weekly perceptions of pain. Higher levels of NA, neuroticism, anxiety and perception of helplessness were also significantly associated with more pain. This model roughly explained 18% of the overall variance and 24% of the between-subjects variance of the level of pain perceived by subjects with osteoarthritis.

DISCUSSION

In this longitudinal study, positive affectivity (PA) showed a statistically significant inverse association with weekly assessments of pain perception. Furthermore, this relationship remained significant after adjusting for several psychosocial and demographic variables including negative affect, anxiety and depression. An extensive body of literature deals with the relationship between measurements of mental distress (i.e., anxiety and depression) and outcomes, not only in arthritis but also in many other chronic diseases. In this sense, it has been reported that people with high levels of negative affect (NA), which is highly related with anxiety, depressive symptoms and the personality trait of neuroticism, tend to have more negative cognitions, to use less effective coping strategies, and to have exaggerated perception of pain.[8,10] Negative affect appears to inhibit performance on cognitive tasks, especially when the negative mood is intense and the task demands effortful and sustained processing.[24] The results of our study support the findings of previous studies furthering the notion that the presence of high levels of negative affect, a state/trait dimension, is a good indicator for increased pain perception in osteoarthritis.

The existence of significant relationships between personality and affect over the lifespan has been reported previously. These correlations appearing stronger in the older adult life.[25] It has been postulated that extraversion and neuroticism are directly responsible for regulating individual differences in the experience of positive and negative affect, respectively [19] or, alternatively, that personality traits indirectly influence affect by predisposing individuals to participate in activities that induce positive and negative affect.[20] The trait dimension of extraversion failed to significantly predict pain in our analyses, not only in the multivariate models where the variable for positive affect was present but also in the univariate analyses. Similar findings have been reported for subjects with rheumatoid arthritis.[26]

In recent years, there has been an increasing interest for the study of the role of what it has come to be known as Positive Mental Health, including positive affect, in symptom perception, other subjective experiences, and, even, disease etiopathology and progression. Little research in this area has been devoted to arthritis and much less to osteoarthritis (OA), however. Positive Affect reflects the extent to which an individual feels hopeful, active and alert, and in general characterizes moderate to high arousal positive emotions.[12] PA is represented as an affective state dimension but is also related to the corresponding personality trait of extraversion.[12] PA has been found to be a good indicator of psychological well being in older adults with chronic arthritis,[9] and has been related to psychological adjustment to a chronic illness such as rheumatoid arthritis,[27,28] along with self-efficacy expectations and disease adjustment in cancer patients.[29] The data here support a model for which lower levels of PA and higher levels of negative affect (NA) are associated with maladaptive coping, which, in turn, is associated with higher pain and limitation.[28] In support of this model, it has recently been reported that initial positive affect, but not negative affect, predicts improved active coping, and initial active coping predicts in turn increased positive affect, but not reductions in negative affect.[30] These findings provide prospective evidence to support the prediction that positive emotions initiate upward spirals toward enhanced emotional well being. There is substantial evidence that suggest that positive affective states are not simply the opposite of negative states.[12,31] Indeed, high ratings of perceived quality of life have been found to derive from a mixture of PA and the relative absence of NA.[32]

PA has also been linked with creative, or divergent, thinking, which would facilitate creative problem solving.[33] Recently, Erez and Isen have reported that positive affect improves people's performance and affects their perceptions of expectancy and valence.[34] Positive affect interacts with task conditions in influencing motivation, which occurs not through general effects, such as response bias or general activation, but rather through its influence on the cognitive processes involved in motivation. Kvaal and Patodia reported that PA scores were positively correlated with pain intensity in a mixed diseased sample.[35] In a recent study, the authors found that PA, as measured by the PANAS, was an independent predictor for overall mobility and physical functioning in older adults.[36] Fisher et al, conducted a two-year prospective cohort study using a population-based sample of 1084 non-institutionalized Mexican American subjects aged 65 or older with arthritis residing in five Southwestern states.[37] They found that higher scores of positive affect were independently associated with less incidence of disability over a two-year period.

One limitation of our study is its relatively small sample size, which could have limited our ability to get more precise estimates and to perform subset analyses. Another limitation relates with the homogeneity of the demographic characteristics of the recruited sample; in general, subjects were older Caucasian females with a high educational and socio-economical level. This fact does not invalidate the results found here but, potentially, limits their generalizability. Finally, even with our longitudinal design, the length of the followup (i.e., 3 months) was probably insufficient to fully characterize the hypothesized relationships. However, most studies investigating the role of psychosocial constructs in arthritis have used cross-sectional designs. In this sense, researchers have studied differences between patients but have, in general, failed to explore the longitudinal associations between psychological profiles and symptoms perception or the changes over time in the same individuals. A longitudinal design, such as the one used here, permits a more thorough examination of the relationships between psychological dimensions and health status.

In conclusion, we have shown positive affectivity to be a relevant determinant of pain perception in subjects with osteoarthritis. These findings suggest that the evaluation of affectivity could be useful for the identification of individuals at higher risk for poor outcomes. Potentially, complementing self-management or behavioral interventions with strategies that specifically are design to promote PA feelings may strengthen these programs and result in better outcomes for individuals with OA.

Table 1. Patients' Characteristics at Baseline *

	n=105
Age (yrs)	65.22 (42-75)
Gender	All women
Duration arthritis (yrs)	13.46 (11.01)
Pain level at Baseline (0 to 100)	44.91 (26.47)
Marital status:	
• ***Never married***	5 (4.9%)
• ***Married***	54 (52.4%)
• ***Widowed***	17 (16.5%)
• ***Divorced***	26 (25.2%)
• ***Separated***	1 (1.0%)
Educational level:	
• ***Less than high school***	9 (8.6%)
• ***High school complete***	15 (14.3%)
• ***Business or trade school***	17 (16.2%)
• ***1-3 years college***	34 (32.4%)
• ***4 years college***	8 (7.6%)
• ***Post-graduate college***	22 (20.9%)
Positive affect (1 to 6)	3.02 (0.72)
Negative affect (1 to 6)	1.72 (0.61)
Extraversion (1 to 4)	2.25 (0.35)
Neuroticism (1 to 4)	1.59 (0.41)
Anxiety (1 to 5)	2.47 (0.84)
Depression (1 to 5)	2.15 (0.86)
Helplessness (1 to 6)	2.94 (1.03)
Social Support (1 to 4)	2.75 (0.67)
Perceived stress (0 to 3)	0.55 (0.56)

* Values expressed as Mean (SD) or Number of subjects (%)

Table 2. Correlation among Psychosocial Variables at Baseline (Pearson's Coefficients)

	Perceived stress	***Positive affect***	***Negative affect***	***Extraver-sion***	***Neuroti-cism***	***Anxiety***	***Depression***	***Helpless-ness***
Positive affect	0.06							
Negative affect	0.54**	-0.09						
Extraversion	0.08	0.43**	-0.08					
Neuroticism	0.04	-0.24*	0.20*	-0.50**				
Anxiety	0.29**	-0.18‡	0.52**	-0.11	0.45**			
Depression	0.10	-0.31**	0.34**	-0.31**	0.48**	0.70**		
Helplessness	0.03	-0.20*	0.11	-0.18‡	0.19*	0.33**	0.39**	
Social Support	-0.18‡	0.04	0.05	0.10	-0.04	0.02	-0.04	-0.02

**p<0.001; * p<0.01; ‡ p<0.05

Table 3. Univariate Predictors of Level of Perceived Pain over a 12-Week Longitudinal Follow-up

Models	***Coefficient***	***SE****	***p***	***95% CI*** [§]	
Positive affect (1 to 6)	-5.69	0.91	<0.001	-7.48	-3.89
Extraversion (1 to 4)	-2.27	6.24	0.716	-14.49	9.95
Negative affect (1 to 6)	6.60	1.01	<0.001	4.62	8.58
Neuroticism (1 to 4)	4.82	5.10	0.345	-5.18	14.81
Anxiety (1 to 5)	10.08	2.36	<0.001	5.44	14.71
Depression (1 to 5)	6.99	2.40	0.004	2.27	11.70
Helplessness (1 to 6)	8.05	1.94	<0.001	4.25	11.84
Social Support (1 to 4)	-4.39	3.14	0.163	-10.54	1.77
Perceived Stress (0 to 3)	2.25	1.07	0.036	0.15	4.35

Random Effects Models. STATA XTREG procedure; * Standard Error; [§] Confidence Interval

Table 4. Predictors of Pain in a 12-Week Longitudinal Follow-up of Women with Arthritis, Inclusive Model *

	Coefficient	*SE*	*p*	*95% CI*	
Positive affect	-4.14	0.761	<0.001	-5.63	-2.65
Extraversion	7.98	4.927	0.105	-1.67	17.64
Negative affect	5.44	0.926	0.000	3.62	7.25
Neuroticism	-0.60	4.467	0.894	-9.35	8.16
Anxiety	6.55	2.606	0.012	1.44	11.65
Depression	-1.70	2.570	0.508	-6.74	3.34
Helplessness	6.25	1.467	<0.001	3.37	9.12
Social Support	-1.86	2.159	0.389	-6.09	2.37
Perceived Stress	0.99	1.003	0.321	-0.97	2.96

* Random Effects Model. STATA XTREG procedure
Adjusted for Demographic variables: age, marital status, education level, income, and disease duration

Table 5. Independent Predictors of Pain in a Longitudinal Follow-up

	Coefficient	*SE*	*p*	*95% CI*	
Positive affect	-3.90	0.756	<0.001	-5.38	-2.42
Negative affect	5.49	0.855	<0.001	3.81	7.16
Anxiety	4.81	1.880	0.010	1.13	8.50
Helplessness	5.50	1.458	<0.001	2.64	8.35
Income	-0.71	0.358	0.049	-1.41	0.00

Random Effects Model. STATA XTREG procedure

Table 6. Independent Predictors of Pain over a Longitudinal Follow-up: Most Parsimonious Model. Positive Affect Entered as Categorical Variables Based on Tertiles

	Coefficient	***SE***	***p***	***95% CI***	
Positive affect2	-4.21	1.095	<0.001	-6.36	-2.06
Positive affect3	-5.18	1.330	<0.001	-7.79	-2.58
Negative affect	5.56	0.860	<0.001	3.88	7.25
Neuroticism	5.10	1.859	0.006	1.46	8.75
Anxiety	5.67	1.442	<0.001	2.85	8.50
Helplessness	0.70	0.354	0.049	0.00	1.39
Income	-4.21	1.095	<0.001	-6.36	-2.06

Random Effects Model. STATA XTREG procedure

Figure 1. Error Bar Graphs for the Relationship between Mean Pain (on a 0 to 100 Scale) and Level of Positive Affect by Tertiles of Positive Affect and for Selected Weeks

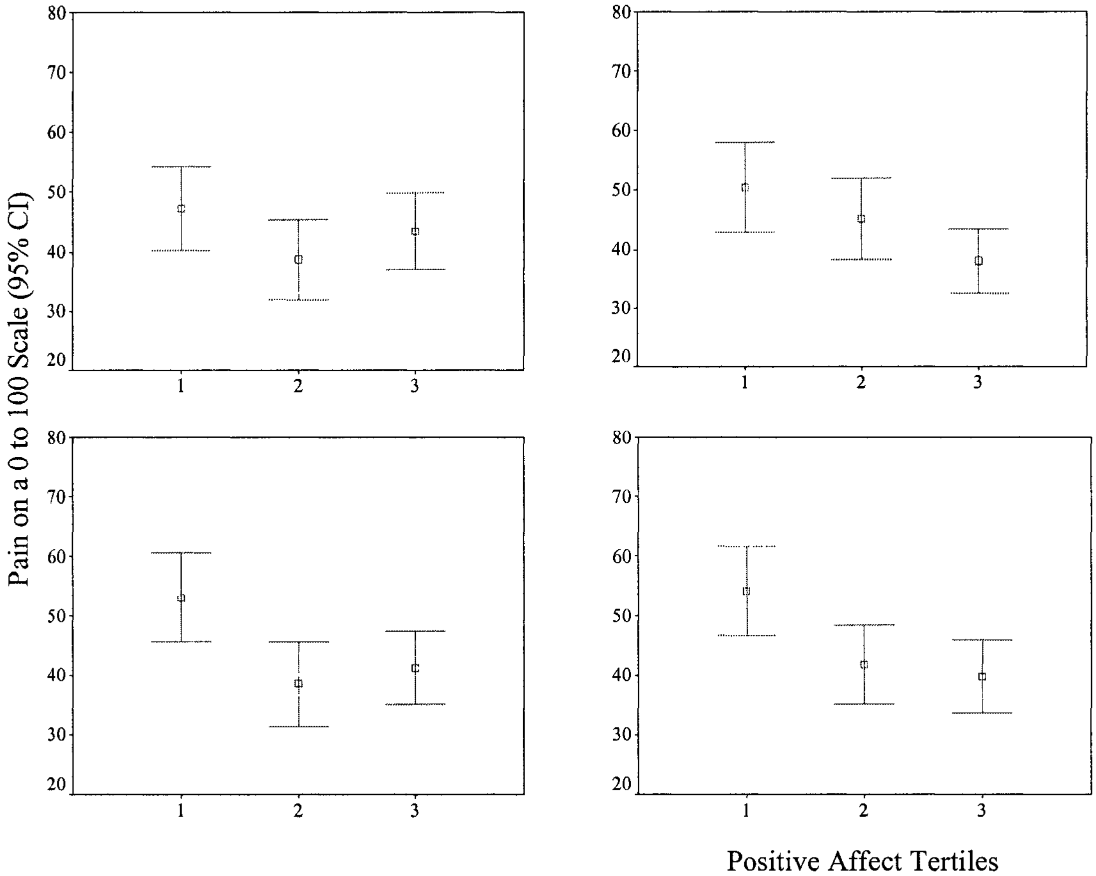
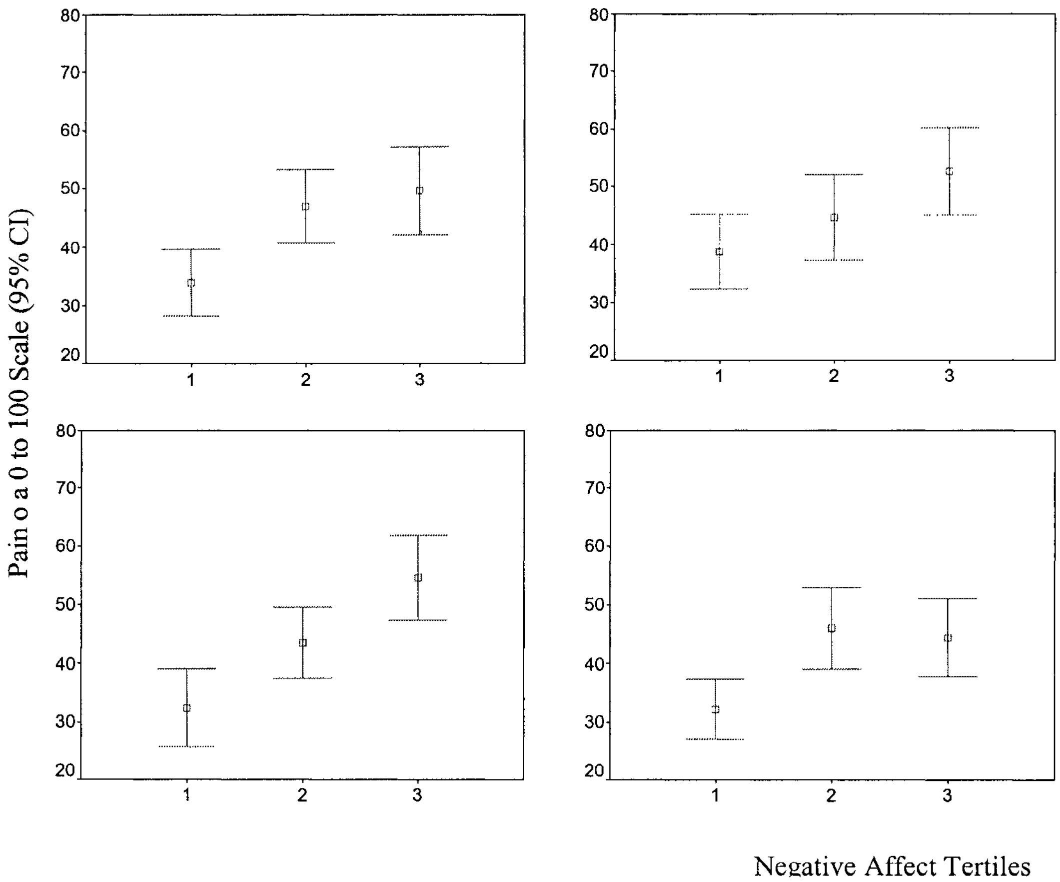


Figure 2. Error Bar Graphs for the Relationship between Mean Pain (on a 0 to 100 Scale) and Level of Negatve Affect by Tertiles of Negative Affect and for Selected Weeks



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APPENDIX B

Manuscript 2

POSITIVE AFFECT AND MINIMAL CLINICALLY IMPORTANT DIFFERENCES IN ARTHRITIS

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INTRODUCTION

Patient education and exercise are two recommended strategies for the management of arthritis.[1] However, reported effects of these interventions for decreased pain and increased quality of life have been shown to be moderate, whereas achieved effect sizes for improvement in self-reported disability have been relatively small.[2-7] Furthermore, results from those intervention programs that include exercise, education (including self-management), or a combination of the two, tend to vary across individuals, regardless of disease activity or medication use.[8] There is a clear need for the identification of additional factors, which, if modifiable, could be targeted in the design of interventions.

Individual differences in psychological make-up have received increasing attention in explaining differences in perceived health, quality of life and well-being.[9]

These aspects could be key factors to explain the observed differences in an individual's response to a health intervention. Others have suggested that changes in outcomes obtained with psycho-educational interventions are not related to changes in behaviors.[10-12] Various psychosocial dimensions have been proposed as potential mediators: including the perception of personal control over the disease (emphasized in three related constructs: health locus of control,[13] learned helplessness,[14] and self-efficacy[15]), coping,[16,17] and optimistic expectations for improvement.[18] Although most, if not all of these proposed mediators are considered cognitive in nature, a themed positive affective response, or its absence, underlies most of these measures.[19] In the current study we pursue a test of the role of positive affect per se as a factor in determining success of a psychosocial intervention in arthritis.

Self-efficacy has been suggested as a common cognitive mechanism mediating behavior change through its influence on choice of activities, effort expended during the performance of these activities, and persistence in the face of adverse conditions such as chronic pain.[20] Lorig and Holman found that promoting self-efficacy beliefs specific to coping resulted in an increase in self-reported physical activity.[21] Moreover, these beliefs may be derived from a general positive affective orientation toward one's own efforts to improve health.

Recently, it has been suggested that affective states, i.e. presence of positive affect and less negative affect, might be influential factors.[22] Positive Affect (PA) reflects the extent to which an individual feels enthusiastic, active and alert. PA has been found to be a good indicator of psychological well-being in elderly people with chronic arthritis.[23] It also has been related with adaptive strategies for psychological adjustment to a chronic illness such as arthritis,[22,24] and underlies patient self-efficacy expectations and disease adjustment in cancer patients.[25] Lorig et al, in an exploratory analysis, identified positive affect as a mediating variable that, in addition to the perception of control, likely influenced health outcomes in a self-management intervention.[26] In a prior report, we propose a model consistent with these findings in which lower levels of PA are associated with the use of specific coping strategies (i.e., higher use of adaptive and lower use of maladaptive strategies) and higher perception of self-efficacy, which, in turn, are associated with perception of lower levels of pain and limitation (figure 1).[22] Higher PA has also been linked with creative, or divergent, thinking, which would facilitate creative problem solving.[27]

The goal of this study was to determine whether behavioral and psychosocial risk factors could predict changes in outcomes. Specifically, we sought to determine the role of positive affect in predicting minimal clinically important differences (MICD). This relationship was evaluated within a community-based intervention for arthritis; the "Living Healthy with Arthritis" program.[28]

SUBJECTS AND METHODS

Subjects

Individuals with both inflammatory and non-inflammatory arthritis were invited by printed advertisements and public announcements to participate in a community-based, 12-session program, the "Living Healthy with Arthritis" program, developed by the Arizona Arthritis Center. Five cohorts of subjects were recruited from a retirement community (Green Valley; population 26,000) located near the Tucson metropolitan area. A total of 86 subjects were recruited with a maximum of 20 participants per cohort.

The "Living Healthy with Arthritis" Program

An integrated team of specialists trained in arthritis and preventive care implemented the program. It was developed to provide a community-based program that integrates traditional and complementary health practices to promote optimal health for individuals with arthritis. The 12-session intervention incorporated both a comprehensive education/self-management component and an exercise (aquatics) component. Participants met for three hours, three times weekly over a four-week period.

The 90-minute psycho-educational portion addressed an overview of arthritis, osteoporosis, stress management, medications, complementary treatments, and a variety of exercise and relaxation techniques. Brief modules on nutrition were presented throughout the month and good nutrition ideas were reinforced at each meeting with the provision of "healthy" snacks and juices with accompanying recipes. The 60-minute aquatic class emphasized stretching, range of motion, and aerobic fitness providing an opportunity to increase endurance over time. The instructor was an American Academy of Family Physicians Certified Medical Exercise Specialist and an Arthritis Foundation Certified Instructor for Aquatics.

Study Design and Data Collection

The study was conducted by researchers from the University of Arizona Arthritis Center under approval of the institution's review board, and consisted of a prospective cohort study with an interventional component. Assessments were made at baseline, end of intervention (4 weeks) and 3 months post-intervention. Participants mailed the completed self-administered questionnaire package to the Arizona Arthritis Center at each follow-up time point. Subjects were phoned if the questionnaires were not received within 2 weeks of the corresponding assessments. Even with the challenge of an estimated time for completion of the questionnaire of about 1 hour, response rate was 96.3% at four weeks and 91.2% at 3 months.

Measures

A packet of standard and validated questionnaires was administered at each time point to all participants. The set of instruments, and their corresponding targeted dimensions, were: psychological status (Positive and Negative Affect Scales,[29] Beck

Depression Inventory,[30] Perceived Stress Scale [31]); psychosocial resistance resources (The Medical Outcomes Study Social Support Survey [32] and the Chronic Pain Coping Inventory [33]); health status (pain on a 0 to 100 VAS and physical function as measured by the Health Assessment Questionnaire [34]); and health related quality of life (SF-36).[35] A description of the instruments and the observed reliability coefficients for these instruments within this population follows:

The Positive and Negative Affect Scales [29] is a brief instrument that is used to assess, by means of two 10-items scales, the primary dimensions of mood – positive (PA) and negative affect (NA). Participants were asked to rate on a 5-point scale (very slightly or not at all, a little, moderately, quite a bit, and very much) the extent to which they experienced each mood state during the previous week. The positive affect items were "interested," "excited," "strong," "enthusiastic," "proud," "alert," "inspired," "determined," "attentive," and "active"; the negative affect items were "distressed," "upset," "guilty," "scared," "hostile," "irritable," "ashamed," "nervous," "jittery," and "afraid." Cronbach's alpha reliability coefficient for this instrument within this sample was 0.90 for PA and 0.83 for NA. Test-retest (Intraclass Correlation) coefficient was 0.77 and 0.66, respectively.

Depression was measured using the Beck Depression Inventory,[30] which is a self- report analysis of depressive symptoms and is not designed to make a diagnosis of depression. The test contains 21 items, most of which assess depressive symptoms on a Likert scale of 0-3. Subjects were asked to report feelings consistent with their own over the past week. Cronbach's alpha coefficient for this scale in this sample was 0.75 and the test-retest correlation was 0.89.

Perceived stress was evaluated using a 10-item abbreviated version of the Perceived Stress Scale.[31] This scale quantified the perception of situations in one's life as unpredictable, uncontrollable, and taxing. Items asked participants how often in the last month they felt unable to control important things in life, deal with daily hassles, cope with life changes, handle personal problems, control irritations, and overcome difficulties, and also how often they felt that things were going well and when they were "on top of things." Responses were provided on a 5-point scale anchored by 1 (never) and 5 (almost always). Cronbach's alpha for the scale in this sample was 0.81 and the test-retest correlation was 0.78.

Social support was measured using the Medical Outcomes Study Social Support Survey.[32] This 20-item instrument provided a brief indicator of the perceived availability of four dimensions of social support: emotional support or informational support, tangible support, positive social interaction, and affection. The questionnaire was self-administered and used five-point answer scales anchored by 1 (none of the time) and 5 (all of the time). The Cronbach's alpha coefficient for each of the subscales in this sample was 0.95, 0.81, 0.92 and 0.92, respectively; and test-retest reliability was 0.78, 0.83, 0.77 and 0.80, respectively.

Coping was evaluated using the Chronic Pain Coping Inventory.[33] This instrument assessed both cognitive and behavioral coping and was comprised of 64 items distributed in 4 scales that target functional (adaptive or active) coping strategies (i.e., coping self-statements, task persistence, relaxation and exercise and stretch) and 4 that target dysfunctional (maladaptive or passive) coping practices (i.e., guarding, resting, asking for assistance and seeking emotional support). Cronbach's alpha coefficients ranged from 0.78 to 0.92 for the 8 subscales. Test-retest (Intraclass Correlation) coefficients ranged from 0.78 to 0.87.

Pain, the main outcome for this study, was measured on a 0 to 100 visual analogue scale (VAS). One advantage of this type of measurement was that it provided the patient with a robust and sensitive method regardless of language, age, or cultural level. Patients were asked to rate their pain answering the following question: How much pain have you had because of your arthritis during the past week? The scale was anchored with the words "No pain" and "Most severe pain possible."

Physical function was measured using the Stanford Health Assessment Questionnaire (HAQ).[34] The HAQ consisted of 20 items in eight domains: dressing and grooming, arising, eating, walking, hygiene, reach, grip and activity. Subjects had to evaluate their level of difficulty for each item on a categorical scale were 0 = no difficulty, 1 = some difficulty, 2 = much difficulty, and 3 = unable to do. The sum of the highest response for each of the dimension was divided by the total number of dimensions to obtain the final score, which ranged from 0 (no/very mild physical dysfunction) to 3 (severe physical dysfunction). Cronbach's alpha for this instrument in this sample was 0.87 and the test-retest correlation coefficient was 0.81.

Health-Related Quality of Life was measured by the Medical Outcomes Study 36-item Short-Form Health Survey (SF-36).[35] This was a 36-item measure of overall health status which included scales targeting the following eight dimensions: bodily pain, physical functioning, role limitations due to physical health, social functioning, general mental health, role limitations due to emotional problems, vitality, and general health perceptions. Each category score was re-coded into a 0 to100 score, oriented so that high values represented more favorable states. All the questions were framed to the previous four weeks. Internal consistency (Cronbach's alpha coefficients) for the eight subscales ranged from 0.74 for the general mental health subscale to 0.86 for the role limitations due to emotional problems subscale. Test-retest coefficients were greater than 0.75 for all scales (up to 0.88), except for role limitations due to emotional problems (0.67).

The scale of general health perception was used as a measure of *patient's global assessment of disease activity*, which was one of the main outcomes in this study (see analysis section). This scale comprised five items that provided an evaluation of the impact of health problems – arthritis in this study. Items such as: "I am as healthy as anybody" or "I expect my health to get worse." Again, the score for the scale was re-coded into a 0-to-100 scale, oriented so that high values represent more favorable states.

To evaluate if this scale was measuring what it was purported to measure (i.e., global assessment of disease activity, for the purpose of this study), we assessed the construct (predictive) validity of the scale. The hypothesized relationships were tested between the general health perceptionsscale and other health status measurements using product-moment (Pearson's) correlation coefficients. It was hypothesized that, for the scale to represent the construct of global assessment of disease activity, the general health perceptionsscale would show negative correlations with pain, disability, and perception of vitality and energy. See results section for the obtained coefficients.

Statistical Analyses

Following standard guidelines for the evaluation of outcomes for arthritis studies, pain, global assessment of disease activity, and physical function were selected as the primary outcomes.[36-38] Changes in levels of perceived pain was the main outcome and changes in global assessment of disease activity (as measured by the SF-36 general health perception scale) and physical function (as measured by the HAQ) were the secondary outcomes. The goal was to determine whether or not there was a relationship between PA (main predictor) and changes in pain, physical function, or global assessment of disease activity over a three-month period (dependent variables). Furthermore, we sought to determine clinically meaningful changes.

Minimal clinically important differences (MCID) were defined for each dependent variable as "the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management."[39] Others have defined MCIDs as "the smallest difference in a score that is considered to be worthwhile or important",[40] the "minimum absolute risk reduction for which patients would take a treatment given their understanding of the risk without that treatment,"[41] or "the mean score for patients with an optimal result minus the mean score for a group with a suboptimal result."[42] In this study, MCID was defined as a 10-units improvement, on a scale of 0 to 100, for pain [43-45] and SF-36 scales [46-48] and 0.2-units improvement on the 0 to 3 scale for physical function as measured by the HAQ.[47,49]

The scale of general health perception was used as a measure of patient's global assessment of disease activity. To evaluate if this scale was measuring what it was purported to measure (i.e., global assessment of disease activity, for the purpose of this study), we assessed the construct (predictive) validity of the scale. The hypothesized relationships were tested between the general health scale and other health status measurements using product-moment (Pearson's) correlation coefficients. For the general health scale to represent the construct of global assessment of disease activity, we needed to show negative correlations with pain, disability, and positive with perception of vitality and energy.

Analysis Strategy

Two general strategies were used to test the relationship between PA and outcomes. Initially, data at baseline were compared with data at 3 months post-intervention using paired t-tests. The sample was then subdivided in two groups based on tertiles of positive affect scores (subjects in the highest tertile compared to the middle and lower tertiles combined). T-tests for independent samples or Chi-square tests were used to compare baseline characteristics between these two subgroups. Effect size, which is a measure of treatment effect, was calculated for the different outcome measures using the formula: effect size= mean change / standard deviation of pre-intervention values.[50] The U-Mann Whitney test assessed significance in change scores between subgroups. Pearson's product moment correlation coefficients were calculated to evaluate associations between the psycho-social variables and between baseline characteristics and changes in the outcome measures.

Finally, univariate and stepwise multivariate logistic regression procedures were used to test the association between positive affect (categorized as mentioned above) and changes in pain, global assessment of disease activity, or physical function (dichotomized as 0=no MCID achieved, or 1=MCID achieved), adjusting for demographic characteristics and the other psychosocial constructs. Odds ratios (OR) and 95% confidence intervals (CI) were obtained for each predictor. Separate models were fitted for each of the three dependent variables. We used the Hosmer-Lemeshow goodness-of-fit test to evaluate fit of the models.[51] SPSS 11.5 (SPSS Inc., Chicago) was used for all these analyses.

Logistic regression is a widely used technique to adjust for confounders, not only in case-control studies but also in cohort studies.[52] However, logistic regression yields an odds ratio (OR) rather than a relative risk (RR), even in a cohort study. When the outcome of interest is common in the study population (i.e., > 10%), the adjusted OR from the logistic regression may exaggerate a risk association or a treatment effect.[53] In our sample, the outcomes of interest were present in more than 10% of the sample. To address this issue we used the method recently proposed by Zhang and Yu to approximate a RR from the adjusted OR and derive an estimate of an association or treatment effect that better represents the true RR even in multivariate analysis.[53] This method uses the following formula to obtain a corrected estimate of the RR:

$$RR = \frac{OR}{(1 - P_0) + (P_0 \times OR)}$$

where, P_0 indicates the incidence of the outcome of interest in the nonexposed group. This method can also be used to correct the lower and upper limits of the confidence interval by applying this formula to the lower and upper confidence limits of the adjusted odds ratio.

RESULTS

A total of 86 subjects (9 male and 77 female) with mean age of 69.2 years (40-88) were recruited into the "Living Healthy With Arthritis" study. Table 1 describes the participants' characteristics at baseline. Sixty-four (75.6%) of the participants had osteoarthritis (OA), including 9 (10.47%) with an additional diagnosis of fibromyalgia. The rest of participants self-reported diagnoses of RA (14), psoriatic arthritis (5) or Systemic Lupus Erythematosus (2).

Correlates of Affect Variables

Table 2 shows the correlation between the SF-36 general health scale and other health status measurements. All observed correlations were as hypothesized supporting the construct validity of this scale as a measure of global assessment of disease activity. We also evaluated the correlations between PA and other psychosocial variables. As expected, higher levels of PA were associated with lower use of dysfunctional coping strategies such as "catastrophizing" and "wishing/hoping" ($r=-0.40$, $p<0.001$ and $r=-0.34$, $p=0.01$); higher use of functional coping strategies such as "positive self-statements" ($r=0.36$, $p=0.01$); lower levels of negative affect ($r=-0.31$, $p<0.001$); and higher levels of perceived social support ($r=0.36$, $p<0.001$). In turn, higher use of maladaptive coping strategies at baseline was significantly correlated with worse outcomes (pain, physical function and quality of life perception) at 3 months follow-up (data not shown here).

Change in Outcomes (Baseline – Three Months) by PA

Paired t-tests were used to compare baseline values with tree-month values. While there was a trend for improvement in pain and physical function, no statistically significant improvements were observed (Table 3). Individuals were then grouped by PA score (i.e., highest PA tertile or "high PA" compared to middle and lowest tertiles combined or "low PA"). Table 4 compares the baseline characteristics of participants by PA group. There were no statistically significant differences between subjects in the "high PA" and "low PA" groups in terms of demographic, health status or psychosocial profiles, with the exception of perceived social support. Those individuals with high PA reported higher social support. Individuals in the higher tertile for PA scores reported significant improvement in mean pain scores (VAS, p=0.04; and SF-36 pain subscale, p=0.03) and mean global assessment of disease activity (SF-36 general health perception subscale, p=0.01) over the three-month period. Participants with lower PA scores reported a statistically significant change only for role limitations due to emotional problems (SF-36 subscale, p=0.04).

This change is demonstrated in Figure 2, which contrasts change in pain perception and general health by PA category. Delta scores were calculated as the measure of change. Subjects in the "higher PA" group experienced a mean improvement of 7.97 units (SD, 29.96) in pain reported using the VAS scale versus a mean delta score of –4.79 units (SD, 27.43) for individuals in the "lower PA" group. This difference in change is equivalent to a detected effect size of 0.4 (i.e., moderate effect size). Similar differences were observed for pain as measured by the SF-36 bodily pain scale and global assessment of disease activity (see Figure 2).

Predictors of Minimal Clinically Important Differences (MCID)

We next sought to determine the ability of PA at baseline to predict MCID in the various outcome measures. Univariate analyses suggested that subjects in the high PA group were 3.3 times as likely to achieve a MCID in pain as compared to subjects in the low PA group (Odds Ratio [OR]=3.3; 95% CI, 1.0 to 11.0), while adjusted for age and baseline level of pain, subjects in the high PA group were 7 times as likely to achieve MCID in pain as compared to subjects in the low affect group (OR=7.1; 95% CI, 1.4 to

36.2). Table 5 reports results from the final modeling. Using stepwise multivariate logistic regression procedures that included all variables that achieved a level of significance ≤ 0.3 in univariate analyses, only PA and baseline levels of pain and physical function predicted MCID in pain (i.e., at least a 10 unit improvement in perceived pain). The corrected values for the OR and 95% confidence interval were OR=2.78; 95% CI, 1.03 to 3.93.

Similar results were seen for PA level to predict changes in global assessment of disease activity. Subjects in the high PA group were 5 times as likely to achieve MCID in the arthritis global assessment as compared to subjects in the low PA group (OR=5.4; 95% CI, 1.6 to 18.4). Adjusted for age and baseline global assessment the OR was 6.1 (95% CI, 1.7 to 21.8). Finally, as reported in Table 5, using multivariate logistic regression procedures, only age and PA were able to significantly predict MCID. The corrected values for the OR and 95% confidence interval were OR=2.93; 95% CI, 1.54 to 3.86.

Finally, PA also significantly predicted clinically meaningful changes in physical function as measured by the HAQ. Adjusted for age, disease duration and baseline HAQ scores, subjects in the high PA group were 14 times as likely to achieve MCID as compared to subjects in the low affect group (OR=14.5; 95% CI, 1.6 to 125.8). In the final stepwise multivariate logistic regression procedure (Table 5), only positive affect, age and baseline physical function (HAQ scores) were retained in the model. Subjects in the high PA group were 13 times as likely to report a 0.2 units improvement in the HAQ score than subjects in the low affect group (OR=13.27; 95% CI, 1.7 to 102.1). Older patients were less likely to achieve MCID; per each year increase in age, the likelihood of improving 0.2 units or more in physical function decreased by 11 %. The corrected values for the OR and 95% confidence interval (see analysis section) were OR=2.60; 95% CI, 1.38 to 2.94.

DISCUSION

In this community-based health intervention, we observed better short-term responses in individuals with higher levels of positive affect (PA). Subjects reporting higher PA levels, showed significant and clinically relevant improvements in pain, global assessment of disease activity and physical function at 3 months follow-up after a four-week health intervention that included exercise and self-management components. In comparison, participants with lower levels of positive affect did not show significant improvement in any of the evaluated outcomes. Furthermore, these results were specific for positive affect and not explained by other factors such as age, disease duration, marital status, education, level of negative affect, perceived stress, depression scores, perceived social support and baseline levels of pain, physical function or global assessment. As far as we know, only one study has previously analyzed the role of PA on treatment efficacy.[54] In that randomized controlled trial, the intervention focused on individualized and generic problem solving approaches facing the subject and his/her family. Results demonstrated the contribution of PA to change processes that were hypothesized to be related with outcomes.

PA has been associated with disease outcomes in other studies. In a recent study, the authors found that PA, as measured by the PANAS, was an independent predictor for overall mobility and physical functioning in older adults.[55] Fisher et al, using a two-year prospective cohort study of 1084 non-institutionalized Mexican American subjects aged 65 or older with arthritis residing in five Southwestern states, found that higher scores of positive affect were independently associated with less incidence of disability over a two-year period.[56] Lorig et al identified positive affect as a mediating variable that likely influenced health outcomes in a self-management intervention.[26] The subgroup of subjects that showed positive outcomes was significantly different from the group with negative outcomes in affective status and perception of control. Perceived support did not distinguish subjects with positive versus negative outcomes in that analysis. In our study, subjects with higher PA levels perceived a significantly higher level of social support, suggesting that social support may have a beneficial effect on outcomes through its influence on positive affective status. The correlation between positive affect and social support was highly significant in our analyses.

The findings of our study suggest that people with a favorable affective profile are more likely to benefit from a multidimensional health intervention. It is possible that people with higher levels of positive affect are more likely to improve or incorporate new health behaviors as a result of a health intervention. However, it has been shown in other studies that, in the context of a self-management intervention, changes in outcomes are not necessarily related with positive effects on health behaviors,[10,57] but more associated with changes in self-efficacy.[11] PA has been related with adaptive strategies for psychological adjustment to a chronic illness such as rheumatoid arthritis,[22,24] and with patient self-efficacy expectations and disease adjustment in cancer patients.[58]

Our results also suggest that older people may be less likely to benefit from the type of intervention modeled in the "Living Healthy with Arthritis" program. This is suggested by the lower likelihood of achieving clinically relevant improvements in global assessment of disease activity and physical function per each year increase in age. Targeting younger ages with these interventions may result in greater improvements in outcomes in people with arthritis. However, it is well known that typical participants in self-management programs are well above 65 years old, probably due to lesser time constraints for this age group, when the chances for significant and relevant improvement seem to be lesser.

Similar to what we observed in the global analysis of the intervention program, the authors of a recent randomized controlled trial did not find any significant improvement in pain, physical or mental health with a self-management program.[59] The authors argued that one possibility was that subjects were actively recruited for the study, and, perhaps, less motivated to adhere to suggestions made in the self-management course. They examined whether there were any patient subgroups that could have experienced improvement based on age, sex, education level, income, and baseline disability. They did not perform any analysis based on psychological profiles.

Limitations of this current study include the open non-randomized pre-post design of the intervention study and the relatively small number of participants available for the subgroup analyses. We do not believe, however, that having had a control group would have changed the observed results with respect to the effect of PA on outcomes. A larger sample would increase the precision for estimates of the differences among subgroups.

If differences in perceived quality of life and well-being depend on affective states, then efforts to improve outcomes through programs that attempt to change individuals' perception of personal control or ways of coping will probably benefit from targeting affect with the intervention. In a prior study, we have shown that a short-term exercise program induced increases in positive affect levels.[60] The observed better response in the current study for individuals with higher levels of PA suggest that an evaluation of affectivity may be useful to identify individuals at higher risk for poor outcomes. Incorporating strategies that specifically alter affect could then strengthen the interventional program and result in better outcomes. In conclusion, this study demonstrated that levels of PA were relevant in predicting MCIDs in pain, global assessment of disease activity and physical function in subjects participating in a self-management intervention.

Table 1. Characteristics of Participants in the "Living Healthy with Arthritis" Study

	n=86
Age (yrs)	69.2 (40-82)
Gender (male/female)	9/77
Duration arthritis (yrs)	15.2 (12.96)
Diagnosis:	
• **Osteoarthritis**	55 (65.12%)
• **RA**	14 (16.28%)
• **Psoriatic Arthritis**	5 (5.81%)
• **Fibromyalgia**	9 (10.47%)
• **SLE**	2 (2.33%)
Educational level:	
• **Up to high school**	20 (22.4%)
• **Technical school**	16 (18.0%)
• **Some college**	22 (24.7%)
• **College**	24 (27.0%)
• **Post-graduate college**	7 (7.9%)
Race/ethnicity:	
• **White non-Hispanic**	83 (96.5 %)
• **Mexican American**	2 (2.3%)
• **Native American**	1 (1.1%)

Table 2. Correlation Between the SF-36 General Health Scale and other Health Status Measurements at Baseline (Pearson's Coefficients)

	SF-36 GH	***Disability (HAQ)***	***Pain (VAS)***	***SF-36 BP***	***SF-36 PF***	***SF-36 RP***
Disability (HAQ)	-0.24*					
Pain (VAS)	-0.24*	0.17				
SF-36 † ***BP***	0.50**	-0.37**	-0.54**			
SF-36 PF	0.24*	-0.61**	-0.21	0.44**		
SF-36 RP	0.39**	-0.39**	-0.31**	0.63**	0.37**	
SF-36 VT	0.46**	-0.27*	-0.31**	0.58**	0.28*	0.51**

* *p<0.05;* ** *p<0.01*; † SF-36 scales are scored on a 0 to 100 basis, with 100 the best outcome
HAQ= Health Assessment Questionnaire; VAS= Visual Analogue Scale.; SF-36 BP=Bodily pain scale; SF-36 PF=Physical function scale; SF-36 RP= Role limitations due to physical problems scale; SF-36 VT=Vitality scale

Table 3. Levels of Perceived Pain and Self-Assessment of Health and Physical Function, at Baseline and Three Months in Participants of a Health Intervention*

	Score Range	Baseline		3 months	
		Mean	*SD*	*Mean*	*SD*
HAQ (0 to 3)	0 - 3	0.98	0.52	0.95	0.51
Pain (0 to 100 VAS)	0 - 100	39.06	25	37.61	29.12
SF-36 † Bodily pain	0 - 100	51.59	18.59	53.53	22.32
SF-36 Role limitations-Emotional Problems	0 - 100	65.49	41.93	69.61	38.95
SF-36 General Health	0 - 100	58.82	19.48	61.72	22.1
SF-36 Mental Health	0 - 100	71.37	16.56	69.91	19.8
SF-36 Physical Function	0 - 100	49.8	21.96	52.06	23.91
SF-36 Role limitations-Physical problems	0 - 100	30.59	35.43	33.82	41.6
SF-36 Social Function	0 - 100	73.26	22.33	74.74	21.82
SF-36 Vitality	0 - 100	44.22	20.77	44.08	25.63

* $p>0.05$ for all comparisons between baseline and three months using paired t-test

† 100 is the most favorable score for all the SF-36 scales

HAQ= Health Assessment Questionnaire; VAS= Visual Analogue Scale

Table 4. Comparison of Baseline Characteristics of Participants Depending on the Level of Positive Affect (PA) at Baseline (Higher Tertile of PA vs. Middle and Lower Tertiles)

	Middle and lower PA (n=59)		***Higher PA (n=27)***		***p****
	Mean	***SD***	***Mean***	***SD***	
Age	68.13	9.00	71.39	7.23	0.099
Disease duration (years)	15.80	13.83	13.46	10.47	0.583
Disability (HAQ)	1.05	0.53	0.83	0.48	0.074
Pain (0 to 100 VAS)	40.28	24.29	35.91	26.72	0.464
Negative Affect	18.05	5.60	15.68	5.60	0.070
Perceived stress	25.02	6.28	21.89	10.33	0.087
Bodily pain (SF-36)	49.56	18.31	55.74	19.18	0.158
General Health (SF-36)	56.84	18.84	62.59	20.82	0.210
Social Support	77.20	20.21	90.25	13.85	**0.003**

HAQ= Health Assessment Questionnaire; VAS= Visual Analogue Scale

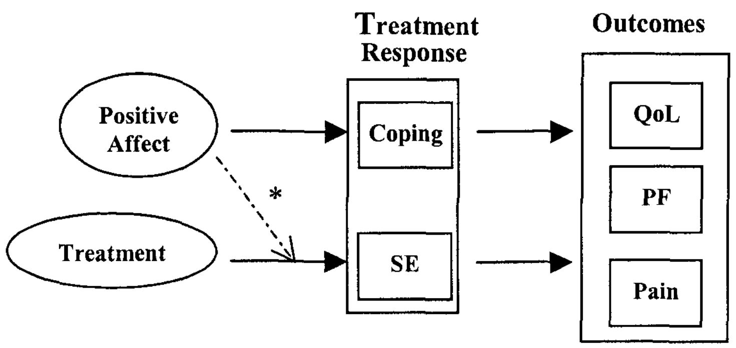
* T-test for independent samples; Chi-square test was performed for categorical variables (not shown in table): diagnosis (p=0.15), education level (p=0.62), marital status (p=0.16) and gender (p=0.63)

Table 5. Predictors of Minimal Clinically Important Differences in Outcomes over a 3-Month Period (Stepwise Multivariate Logistic Regression)

Models	OR	p	95.0% C.I.	
			Lower	Upper
<u>**MCID in pain**</u>:				
Positive affect*	6.06	0.045	1.04	35.31
Physical function at baseline (HAQ)	0.13	0.023	0.02	0.75
Pain at baseline (0 to 100 VAS)	1.07	0.000	1.03	1.12
Hosmer-Lemeshow goodness-of-fit test		0.898		
<u>**MCID in global disease activity**</u>:				
Positive affect*	6.91	0.004	1.84	25.92
Age (per unit change)	0.92	0.038	0.86	0.99
Hosmer-Lemeshow goodness-of-fit test		0.708		
<u>**MCID in global physical function**</u>:				
Positive affect*	13.27	0.013	1.72	102.15
Age (per unit of change)	0.89	0.024	0.81	0.98
Physical function at baseline (HAQ)	3.95	0.118	0.71	22.17
Hosmer-Lemeshow goodness-of-fit test		0.417		

HAQ= Health Assessment Questionnaire; VAS= Visual Analogue Scale
* *Positive affect entered as a dichotomous variable: high tertile vs. middle and lower tertile combined*
Other variables entered in the models were: age, disease duration, baseline assessment of disease activity, social support perceived stress, negative affect, and age

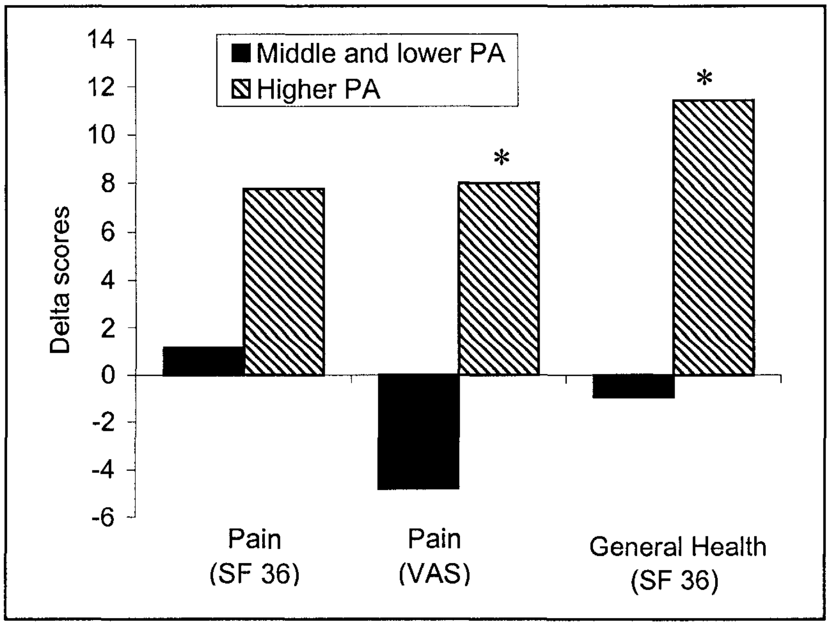
Figure 1. Theoretical model



SE=Self-Efficacy; QoL=Health-Related Quality of Life; PF=Physical Function

* *Moderation of the effect of therapy*

Figure 2. Change in Self-reported Pain and General Health over a 3-month Period by Positive Affect Category*



* p<0.05 U-Mann Whitney test

Delta score= 3-month score – baseline score

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APPENDIX C

Manuscript 3:

POSITIVE AFFECT AS A PREDICTOR OF VISITS TO OUTPATIENT CLINICS

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INTRODUCTION

In the last 60 years, the total health care cost in the United States increased from 4% to almost 14% of the Gross National Product and expenditures for personal medical care rose at a faster pace than expenditures in almost any other good or service.[1] Arthritis was responsible for a considerable fraction of these healthcare expenditures. The estimated medical care costs for individuals with arthritis were $15 billion, while total costs (medical care and lost productivity) were $65 billion in 1992.[2] The Centers for Disease Control and Prevention (CDC) reported that arthritis was the first listed hospital discharge diagnosis for 744,000 hospitalizations annually and 3.8 million hospital days.[3] Using the National Hospital Ambulatory Medical Care Survey Data, the same CDC report also estimated that 44 million ambulatory care visits were attributed to arthritis, of which almost 39 million were to physician offices.[3] Data from 6,230 participants in the

Asset and Health Dynamic Survey Among the Oldest Old (AHEAD) showed that older adults with arthritis were three times more likely to have had a physician visit, 1.6 times more likely to have had a hospital admission, and 1.6 times to have had out-of-pocket cost >$5,000 than contemporaries not reporting arthritis.[4]

Furthermore, all these costs are expected to rapidly increase during the next two decades due, in part, to the progressive aging of the US population.[1] This makes it of primary interest for public health policy makers to optimize health care expenditures. To permit such optimization, it is crucial to identify determinants of health care services utilization by people with arthritis and other chronic conditions. The demand for healthcare resources in arthritis has been related primarily to the patient's physical condition (i.e., disease status), and to the patient observed and self-reported level of physical function and functional decline.[5-9] Other identified factors include age, gender, education, socioeconomic status, prior health care use, costs of services, and perception of quality of life.[10-14]

Health care services utilization has been related to anxiety and depression scores in arthritis patients,[15,16] although not much research has focused on the evaluation of the role of other psychosocial factors. Individual differences in psychological make-up have received increasing attention in explaining differences in perceived health, quality of life and well-being.[17] Positive affect (PA) has been found to be a good indicator of psychological well-being in elderly people with chronic arthritis.[18] It also has been related with adaptive strategies for psychological adjustment to a chronic illness such as arthritis,[19,20] and underlies patient self-efficacy expectations and disease adjustment in cancer patients.[21] Higher levels of PA have also been linked with creative, or divergent, thinking, which would facilitate creative problem solving.[22] The Andersen Model is a behavioral model that provides a structure for the classification of psychosocial factors as predictive of health care services utilization.[23] This model categorizes psychosocial constructs as predisposing and need factors (perceived need). Using this model, we sought to analyze the role of psychosocial variables as determinants of future health care service utilization for patients with arthritis, with particular focus on the role of positive affect (PA), a potential psychological resource during illness episodes.[24]

SUBJECTS AND METHODS

Utilizing initial psychosocial data from two cohorts of arthritis patients, we sought to determine how these baseline psychosocial characteristics, in particular level of PA, predicted future health care services utilization. Individuals with arthritis originally recruited for participation in two different studies comprised the target sample. One of these studies was the NIH/NIAMS funded "Interpersonal Stress and Disease Activity in Arthritis Study", which examined the influence of interpersonal stress on arthritis symptoms, affective distress and disease activity. The other study was the "Living Healthy with Arthritis)" , which examined the impact of a combined exercise and self-management health intervention on outcomes in patients with arthritis.

The Interpersonal Stress and Disease Activity in Arthritis Study methodology has been published previously.[25] In brief, the sample consisted of 307 women with inflammatory or non-inflammatory arthritis. All diagnoses were reconfirmed as meeting the American College of Rheumatology criteria by one of the study investigators based on comprehensive reviews of medical history, medication use and joint tenderness and swelling evaluations. Data were collected from an initial mailed questionnaire, two in-home visits by nurse clinicians, and 12 to 20 weekly telephone interviews. At baseline, data on demographic characteristics, perceived social support, arthritis helplessness, depression, anxiety, extraversion, neuroticism, and level of perceived pain were collected. Then each week, perceived stress, coping difficulty with week's most stressful event, perceived change in the amount of stress, positive affect (PA), and negative affect (NA) were evaluated. The weekly interviews were conducted by trained research assistants and included measures of interpersonal stress and self-reported arthritis disease activity.

The Living Healthy with Arthritis Study was an evaluation among 106 individuals with both inflammatory and non-inflammatory arthritis recruited to participate in a community-based, 4-week intervention. The program was developed to provide a community-based program that integrates traditional and complimentary health practices to promote optimal health for individuals with arthritis. An integrated team of specialists trained in arthritis and preventive care implemented the program. Assessments were made at baseline, end of intervention (4 weeks) and 3 months post-intervention by means of a set of self-administered questionnaires. The original variables included:

psychological status (i.e., positive and negative affect, depression, perceived stress), psychosocial resistance resources (i.e., social support, coping), health status (i.e., physical function, pain), and health-related quality of life.

Follow-up Procedures

Subjects that participated in the above-described studies were recontacted in 2003 and information collected on their health services utilization in the last six months. The average period of time between original study entry and recontact was approximately seven years. Variables originally collected by the parent studies were used as baseline data for this followup study.

Potential participants were contacted by telephone by researchers from the original studies (Arizona Arthritis Center at the University of Arizona or the Department of Psychology at the Arizona State University). The project was explained to subjects and permission sought for them to be mailed a packet of materials with further details about the study and appropriate privacy authorization and consent forms. After signed consent was received, data collection procedures began. Due to logistic arrangements, this process was slightly different for the two participating centers. At the Arizona Arthritis Center, subjects completed a 10-15 minutes phone interview about their perceived health status (i.e., pain, fatigue, global assessment of disease activity) and health services utilization during the previous six months. Subjects were then mailed a short questionnaire that assessed health-related quality of life, physical functioning, affective status as well as type of insurance. At the Arizona State University center, all information was collected during a 25-30 minutes phone interview. All subjects at both locations, however, completed the same set of followup questions, using standardized scripts and questionnaires.

Data were entered to a Microsoft Access database using either a direct entry format or optical scanning of questionnaires (TELEform Enterprise 8.0, a network Optical Character Recognition software application). Data were then extracted into SPSS 11.5 files for analysis. All procedures and survey materials were approved by the institution's Internal Review Board.

Measures

Baseline Variables

Baseline variables were used as predictors. The two original studies measured similar psychosocial and demographic variables. In most cases, these were measured using the same instruments. The databases were pooled after the scores for those variables measured in the two studies were transformed for equivalency.

In both studies, subjects had assessed their level of pain during the previous week on a 0 to 100 pain rating scale. Functional status was evaluated using the Stanford Health Assessment Questionnaire.[26] Positive and negative affects were measured using the Positive and Negative Affect Schedule,[27] the construct of Learned Helplessness with the Arthritis Helplessness Index,[28] and perceived social support with the Medical Outcomes Study Social Support Survey.[29] The measure for depression in one of the studies consisted of nine items taken from the Mental Health Inventory;[30] in the other study, depression was assessed using the Beck Depression Inventory.[31] Perceived stress in one study was measured asking three questions:[25,32] (1) overall, how stressful were your relations with your spouse (or significant other) this past week? (2) Overall, how stressful were your relations with your family members this past week? And (3) Overall, how stressful were your relations with friends this past week? In the other study, it was measured using the Perceived Stress Scale.[33]

Outcome Variable

The main outcome was health services utilization in the six months the followup survey interview. Participants were asked to report the number of times they accessed a series of health care services during those six months. The list included 10 items: family doctor, specialist physician, nurse practitioner/physician assistant, physical/occupational therapist, lab tests, home care nurse, x-rays/CT scans/MRI scans, hospitalization, emergency room, urgent care and surgery. For the purpose of the analysis presented here, a score was derived from the sum of the service items associated with outpatient visits (i.e., visits to a family doctor, specialist physician, nurse practitioner/physician assistant, or physical/occupational therapist). This score, referred to as "outpatient visits", was used as the dependent variable for our analyses. In addition, participants were asked about their current type of health insurance.

Analyses

The null hypothesis for these analyses was that arthritis patients with higher levels of positive affect (PA) and lower levels of negative affect (NA) will report similar levels of future health care services utilization as compared to subjects with lower levels of initial PA and higher levels of NA. Univariate and multivariate linear regression procedures were used to evaluate the association between psychosocial characteristics and future outpatient care utilization (i.e., outpatient visits). The dependent variable in these analyses was the number of outpatient visits, defined as the number of visits to health care providers reported for the six months previous to the followup survey. Demographic, health status, and psychosocial variables collected in the original studies were evaluated as potential predictors for the analyses.

Scores for those constructs measured in the parent studies with different instruments (i.e., depression and perceived stress) were standardized to 0 to 100 scales by dividing each individual's score by the maximum score possible for the instrument. Correlation matrices among predictor variables provided initial test for associations and potential collinearity. Additionally, to further test for collinearity, tolerance statistics were obtained with the multivariate procedures.

The multivariate procedures evaluated the relationship between the predictors of interest (i.e., PA and NA) and outpatient care utilization, controlling for other baseline characteristics. Variables included in the model were those found in previous research to be significant predictors for health services utilization: age, education, income level, functional status, anxiety, and depressive symptoms. The selection of variables for the final model was a backwards elimination procedure. The criteria for entry were based on the probability for the F statistics (from the ANOVA test), with probability of entry set at 0.05 and probability of removal at 0.1. Potential effect modification of the association between positive affect and outpatient care utilization due to the different study source was tested by entering an interaction term into the univariate and multivariate models. The coefficient for this interaction term was not statistically significant ($p=0.29$). SPSS 11.5 (SPSS Inc., Chicago) was used for all analyses.

RESULTS

Participants

A total of 101 arthritis subjects from the original studies have agreed to participate in this follow-up study, which represents 25.9% of the original study samples. Table 1 describes the participants in the followup study by their baseline characteristics. On average, the cohort was 65.8 years (range, 40 to 82 years) and had arthritis for 16.9 years (SD=11.3 years). Sixty-six percent of the sample was married and 42% had completed college or had some postgraduate college education. As seen in Table 2, there were few differences between those individuals who participated in the followup study and those who did not. Participants reported more perceived stress and lower level of pain at baseline, which have not been related with health care services utilization in previous research or in the present study.

Outpatient Visits at Follow-up

The average number of visits to health care providers in a six-month period was 7.63 (SD 8.42), with 57 % reporting 5 or fewer visits and only 7% reporting no visits (Figure 1). Although somewhat skewed, the distribution of outpatient visits was fairly normal (kurtosis= 1.89 with standard error =0.48; and skewness= 1.41 withstandard error =0.25). There were not clear outlier observations; however there were four subjects with >20 outpatient visits in the previous six months – two of them had a PA score of ~20, and the other two a PA score of ~40 –. At follow-up all participants were covered by health insurance with 18.9% reporting a fee-for-service indemnity plan, 39.2% a HMO or PPO plan, and 86.5% government health insurance such as Medicare or Medicaid.

Predictors

Table 3 shows the correlation among study predictors. PA was inversely related with NA, anxiety levels and depressive symptoms, and positively correlated with perception of social support. NA showed moderate to high positive correlation with anxiety, perceived stress and perception of helplessness. High positive correlations were also observed between anxiety and depression ($r=0.67$; $p<0.01$) and between perceived stress and perception of helplessness ($r=0.78$; $p<0.01$). The observed magnitude and sign for all these correlations were as expected. Due to the high correlation observed between these variables, different models were fitted using only one variable of each pair (for example, a model using anxiety as a predictor leaving out depression or a model using perceived stress as a predictor and leaving out helplessness).

Multivariate Linear Regression Procedures

Table 4 reports results of multivariate regression analyses for the association between the psychosocial variables and number of outpatient visits, adjusted for age, income and years of education. Higher levels of PA at baseline were associated with lower number of contacts with the health care system ($B=-0.39$; $p=0.06$). When all potential variables were included in the model (excluding depression and perceived stress for their high correlation with anxiety and helplessness, respectively) positive affect was significantly associated with outpatient visits ($p=0.048$) and social support marginally associated ($p=0.09$) (Table 5).

Stepwise multivariate linear regression modeling was used to evaluate the long term relationship between positive affect and future outpatient care utilization. Variables considered for inclusion were: age, disease duration, physical function, negative affect, anxiety / depression, perceived stress / helplessness, and social support. As described before, different models compared effectiveness with the inclusion of anxiety or depression, and helplessness or perceived stress. The final model included anxiety and helplessness and left out depression and perceived stress – models including these last two variables explained a slightly lower amount of the variance of outpatient care utilization. The final model included only PA, social support, and anxiety. Higher levels of positive affect significantly predicted fewer outpatient visits at follow-up ($B=-0.43$; $p=0.04$). Higher perception of social support and lower levels of anxiety were associated with fewer contacts with health care providers at follow-up (see Table 6). These three variables explained slightly over 21% of the variance of long term health care services utilization (R=0.508; Adjusted R-square=0.217).

DISCUSSION

We examined the relationship between psychosocial factors and future use of outpatient health care services. Subjects initially reporting higher levels of positive affect, higher perception of social support, and lower levels of anxiety, reported lower number of contacts with health care providers at a distant (i.e., seven years) followup. These results support a model that we have proposed by which the association between positive affect and health care seeking behavior could be explained by the effect of affective status on the use of specific coping strategies (i.e., positive affect would determine a higher use of adaptive or active strategies and lower use of maladaptive or passive strategies) and the perception of control or self-efficacy (i.e., higher levels of positive affect increasing the perception of control over the course of the disease).[19,34] These effects on coping and self-efficacy would explain the lower level of interaction with the health care system and, especially, the lower number of contacts with health care providers.

Psychosocial constructs could be categorized as both predisposing and need factors (perceived need) under the Andersen Model.[23] This behavioral model relates use of health services to: 1) predisposing factors (i.e., socio-demographic characteristics and health beliefs); 2) enabling factors (i.e., ability to secure health services); and 3) need factors (i.e., illness related factors). This model was proposed in response to a number of sociological studies indicating that the decision to seek medical care involved cultural, structural, and psychological factors that are irrelevant to the presence and severity of disease. Need factors may be divided between "perceived need" and "evaluated need". Studies predicting health care services utilization for the elderly population have shown that the most important predictors are the need factors,[35-37] although predisposing and enabling factors have been shown to contribute to the explained variance after adjusting for need factors.[38]

health care services utilization has been related with anxiety and depression scores in arthritis,[15,16] but little emphasis has been placed on the evaluation of the role of other psychosocial constructs as predictors of health care utilization. In a study among HMO members over 60 years of age with arthritis, perceived self-efficacy, arthritis helplessness, perceived emotional support and depression did not significantly contribute to the variance of utilization rates.[14] The best single predictor of health care services utilization was prior use of the system. Lorig et al suggested that the reduction in the number of ER/outpatient visits at 2 years was related with increases in the perception of self-efficacy.[39] Similar results were reported for an arthritis sample and a 4-years follow-up period.[40] Recently, a study of determinants of SU was conducted in our center using a national registry sample.[41] Both the cross-sectional analysis with 2381 subjects and the longitudinal analysis with 461 subjects showed that mental distress, as measured by the mental health component of the modified Health Assessment Questionnaire, was one of the most significant predictors of health care services utilization after adjusting for demographic and health status variables.

The substantial economical burden imposed by arthritis arises from is relatively high rate of disability, as compared with other chronic conditions.[42] In this sense, the amount of demand for healthcare resources in arthritis has been related primarily to the patients' level of physical function. [5-9] Poorer function as evaluated by the Health Assessment Questionnaire disability index has been shown to be associated with higher direct medical costs in patients with arthritis.[8,43-45] Ethgen et al [9] found health care services utilization to be related with physical functioning and the perception of health-related quality of life, for both osteoarthritis and rheumatoid arthritis patients.

In our study, physical function, as measured by the HAQ, was not related with SU. A potential explanation for this finding is the fact that our sample was relatively homogeneous in terms of perceived level of disability. Moderate to higher levels of activity limitation were among the criteria for subject selection. In addition, it has been reported that psychological factors influence the pathways leading to physical disability in people with arthritis. Psychological factors such as perception of self-efficacy, coping and depression have been shown to be independent predictors of disability in arthritis.[46-49] In the model that we propose, lower levels of positive affect and higher levels of negative affect are associated with maladaptive coping, which, in turn, is associated with higher pain and limitation. This association between psychosocial factors and disability could explain, at least in part, the dilution of the effect of physical function on health care services utilization when adjusting for psychosocial variables in multivariate models.

A limitation of the present study is that health care services utilization was based on self-report. When assessing health care services utilization is common practice to rely on self-reported data, as such data are very convenient and inexpensive to obtain. However, the accuracy of this information obtained from the patient is less than ideal.[50,51] However, many studies have reported moderate to high correlations between self-reported and agency-reported health care services utilization.[52,53] In general, inaccuracy in self-reported health care services utilization has been associated with age (older adults and children are less accurate), low income, low education level, poorer health status, having a chronic disease, greater levels of disability, and high levels of health care services utilization.[50,51,54] Because subjects participating in our study were mostly elderly adults with arthritis, it would be reasonable to think that they underreported health care services utilization. However, the sample was in general well educated, with medium to high level of income and the time frame for responses was the previous 6 months, all these factors related with a more precise recall.

In summary, we were able to predict a sizable amount of variance of long-term health care services utilization with a small set of psychosocial variables. Positive affect, perceived social support and anxiety levels all contributed to the prediction of the number of outpatient visits in a long-term follow-up.

Table 1. Patients' Characteristics at Baseline *

	n=101
Age	65.8 (40-82)
Gender (male/female)	4/97
Duration arthritis (yrs)	16.9 (11.3)
Pain level at Baseline (0 to 100)	37.0 (23.5)
Marital status:	
• ***Never married***	5 (5.0%)
• ***Married***	67 (66.3%)
• ***Widowed***	14 (13.9%)
• ***Divorced***	15 (14.9%)
Educational level:	
• ***High school incomplete***	3 (3.0%)
• ***High school complete***	28 (27.7%)
• ***Business or trade school***	17 (16.8%)
• ***1-3 years college***	11 (10.9%)
• ***4 years college***	36 (35.6%)
• ***Post-graduate college***	6 (5.9%)

* Values expressed as Mean (SD) or Number of subjects (%)

Table 2. Comparison of Recruited vs. Non-recruited Participants

	Score range	**Participants (n=101)**		**Non-Participants (n=283)**		*p*
		Mean	***SD***	***Mean***	***SD***	
Age		65.91	8.60	64.44	7.93	ns.
Disease duration		16.89	11.25	15.66	13.23	ns.
Education	0 - 8	5.77	1.57	5.52	1.56	ns.
Income	0 - 100	68.94	26.33	70.07	25.62	ns.
Pain	0 - 100	36.99	23.61	44.14	26.07	0.033
Physical function	0 - 3	0.87	0.58	0.99	0.75	ns.
Positive affect	10 - 50	33.31	8.06	31.84	7.30	ns.
Negative affect	10 - 50	16.59	5.62	16.75	5.99	ns.
Anxiety	0 - 100	44.95	15.32	47.41	16.69	ns.
Depression	0 - 100	37.45	13.28	40.59	17.42	ns.
Perceived stress	0 - 100	33.22	22.36	23.63	22.47	0.001
Social support	0 - 100	74.35	17.14	70.88	18.64	ns.
Helplessness	0 - 100	48.59	19.34	52.29	17.79	ns.

ns= non statistically significant

Table 3. Correlation among Psychosocial Variables at Baseline

	Positive affect	***Negative affect***	***Anxiety***	***Depres.***	***Perceived stress***	***Social Support***
Negative affect	-0.17					
Anxiety	-0.21	0.52**				
Depression	-0.43**	0.15	0.67**			
Perceived stress	0.06	0.39**	0.42**	0.34*		
Social Support	0.34**	-0.04	-0.11	-0.16	0.06	
Helplessness	0.08	0.40**	0.36*	0.19	0.78**	0.20

**p<0.01; * p<0.05; Depres.= Depression
Pearson's coefficients

Table 4. All Potential Predictors of Number of Outpatient Visits *

Models	***Coefficient***	***SE*** ‡	***p***	***95% CI***	
Positive affect	-0.39	0.21	0.065	-0.81	0.03
Negative affect	0.13	0.29	0.656	-0.46	0.71
Anxiety	0.06	0.12	0.618	-0.18	0.31
Depresion	0.06	0.12	0.610	-0.18	0.31
Perceived stress	-0.06	0.08	0.454	-0.21	0.10
Helplessness	0.03	0.09	0.726	-0.15	0.22
Social support	-0.11	0.10	0.280	-0.31	0.09
Pain	-0.01	0.09	0.877	-0.19	0.16
Physical function	3.53	2.61	0.184	-1.74	8.80
Disease duration	0.03	0.15	0.820	-0.27	0.34

* Linear Regression Analysis. Coefficients correspond to each predictor regressed on outpatient visits individually and adjusted for age, income, and education level

‡ SE=Standard Error

Table 5. Predictors of Number of Outpatient Visits. Inclusive Model

	Coefficient	***SE*** ‡	***p***	***95% CI***	
Positive affect	-0.32	0.15	0.048	-0.63	0.00
Negative affect	0.19	0.28	0.505	-0.38	0.76
Anxiety	0.10	0.09	0.301	-0.09	0.28
Helplessness	0.06	0.08	0.419	-0.09	0.22
Social support	-0.12	0.07	0.093	-0.27	0.02
Pain	-0.07	0.06	0.230	-0.19	0.05
Physical function	2.22	1.99	0.273	-1.84	6.28
Disease duration	0.03	0.11	0.795	-0.19	0.25
Age	0.12	0.14	0.400	-0.17	0.40
Income	0.05	0.05	0.383	-0.06	0.15
Education level	-0.36	0.96	0.707	-2.31	1.58

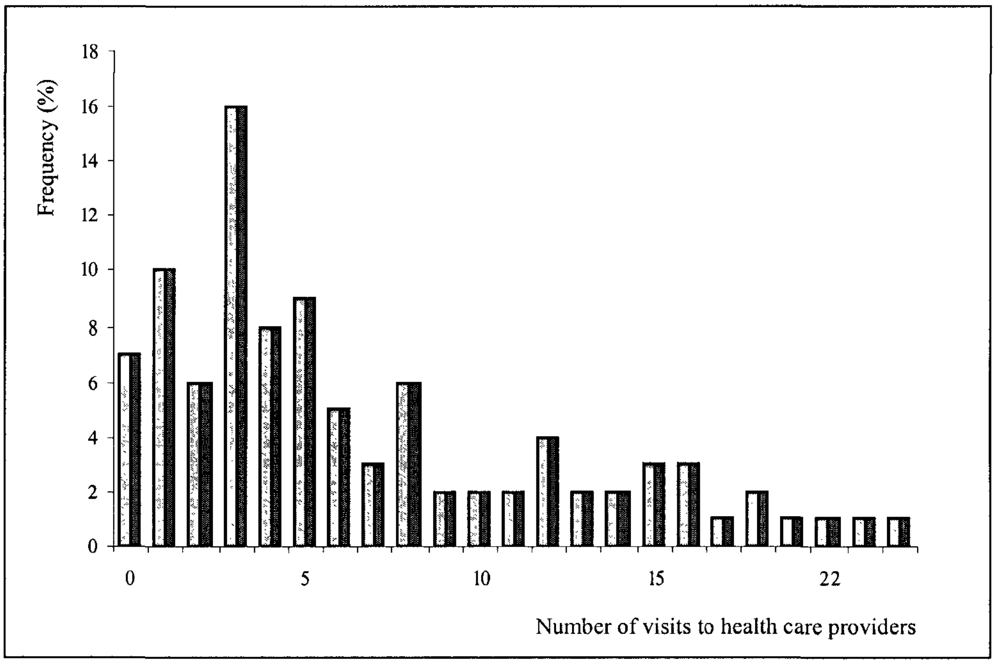
‡ SE=Standard Error

Table 6. Predictors of Number of Outpatient Visits. Results from Final Stepwise Multivariate Regression Model *

	Coefficient	*SE* ‡	*p*	*95% CI*	
Positive affect	-0.29	0.13	0.041	-0.56	-0.01
Social support	-0.16	0.06	0.014	-0.28	-0.03
Anxiety	0.14	0.06	0.033	0.01	0.27

R = 0.51 ; Adjusted R-square = 0.217
‡ SE=Standard Error

Figure 1. Number of Visits to Health Care Providers



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APPENDIX D

Questionnaires

SOCIODEMOGRAPHIC PROFILE

Subject # ____________________

SECTION 1

Please check (4) the one best answer and/or fill in the blanks.

1. Sex
- ☐ male ☐ female

J. **Birthdate** (mm/dd/yy)

_____/_____/_____

K. **Race/Ethnicity**
- ☐ Caucasian, non-Hispanic
- ☐ Hispanic
- ☐ Native-American/ American Indian Tribe________
- ☐ African-American
- ☐ Asian
- ☐ Other (Specify below)

____

L. **Employment**
- ☐ Full-time
- ☐ Part-time
- ☐ Self -employed
- ☐ Homemaker
- ☐ Retired
- ☐ Student
- ☐ Unemployed
- ☐ Other (Specify Below)

____

M. **Occupation** (if currently Employed)______________

N. **Total # in Household**

(Include yourself) ______

O. **Marital Status**
- ☐ Married
- ☐ Single
- ☐ Divorced
- ☐ Widowed

P. **Yearly Household Income**
- ☐ Less than 20,000
- ☐ 20,001-30,000
- ☐ 30,001-40,000
- ☐ 40,001-50,000
- ☐ 50,001-60,000
- ☐ Above 60,001

Q. **Receiving Disability?**
- ☐ Yes ☐ No

R. **Highest Education Completed**
- ☐ Grade School
- ☐ Some High School
- ☐ High School
- ☐ Technical School
- ☐ Some College
- ☐ College
- ☐ Post-graduate Training
- ☐ Masters µ Ph.D., M.D.

SECTION 2

Please list the number of times you accessed the following health care over the last 6 months

- ____ Family Doctor
- ____ Specialist Physician
- ____ Nurse Practitioner/Physician Asst.
- ____ Psychologist/Mental Health Counselor
- ____ Physical/Occupational Therapist
- ____ Lab Test
- ____ Home Care Nurse
- ____ X-rays, CT Scans, MRI Scans
- ____ Hospitalization
- ____ Emergency Room
- ____ Urgent Care
- ____ Surgery (specify below)

____

SECTION 3

What type of arthritis do you have?

____

How long have you had this arthritis? (years)

____

Please check all other forms of arthritis that you have ☐ None

- ☐ 1. Rheumatoid Arthritis
- ☐ 2. Osteoarthritis
- ☐ 3. Low Back Pain
- ☐ 5. Scleroderma
- ☐ 6. Psoriatic Arthritis
- ☐ 7. Reiter's Syndrome
- ☐ 9. Systemic Lupus Erythematosus
- ☐ 10. Tendonitis/Bursitis
- ☐ 11. Osteoporosis

ARTHRITIS HELPLESSNESS INDEX

Please check one box for each question that best describes your perception of your ability to control your arthritis.

1 = Strongly Disagree	2 = Disagree	3 = Agree	4 = Strongly Agree

1.	Arthritis is controlling my life.	☐ 1	☐ 2	☐ 3	☐ 4
2.	Managing my arthritis is largely my own responsibility	☐ 1	☐ 2	☐ 3	☐ 4
3.	I can reduce my pain by staying calm and relaxed.	☐ 1	☐ 2	☐ 3	☐ 4
4.	Too often, my pain just seems to hit me out of the blue.	☐ 1	☐ 2	☐ 3	☐ 4
5.	If I do all the right things, I can successfully manage my arthritis.	☐ 1	☐ 2	☐ 3	☐ 4
6.	I can do a lot of things myself to cope with my arthritis.	☐ 1	☐ 2	☐ 3	☐ 4
7.	When it comes to managing my arthritis, I feel I can only do what my doctor tells me to do.	☐ 1	☐ 2	☐ 3	☐ 4
8.	When I manage my personal life well, my arthritis does not flare up as much.	☐ 1	☐ 2	☐ 3	☐ 4
9.	I have considerable ability to control my pain.	☐ 1	☐ 2	☐ 3	☐ 4
10.	I would feel helpless if I couldn't rely on other people for help with my arthritis.	☐ 1	☐ 2	☐ 3	☐ 4
11.	Usually, I can tell when my arthritis will flare up.	☐ 1	☐ 2	☐ 3	☐ 4
12.	No matter what I do, or how hard I try, I just can't seem to get relief from my pain.	☐ 1	☐ 2	☐ 3	☐ 4
13.	I am coping effectively with my arthritis.	☐ 1	☐ 2	☐ 3	☐ 4
14.	It seems as though fate and other factors beyond my control affect my arthritis.	☐ 1	☐ 2	☐ 3	☐ 4
15.	I want to learn as much as I can about arthritis	☐ 1	☐ 2	☐ 3	☐ 4

DEPRESSION AND ANXIETY SCALES FROM THE AIMS QUESTIONNAIRE

The questions below ask you about your feelings, thoughts and activities during *the last month.* Please check one box for each question.

1 =All of the time	2 =Most of the time	3 =A good bit of the time
4 = Some of the time	5 = A little of the time	6 = None of the time

In the last month, how much of the time.........

1. Have you felt downhearted and blue?	□1	□2	□3	□4	□5	□6
2. Have you been in low or very low spirits?	□1	□2	□3	□4	□5	□6
3. Have you enjoyed the things you do?	□1	□2	□3	□4	□5	□6
4. Have you felt tense or "high strung"?	□1	□2	□3	□4	□5	□6
5. Were you able to relax without difficulty?	□1	□2	□3	□4	□5	□6
6. Have you felt calm and peaceful?	□1	□2	□3	□4	□5	□6
7. Did you feel relaxed and free of tension?	□1	□2	□3	□4	□5	□6

1 = Always	2 = Very Often	3 = Fairly Often
4 = Sometimes	5 = Almost Never	6 = Never

In the last month, how often.........

8. Did you feel that others would be better off if you were dead?	□1	□2	□3	□4	□5	□6
9. Have you felt so down in the dumps that nothing could cheer you up?	□1	□2	□3	□4	□5	□6
10. Did you feel that nothing turned out for you the way you wanted it to?	□1	□2	□3	□4	□5	□6
11. Did you find yourself having difficulty trying to calm down?	□1	□2	□3	□4	□5	□6
12. Have you been bothered by nervousness, or your "nerves"?	□1	□2	□3	□4	□5	□6

THE MEDICAL OUTCOMES STUDY SOCIAL SUPPORT SURVEY

Next are some questions about the support that is available to you.

1. **About how many close friends and close relatives do you have (people you feel at ease with and can talk to about what is on your mind)?**

   Write in the number of close friends and close relatives: ________

People sometimes look to others for companionship, assistance, or other types of support. How often in the past week have each of the following kinds of support been available to you if you needed it?

1 = None of the time	2 = A little of the time	3 = Some of the time
4 = Most of the time	5= All of the time	

2. Someone to help you if you were confined to bed.	□ 1	□ 2	□ 3	□ 4	□ 5
3. Someone you can count on to listen to you when you need to talk.	□ 1	□ 2	□ 3	□ 4	□ 5
4. Someone to give you good advice about a crisis.	□ 1	□ 2	□ 3	□ 4	□ 5
5. Someone to take you to the doctor if you needed it.	□ 1	□ 2	□ 3	□ 4	□ 5
6. Someone who shows you love and affection.	□ 1	□ 2	□ 3	□ 4	□ 5
7. Someone to have a good time with.	□ 1	□ 2	□ 3	□ 4	□ 5
8. Someone to give you information to help you understand a situation.	□ 1	□ 2	□ 3	□ 4	□ 5
9. Someone to confide in or talk to about yourself or your problems.	□ 1	□ 2	□ 3	□ 4	□ 5
10. Someone who hugs you.	□ 1	□ 2	□ 3	□ 4	□ 5
11. Someone to get together with for relaxation.	□ 1	□ 2	□ 3	□ 4	□ 5
12. Someone to prepare your meals if you were unable to do it yourself.	□ 1	□ 2	□ 3	□ 4	□ 5
13. Someone whose advise you really want.	□ 1	□ 2	□ 3	□ 4	□ 5

THE MEDICAL OUTCOMES STUDY SOCIAL SUPPORT SURVEY (Continuation)

14. Someone to do things with to help you get your mind off things.	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**
15. Someone to help with daily chores if you were sick.	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**
16. Someone to share your most private worries and fears with.	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**
17. Someone to turn to for suggestions about how to deal with a personal problem.	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**
18. Someone to do something enjoyable with.	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**
19. Someone who understands your problems.	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**

POSITIVE AND NEGATIVE AFFECT SCALES

The following words describe different feelings and emotions. Please indicate the extent to which you have felt this way during the past week by marking the circle under your choice.

1 = None of the time   2 = A little of the time   3 = Some of the time
4 = Most of the time   5= All of the time

	1	2	3	4	5		1	2	3	4	5
1. interested	☐	☐	☐	☐	☐	11. irritable	☐	☐	☐	☐	☐
2. distressed	☐	☐	☐	☐	☐	12. alert	☐	☐	☐	☐	☐
3. excited	☐	☐	☐	☐	☐	13. ashamed	☐	☐	☐	☐	☐
4. upset	☐	☐	☐	☐	☐	14. inspired	☐	☐	☐	☐	☐
5. strong	☐	☐	☐	☐	☐	15. nervous	☐	☐	☐	☐	☐
6. guilty	☐	☐	☐	☐	☐	16. determined	☐	☐	☐	☐	☐
7. scared	☐	☐	☐	☐	☐	17. attentive	☐	☐	☐	☐	☐
8. hostile	☐	☐	☐	☐	☐	18. jittery	☐	☐	☐	☐	☐
9. enthusiastic	☐	☐	☐	☐	☐	19. active	☐	☐	☐	☐	☐
10. proud	☐	☐	☐	☐	☐	20. afraid	☐	☐	☐	☐	☐

PERCEIVED STRESS SCALE

The questions below ask you about your feelings, thoughts and activities during *the last month*. Please check one box for each question.

1 = None of the time   2 = A little of the time   3 = Some of the time 4 = Most of the time   5 = All of the time

In the last month, how often have you.......

1. Been upset because of something that happened unexpectedly?	□ 1	□ 2	□ 3	□ 4	□ 5
2. Felt that you were unable to control the important things in your life?	□ 1	□ 2	□ 3	□ 4	□ 5
3. Felt nervous and "stressed"?	□ 1	□ 2	□ 3	□ 4	□ 5
4. Felt confident about your ability to handle your personal problems?	□ 1	□ 2	□ 3	□ 4	□ 5
5. Felt that things were going your way?	□ 1	□ 2	□ 3	□ 4	□ 5
6. Found that you could not cope with all the things that you had to do?	□ 1	□ 2	□ 3	□ 4	□ 5
7. Been able to control irritations in your life?	□ 1	□ 2	□ 3	□ 4	□ 5
8. Felt that you were on top of things?	□ 1	□ 2	□ 3	□ 4	□ 5
9. Been angered because of things that happened that were outside of your control?	□ 1	□ 2	□ 3	□ 4	□ 5
10. Felt difficulties were piling up so high that you could not overcome them?	□ 1	□ 2	□ 3	□ 4	□ 5

HEALTH ASSESSMENT QUESTIONNAIRE

For each of the 8 categories listed below, select the response that best describes how the illness affects the daily activities of your life over the past week. **Please ask yourself, are you able to…**

	Without any difficulty 1	**With some difficulty 2**	**With much difficulty 3**	**Unable to do 4**
Dressing and Grooming				
1. …dress yourself, including shoelaces and buttons?	❍ 1	❍ 2	❍ 3	❍ 4
2. …shampoo your hair?	❍ 1	❍ 2	❍ 3	❍ 4
Hygiene				
3. …wash and dry your entire body?	❍ 1	❍ 2	❍ 3	❍ 4
4. …take a tub bath?	❍ 1	❍ 2	❍ 3	❍ 4
5. …get on and off the toilet?	❍ 1	❍ 2	❍ 3	❍ 4
Walking				
6. …climb up 5 steps?	❍ 1	❍ 2	❍ 3	❍ 4
7. …walk outdoors on flat ground?	❍ 1	❍ 2	❍ 3	❍ 4
Grip				
8. …open car doors?	❍ 1	❍ 2	❍ 3	❍ 4
9. …turn faucets on and off?	❍ 1	❍ 2	❍ 3	❍ 4
10. open jars which have been previously opened?	❍ 1	❍ 2	❍ 3	❍ 4
Arising				
11. …stand up from an armless straight chair?	❍ 1	❍ 2	❍ 3	❍ 4
12. …get in and out of bed?	❍ 1	❍ 2	❍ 3	❍ 4

HEALTH ASSESSMENT QUESTIONNAIRE (continuation)

	Without any difficulty 1	**With some difficulty 2**	**With much difficulty 3**	**Unable to do 4**
Eating				
13. ...lift a full cup or glass to your mouth?	❍ 1	❍ 2	❍ 3	❍ 4
14. ...cut your meat?	❍ 1	❍ 2	❍ 3	❍ 4
15. ...open a new milk carton?	❍ 1	❍ 2	❍ 3	❍ 4
Reach				
16. ...reach and get down a 5 pound object?	❍ 1	❍ 2	❍ 3	❍ 4
17. ...bend down and pick up clothing from the floor?	❍ 1	❍ 2	❍ 3	❍ 4
Activities				
18. ...run errands and shop?	❍ 1	❍ 2	❍ 3	❍ 4
19. ...get in and out of a car?	❍ 1	❍ 2	❍ 3	❍ 4
20. ...do chores such as vacuuming or yard work?	❍ 1	❍ 2	❍ 3	❍ 4

Aids and Devices

21. Please check any aids or devices that you usually use for any of these activities:

- ☐1. Raised toilet seat
- ☐2. Bathtub seat
- ☐3. Bathroom bar
- ☐4. Long-handled appliances for bathroom
- ☐5. Wheelchair
- ☐6. Walker
- ☐7. Cane
- ☐8. Corset
- ☐9. Jar opener (for jars previously opened)
- ☐10. Devices used for dressing (eg. zipper pull)
- ☐11. Long-handled appliances for reach
- ☐12. Back support (home)
- ☐13. Back support (car)
- ☐14. Special or built-up chair

22. Please check any category for which you usually need help from another person:

- ☐1. Dressing and grooming
- ☐2. Arising
- ☐3. Hygiene
- ☐4. Eating
- ☐5. Walking
- ☐6. Reach
- ☐7. Grip
- ☐8. Activities

THE MEDICAL OUTCOMES SHORT-FORM-36 HEALTH SURVEY

1. In general, would you say your health is...
   - ☐1. Excellent
   - ☐2. Very good
   - ☐3. Good
   - ☐4. Fair
   - ☐5. Poor

2. Compared to one year ago, how would you rate your health in general now?
   - ☐1. Much better now than one year ago
   - ☐2. Somewhat better now than one year ago
   - ☐3. About the same as one year ago
   - ☐4. Somewhat worse now than one year ago
   - ☐5. Much worse now than one year ago

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot 1	**Yes, limited a little 2**	**No, not limited at all 3**
3. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	❍ 1	❍ 2	❍ 3
4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?	❍ 1	❍ 2	❍ 3
5. Lifting or carrying groceries?	❍ 1	❍ 2	❍ 3
6. Climbing several flights of stairs?	❍ 1	❍ 2	❍ 3
7. Climbing one flight of stairs?	❍ 1	❍ 2	❍ 3
8. Bending, kneeling, or stooping?	❍ 1	❍ 2	❍ 3
9. Walking more than a mile?	❍ 1	❍ 2	❍ 3

THE MEDICAL OUTCOMES SHORT-FORM-36 HEALTH SURVEY (Continuation)

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes 1	No 2
13. Cut down the amount of time you spent on work or other activities?	○ 1	○ 2
14. Accomplished less than you would like?	○ 1	○ 2
15. Were limited in the kind of work or other activities?	○ 1	○ 2
16. Had difficulty performing the work or other activities?	○ 1	○ 2

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional health?

	Yes 1	No 2
17. Cut down the amount of time you spent on work or other activities?	○ 1	○ 2
18. Accomplished less than you would like?	○ 1	○ 2
19. Didn't do work or other activities as carefully as usually?	○ 1	○ 2

20. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, neighbors, or groups?

☐1. Not at all
☐2. Slightly
☐3. Moderately
☐4. Quite a bit
☐5. Extremely

21. How much bodily pain have you had during the past 4 weeks?

☐1. None
☐2. Very mild
☐3. Mild
☐4. Moderate
☐5. Severe
☐6. Very severe

THE MEDICAL OUTCOMES SHORT-FORM-36 HEALTH SURVEY (Continuation)

22. During the past 4 weeks, how much did pain interfere with your normal work including both outside the home and housework?

- ☐1. Not at all
- ☐2. Slightly
- ☐3. Moderately
- ☐4. Quite a bit
- ☐5. Extremely

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

	All of the time 1	**Most of the time 2**	**A good bit of the time 3**	**Some of the time 4**	**A little of the time 5**	**None of the time 6**
23. Did you feel full of pep?	❍ 1	❍ 2	❍ 3	❍ 4	❍ 5	❍ 6
24. Have you been a very nervous person?	❍ 1	❍ 2	❍ 3	❍ 4	❍ 5	❍ 6
25. Have you felt down in the dumps that nothing could cheer you up?	❍ 1	❍ 2	❍ 3	❍ 4	❍ 5	❍ 6
26. Have you felt calm and peaceful?	❍ 1	❍ 2	❍ 3	❍ 4	❍ 5	❍ 6
27. Did you have a lot of energy?	❍ 1	❍ 2	❍ 3	❍ 4	❍ 5	❍ 6
28. Have you felt downhearted and blue?	❍ 1	❍ 2	❍ 3	❍ 4	❍ 5	❍ 6
29. Did you feel worn out?	❍ 1	❍ 2	❍ 3	❍ 4	❍ 5	❍ 6
30. Have you been a happy person?	❍ 1	❍ 2	❍ 3	❍ 4	❍ 5	❍ 6
31. Did you feel tired?	❍ 1	❍ 2	❍ 3	❍ 4	❍ 5	❍ 6

THE MEDICAL OUTCOMES SHORT-FORM-36 HEALTH SURVEY (Continuation)

32. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?
   - ☐1. All of the time
   - ☐2. Most of the time
   - ☐3. A good bit of the time
   - ☐4. Some of the time
   - ☐5. A little of the time
   - ☐6. None of the time

How true or false is each of the following statements for you?

	Definitely true 1	**Mostly true 2**	**Don't know 3**	**Mostly false 4**	**Definitely false 5**
33. I seem to get sick a little easier than other people.	❍ 1	❍ 2	❍ 3	❍ 4	❍ 5
34. I am as healthy as anybody I know.	❍ 1	❍ 2	❍ 3	❍ 4	❍ 5
35. I expect my health to get worse.	❍ 1	❍ 2	❍ 3	❍ 4	❍ 5
36. My health is excellent.	❍ 1	❍ 2	❍ 3	❍ 4	❍ 5

THE COPING WITH CHRONIC PAIN QUESTIONNAIRE

During the past week, how many days did you use each of the following at least once in the day to cope with your arthritis pain? (Note: You may have used some of these coping strategies on days that you did not have pain to prevent or minimize pain in the future. Please indicate the number of days you used each strategy FOR PAIN, whether or not you were experience pain a the time).

		NUMBER OF DAYS							
		0	**1**	**2**	**3**	**4**	**5**	**6**	**7**
1.	Imagined a calming or distracting image to help me relax..	☐	☐	☐	☐	☐	☐	☐	☐
2.	Kept on doing what I was doing.................................	☐	☐	☐	☐	☐	☐	☐	☐
3.	Stretched the muscles in my legs and held the stretch for at least 10 seconds...	☐	☐	☐	☐	☐	☐	☐	☐
4.	Ignored the Pain..	☐	☐	☐	☐	☐	☐	☐	☐
5.	I took a rest..	☐	☐	☐	☐	☐	☐	☐	☐
6.	Made arrangements to see a friend or family member......	☐	☐	☐	☐	☐	☐	☐	☐
7.	I went to bed early to rest..	☐	☐	☐	☐	☐	☐	☐	☐
8.	Wish the doctor would prescribe better pain medication....	☐	☐	☐	☐	☐	☐	☐	☐
9.	I got support from a friend..	☐	☐	☐	☐	☐	☐	☐	☐
10.	Asked someone to do something for me.......................	☐	☐	☐	☐	☐	☐	☐	☐
11.	Reminded myself that things could be worse.................	☐	☐	☐	☐	☐	☐	☐	☐
12.	Avoid using part of my body (e.g., hand, arm, leg)..........	☐	☐	☐	☐	☐	☐	☐	☐
13.	Focused on relaxing my muscles...............................	☐	☐	☐	☐	☐	☐	☐	☐
14.	Sat on the floor, stretched, and held the stretch at least 10 minutes..	☐	☐	☐	☐	☐	☐	☐	☐
15.	Told myself things will get better................................	☐	☐	☐	☐	☐	☐	☐	☐
16.	Thought about how much the pain was wearing me down.	☐	☐	☐	☐	☐	☐	☐	☐

THE COPING WITH CHRONIC PAIN QUESTIONNAIRE (Continuation)

During the past week, how many days did you use each of the following at least once in the day to cope with your arthritis pain?

		NUMBER OF DAYS							
		0	1	2	3	4	5	6	7
17.	Held on to something when getting up or sitting down……	☐	☐	☐	☐	☐	☐	☐	☐
18.	I got support from a family member………………………..	☐	☐	☐	☐	☐	☐	☐	☐
19.	Exercised to strengthen the muscles in my arms for at lease 1 minute………………………………………………	☐	☐	☐	☐	☐	☐	☐	☐
20.	I rested as much as I could……………………………….	☐	☐	☐	☐	☐	☐	☐	☐
21.	Thought about someone with problems worse than mine..	☐	☐	☐	☐	☐	☐	☐	☐
22.	I talked to someone close to me…………………………..	☐	☐	☐	☐	☐	☐	☐	☐
23.	Told myself that I am adjusting to my pain problem better than many other people……………………………………	☐	☐	☐	☐	☐	☐	☐	☐
24.	Thought it was terrible, and that it was never going to get any better………………………………………………	☐	☐	☐	☐	☐	☐	☐	☐
25.	Called a friend on the phone to help me feel better………	☐	☐	☐	☐	☐	☐	☐	☐
26.	Thought it was terrible, and that it was never going to get any better………………………………………………	☐	☐	☐	☐	☐	☐	☐	☐
27.	Listened to music to relax…………………………………	☐	☐	☐	☐	☐	☐	☐	☐
28.	Asked for help with a chore or task………………………..	☐	☐	☐	☐	☐	☐	☐	☐
29.	Stretched the muscles in my neck (and held the stretch) for at least 10 seconds……………………………………	☐	☐	☐	☐	☐	☐	☐	☐
30.	Told myself my pain will get better………………………..	☐	☐	☐	☐	☐	☐	☐	☐
31.	I didn't let the pain interfere with my activities……………...	☐	☐	☐	☐	☐	☐	☐	☐
32.	Worried the whole time about whether it will end…………	☐	☐	☐	☐	☐	☐	☐	☐
33.	Exercised to strengthen the muscles in my legs for at least I minute………………………………………………..	☐	☐	☐	☐	☐	☐	☐	☐

THE COPING WITH CHRONIC PAIN QUESTIONNAIRE (Continuation)

During the past week, how many days did you use each of the following at least once in the day to cope with your arthritis pain?

	NUMBER OF DAYS							
	0	1	2	3	4	5	6	7
34. Thought about a friend who has coped well with a problem	☐	☐	☐	☐	☐	☐	☐	☐
35. Listened to a relaxation tape to relax	☐	☐	☐	☐	☐	☐	☐	☐
36. Engaged in aerobic exercise (exercise that made my heart beat faster) for at least 15 minutes	☐	☐	☐	☐	☐	☐	☐	☐
37. Limited my walking because of pain	☐	☐	☐	☐	☐	☐	☐	☐
38. Just didn't pay attention to the pain	☐	☐	☐	☐	☐	☐	☐	☐
39. Walked with a limp to decrease the pain	☐	☐	☐	☐	☐	☐	☐	☐
40. Admitted to myself that I couldn't deal with it and quit trying	☐	☐	☐	☐	☐	☐	☐	☐
41. Mediated to relax	☐	☐	☐	☐	☐	☐	☐	☐
42. Reminded myself that I had coped with the pain before	☐	☐	☐	☐	☐	☐	☐	☐
43. Lay on my back, stretched, and held the stretch for at least 10 seconds	☐	☐	☐	☐	☐	☐	☐	☐
44. Held part of my body (e.g., arm)) in a special way	☐	☐	☐	☐	☐	☐	☐	☐
45. Rested in a chair or recliner	☐	☐	☐	☐	☐	☐	☐	☐
46. Avoided putting weight on feet or legs	☐	☐	☐	☐	☐	☐	☐	☐
47. Asked for help in carrying, lifting or pushing something	☐	☐	☐	☐	☐	☐	☐	☐
48. Felt like I couldn't stand it anymore	☐	☐	☐	☐	☐	☐	☐	☐
49. Exercised to improve my overall physical condition for at least 5 minutes	☐	☐	☐	☐	☐	☐	☐	☐
50. Talked to a friend or family member for support	☐	☐	☐	☐	☐	☐	☐	☐

THE COPING WITH CHRONIC PAIN QUESTIONNAIRE (Continuation)

During the past week, how many days did you use each of the following at least once in the day to cope with your arthritis pain?

		NUMBER OF DAYS							
		0	**1**	**2**	**3**	**4**	**5**	**6**	**7**
51.	Reminded myself that there are people who are worse off than I am..	☐	☐	☐	☐	☐	☐	☐	☐
52.	Limited by standing time..	☐	☐	☐	☐	☐	☐	☐	☐
53.	Lay down on a bed..	☐	☐	☐	☐	☐	☐	☐	☐
54.	Avoided some physical activities (lifting, pushing, carrying)..	☐	☐	☐	☐	☐	☐	☐	☐
55.	Reminded myself about things that I have going for me such as intelligence, good looks, and good friends..........	☐	☐	☐	☐	☐	☐	☐	☐
56.	Thought that I couldn't do anything to cope with the pain..	☐	☐	☐	☐	☐	☐	☐	☐
57.	Used self-hypnosis to relax......................................	☐	☐	☐	☐	☐	☐	☐	☐
58.	I just kept going..	☐	☐	☐	☐	☐	☐	☐	☐
59.	Exercised to strengthen the muscles in my stomach for at least 1 minute.	☐	☐	☐	☐	☐	☐	☐	☐
60.	Got together with a friend..	☐	☐	☐	☐	☐	☐	☐	☐
61.	Reminded myself that others have coped well with pain problems..	☐	☐	☐	☐	☐	☐	☐	☐
62.	Stretched the muscles where I hurt and held the stretch for at least 10 seconds..	☐	☐	☐	☐	☐	☐	☐	☐
63.	Avoid activity..	☐	☐	☐	☐	☐	☐	☐	☐
64.	Felt like I couldn't go on...	☐	☐	☐	☐	☐	☐	☐	☐

BECK DEPRESSION INVENTORY

After reading each group of statements carefully circle the number (0,1,2,3) next to the one statement in each group which **best** describes the way you have been feeling the **past week, including today**. If several statements within a group seem to apply equally well, circle each one. **Be sure to read all the statements in each group before make your choice.**

0 = I do not feel sad.
1 = I feel sad.
2 = I am sad all the time and I can't snap out of it.
3 = I am so sad or unhappy that I can't stand it.

0 = I am not particularly discouraged about the future.
1 = I feel discouraged about the future.
2 = I feel I have nothing to look forward to.
3 = I feel that the future is hopeless and that things cannot improve.

0 = I do not feel like a failure.
1 = I feel I have failed more than the average person.
2 = As I look back on my life, all I can see is a lot of failures..
3 = I feel I am a complete failure as a person.

0 = I get as much satisfaction out of things as I used to.
1 = I don't enjoy things the way I used to.
2 = I don't get real satisfaction out of anything anymore.
3 = I am dissatisfied or bored with everything.

0 = I don't feel particularly guilty.
1 = I feel guilty a good part of the time.
2 = I feel quite guilty most of the time.
3 = I feel guilty all of the time.

0 = I don't feel I am being punished.
1 = I feel I may be punished.
2 = I expect to be punished.
3 = I feel I am being punished.

BECK DEPRESSION INVENTORY (Continuation)

0 = I don't feel disappointed in myself.
1 = I am disappointed in myself.
2 = I am disgusted with myself.
3 = I hate myself.

0 = I don't feel I am any worse than anybody else.
1 = I am critical of myself for my weaknesses or mistakes.
2 = I blame myself all the time for my faults.
3 = I blame myself for everything bad that happens.

0 = I don't have any thoughts of killing myself.
1 = I have thoughts of killing myself, but I would not carry them out.
2 = I would like to kill myself.
3 = I would kill myself if I had the chance.

0 = I don’t cry any more than usual.
1 = I cry more now than I used to.
2 = I cry all the time now.
3 = I used to be able to cry, but now I can't cry even though I want to.

0 = I am no more irritated now than I ever am.
1 = I get annoyed or irritated more easily than I used to.
2 = I feel irritated all the time now.
3 = I don't get irritated at all by the things that used to irritated me.

0 = I have not lost interest in other people.
1 = I am less interested in other people than I used to be.
2 = I have lost most of my interest in other people.
3 = I have lost all of my interest in other people.

0 = I make decisions about as well as I ever could.
1 = I put off making decisions more than I used to.
2 = I have greater difficulty in making decisions than before.
3 = I can't make decisions at all anymore.

0 = I can work about as well as before.
1 = It takes an extra effort to get started at doing something.
2 = I have to push myself very hard to do anything.
3 = I can't do any work at all.

BECK DEPRESSION INVENTORY (Continuation)

0 = I don't feel I look any worse than I used to.
1 = I am worried that I am looking old or unattractive.
2 = I feel that there are permanent changes in my appearance that make me look unattractive.
3 = I believe that I look ugly.

0 = I can sleep as well as usual.
1 = I don't sleep as well as I used to.
2 = I wake up 1-2 hours earlier than usual and find it hard to get back to sleep.
3 = I wake up several hours earlier than I used to and cannot get back to sleep.

0 = I don't get more tired than usual.
1 = I get tired more easily than I used to.
2 = I get tired from doing almost anything.
3 = I am too tired to do anything.

0 = My appetite is worse than usual.
1 = My appetite is not as good as it used to be.
2 = My appetite is much worse now.
3 = I have no appetite at all anymore.

0 = I haven't lost much weight, if any, lately.
1 = I have lost more than 5 pounds.
2 = I have lost more than 10 pounds.
3 = I have lost more than 15 pounds.

0 = I am no more worried about my health than usual.
1 = I am worried about physical problems such as aches and pains; or upset stomach; or constipation.
2 = I am very worried about physical problems and it's hard to think of much else.
3 = I am so worried about my physical problems that I cannot think about anything else.

0 = I have not noticed any recent change in my interest in sex.
1 = I am less interested in sex than I used to be.
2 = I am much less interested in sex now.
3 = I have lost interest in sex completely.

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