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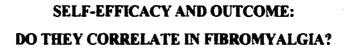
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ABSTRACT

This prospective observational study examined whether baseline self-efficacy can predict health status, post-rehabilitation and whether changes in self-efficacy are associated with changes in health status. Thirty-one subjects with fibromyalgia were recruited consecutively from referrals to rehabilitation programs in Montreal area centers. Assessments, including the Arthritis Self-Efficacy Scale and the Medical Outcomes Study 36-Item Short-Form Health Survey, were done before and after completion of the program, to provide baseline and outcome measures of self-efficacy and health status. Baseline correlations showed a mild-to-moderate association of selfefficacy with physical and mental health status. Baseline self-efficacy for function (FSE) showed a trend towards predicting physical functioning and bodily pain. Baseline selfefficacy for other symptoms (OSE) also showed a trend towards being predictive of bodily pain and mental health. Correlations of the changes showed that FSE and OSE were associated with physical functioning, vitality, social functioning and rolefunctioning emotional. This research contributes to the understanding of fibromyalgia patients' responses to rehabilitation.

RÉSUMÉ

La présente étude d'observation prospective vise à examiner si l'efficacité personnelle de base peut prédire l'état de santé, la post-réadaptation, et si les changements de l'efficacité personnelle ont un rapport avec les changements de l'état de santé. Trente-et-un sujets atteints de fibromyalgie furent recrutés à même les patients référés aux divers programmes de réadaptation dans des centres de la région montréalaise. Ces sujets furent soumis à des tests d'évaluation tels Arthritis Self-Efficacy Scale et Medical Outcomes Study 36-Item Short-Form Health Survey au début et à la fin du programme afin de mesurer les données initiales et finales de l'efficacité personnelle de base et de l'état de santé. La corrélation des données de base a démontré un rapport de faible à modéré entre l'efficacité personnelle et l'état de santé physique et mental. L'efficacité personnelle de base des fonctions a démontré une tendance à prédire les fonctions physiques et la douleur corporelle. De même, l'efficacité personnelle de base des autres symptômes a aussi démontré une tendance à prédire l'état de santé mental et la douleur corporelle. La corrélation des changements a démontré que l'efficacité personnelle de base des fonctions et celle des autres symptômes sont reliées aux fonctions physiques, à la vitalité, aux fonctions sociales et émotionnelles. Cette recherche contribue à comprendre comment les patients atteints de fibromyalgie répondent à la réadaptation.

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INTRODUCTION

Fibromyalgia Syndrome (FMS) is a musculoskeletal condition characterized by widespread, chronic, musculoskeletal pain (>3 months) and multiple tender points. It is also associated with fatigue, nonrestorative sleep, and psychological disturbance (Wolfe et al., 1995). Health surveys suggest that the prevalence of FMS in the North American general population is 2.0% for men and women combined, 3.4% for women and 0.5% for men (Wolfe et al, 1995). In a recent survey of Canadian rheumatologists, FMS was reported as one of the three most common disorders (including Osteoarthritis and Rheumatoid Arthritis) seen among new rheumatology consultations (White et al., 1995). Reports of the incidence of FMS in rheumatology practices range from 14 - 20% (Fibromyalgia workshop, 1993).

The impact of FMS on everyday life activities is considerable, as shown in the recent study by Henriksson & Burckhardt (1996). The subjects experienced pain and fatigue for more than 90% of their time awake which resulted in tasks taking longer, dissatisfaction with leisure and social relations, and difficulty with many common motor tasks. In addition subjects complained of disturbed cognitive function, especially forgetfulness, difficulties in planning and organizing their actions, along with irritability, a lack of patience and difficulty concentrating.

The chronic nature of FMS and its devastating effect upon the functional ability of the patient requires the evaluation and refinement of therapeutic strategies employed in the rehabilitation of the individual. Although some therapeutic strategies have been studied with scientific rigor, no definitive treatment strategy has emerged and the treatment of FMS remains problematic (Rachlin, 1994). The impact of health care on quality of life as perceived by the patient has become an important measure for evaluating the benefits of rehabilitation programs. The patient's perception of his quality of life is a key factor to be considered when setting rehabilitation goals (Pransky & Himmelstein, 1996). Henrikkson (1994) states 'the patient's perspective decides the ultimate outcome of any rehabilitation program and this information is a necessary basis for intervention measures'.

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Self-efficacy (SE) is receiving increased recognition in the literature for its association with health status in patients participating in rehabilitation programs for pain-related diseases such as chronic arthritis (Lorig et al., 1989) and FMS (Lomi et al., 1995). SE is defined as "... people's judgements of their capabilities to organize and execute courses of action required to attain designated types of performance. It is concerned not with the skills one has, but with the judgements of what one can do with whatever skills one possesses" (Bandura, 1977). SE for a particular situation is the measure of the individual's belief in himself and his ability to perform specific behaviors which have been shown to result in positive outcomes. Initial research shows that a high level of SE before treatment and an increase in level of SE pre- to post- treatment is predictive of greater improvement in health status after a therapeutic intervention (Buckelew et al., 1996). Treatment programs which enhance SE in patients appear to be more effective in improving health status outcomes (Lorig et al., 1989; Smarr et al., 1997).

To date, only one study has been found which has examined SE as a predictor of outcomes in FMS patients (Buckelew et al., 1996). The purpose of this prospective observational study was to investigate the ability of self-efficacy to predict health status outcomes in participants diagnosed with FMS, who accept to participate and complete a multidisciplinary rehabilitation program for fibromyalgia. Thirty-one patients, with FMS were recruited, consecutively, from patients attending rehabilitation programs at two centers in the Montreal area. SE and health status were assessed pre- and postrehabilitation, using the Arthritis Self-Efficacy Scale (ASES) and the Medical Outcomes Study (MOS) 36-Item Short-Form (SF-36) Health Survey, respectively. The long-term maintenance of the health status change, which is very important is beyond the scope of this project.

The following literature review will present a description of fibromyalgia including etiology, symptoms, classification and treatment protocol. The impact of the syndrome upon the health status and quality of life for the patient will also be discussed. A thorough description of self-efficacy theory will be presented with a focus on the measurement of self-efficacy and fibromylagia.

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CHAPTER 1

LITERATURE REVIEW

1.1 FIBROMYALGIA - ETIOLOGY

Much controversy exists over the cause of FMS and its pathogenesis. Etiological factors which have been considered are: *extrinsic*, such as infection, musculo-skeletal overuse, trauma, and stress; and *intrinsic/genetic* such as hypermobility, immunology, and gender. The pathogenesis has been investigated by studies of psychological factors, sleep disturbance, muscle studies, altered pain modulation, and increased sympathetic activity. These studies have shown support for the various factors being prevalent in FMS patients but none have been conclusively proven to be causative (Jacobsen et al., 1993). Current studies are providing data that show a link of hormonal, biochemical, and neurotransmitter abnormalities in FMS (Claw, 1995).

1.2 FIBROMYALGIA - SYMPTOMS

In the past, there has been much confusion concerning the accurate diagnosis of FMS. It has overlapped with conditions such as myofascial pain syndrome and chronic fatigue syndrome (Clauw, 1995). The American College of Rheumatology (ACR) developed the 1990 ACR criteria (Appendix A), which have been instrumental in the diagnosis and study of this disease (Wolfe et al., 1990).

1.2.1 Pain

In a large study conducted by the Multi-center Criteria Committee of the ACR (Wolfe et al., 1990), widespread pain was found in 97.5% of FMS patients. The pain associated with FMS is widespread over the body, with specific tender points that are painful when pressure is applied. The combination of widespread pain and mild or greater tenderness in greater than or equal to 11 of 18 tender points, yielded a sensitivity of 88.4% and a specificity of 81.1% when these criteria were used for diagnosis of FMS.

Pain, the most important symptom of FMS (Raichlin, 1994), has been defined for

purposes of study as 'an unpleasant sensory and emotional experience associated with actual potential tissue damage or described in terms of such damage'(Gerdle & Elert, 1995). Words used by FMS patients to describe their pain are: aching, tender, burning, or spasm-like (Leavitt, 1986).

1.2.2 Nonrestorative sleep, fatigue, and morning stiffness

The study conducted by Wolfe et al. (1990) reported that 75.6% of FMS patients suffer the consequences of nonrestorative sleep. The nonrestorative sleep compounds the symptom of general fatigue, which 78.2% of FMS patients exhibit. Stiffness after a period of rest, especially in the morning lasting longer than 15 minutes was found in 76.2% of FMS study participants.

The patient's complaint is of either not falling asleep easily, not sleeping well, or waking up not feeling refreshed. This is the result of an alpha, non-rapid eye movement (NREM) sleep anomaly in which nonrestorative sleep occupies 60 - 80% of total sleep time in FMS patients versus 20% in normals (Raichlin, 1994). Sleep is divided into NREM and rapid eye movement (REM) I, II, III, IV. The deeper delta stages of sleep (III, IV) are interrupted by the lighter alpha sleep.

It is during the delta sleep that approximately 80% of the body's daily production of its growth hormone is secreted. This plays a critical role in muscle homeostasis and repair. The growth hormone Somatomedin C was found to be significantly lower in FMS patients compared with healthy controls. The authors of this study conclude that their findings could provide a link between disrupted sleep and predisposition to muscle pain (Bennett et al., 1992).

1.2.3 Other symptoms

There are several other symptoms, which are often found in these patients. Paresthesias and swollen feeling, headaches, and anxiety are exhibited in 45-69% of patients; and irritable bowel syndrome, sicca symptoms, and Raynaud's Syndrome-like symptoms are less common, occurring in <35% of FMS patients (Wolfe et al., 1990). Depression, dysmenorrhea, and female urethral syndrome have also been cited (Rachlin, 1994).

The FMS patient is now recognized as an increasing part of the case load in the health care system. The constant pain, fatigue, stiffness and disturbed sleep contribute to reduced, overall physical fitness (Mannerkorpi et al., 1994). A study conducted by Henriksson et al. (1992), showed FMS patients (n = 56) often suffer from severe consequences upon the activities of daily living (ADL), as a direct result of the unremitting symptoms of FMS. Another study, conducted in Sweden (n = 97), of the physical performance characteristics of women with FMS, found the group's level of physical fitness and flexibility to be significantly below the average age specific norms for healthy women (Mannerkorpi et al., 1994). Ledingham et al. (1993) conducted a review of FMS patients (n = 72) at a mean of four years (range 1.5 - 6 years) following diagnosis. The prognosis was very poor, with 97% of patients with persistent symptoms and 85% still fulfilling criteria for FMS. Fibromyalgia is a chronic disease with an average symptom duration of six to seven years before the patient is seen and diagnosed by a rheumatologist.

1.3 CLASSIFICATION OF FIBROMYALGIA

Several types of FMS have been distinguished in the literature:

Regional fibromyalgia is characterized by *localized* pain and tender points called 'localized fibromyalgia' or 'myofascial pain syndrome'(Raichlin, 1994).

Primary fibromyalgia is characterized by *widespread* pain, tender points, sleep disorder, and fatigue, with no underlying or concomitant conditions (Yanus et al., 1981).

Secondary fibromyalgia shows a *causal link* to an underlying condition such as active rheumatoid arthritis or hypothyroidism. The symptoms of FMS remit when underlying condition is treated (Raichlin, 1994).

Concomitant fibromyalgia symptoms do not remit with the treatment of an underlying condition, such as active rheumatoid arthritis or hypothyroidism (Rachlin, 1994).

Reactive fibromyalgia symptoms develop after a *precipitating event* of a traumatic, surgical or medical nature (Greenfield et al., 1992).

The 1992 Myopain conference in Copenhagen produced the 1992 Copenhagen Declaration by which it was agreed to accept the American College of Rheumatology (ACR) criteria of 1990 (Appendix A). According to these criteria the older primary and secondary divisions no longer are considered when diagnosing FMS. The associated symptoms such as sleep disturbance and psychological distress are not part of the diagnostic criteria. It is thought that the new definition will mean a higher degree of heterogeneity in the study of FMS (Gerdle & Elert, 1995).

1.4 FIBROMYALGIA - TREATMENT

Treatment may be divided into pharmacological and non-pharmacological approaches.

1.4.1 Pharmacologic treatment

Pharmacologic treatment is directed at pain relief and restoration of sleep. Nonrestorative sleep is treated with antidepressant medications (e.g., amitripyline or cyclobenzaprine). The typical dosage is only 1/10 of the usual dosage for treating depression and its effect is seen more quickly in the FMS patient (Jacobsen, 1993 et al.). Nonsteroidal anti-inflammatory medications have not been proven effective for pain control (Goldenberg et al., 1986). Combinations of sleep and pain medications appear to have better results. A new compound S-adenosylmethionine (SAMe), which has both anti-inflammatory and anti-depressant properties, has been shown to be effective (Rachlin, 1994).

1.4.2 Nonpharmacologic treatment

Nonpharmacologic treatment is directed towards physical fitness, patient education, and psycho-social support. Bennett (1989) states that FMS patients are physically unfit, possibly due to inactivity resulting from the chronic pain and fatigue. Programs which focus on cardio-vascular fitness rather than flexibility are showing more of a trend towards success in ameliorating pain (Raichlin, 1994). Cardio-vascular exercise which is greater than the amount necessary to produce cardiovascular fitness in non-disabled subjects is required by FMS patients. It must raise the participants' heart rate to greater than 60 - 70% of the predicted maximum for their heart rate for 20 minutes (Nichols & Glenn, 1994). Significant improvement is reported after 20 weeks of aerobic fitness versus flexibility exercise in peak work capacity at 170 beats per minute(p < 0.001) and total myalgic score (p < 0.02; McCain et al., 1988). Pain intensity as measured on a visual analogue pain scale, showed a trend toward improvement (p < 0.09). Minimally improved scores for total percentage of painful body area and sleep disturbances were insignificant.

Relaxation techniques and EMG-biofeedback training have been used to help patients overcome pain and anxiety and to increase the benefits of exercise. A graded exercise program for the treatment of FMS can reinforce in the patient that 'hurt does not cause harm', improve mastery over the painful experience, improve self-esteem and provide the physiological effect which may be reparative to the painful muscles (Raichlin, 1994).

In a report from the consensus conference on FMS which took place in Copenhagen on August 20, 1992 (Jacobsen et al., 1993), it was stated that 'individualized multi-disciplinary treatment programs are of importance because FMS affects the patient physically, psychologically and socially'. The report also states 'that FMS is a chronic disorder and long term treatment is required'.

1.5 HEALTH STATUS

The World Health Organization (WHO) published a model for the classification of the consequences of any disease: The International Classification of Impairments, Disabilities and Handicaps (ICIDH). The basic premise of this model is that any disease can be considered at four levels: pathology, impairment, disability and handicap (WHO, 1980)¹. FMS can be discussed within the framework of this model.

1.5.1 Pathology

¹ The WHO has released a new version, the ICIDH-2 which is presently being tested until July 2000. It will be presented to the World Health Assembly in 2001.

Pathology 'refers to the damage or abnormal processes occurring within an organ or organ system inside the body' (WHO, 1980). Much research is focusing on the etiology and pathogenesis of FMS. No underlying pathology has been found in FMS, however particular attention is being given to pain and central nervous system (CNS) factors which appear to play a relevant role. Functional changes can occur in the CNS due to prolonged pain from the normal perception of a noxious stimulus known as primary hyperalgesia. It can cause secondary hyperalgesia, which is pain perceived in uninjured tissue in the absence of noxious stimuli. This demonstrates the involvement of the CNS and neuroplastic changes in depicting the concept of chronic pain in FMS (Bennett, 1996).

1.5.2 Impairment

Impairment 'is any loss or abnormality of psychological, physiological or anatomical structure or function. It represents the exteriorization of a pathological state' (WHO, 1980). The impairments of FMS are pain, fatigue, sleep problems, psychological distress, morning stiffness, hyperalgesia, anxiety, headache and other signs and symptoms noted above. The quantitative aspects of sleep disturbance of FMS patients can be measured objectively by polysomnography (Wolfe et al., 1995). The use of antidepressant medications for FMS to correct sleep abnormalities focuses on correcting some underlying physiological impairment. Certain factors, such as loss of motivation, lack of self-efficacy, and dysfunctional cognition, may also be included along with the resulting physical impairments of muscle and cardio-vascular de-conditioning (Wolfe et al., 1995).

1.5.3 Disability

Disability 'is any restriction or lack (resulting from an impairment) of ability to perform an activity within the range considered normal for a human being. It represents objectification of an impairment and disturbances at the level of the person'. (WHO, 1980). It is the external, behavioral consequence of the disease (Wade, 1992). The reduced ability to perform repetitive motor tasks (Felson & Goldenberg, 1986); to do everyday activities such as carrying groceries, holding tools, and cleaning the house; and to take part in leisure activities such as sports, camping, dancing, and inviting guests to their home (Henriksson, 1992), are some of the disabilities FMS patients exhibit. The valid assessment of disability in the FMS patient is hindered by the lack of objective methods of measuring their ability to perform these activities. Self-report and work performance measures are often not reliable or valid (Bennett, 1996).

1.5.4 Handicap

A handicap 'is a disadvantage for a given individual resulting from an impairment or a disability that limits or prevents the fulfilment of a role that is normal (depending on age, sex, and social and cultural factors) for that individual. It represents socialization of an impairment or disability, and reflects the consequences for the individual - cultural, social, economic, and environmental - that stems from the presence of impairment and disability' (WHO, 1980). Pain and fatigue are often cited as major causes of disability resulting in the handicapping of the patient by preventing gainful employment and the fulfillment of one's obligation to society and the family, maintaining self-esteem and earning an income (Bennett, 1996).

Wade (1992) refers to handicap in terms of the change in a patient's quality of life (Q.O.L). The term 'quality of life' has been used often in the literature without clear definition, often synonymously with health status (Mayers, 1995). Niemi et al (1988), describe Q.O.L. as follows: 'Although the concept has been only loosely defined there is agreement that quality of life refers to a person's subjective well-being and life satisfaction and that it includes mental and physical health, material well-being, interpersonal relationships within and without the family, work, and other activities within the community, personal development and fulfillment, and active recreation'. The normality of that Q.O.L. is judged with reference to the patient's own immediate social context (Wade, 1992).

Burckhardt et al. (1993) found that FMS patients scored among the lowest in Q.O.L. in several domains (health, learning, self-understanding, work, and active recreation) when compared with patients with RA, osteoarthritis, permanent osteomies,

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chronic obstructive pulmonary disease, or insulin diabetes, and healthy controls. The results of a long-term study of the effects of FMS on everyday life confirm the opinion that 'FMS is a chronic condition with a severe impact on the patient's life' (Henrikkson, 1994).

Patients suffering from chronic conditions often exhibit multiple coexisting conditions, both physical and mental, which require a multidimensional assessment of health to understand the impact disease has on health-related quality of life (McHorney et al., 1994). The patient's 'personal assessment' of medical outcomes is key to the evaluation of whether a treatment program has targeted the issues which are of relevance to the patient and his perception of quality of life (Ware & Sherbourne, 1992).

1.6 SELF-EFFICACY

1.6.1. Theoretical framework

The *theory of self-efficacy* set forth by Bandura (1977) is based on the principle that cognitive processes can mediate behavioral change, but cognitive events are most readily induced and altered by successful mastering of a situation as a result of effective performance. Self-efficacy is assigned a central role in which it analyzes and monitors behavioral changes which have been acquired via different methods. Bandura has outlined his theory utilizing the paradigm depicted in Figure 1. According to this paradigm, behavioral change and its maintenance is a function of one's expectations that a given behavior will lead to a certain outcome (outcome expectation) and one's belief in his ability to successfully perform the required behavior (efficacy expectation). If the individual believes that he is not capable of performing the necessary behavior which will lead to the desired outcome (efficacy expectation), then the behavior may not be attempted, regardless of whether he believes, that the behavior will likely produce a favorable outcome (outcome expectation; Bandura, 1977).

Outcome expectations may play a large role in influencing the initial motivation and decision to change a health practice (Strecher et al., 1986). The engagement in health practices or behaviors which are easier to modify do not depend on high outcome expectations, whereas more difficult behaviors may require an incentive of more assured

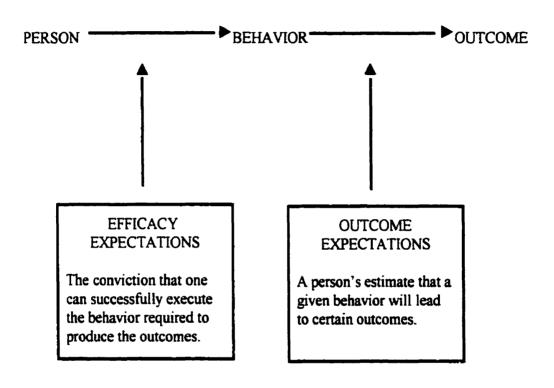


Figure 1. Bandura's diagrammatic representation of the difference between efficacy expectations and outcome expectations.

outcomes. FMS patients who have difficulty sleeping may utilize different strategies to combat the problem. A patient with low SE in his ability to maintain a program of exercise and relaxation will be more likely to try the easier behavior of taking an antidepressant medication than participating in an exercise program to promote better sleep.

Efficacy expectations are more influential when the behavioral change is more difficult to make regardless of the belief that it will result in the desired outcome. A higher level of self-efficacy may result in the individual trying longer and utilizing different strategies to master a situation. Low self-efficacy may result in the individual giving up prematurely with the misconception that he is unable to succeed. For example, exercise has been shown to improve FMS symptoms, but patients find the initial pain and fatigue are deterrents to performing this behavior and often do not persevere for sufficient time to experience improvement.

When behavior is very difficult to change and when the outcome is uncertain, then both outcome and efficacy expectations may be required to explain the behavior change process.

Efficacy expectations vary in the dimensions of magnitude, generality and strength which have important performance implications. For tasks which can be ordered in level of difficulty, the **magnitude** of SE will control the level of the task attempted. People with lower efficacy expectations may be limited to attempting the easier tasks, whereas those with higher efficacy expectations may attempt more difficult tasks. The nature of a task may instill a more **generalized** sense of efficacy, which may extend beyond the specific treatment situation. FMS patients with low **strength** SE will find it difficult to maintain the behaviors deemed necessary to ameliorate their symptoms, especially since positive outcomes are not guaranteed.

1.6.2 Efficacy sources

Four major sources of information are depicted as the basis for the development of self-efficacy: performance accomplishments, vicarious experiences, verbal persuasion, and emotional arousal. Therapists may utilize these sources as the basis for enhancing a patient's self-efficacy during rehabilitation (Strauser, 1995).

The most influential source for the development of self-efficacy is performance accomplishment. Successful mastery of a step-wise accomplishment of tasks which motivate the patient to take on more difficult tasks leading to specific target behavior will enhance self-efficacy for the specific situation and help in the development of a repertoire of coping mechanisms to deal with problems encountered (Stretcher et al., 1986). Many years of pain and unsuccessful attempts to control the symptoms leads to a 'learned helplessness' within the patient (Lindroth et al., 1994). Goldenberg et al. (1995) reported helplessness to have a significant relationship to disease severity and function in FMS patients. The patient feels that he does not possess the skills or ability to perform the required behavior and is unable to control or cope with the symptoms, especially the pain. It is important that a rehabilitation program is designed to empower and educate the patient so that the locus of responsibility (locus of control) in producing the desirable behavior remains within the patient. The self-efficacy of the individual will be enhanced only if he feels that the change in behavior and the outcome are a result of his abilities and participation (an internal locus of control), and not the abilities of the therapist and treatment (an external locus of control).

Vicarious experience is derived in group treatment as patients are able to observe other patients participating and benefitting from therapy. However, efficacy expectations which are enhanced by this source tend to be weaker and more vulnerable to change because they rely on social comparison which is less dependable than the direct evidence of personal accomplishment (Bandura, 1977)

Verbal persuasion is used often in the clinical setting by therapists who are usually viewed as a credible source to encourage the patient through difficult times. For FMS patients, the exercise program is often perceived as difficult because of the accentuation of muscle pain after exercise (Bennet, 1989). Indeed, the McCain et al. (1988) study reported a deterioration due to post-exertion pain and stiffness in the cardiovascular group (CVR), during the first 12 weeks of a 20-week controlled study. The CVR group did show improvements over the flexibility group at the completion. It is necessary for the patient to be educated and supported through this difficult process to prevent him from giving up prematurely. The experience of completing the treatment program and the improved physical status will enhance the patient's self-efficacy.

Emotional arousal due to fear, pain or lack of self confidence, is often experienced by a patient with low SE, when approaching a new or difficult task. The use of relaxation techniques and biofeedback help to reduce anxiety and to control its accompanying physiological symptoms.

Finally, it is important to remember Bandura's assertion that efficacy expectations reflect a person's perceived, rather than actual, capabilities and that it is these perceptions and not one's true abilities that often influence behavior (Stretcher et al., 1986). Self-efficacy is different from other psychological concepts, such as locus of control and learned helplessness, in that it is behavior-specific and must be measured as a specific state and not a generalized state (Lorig et al., 1989).

1.6.3 Self-efficacy assessment

The Arthritis Self-Management Course (ASMC) was developed in 1979 by the Stanford Arthritis Center to assist patients in gaining new understanding about chronic illness and skills for coping with the effects. Lorig et al. (1981) reported significant positive changes in practice of behaviors that were taught and in health status outcome. In comparison to a control group, the experimental group who participated in the ASMC, showed significant increases in arthritis self-management knowledge, in frequency of specific exercise and relaxation methods and in composite scores of self-management activities (frequency of walking 4 blocks, swimming, bicycling, relaxation, and specific arthritis exercises). There was a significant decrease in pain ($p \le 0.05$) and a tendency towards less depression (Lorig et al., 1989)

When the data were analyzed for associations of changes in health behavior (exercise, relaxation, and composite self-management activities) with changes in health status (pain disability, and depression), the associations were weak or absent (Lorig et al., 1982; Lorig et al., 1989). The weakness of associations prompted the search for other factors which might mediate the change in health status. The patients who participated in the ASMC program were questioned about what benefits they derived from the course. The positive outcome subjects, whose pain and/or disability had decreased, attributed this to their increased sense of influence over the consequences of the arthritis. The negative outcome subjects, whose pain and/or disability stayed the same or increased, believed there was little they could do to improve upon their situation (Lenker et al., 1984; Lorig et al., 1989).

Lorig et al. (1989) equated this sense of one's ability to affect the consequences to Bandura's psychological concept of self-efficacy. A preliminary study found a statistically significant correlation between perceived SE and health status (O'Leary et al., 1988). It was deduced that the belief one had in one's ability to affect the consequences of the disease interacted with the ASMC, to result in the improved health outcomes.

In response to these findings, Lorig et al. (1989) developed the Arthritis Self-Efficacy Scale (ASES; Appendix B) to measure perceived self-efficacy in people with arthritis. It is a 20-item, self-administered instrument with 3 subscales: (1) Self-Efficacy for Physical Function (FSE), (2) Self-Efficacy for Pain Management (PSE), and (3) Self-Efficacy for Controlling Other Arthritis Symptoms (OSE). Three randomized controlled trials were conducted (n = 97, n = 144, n = 91) for purposes of development, replication, and reliability. Based on the premise of self-efficacy theory, it was surmised that selfefficacy would be related to present health status and, more importantly, to future health status. The results of their study support their view that an arthritis-specific instrument can reveal important psychological determinants of present and future health status for persons with chronic arthritis. Furthermore, the study revealed that self-efficacy can be changed by education and that growth in self-efficacy is associated with improvement in health status.

Lomi et al. (1995) conducted a study (n = 99) in Sweden, to validate the use of the ASES, translated into Swedish (ASES-S), for evaluation of self-efficacy in the FMS population. Self-efficacy was correlated with: the Fibromyalgia Impact Questionnaire, the Short Form McGill Pain Questionnaire, the Fibromyalgia Attitudes Index, the Quality of life Scale, the Beck Depression Inventory, and a test of physical functioning (the sixminute walk). As hypothesized, there were significant correlations between most of the baseline SE subscale measures and present and future health status measures, psychological function and quality of life. The baseline, pre-treatment ASES score was the 'strongest' predictor of post-treatment SE. Positive change in SE was associated with positive change in health status. This finding supports Bandura's theory of SE as a mediating variable which affects perceived health status outcome.

1.6.4 Self-efficacy and pain behavior

Pain, a key factor in the diagnosis of FMS includes **pain behavior** as one component which is observable by another person (Fordyee et al., 1984). The pain behavior methodology developed by Keefe and Block (1982) was used to study pain behaviors which are observable movements by patients, such as guarding, bracing, rubbing, sighing, limps or facial grimaces that communicate to others that they have pain. Pain is considered a key health status component (Kazis et al., 1983) and therefore the identification of factors which affect pain behavior may help in the development of treatment strategies for improving health outcomes for patients (Buescher et al., 1991). The pain behavior methodology was found to be a valid tool for assessing pain behavior in FMS patients (Buckelew et al., 1994).

Beuesher et al. (1991) studied the relationship of self-efficacy to pain behavior in people with rheumatoid arthritis and found a significant relationship between the three forms of self efficacy (FSE, PSE, and OSE) and pain behavior. Fewer pain behaviors were noted in patients with high self-efficacy. The ASES has been used in many subsequent studies of the correlation of SE to pain, physical activity and outcomes in arthritic and FMS populations. The three forms of SE were found to be significantly related to pain behavior (FSE -0.42, p = 0.0002; PSE -0.39, p = 0.0007; OSE -0.47, p =0.0001). It is noted that the amounts of the variance in pain behavior accounted for by SE ranged from only 10% to 14%, and so there are clearly other variables to be determined by future study.

1.6.5 Self-efficacy, pain and physical activity

In a study of self-report FMS pain and self-efficacy, Buckelew et al. (1990)

reported that pain and disability were predicted by self-efficacy beliefs, over and above psychological distress and myalgic scores from a physical exam. Subjects who believed that they were capable of the management of their pain and symptoms reported less pain and less disability. A subsequent study by Buckelew et al. (1995) reported that higher self-efficacy was associated with less pain and less impairment in physical activities.

1.6.6 Self-efficacy and prediction

In a review called 'The role of self-efficacy in achieving health behavior change' Stretcher et al. (1986) stated that self-efficacy appeared to be a consistent predictor of short- and long-term success. The general health related areas of this review included: smoking, weight control, contraceptive behavior and exercise. At the time of this review, the authors were only able to find two studies examining patient populations and the effect of efficacy expectations on compliance with exercise regimens. Experimental studies showed that manipulations of self-efficacy had a powerful effect in initiation and maintenance of behavioral change. Studies which measured the effect of a standard behavior change program on SE found overall increases in SE over the course of treatment and found SE to be related to short and long-term success as a result of the program. The review findings suggest an association between SE and progress in health behavior change and maintenance.

Subsequent to this review, Ewart (1989) demonstrated that SE improves with adherence to exercise programs and that the increased SE promotes long-term adherence with further verbal persuasion. In 1988, Council et al. reported the ability of SE to predict both movement ability and pain, and their outcomes in low back pain patients. Jensen et al. (1991) studied the relationship of SE and outcome expectancies for chronic pain coping strategies and adjustment in chronic pain patients (n = 114). The patients' beliefs about their capabilities were strongly related to reported coping efforts.

Buckelew et al. (1996) studied the role of self-efficacy in predicting outcome among fibromyalgia patients stating that to date no other study has done so for the FMS population. Pre-treatment SE was found to be a significant predictor of treatment outcome for physical activity, but not for tender point index, disease severity or visual analogue scale (VAS) for pain. Pre- to post-treatment changes in SE significantly predicted a greater number of the outcome variables (tender point index, disease severity and VAS pain). Physical activity was predicted for only one of the three treatment groups which received a combined treatment of biofeedback/relaxation training and exercise which were provided separately to the other two groups. The authors note that this may be an indication for the need of treatment programs to enhance SE which may influence the patient's ability to cope with the many stressors associated with the pain and fatigue (Buckelew et al., 1995).

In summary, SE has been shown to be associated with health status outcomes, and may be an important factor involved in the success of intervention programs for FMS patients, in particular when confronted with chronic pain. Self-efficacy for pain management, function and managing other symptoms appear to be specific to outcomes in particular domains (pain, physical activity, psychological status, etc.).

CHAPTER 2

RATIONALE AND OBJECTIVES

2.1 RATIONALE

The literature review has demonstrated the direction of FMS research and treatment. The individual is burdened by a chronic condition which can cause disability and impairment resulting in a decline in quality of life. Feedback loops such as the one depicted in Figure 2 show the increase in symptom severity which occurs when intervention does not control the cyclical process.

Comprehensive rehabilitation programs including education, amelioration of pain strategies, and improving physical status, provide only limited success. Due to drastic reductions in health-care funding, therapeutic interventions must be concise and effective. The goal of these programs is to educate the participants in a manner which promotes self-directed management of the symptoms of fibromyalgia. The hypothesis underlying these programs is that a multidisciplinary program that provides education, techniques and self-awareness will enable the client to self-manage the symptoms of FMS when he leaves the therapeutic milieu. It is necessary to determine which factors, such as self-efficacy, might predict outcomes, and possibly enhance the benefits derived from the therapeutic experience. Ultimately, this will lead to the development and use of strategies to strengthen the attribute within the individual prior to or during rehabilitation, thereby promoting improvements in health status outcomes.

The results of this type of research would be clinically beneficial to therapists utilizing the results of both the SE and health status measurement scales. An awareness of patient characteristics which mediate the response to therapy and a better understanding of the patient's perspective on his condition, would promote the development of rehabilitation programs which would empower the patient to control the devastating consequences of FMS.

18

Fibromyalgia and Feedback Loops

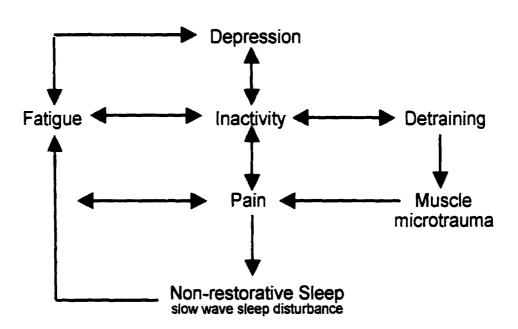


Figure 2. Fibromyalgia and feedback loops. There are several feedback loops which tend to result in the perpetuation and amplification of FMS symptoms.

Figure is used with permission from Dr. Patricia McKinley who adapted it from a rudimentary schematic by RM Bennet (1989). Beyond fibromyalgia: Ideas on etiology and treatment. Journal of Rheumatology (supp 19) 16, 185-191.

2.2 OBJECTIVES

The primary purpose of this study was to determine the association between selfefficacy (situation specific) and health status (quality of life) measures in patients with FMS. The specific aims were as follows:

- 1. To determine whether a correlation between level of SE and health status, existed prior to beginning rehabilitation. These measures served as the baseline.
- 2. To determine whether there was a change in self-efficacy following the rehabilitation program.
- 3. To determine whether there was a change in health status following the rehabilitation program.
- To determine whether a change in health status could be predicted by baseline SE: i.e. Do subjects with higher levels of self efficacy (pre-rehabilitation) make greater gains in health status (post rehabilitation).
- 5. To determine whether a change in health status was associated with a change in self-efficacy.

CHAPTER 3

METHODOLOGY

3.1 RESEARCH DESIGN

Self-efficacy has been discussed in the literature as possibly being a predictor and mediator of improved health status in FMS. The goal of this study was to ascertain the association between self-efficacy and health status outcome in FMS patients participating in outpatient rehabilitation programs.

This study was designed as a prospective observational study. The prospective study ensures that the data collected is unbiased by the passage of time. However, the time required to collect data on a sufficient number of subjects may exceed the time constraints of a prospective study (Hulley & Cummings, 1988).

Initially the researcher set out to collect data on a single cohort of fifty patients. The design with a single cohort of subjects was ideal for the repeated measures pre- and post rehabilitation of the subjects who participated in outpatient FMS rehabilitation programs. This design allowed each subject to be his own control lending more power to the study (Olson, 1988).

3.2 SUBJECTS

The target group for this study was patients, diagnosed with FMS by their physicians, who were referred to a rehabilitation program in a Montreal area hospital/center for help in coping with their symptoms. Subjects were recruited from the following two facilities: The Constance Lethbridge Rehabilitation Center (CLRC), Rheumatology Department and St. Mary's Hospital Center (SMHC), Outpatient Rehabilitation Department.

The initial intent was to recruit a convenience sample of fifty FMS patients consecutively from patients admitted to the FMS rehabilitation programs at the participating hospitals. Thirty-one subjects (N = 31) were recruited into the study. Five subjects (n = 5) were from the Constance Lethbridge Rehabilitation Center and twentysix subjects (n = 26) were from the St. Mary's Hospital Center.

3.2.1 Inclusion criteria

Inclusion into the study required that all FMS patients meet the following criteria.

- The diagnostic criteria as set forth by the ACR (Wolf, 1990) are a history of widespread chronic pain (>3 months) and pain at 11 or more of 18 specific tender point sites.
- 2. Must speak and read English because the ASES is not available in French.

3.2.2 Exclusion criteria

After a review of the intake information and charts, patients exhibiting the following conditions were excluded.

- 1. A history of organic brain syndrome.
- 2. A history or presence of a psychotic disorder.
- 3. An unstable or uncontrolled medical condition.
- 4. The presence of a major communicative disorder.
- 5. Current participation in another rehabilitation program.

3.2.3 Sample size calculation

The first consideration in calculating sample size was the comparison of the means between pre- and post-rehabilitation SE and SF 36 scores. The two-tailed t test for paired measurements was used to determine the statistical significance of the difference between the means of continuous variables.

For SE the standardized effect size (.6) is calculated by dividing the effect size (23.5) by the standard deviation (42.2). The values for this equation were taken from a similar study by Buckelew et al. (1996). The sample size of n = 44 was required to show a significant difference for an alpha level of 0.05 and a statistical power of 80% (Hulley & Cummings, 1988, p.148).

The SF-36 user's manual (Ware et al., 1994) provides the sample size (n = 23) needed to detect differences over time within one group for an alpha level of 0.05 and a

statistical power of 80%. The preliminary results of a pilot study in progress at Constance Lethbridge supported the use of this calculation to show a difference of 5 points for the FMS population.

The second consideration was the use of the correlation coefficient (r) to show the measure of strength of the linear association between self-efficacy and health status. The r of .49 in the Buckelew et al. (1996) study was used to calculate a sample size of n = 29 (Hulley, 1988, p.218) with an alpha of 0.05 and a statistical power of 80%.

The largest sample size of n = 44 was formulated for use in this study as the number of subjects required in order to perform reliable statistical analysis. Therefore, 50 subjects were to be recruited to allow for dropouts.

3.2.4 Subject recruitment procedures

An informed consent form was drafted which complied with the specifications of the respective centers and was approved by each facility's ethical review board (Appendices C and D). The intake personnel at each participating center invited eligible patients to participate in the study. They explained details of the study to the participants and then had the consent forms signed. The participants were also told that they could withdraw anytime should they wish to do so.

An information letter was given to each participant to take home. The letter outlined the study for them in case they needed to refresh their memories about it at home. They were told that they could continue any other physical exercise that was part of their 'normal' routine. Due to the psychological component of the study, a more general explanation was given to the patient. Subjects might systematically alter their behavior if they know they are being observed, resulting in a "Hawthorne effect", which is a bias caused by the process of being studied (Hulley & Cummings, 1988).

3.3 DATA COLLECTION PROCEDURES

Descriptive data for the socio-demographics of all subjects were recorded at the beginning of the study. The information obtained by chart review and self-report included: age, gender, marital status, level of education, duration of pain, work status and

rehabilitation location.

Baseline health status and self-efficacy measurements were performed, before beginning the rehabilitation program, and then repeated at the end of the program on the single cohort of subjects. This approach reduces measurement error and may lend more power to the study (Hulley & Cummings, 1985). The participants at the CLRC were given the questionnaires during an intake session and were requested to mail them back to the center in a pre-addressed, stamped envelope. The SMHC participants were given the questionnaires during a routine information session prior to commencing the rehabilitation program.

The post-rehabilitation questionnaires were completed during the last session for the SMHC subjects. The subjects at the CLRC were given the second questionnaire during the last week of the program and asked to mail it back in a pre-addressed, stamped envelope. At the CLRC, the team is changed routinely and so a guideline was prepared to keep all staff well informed about the study.

3.4 ASSESSMENTS

3.4.1 Arthritis Self-Efficacy Scale

Self-efficacy was assessed using the Arthritis Self-Efficacy Scale (ASES; Appendix B) which was developed by Lorig, et al.(1989). It is a self-administered instrument including three subscales with a total of twenty questions: Self-Efficacy for Physical Function (FSE), Self-Efficacy for Pain (PSE), and Self-Efficacy for Controlling Other Arthritis Symptoms (OSE). It has been standardized for construct and concurrent validity and test-retest reliability (Lorig et al., 1989) and validated for use with the FMS population (Lomi et al., 1995).

Measurement is on a scale of 10 (very uncertain) to 100 (very certain) with 10 point increments. The score for each subscale is computed separately by taking the average of the items which make up the subscale. The subscale score can range from 10 to 100 with higher scores indicating higher SE. If one-fourth or less of the data is missing, the score is the average of the completed data. If more than one quarter of the data is missing, no score is calculated.

This score does not provide an actual measure of accomplishment (Lorig et al., 1989). The scale will measure the magnitude and strength of the person's *belief* in his ability to perform specific tasks (Strecher et al., 1986). The self-efficacy score prerehabilitation and the change score post-rehabilitation denote the **predictor variable**.

3.4.2 Medical Outcomes Study 36-Item Short-Form Health Survey

The patient's health status, prior to rehabilitation was assessed using the Medical Outcomes Study (MOS) 36-Item Short Form (SF-36) Health Survey (Appendix E). The measurement of the health status outcome prior to rehabilitation is required to calculate the change score post-rehabilitation.

A major goal in the development of the MOS was to provide a tool that is comprehensive, psychometrically sound and brief that can be used for the routine monitoring of patient outcomes in medical practice and clinical research (Ware, 1992). It will provide a comprehensive, multidimensional assessment of two major dimensions of health status (physical and mental) to help understand the impact of disease on healthrelated quality of life (McHorney et al., 1994). Reliability (test-retest and internal consistency; McHorney et al., 1994), validity (content, criterion and construct; McHorney et al., 1993), and responsiveness to clinical changes have been demonstrated (Ware et al., 1993).

The SF-36 includes eight multi-item scales measuring the following general health concepts widely used in other health surveys (McHorney et al., 1994): Physical Functioning (PF, limitations in physical activities because of health problems), Role Functioning-Physical (RP, limitations in usual role activities because of physical health problems), Bodily Pain (BP, pain and its impact on work-related activities), General Health (GH, personal evaluation of health and illness), Vitality (VT, energy and fatigue), Social Functioning (SF, limitations in social activities because of physical or emotional problems), Role Functioning-Emotional (RE, limitations in usual role activities because of emotional problems), and Mental Health (MH, general mental health, psychological distress and well-being). The eight scales have means which range from 61 - 84 and standard deviations ranging from 18 - 34 in the general US population (Ware et al.,

1993). A single-item measure of health transition, which is not included in the scoring is also included in the SF-36 (Ware, 1992).

The development of the two summary measures, a physical component summary scale (PCS) and a mental component summary scale (MCS) has simplified and refined the interpretation of scores. Extensive exploration of the generalizability of this two dimensional model of health to specific patient subgroups (McHorney et al., 1993) and to the general US population (Ware et al., 1993) have generated normative data which enable the interpretation of subject or group data within the realm of the total population. Specific norms, for gender and age in the general US population, and for arthritic and back pain/sciatica conditions in patient subgroups, will be referred to in this report.

The computerized scoring process utilizes a complex algorithm which uses standardized forms of the eight SF-36 scores, based upon norms (mean scores and standard deviations) taken from the general US population. The PCS and MCS scores are then aggregated using weights derived from the factor coefficients of the population scale scores and they are standardized using a linear T-score transformation. Each of the component summary scores has a mean of 50 and a standard deviation of 10.

Ware et al. (1994) report that between 80 - 85% of the reliable variance in the eight SF-36 scales is accounted for by the PCS and MCS. An increase in power results from the decrease in the number of statistical comparisons without a great loss of information when using the PCS and MCS, which are more reliable and precise in detecting differences between groups of patients (McHorney et al., 1992). Some beneficial features of the two scale versus the eight scale profiles are the very large increase in the number of levels defined from 4 - 26 for the eight scales to 567 for the two summary scales, the total elimination of both floor and ceiling effects and smaller confidence intervals from 12.3 - 28 for the eight scales to 5.7 (PCS) and 6.3 (MCS) for the two scales (Ware et al., 1994).

The observed range of component summary scale scores from the general US population has been divided by Ware et al. (1994) into eight levels (PCS) and nine levels (MCS) to facilitate interpretation of the scores within a content-based framework. Items from the SF-36 which had good face validity and were representative of the scales which

correlated most highly with the individual component scores were used. The responses for each item were dichotomized and the percentage of the general US population in each of the levels likely to respond positively to the item is tabulated (Ware et al., 1994).

The SF-36 can be self-administered, or by a trained interviewer in person, or over the telephone. It takes only fifteen minutes to complete. Responses vary from dichotomous (yes/no) to six-point verbal rating scales (ordinal). The scoring process is computerized and provides a physical component summary score (PCS) and a mental component summary score (MCS). Higher scores represent better health. The health status score post-rehabilitation serves as the **outcome variable**.

3.5 THE REHABILITATION PROGRAM

The rehabilitation program is not a variable under investigation. Both rehabilitation programs (CLRC and SMHC) provide sessions devoted to education about FMS, training in techniques of relaxation, energy conservation, postural hygiene, stress management, proper nutrition and proper use of community resources. Fitness sessions are also conducted at both centers incorporating stretch and flexibility and cardiovascular training. There tends to be a little more emphasis on the psychological aspects of treatment such as mindfulness and relaxation at SMHC.

The programs run for ten and twelve weeks at the SMHC and CLRC respectively. Each group usually has twelve participants enrolled. The format provides a multidisciplinary approach utilizing Nursing, Physical and Occupational Therapy and Psychology. Overall the sessions at both centers provide the participants with very similar education, cognitive and physical training.

3.6 STATISTICAL ANALYSIS

All data were recorded and stored on an Excel spreadsheet in Microsoft Office 97 (Microsoft, 1997). Statistical analyses were performed using a software program called Minitab, Student Version (Minitab, 1998) and the Microsoft Excel Program. Descriptive statistics are used to present the socio-demographic information for the subjects. Statistical analyses were performed in the following manner on the single cohort which

completed the program. Descriptive data including means, standard deviations and ranges were tabulated. Stem-and-Leaf displays were also examined to establish the normality of the score distributions (a divergence from normality in the RP and RE (SF-36) scales will be addressed in the discussion section).

Both the predictor or independent (ASES scores) and the outcome or dependent (SF-36 scores) variables were represented by continuous data. The ASES measure has three subscales and the SF-36 measure has eight scales yielding a large number of analyses, depending on the comparison being performed (13 for T-tests and 24 for correlations and regression analyses).

The pre- and post-rehabilitation means for the within-individual differences of each variable (ASES and SF-36) were compared separately using the paired form of the two-tailed t-test. Then, Pearson product-moment correlation coefficients (r) were calculated to quantify the degree of the linear relationship (magnitude and direction) between health status (eight SF-36 scale scores) and self-efficacy (three ASES subscale scores). All statistical analyses were restricted to the eight scales of the SF-36 along with the three scales of the ASES. The eight SF-36 scales are utilized in aggregating the PCS and MCS, therefore analyzing the component summary scores, in addition to the eight SF-36 scales, would have resulted in a redundancy issue. The PCS and MCS scores were utilized for descriptive purposes only. Scatter plots were examined to verify the linearity of all comparisons. Baseline ASES scores were correlated with pre- and postrehabilitation SF-36 scores, and changes from pre- to post -rehabilitation in both measures were correlated to ascertain if an association existed. Multiple linear regression analyses were conducted to determine whether the post-rehabilitation SF-36 scores could be predicted by baseline ASES scores.

All statistical tests were non-directional (two-tailed) with an alpha level of 0.05 and a statistical power of 80%. With the large number of calculations being performed, there is a higher chance of a Type I error, occurring. To control for this, a Bonferroni Adjustment was performed which gives a modified p-value~ 0.05. A Bonferroni corrected p -value is calculated by dividing the alpha level by the number of calculations being performed. The alpha level is set for each comparison being performed. For

example, the t-tests used for comparing the means for the three ASES subscales would utilize a Bonferroni corrected p-value = 0.05/3 = 0.017.

CHAPTER 4

RESULTS

4.1 STUDY GROUP SOCIO-DEMOGRAPHICS

The single cohort of subjects who participated in this study was 9.7% male (n = 3) and 90.3% female (n = 28), a total of thirty-one subjects (N = 31). Five subjects (16.1%) were recruited from Constance Lethbridge Rehabilitation Center (CLRC) and twenty-six (83.9%) subjects were from Saint Mary's Hospital Center (SMHC).

The original number of subjects recruited at baseline, from CLRC was eight (n = 8), and from SMHC was thirty-four (n = 34). Although no one withdrew from the study, some did not complete the program and one participant, referred to both centers at different times, was not eligible due to a history of a psychotic disorder. This resulted in fewer post-rehabilitation responses than the researcher set out to collect. Time limitations for thesis completion prevented continued recruitment of new subjects. However, interesting results were obtained from the data collected.

The mean age was 51.1 ± 7.9 years (range: 34 - 63 years). The average amount of time with bodily pain was 9.15 ± 7.11 years (range: 1.5 - 29 years) as reported by twentysix of the subjects (5 subjects did not answer the question). Twenty-two subjects (71%) reported participating in some form of physical exercise, mostly walking either daily or several times per week. Twenty-three subjects (74%) reported having seen either their doctor or another medical professional during the previous ten weeks. Of the six subjects (19%) working, one reported missing work the previous week and five subjects (16%) reported quitting work, all due to FMS.

Results from two other FMS studies which have been conducted at CLRC (n = 23) and SMHC (n = 40) have shown that there are no significant differences in the characteristics of the participants at the two centers.

4.2 PRE-REHABILITATION STATUS OF STUDY SAMPLE

4.2.1 Baseline self-efficacy of the study sample - ASES results

The scores for self-efficacy (SE) as measured by the Arthritis Self-Efficacy Scale (ASES) help to quantify the individual's perceived self-efficacy to cope with specific tasks (Figure 3). The Self-Efficacy for Function (FSE) average score of 63.30 was the highest of the three subscales (range: 16 - 100), placing the subjects into the higher end of the moderately uncertain range, and indicating that this cohort had the most belief in their ability to perform certain daily activities, such as walking 100 feet in 20 seconds, buttoning and unbuttoning 3 medium buttons in 12 seconds and getting in and out of a chair or car. The PSE average score of 53.94 (range: 12 - 96), characterized a group of individuals who were moderately uncertain in their ability to accomplish the following: to control pain, to decrease pain and prevent it from interfering with sleep and to continue most of their daily activities. Although it was still a moderate score, the OSE average score of 51.81 (range: 10 - 92) was the lowest for this group. This subscale addresses issues concerning the subject's degree of certainty as to whether he can control the other symptoms of fibromyalgia such as: fatigue, feeling blue, feelings of frustration and being able to regulate activities, so as not to aggravate pain. Indeed, there was great variation in scores across all three subscales indicating that some individuals were quite certain and others were very uncertain that they could control one or all of the subscales.

4.2.2 Baseline health status of the study sample - SF-36 results

The average baseline scores for the eight scales and two summary scores of the SF-36 Health Survey (Figure 4) were very low. The average score for the physical component summary (PCS) of 30.86 (range: 18 - 45) and for the mental component summary (MCS) of 38.53 (range: 17 - 60) reflect great variation in individual scores.

The average scores for the eight SF-36 scales ranging from 17.74 - 54.90 also reflect great variation in the individual scores: Physical Functioning (PF; range: 0 - 95), Role-Physical (RP; range: 0 - 100), Bodily Pain (BP; range: 0 - 62), General Health (GH; range: 0 - 92), Vitality (VT; range: 0 - 70), Social Functioning (SF; range: 0 - 100), Role-

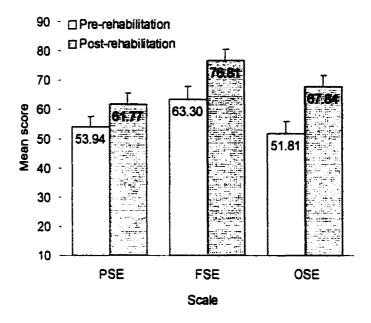
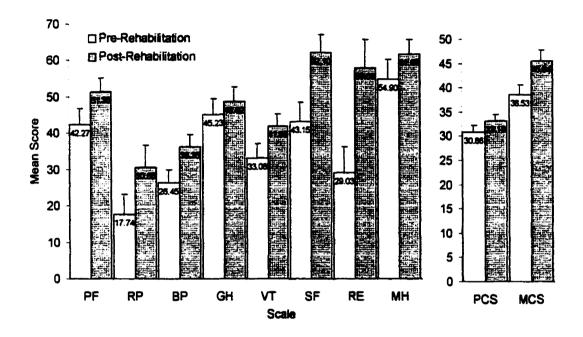
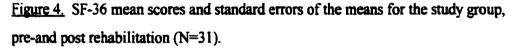


Figure 3. Arthritis Self-Efficacy Scale mean scores and standard errors of the means for the study group, pre- and post-rehabilitation (N= 31). PSE = Self-Efficacy for Pain, FSE = Self-Efficacy for Function, OSE =Self-Efficacy for Other Symptoms. The mean scores are included within each bar. The error bars depict the standard error of the mean.





PF = Physical Functioning, RP = Role Physical, BP = Bodily Pain, GH = General Health, VT = Vitality, SF = Social Functioning, RE = Role Emotional, MH = Mental Health, PCS = Physical Component Summary, MCS = Mental Component Summary. Error bars depict the standard error of the mean and mean scores are included within each bar.

Emotional (RE; range: 0 - 100) and Mental Health (MH; range: 0 - 100).

The following percentages represent the number of subjects, who endorsed the five responses for the single-item measure of health transition, compared to one year ago, which is not included in the aggregation of any of the scale scores: 0% felt much better, 9.7% felt somewhat better, 35.5% felt about the same, 32.3% felt somewhat worse, and 22.6% felt much worse.

4.3 BASELINE ASSOCIATION OF SELF-EFFICACY AND HEALTH STATUS

To determine the extent to which self-efficacy and health status were associated or varied together prior to rehabilitation, Pearson product-moment correlations were calculated for the two measures, ASES and SF-36 (Table 1). Positive correlations were revealed and significance was established using a modified Bonferroni, p-value = 0.002, for the following comparisons.

4.3.1 Relationship between self-efficacy and physical health status

Significant correlations (r = .54 - .77) were detected for physical health status and self-efficacy (Table 1). For the four SF-36 scales (PF, RP, BP, and GH) predominantly utilized in formulating the physical component summary score (PCS; Ware et al., 1994), the most noteworthy observations were for the PF scale which correlated significantly with all three ASES subscales (PSE, FSE, and OSE).

Although the FSE subscale coefficient accounted for the greatest amount of variation in the PF scale, $r^2 = 33.6\%$. It was the baseline OSE subscale scores which were most highly correlated with physical health status. The OSE subscale was significantly correlated to PF, BP and GH, $r^2 = 50\%$, 29.1% and 33.6%, respectively.

The only significant correlation detected for the PSE subscale, was with PF scale accounting for $r^2 = 34\%$ of the variation. No significant correlations were detected for the RP scale.

4.3.2 Relationship between self-efficacy and mental health status

As compared with physical health status, mental health status was more highly

<u>Pearson product-moment correlation analysis:Coefficients (and p-values)</u> for baseline Arthritis Self-Efficacy Scale with baseline SF-36 (N = 31).

	Art	hritis Self-Effica	cy Scale
SF-36 Scale	Self-Efficacy for Pain (PSE)	Self-Efficacy for Function (FSE)	Self-Efficacy for Other Symptoms (OSE)
Physical Functioning (PF)	0.58 (0.001)*	0.76 (0.000)*	0.71 (0.000)*
Role Functioning-Physical (RP)	0.25 (0.181)	0.27 (0.147)	0.31 (0.0 87)
Bodily Pain (BP)	0.32 (0.082)	0.52 (0.003)	0.54 (0.002)*
General Health (GH)	0.42 (0.020)	0.50 (0.004)	0.58 (0.001)*
Vitality (VT)	0.49 (0.005)	0.51 (0.003)	0.55 (0.001)*
Social Functioning (SF)	0.58 (0.001)*	0.68 (0.000)*	0.84 (0.000)*
Role Functioning-Emotional (RE)	0.41 (0.021)	0.35 (0.052)	0.47 (0.007)
Mental Health (MH)	0.42 (0.020)	0.65 (0.000)*	0.74 (0.000)*

* Statistically significant Bonferroni corrected p-value of 0.002

correlated (r = .55 -.85) with self-efficacy (Table 1). Of the four scales predominantly used in aggregating the mental component summary (MCS) score, (VT, SF, RE, and MH), the SF scale was most highly related to all three ASES subscales (PSE, FSE, and OSE). The correlation with the OSE subscale accounted for the greatest amount of variation in the SF scale: $r^2 = 69.2$ %. In addition, the OSE subscale correlated with the MH and the VT scales accounting for the greatest amounts of variation: $r^2 = 54.8\%$ and 30%, respectively. Again, it was the baseline OSE subscale scores which were most highly correlated with baseline mental health status.

The correlations of the FSE subscale with the SF and MH scales accounted for: $r^2 = 46\%$ and 42%, of the variations, respectively. The only significant correlation detected for the PSE subscale, was with SF scale accounting for $r^2 = 34\%$ of the variation. Nothing significant was found for the RE scale.

4.4 POST-REHABILITATION STATUS OF STUDY SAMPLE

4.4.1 Self-efficacy of the study sample - ASES results

Upon completion of the rehabilitation program, significant improvement was detected in the differences for the FSE and OSE subscales using the Student's two-tailed paired *t*-test (Bonferroni p-value ≤ 0.017 ; Table 2). This can also be seen by the comparison of pre- and post-treatment mean scores and standard errors of the means in Figure 3. The post-rehabilitation PSE subscale mean score, showed a modest nonsignificant increase of $\Delta = 7.84$ (range: -34 - 44). By contrast, the post-rehabilitation FSE and OSE mean scores showed substantial significant increases of $\Delta = 13.51$ (range: -36.67 - 68.33) and $\Delta = 16.03$ (range: -36.67 - 68.33), respectively.

The post-rehabilitation percentages (versus the baseline percentages) represent the number of subjects endorsing the five responses for the single-item measure of health transition relating to improvement: 16.1% (versus 0%) felt much better, 35.5% (versus 9.7%) felt somewhat better, 25.8% (versus 35.5%) felt about the same, 12.9% (32.3%) felt somewhat worse, and 9.7% (versus 22.6%) felt much worse, as compared to one year ago.

A correlational analysis of the relationship of the three baseline ASES subscale

<u>Predictor' and Outcome^b measures - mean values and differences (and standard</u> <u>deviations) for pre-and post-rehabilitation; and T-test^e results (and p-values) for prepost rehabilitation comparison of the means (N = 31).</u>

Vari	able	Baseline	Post-rehabilitation	Difference	T-Value (p-value)
ASES		_			
	PSE	53.94 ±20.39	61.77 ±21.23	7.48 ±18.54	2.35 (0.025)
	FSE	63.30 ±24.62	76.81 ±20.59	13.51 ±21.71	3.46 (0.002)*
	OSE	51.81 ±23.37	67.84 ±21.33	16.03 ±24.50	3.64 (0.001)*
SF-36					
	PF	42.27 ±25.47	51.35 ±21.11	9.07 ±23.71	2.13 (0.041)
	RP	17.74 ±30.41	30.65 ±33.98	12.90±39.20	1.83 (0.077)
	BP	26.45 ±19.42	36.35 ±18.44	9.90 ±19.86	2.78 (0.009)
	GH	45.23 ±23.63	48.62 ±22.82	3.40 ±14.06	1.35 (0.188)
	VT	33.06 ±22.46	41.95 ±18.96	8.89 ±23.07	2.14 (0.040)
	SF	43.15 ±29.90	62.10 ±27.67	19.35±28.84	3.74 (0.001)*
	RE	29.03 ±40.13	58.06 ±43.01	29.03±47.72	3.39 (0.002)*
	MH	54.90 ±24.00	61.68 ±23.41	6.77 ±17.49	2.16 (0.039)

* ASES = Arthritis Self-Efficacy Scale, PSE = Self-Efficacy for Pain,

FSE = Self-Efficacy for Function, OSE = Self-Efficacy for Other Symptoms.

 ^b PF = Physical Functioning, RP = Role Functioning-Physical, BP = Bodily Pain, GH = General Health, VT = Vitality, SF = Social Function, RE = Role Emotional, MH = Mental Health.

• df = 30 for all t-tests, * Statistically significant Bonferroni corrected p-value of 0.017 for the ASES and 0.006 for the SF-36.

scores with the ASES subscale's change scores was performed to understand the nature of the improvement detected in the ASES measure (Appendix F). The analysis revealed significant negative coefficients (Bonferroni p-value = 0.006) for the FSE, r = -0.61, (p = 0.000) and OSE subscales, r = 0.60, (p = 0.000); $r^2 = 37.2\%$ and 36%, respectively. Thus, it appears that the subjects with lower baseline levels of FSE and OSE tended to show more improvement post-rehabilitation.

4.4.2 Health status of the study sample - SF-36 results

Although the post-rehabilitation scores for the SF-36 remained very low, all of the mean difference scores calculated for the SF-36 were positive, indicating improvement in the level of health status (Table 2). Differences in pre- and post-treatment values for the eight scales were tested for significance using the Student's two-tailed paired *t*-test, (Bonferroni p-value ≤ 0.006) resulting in two significant changes (SF and RE).

4.4.2a Post-rehabilitation physical health status

No statistically significant improvement of physical health status was detected for the comparisons of the baseline and post-rehabilitation SF-36 (PF, RP, BP and GH) mean scores (Table 2).

4.4.2b Post-rehabilitation mental health status

By contrast, significant improvement was detected for mental health status. This is seen in the comparison of pre- and post-treatment means and standard errors of the means in Figure 4. The average scores for the SF and RE scales showed significant improvements of $\Delta = 18.95$ (range: -37.50 - 100) and $\Delta = 29.03$ (range: -66.67 - 100), respectively (Table 2). The improvements detected in the VT and MH scales were nonsignificant.

An exploratory correlation analysis of the eight SF-36 scale scores was performed to understand if a relationship existed between baseline health status and the change in health status post-rehabilitation (Appendix G). The results revealed significant (Bonferroni p-value ≤ 0.001) negative correlations, r = (-0.55) - (-0.65), for the PF, RP, BP, VT, and SF scales which accounted for $r^2 = 28.0 \% - 42.2 \%$. The negative correlations for GH, RE and MH did not attain significance. There was a tendency for subjects with lower levels of baseline health status to show greater improvement post-rehabilitation.

4.5 BASELINE SELF-EFFICACY PREDICTING HEALTH STATUS OUTCOME

To explore the relationship between the association of the three baseline ASES subscales with the post-rehabilitation SF-36 scales, Pearson product-moment correlations were performed. Positive correlations were detected and scatter plots were examined to establish the linearity of the correlations (Table 3). Subsequently, multiple regression (MR) analyses were performed to determine whether initial self-efficacy measures could predict health status post rehabilitation.

A hierarchical MR analysis was performed separately for each of the dependent variables (eight SF-36 scales). Separate models for prediction were built for each of the ASES subscales (PSE, FSE, and OSE) along with age and baseline SF-36 scores as predictors.

4.5.1 Relationship between baseline self-efficacy and post-rehabilitation health status

Significant positive correlations (Bonferroni, $p \le 0.002$) were detected between the three baseline ASES subscales (PSE, FSE, and OSE) and the four post-rehabilitation SF-36 physical health status scales (PF, RP, BP, and GH). By contrast to the baseline PF scale, the post-rehabilitation PF scale correlated significantly only with the FSE subscale, accounting for $r^2 = 36$ % of the variation. The FSE and the OSE subscales correlated with and the BP scale accounting for $r^2 = 29.2$ % and 32.5%. No significant correlations were detected for the PSE subscale or the RP and GH scales.

Only one significant correlation was detected between the three ASES subscales (PSE, FSE, and OSE) and the four SF-36 scales (VT, SF, RE, and MH) representing mental health status. The MH scale correlated with the OSE subscale accounting for $r^2 = 44.8$ % of the variation. No significant correlations were detected for the PSE, FSE

	Arti	nritis Self-Effica	cy Scale
SF-36 Scale	Self-Efficacy for Pain (PSE)	Self-Efficacy for Function (FSE)	Self-Efficacy for Other Symptom (OSE)
Physical Functioning (PF)	0.43 (0.016)	0.60 (0.000)*	0.41 (0.023)
Role Functioning-Physical (RP)	0.32 (0.079)	0.31 (0.088)	0.35 (0.053)
Bodily Pain (BP)	0.45 (0.010)	0.54 (0.002)*	0.57 (0.001)*
General Health (GH)	0.34 (0.060)	0.30 (0.100)	0.41 (0.023)
Vitality (VT)	0.40 (0.027)	0.35 (0.051)	0.42 (0.020)
Social Functioning (SF)	0.41 (0.022)	0.37 (0.041)	0.49 (0.005)
Role Functioning-Emotional (RE)	0.30 (0.109)	0.17 (0.364)	0.23 (0.218)
Mental Health (MH)	0.47 (0.008)	0.48 (0.006)	0.70 (0.000)*

Pearson product-moment correlation analysis - coefficients (and p-values) for

* Statistically significant Bonferroni corrected p - value = 0.002.

subscales or the VT, SF and RE scales.

4.5.2 Baseline self-efficacy for function (FSE) predicting health status outcome

Separate hierarchical MR analyses were conducted to examine the ability of the baseline FSE subscale to predict outcome for the eight dependent variables (eight SF-36 scales; Table 4). Models were tested separately for each dependent variable in the following fashion. Age was introduced into the analysis and then the respective baseline dependent score (SF-36) was added to the model. Finally, the FSE scale was added to the model and its contribution to the total variance was determined.

Using the adjusted Bonferroni, p - value = 0.002, no predictive ability of the FSE subscale was detected. However the results of the MR analyses for the PF and BP scales showed a trend towards the addition of the FSE subscale score contributing to the respective variances. The analysis, for the PF scale indicated that the overall FSE model predicted 35.8% (R^2 [adj]= 28.7%) of the variance in the post-rehabilitation PF scores. The addition of the FSE scores to the model added 10.8% (R^2 [adj]= 9.1%) of the variance. Similarly, the analysis for the BP scale indicated that the overall FSE model predicted 35.1% (R^2 [adj]= 27.9%) of the variance. The addition of the FSE subscale to the model contributed 12.4% (R^2 [adj]= 10.7%) to the total amount of the predicted variance.

4.5.3 Baseline self-efficacy for other symptoms (OSE) predicting health status outcome

In the same manner, hierarchical MR analyses were conducted to examine the ability of baseline OSE to predict outcome for each of the dependent variables (Table 5). Although no significant results were detected, the MR analyses for the BP and MH scales also showed trends in which the addition of the OSE score increased the respective variances. The analysis for the BP scale indicated that the overall OSE model predicted 37% (R² [adj]= 30%) of the variance, with the OSE contributing 14.3% (R² [adj] = 12.8%) towards the variance. The analysis for the MH score indicated that the OSE model significantly predicted 59.4% (R² [adj] = 54.9%) of the variance. The addition of

Summary table of multiple regression analyses for baseline Self-Efficacy for Function (FSE) predicting outcome for the dependent variables (SF-36 scales; N=31)

Source	Physical Functioning (PF)	Role Functioning Physical (RP)	Bodily Pain (BP)	General Health (GH)	Vitality (VT)	Social Function (SF)	Role Functioning Emotional (RE)	Mental Health (MH)
Overall model								
F (df) P	5.02 (3,27) 0.007	1.64 (3,27) 0.204	4.87 (3,27) 0.008	19.80 (3,27) 0.000*	2.12 (3,27) 0.121	3 22 (3,27) 0.038	1.32 (3,27) 0.289	10.29 (3,27) 0.000*
R ² (R ² adj)	0.358 (0.287)	0.154 (0.060)	0.351 (0.279)	0.688 (0.653)	0.191 (0.101)	0.264 (0.182)	0.128 (0.033)	0.534 (0.482)
Self-Efficacy for Function (FSE)								
F (df)	4.58 (1,29)	1.93 (1,29)	5.15 (1,29)	0.42 (1,29)	0.98 (1,29)	0.03 (1,29)	0.06 (1,29)	0.03 (1,29)
P	0.042	0.177	0.031	0.263	0.333	0.875	0.808	0.864
$\Delta R^2 (R^2 adj)$	0.108 (0.091)	0.060 (0.031)	0.124 (0.107)	0.016 (0.004)	0.030 (-0.001)	0.001 (-0.015)	0.002 (-0.032)	0.001 (0.017)
Pre-rehabilitation								
dependant variable								
F (df) P	9.30 (1,29) 0.005	1.39 (2,29) 0.249	6.60 (1,29) 0.016	57 46 (1,29) 0 000*	5.06 (1,29) 0.033	9 61 (1,29) 0 004	3.61 (1,29) 0.067	31.81 (1,29) 0.000*
$\Delta R^2 (R^2 adj)$	0.250 (0.196)	0.045 (0.013)	0 181 (0.159)	0 672 (1) 649)	0.151 (0.102)	0 252 (0.210)	0.114 (0.063)	0.531 (0.500)
Аде								
– F (df)	0.00 (1,29)	1.50 (1,29)	1.39 (1,29)	0.01 (1,29)	0.30 (1,29)	0 31 (1,29)	0.37 (1,29)	0.05 (1,29)
р	0.955	0.231	0 249	0.915	0.589	0.579	0.550	0.827
$\Delta R^2 (R^2 adj)$	0.000 (0.000)	0.049 (0.016)	0.046 (0.013)	0.000 (0.000)	0.010 (0.000)	0.011 (0.000)	0.012 (0.000)	0.002 (0.000)

* Statistically significant Bonferroni corrected p - value = 0.002. $\Delta R^2 (R^2 adj) =$ the amount of variance accounted for while controlling for other predictor variables.

Summary table of multiple regression analyses for baseline Self-Efficacy for Other Symptoms (OSE) predicting outcome for the

Source	Physical Functioning (PF)	Role Functioning Physical (RP)	Bodily Pain (BP)	Cieneral Health (GH)	Vitality (VT)	Social Function (SF)	Role Functioning Emotional (RE)	Mentał Health (MH)
Overall model								
F (df)	3 11 (3,27)	1.84 ((3,27)	5 29 (3,27)	18 90 (3,27)	2.45 (3,27)	3.42 (3,27)	1.34 (3,27)	13.17 (3,27)
P	0.042	0.164	0.005	0.000*	0.085	0.031	0.281	0.000*
R ² (R ² adj)	0.257 (0.174)	0 78 (0 0 78)	0.370 (0.300)	0 677 (0 642)	0 214 (0 126)	0.275 (0.195)	0 130 (0.033)	0.594 (0.549)
Self-Efficacy for Other Symptoms (OSE) F								
(df)	0.26 (1,29)	2.46 (1,29)	6.10(1,29)	0.42 (1,27)	1.80 (1,29)	0 46 (1,29)	0.13 (1,29)	4.04 (1,29)
P	0.615	0.128	0.020	0.522	0.191	0.503	0.723	0.054
ΔR^2 (R ² adj)	0.007 (-0.022)	0.084 (0.049)	0 143 (0 128)	0.005 (-0.007)	0.053 (0.024)	0.012 (-0.015)	0.004 (-0.030)	0.061 (0.049)
Pre-rehabilitation dependant variable								
F (df)	9.30 (1,29)	1.39 (2,29)	6.60 (1,29)	57.46 (1,29)	5.06 (1,29)	9.61 (1,29)	3.61 (1,29)	31.81 (1,29)
P	0.005	0.249	0.016	0.000*	0.033	0.004	0.067	0.000*
ΔR^2 (R ² adj)	0.250 (0.196)	0 045 (0.013)	0 181 (0 159)	0 672 (0 649)	0.151 (0.102)	0 252 (0 210)	0 114 (0.063)	0.531 (0.500)
Аде								
- F (df)	0.00 (1,29)	1 50 (1,29)	1.39 (1,29)	0.01 (1,29)	0.30(1,29)	0.31 (1,29)	0.37 (1,29)	0.05 (1,29)
P	0.955	0.231	0 249	0 91 5	0.589	0.579	0.550	0.827
ΔR^2 (R^2 adj)	0.000 (0.000)	0.049 (0.016)	0.046 (0.013)	0 000 (0.000)	0.010 (0.000)	0.11 (0.000)	0 012 (0.000)	0.002 (0.000)

dependent variables (SF-36 scales; N=31)

* Statistically significant Bonferroni corrected p - value = 0.002. $\Delta R^2 (R^2 adj) =$ the amount of variance accounted for while controlling for other predictor variables

the OSE score to the model showed increasing the total amount of variance which could be predicted by 6.1% (R² [adj] = 4.9%).

4.5.4 Baseline self-efficacy for pain (PSE) predicting health status outcome

The same process of hierarchical MR analysis was conducted to evaluate the predictive ability of PSE for the outcome of the dependent variables (Table 6). No significant predictive ability was detected, however the analyses showed a tendency for 34.9% (R² [adj] = 27.7%) of the variance in BP outcome to be predicted by the overall model for the PSE subscale, with the contribution of the PSE scale, adding 12.2% (R² [adj] = 10.5%) to the total variance.

4.6 ASSOCIATION OF CHANGES IN SELF-EFFICACY AND HEALTH STATUS

To establish an association for the changes in the ASES subscales (PSE, FSE, and OSE) with the change in the eight SF-36 scales, Pearson product-moment correlations were performed (Table 7). Scattergrams were examined to establish linear relationships.

None of the correlations for the PSE subscale changes with the eight SF-36 scale changes were significant, r = (-.09) - .43. In fact, the correlations with the BP, GH, and MH scales resulted in three small negative correlations, r = (-.01) - (-.09). However, the following correlations for the changes in the FSE and OSE subscales (r = .54 - .65) with the SF-36 scales, were significant (Bonferroni corrected p - value = 0.002).

4.6.1 Association of self-efficacy change (ASES) and physical health status change (SF-36)

Two significant positive correlations were detected for the association of selfefficacy and physical health status (Table 7). The change scores for the PF subscale correlated with the FSE and OSE change scores, accounting for $r^2 = 29.2\%$ and 33.6% of the variation in the scales. No significant correlations were detected for the RP, BP and GH scales.

Summary table of multiple regression analyses for baseline Self-Efficacy for Pain (PSE) predicting outcome for the dependent variables (SF-36 scales; N=31)

Source	Physical Functioning (PF)	Role Functioning Physical (RP)	Bodily Pain (BP)	General Health (GH)	Vitality (VT)	Social Function (SF)	Role Functioning Emotional (RE)	Mental Health (MH)
Overall model								
F (df) P	3.47 (3,27) 0.030	1.95 (3,27) 0.145	4.83 (3,27) 0.008	18.48 (3,27) 0.000*	2 57 (3,27) 0 075	3.54 (3,27) 0.028	1.69 (3,27) 0.195	11.70 (3,27) 0.000*
R² (R² adj)	0.278 (0.190)	0.145	0 349 (0 277)	0 672 (0 636)	0 222 (0 1 36)	0.282 (0.202)	0.157 (0.064)	0.565 (0.517)
Self-Efficacy for Pain (PSE)								
F (df) P	1.06 (1,29) 0.311	2 76 (1,29) 0.108	5.15 (1,29) 0.033	-0 005 (1,29) 0 544	2 10(1,29) 0 159	0 72 (1,29) 0.402	1.02 (1,29) 0.324	2.02 (1,29) 0.168
$\Delta R^2 (R^2 adj)$	0.028 (-0.006)	0.084 (0.058)	0.122 (0.105)	0.000(-0.013)	0.061 (0.034)	0.019 (-0.008)	0.031 (0.001)	0.032 (0.017)
Pre-rehabilitation lependant variable								
F (df) P	9.30 (1,29) 0.005	1.39 (2,29) 0.249	6 60 (1,29) 0 016	57 46 (1,29) 0 000*	5 06 (1,29) 0.033	9 61 (1,29) 0.004	3.61 (1,29) 0.067	31.81 (1,29) 0.000*
$\Delta R^2 (R^2 adj)$	0.250 (0.196)	0.045 (0.013)	0 181 (0 159)	0 672 (0 649)	0 151 (0 102)	0.252 (0.210)	0 114 (0.063)	0.531 (0.500)
Аде								
F (df)	0.00 (1,29) 0.955	1.50 (1,29) 0.23 J	1 39 (1,29) 0 249	0.01 (1,29) 0.915	0.30(1,29) 0.589	0.31 (1,29) 0.579	0.37 (1,29) 0 550	0.05 (1,29) 0.827
$\Delta R^2 (R^2 adj)$	0.000 (0.000)	0.049 (0.016)	0.046 (0.013)	0.915 0.000 (0.000)	0.010 (0.000)	0.11 (0.000)	0.012 (0.000)	0.827

* Statistically significant Bonferroni corrected p - value = 0.002 $\Delta R^2 (R^2 adj) =$ the amount of variance accounted for while controlling for other predictor variables

Arthritis Self-Efficacy Scale with changes in the SF-36 scores (N = 31) Arthritis Self-Efficacy Scale Δ Self-Efficacy Δ Self-Efficacy Δ Self-Efficacy for for Other for Pain Function Symptoms SF-36 (PSE) (FSE) (OSE) Δ Physical Functioning (PF) 0.58 (0.001)* 0.06 (0.746) 0.54 (0.002)* Δ Role Functioning-Physical (RP) 0.33 (0.071) 0.10 (0.578) 0.34 (0.059) Δ Bodily Pain (BP) -0.01 (0.962) 0.51 (0.003) 0.48 (0.007) Δ General Health (GH) -0.02 (0.938) 0.49 (0.005) 0.38 (0.034) Δ Vitality (VT) 0.57 (0.001)* 0.21 (0.248) 0.52 (0.003) Δ Social Functioning (SF) 0.65 (0.000)* 0.15 (0.434) 0.63 (0.000)* Δ Role Functioning-Emotional (RE) 0.43 (0.016) 0.37 (0.042) 0.57 (0.001)* Δ Mental Health (MH) -0.09 (0.643) 0.30 (0.098) 0.43 (0.016)

Pearson product-moment correlations - coefficients (and p-values) for changes in the

* Statistically significant Bonferroni corrected p - value = 0.002.

4.6.2 Association of self-efficacy change (ASES) and mental health status change (SF-36)

In comparison to physical health status, more significant correlations (r > 0.56 < 0.65) were detected for the association of self-efficacy changes with mental health status changes (Table 7). Overall, the SF score changes were most highly related to both FSE and OSE changes, $r^2 = 42.3\%$ and 39.7%. The VT changes correlated with FSE accounting for $r^2 = 32.4\%$ and the RE correlated with OSE accounting for $r^2 = 32.4\%$. No significant correlation was detected for MH.

CHAPTER 5

DISCUSSION

The results of this study indicate that FMS patients enrolled in multidisciplinary treatment programs report psychological and physical improvement. The following discussion will demonstrate how the findings of this study are consistent with other fibromyalgia studies which also utilized the theoretical framework of self-efficacy as set forth by Bandura. The discussion will focus on the nature of the relationship between health status and self-efficacy and the degree of improvement detected in health status by the FMS patient.

5.1 SELF-EFFICACY

Self-efficacy has been hypothesized to be one of the mediators capable of predicting and promoting improvement in health status for the FMS population. The baseline levels of SE observed in this study were similar to those found in other fibromyalgia and rheumatoid arthritis studies (Table 8). The individual scores for the three subscales in this study were quite uniform, with subjects who scored low for one scale, scoring low for the other two as well. As noted in the results, the subjects with lower baseline levels of SE showed the greater gains in SE post-rehabilitation.

The results indicate a mild to moderate association of the two variables, the ASES (PSE, FSE and OSE) and the SF-36 (eight scales) at baseline, which indicate that there is some relationship between the variables. In particular, this study suggests the importance of OSE at baseline, which is correlated with six of the eight SF-36 scales (PF, BP, GH, VT, SF, and MH). This study confirms the results of a cross-sectional study conducted by Buckelew (1995), wherein the subjects who reported lower levels of SE also had lower levels of health status, while those with higher scores on the ASES scored higher on the SF-36.

A previous longitudinal study which utilized a global SE score (Buckelew et al., 1996), reports the ability of SE to predict post-treatment physical activity, with higher SE

A comparison of the Arthritis Self-Efficacy Scale mean scores (and standard deviations) for the baseline scores of present study and other fibromyalgia (FMS) and rheumatoid arthritis (RA) studies cited in the literature.

	Ar	thritis Self-Efficac	y Scale
Study	Self-Efficacy for Pain (PSE)	Self-Efficacy for Function (FSE)	Self-Efficacy for Other Symptoms (OSE)
Buescher, 1991(RA)	51.20 (19.70)	54.50 (19.30)	59.30 (18.10)
Buckelew, 1994 (FMS)	46.10 (15.10)	71.50 (22.70)	55.70 (18.00)
Buckelew, 1995 (FMS)	46.20 (15.60)	70.94 (22.48)	55.37 (17.84)
Burckhardt, 1995 (FMS)	33.15 (20.64)	59.05 (22.31)	40.58 (18.72)
Holm, 1998 (RA)	53.10 (NA)	48.60 (NA)	59.30 (NA)
Lorig, 1998 (RA)	52.04 (21.14)	73.27 (20.22)	55.62 (21.65)
Present Study (FMS)	53.94 (20.39)	63.30 (24.62)	51.81 (23.37)

RA = Rheumatoid Arthritis, FMS = Fibromyalgia, NA = not available

associated with better physical activity outcome. In addition, changes in SE significantly predicted² post-treatment tender point index, disease severity, and pain, wherein the improvements in SE are associated with better outcomes on each measure. This study supports several of these findings as shown below.

5.2 HEALTH-STATUS

Table 9 illustrates and compares the mean scores for the eight scales of the Medical Outcome Study, SF-36 Health Survey. Consistent with FMS literature, substantial deficits are observed at baseline for virtually all scales and both component summary scores, but especially in the domains of role-functioning (physical and emotional) and bodily pain. In fact, studies have shown that 85% of fibromyalgia patients (Henriksson & Burckhardt, 1996) report a tremendous negative impact on daily life activities as a direct result of the pain and fatigue.

5.2.1 Norm-based interpretation of PCS and MCS

Norm-based interpretation of the baseline physical component summary (PCS) score ranked this subject group well below (1.8 standard deviations) the mean as compared with the general US population scores for females, age 45 - 54 years and lower than 92.5% of the general U.S. population, for physical health (Ware et al., 1994). The group remained 1.6 standard deviations below the mean, and lower than 90.2% of the general US population.

By contrast to the PCS, Figure 4 illustrates that the mental component summary (MCS) seen at baseline make a very substantial improvement post-rehabilitation. Normbased interpretation places the study group, at the baseline, 1.2 standard deviations below the mean for the general US population, females age 45 - 54 years and below 84.5% of

² The exact sequencing of timing for the post-rehabilitation assessments for the predictor and outcome variables in many of the referenced articles is unclear. After consultation with Dr. Abramovitch (statistician at St. Mary's Hospital) it was determined that for this study, no conclusions re: prediction could be made for changes in SE inasmuch as the final measurement was performed at the same time as the final measurement for health status outcome.

SF-36 scale score means (and standard deviations) for present and other FMS studies; and general US population subgroup norms[#] for females, 45 - 55 years old

		nt study		RC ^b		1HC ^c	U.S. females
SF-36 Scores	Pre	Post	Pre	Post	Pre	Post	45-55 yrs
Physical Functioning (PF)	42.27 (25.47)	51.3 5 (21.11)	37.39 (25.70)	40.24 (25.99)	47	53	84.52 (22.89)
Role Functioning-Physical (RP)	17.74 (30.41)	30.65 (33.98)	14.13 (25.35)	28.26 (37.08)	11.9	25.29	81.20 (33,80)
Bodily Pain (BP)	26.45 (19.42)	36.35 (18.44)	27.17 (18.29)	34.52 (16.80)	32	37	75.49 (23.56)
General Health (GH)	45.23 (23.63)	48.62 (22.82)	34.76 (20.30)	46.62 (19.55)	39	46	72.21 (20.17)
Vitality (VT)	33.06 (22.46)	41.95 (18.96)	29.85 (18.27)	38.91 (24.00)	31	36	61.05 (20.87)
Social Functioning (SF)	43.15 (29.90)	62.10 (27.67)	51.63 (20.29)	59.78 (26.82)	52	55	83.60 (22.38)
Role Functioning- Emotional (RE) Mental Health (MH)	29.03 (40.13) 54.90 (24.00)	58.06 (43.01) 61.68 (23.41)	40.58 (41.65) 60.70 (16.75)	71.01 (42.05) 69.39 (17.56)	38 52	43 59	81.29 (33.03) 74.84 (18.01)
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* Norms taken from SF-36 Physical and Mental Health Summary Scales: A User's Manual (Ware, 1994).
 * CLRC = Constance Lethbridge Rehabilitation Center.
 * SMHC = Saint Mary's Hospital Center, standard deviations for SMHC are not available.

the general U.S. population for mental health (Ware et al., 1994). Although improved, group placement post-rehabilitation remains 0.5 standard deviations below the mean and lower than 74.4 % of the general US population.

In addition, this study and the FMS studies conducted at SMHC and CLRC produced lower scores when compared to US population, arthritis and pain/sciatica subgroups, with the exception of the CLRC's post rehabilitation MCS score which was equal to the average score for females, age 45 - 54 years, in the general US population (Table 10; Ware et al., 1994).

5.3 PHYSICAL HEALTH STATUS AND SELF-EFFICACY

The nature of the relationship between self-efficacy and physical health status is understood by looking at the scales which are predominantly used in aggregating the PCS score. In the formation of the PCS scale, the PF, RP, BP and GH scores correlated higher with the PCS scores than with the MCS scores (Ware et al., 1994). A correlation analysis of both the baseline and post-rehabilitation scores for this study (Appendix H) describes the same scenario. It is due to this observation that these four scales are discussed in this report in relation to physical health status.

5.3.1 The relationship between self-efficacy and physical functioning

In the construction of the two component summary scores, the physical functioning (PF) scale correlated most highly with the PCS (Ware et al., 1994) and the same was seen in this study (Appendix H). It is associated at baseline with all three self-efficacy subscales, but most highly with the FSE subscale. The improvements in both the FSE and the OSE subscales were associated with improvements in the PF scale. The OSE which made the greatest gains during rehabilitation was most highly related to the PF changes.

The PF scale measures the extent to which health limits physical activities such as self-care, walking, climbing stairs, bending, lifting and moderate and vigorous exercise. The FSE scale measures the subjects confidence in performing certain daily activities such as walking 100 feet in 20 seconds, buttoning and unbuttoning 3 medium

<u>SF-36^a component summary score means (and standard deviations) of present and other FMS studies; and general US population and subgroup norms^b</u>

	PCS	MCS
FMS, present study (n=31)		
Pre-rehabilitation	30.86 (8.06)	38.53 (11.96)
Post-rehabilitation	33.18 (6.92)	45.64 (12.13)
FMS, CLRC ^e (n=23)		
Pre-rehabilitation	26.93 (8.99)	42.94 (8.33)
Post-rehabilitation	28.65 (10.25)	50.09 (9.73)
FMS, SMHC ^d $(n=42)$		
Pre-rehabilitation	31.04 (NA)	39.58 (NA)
Post-rehabilitation	33.88 (NA)	41.68 (NA)
US Arthritis	43.15 (11.62)	48.81 (11.11)
US Back Pain/sciatica	43.14 (11.56)	46.88 (11.73)
General US population,		
females 45 - 54 years old	48.95 (9.64)	50.07 (10.18)

^b Norms taken from SF-36 Physical and Mental Health Summary Scales: A user's manual.(Ware, 1994).

^e CLRC = Constance Lethbridge Rehabilitation Center.

^d SMHC = Saint Mary's Hospital Center, NA = not available.

buttons in 12 seconds and getting in and out of a chair or car. The similarity in the content of the two measures is consistent with Bandura's assertion that the instrument measuring self-efficacy must be specifically related to the behavior in question. The relationship between the FSE and the PF scale accounts for over half (58%) of the variation seen in the individual variables.

Although a significant result was not obtained for the prediction of PF, as noted in the results, a trend was seen, which has been shown in previous studies. Lorig et al. (1989) reported similar findings in the process of developing the ASES, showing that higher levels of FSE were associated with lower levels of physical disability. Buckelew et al. (1995) found FSE to be the higher predictor for physical activity and reported that the improvement in a *global score for* SE^3 predicted better outcome for physical activity (Buckelew et al., 1996).

Mandel and Keller (1986) found that self-management (SM) was beneficial in reducing levels of anxiety in patients with chronic disability including pain. This is reinforces the importance of emotional arousal, one of Bandura's four sources for enhancing SE. Bandura (1977) states that the therapeutic process must reduce anxiety and physiological arousal in order to facilitate performance, which is the most influential source for the enhancement of SE. Anxiety level has been shown to be an important correlate of functional impairment in FMS (Epstein et al., 1999).

In this study, the variance for prediction of PF outcome accounted for by the total models, including age, the baseline dependent variable and self-efficacy, ranged from 35% to 37%. Clearly, there are other factors which play a major role in mediating PF outcome, which remain to be determined by future research.

5.3.2 The relationship of self-efficacy and bodily pain

The bodily pain (BP) scale is a measure of the amount of pain and its interference with normal work for the previous four weeks. The improvement seen for PSE was the

³ Buckelew combined the three subscales of the ASES to produce a global index of self-efficacy which was used in the 1996 study.

least of the three scales, indicating less enhancement of the patients' self-efficacy for controlling and reducing pain and preventing it from interfering with sleep and the ability to continue most of their daily activities. Although BP was not significantly correlated with any of the ASES subscales at baseline, it was the only dependent variable which showed a trend towards being predicted by all three measures of self-efficacy. Curiously, both FSE and OSE improvements showed a strong trend towards being associated with BP improvement, but PSE improvement showed absolutely no relationship with the change scores for the BP scale.

These results are in contrast to other studies, where a significant interrelationship between self-efficacy and pain was detected. An FMS correlation study conducted by Buckelew et al. (1994) found all three scales of the ASES (PSE, FSE and OSE) negatively correlated to pain behavior, with FSE accounting for the greatest amount of variation. Further, Buckelew et al.(1995) report all three ASES subscales were associated with self-report pain, measured on a visual analogue scale (VAS), with FSE accounting for the greatest amount of variance. Finally, while a prediction study conducted by Buckelew et al. (1996) found that the baseline *global score for SE* was not predictive of self-report pain measured with the VAS, the increases in *global score for SE* was predictive of lower levels of pain post-rehabilitation.

The present study measured the level of pain *and* its effects, rather than just the level of pain. Perhaps the difference between the dependent variables, explains why this study showed more of a trend towards the ability of PSE to predict bodily pain but did not establish any association for the changes in the PSE subscale with the changes in the BP scale.

5.3.2a Motivation and efficacy expectations

Fibromyalgia patients have a long history of pain which limits movement required for various daily activities. Bandura (1977) states that behavioral change draws upon past experiences. Motivation to change in the FMS patient may be impeded by patterns of negative feedback resulting from his painful past experiences. The mastery of behavioral change requires that the patient learns to suppress the negative patterns and

learn new sagnitive processes during the remainification program. As they begin to practice the behavioral changes in their daily lives, which are taught during rehabilitation, the freory mannans that this will lead to the expected outcome, which in this instance is a decrease in the pain and improved health status, and at the same time will emance Ξ efficacy expectations. In this manner the strongest source for SS eminancement, performance accomplishment is employed.

5.3.2b Outcome expectations

The health practices which are more difficult to change are thought to require ingher levels of SE. Bandims (1977) reports that outcome expectations pilly a major twice in influencing mutal motivation and decision to change health practice. The subjects may have low outcome expectations resulting from longtime suffering with clavate debilitating pain which has been unresponsive to conventional methods of treatment. Pastor et al. (1993) found that FMS patients believe that pain and its relief are externally controlled by 'Powerful Professionals'. Furthermore, they believed that chance (luck and fate) rather than the professional was in control of the outcome, over and above other rheumatoid and osteoarthritis groups, who felt that they had personal control over their pain. This postulates another possible reason why the changes in the PSE subscale are small and not related to the changes in the BP scale.

5.3.2c Other predictors for the reduction of pain

The baseline BP score in this study only predicted 18% of the BP outcome, while PSE accounted for an additional 12%. A study conducted by Turk et al. (1998b) to evaluate the efficacy of an outpatient, interdisciplinary treatment program for FMS found that pretreatment level of pain was not a significant predictor of the degree of pain improvement post-rehabilitation. Clearly, there are other factors which are responsible for the large percentage of the variance in the BP outcome which remains unaccounted for. Turk et al. (1998a) suggests that there are subgroups of FMS patients who respond differently to interdisciplinary treatment consisting of medical, physical, psychologic and occupational therapies. His findings suggest a specific set of predictors for the reduction

of pain severity which are low baseline levels of depression and perceived disability, high levels of perceived control over life activities, idiopathic (versus identifiable) onset of symptoms and solicitous responses from significant others in their environment. These predictors are very related to the FSE and OSE subscales, therefore it follows that improvement in these domains of SE would be associated with improvement in BP.

5.3.3 The relationship of self-efficacy and role functioning-physical

The role functioning-physical (RP) scale deals with work-related problems due to physical limitations. The baseline correlations for the role functioning-physical (RP) scale with the ASES were the lowest of all eight scales. A closer look at the scores for the eight SF-36 scales (Figure 2; Table9) shows the possibility of a floor effect distorting several of the mean scores. There was a clustering of scores at the zero mark for both the baseline (68%) and the post-rehabilitation (42%) RP scores. The character stem-and-leaf display did not show a normal distribution for baseline or post-rehabilitation scores, therefore the reliability of the correlation coefficients is questionable for this study.

The floor effect diminishes the ability of the SF-36 to detect a significant change. Nevertheless, the improvement detected for the average RP score in this study was large. The MR analyses for the prediction of RP from baseline ASES scores showed a trend towards the PSE and OSE predicting RP outcome. However, only 17.8% of the total variance was accounted for by this analysis. Reliability of this analysis must also be questioned due to the nonlinearity of the scores.

Furthermore, the character stem-and-leaf display for the change in RP scale showed a normal distribution. There was a strong trend towards the changes in PSE and OSE being associated with changes in the RP scale (Table 6). The possibility exists that self-efficacy and role functioning-physical are more highly related than the results reveal. This scale is probably not sensitive enough to detect the true nature and severity of disability in this domain, for this group of FMS patient.

5.3.4 The relationship of self-efficacy and general health

The general health (GH) subscale represents the subject's personal evaluation of

health, including current health, health outlook and resistance to illness. Minimal change in GH was detected from pre- to post-rehabilitation. It was moderately correlated at baseline with self-efficacy for other symptoms. However the changes in self-efficacy for function tended to be more associated with the change in GH. The baseline dependent variable (GH) accounted for almost all (67.2 % out of a total of 68.8 %) of the variance in the GH scale, with the addition of SE to the model having virtually no effect on GH outcome.

5.4 MENTAL HEALTH STATUS AND SELF-EFFICACY

Overall, the relationship between mental health status and self-efficacy appears to be much stronger than that between physical health status and SE. The following discussion of the scales (VT, SF, RE and MH) predominantly used in aggregating the MCS score (Ware et al., 1994) clarifies the relationship between mental health status and self-efficacy.

5.4.1 The relationship of self-efficacy and mental health

Ware et al. (1994) found the mental health (MH) scale correlated most highly with the MCS and the same was seen in this study (Appendix H). The very small changes detected for the MH scale were only minimally associated with changes in OSE, which were very substantial. The baseline level of MH predicted most of the accountable variance (53%). Only the OSE subscale showed a trend at increasing the total accountable variance to 59%.

The OSE scale measures the subject's perceived ability to control the psychosocial aspects of his fibromyalgia such as fatigue, feeling blue, feelings of frustration and being able to regulate activities, so as not to aggravate pain. The MH measures general mental health, including depression, anxiety, behavioral-emotional control and general positive affect. Perhaps the close relationship of the content for the two measures (OSE and MH) as stipulated by Bandura's (1977) theory, is accredited with showing the trend for prediction of the very small percentage of variance.

While exploring the mediating factors for the improvement in health status after

completion of the ASMC, two dimensions, control and affect, were significantly related to improvement (Lenker et al., 1984). The literature supports the notion that the subjects with a more positive affective status and with a greater perceived control over their symptoms show more improvement after completion of the ASMC than subjects with poor affect who were depressed and felt they had little control over their symptoms. Lorig et al. (1989) found that the OSE scale was the one most highly related at baseline with depression, and that as self-efficacy improved after therapy, the level of depression dropped. Smarr et al. (1996) performed analyses utilizing a *global score for SE* (as previously described) and found a significant negative correlation for the changes in SE with the changes in level of depression.

5.4.2 The relationship of self-efficacy and role functioning-emotional

Although the correlations of role functioning-emotional (RE) and the ASES were not significant at the baseline, they did show a trend towards an interrelationship. Neither the baseline ASES (PSE, FSE and OSE) nor the baseline dependent variable (RE) scores were able to predict the RE outcome. In fact, only 15% of the total variance was accounted for. The same floor effect as discussed previously for RP appears to be affecting RE. However, the clustering of scores around zero for the baseline score (58%) is somewhat reduced for the post-rehabilitation scores (26%). The changes in the OSE, which were quite large were noticeably associated with the changes in RE, which were the greatest detected for any of the SF-36 scales.

5.4.3 The relationship of self-efficacy and social function

The social function scale (SF) measures the extent to which physical health or emotional problems interfere with normal social activities. Fibromyalgia affects everyday life as Henriksson (1994) reports that 80% of the subjects (n = 56) claim that their symptoms negatively influenced their relations with persons outside the family and 73% suffered consequences for the relationships with their family. Also, 90% of the subjects complained that FMS negatively influenced their leisure activities.

SF is associated at baseline with all three ASES scales. The most impressive

amount of variation accounted for in this study was for the baseline relationship with the two variables (SF and ASES) which ranged from $r^2 = 33\% - 69\%$. Additionally, the greatest interrelationships for changes were for the OSE and the FSE subscales with the SF scale. However, the most significant improvement detected after therapy for the SF scale was predicted by the baseline dependent variable rather than any of the ASES variables. Furthermore, only 26% of the variance was predicted by the baseline dependent variable rather than any of the ASES variables. Furthermore, only 26% of the variance was predicted by the baseline dependent variable (SF). Again, other important factors remain undetermined.

5.4.4 The relationship of self-efficacy and vitality

The vitality scale (VT), which measures energy and fatigue level is moderately related at the baseline with the OSE subscale, while it is the change in the FSE scale which is most highly associated with the VT scale change. A randomized, controlled trial for exercise and education with a very debilitated group of FMS patients found a decrease in morning fatigue post-rehabilitation, which was maintained at the 3-month followup, along with an improvement in SE (Gowans et al., 1999). In contrast to this study, Gowan et al. (1999) detected a significant improvement in PSE post-rehabilitation, which was also maintained at the followup. However, no correlations for the association of SE and VT were performed.

5.5 THE THERAPEUTIC PROGRAM

5.5.1 Utilization of self-efficacy enhancement strategies

The rehabilitation programs at both centers place major emphasis on education and cognitive training, while integrating the four major sources for improving self efficacy (performance accomplishments, vicarious experience, verbal persuasion and emotional arousal). As a result, it was not surprising that improvement in all levels of self-efficacy occurred simultaneously with the improvement in health status. In fact, the improvements in SE were much greater than those for health status.

Higher self-efficacy is associated with better coping skills for pain and other difficulties in activities of daily living for persons with Rheumatoid Arthritis. Lorig, et al. (1989) found subjects who expressed higher levels of self-efficacy after completing the Arthritis Self-Management Program (ASMP) made greater gains in health status. One might presume that the improved health status mediated the enhancement of selfefficacy post rehabilitation. However, when efficacy-enhancing strategies were incorporated into the ASMP, the effect of the program on health status was increased (Lorig & Gonzalez, 1992).

In fact, FMS rehabilitation programs which incorporate education and exercise, rather than exercise alone, have produced beneficial results. Burckhardt et al. (1994) indicated that six educational sessions enhanced the patients' self-efficacy and decreased the number of days they felt bad. The addition of physical training to the education did not increase the improvement resulting from the education group alone. While this reinforces the importance of cognitive training in the FMS population, it may be that the short period of time for the study (six weeks) was insufficient to allow other factors such as the exercise to have an effect upon health status outcome.

5.5.2 Patient subgroups

Overall, the program tended to impact upon the lower level subjects for both health status and self-efficacy. Turk et al. (1998a) has suggested the need to identify subgroups of FMS patients and their specific clinical characteristics because his study detected large individual differences in the patients' responses to treatment. This leads one to query whether the subjects in this study, with higher levels of self-efficacy and health status, at baseline represent a subgroup of FMS patients who may have responded differently to the program. As was shown by the correlation between baseline SE and changes in SE, patients with the lower levels of SE tended to make the greater gains postrehabilitation. Which factors mediate the improvements detected by both the ASES and SF-36 remain to be determined by future studies.

5.5.3 Explanations for minimal physical health status change

In an attempt to explain the small degree of change in physical health status, a review of the literature revealed several interesting theories. The length of time between tests (approximately 12 weeks) was short. Lorig et al.(1989) suggest that in order for

behavioral changes to occur and then produce changes in health status one needs a longer period of time. Bandura (1977) suggests that the SE should be retested at the end of the program, but before the testing for behavioral change. This study did not test for behavioral change. Only health status change was evaluated at the end of the program, at the same time that the SE was tested. Ideally, a follow-up of this group might detect further improvement in health status resulting from the enduring effects of enhanced SE as described in the following studies.

Many studies have been reported in the literature which describe more improvement at follow-ups, over and above that which is seen at the post-rehabilitation assessment. Important clinical benefits are seen in rheumatoid arthritis patients trained in stress management (SM), a psychological intervention. Decreased pain, reduced helplessness, enhanced self-efficacy, increased confidence in their ability to manage pain and to utilize more active coping efforts, all detected immediately post-intervention, are maintained at 15 months (Parker et al., 1995).

Buckelew et al. (1998) propose that only studies which include long-term followup might be able to detect an additive effect of a psychologically based exercise intervention. An FMS clinical trial comparing four groups (biofeedback, exercise, combination biofeedback/exercise and attention control groups), found improvement in FSE for all three groups compared to the attention control group. A modest improvement in the physical activity measure was maintained only by the combination group at the two-year followup. It is interesting to note that pain behavior was not significantly reduced post treatment, but was reduced at the 3 month, 1 year, and 2 year followup, as compared to the baseline level. In fact, their study revealed that the combination group, when compared with the two other therapy groups resulted in the fewest statistically significant within-group differences at post-treatment, but showed the most differences at the 2-year followup. In addition, results were best maintained by the combination group across the two-year followup.

Gowans et al. (1998) report the maintenance of gains in a clinical trial of exercise and education in subjects sense of well-being, self-efficacy for pain and physical function (measured by the 6-minute walk test). It is interesting and disconcerting, that Gowans et

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al. found the gains which had been detected post-treatment in morning stiffness and knowledge of FMS were lost at the 3-month followup.

5.6 CLINICAL IMPORTANCE OF THE HEALTH STATUS RESULTS

Despite the severity of symptoms, there are no objective measures, such as laboratory and physical examination findings which are able to diagnose and evaluate the impact FMS has upon the individual's functioning and ensuing disability. The subjective nature of the syndrome calls for the use of self-report instruments. The benefit in using the SF-36 component summary scores is that it allows the clinician to assess the patient in comparison to the general US population subgroups.

5.6.1 Content-based interpretation

Although the improvement detected for the PCS score was not statistically significant according to the *norm-based interpretation*, there is a definite trend for improvement which can be of great clinical and social relevance. The PCS scale reflects physical morbidity and etiology (Ware et al., 1994). *Content-based interpretation* of the average baseline PCS score mean which is based upon the analysis of the content of the SF-36 items, placed the subjects in the 7th level (mean range: 30 - 34), barely escaping the bottom 8th level. The change of 2.32 points maintained the group's status well within the 7th level. Table 11 compares the percentage of adults who endorsed the ten content-based items for the general US population and the study group (pre- and post-rehabilitation), all at the 7th level. It can be noted, that the percentages for the study sample's post-rehabilitation mean score are higher than those for the general US population's mean score for level 7, with the exceptions of vigorous activities and bodily pain. Nevertheless, when the pre- and post-rehabilitation percentages are examined, one can definitely see a trend for improvement for all items.

The MCS scale reflects psychological or mental morbidity and etiology (Ware et al., 1994). Content-based interpretation for the MCS average change ($\Delta = 7.11$) raised this study group from the 7th to the 5th level which is very close the population mean for the general US population. Table 12 presents and compares the percentage of adults, at

Table 11

Percentage of adults in the 7 th level for PCS scores endorsing the content-based items utilized in formulating the eight	
levels for the US general population and for the study sample	

Content-based item	% US population*	% Study Sample Pre-rehabilitation ^b	% Study Sample Post-rehabilitation
% any limitations in vigorous activities	95.3	100	96.77
% any limitations in walking one block	44.5	38.7	35.48
% any limitations in climbing one flight of stairs	66.9	77.42	61.29
% reporting difficulty performing at work due to physical health	88.5	83.87	77.42
% reporting cutting down amount of time spent on work due to physical health	65.1	80.65	61.29
% reporting very severe or severe bodily pain	21	54,84	35.48
% reporting having a lot of energy all or most of the time	9,9	9.68	9.68
% reporting feeling tired all or most of the time	37.4	48.39	35.48
% reporting excellent health	0	3.23	3.23
% reporting fair or poor health	60.5	45,16	41.94

* The numbers in this column represent the % of the general US population (mean PCS score = 32.1) who endorsed the content-items (Ware et al., 1994). ^b The numbers in this column represent the % of the study sample at baseline (mean PCS score = 30.86) who endorsed

the content-items.

^e The numbers in this column represent the % of the study sample post-rehabilitation (mean PCS score = 33.18) who endorsed the content-items.

Table 12

Percentage of adults in the 7th and 5th levels endorsing the SF-36 items utilized in formulating the nine levels of MCS scores for the general US population and the study sample.

Content-based items	% US population 7 th level*	% US population 5 th level ^b	% Study Sample 7 th level ^e	% Study Sample 5 th level ^d
% report being-downhearted or blue all or most of the time	8.6	1.4	16.1	9.9
% reporting being happy all or most of the time	28 . I	38.3	29 .0	35.5
% cut down amount of time spent at work due to emotional problems	59.5	12.2	67.7	41.9
% accomplished less than would like due to emotional problems	81.0	31.0	74.2	48.4
% didn't do work as carefully due to emotional problems	62.7	20.6	71.0	35.5
% physical or emotional problems interfere with social activities	18,3	14.0	38.7	22.6
% reporting feeling tired all or most of the time	29.4	14.3	51.6	35.5
% reporting having a lot of energy all or most of the time	13.8	21.0	9.7	9.7

* This column represents the % of the general US population (mean MCS score = 37.2; range: 35 - 39) in 7th level who endorsed the content-item (Ware et al., 1994).

^b This column represents the % of the general US population (mean MCS score = 47.2; range: 45 - 49) in 5th level who endorsed the content-item (Ware et al., 1994).

^c This column represent the % of the study sample (baseline mean MCS score = 38.53) in 7th level who endorsed the content-item.

^d This column represent the % of the study sample (post-rehabilitation mean MCS score = 45.64) in the 5th level who endorsed the content-item.

the 5th and 7th level for the general US population and the study group, who endorsed the eight content-based items. It is interesting to note that the actual percentages for the study group post-rehabilitation are lower than the general US population mean percentages for all items. In fact cutting down time spent at work and feeling tired remained lower than the 6th level, feeling downhearted or blue and having a lot of energy remained below the 7th level and social limitations remained below the 8th level⁴. Interpretation in this manner, shows that overall the health status post-rehabilitation remains quite low, when considering the main symptoms of FMS (pain, fatigue, psychological distress).

5.6.2 Criterion-based interpretation

A third method of interpreting the results, *criterion-based interpretation* which is based on analyses of relationships between the measures in question (PCS and MCS) and other variables called 'criteria' helps to understand the patient's health status within a social context. Criterion items, conceptually related to the PCS and MCS were measured and compared to the respective scales (Ware et al., 1994). Table 13 shows the percent of change *likely* to be associated with a 2.32 point change in the PCS and a 7.11 point change in the MCS score, post-rehabilitation. Five criterion items are presented for each scale (the 5-year mortality rate for PCS was not included). Overall, the percentages for the MCS improvements seen post-rehabilitation for the study group are considerably higher than those seen for the PCS criterion items. Of particular clinical and social importance, are the large reductions in the percentages of subjects with a likelihood of clinical diagnosis of depression or requiring mental health specialty care.

A longitudinal study conducted by Wolfe et al. (1997) found that fibromyalgia patients reported more symptoms and comorbid or associated conditions (ulcers, stomach problems, depression, severe allergy and hypertension) when compared other rheumatic conditions. Fibromyalgia patients place a great burden upon the economy with an annual average cost of \$2,274 per patient, for utilization of services such as hospitalization,

⁴ The percentages for these comparisons are taken from the SF-36 Physical and Mental Health Summary Scales: A user's manual (Ware et al., 1994).

Table 13

The percent change in the percentage of study subjects endorsing the criterion-based items for the SF-36 component summary scores (PCS and MCS; N = 31)

Criterion-based items	% Change Study sample
PCS*	
% likely to be unable to work	11.1% (from 47.1% to 41.9%)
% of working patients reporting job loss at: 1 year follow-up 2 year follow-up	8.9% (from 28.3% to 25.7%) 7.8% (from 31.9% to 29.4%)
% reporting visit to doctor within previous month	4.4% (from 46.4% to 44.4%)
% reduction reporting one or more physical conditions	1.7% (from 91.8% to 90.2%)
% likelihood of being hospitalized overnight	5.9% (from 11.6% to 11%)
MCS⁵	
% likelihood of feeling depressed or sad	18.7% (from 71.4% to 58.1%)
% likely of a great deal of stress in daily living	13.8% (from 41% to 35.4%)
% likely to report life satisfaction	31.8% (from 19.98% to 26.34%)
% with diagnosis of clinical depression	47.6% (from 26.3% to 13.8%)
% receiving mental health specialty care	41.7% (from 32.6% to 19%)

 PCS percentages represent change from pre (30.86) to post (33.18) rehabilitation PCS mean scores.

^b MCS percentages represent change from pre (38.53) to post (45.64) rehabilitation MCS mean scores.

drugs, outpatient services, laboratory and radiologic tests (Wolfe et al., 1997). The need to reduce medical costs is a key issue in rehabilitation literature today. The baseline data for this study displays 73% of the subjects reported visiting a doctor or health professional within the last month and 81% were not working. FMS is a common cause of sick leave, estimated in Canada to have cost 200 million dollars in long term disability in 1989 (Goldenberg et al., 1995). Thus, even the smallest increment in scores could impact positively on health care and sick leave costs.

Of interest, there appears to be a trend in the literature that the proper diagnosis of FMS leads to diminished utilization of hospital and medical professionals (Cathey et al., 1986). Curiously, a model developed by Goldenberg et al. (1999) to assess the severity and impact of FMS, actually cites pending litigation as being significantly, positively correlated with severity and impaired functional status. Regrettably the possibility of patients being *motivated* to remain sick in order to obtain full health insurance benefits has been cited in the literature (Burkhardt et al., 1994).

CHAPTER 6

CONCLUSION

This study was designed to ascertain the relationship between self-efficacy and health status in a cohort of fibromyalgia patients attending a three month rehabilitation program. Results of this study indicate that the higher baseline levels of self-efficacy, especially self-efficacy for other symptoms, were associated with higher baseline levels of physical and mental health for all domains except role functioning-physical and emotional. Although the size of the effect was small, pre-treatment scores for self-efficacy for function and self-efficacy for other symptoms, showed a trend towards predicting post-treatment physical health status in specific domains (physical functioning, bodily pain and mental health). Also, changes in self-efficacy for function and self-efficacy for other symptoms were associated with changes in specific domains of physical functioning) and mental (vitality, social function, and role functioning-emotional) health status. The importance of self-efficacy in the rehabilitation of FMS is based upon the strong evidence that changes in SE are long-lasting and affect changes in health behavior and health status (Bandura, 1977; Lorig et al., 1989).

Self-efficacy theory provides very useful guidelines for the development of rehabilitation programs aimed at improving health status. The therapeutic programs at both centers were similar and utilized strategies which are known to promote SE. Regardless of the SE-modifying aspects of the program, the predictor variables (ASES scales) are independent from the effects of the therapeutic program because they are measured before the program begins. There is a need to align the FMS patient with peers and supportive staff, within a multidisciplinary therapeutic environment which will educate and empower the patient to take responsibility for his health and well being. Removing that 'perceived' responsibility for the amelioration of symptoms from the medical professionals and transferring it to the patient, will ultimately promote change and personal coping skills, thereby enhancing self-efficacy and hopefully inducing

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improved physical and mental health status.

In conclusion, this study established a positive correlation between self-efficacy and health status, both cross-sectionally and longitudinally. However, regression analysis controlling for baseline level of health status found minimal evidence that SE explained outcomes. No causality is demonstrated, but self-efficacy is seen as a plausible predictor and mediator of improvement for specific aspects of health status. Studies must continue to explore the importance of SE and its role in promoting and maintaining improved health status for fibromyalgia patients.

6.1 LIMITATIONS OF THE STUDY

As with other FMS studies, the results of this study are limited to a very debilitated subgroup of the FMS population with increased disability in daily functioning, who have made their way to rehabilitation programs (Buchwald, 1996). In fact, there may exist within the community an even more debilitated group of FMS patients which is too debilitated to attend the program. This precludes the generalizability of the results to the FMS population in the community.

As previously mentioned, the use of the SF-36 may be limited with a population with such a high degree of functional impairment which results in a great "floor effect" for two of its eight scales. Ware et al. (1994) report a floor effect ranging from 1% to 24% in the use of the eight SF-36 scales. The floor effect is eliminated by using the PCS and MCS scores. However if one does not look at the individual domains which the eight scales measure, a great deal of clinically meaningful information is overlooked.

The subjective nature of the syndrome calls for the use of subjective instruments to measure levels of pain, fatigue, sleep quality and psychological disturbance. This study was lacking in objective measures of pain, physical function, sleep and overall symptom severity. There is a paucity of tools which can measure the effects of these symptoms due to their subjective nature. Although some of the items were addressed by the SF-36, no concrete information about these issues is obtained. Nevertheless in retrospect, there were other measures for pain assessment, such as the Visual Analogue Scale and the Pain Behavior Methodology, which could have been included to provide more concrete information.

Unfortunately, time constraints limited the final number of subjects recruited into the study. As a result, the sample size did not provide enough power to detect many significant results. When performing multiple tests one must allow a 5% chance that a significant result will occur by chance. The Bonferroni Adjustment which is used quite often in medical and pharmaceutical journals is very rigorous in correcting for multiple tests. There is debate among researchers and statisticians as to whether the Bonferroni Adjustment is much too stringent of a correction. If the results of this study are reexamined without the Bonferroni correction, the findings are more supportive of the notion that SE can predict health status outcome, as is presented in the literature.

There were some problems with patient drop-out (from the program) and collection of final data on some of the patients who did not return. This may have resulted in a bias, whereby perhaps the patients with more motivation and better outcomes remained in the program until the end. Another limitation of this study was the time constraint which did not allow for long-term follow-up. This would have provided valuable information regarding the long-term effects of enhanced self-efficacy.

6.2 FUTURE STUDIES

Most treatment programs for fibromyalgia are clinic or hospital based. Many patients believe that the power to produce change lies within the professional or program. In order to promote behavior change the perceived responsibility must be shifted from the external source (hospital, healthcare-worker) to an internal source (the individual). It would be interesting to run a controlled study comparing the same treatment programs in hospital-based versus community-based settings. Factors to observe would be the level of baseline self-efficacy, the severity of symptoms and the levels of disability to compare for the possibility of different subgroups of FMS patients, who might be attracted by the different settings for the two programs.

The analyses were performed with the intent to portray SE as a predictor and mediating factor of the health status outcome. It would be of interest to explore combinations of predictor variables including some of the dependent variables as well. Longterm follow-up might reveal that the improvement seen in mental health and selfefficacy combined might mediate further improvement in physical health status. Likewise the improvement in pain might mediate improved mental health status. In the same fashion that feedback loops depict the heightened severity of the symptoms feeding back into each other, they might also depict the positive effects of therapy amplifying each other.

Future research should aim to measure levels of impairment (pain, fatigue, sleep etc.) and the resultant disability and handicap. To date there is very little information on the establishment of levels of severity of Fybromyalgia Syndrome (Wolfe et al., 1995). Grouping the patients according to the different psychosocial characteristics, severity of their condition and variable responses to treatment may promote and facilitate the treatment process.

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APPENDIX A

The American College of Rheumatology 1990 Criteria for the Classification of Fibromyalgia

1. History of widespread pain

Definition: Pain is considered widespread when all of the following are present: pain in the left side of the body, pain in the right side of the body, pain above the waist, and pain below the waist. In addition, axial skeletal pain (cervical spine or anterior chest or thoracic spine or low back) must be present. In this definition, shoulder and buttock pain is considered as pain for each involved side. "Low back" pain is considered lower segment pain.

2.Pain in 11 of 18 tender points on digital palpation

Definition: Pain, on digital palpation, must be present in at least 11 of the following 18 tender point sites:

Occiput: bilateral, at the suboccipital muscle insertions.

Low cervical: bilateral, at the anterior aspects of intertransverse spaces at C5-C7. Trapezius: bilateral, at the midpoint of the upper border.

Supraspinatus: bilateral, at origins, above the scapula spine near the medial border.

Second rib: bilateral, at the second costochondral junctions, just lateral to the junctions on upper surfaces.

Lateral epicondyle: bilateral, 2 cm distal to the epicondyles.

Gluteal: bilateral, in upper quadrants of buttocks in anterior fold of muscle.

Greater trochanter: bilateral, posterior to the trochanteric prominence.

Knee: bilateral, at the medial fat pad proximal to the joint line.

Digital palpation should be performed with an approximate force of 4 kg.

For a tender point to be considered "positive" the subject must state that the palpation was painful. "Tender" is not to be considered "painful".

APPENDIX B

ARTHRITIS SELF-EFFICACY SCALE

Self-efficacy pain subscale

In the following questions, we would like to know how your fibromyalgia pain affects you. For each of the following questions, please circle the number which corresponds to your certainty that you can now perform the following tasks.

1. How certain are you that you can decrease your pain quite a bit?

10	20	30	40	50	60	70	80	90	100
very unce	rtain			mode unce	rately rtain			C	very ertain

2. How certain are you that you can continue most of your daily activities?

10	20	30	40	50	60	70	80	90	100
very uncer	rtain			mode unce	rately rtain				very certain

3. How certain are you that you can keep fibromyalgia pain from interfering with your sleep?

10	20	30	40	50	60	70	80	90	100
very uncer	tain			mode unce				C	very ertain

4. How certain are you that you can make a small-to-moderate reduction in your fibromyalgia pain by using methods other than taking extra medication?

10	20	30	40	50	60	70	80	90	100
very uncer	tain			moder uncer					very certain

5. How certain are you that you can make a large reduction in your fibromyalgia pain by using methods other than taking extra medications?

10	20	30	40	50	60	7 0	80	90	100
very uncer	tain			mode unce	rately rtain			l	very certain

Self-efficacy function subscale

We would like to know how confident you are in performing certain daily activities. For each of the following questions, please circle the number which corresponds to your certainty that you can perform the tasks as of now, without assistive devices or help from another person. Please consider what you routinely can do, not what would require a single extraordinary effort.

AS OF NOW, HOW CERTAIN ARE YOU THAT YOU CAN: 1. Walk 100 feet on flat ground in 20 seconds?

	_									
	10 very unce	20 rtain	30	40	50 moder uncer	•	70	80	90	100 very certain
2. Walk 10 ste	ps down	stairs	in 7 se	conds	5?					
	10 very unc	20 , ertain	30	40		60 crately crtain	70	80	90	100 very certain
3. Get out of a	n armles	is chai	r quic	kly, w	ithout	using y	our ha	unds fo	or sup	port?
	10 very unc	20 / ertain	30	40		60 crately crtain	70	80	90	100 very certain
4. Button and	unbuttor	1 3 me	dium-	size b	uttons	in a rov	v in L	2 seco	nds?	
	10 very unc	20 / ertain	30	40		60 erately ertain	70	80	90	100 very certain
5. Cut 2 bite-s	ize piece	es of n	neat w	ith a l	cnife ar	nd fork	in 8 s	econd	s?	
	10 verj unc	20 y ertain	30	40		60 erately ertain	70	80	90	100 very certain
6 Tum an aut	daar far		1 +h		الم المحم	46	C	5		

6. Turn an outdoor faucet all the way on and all the way off?

10	20	30	40	50	60	70	80	90	100
very unce	rtain				erately ertain	r			very certain

AS OF NOW HOW CERTAIN ARE YOU THAT YOU CAN:

10	20	30	40	50	60	70	80	90	100
very	Y			mode	erately			very	
unc	ertain			unce	ntain				certain

7. Scratch your upper back with both your right and left hands?

8. Get in and out of the passenger side of a car without assistance from another person and without physical aids?

10	20	30	40	50	60	70	80	90	100
very	/			mode	erately				very
unc	ertain			unce	ertain				certain

9. Put on a long-sleeve front-opening shirt or blouse (without buttoning) in 8 seconds?

10	20	30	40	50	60	70	80	90	100
very unce	rtain				erately ertain				very certain

Self-efficacy other symptoms subscale

In the following questions, we would like to know how you feel about your ability to control your fibromyalgia. For each of the following questions, please circle the number which corresponds to the certainty that you can now perform the following activities or tasks.

1. How certain are you that you can control your fatigue?

10	20	30	40	50	60	70	80	90	100
very unce	rtain				erately ertain				very certain

2. How certain are you that you can regulate your activity so as to be active without aggravating your fibromyalgia?

10	20	30	40	50	60	70	80	9 0	100
very unce	ertain				erately ertain				very certain

3. How certain are you that you can do something to help yourself feel better if you are feeling blue?

10	20	30	40	50	60	70	80	90	100
very unce	rtain				erately ertain				very certain

4. As compared with other people with fibromyalgia like yours, how certain are you that you can manage fibromyalgia pain during your daily activities?

10	20	30	40	50	60	70	80	90	100
very unce	rtain				erately ertain	,			very certain

5. How certain are you that you can manage your fibromyalgia symptoms so that you can do the things that you enjoy doing?

10	20	30	40	50	60	70	80	90	100
ver	y			mod	erately	r			very
unc	ertain			unce	ertain				certain

6. How certain are you that you can deal with the frustration of fibromyalgia?

10	20	30	40	50	60	70	80	90	100
very unce	ertain				erately ertain				very certain

APPENDIX C

ST. MARY'S HOSPITAL

PATIENT CONSENT FORM Department of Rehabilitation MCGILL UNIVERSITY School of Physical and Occupational Therapy

Title of the Study: Self-Efficacy and Outcome: Do they correlate in Fibromyalgia?

Purpose: This study is being conducted by researchers at St. Mary's Hospital and McGill University to evaluate the effectiveness of the rehabilitation program for fibromyalgia patients which you are about to commence.

Procedure: You are invited to participate in this research study. The questionnaire will take approximately 15 minutes to complete. You will be requested to answer a questionnaire at each of the following times:

(1) prior to beginning the rehabilitation program, and

(2) immediately after completion of the rehabilitation program.

The questionnaires will be answered by you in one of the following methods:

- (1) self-administered
- (2) by an interviewer over the telephone
- (3) by an interviewer in person.

Participation: Your decision to participate in this study is strictly voluntary and will not interfere in your participation in the rehabilitation program in any manner. You may withdraw from the study at any time. If you choose to withdraw, it will not affect your participation in the rehabilitation program.

Confidentiality: The information obtained from the questionnaire and your medical file will be kept totally confidential. Any results of this study which are used for scientific purposes will be used with total confidentiality.

Risk: There are no risks or disadvantages to you if you chose to participate or to withdraw at any time from the study.

Benefits: The results of this study may help in the development of more effective methods of treating fibromyalgia, however, there will be no direct benefit to you.

Contact Numbers: If you have any questions about the study, you are encouraged to ask at any point in the study. Questions may be addressed to the following people: Dr. Patricia McKinley, researcher at McGill University (514) 398-5588 Mrs. Myra Siminovitch, physiotherapist at St. Mary's Hospital (514) 734-2612 Ms. Monique Robitaille, patient representative at St. Mary's Hospital (514) 734-2618 Page 1 of 2

ST. MARY'S HOSPITAL

PATIENT CONSENT FORM Department of Rehabilitation MCGILL UNIVERSITY School of Physical and Occupational Therapy

Title of the Study: Self-Efficacy and Outcome: Do they correlate in Fibromyalgia?

I,_____, voluntarily consent to participate in this research study as described above. I have had a chance to ask questions of the researcher, and have had any questions answered to my satisfaction.

Participant signature

Date

Researcher signature

Date

Witness signature

Date

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Constance Lethbridge Rehabilitation Center

PATIENT CONSENT FORM Department of Rheumatology MCGILL UNIVERSITY School of Physical and Occupational Therapy

Title of the Study: Self-Efficacy and Outcome: Do they correlate in Fibromyalgia?

Purpose: This study is being conducted by researchers at Constance Lethbridge Rehabilitation Center and McGill University to evaluate the effectiveness of the rehabilitation program for fibromyalgia patients which you are about to commence.

Procedure: You are invited to participate in this research study. The questionnaire will take approximately 15 minutes to complete. You will be requested to answer a questionnaire at each of the following times:

- (1) prior to beginning the rehabilitation program, and
- (2) immediately after completion of the rehabilitation program.

The questionnaires will be answered by you in one of the following methods:

- (1) self-administered
- (2) by an interviewer over the telephone
- (3) by an interviewer in person.

Participation: Your decision to participate in this study is strictly voluntary and will not interfere in your participation in the rehabilitation program in any manner. You may withdraw from the study at any time. If you choose to withdraw, it will not affect your participation in the rehabilitation program.

Confidentiality: The information obtained from the questionnaire and your medical file will be kept totally confidential. Any results of this study which are used for scientific purposes will be used with total confidentiality.

Risk: There are no risks or disadvantages to you if you chose to participate or to withdraw at any time from the study.

Benefits: The results of this study may help in the development of more effective methods of treating fibromyalgia, however, there will be no direct benefit to you.

Contact Numbers: If you have any questions about the study, you are encouraged to ask at any point in the study. Questions may be addressed to the following person:

Dr. Patricia McKinley, researcher at McGill University (514) 398-5588

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Constance Lethbridge Rehabilitation Center

PATIENT CONSENT FORM Department of Rheumatology MCGILL UNIVERSITY School of Physical and Occupational Therapy

Title of the Study: Self-Efficacy and Outcome: Do they correlate in Fibromyalgia?

I,_____, voluntarily consent to participate in this research study as described above. I have had a chance to ask questions of the researcher, and have had any questions answered to my satisfaction.

Participant signature

Date

Researcher signature

Date

Witness signature

Date

Page 2 of 2

APPENDIX E

SF - 36 HEALTH SURVEY

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is:

(circle o	
Excellent	1
Very good	2
Good	3
Fair	4
Poor	5

2. Compared to one year ago, how would you rate your health in general now?

	(circle one)
Much better than one year ago	1
Somewhat better now than one year ago	2
About the same as one year ago	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

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

	Circle one nu	mber on e	ach line)
ACTIVITIES	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b. Moderate Activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
c. Lifting or carrying groceries	1	2	3
d. Climbing several flights of stairs.	1	2	3
e. Climbing one flight of stairs.	1	2	3
f. Bending, kneeling, or stooping.	1	2	3
g. Walking more than a mile	1	2	3
h. Walking several blocks	1	2	3
i. Walking one block	1	2	3
j. Bathing or dressing yourself	1	2	3

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

(Circle one number on each line)

	YES	NO
a. Cut down the amount of time you spent on your work or other activities	1	2
b. Accomplished less than you would like	1	2
c. Were limited in the kind of work or other activities	1	2
d. Had difficulty in performing the work or other activities (For example, it took extra effort)	1	2

5. During the <u>past 4 weeks</u>. Have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

(Circle one number on each line)

	YES	NO
a. Cut down the amount of time you spent on work or other activities	1	2
b. Accomplished less than you would like	1	2
c. Didn't do work or other activities as carefully as usual	1	2

6. During the <u>past 4 weeks</u> to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? (circle one)

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

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

(circle one)

None	1
Very mild	
Mild	
Moderate	4
Severe	5
Very Severe	6

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

	(circle one)
Not at all	1
A little bit	2
Moderately	
Quite a bit	4
Extremely	5

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

					umper on e	
	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
a. Did you feel full of pep?	1	2	3	4	5	6
b. Have you been a very nervous person?	1	2	3	4	5	6
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d. Have you felt calm and peaceful?	1	2	3	4	5	6
e. Did you have a lot of energy?	1	2	3	4	5	6
f. Have you feit downhearted and blue?	1	2	3	4	5	6
g. Did you feel worn out?	1	2	3	4	5	6
h. Have you been a happy person?	1	2	3	4	5	6
i. Did you feel tired?	1	2	3	4	5	6

(Circle one number on each line)

10. 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.)?

All of the time	(circle one)
All of the time	1
Most of the time	2
Some of the time	
A little of the time	4
None of the time	5

11. How True or FALSE is each of the following statements for you?

	(Circle one number on each line)					
	Definitely True	Mostly True	Don't Know	Mostly Faise	Definitely False	
a. I seem to get sick a little easier than other people	1	2	3	4	5	
 b. I am as healthy as anybody I know 	1	2	3	4	5	
c. I expect my health to get worse	1	2	3	4	5	
d. My health is excellent	1	2	3	4	5	

APPENDIX F

Correlations for the pre-rehabilitation ASES and ASES change scores

	pre PSE	pre FSE	pre OSE
Δ PSE	-0.408	-0.209	-0.337
	0.023	0.258	0.064
Δ FSE	-0.254	-0.611	-0.546
	0.1 68	0.000	0.001
Δ OSE	-0.332	-0.449	-0.604
	0.068	0.011	0.000

Cell Contents: Correlation P-Value

APPENDIX G

Correlations for the pre-rehabilitation and change scores for the SF-36

	Pre PF	Pre RP	Pre BP	PreGH	Pre VT	Pre SF	Pre RE	PreMH
PF ∆	-0.634	-0.406	-0.506	-0.376	-0.302	-0.500	-0.313	-0.387
	0.000	0.023	0.004	0.037	0.099	0.004	0.086	0.032
RP Δ	-0.068	-0.548	-0.016	0.103	-0.141	0.016	-0.423	0.003
	0.717	0.001	0.934	0.582	0.449	0.933	0.018	0.987
BP 🛆	-0.306	0.331	-0.559	-0.314	-0.338	-0.142	-0.1 8 0	-0.269
	0.095	0.069	0.001	0.085	0.063	0.445	0.331	0.144
GH ∆	-0.473	-0.382	-0.497	-0.355	-0.468	-0.436	-0.204	-0.314
	0.007	0.034	0.004	0.050	0.008	0.014	0.270	0.085
VT Δ	-0.355	-0.529	-0.312	-0.151	-0.654	-0.293	-0.308	-0.331
	0.050	0.002	0.0 88	0.416	0.000	0.109	0.091	0.069
SF 🛆	-0.538	-0.413	-0.677	-0.353	-0.485	-0.552	-0.449	-0.500
	0.002	0.021	0.000	0.052	0.006	0.001	0.011	0.004
RE 🛆	-0.234	-0.405	-0.1 8 7	0.041	-0.231	-0.167	-0.532	-0.410
	0.204	0.024	0.313	0.825	0.211	0.368	0.002	0.022
МН ∆	-0.372	-0.155	-0.294	-0.136	-0.318	-0.079	-0.065	-0.398
	0.039	0.404	0.109	0.466	0.082	0.674	0.729	0.027
Cell conte	nts: Correl		0.107	0.400	0.002	0.074	G.123	0.041

P-Value

APPENDIX H

Correlations of baseline SF-36 scales with baseline component summary scores (PCS and MCS)

	PRE PF	PRE RP	PRE BP	PRE GH	PRE VT	PRE SF	PRE RE	PRE MH
PRE PCS	0.808 0.000	0.578 0.001	0.782 0.000	0.595 0.000	0.649 0.000	0.656 0.000	0.276 0.133	0.292 0.111
PRE MCS	0.500 0.004	0.460 0.009	0.532 0.002	0.571 0.001	0.636 0.000	0.825	0.767 0.000	0.875 0.000

Correlations of post-rehabilitation SF-36 scales with post-rehabilitation component summary scores (PCS and MCS)

5	ost pf	POST RP	POST BP	POST GH	POST VT	POST SF	POST RE	POST MH
POST PCS						0.491 0.005		
POST MCS				- +		0.762		

Cell Contents: Correlation P-Value