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Randomized Controlled Trial of a Community-Based Nursing Intervention for Those Experiencing Chronic Non-Malignant Pain

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A Thesis submitted to the faculty of Graduate Studies and Research in partial fulfilment of the requirements of the degree of Ph.D.

ABSTRACT

The major purpose of this randomized controlled trial was to examine the effect of a low-cost, community-based, nurse-delivered, group psychoeducation program entitled the Chronic Pain Self-Management Program (CPSMP) on a number of pain-related and other quality of life outcomes in those experiencing an idiopathic chronic non-malignant pain problem. One hundred and ten individuals referred by community-based health care professionals, a pain clinic service, or self-referral were randomly assigned to one of two conditions: the 12-hour CPSMP intervention group or the 3-month wait-list control group. One hundred and two individuals completed the study. Results of intention-to-treat statistical analyses indicated that the treatment group had significant improvement or strong positive trends to improvement in pain, dependency, mental health, disability, vitality, self-help role behaviours and other role functioning indicators, life satisfaction, and in self-efficacy and resourcefulness compared to the wait-list control group.

An additional purpose of this study was to test the hypothesized relationships in the Self-Help Model: Learned Response to Chronic Illness Experience. Causal modeling using path analyses tested the Model at two points in time: pretest and posttest. Overall, the hypothesized pattern of relationships in the Self-Help Model were supported by the data.

ABSTRACT

Le but principal de cette étude aléatoire fut d'examiner l'impact d'un programme de psycho-éducation de groupe, soit le Programme d'Auto-Gérance de la Douleur Chronique (PAGDC), sur un nombre de facteurs reliés à la douleur et à la qualité de vie d'un groupe de patients souffrant de douleur chronique idiopathique. Ce programme de psycho-éducation à coûts minimes fut administré par l'infirmière dans un milieu communautaire. Cent dix patients référés par des professionnels de la santé communautaire, une clinique pour la douleur, ou par eux-mêmes furent randomisés à un de deux groupes, soit: le groupe d'intervention PAGDC de douze heures et le groupe contrôle en attente pour 3 mois. Cent deux individus complétèrent l'étude. Les statistiques démontrent une amélioration significative ou une tendance positive vers une amélioration de la douleur, de la dépendance, de la santé mentale, de l'incapacité, de la vitalité, des comportements d'efforts personnels et de fonction de rôles, de satisfaction de vie, d'efficacité personnelle et de compétence à se procurer des ressources chez le groupe expérimental comparé au groupe contrôle.

Un but secondaire de cette étude fut de tester les hypothèses de relation dans le modèle "self-help": apprentissage de réponses à l'expérience de la maladie chronique. Le modèle fut testé à deux périodes séparées: avant et après le programme. En général, les données soutiennent le thème des relations hypothétiques du modèle.

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CHAPTER 1

Introduction and Statement of the Problem

Chronic illnesses now constitute the majority of health problems in North America and in most of the world's industrialized nations (Badura, 1991; Naegele, 1992). Although chronic illness is an umbrella term that encompasses a wide variety of long lasting conditions, the consequences of chronic illness with respect to functional status and well being and the self-management skills necessary for successful adaptation appear to be strikingly similar across diagnoses (Arpin, Fitch, Browne, & Corey, 1990; Cassileth et al., 1984; Felton, Revenson, & Hinrichsen, 1984; Pollack, Christian, & Sands, 1990). Consequences of chronic illness can range from those requiring relatively small adjustments in lifestyle to what have been described as catastrophic disabling consequences, those that radically alter people's existence and accustomed way of life including major disruption in vocational, family, and social roles and activities (Aiken & Mechanic, 1986; Dimond, 1983; Mechanic, 1977). The extent to which individuals are able to manage and successfully cope with these consequences depends upon multiple factors ranging across the biological, psychological, interpersonal, spiritual, sociocultural, and economic spheres of life.

Chronic non-malignant pain (i.e., long lasting pain that is unrelated to malignant disease such as cancer or AIDS) is a disabling health problem that is receiving increased attention from clinicians, researchers, and health care policy makers alike (Institute of Medicine Committee on Pain [IOM], 1987; Turczyn & Drury, 1992). The reason for this attention stems from the high prevalence of chronic pain in the general population, its' deleterious impact on quality of life, and the direct and indirect economic and social costs that can accompany this condition.

Background: Scope and Impact of Chronic Pain

Chronic pain is defined by Bonica (1990) as pain that "persists a month beyond the usual course of an acute disease or reasonable time for an injury to heal, or pain that

recurs at intervals for months or years" (p.180). The Subcommittee on Taxonomy of the International Association for the Study of Pain (IASP) further simplified this definition by stating that chronic pain is pain which persists past the normal time of healing. Although the time frame that distinguishes acute from chronic pain is variable depending on the nature of the original problem, chronic pain is defined most commonly as pain that persists for 3 to 6 months (Mersky & Bogduk, 1994).

Persistent pain may have serious physical, behavioural, psychosocial, and economic consequences for the afflicted individual and his/her family as well as having an enormous impact on the health care system and on industry. Until relatively recently, there were little epidemiological data that documented the size and scope of the chronic pain problem in the community. However, several recent population-based surveys have reported that from 11% to 33% of the general population suffers from chronic pain most often located in the back, head, and joints (Crook, Rideout, & Browne, 1984; Magni, Caldieron, Rigatti-Luchini, & Mersky, 1990; Magni, Marchetti, Moreschi, Merskey, & Luchini, 1993; Magni, Moreschi, Rigatti-Luchini, & Mersky, 1994; Sternbach, 1986). While some will have pain as a result of a recognized disease process such as arthritis, an estimated 64% will have pain of undefined or poorly understood pathology that is frequently classified as idiopathic (Bonica, 1990). Many musculoskeletal pains that initially involved soft tissue and/or ligamental damage such as low back pain, neck pain or whiplash, etc. fall within this classification.

Regardless of the etiology of the pain, many pain sufferers are either partially or totally disabled for periods of days, weeks, or months and some permanently (Bonica, 1990). In the Nuprin Pain Report, the first American community-based national survey on pain, all persons with pain reported that at the very least, pain minimized their quality of life by interfering with their daily routines and by decreasing their ability to concentrate on their work and to enjoy leisure and family activities (Sternbach, 1986). Recent Canadian data from the 1994-95 National Population Health Survey (NPHS) indicated that 3.9 million Canadians (17%) over the age of 15 have chronic pain and that 70% of them rated their usual pain intensity as moderate to severe (Millar, 1996). Sixty eight percent of those with chronic pain reported pain-related limitation in their daily

activities with the majority reporting ongoing sleep difficulties and mental distress (Millar, 1996). For the most severely affected, chronic pain can lead to complete work disability, can generate feelings of deep distress, hopelessness and despair, and can result in tremendous disruption to individual and family functioning (Rowat, 1992; Sternbach, 1989). As Bonica (1990) points out, it is seldom the underlying pathology that results in disability but the consequences of living with pain on an on-going basis that prevents people from carrying on with their lives.

The economic impact of chronic pain to society as a whole is considerable and continues to rise (IOM, 1987). Health services research indicates that chronic pain complaints, particularly of musculoskeletal origin, are among the most frequent reasons for visits to doctors offices (Koch, 1986; Schappert, 1994). For example, over 72 million visits for chronic pain were made to office-based physicians practising in the United States during the 2-year period 1980-1981 (Koch, 1986). Two-thirds of these visits were to medical specialists such as internists, general and orthopaedic surgeons, and neurologists (Koch, 1986; Nelson, 1994; Woodwell, 1993). Looking at the most recent American data on back symptoms alone, there is no evidence to suggest that the number of visits for chronic pain are decreasing in that country (Schappert, 1994). In Canada, the 1994-95 NPHS found that those with moderate to severe chronic pain averaged between 10.1 to 12.9 doctor visits in the past year compared to 3.8 visits for those with no chronic pain (Millar, 1996).

In addition to frequency of contact, chronic pain visits require more physician time per visit than any other type of health problem. Koch (1986) reported that chronic pain visits averaged 17 minutes which exceeded the mean contact time found for office visits for all other conditions. The increased need for counselling to educate patients about treatment and to help them cope with pain-related psychosocial, work and family problems was cited as the primary reason for this extra contact time (Koch, 1986). In addition to physician services, persons with chronic pain use a broad range of other community-based treatment services (Crook, Tunks, Rideout, & Browne, 1986) as well as costly hospital-based investigative and treatment services more frequently than do those individuals experiencing acute or temporary pain (Aronoff, McAlary, Witkower, &

Berdell, 1988; Crook et al., 1984). Recently, Millar (1996) reported that Canadians with moderate to severe chronic pain averaged 2.2 to 4 days in hospital in the previous year compared to less than one day for those who experienced no chronic pain. Overall, this high rate of health care utilization points to a group of patients who continue to seek help for this very difficult problem in their lives.

Recent research reports have presented compelling evidence that psychosocial variables rather than illness variables explain health service utilization and cost with various chronic illness groups including chronic pain (Browne et al., 1993; Weir, Browne, Tunks, Gafni, & Roberts, 1992). In a Canadian study of 571 patients referred to an outpatient chronic pain clinic, Weir and colleagues (1992) found that psychosocial adjustment to chronic pain, attitudes about one's health, and social support variables were more important in determining health care utilization and cost than the nature or severity of the chronic pain problem or level of associated disability. Total annual expenditure (in Canadian dollars) on care and support for individuals who had poor to fair psychosocial adjustment to their chronic pain ranged from an average of $9723 to $14744 per person annually compared to $4212 for those who displayed good psychosocial adjustment (Browne et al., 1993). Of additional significance was that the prevalence of poor adjustment in this chronic pain group was 55.7% which was high in comparison with those attending other chronic illness clinics in the same hospital.

In the United States, the direct health care costs in 1986 attributed to chronic pain were an estimated $40 billion, an expenditure just over 50% of the total cost of chronic pain to society (Bonica, 1990). The indirect cost of chronic pain, most often measured as potential productivity lost, was also substantial (Turczyn & Drury, 1992). In the United States, chronic pain is estimated to result in over 400 million days of work lost, a tremendous cost to industry in terms of work productivity alone (Bonica, 1990). In addition, Worker's Compensation payments for chronic pain disability resulting from job-related injuries continue to rise further adding to the burden on industry (Andersson, Pope, Frymoyer, & Snook, 1991; Bombardier, Baldwin, & Crull, 1985; Rossignol, Suissa, & Abenhaim, 1988; Wilkenson &Carmen, 1995).

In Canada, the total economic burden of illness in 1993 was estimated at $157 billion

(Moore, Mao, Zhang, & Clarke, 1997). Although chronic pain was not specifically categorized, musculoskeletal diseases (which include arthritis and disorders of the back and spine) and injuries, both of which have pain as a major symptom, ranked second and third overall with total costs of $17.8 billion and $14.3 billion, respectively. Only cardiovascular diseases cost more. Direct health care costs incurred were small as compared to the enormous indirect costs of these two disorders (musculoskeletal disorders - $15.3 billion; injuries - $11.2 billion). Musculoskeletal conditions had the highest indirect costs of all conditions and this category was the leading cause of long-term disability in Canada, accounting for over one third of all long-term disability costs ($13.5 billion). These figures are a significant change from the previous 1986 data where musculoskeletal disorders had the third highest indirect cost after cardiovascular disease and cancer (Health and Welfare Canada [HWC], 1991). Whether this change is due to improved clinical treatment for cardiovascular disease and cancer, to a significant increase in the numbers of people with musculoskeletal conditions, or to the new statistical approaches used to measure lost lifetime productivity is not clear. However, what is clear is that pain-related conditions are costly to society as a whole and these costs appear to be rising.

Although the modelling approach used to estimate lost lifetime productivity now includes an estimate of non-labour force participation (i.e., puts a monetary value on activities such as housework and childcare) (Moore et al., 1997), these recent Canadian estimates of indirect costs of illness may still be conservative since they do not account for the psychosocial costs to individuals and families such as economic dependence, social isolation, lost opportunities for promotion and education, and other unwanted changes in life plans (Rice, Hodgson, & Kopstein, 1985). Considering the evidence that a significant group of chronic pain patients have a high rate of psychosocial dysfunction compared to those with other kinds of chronic illness (Browne et al., 1993), these unestimated costs may be high. In summary, examining the data that document prevalence, disabling consequences and cost, it is not surprising that chronic pain is now considered to be a major public health problem (Bonica, 1990; IOM, 1987; James, Large, Bushnell, & Wells, 1991; National Institute of Health. Consensus Development

Conference [NIH], 1987; Turczyn & Drury, 1992).

Response to the Chronic Pain Problem

The response to the problem of chronic pain has been a marked increase in the number of specialty clinics and programs for this population of patients (Bonica, 1990; HWC, 1990). This is particularly evident in the United States where there are an estimated 1200 such programs (Bonica, 1990). In 1987, there were an estimated 40 chronic pain clinics in Canada, up from 6 in 1972 (Catchlove & Hoirch, 1989).

Chronic pain clinics exist in many forms and range from those that are oriented towards a single treatment modality such as nerve block clinics to those that provide a comprehensive, multi-disciplinary, multi-modal approach to assessment and treatment for a wide range of chronic pain problems. The former approach is based on the medical model of cure while the latter is based on a rehabilitation/adaptation model of care, the goal of which is to optimize physical, psychological and social functioning despite pain (Crook, Weir, & Tunks, 1989). Although both the research and clinical literatures strongly support a rehabilitation/adaptation model, there is evidence to suggest that relatively few clinics have the resources necessary to deliver the full range of comprehensive services to deal with the complex problem of chronic pain.

A growing body of evidence suggests that short-term, educational programs (often termed psychoeducation) that foster a sense of hope and resourcefulness by emphasizing cognitive-behavioural coping strategies, problem solving, and skills training can be beneficial in improving the day-to-day functioning and the quality of life of those living with chronic pain (Basler, 1993; Flor, Fydrich, & Turk, 1992; Malone, Strube, & Scogin, 1988; Philips, 1987; Spence, 1989; Thorn, Williams, & Johnson, 1986; Turner & Chapman, 1982; Turner & Clancy, 1988; Williams et al., 1993). Such programs, however, are usually available only through costly hospital-based, multi-disciplinary pain clinics and are delivered by specialist health care professionals who have postgraduate training in pain. Pain clinics of this kind are located in large metropolitan areas thus making access difficult for those who live in smaller cities or rural areas of the country (Weir et al., 1992). In addition, due to the nature of the referral process, specialized

programs are often restricted to the most severely disabled group of chronic pain patients who typically have suffered from chronic pain for at least three years and sometimes decades (Crook et al., 1986; HWC, 1990; Weir et al., 1992). As well, other fiscal factors may further decrease the availability of pain management programs to the broad range of individuals with chronic pain since the health care system is under tremendous pressure to contain costs (Deber, Hastings, & Thompson, 1991; Vance, 1991). Thus, accessibility and cost are issues of concern to chronic pain patients and to those who care for them (Weir et al., 1992).

Statement of the Problem

Given the prevalence of chronic pain in the community, the cost to society, the personal suffering involved, and the limited availability of resources, there is a need to test the efficacy of a community-based intervention that has the potential to be widely disseminated, that can be accessed in the early phase of chronic pain, and that can be delivered reliably by generalist health care providers such as nurses and perhaps by lay leaders who have chronic pain themselves (IOM, 1987). As Turk, Rudy and Sorkin (1993) have noted in referring to chronic pain interventions:

> An intervention that can be widely disseminated even if it is only moderately effective, may have greater impact on patient care than a more effective treatment approach that is more restricted in terms of number of patients that can be treated (p. 13).

As an adjunct to biomedical or physical therapy, an affordable and accessible community-based educational program based on a self-help philosophy (i.e., that individuals are willing to learn more about and take responsibility for the daily management of their chronic pain) may serve to enhance daily functioning and sense of well being in individuals with varying levels of chronic pain disability.

Purposes of the Study

Therefore, the main purpose of this study was to adapt an effective, standardized, community-based education intervention initially developed for those with arthritis (i.e.,

Arthritis Self-Management Program) (Lorig, 1986; Lorig & Gonzalez, 1992), and to test the efficacy of this adapted program in those suffering from various types of idiopathic chronic pain conditions. This intervention, titled the Chronic Pain Self-Management Program (CPSMP), is psychoeducational in nature, utilizes cognitive-behavioural approaches frequently employed in the treatment of chronic pain, and is based on the belief that people are capable and willing to help themselves in the daily management of their pain problem (Turk & Meichenbaum, 1994). In addition, the intervention includes health promotion components addressing such lifestyle issues as nutrition, aerobic exercise, and general stress management. The question this study sought to address was whether an intervention with proven efficacy for those with arthritis would also be effective for those with other types of chronic pain. To evaluate the full impact of the program, theory-guided measures of process and outcome as well as a standardized, norm-referenced, psychometrically strong instrument of health-related quality of life were utilized in this study.

In addition to evaluating the overall efficacy of the CPSMP, the study also examined one theoretical explanation of how individuals respond to the experience of living with chronic pain and how participation in interventions that enhance learning such as the CPSMP might alter that response. A middle-range nursing theory entitled The Self-Help Model: Learned Response to Chronic Illness Experience describes the dynamics of a learned self-help response as opposed to a learned helplessness or passive response to the experience of chronic illness (Braden, 1990b). Propositions derived from the theory have been tested with American patient populations who have arthritis, systemic lupus erythematosus, breast cancer, and HIV disease (Braden, 1990a, 1991b; Braden, Mishel, & Longman, 1998; Braden, Mishel, Longman, & Burns, 1990; Grimes & Cole, 1996; Longman, Braden, & Mishel, 1996). Scholars in the field of nursing have identified the importance of repeated testing and refinement of nursing theories with different patient populations under different conditions (Acton, Irvin, & Hopkins, 1991).

Therefore, the second purpose of this study was to explore the explanations and predictions that evolve from Braden's Self-Help Model in a sample of individuals with chronic pain who reside in Newfoundland, Canada. The cultural, economic, and climatic

differences of Newfoundland provided a dynamic contrast to the previously studied chronic illness populations who have resided in the southern United States.

Summary

Chronic pain is now considered to be a major public health problem because of its prevalence, its economic cost, and its negative impact on quality of life for both the individual and family. Despite a growing body of evidence supporting the benefits of psychoeducation programs for those with chronic pain, access to such programs remains limited for the majority of chronic pain sufferers due to the nature of the referral process, geographic location, and cost and resource issues. The purpose of this study was to evaluate the efficacy of a community-based, low-cost, psychoeducation program for the self-management of chronic pain and to explore one theoretical explanation of how individuals respond to the chronic pain experience.

CHAPTER 2

Literature Review

This literature review is divided into four sections. The first examines the theories that have served as the underpinnings of educational approaches to the self-management of chronic conditions including chronic pain. These include both behavioural and cognitive theories of learning and behaviour change as well as broad conceptual frameworks, specifically the Health Belief Model and the PRECEDE Model, that have been frequently used in the design of educational interventions. The second section examines the state of knowledge regarding the effectiveness of educational interventions for chronic illness in general and chronic pain in particular. This discussion is limited to comprehensive meta-analytic reviews of broadly-based education interventions. The third section reviews the recent clinical outcome studies that have tested the efficacy of the Arthritis Self-Management Program (ASMP). The ASMP served as the prototype for the Chronic Pain Self-Management Program (CPSMP) which was developed and tested in this study. The final section of this chapter describes the Self-Help Model (Braden, 1990b, 1993b), the theoretical model that both guided this study and was explored in terms of its' applicability to the broader chronic pain experience. The chapter concludes with the research questions and hypotheses that were tested in this investigation.

Part I: Theoretical Underpinnings of Educational Intervention Strategies for Chronic Illness including Chronic Pain

The theoretical underpinnings of health and patient education programs that aim to enhance self-management include specific theories as well as broad frameworks from a number of disciplines. For purposes of this review, two bodies of literature were examined: (1) the experimental and cognitive psychology literature pertaining to theories of learning and behaviour change; and, (2) the health education and health promotion literature that describes the use of broad frameworks to guide overall approaches to

educational interventions. The intervention strategies that accompany each theory are also briefly described particularly as they apply to chronic pain.

Throughout the history of the psychology of learning, debate has been heated regarding what is learned, how learning takes place, and the role of mediating variables in learning and behaviour change. The major views in the psychological literature may be reduced to three broad conceptual positions: stimulus-response theories, cognitive theories, and most recently a reconciling and extension of these two positions to produce a cognitive-behavioural theoretical perspective (Hollon & Beck, 1994; Kazdin, 1978; Krasner, 1990).

Behavioural Theories and Interventions

Stimulus-response (S-R) theories are derived from the behaviourism movement in experimental psychology that began with John B. Watson (1879 - 1958) and was extended by B.F. Skinner (Mahoney, 1974). The basic tenets of behaviourism include: the primacy of environmental influence on behaviour, the empirical study of observable behaviour as the only method of psychological investigation, the rejection of private mental events as appropriate subject matter of psychology, and the avoidance of cognitive-symbolic concepts as mediational or intervening variables between a stimulus (S) and a response (R) (Hayes & Hayes, 1992; Kazdin, 1978; Wilson, 1995). Two behavioural learning theories, classical or respondent conditioning theory and operant conditioning theory, are of particular importance both historically and in their influence on current educational and therapeutic programs for those with a variety of clinical problems. Both are examples of stimulus-response learning.

Classical conditioning. Classical conditioning was first reported by Ivan Pavlov (1849 - 1936) who proposed that an organism has a repertoire of simple reflexive behaviours, often autonomically mediated, which Pavlov termed unconditioned responses. Correspondingly certain environmental stimuli, such as nociceptive stimuli or very loud noises, which produce reflexive responses were termed unconditioned stimuli. In laboratory experiments with dogs, Pavlov paired a neutral stimulus (a tone) with an unconditioned stimulus (food) that produced an unconditioned response (salivation). After repeated pairings of the neutral stimulus with the unconditioned stimulus, the

neutral stimulus alone elicited the response. Thus, the previously neutral stimulus (the tone) had become a conditioned stimulus through learning and was able to elicit the conditioned salivation response in the dogs (Keefe & Lefebvre, 1994). For individuals with pain-related movement for example, a neutral stimulus such as seeing a staircase may acquire the ability to elicit anticipatory pain behaviours such as tensed body posture, and facial and verbal expressions of pain. Behaviourally-based techniques such as graded exposure or systematic desensitization to the stimuli can weaken the connection between the conditioned stimulus and the response (Scott, 1989).

Operant conditioning. While classical conditioning refers to behaviours that occur in response to an *antecedent* stimulus, operant conditioning refers to behaviours that are shaped by their *environmental consequences*. Thus, a consequence that is favourable to the individual (i.e., a positive reinforcer) is likely to increase the probability of the behaviour being repeated. Similarly, a consequence that results in the removal or withdrawal of an aversive stimulus (i.e., negative reinforcer) also increases the likelihood of the behaviour being repeated. For example, a person with constant pain who finds sitting or walking uncomfortable is likely to find lying in bed very reinforcing if pain is significantly relieved by this action. Hence, reclining in bed is negatively reinforced. In contrast, when behaviour leads to an aversive outcome or when behaviour leads to withdrawal of a positive stimulus, the behaviour is less likely to be repeated. Once established, however, operant responses become learned patterns of behaviour and are extremely persistent. These patterns can continue virtually indefinitely as long as reinforcing consequences occasionally occur (Fordyce, 1989).

Behavioural interventions. When applied to pain and other health-related conditions, many educationally-based treatments that use operant behavioural conditioning techniques have two goals: to decrease "unhealthy" or sick-role behaviours, and to increase "well" behaviours by modifying associated social and environmental reinforcers (Fordyce, 1986; Turk & Rudy, 1990; Turner & Clancy, 1988). Particular strategies used include:

- positive social reinforcement of well behaviours and ignoring illness-related or negative behaviours;

- teaching family members appropriate reinforcement patterns;
- graded activity and exercise;
- relaxation training and biofeedback;
- self-monitoring of target well behaviours and establishing quota systems
- time-contingent behaviour (eg., medication, smoking etc.).

Many health education programs that aim to modify behaviour to produce life-style change use operant conditioning principles (Blanchard, 1994). Fordyce and colleagues (1973, 1976) were the first to apply operant principles to the treatment of chronic pain and a growing body of literature has documented significant improvement in measures of subjective health status, psychosocial adjustment, and behavioural variables such as physical activity, exercise tolerance, and return to work for chronic pain patients participating in behaviourally-oriented treatment programs (Beekman & Axtell, 1985; Cassisi, Sypert, Salamon, & Kapel, 1989; Cinciripini & Floreen, 1982; Fordyce, Roberts, & Sternbach, 1985; Hazard et al. 1989; Keefe & Gil, 1986; Linton, 1982; Malec, Cayner, Harvey, & Timming, 1981; Mayer et al., 1987; Nicholas, Wilson, & Goyen, 1991; Roberts & Reinhardt, 1980; Roberts, Sternbach, & Polich, 1993; Turner & Chapman, 1982; Turner & Clancy, 1988; Turner, Clancy, McQuade, & Cardensas, 1990).

Cognitive Theories and Interventions

Mentalist tradition. At the same time that Watson, Skinner and others were guiding psychology towards behaviourism and S-R learning, theorists in the "mentalist" tradition continued in their study of the psychology of inner experience. William James, who espoused the interdependence of mind and body, and Freud and his followers generated many phenomenological and cognitive theories of personality and psychotherapy, among them neo-Freudian, Gestalt, humanist, Rogerian, and existential that addressed the conscious and unconscious mental processes that influence human learning and behaviour (Mahoney & Lyddon, 1988).

Cognition as mediator. Many behaviourists began to be dissatisfied with the black box psychology of S-R learning. Non-mediational accounts of learning could not adequately explain the complexity encountered in experiments and therapeutic interventions with humans (Bandura, 1977b, 1996; Mahoney & Lyddon, 1988).

Consequently, many behaviourists began examining the utility of cognitive processes such as thinking, memory, perception, attention, complex motivational processes, and feeling states as mediators of learning and behaviour change (Bandura, 1995; Hollon & Beck, 1994; Kazdin, 1978).

With increased theoretical interest in and scientific study of the role of perceptual processing variables, it became apparent that "naive realism" was functionally untenable in human behaviour (Bandura, 1969; Mahoney, 1974). Humans do not passively observe and respond to some "true reality out there" but respond instead to a mediated rendition of it, a perceived reality (Mahoney, 1974; Mahoney & Lyddon, 1988). Cognitive theorists hold that individuals actively construct their own private reality by attending to selected stimuli, and then process and transform those that are significant to them. Thus, individuals have the ability to cognitively transform the meaning and impact of stimuli in any given situation which in turn affects emotional and behavioural response to the stimuli (Mahoney, 1993; Mishel, 1973). In contrast to traditional behaviourist formulations of humans as essentially passive creatures whose behaviours can be altered by modifications to their external environment, cognitive theorists stressed that learning and behaviour are contingent on active process variables that mediate an individual's perception and interpretation of the environment (Hayes & Hayes, 1992; Kazdin, 1978; Neimeyer, 1993; Scott, 1989).

Cognitive interventions. Over the past thirty years, there has been a virtual explosion of interest in cognitively-focussed interventions for a variety of chronic disorders including chronic pain (Hollon & Beck, 1994; Turner & Jensen, 1993). Cognitive processes such as attention, attributions, appraisals, meaning, beliefs and values, expectancies, and self-statements or self-talk are thought to have a major impact on health- and illness-related behaviour and on health outcomes (Beck, 1993; Kendall, 1992; Mahoney, 1993; Robins & Hayes, 1993). In the area of chronic pain, a growing body of research has demonstrated the important role that cognitive factors play in exacerbating pain and suffering, in contributing to disability, and in influencing psychosocial adjustment (Browne et al., 1993; Craig, 1994; Dwyer, 1997; Jensen & Karoly, 1991, 1992; Jensen, Turner, & Romano, 1991, 1994; Jensen, Turner, Romano, & Lawler, 1994;

Turk, Meichenbaum, & Genest, 1983; Turner & Jensen, 1993; Weir, Browne, Tunks, Gafni, & Roberts, 1996). The goal of cognitive interventions is to change or modify negative thoughts or dysfunctional attitudes both indirectly as a result of education (Mahoney, 1978; Scandrett-Hibdon, 1992) and directly through techniques such as cognitive reframing (i.e., recognizing negative thoughts and generating more positive cognitions), coping self-statements training and problem-solving techniques (Meichenbaum, 1993).

Integration of Behavioural and Cognitive Theories

Social Learning Theory. According to a number of observers (Blackburn, 1986; Mahoney & Lyddon, 1988; Scott, 1989; Tobin, Reynolds, Holroyd, & Creer, 1986), it was Albert Bandura's (1969, 1977b) discourse on social learning theory (SLT) that was instrumental in first bridging the gap between the diametrically opposite poles of traditional behaviourism and psychodynamic (cognitive) theories within a learning and behaviour change framework. By integrating classical conditioning, operant conditioning, and cognitive-symbolic variables into a single conceptual framework, Bandura's SLT offered a revolutionary conceptualization of human change processes (Mahoney & Lyddon, 1988). For example, Bandura's (1977b, 1978) concept of "reciprocal determinism" was a pivotal departure from exclusive environmental determinism. In the social learning view, people are neither driven by inner forces nor buffeted by environmental stimuli. Rather, functioning is explained in terms of a continuous reciprocal interaction among intra-person factors, social and environmental determinants, and behaviour which is itself an interacting determinant. Reinforcement is considered a facilitative factor that influences motivation rather than a necessary condition for learning because factors other than response consequences influence what people attend to, appraise, and subsequently respond to (Bandura, 1977a, 1996).

Although Bandura underscored the role of behavioural techniques in effecting behaviour change, he argued that a central process of all such change occurs through a common cognitive mechanism, perceived self-efficacy (Bandura, 1977a, 1982; Bandura, Adams, & Beyer, 1977). Perceived self-efficacy refers to beliefs in one's capacities to mobilize the motivation, cognitive resources, and courses of action needed to meet a

particular situational demand (Bandura, 1991). It acts as the fulcrum of one's sense of personal agency, the ability to regulate the self, and the ability to produce and regulate specific events in one's life (Bandura, 1982). In social learning analysis, expectations of personal efficacy stem from four sources of information: mastery experiences, exposure to modelling influences (vicarious learning), learning to reinterpret physiological signs and symptoms, and social persuasion (Bandura, 1977a, 1996). In terms of impact, self-efficacy expectations will affect what people choose to do, how much effort they will mobilize in a given endeavour, how long they will persist in the face of difficulties and setbacks, whether their thought patterns will hinder or aid the activity, and the amount of stress and despondency they will experience in coping with environmental demands (Bandura, 1991, 1996).

In summary, social learning theory is embedded in a theory of human agency that emphasizes the human capacity for self-directed behaviour change. Bandura has proposed that the self-efficacy mechanism is an important cognitive mediator underlying psychological and behaviour change. Integrative reviews of the research literature have supported the significant influence of perceived self-efficacy in health-promoting action (Bandura, 1991; O'Leary, 1985; Schwarzer & Fuchs, 1995; Strecher, DeVellis, Becker, & Rosenstock, 1986) and additional research has supported the mediating effects of self-efficacy beliefs in those with various chronic pain conditions (Benjamin, 1989; Blanchard, 1987; Buckelew et al., 1996; Council, Ahern, Follick, & Kline, 1988; Dwyer, 1997; Jensen et al., 1991).

Cognitive-Behavioural Perspective The latest addition to the theoretical perspectives on human functioning is the cognitive-behavioural perspective. It is a blending of behavioural conditioning theory, psychodynamic and cognitive processing models, and social learning theory (Novy, Nelson, Francis, & Turk, 1995). As described by Turk and Meichenbaum (1994, p. 1338), this perspective is based on five central assumptions arising from its parent theories and recent research:

1. Individuals are active processors of information and not passive reactors.

2. Thoughts and other cognitive processes can elicit and influence mood, affect physiological processes, have social consequences, and can also serve as an impetus for behaviour. Conversely, mood, physiology, environmental factors and behaviour can influence the nature and content of thought processes.

3. Behaviour is reciprocally determined by both the individual and socio-environmental factors.

4. Individuals can learn more adaptive ways of thinking, feeling, and behaving.

5. Individuals need to be active collaborative agents in the process of change.

Although the cognitive-behavioural perspective was initially applied to the treatment of psychologically-based disorders, it has been utilized with a variety of clinical health problems that require self-management including chronic non-malignant pain (Holroyd & Creer, 1986; Meichenbaum & Turk, 1987; Turk & Meichenbaum, 1994). The cognitive-behavioural perspective is entirely consistent both with Melzack and Wall's (1965) multi-dimensional gate control theory of pain that integrates the affective, behavioural, cognitive, as well as sensory mechanisms in pain perception and modulation and with Melzack's (1993) more recent discussion of theory related to an overarching integrated chronic pain system (Novy et al., 1995). The rationale for applying cognitive-behavioural treatment strategies to chronic pain problems is that learning new cognitive and behavioural coping strategies in response to pain and stress can enhance an individual's sense of control or self-efficacy over pain and decrease negative emotions, thoughts, and judgments related to pain and associated symptoms (Turner & Romano, 1990). This in turn may reduce pain and distress and influence physical and psychosocial adjustment.

Cognitive-behavioural programs (frequently termed "pychoeducation" in the broader health care literature) are characterized as being: interactive, collaborative, structured and time limited, providing information and support, focussed on skills development, and fostering a sense of hope and resourcefulness (Bernier, 1992; Turk & Meichenbaum, 1994; Walsh, 1992). The specific "technology" or techniques used are varied and may consist of a combination of standard behavioural and cognitive techniques previously described (e.g., cognitive reframing, coping skills training, relaxation, imagery, self talk, goal setting, etc.) as well as education about the pain cycle (inter-relationships among

psychological stress, muscle tension, depression, fatigue and pain), and strategies to improve communication (Keefe, Dunsmore, & Burnett, 1992; National Institutes of Health Technology Assessment Panel [NIH], 1995; Turner & Romano, 1990).

Broad Frameworks for Health Education

In contrast to the theories outlined above that have guided treatment approaches to specific clinical problems, the fields of health and patient education have tended to use broader conceptualizations to guide educational program development. No single theory or conceptual framework dominates research or practice in health education today (Glanz, Lewis, & Rimer, 1997). However, two of the most frequently cited models, the Health Belief Model and the PRECEDE Model, will be briefly reviewed and critiqued (Glanz, Lewis, & Rimer, 1990; Green & Kreuter, 1991; Lorig, 1996; Strecher & Rosenstock, 1997). These models are important to understand because they have guided the choice of outcome variables that health education programs have traditionally measured.

Health Belief Model. Over the past four decades, one of the most influential and widely used conceptual models applied to health and patient education programs has been the Health Belief Model (HBM) (Janz & Becker, 1984; Harrison, Mullen, & Green, 1992). Developed and tested by a group of social psychologists at the U.S. Public Health Service, it was developed to understand and explain: (a) the widespread failure of the public to participate in low-cost screening programs for asymptomatic disease (Rosenstock, 1974); (b) the poor rates of patient compliance with prescribed medical therapies (Becker et al., 1977); and (c) the range of individual patient responses to symptoms (Kirscht, 1974). In short, the HBM was an attempt to better understand the determinants of voluntary health-related action in both disease prevention and illness and symptom management (Becker et al.,1977; Strecher & Rosenstock, 1997).

The HBM is based on a well-established body of psychological and behavioural theory, most notably the work of Kurt Lewin, whose various conceptualizations hypothesized that behaviour depends on: (a) The value placed by an individual on a particular goal (e.g., avoidance of illness), and (b) the individual's estimate of the likelihood that a given behaviour (e.g., health-related action) will achieve that goal (e.g., avoid illness and its consequences) (Maiman & Becker, 1974; Strecher & Rosenstock,

1997).

As originally conceived, the Health Belief Model proposed that generally individuals will perform voluntary health-related activities only if they possess sufficient levels of health motivation and knowledge, view themselves as potentially vulnerable to the illness condition, view the condition as having serious consequences and thus perceive it as a threat, are convinced that the intervention or the action will be effective, and see few difficulties in undertaking the particular health-promoting actions (Becker et al., 1977). In addition, a cue to action, either internal (e.g., symptoms) or external (e.g., advice, mass media) must occur to trigger the appropriate health behaviour. It is further assumed that diverse demographic, sociopsychological and structural variables affect an individual's health motivation and perceptions but are not direct causes of health-related action.

More than four decades of research have provided substantial empirical support for the dimensions in the HBM as important contributors to the explanation of individual health-related behaviours (Janz & Becker, 1984; Strecher & Rosenstock, 1997). Despite this body of evidence, a number of criticisms have been made against the validity or predictive utility of the model (Gillespie, 1997; Harrison, Mullen, & Green, 1992; Parcel, Bartlett, & Bruhn, 1986; Rosenstock, 1990). Pender (1982), Rosenstock (1974) and others have pointed out that the HBM and its modified versions are based on the notion of value expectancy (i.e., health-related decisions are made in order to avoid negative outcomes or personal threats such as illness or disability). However, it has been argued that a threat-avoidance model cannot adequately explain health behaviours that are directed towards more positive outcomes such as enhanced health and self actualization. This has led to the development of more health-oriented models such as the Health Promotion Model (Pender, 1982) which emphasizes health promotion versus disease avoidance motivational processes.

The inadequate application of the Health Belief Model in health education programs is another problematic issue (Harrison et al., 1992; Parcel et al., 1986). Although there are a number of important constructs in the HBM in addition to knowledge and attitudes, most educational programs based on this model have emphasized knowledge acquisition, attitude change and compliance to therapeutic regimes. There has been little or no

attention directed to what specific interventions caused changes in these variables or to whether change in these variables had any significant impact on physical or psychosocial health status (Parcel et al., 1986). In response to this practice limitation of the HBM, more robust behaviour change theories that include specific interventions that mediate change (e.g., Bandura's Social Learning Theory and Self-Efficacy Theory) have been incorporated into the model (Rosenstock, 1990; Rosenstock, Strecher, & Becker, 1988).

PRECEDE Model. In the past two decades, the PRECEDE Model has become a frequently used conceptual framework for health and patient education interventions (Green & Kreuter, 1991; Lorig, 1992, 1996; Parcel et al., 1986). PRECEDE is an acronym for predisposing, reinforcing, and enabling constructs in educational diagnosis and evaluation and is characterized as an overarching diagnostic framework using theory and techniques from four disciplines: epidemiology, social and behavioural sciences, administration, and education (Green, Kreuter, Deeds, & Partridge, 1980; Green & Kreuter, 1991). The uniqueness of this framework is that it initially directs attention to broad quality of life outcomes rather than to inputs. As Green and Kreuter (1991) described it, the planning of an education program correctly begins at the outcome end. Thus, the first step is identifying the desired outcomes one wishes the educational program to achieve followed by consideration of the factors that are likely to lead to the desired outcome – that is, what must precede the outcome?

The PRECEDE framework has been applied to numerous health education programs with a focus on self-management of chronic illness (Fisher et al., 1996; Furst, Gerber, Smith, Fisher, & Shulman, 1987; Mann, 1989; Opdycke, Ascione, Shimp, & Rosen, 1992; Parcel et al., 1986; van Veenendaal, Grinspun, & Adriaanse, 1996). The strength of the model lies in its direction regarding planning and evaluation of health education programs and its emphasis on outcomes. Hence, outcomes of educational interventions have shifted from measuring not only knowledge, attitudes and compliance but also to evaluating intended health status outcomes.

The PRECEDE model does not specify the particular strategies to guide interventions. Rather, designers of educational interventions using the PRECEDE model decide which health-related theories and concepts are best suited to meet the health

outcomes specific to the target population (Green & Kreuter, 1991; Parcel et al.. 1986). Authors have suggested that the HBM would be most useful within a planning model like PRECEDE with the addition of robust behaviour change theories that guide the choice of specific interventions to facilitate change (e.g., Bandura's Theory of Self-Efficacy, and other cognitive-behavioural approaches) (Mullen, Hersey, & Iverson, 1987; Gillespie, 1997). This integration of models is being applied with more consistency in health education programs (Lorig, 1996).

Part II: Effectiveness of Educational Interventions for Chronic Illness and Chronic Pain – Meta-Analytic Reviews

The important role that self-care and self-management approaches play in maintaining and improving the health and well being of those with chronic illness has spurred the development and investigation of educationally-based interventions. Research evaluating the full impact of educational approaches for those with chronic illness has moved beyond the assessment of knowledge, beliefs and attitudes alone, to include important health-related outcomes such as psychosocial adjustment, health status and quality of life as well as the variables that may mediate positive change in these outcomes. Researchers have also been interested in discovering answers to such questions as: what combination of techniques and strategies, for whom, at what point in time, in what settings, and for how long?

The number of studies evaluating the impact of patient education for those with chronic illness has grown rapidly and the publication rate has increased geometrically since the 1970's (Mullen & Green, 1990). These research studies, published in a wide collection of behavioural and health sciences journals, have varied in educational and other intervention methods, patient populations, practitioners, settings, research methods, and criteria for success. As a result, analyses and comparisons of study results have proven to be a challenge to scholars in the field (Mullen & Green, 1990; Redman, 1997). In an effort to synthesize this large body of work, there has been an increasing number of integrative reviews of the literature. Redman (1997), for example, cited 45 major reviews of the patient education literature. Although narrative reviews are still published, an

increasing number of comprehensive reviews of education intervention studies have used a statistical technique known as meta-analysis to compare outcomes across studies.

Statistical techniques of meta-analysis date back to 1916 with Fisher's early descriptions, and subsequently have been refined and further developed by Glass and colleagues (Glass, McGaw, & Smith, 1981). Meta-analysis has made it possible to systematically review and quantitatively integrate results from experimental and quasi-experimental studies in a field of interest. The advantage of meta-analysis is that each test of a dependent variable yields an estimate of the effect size (ES) which can be readily interpreted as the change in standard deviation units attributable to the experimental intervention. Thus, a common metric is established that estimates the strength as well as the reliability of a change which can then be compared across studies (Posavac, Sinacore, Brotherton, Helford, & Turpin, 1985). Cohen (1977, 1988) has interpreted effect sizes as follows: ES = 0.2 represents a small change; ES = 0.5 represents a moderate change; and, ES = 0.8 represents a large change. Although certain controversies still surround meta-analysis, recently it has gained recognition in the scientific community as a way of avoiding the biases of the traditional narrative review particularly when evaluating the efficacy of health care interventions and in overcoming methodological flaws such as small sample size (Conn, 1997; Jenicek, 1989; Mann, 1990).

Because of the large and diverse literature in the field of health education and chronic illness, this section of the literature review is limited to the appropriate and recent comprehensive meta-analytic reviews in the field. Mullen, Green and Persinger (1985) have suggested that studies of educational approaches for those with chronic illness can be broadly classified into first and second generation studies. Because comprehensive reviews have tended to fall within this classification, this taxonomy will be used here.

First Generation Studies

Mostly published before 1980, first generation studies of education for those with chronic illness were greatly influenced by the social psychological research on attitude change, fear arousal, and information processing paradigms that had informed the Health Belief Model (Parcel et al., 1986). Commonly, these studies tested a single educational approach rather than a combination of strategies and the educational quality of the

interventions was low. The major dependent variable measured in most studies was adherence to medical regimens with knowledge and attitude change as the principle intermediate outcomes (Mullen et al., 1985).

Five comprehensive reviews of clinical trials of the early patient education literature were found. One review was narrative in style but it had used an ad hoc rating system with three independent raters to evaluate the clinical significance of results (Haynes, 1976). The other four reviews used meta-analytic techniques to determine the effect size of the educational intervention (Mazzuca, 1982; Mullen et al., 1985; Posavac, 1980; Posavac et al., 1985). Although there was some small overlap, well over 200 research reports published from 1950 to 1984 were reviewed in these papers. Study samples represented adult populations with mixed chronic illness conditions most often hypertension, diabetes, mental problems, asthma, and cardiovascular disease. Study designs included those that were experimental with randomization, quasi-experimental with a control or comparison group, and one group pretest-posttest designs. The major question these reviews sought to answer was: What was the average effect of patient education for chronic illness across studies on the following outcomes: adherence to therapeutic or preventive regimens, and on knowledge and attitudes? Reviews also reported on other physiologic, psychologic (mood and anxiety) and other outcomes (length of hospital stay, readmission rates). However, in general, there were too few studies measuring these outcomes to draw firm conclusions regarding change as a result of an education intervention.

In addition, all but one of the reviews (Posavac, 1980) investigated the differential impact on outcomes of various types of educational approaches. Two reviews (Haynes, 1976; Mazzuca, 1982) classified educational approaches into 3 broad groups: educational/didactic, behavioural, or mixed approaches. A pure didactic approach, most commonly defined as the transmission of information about the disease and its treatment, was very common in the 1960's (Mullen & Green, 1990). Behavioural methods were described as drawing on the patients unique circumstances including their own regimen and routine as part of the content, as well as using techniques such as cuing or reinforcement. Mixed approaches included patient education programs that used a blend

of didactic and behavioural methods.

Two reviews used a broader classification system to evaluate education content and process. In their review of 58 papers, Posavac and colleagues (1985) evaluated both *type* of intervention (e.g., didactic, behavioural, environmental, encouraging social support, etc.) as well as *mode of delivery* (e.g., one-to-one contact, group classes, written material, AV material, etc.). The meta-analysis by Mullen and colleagues (1985), the most comprehensive of the 5 reviews (n = 70 studies), took this a step further and classified educational interventions on the basis of *educational quality* as well as *mode of delivery*. Educational quality was evaluated, not on the basis of broad groupings as had previously been done, but on adherence to seven educational principles: consonance (degree of fit between the program and the program objectives), relevance, individualization, feedback, reinforcement, facilitation by use of appropriate written or other materials, and whether the program provided multiple or alternative learning experiences rather than a single approach (Mullen et al., 1985). Each intervention was given an educational quality score based on a rating scheme by Neufeld (1976).

Across the five reviews, the reported range of pooled mean effect sizes and when available their standard deviation (s.d.) or standard error (s.e.m.) are as follows: compliance or adherence to medical regimes ranged from 0.37 (s.d = 0.06) to 1.08; knowledge ranged from 0.73 (s.d.= 0.12) to 1.13 (s.d.= 0.15); other therapeutic change (psychological and physical variables) ranged from 0.17 to 0.80; and, decreases in health care utilization were 0.20 (s.e.m.= 0.06). Because of the poor methodological quality of many of these early studies, however, these results (particularly those reporting moderate to high effect sizes) need to be interpreted with caution. Studies consistently reported that behaviourally-oriented or combined behavioural/didactic interventions produced significantly larger effect sizes than straight didactic approaches alone (Bernier, 1992; Haynes, 1976; Mullen et al., 1985; Posavac et al., 1985) and that individual or group delivery were equally effective (Mullen et al., 1985). In addition, Mullen and colleagues (1985) found that the educational quality score (particularly ratings of individualization, feedback and reinforcement) was the most powerful predictor of effect size.

Second Generation Studies

In contrast to first generation studies, research reports of educational interventions conducted after 1980 were more likely to test combinations of educational strategies, to demonstrate better adherence to educational principles, and to examine more sophisticated questions such as timing of interventions and the differential impact of particular treatment approaches. In addition, although this was not always explicitly stated, many of these studies reflected the change in theoretical position from the knowledge/attitudes paradigm of the Health Belief Model to social learning theory and broader cognitive-behavioural perspectives (Simons-Morton, Mullen, Mains, Tabak, & Green, 1992). Hence, dependent variables in these later studies were more apt to include reliable and valid measures of physical and psychological health status and well being, rather than just compliance and knowledge. This parallelled the shift in the broader health care literature to consider quality of life indicators as important outcomes of all health-related interventions (Stewart et al., 1989).

Chronic disease education. By the late-1980's, ample numbers of educational intervention studies had been published to generate meta-analytic reviews for five specific chronic diseases. Meta-analytic reviews that included studies from 1954 to 1994 (with most published after 1980) were found for cardiac patient education (n = 28 studies) (Mullen, Mains, & Velez, 1992), diabetic patient education (n = 82 and 93 studies) (Brown, 1990, 1992; Padgett, Mumford, Hynes & Carter, 1988), psychoeducation for hypertension (n = 102 studies) (Devine & Reifschneider, 1995), cancer (n = 116 studies) (Devine & Westlake, 1995), and chronic obstructive pulmonary disease (n = 65 studies) (Devine & Pearcy, 1996). These studies included a wide variety of interventions which, depending on the disease, included: straight didactic teaching (e.g., disease and dietary information), behavioural interventions (e.g., exercise programs, relaxation techniques, technical skills training, etc.), psychosocial support and counselling, mixed cognitive-behavioural approaches (relaxation, desensitization, cognitive reframing, problem solving training, etc.) and combinations of all these strategies. The majority of interventions for all chronic disease groups were behavioural and/or cognitively-oriented versus straight didactic. All the meta-analytic reviews concluded that psychoeducation had a

demonstrable, significant impact on outcomes. Small to moderate effect size estimates were reported for self-care behaviours (ES = 0.17 to 0.57), psychological health (ES = 0.27 to 0.58), physical/functional health status (ES = 0.24 to 0.63), and management of problematic symptoms (ES = 0.34 to 0.71). Moderate to large effect sizes were reported for knowledge (ES = 0.49 to 1.05). Although there was an overall improvement in methodology in this second generation group of studies (eg., larger sample sizes, more use of experimental studies with randomization, quasi-experimental studies with comparison groups, etc.), a number of authors identified the overall quality of study designs to be a continuing weakness of many educationally-based intervention research studies (Devine & Pearcy, 1996; Devine & Reifschneider, 1995; Flor, Fydrich, & Turk, 1992; Malone, Strube, & Scogin, 1988; Mullen & Green, 1990; Mullen, Laville, Biddle, & Lorig, 1987). Hence, effect size results reported in these studies may be inflated estimates.

As noted in the first generation studies, mode or type of communication channel did not influence outcome, but adherence to educational principles did. In the reviews that rated educational quality, the higher the quality rating, the larger the effect (Brown, 1992; Mullen et al., 1992). Interestingly, neither the number of education contacts nor total contact hours influenced outcome suggesting that it was not the *total amount of time* spent in an education program per se but *how it was spent* that made the difference (Brown, 1992; Mullen et al., 1992). The meta-analyses of the cancer and hypertension studies reported that 40% to 69% of the studies lacked specific information about the intervention approaches with no reporting of the frequency of administration or duration of the intervention which may explain why educational quality ratings were not reported for these sets of studies (Devine & Reifschneider, 1995; Devine & Westlake, 1995).

Chronic pain psychoeducation. Three meta-analytic studies of interventions for those suffering from a chronic pain problem have been published. In a review of 15 controlled, experimental trials of psychoeducational interventions for those with arthritis published from 1982 to 1986, Mullen, Laville et al. (1987) reported modest improvements in pain (ES = 0.21, s.d.= 0.06), depression (ES = 0.28, s.d.= 0.07) and disability (ES = 0.13, s.d.= 0.06). Although small, the effect sizes for pain and depression were noted to be in the

same direction and magnitude in all 15 studies reviewed. In explaining the very low rate of improvement in disability, the authors noted that measures of disability varied across studies, were too broad, and were conceptually poor. In comparing these results to a series of seven studies of non-steroidal anti-inflammatory drugs (Nsaids) and arthritic pain, Mullen, Laville and colleagues concluded that the effect size estimates could be interpreted as the increment in pain reduction obtained by adding a psychoeducation intervention to Nsaids.

Malone, Strub and Scogin (1988) reviewed 109 studies that evaluated the outcome of various non-medical treatments for chronic pain of various etiologies. Eighty-seven percent of these studies ($n = 95$) were published between 1975 and 1984. The treatments included a wide range of approaches including: behavioural interventions such as operant conditioning, biofeedback, and relaxation training; cognitive interventions including hypnosis and autogenic training; physical interventions such as trans-electrical nerve stimulation (TENS); and, "package" or combinations of interventions. Chronic pain sufferers in these studies included those with back and neck pain, joint pain, dental pain, headache, and phantom pain.

Of the 109 studies reviewed, only 48 experimental and quasi-experimental studies provided enough data to estimate effect sizes. Moderate to very high mean effect sizes as a function of type of treatment were reported. For example, mean effect size and standard deviation for behavioural interventions ranged from 0.55 (± 0.09) to 0.95 (± 1.16); cognitive interventions ranged from 0.76 (± 0.31) to 2.74 (± 1.95); and, "package" treatments were 1.33 (± 1.59). When examining specific outcome measures, results indicated that those receiving a chronic pain intervention compared to no treatment controls demonstrated improvement in activity level (1.48 ± 1.86), subjective symptoms (1.12 ± 0.40), mood (1.91 ± 0.92), medication intake (1.21 ± 1.88), and pain intensity (0.75 ± 1.05).

In reviewing the results, Malone and colleagues (1988) found that all treatment approaches produced about the same level of improvement despite differences in types of pain treated, dependent measures used, inpatient or outpatient status, or other patient characteristics. They suggested that treatment effectiveness was likely attributable to

features that all treatments have in common such as contact with an empathic professional, installation of hope, and reduction of fear and depression. These comments are interesting in light of Bandura's (1977b, 1982) hypothesis that self-efficacy is the common underlying mechanism that influences efficacy of treatment.

Turk and Holzman (1986) have supported these ideas. In reviewing the most common psychosocial interventions employed with chronic pain patients, they concluded that there was a set of features that appeared to underlie each of them. These included: (1) fostering optimism and combating patient demoralization, (2) individualizing treatment, (3) active patient participation and responsibility, (4) skills acquisition, (5) fostering self-efficacy, and (6) self-attribution of improvement. These features are somewhat analogous to the established educational principles previously described (Mullen & Green, 1990; Mullen et al., 1985; Neufeld, 1976). In other words, interventions based on educational principles that enhance these six features are likely to be effective, regardless of the specific techniques taught.

The most recent meta-analytic review included 65 quasi-experimental and experimental studies that evaluated multi-disciplinary treatment rather than single treatment modalities for chronic pain (Flor, Fydrich, & Turk, 1992). Studies contained in the review were published from 1973 to 1989. Multi-disciplinary treatment approaches included psychoeducational interventions (e.g., cognitive and behavioural modalities), standard medical therapy, and physical/occupational therapy. The average duration of these inpatient ($\underline{n}$ = 32), outpatient ($\underline{n}$ = 19), and combined inpatient-outpatient ($\underline{n}$ = 14) programs was 7 weeks. Contact hours ranged from a low of 4 hours to a high of 264 hours. More than 50% of subjects suffered from chronic low back pain, and the remainder had mixed chronic pains. A total of 3089 subjects were included in these studies with an average of 61 subjects per study.

Flor and colleagues (1992) calculated two overall effect sizes: those that reflect the short term overall impact of the program (based on measures taken less than 6 months after program completion) and those that reflect long term overall impact (measured greater than 6 months after program completion). Short term effect size and standard deviation was 0.62 (± 0.47) while long term effect size was 0.81 (± 0.66). Therefore, at

long term follow-up, chronic pain patients who completed multi-disciplinary treatment demonstrated at least twice the change reported by either the no treatment control/ comparison groups or by groups that received single modality treatment alone (e.g., physical therapy or standard medical care).

Effect sizes were also calculated for specific outcome measures in the treatment groups compared to control/comparison groups. Results on outcome measures were (effect size ± standard deviation): pain (0.70 ± 0.66), mood/depression (0.63 ± 0.33), behaviour which included activity level, return to work, health care utilization (0.65 ± 0.70), and interference with life roles (1.10 ± 0.67).

In reviewing variables that might influence treatment outcome, the authors noted that neither patient characteristics such as litigation and compensation status nor program characteristics such as length of the treatment were significantly associated with effect size. However, they did note that studies using non-random control/comparison groups yielded higher effect sizes. Because the majority of studies in the review were conducted without appropriate random control groups, the authors suggested that these moderate to large effect sizes were inflated estimates and should be interpreted in light of this limitation. Overall, however, Flor and colleagues concluded that the results of the meta-analysis provided support for the efficacy of multi-disciplinary approaches to the treatment of chronic pain over single modality medical or physical treatment approaches.

In support of these conclusions, the recent report of the National Institutes of Health Technology Assessment Panel (1995) found that there was enough rigorous research to conclude that relaxation and cognitive-behavioural techniques were efficacious in the treatment of chronic pain, however, the data were not sufficient to conclude that one technique was usually more effective than another for a given condition.

Summary of the Literature: First and Second Generation Studies

Within the limitations of the meta-analytic reviews of both first and second generation studies, evidence supports the following generalizations about educational treatment approaches for chronic illness including chronic pain:

1. Overall, educational interventions have a demonstrable impact on knowledge, attitudes and measures of health and well being.

2. Therapeutic regimes that are complex, of long duration, and require a high degree of behaviour change have greater levels of non-compliance.
3. For most chronic illness conditions, cognitive and behaviourally-oriented interventions that are designed: (a) to help individuals cope with both the physical and psychosocial impact of their illness, and (b) to address their unique self-management needs are more likely to be effective than single modality treatments such as straight didactic teaching or medical/physical interventions alone.
4. Regardless of mode of delivery or program length, educational interventions that adhere to educational principles, particularly individualization, feedback and reinforcement, are more likely to produce the greatest change.
5. The cumulative evidence suggests that the durability of cognitive and behavioural change depends on the degree of active rather than passive participation of the learner.
6. There is evidence that an underlying mechanism(s) common to all educationally-based treatments (whether they be cognitive, behavioural, supportive or physically-based) may be the important "active" ingredient in determining improvement. This active ingredient has not yet been determined but may be a mediating process such as self-efficacy.

Part III: Literature Review of the Arthritis Self-Management Program

Given that the overall purpose of this study was to test the efficacy of a community-based intervention for those with chronic pain, a comprehensive search of the pain-related literature was undertaken to locate whether such a program already existed. Although no description of a community-based chronic pain program was located, a series of studies were found that reported the success of a low cost, community-based program for the self-management of arthritis (Lenker, Lorig, & Gallagher, 1984; Lorig & Gonzalez, 1992; Lorig & Holman, 1989, 1993; Lorig, Chastain, Ung, Shoor, & Holman, 1989; Lorig, Lubeck, Kraines, Seleznick, & Holman, 1985; Lorig, Mazonson, & Holman, 1993). The Arthritis Self-Management Program (ASMP), developed by Kate Lorig, R.N., Dr.P.H. at the Stanford University Patient Education Research Center with funding from the

National Institutes of Health (Lorig, 1986), warranted in-depth examination for the following reasons: (a) the strong theoretical underpinnings of the ASMP which were consistent with other cognitive-behavioural programs for those with chronic pain; (b) the high educational quality of the ASMP as demonstrated by its adherence to established educational principles especially reinforcement, individualization, and feedback; (c) and, the rigorous methodology of the ASMP outcome studies that consistently demonstrated positive outcomes, not only in knowledge and behaviour, but also in quality of life variables (pain, disability and depression) and health care costs.

Theoretical Underpinnings

In terms of theoretical underpinnings, the ASMP has evolved since 1978 from a program that was loosely developed within a PRECEDE-like framework and which according to Lorig and Gonzalez (1992) was built with "bits and pieces taken from theory, accepted practice, and good intentions" (p. 356) into one that became firmly grounded in Bandura's (1977a, 1977b, 1982) Social Learning Theory (SLT). The transition from a psychoeducation program with a weak conceptual base to a highly developed theoretical foundation was the result of unexpected research findings. The early clinical trials of the ASMP, with more than 300 subjects, showed significant improvement in knowledge, pain, disability, and behaviours for the treatment group compared to wait-list controls (Lorig, Seleznick, et al., 1989). The mechanism through which the ASMP affected health status was hypothesized to be directly linked to changes in behaviour. However, when this hypothesis was tested, measures of association between health status outcomes and behaviour change were weak ($r = 0.10$ to 0.14) (Lorig, Seleznick, et al., 1989).

This unexpected lack of association led Lorig and colleagues to conduct a grounded theory study to investigate attribution of improvement by program participants (Lenker et al., 1984; Lorig & Holman, 1993). In general, individuals who demonstrated significant improvement in health status outcomes attributed this to a feeling of increased personal control over the symptoms of their disease, not because they were exercising, relaxing or practising pain management techniques more often (Lorig & Holman, 1993). Based on Bandura's SLT (1977a, 1986), Lorig operationalized this sense of control as perceived

self-efficacy (Lorig & Gonzalez, 1992). The ASMP was fully revised in 1989 to reflect this broader conceptual base including the integration of strategies known to enhance self-efficacy (skills mastery, modelling, reinterpreting symptoms and changing beliefs, and social persuasion). Lorig and colleagues have reported that clinical trials of the efficacy-enhanced ASMP have produced greater improvement in health status in treatment subjects than the original program and that these improvements were significantly correlated to higher levels of self-efficacy ($\underline{r} = 0.45$) but were independent of the specific behaviours taught in the program ($\underline{r} = 0.16$) (Lorig & Gonzalez, 1992; Lorig et al., 1993). Hence, research evidence supports the role of self-efficacy as a mediator of health status outcomes.

In addition to its social learning foundation, the ASMP is also based on a cognitive-behavioural perspective similar to that articulated by Turk and Meichenbaum (1994), namely that individuals are intelligent and capable of learning new ways to manage problems through cognitive and behavioural strategies and that through active participation, individuals learn what works best for them (Lorig & Gonzalez, 1992; Lorig, Laurin, & Gines, 1984). Two other cognitive-behavioural theories have also guided aspects of the process and content of the ASMP. Lazarus and Folkman's (1984) Theory of Stress and Coping underscored the importance of primary and secondary appraisal and of including both cognitive and behavioural coping strategies into the program; use of Seligman's (1975) Theory of Learned Helplessness led to the incorporation of realistic goal setting as an important learning activity that serves to increase feelings of control over the environment (Lorig, 1996; Lorig et al., 1984).

ASMP Program Description and Adherence to Educational Principles

The ASMP is a psychoeducation program of 12 hours in length (2 hours per week for 6 weeks) designed for group presentation. The course is not prescriptive but rather facilitates individual exploration of a broad range of approaches to self-management so that participants can learn what works best for them. The course includes: (a) discussion of a number of issues that are relevant to arthritis including self-help/self-management principles, problem solving principles, appropriate exercise, fitness and nutrition, medications for arthritis (including a discussion of the broad classifications of drugs for

pain), how to safely choose non-traditional treatments; (b) weekly practice of various cognitive-behavioural approaches to pain management (e.g., relaxation, imagery, distraction); (c) teaching cognitive strategies to deal with emotions and feelings of depression (e.g., encouraging positive self talk, decreasing negative self talk, cognitive reframing); (d) improving communication skills with family and others; (e) teaching other behavioural strategies such as individual realistic goal setting, weekly contracting to meet individual goals, and weekly feedback and reinforcement of goal attainment. The course is designed to maximize group discussion and group problem solving, and to provide opportunities for the practice of different self-management techniques. Consequently, didactic presentation is kept to a minimum and the process components are emphasized. In addition, social support is provided by means of a buddy system. Supplementary reading material is provided to all participants (Lorig & Fries, 1990, 1995). This program is of high educational quality since it consistently applies strategies that incorporate the five educational principles of relevance, reinforcement, feedback, individualization, and facilitation.

ASMP Intervention Studies.

Four randomized controlled trials (including one that used a Solomon 4-group design) and one trial using a non-random comparison group have evaluated the impact of the ASMP since 1981. These studies have measured change in specific outcomes such as knowledge, behaviour, health status (specifically pain, depression and disability), and health care utilization and associated health care costs up to 4 years post-intervention. In the randomized studies, individuals with arthritis were randomly assigned to take the course immediately, or to become wait-listed controls and were offered the course 4 or 8 months later. Therefore, although not ideal, long-term follow-up studies have been limited to within-group comparisons (pre versus post-treatment scores) or between-group comparisons with a non-randomized, no treatment comparison group.

Lorig and Holman (1993) have summarized the results from all the ASMP studies and have suggested that the evidence supports the following conclusions:

1. The ASMP has been shown to improve knowledge, behaviours, self-efficacy, and aspects of health status (Lorig, Chastain, et al.,1989; Lorig & Gonzalez, 1992; Lorig

& Holman, 1989, 1993; Lorig et al., 1985; Lorig et al., 1993; Lorig, Seleznick. et al.,1989). Studies of the original ASMP (n = 707) (Lorig, Seleznick, et al., 1989) and the efficacy-enhanced version (n = 231) (Lorig & Gonzalez, 1992) have reported that. at 10-weeks post intervention, treatment subjects when compared to randomized wait-list controls had statistically significant improvement in the following variables: 32% improvement in knowledge about arthritis; 88% increase in time spent exercising; 80% increase in time spent practising relaxation; 8% to 22% reduction in pain; and, 14% to 19% increase in self-efficacy ratings. There were also positive trends to improvement in depression (9% to 14%) and disability (4% to 6%). Overall, these improvements were retained by the treatment group at 8 months and 20 months when compared with their pre-treatment scores (Lorig, Chastain, et al., 1989; Lorig et al., 1993).

2. Formal reinforcement did not improve the long-term outcomes of the ASMP. A sample of 543 ASMP participants were randomized into one of three groups: a bi-weekly arthritis newsletter, a 6-week reinforcement class at 12 months, or no reinforcement (Lorig & Holman, 1989). By 20 months, there were no significant differences between the 3 groups on measures of pain, depression, or visits to physicians. At 20 months, pain scores were decreased by 20%, depression decreased by 14%, and there were 35% fewer visits to physicians. There were no trends toward loss of these effects over time. Therefore, the effects of this self-help intervention were sustained over 20 months with no added benefit of reinforcement strategies.
3. The effects of the ASMP have lasted for as long as 4 years without long-term formal reinforcement (Lorig & Holman, 1993; Lorig et al., 1993). These improvement gains by the ASMP participants have importance both clinically and in terms of cost saving. Lorig, Mazonson and Holman (1993) have reported on a 4-year study of ASMP participants (n=401) and a comparison group of arthritis patients (n=567) who received conventional therapy and who lived in the same geographic region as ASMP treatment subjects. Results at 4-year follow-up indicated that the ASMP group had a mean decline in pain of 20%, a mean decrease in physical disability of 9% (even though the disease had progressed), and a mean reduction in physician visits of 40%.

By contrast, subjects in the comparison group showed little or no change in these variables compared to their baseline scores. Estimated 4-year health cost savings were $648 (American dollars) for the patient with rheumatoid arthritis and $189 for the patient with osteoarthritis.

In 1991, there were an estimated 120,000 individuals in the United States, Canada, Australia, and New Zealand who had participated in the ASMP (Lorig & Holman, 1993). The program has been well accepted by both patients, physicians and other health professionals. It is inexpensive to operate and has been adequately delivered by both health care professionals and trained lay persons (Cohen, van Houten Sauter, DeVellis, & McEvoy Devellis, 1986; Lorig et al., 1986). In addition, the program has been extended to include those with fibromyalgia (Lorig & Fries, 1995) and those living with a variety of co-morbid conditions including heart disease, stroke, diabetes, asthma, bronchitis, and emphysema (Lorig, 1994).

In summary, the ASMP has been evaluated in randomized clinical trials and has demonstrated efficacy in improving important aspects of health status and in decreasing health care utilization in those with arthritis-related disease. The theoretical underpinnings of the ASMP program as well as its content and process appear to be entirely consistent with a number of outpatient cognitive-behavioural programs that are generally available in multi-disciplinary pain centres for those with various non-malignant chronic pain problems (Basler, 1993; Caudill, Schnable, Zuttermeister, Benson, & Friedman, 1991; Nicholas, Wilson, & Goyen, 1992; Philips, 1987; Spence, 1989; Turner & Clancy, 1988; Turner, 1982). The evidence strongly suggests that the ASMP is a practical, cost-effective prototype on which to base educational programs for those with various chronic health problems including chronic pain. Consequently, the ASMP was used as a model for the development of the Chronic Pain Self-Management Program (CPSMP) that was tested in this investigation.

Part IV: Conceptual Framework: Braden's Self-Help Model

Although the intervention in this study was based on self-efficacy and related theory,

a search was initiated for a broader theoretical framework that, in addition to specifying possible mediating processes such as self-efficacy, would also identify the critical variables that might be expected to improve as a result of a psychoeducation program. The conceptual framework chosen to guide this study was Braden's Self-Help Model and associated middle-range nursing theory. This theory describes the dynamics of a learned self-help response to the experience of living with a chronic health problem as opposed to a learned helplessness or passive response (Braden, 1990a, 1990b). As defined by Braden (1993b), a learned self-help or self-management response represents "an informed process of facing definable, manageable adversities by maintaining control of everyday problems" (p. 38). This definition stems from the broader self-help and primary health care literature and can be applied equally well to individuals, families, groups, and communities (Robinson, 1981). In contrast to a self-help response, those who exhibit a learned helplessness or passive response do not actively seek solutions to problems but remain uninformed, withdraw from definable, manageable difficulties, and succumb to everyday problems (Braden, 1990b, 1993c). Haug and Lavin (1983) have suggested that most individuals adjust to the experience of chronic illness over time on the basis of trial-and-error learning. In support of this proposition Verbrugge and Ascione (1987), in a study of self-care activities of 589 individuals, reported that those with chronic symptoms "craft strategies of care over months and years" (p. 560). Braden (1990a) proposed that by understanding the dynamics involved in developing a self-help response to the stressors accompanying chronic health problems, nurses will be better able to develop interventions that enhance the efficiency of this trial-and-error "crafting" process. Such interventions should facilitate the learning of healthy behaviours and have the potential to improve symptom management, promote independent functioning, enhance psychosocial well being, and reduce health care costs.

Model Development

Braden (1993b) has stated that her interest in learned response to chronic illness experience began by observing the variability of responses exhibited by individuals who live with chronic health problems. Why is it, for example, that some persons with moderate to severe disability as a result of a chronic condition continue to be involved in

work, family, and social/community activities while others with similar or much less debility withdraw from various roles and responsibilities and become overly dependent on others?

The Self-Help Model emerged from three different study designs with three different data sets: (1) a descriptive-correlational, cross-sectional study of 396 individuals enrolled in the Arthritis Self-Management Program (ASMP) (Braden, 1990a, 1990b); (2) a pre-experimental, longitudinal study of 313 persons with systemic lupus erythematosus (SLE) who participated in an SLE Self-help Course (adapted from the ASMP) (Braden, 1991b, 1992; Braden, McGlone, & Pennington, 1993); and, (3) a descriptive-correlational, 5-year longitudinal study of 910 subjects with arthritis at time one, 516 at time 2, and 411 at time three (C.J.Braden, personal communication, June 1994).

Mechanic (1977), Dimond (1983), and others have built a case for viewing adjustment to chronic illness from an educational or learning model perspective, as opposed to a trait-based perspective. In keeping with this orientation, Braden (1990a, 1990b) generated and tested 36 hypotheses from three learning-based theories in order to explain a self-help response to chronic illness experience. Two of these alternative theories, Learned Helplessness Theory (Seligman, 1975; Winefield, 1982) and Instrumental Passivity Theory (Baltes, 1982; Barton, Baltes, & Orzech, 1980) illustrate pathogenic responses to the various unremitting stressors associated with chronic illness. In contrast, Learned Resourcefulness Theory (Rosenbaum, 1983; Rosenbaum & Palmon, 1984), the third alternative theory, offers a theoretical explanation for a health-promoting response that highlights self-care and self-management processes in the face of chronic stressors.

Causal modelling and path analyses demonstrated that Rosenbaum's Learned Resourcefulness Theory was the most credible of the three learning theories in explaining the self-help response to chronic illness. This theory recognizes the resiliency of people and seeks to explain how most individuals adjust to the situational and cognitive challenges of stressful life circumstances such as chronic illness experience. The theory is based on cognitive-processing approaches to behaviour change such as Kanfer's (1977) model of self-regulation, Meichenbaum's (1977) cognitive-behavioural model, Bandura's

(1977a, 1978) Social Learning and Self-Efficacy Theories, and Lazurus and Folkman's (1984) theory of stress and coping.

Learned Resourcefulness Theory proposes that individuals exposed to aversive events are able to mediate the negative effects of adversity by the use of enabling skills that provide the basis for additional learning (Rosenbaum, 1990). These enabling or coping skills constitute a learned set of behaviours, cognitions, and affects that are in constant interaction with the social and physical environment. Through the processes of problem-solving, cognitive-reframing, delay of gratification, and a general belief in self, an individual is able to continue engaging in goal-directed behaviours. People who acquire and use these skills have a sense of 'learned resourcefulness', a belief that they can deal effectively with stressful circumstances that call for self direction.

Rosenbaum (1988) has conceptualized learned resourcefulness as a personality repertoire that is usually acquired from early childhood and throughout life by informal learning. However, he suggested that educational programs that incorporate cognitive-behavioural interventions may be the way in which adults can acquire these skills in the face of health-related stressors (Rosenbaum, 1990a).

Model Constructs and Description

The constructs in the Self-Help Model are conceptualized as antecedents (severity of illness, limitation, and uncertainty), mediators (enabling skill), and outcomes (self-help and life quality). (See Figure 1).

Antecedents

Perceived severity of illness. Severity of illness, defined as the perceived level of affliction due to a chronic health problem, operates as the stimulus for learning and behaviour change (Braden, 1990b). Perceived severity of illness is a variable that increases exposure to the aversive aspects of chronic health problems such as perceived limitation and uncertainty.

A number of studies have found that adjustment to a chronic physical condition is independent of specific medical diagnosis (Bombardier, D'Amico, & Jordan, 1990; Browne, Arpin, Corey, Fitch, & Gafni, 1990; Cassileth et al., 1984; Pollack et al., 1990) and that illness severity as perceived by the individual is a better predictor of adjustment

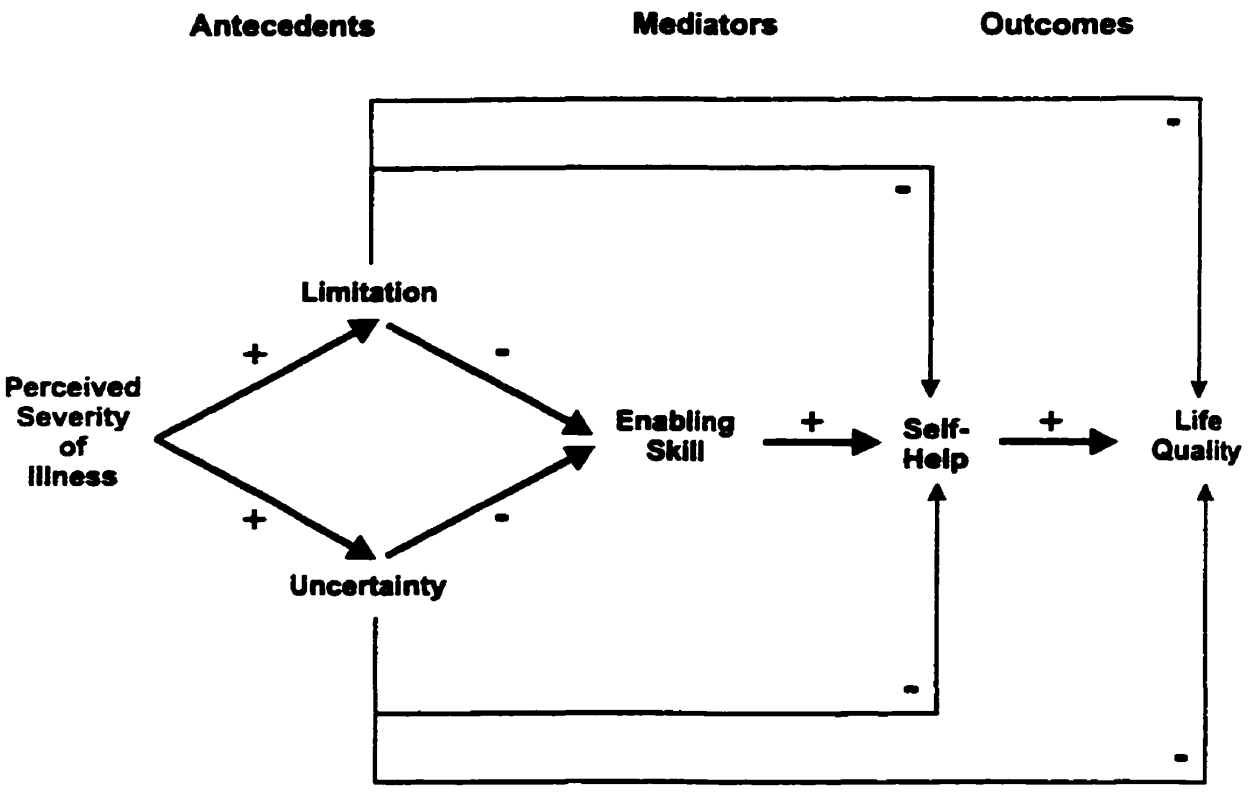


Figure 1. The Self-Help Model Constructs and Hypothesized Relationships

than are objectively-rated indicators of illness (Brooks & Matson, 1982; Felton et al., 1984; Viney & Westbrook, 1981; Westbrook & Viney, 1982). These findings are consistent with other studies of general health perceptions indicating that subjective ratings are among the best predictors of morbidity, mortality, and health care utilization (Idler & Benyamini, 1997; Idler & Kasl, 1995; Ware, 1986). In testing the contribution of sociodemographic, disease-related and other background characteristics, Braden (1993a, 1993c) found that the amount of influence in terms of magnitude of relationship to other Model variables was small compared to the effect of perceived severity of illness.

Limitation and uncertainty. Limitation and uncertainty are major adversities that are often part of the chronic illness experience and are derived from Seligman's (1975) and Baltes's (1982) learned helplessness models and Mishel's (1988) uncertainty in illness theory. Braden hypothesized that the higher the perceived severity of illness, the higher the levels of perceived limitation and uncertainty.

The perceived inability to do things one wants to do has been conceptualized as both

perceived limitation (Braden, 1991b, 1992) and as dependency (Braden, 1990b) defined as one's perceived level of reliance on others for direct or indirect assistance to carry out routine activities of daily life. The chronic illness and chronic pain literature and data from population-based surveys have reported that perceived dependency and limitations resulting from perceived disability are related to poorer overall functioning and a decreased quality of life (Dowler & Jordan-Simpson, 1990; Gallagher, 1976; Health and Welfare Canada, 1988; Hyman, 1975; Jensen, Turner, & Romano, 1994; Jensen, Turner, Romano, & Lawlor, 1994; Strauss & Glasser, 1975).

Uncertainty, the other major adversity, relates to the difficulty or confusion in assigning meaning to events associated with health problems. Mishel (1988) stated that this situation occurs when individuals are unable to assign definite values to health-related events or are unable to accurately predict outcomes due to lack of sufficient cues. Uncertainty about the severity of illness, about the success of treatment, about the impact of the health problem on one's life and on the life of the family, and uncertainty about the ability to pursue life goals constitute major areas of concern for those with chronic health problems. A growing body of literature has suggested that uncertainty may have a number of negative effects including: preventing individuals from obtaining information necessary for controlling events (Staub & Kellett, 1972); disrupting many important life areas (Mishel, Hostetter, King, & Graham, 1984); enhancing a sense of danger (Mishel, 1990); and, reducing a person's sense of mastery over events (Mishel, Padilla, Grant, & Sorenson, 1991). Uncertainty has also been associated with psychological distress (Mishel, 1990). In addition, uncertainty was found to be a core variable that contributed to the stress and overall negative impact of the chronic pain experience for both the individual and family (Rowat & Knafl, 1985).

Mediators

Enabling skill. Mediating the effects of limitation/dependency and uncertainty on outcomes such as self-help behaviour is enabling skill. Enabling skill, from Rosenbaum's Learned Resourcefulness Theory, is defined as one's perceived ability to manage adversity and includes such self-regulating activities as problem-solving, cognitive reframing, belief in self and delay in immediate gratification.

Recent studies have substantiated the role of learned resourcefulness in adjustment to various chronic health problems. In a sample of 87 individuals with mixed idiopathic chronic pain problems, higher levels of resourcefulness were significantly associated with less psychological distress ($r = -0.35$) and with fewer emergency room visits (Toomey, Seville, Mann, Abashian, & Wingfield, 1995). Derry, Chovaz, McLachlan and Cummings (1993) reported that learned resourcefulness explained 40 percent of the variance in psychosocial adjustment in those with epilepsy, while other hypothesized variables (e.g., health locus of control and family cohesion) did not significantly contribute to the prediction. Braden's (1990a, 1990b) initial studies found that enabling skill (i.e., resourcefulness) explained 30 percent of the variance in self-help behaviour and life quality for those with arthritis or arthritis-related disease and together with dependency and uncertainty explained 52 percent of the variance. Enabling skill has also been found to be related to positive health outcomes in those under stress (Rosenberg, 1989), and in persons with kidney disease (Rosenbaum & Smira Ben-Ari, 1986), dysmenorrhea (Gruber & Wildman, 1987), seasickness (Rosenbaum & Rolnick, 1983), and in both heart disease and chronic headache (Rosenbaum, 1990). As well, learned resourcefulness appears to be important for the adoption and maintenance of health-promoting behaviour. For example, high resourceful subjects were found to be more successful in giving up smoking (Carey, Carey, Camrike, & Meisler, 1990; Katz & Singh, 1986), in changing their eating habits (Leon & Rosenthal, 1984), in maintaining weight loss (Kennett & Ackerman, 1995) and in curbing alcohol intake (Carey et al., 1990). Thus, enabling skill appears to be important in enhancing a self-help response.

Braden's Self-Help Model suggests that if sufficient enabling skills are present, uncertainty and limitation/dependency will not overwhelm the person and hope and optimism will be maintained in spite of chronic illness adversities. That is, if persons are able to problem-solve and, in particular, to generate alternate solutions to problems, if they are able to cognitively reframe events and use non-negative thinking, and if they believe themselves to be capable persons, then they will be able to minimize the effects of the uncertainties in the illness experience as well as the effects of circumstances that promote dependency and disability.

Outcomes

Self-help and life quality. There are two outcome variables in the Self-Help Model: self-help and life quality. Self-help is defined as one's perceived ability to maintain valued adult roles (i.e., involvement in broad role functioning regarding household, family and occupational activities including social and community activities). Braden (1993b) defines this as "being able to do things one finds important in life, the things that define who one is" (p. 160).

In specifying self-help as a major outcome of the Model, Braden (1993b) is in agreement with Dimond (1983), Levine and Croog (1985), McBride (1993), Mechanic (1978, 1991), Tarlov (1992) and many others who have argued that maximizing a person's ability to take part in everyday activities with family, friends, neighbours and colleagues at home, at the workplace and in the community, to his/her satisfaction, is a fundamental goal of health care. This is clearly consistent with the World Health Organization's (1986) socio-ecological approach that situates health as a resource for everyday living, and not the objective of living. It also reflects the position of the eminent biologist René Dubos (1984) who stated: "For most of us, health is the ability to function. To be healthy does not mean you are free of all disease; it means that you can function, do what you want to do and become what you want to become" (p. 34).

Although the importance of the broad spectrum of role functioning on quality of life has long been underestimated (Levine & Croog, 1985; Schipper, Clinch, & Powell, 1990), research evidence lends support to viewing self help as an important outcome. For example, role retention has been found to be significantly related to overall life satisfaction in studies of cancer survivors (Baker, Curbow, & Wingard, 1991b; Barofsky, 1989; Vess, Moreland, & Schwebel, 1985). A recent qualitative study found that AIDS patients describe that "Being Active" (i.e., being with people, working (paid or volunteer), being involved in leisure activities, staying connected to life, and engaging and relating to others) is a key aspect of "Doing Well" (Gloersen et al., 1993).

In economic terms, the importance of role functioning as an outcome is highlighted by results of a study by Browne and colleagues (1990). They found that psychosocial adjustment defined as the capacity to live with a chronic health problem with a minimum

loss of one's previous vocational, domestic, social, and family roles was the strongest correlate of health care service utilization. Their study of 215 chronically ill individuals from oncology, rheumatology, and gastroenterology clinics in Toronto found a statistically significant association between total annual health costs per patient and the patient's level of adjustment. The higher the adjustment, the lower the cost. There were no important relationships found between type of disease, objectively-rated disease severity, or socioeconomic variables and health care utilization. Thus, the benefits of nursing interventions that are able to enhance psychosocial adjustment are potentially far-reaching.

Self-care roles, which are integral to self-help, are those personal care behaviours directed at promoting health and wellness. Compared to the large body of literature on illness or sick role behaviour, there has been relatively little study of health-promoting self-care behaviour in those with chronic illness (Brooks, 1984; IOM, 1987; Woods, 1989). Studies of those with diabetes (George & Bearon, 1980), hypertension (Bomar & Hautman, 1990), cancer (Dodd & Dibble, 1993; Frank-Stromberg, Pender, Walker, & Sechrist, 1990), and various physical disabilities (Davidhizar & Shearer, 1997; Marge, 1988; McWilliam, Stewart, Brown, Desai, & Coderre, 1996; Stuifbergen & Becker, 1994) highlight the need for interventions that encourage self-management of common symptoms and the adoption of healthy lifestyles. Health promotion strategies such as physical activity, good nutrition, and stress management are important in reducing the risk of secondary health problems in those with chronic conditions (Stuifbergen & Becker, 1994). Maximizing functioning in relation to self-care, family, work, and social roles is thought to enhance overall life quality, the last outcome in Braden's Self-Help Model.

Braden (1993b) defines life quality as the level of satisfaction with one's current life situation. Since the 1960's, there has been active and ongoing debate concerning the definition of quality of life and the elements that contribute to this construct. Although concern over quality of life in the health care field is comparatively new, social scientists have had a long-standing interest in measuring life quality in the general population (McDowell & Newell, 1987). The best known studies of the quality of life of individuals

are national surveys conducted by Andrews and Withey (1976) and Campbell and associates (1976). Both sets of investigators conceptualized quality of life in terms of satisfaction with various life domains.

In support of using satisfaction in defining quality of life rather than other concepts of well being such as happiness or morale, Campbell (1981) and Laborde and Powers (1980) have found that when questioned about the quality of their lives, healthy individuals respond in terms of life satisfaction, often referring to specific domains. As McDowell and Newell (1987) point out, life satisfaction generally refers to a personal assessment of one's condition. Schneider (1975) and others assert that this subjective appraisal approach allows each respondent to rate life quality in terms of individually important values and standards. Although there is still no universal agreement on the definition of quality of life, a number of authors contend that life satisfaction is the most important dimension to include in life quality assessment (Campbell, Converse, & Rodgers, 1976; Cantril, 1965; Diener, Emmons, Larsen, & Griffin, 1985; Ferrans & Powers, 1985; George & Bearon, 1980; Laborde & Powers, 1980; Osberg, McGinnis, DeJong, & Seward, 1987). In addition, Rosenblatt and Atkinson (1993) maintain that good health care treatments ultimately ought to enhance a person's capacity to achieve improved life satisfaction.

In summary, the Self-Help Model proposes that when persons dealing with the adversities related to chronic health problems find ways to continue valued adult role activities and institute strategies to promote their level of health, then life quality can be maintained or enhanced. Braden (1993a) has also proposed that feedback features of the Self-Help Model link life quality to subsequent perception of illness severity, dependency and uncertainty. This middle-range nursing theory, along with Rosenbaum's (1990) Learned Resourcefulness Theory, are based on the premise of enabling skill as a positive mediator and on the existence of feedback loops that carry what is learned into the future.

Applicability of the Self-Help Model to the Proposed Study

There are a number of reasons why the Self-Help Model: Learned Response to Chronic Illness Experience was thought to be an appropriate conceptual framework for this nursing study. First of all, Braden's model is consistent with broader nursing conceptualizations such as the McGill Model of Nursing. The McGill Model highlights

the inherent strengths and capacities of the individual to actively learn ways to successfully cope with adversities by the application of strategies such as problem solving in order to enhance health defined as the ability to function at a maximum perceived capacity and to achieve a high level of life satisfaction (Gottlieb & Rowat, 1987). In addition to its congruence with theoretical thinking in nursing, the Self-Help Model and the model variables are entirely congruent with the broader theoretical and clinical literature in the field of pain, as discussed in the review of the literature.

In addition, the intervention developed for this study (the Chronic Pain Self-Management Program) directly and indirectly targets the variables in the model. For example, discussion about self-help/self-management principles and self-responsibility may highlight aspects of perceived limitation and dependency. Discussion about the nature of chronic pain, the links with stress and depression, and general information about self-care issues such as physical activity, nutrition, and medication may influence how individuals perceive their pain problem and disability, help to decrease their feelings of uncertainty, and improve their self-care. The content of the program relating to skills development including setting appropriate and graded goals each week, group problem solving, and weekly practice of pain coping strategies such as imagery, cognitive reframing, and relaxation are included to enhance enabling skill and self-efficacy. Self-help and life satisfaction are indirectly targeted in that changes in the other variables may influence these outcomes.

Another reason for the model's applicability to a chronic pain intervention is that it provides a theoretical explanation to account for the process of change. Intervention studies with chronic pain patients have, on the whole, been outcome driven, rather than theory driven studies that test the specific mechanisms that underlie the effectiveness of particular treatments. Hence, although there is evidence to suggest that cognitive-behavioural interventions improve outcomes, the underlying process by which positive outcomes are achieved remains unclear. This may be because few outcome studies have systematically tested theoretically-linked antecedent, process, and outcome variables simultaneously. The strength of the Self-Help Model is that it links these three sets of variables together.

Finally, this model was chosen because there is a need to provide further support for middle-range nursing theory in order to better evaluate how well theoretical explanations and predictions hold up with different clinical populations, under different environmental, social and cultural circumstances (Acton, Irvin, & Hopkins, 1991).

Part V: Research Questions and Research Hypotheses

Based on the study purpose, the review of the literature, and the conceptual framework, this study answered three research questions and tested eight research hypotheses.

Research Questions

1. Does participation in the CPSMP significantly improve scores of variables that operationalize constructs in Braden's Self-Help Model including: antecedent variables (perceived severity of illness, limitation and uncertainty), mediator/process variables (enabling skills), and outcome variables (self-help and life quality) compared to wait-list controls?
2. Does participation in the CPSMP significantly improve health-related quality of life as measured by a standardized, normed, psychometrically strong instrument compared to wait-list controls?
3. Do chronic pain subjects' scores of variables that operationalize constructs in Braden's Self-Help Model support the predicted relationships in the Model?

Research Hypotheses

1. Participants in the CPSMP will achieve statistically significant improvement in variables that operationalize Braden's Self-Help Model including antecedent variables (perceived severity of illness, limitation and uncertainty), mediator/process variables (enabling skills), and outcome variables (self-help and life quality) compared to wait-list controls.
2. Participants in the CPSMP will achieve statistically significant improvement in health-related quality of life compared to wait-list controls.
3. Perceived severity of illness is significantly positively associated with two adversities related to chronic illness, limitation and uncertainty.

4. Limitation and uncertainty are significantly negatively associated with enabling skill. Enabling skill is significantly positively associated with self-help
6. Limitation and uncertainty are significantly negatively associated with self-help.
7. Self-help is significantly positively associated with life quality.
8. Limitation and uncertainty are significantly negatively associated with life quality.

CHAPTER 3

Methodology

This chapter describes the research design of the study, the study population, the recruitment of the sample, the study procedures and setting, as well as explaining the experimental intervention tested in the study. A full discussion of the measurement instruments used in the study as well as a description of the pilot testing of the complete set of instruments is provided. The ethical considerations and a description of the statistical data analysis used to answer the research questions and to test the study hypotheses are presented.

Research Design

A randomized clinical trial was used to evaluate the impact of a standardized, psychoeducation program for those with chronic non-malignant pain. Eligible subjects who consented to participate in the study were randomly allocated to one of two conditions: (a) the 6-week Chronic Pain Self-Management Program (CPSMP) intervention group, or (b) the 3-month wait-list control group. Pre-treatment measures were administered prior to randomization and post-treatment measures were collected approximately 3 months later.

For both ethical and pragmatic reasons, a wait-list control rather than a no treatment control was selected as the most appropriate comparison group for this study. Because the proposed experimental treatment had been shown to be efficacious with other patient populations including those with arthritis (Lorig & Holman, 1993), systemic lupus erythematosus (Braden et al., 1993) and breast cancer (Braden et al., 1990), withholding the psychoeducation intervention from some study subjects with chronic non-malignant pain was thought to be ethically questionable (Cook & Campbell, 1979). Also, given the paucity of accessible services for this population, it was anticipated that the recruitment of subjects for the study would be more successful if a timely service component was

offered to all potential subjects. In addition to these considerations, it was also important to utilize a comparison group that would adequately address threats to internal validity such as the effects of history, maturation, selection and testing. Because wait-listed subjects completed pretest and posttest assessments during the same time frame as those in the experimental group prior to being offered treatment themselves, major threats to internal validity were minimized.

Sampling

The Sample. The study was conducted in St. John's, Newfoundland, Canada over a 17-month period from May 1995 to September 1996. Subjects were drawn from a target population of men and women suffering from a chronic non-malignant pain problem that was idiopathic in nature. Chronic pain is defined as pain lasting longer than expected healing time (> 3-6 months) (Mersky & Bogduk, 1994). Idiopathic refers to any pain condition where there is no readily identifiable cause or pathology, such as with many soft tissue and musculoskeletal chronic pains. Eligibility criteria for inclusion in the study were:

1. 18 years of age or older.
2. Idiopathic persistent pain of longer than 3 months duration.
3. Able to speak and read English.
4. Free of major cognitive or psychiatric disorder.
5. Not currently participating in other educational, counselling or supportive interventions for their chronic pain problem.
6. Not awaiting surgery.

Because this intervention was designed to be an adjunct to current management approaches to chronic pain, subjects were not excluded if they were receiving common medical and physically-based therapies (e.g., analgesics or other medication, physio-therapy, chiropractic, acupuncture, massage, etc.).

Sample Size. Sample size was originally calculated using the following formula:

$$N = [(1/q_1 + 1/q_2)\, S^2\, (z_\alpha + z_\beta)^2] \div E^2$$

where E is the mean change score from pretest to posttest of the experimental group over the change in the control group and S is the standard deviation of the change (Hulley &

Cummings, 1988, p. 148, 215). Statistically significant change scores of pain ratings and depression in subjects ($n = 144$) who participated in a clinical trial of the Arthritis Self-Management Program (ASMP) were used as approximate indicators of the effect size that might be anticipated in this study of the CPSMP (Lorig, Chastain, et al., 1989). For a two-tailed alpha set at 0.05 and beta at 0.20 to achieve 80% power, total estimated sample size was 142 subjects based on the pain data and 172 subjects based on the depression data (see Appendix A for calculations). In addition, every attempt was made to locate data on change scores and standard deviations of several other important outcome measures proposed in this study. An extensive review of the chronic pain and related literature was conducted, however, no additional change score data were found on variables of interest.

Another approach to sample size estimation was to review studies that reported statistically significant differences between groups as a result of the same or similar interventions as the ASMP. In a randomized controlled trial of a 6-week self-help intervention for women with breast cancer, preliminary analyses indicated that the experimental group comprised of 48 women had statistically significant improvement on measures of self-help and quality of life as compared to 52 women randomized to the control group ($p \leq 0.001$) (C.J. Braden, personal communication, May 1994). These same variables also were measured in the present study.

There are a number of published reports of randomized clinical trials of cognitive-behavioural interventions for those with chronic non-malignant pain. Some of these interventions were similar in strength (12-14 hours of contact in total) and in content (emphasis on pain coping strategies, for example) to the ASMP (Philips, 1987; Spence, 1989; Turner & Clancy, 1988; Turner & Jensen, 1993). Sample sizes in these studies were small and ranged from 14 to 29 subjects per group. Not surprisingly, study results were conflicting. This was attributed to the generally low power of these studies to detect important group differences.

In light of the sample sizes reported in the ASMP clinical trial, other related studies and in chronic pain intervention trials, the estimate of 142 subjects was accepted as a reasonable number of subjects for this study. This number was further reduced to 110

subjects after a preliminary data analysis of the first 50 subjects in the study found that variation was lower than expected in several outcome variables making it possible to use a smaller sample to test for the same effect size.

Recruitment. Subjects were recruited into the study in one of three ways. First, the most recent 2-year roster (1993 - 1995) of a hospital-based "anaesthetic block" pain clinic was used to identify patients with the help of the clinic anaesthetist. In all, 116 chronic pain patients were listed, 84 of whom lived within 80 kilometres of the city. This distance was selected as the maximum commuting distance individuals were likely to travel for an intervention of this kind. Of these 84 subjects, 22 were unable to be contacted (two were deceased and 20 had moved). Nineteen were ineligible (10 no longer had a pain problem; three were currently enrolled in a educationally-based rehabilitation program; two were cognitively impaired due to head injuries; and, four were scheduled for back surgery). Twenty-one refused (five had problems with scheduling or transportation; two were unable to sit for long periods and felt unable to participate; 14 were not interested at this time). The number of study participants from this source was 22 or 51% of eligible subjects.

The second recruiting technique involved contacting health professionals who treat chronic pain patients in the community. A letter explaining the study was mailed to 50 family physicians, 11 medical/dental specialists, 11 physiotherapy clinics, 8 chiropractic clinics, 7 massage therapy clinics, 2 occupational health departments of large corporations, and 1 acupuncturist (see Appendix B for referral letter). In all, 82 referrals were obtained from the following sources: physiotherapists (n = 24), medical and dental specialists (n = 18), family physicians (n = 17), occupational health nurses (n = 10), registered massage therapists (n = 4), chiropractors (n = 4), rehabilitation specialists (n = 3), and psychologists (n = 2). Of these, all were eligible to participate in the study; 75 agreed and 7 refused. The final recruitment approach was self-referral. Fourteen people were self-referred having heard about the program by "word of mouth". Thirteen agreed to participate and one was ineligible. In summary, the final sample of 110 eligible, consenting subjects included 22 subjects referred by an anaesthetic block clinic, 75 by community-based health practitioners, and 13 were self-referred.

Procedure and Setting

Individuals identified from the roster of patients attending the anaesthesia block clinic were telephoned by one of three clinic nurses to request permission for the researcher to contact them directly; the nurses used a telephone protocol (see Appendix C for script). If individuals agreed to be contacted, the nurses provided their names and phone numbers to the investigator. Those who were referred by a community-based health professional gave permission for their name and phone number to be given to the researcher or they contacted the researcher themselves as did those who were self-referred.

Study eligibility was initially assessed by the researcher by telephone. If the individual was eligible and expressed an interest in learning more about the study, a face-to-face interview was scheduled. Interviews were held in a dedicated office space located at the general hospital that housed the anaesthesia block pain clinic. The researcher interviewed interested individuals to confirm eligibility, to obtain informed consent, and to administer the pre-treatment measures. Most individuals completed the instrument booklet in one sitting; the rest (less than 15%) returned the following day to complete the measures or took the booklet home and returned it within 48 hours. Once pre-treatment measures were completed, individuals were randomly allocated to either the treatment or the wait-list control group. Randomization was stratified on the basis of gender using opaque sealed sequentially numbered envelopes that were prepared by Dr. Gray-Donald, a member of the researcher's dissertation committee. Each opaque envelope contained the randomization designation that was generated from a random numbers table. The name of the individual and the number of the envelope were recorded prior to the envelope being opened by the subject. Those randomized to the treatment condition were invited to participate in the next available program (within 3 weeks of the initial interview). The intervention was given in a weekly 2-hour class given over 6 weeks. All classes were taught by the researcher.

Data were collected again 6 weeks post-treatment (i.e., 6 weeks after the last CPSMP session) for both the treatment and control subjects. The time between pre- and post-treatment measures for all individuals enrolled in the study ranged from 12 to 15 weeks. A research assistant who was blind to group allocation telephoned subjects to arrange for

the follow-up interviews and subsequently administered the post-treatment questionnaires in the study office at the hospital. Every effort was made to obtain post-treatment measures on all individuals enrolled in the study (e.g., three phone calls by the research assistant and a follow-up letter) (see Appendix D). Once post-testing was completed, those in the wait-list control were offered enrolment in the next available program, however they did not become treatment subjects.

The decision to collect posttest data at 3 months after the commencement of the intervention was made based on results of previous intervention studies. Clinical trials of the ASMP consistently used a 3-month or 4-month assessment as the first posttest measure and found statistically significant improvement in both process and outcome variables (Lorig & Gonzalez, 1992; Lorig, Chastain, et al., 1989; Lorig et al., 1985; Lorig et al., 1993). Braden, in her set of studies which examined self-management programs with other chronic illness populations (systemic lupus erythematosus and breast cancer patients) utilized two posttest measurement times: immediately after the intervention and two or three months later (Braden, 1991b, 1992; Braden et al., 1990; Braden et al., 1993). In all studies, significant improvement found at the immediate posttest tended to remain significant at the two-month assessment. For some variables, such as enabling skill and self-help, significant change was evident only at the second posttest indicating that consolidation of skills took place over time. Given these data, posttest measures collected at 3 months were thought likely to reflect immediate changes that have endured over time as well as those that have occurred as a result of consolidating the skills learned in the program.

Description of the Experimental Intervention

The Chronic Pain Self-Management Program (CPSMP) is a standardized, psychoeducation program (2 hours per week for 6 weeks) developed for group presentation in community settings. The course is designed to maximize discussion and group problem-solving, encourage individual participation and experimentation with various cognitive/behavioural self-management techniques, and facilitate mutual support. Consequently, didactic presentation is kept to a minimum and the process components are emphasized. The content of the program, although similar to the ASMP as described

previously in Chapter 2, Part III, was adapted with permission of the program developer, to be more directly applicable to those with various idiopathic chronic pain conditions (see Appendix E for letter of permission from Dr. K. Lorig). The 1992 version of the ASMP Leader's Manual (Lorig, 1992) was used as the prototype program and changes were made to include the following content areas: (a) common myths about chronic pain (b) what is chronic pain? (c) a safe flexibility exercise routine entitled the ROM Dance (Harlowe & Yu, 1992) (d) approaches to communicating with your doctor and family about pain, and (e) commonly prescribed medications for chronic pain. Correspondingly, content that was more applicable to arthritis was left out of the CPSMP (e.g., joint protection, osteoporosis, etc.). Content areas were validated by six local health professionals who work with chronic pain patients. (See Table 1 for the CPSMP course overview). As strongly suggested by Lorig, the instructional methods or process components of the ASMP which are thought to enhance self-efficacy were retained in the CPSMP as originally developed.

Because the ASMP includes a detailed workbook (Lorig & Fries, 1990, 1995) and encourages individuals to use relaxation tapes, program materials were developed for the CPSMP and given to each participant at the first program session. These materials included:

1. A copy of a 150-page Chronic Pain Self-Management Program Workbook which was developed by the researcher for the CPSMP (see Appendix F for table of contents and acknowledgements).
2. A relaxation audio tape developed for the CPSMP that included a variety of relaxation techniques including progressive muscle relaxation, guided imagery, visualization, and autogenic relaxation. The text for the various types of relaxation were modified from the ASMP.
3. A variety of current pamphlets on chronic pain, nutrition and walking (International Pain Foundation, 1991; Health and Welfare Canada, 1992, 1993; Health Canada, 1993).
4. A carrier bag for easy portability and storage of the program materials.

Table 1

Chronic Pain Self-Management Program Course Overview*

Topic	Session					
	1	2	3	4	5	6
Self-help principles	✔					
Myths about chronic pain	✔					
What is chronic pain?	✔					
Balancing rest/activity	✔			✔		
Exercise for health		✔	✔	✔	✔	✔
Pain management strategies (cognitive & behavioral)		✔	✔	✔	✔	✔
Depression			✔			
Nutrition				✔		
Evaluating non-traditional treatments					✔	
Communication skills					✔	
Medications						✔
Fatigue						✔
Problem-solving	✔	✔	✔	✔	✔	✔
Contracting/feedback	✔	✔	✔	✔	✔	✔

*Adapted with permission from: Lorig, K. (1992). Arthritis Self Help Course. Leader's manual and reference materials. Atlanta, Georgia: Arthritis Foundation.

The intervention was delivered by the researcher who participated in a 3-day intensive training workshop for ASMP course leaders given by certified ASMP trainers (see Appendix G for verification of attendance). The researcher also attended one 6-week ASMP program to become familiar with all aspects of the course. In all, 11 CPSMP programs with 6 to 10 participants per group were taught by the researcher using the detailed treatment protocol that specified content and process to ensure consistency across every session of all programs. The intervention was delivered in the same location each time, a comfortable room in a building adjacent to a general hospital.

Measurement Instruments

The variables measured in this study were guided by Braden's (1990b, 1993b) Self-Help Model of Learned Response to Chronic Illness Experience. The model includes antecedent variables (severity of illness, limitation, uncertainty), process or mediating variables (enabling skill), and outcome variables (self-help and life quality). They were operationalized with a variety of instruments selected from the nursing, chronic pain, and medical literatures. These instruments were selected to measure the variables targeted for change either as a direct or indirect result of the intervention. In addition to these theory-guided measures, a standardized, norm-referenced multi-scale instrument of health-related quality of life (HRQOL) was also used to further assess outcomes of this psychoeducation intervention for those with chronic pain. The scales of the HRQOL instrument are consistent with the Self-Help Model and approximate to some extent the 'perceived severity of illness', 'limitation' and the 'self-help' constructs in the model.

Information on sociodemographic variables and pain-related background characteristics were obtained by a self-report 16-item instrument, titled the General Information Questionnaire, developed by the researcher (see Appendix H). Specifically, subjects were asked about: (a) sociodemographic characteristics such as age, gender, marital status, household members, education, occupation, employment status, and whether they were receiving worker's compensation or other benefits; (b) aspects of the chronic pain problem including body areas affected, length of time of pain, perceived cause of pain, current medication for pain, whether subjects have had surgery for their

pain, and whether they have seen other health professionals in the past month; (c) other ongoing medical conditions in addition to the pain problem.

Antecedent Variables

Perceived Severity of Illness

Perceived severity of illness is defined as the perceived level of affliction as a result of a chronic health problem (Braden, 1993b). Because no single measure of this construct was found in the pain literature, a combination of three variables were thought to best reflect this dimension: (a) pain ratings (b) depression, and (c) a global indicator of perceived severity of the pain problem. Because subjects in this study had a chronic pain problem, a measure of perceived severity of pain was used. In addition, because a positive relationship between pain and negative mood/depression has been a frequent finding in chronic pain studies, depression was thought to reflect an aspect of "perceived affliction" that may be linked to the chronic pain experience (Magni et al., 1990). Finally, a judgment of the perceived severity of the 'pain problem as a whole' allowed individuals to take personally salient features of their situation into account, features that may not have been captured in the pain rating or depression measures.

Pain: Pain ratings that measure aspects of the multi-dimensional qualities of the pain experience such as sensory, affective, and evaluative dimensions combined with intensity ratings are thought to be a better index of the overall pain experience than a numerical pain intensity rating alone (Melzack & Katz, 1994). Therefore, in this study, perceived severity of pain was measured using the Pain Rating Index (PRI) of the short form of the McGill Pain Questionnaire (SF-MPQ) (Melzack, 1987). It lists 15 word descriptors (11 sensory and 4 affective) most frequently endorsed by patients with a variety of acute, intermittent and chronic pains. Each descriptor is rated on an intensity scale as 0 = none, 1 = mild, 2 = moderate and 3 = severe. A final score, which ranges from 0 to 45, is obtained by summing the ratings (see Appendix I).

The standard or long form of the MPQ (Melzack, 1975) has well-established reliability and validity and remains the most widely used measure of self-reported pain in the literature (Melzack & Katz, 1994; Wilke, Savedra, Holzemier, Tesler, & Paul, 1990).

However, the short form has been used in an increasing number of studies of patients with pain of diverse etiology including chronic low back pain (Gronblad, Lukinmaa, & Konttinen, 1990; Serrao, Marks, Morley, & Goodchild, 1992), mixed chronic pains (Guieu, Tardy-Gervet, & Roll, 1991; Swanston et al., 1993), osteoarthritis (Stelian, Gil, Habot, & Rosenthal, 1992), and chronic cancer pain (Dudgeon, Raubertas, & Rosenthal, 1993). The PRI of the SF-MPQ has been reported to correlate in the high range with the long form (r = 0.70 to 0.93) (Dudgeon et al., 1993; Melzack, 1987) and has also demonstrated sensitivity to change comparable to the long form as a result of interventions and therapies (Melzack & Katz, 1994). In addition, concurrent validity of the SF-MPQ was reported by Dudgeon and colleagues (1993) in a study of patients with chronic cancer pain. On each of three occasions separated by at least 3 weeks, the pain rating indices correlated highly with scores on the long form. Furthermore, initial data suggest that the SF-MPQ may be capable of discriminating among different pain syndromes which is an important property of the long form (Melzack, 1987).

The SF-MPQ was used in this study for two major reasons: ease of self-administration and brevity (i.e., takes less than 5 minutes to complete). Because the short form is being used with greater frequency in intervention studies, it was thought to be appropriate for this study of chronic pain patients. Permission to use the tool was obtained from the tool developer (see Appendix J). Internal consistency reliability for this study sample of 110 subjects using pretest scores was $\alpha = 0.79$.

Depression. Depression was measured using the short form of the Beck Depression Inventory (SF-BDI) (Beck & Beck, 1972). The short version, developed from the original 21 items (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961), assesses 13 symptoms and attitudes: sadness, pessimism, sense of failure, dissatisfaction, guilt, self-dislike, self-harm, social withdrawal, indecisiveness, self-image change, work difficulty, fatigue, and anorexia. Items are scored from 0 to 3 in terms of intensity and the total score is derived by summing the items. Scores range from 0 to 39 with a score of 8 or above indicative of clinical depression (Turner & Romano, 1984). Higher scores indicate higher levels of depression. The SF-BDI takes less than five minutes to complete (see Appendix K).

Considerable evidence for the reliability and validity of the standard BDI and the SF-BDI is presented by Beck, Steer and Garbin (1988) in their comprehensive 25-year meta-analytic review of the inventory. Correlations between the short form and the long form have been consistently high ranging from $\underline{r} = 0.89$ to 0.97 in studies of both clinical and non-clinical populations. Internal consistency reliability for the SF-BDI has also been high with Cronbach's coefficient alpha ranging between $\alpha = 0.78$ to 0.90. Stability estimates have been reported for the long form BDI only. Test-retest reliability for nonpsychiatric subjects have ranged from $\underline{r} = 0.62$ to 0.90 with time periods between testing ranging from hours to 4 months. In addition, content, concurrent and construct validity as well as diagnostic sensitivity and specificity has been reported for the SF-BDI (Beck & Beck, 1972; Beck et al., 1961; Foelker, Shewchuk, & Niederehe, 1987; Leahy, 1992; Scogin, Beutler, & Corbishley, 1988). Beck, Steer and Garbin (1988) have suggested that the short form is a satisfactory substitute for the long form of the inventory in research studies when brevity is an important consideration.

In studies of the chronic pain population, Turner and Romano (1984) found good evidence for the concurrent validity of the SF-BDI. In a sample of 40 chronic pain inpatients and outpatients, the SF-BDI was highly correlated with: (a) the LF-BDI ($\underline{r} = 0.86$); (b) the Zung Depression Inventory ($\underline{r} = 0.85$), and (c) with the DSM-III clinical interview ($\underline{r} = 0.73$). In addition, the short form demonstrated 83% sensitivity (i.e., ability to identify truly depressed patients) and 89% specificity (i.e., ability to identify non-depressed patients) when the cut-off for depression was a score of 8. The short form was able to correctly classify 88% of patients using the DSM-III clinical interview as the "gold standard". Permission to use the SF-BDI in this study was obtained from the publisher (see Appendix L). Internal consistency reliability for this study sample was $\alpha = 0.80$.

Perceived severity of the pain problem. A global judgment of the perceived severity of the pain problem was assessed by a 100 mm visual analogue scale (VAS) that asks: "How severe a problem is chronic pain in your life?" with anchors "0- Not problem at all" and "100 - Major incapacitating problem" (see Appendix M). This single-item indicator was used by Phillips (1987) in a study of 40 chronic pain patients receiving a 9-

week cognitive-behavioural intervention. Study results indicated that perceived severity of the pain problem decreased significantly from pre- to post-treatment and continued to decrease at two-month and 12-month follow-up. At post-treatment follow-up, perceived severity of the pain problem was significantly negatively correlated to perceived control of the pain problem or self-efficacy ($r = -0.70$). This was in marked contrast to the lack of any association between self-efficacy and perceived problem severity pre-treatment. In addition, problem severity was significantly positively correlated to measures of pain ($r = 0.66$) and pain behaviour ($r = 0.77$). Similar or higher correlations were reported for the 12-month follow-up. Because these correlations are consistent with theoretical expectations, they represent initial criterion and construct validity testing as well as lower bound reliability of this single-item indicator (Youngblut & Casper, 1993).

Limitation

The construct "limitation" is depicted as an adversity of the chronic illness experience and is defined as the perceived inability to do things for one's self (Braden, 1991b). It has been operationalized as perceived disability and as perceived dependency on others.

Disability. Disability was measured using the disability subscale of the Survey of Pain Attitudes (D-SOPA). It contains 10 items that assess the degree to which individuals believe themselves to be disabled by pain and hence limited in their ability to do things in life (Jensen & Karoly, 1989; Jensen, Karoly, & Huger, 1987). Respondents are asked to indicate their agreement with each item on a 5-point Likert scale and a total score is calculated by summing the ratings and dividing by 10. The final score ranges from 0 to 4 with higher scores indicating higher levels of perceived disability (see Appendix N). A number of studies have found that the belief that one is disabled by pain is significantly associated with both psychosocial and, in some cases, physical dysfunction (Jensen & Karoly, 1991, 1992; Jensen, Turner, Romano, & Lawler, 1994; Strong, Ashton, Cramond, & Chant, 1990).

The seven subscales in the SOPA can be used separately and norms for each subscale are reported on two samples of patients with mixed chronic pain problems who attended a large multi-disciplinary pain centre ($n = 335$) (M. Jensen, personal communication, April

1994). Jensen reported that the internal consistency reliability for the D-SOPA was 0.81. Two-week test-retest stability was high ($r = 0.80$) but long-term test-retest coefficient was lower ($r = 0.63$). In addition, when SOPA scores taken before treatment with a cognitive-behavioural program were compared to scores taken immediately post-treatment, correlations were low ($r = 0.29$ to $r = 0.59$). The tool developers suggest that these low correlations reflect the process of attitude change brought on by the treatment program. All scales have shown criterion validity (Jensen & Karoly, 1989; Jensen et al., 1987). In addition, the tool has been tested in a population of 100 chronic low back pain patients in Australia (Strong, Ashton, & Chant, 1992). Findings from this study provide additional support for the psychometric properties of the SOPA. Permission to use the SOPA in this study was obtained from one of the tool developers (see Appendix O). Internal consistency reliability of the D-SOPA in the present study was $\alpha = 0.87$.

Dependency. A global judgment of the individual's perception of dependency or reliance on others was measured with a 100 mm VAS that asked: "As a result of your chronic pain, how much do you depend or rely on others in your daily life?" with anchors "0 - Not at all dependent on others" and "100 - Extremely dependent on others" (see Appendix M). Because no appropriate instrument could be found in the literature to assess perceived dependency in patients with mixed idiopathic chronic pain, this single item indicator was developed for this study based on the work of Phillips (1987) and others (Wewers & Lowe, 1990; Youngblut & Casper, 1993). Youngblut and Casper (1993) suggest that single-item indicators that ask respondents for a global rating of a specific concept are congruent with nursing's emphasis on holism. Such indicators allow individuals to take their unique experience into account and therefore may improve responsiveness of the item to individual change over time.

Psychometric properties of this single-item measure were assessed by investigating the correlations between dependency scores and three other measures for the 110 subjects in this present investigation. At pretest, the VAS dependency measure was moderately positively correlated ($r = 0.51$) with the 10-item disability scale (D-SOPA) and negatively correlated with both the 45-item measure of self-help (IARB) ($r = -0.45$) and the 16-item life satisfaction instrument (SLDS) ($r = -0.43$) as would be predicted with a measure of

perceived dependency. This preliminary analysis represents initial criterion and construct validity and lower bound reliability.

Uncertainty

Another adversity of the chronic illness experience is uncertainty defined as the inability to determine the meaning of illness-related events. This was measured with a single instrument of uncertainty in illness.

Uncertainty in Illness. Uncertainty was measured by the 23-item version of the Mishel Uncertainty in Illness Scale - Community Form (MUIS-C). The original MUIS assesses the degree of uncertainty in ill, hospitalized patients (Mishel, 1981) while the shorter community form assesses uncertainty in persons who are not hospitalized and not receiving ongoing medical intervention for their chronic problem (Mishel, 1991). The tool has a Likert-type response format ranging from (1) strongly disagree to (5) strongly agree. The MUIS-C consists of 23 items which are summed to obtain a total score ranging from 23 to 115 units with 115 reflecting the highest uncertainty (see Appendix P).

Mishel (1991) reports that the MUIS-C has been used extensively in samples of subjects with various kinds of chronic illness including cancer, heart disease, irritable bowel disease, epilepsy, lupus erythematosus, multiple sclerosis, chronic fatigue syndrome, the human immunodeficiency virus, kidney disease, and arthritis. The original MUIS has also been used with chronic illness populations including those with chronic low back pain. Internal consistency reliabilities for the MUIS-C are in the moderate to high range ($r = 0.75$ to $r = 0.90$) (Mishel, 1991). Test-retest reliabilities are not reported. Evidence supporting the construct validity of the scale has been demonstrated by the scale's performance consistent with theoretical predictions (Mishel, 1983, 1984, 1991; Mishel & Braden, 1987, 1988; Mishel, Padilla, Grant, & Sorenson, 1991). Permission to use the MUIS-C in this study was obtained from the tool developer (see Appendix Q). Internal consistency reliability of the MUIS-C in this present investigation was $\alpha = 0.83$.

Mediating Variables

Enabling skill is defined by Braden (1990b) as one's perceived ability to manage day-

to-day adversities of illness. In this study, enabling skill was operationalized using measures of self-efficacy and resourcefulness.

Self-efficacy: Self-efficacy was measured using a modified version of the Self-Efficacy Scale (SES) originally developed by Lorig and colleagues (1989) for use in their studies evaluating the Arthritis Self-Management Program (ASMP). The SES assesses patients' perceived self-efficacy to cope with the consequences of chronic arthritis – namely, pain, other associated symptoms, and aspects of functioning. For purposes of this study, only items from the "pain" and "other symptom" subscales were used because these items reflect consequences common to all chronic pain conditions. By contrast, items from the "function" subscale were specific to those with arthritis and consequently were not included in this version. The only other adaptation made to the scale was to replace "arthritis" with "chronic pain". Permission to adapt the original instrument was obtained from the tool developer (see Appendix E). Subjects respond to each of the 11-items on a 10-point numerical graphic rating scale (10 to 100) that indicates the certainty with which a person feels he/she can accomplish a specific task related to pain and symptom control. Higher scores reflect higher self-efficacy. A total score was obtained by summing all items and dividing by the number of completed items (see Appendix R).

The development of the SES was conducted on an original sample of 97 individuals with arthritis and replicated with a sample of 144 individuals who were enrolled in the ASMP. Internal consistency reliabilities were $\alpha = 0.75$ and $\alpha = 0.76$ for the five pain-related items and $\alpha = 0.87$ for the six items related to other symptoms for the two samples. Item-total correlations ranged from $r = 0.48$ to $r = 0.79$. Nine-day test-retest reliability ($n = 91$) ranged from $r = 0.87$ to $r = 0.89$. Construct validity of the scales was assessed by factor analytic techniques and by its' expected performance based on self-efficacy theory (Lorig et al., 1989). Self-efficacy theory predicts that present self-efficacy will be related to both present and future health status. Using baseline and 4-month scores from the two samples, construct validity of the instrument was supported by the finding of significant correlations between baseline self-efficacy and present health status, between baseline self-efficacy and 4-month health status, and between 4-month self-efficacy and 4-month health status. In addition, self-efficacy scores improved for those

enrolled in the ASMP as would be expected. In this present investigation, internal consistency reliability for the combined 11-item SES measure was $\alpha = 0.90$.

Resourcefulness. Resourcefulness was measured using Rosenbaum's (1980) Self Control Schedule (SCS) which assesses individual tendencies to apply a repertoire of complex cognitive and behavioural skills when dealing with stressful circumstances. The 36-item SCS covers the following content areas: (a) use of cognitions and self-instructions to cope with emotional and physiological responses; (b) application of problem-solving strategies (eg., planning, problem definition, evaluating alternatives, and anticipation of consequences); (c) ability to delay immediate gratification; and, (d) a general belief in one's ability to self-regulate internal events. This set of skills is what Rosenbaum (1990a) has termed learned resourcefulness.

Strong evidence of the psychometric adequacy of the tool can be found in a number of publications (Redden, Tucker, & Young, 1983; Richards, 1985; Rosenbaum, 1980, 1988). Four week test-retest reliabilities for over 600 patients is reported to be $\underline{r} = 0.96$ (Rosenbaum, 1980; Rosenbaum & Palmon, 1984) indicating that it is a stable construct. Internal consistency alpha coefficients have ranged from 0.78 to 0.86 on 7 independent samples (Rosenbaum, 1980; Rosenbaum & Palmon, 1984). Evidence also supports the construct validity of the SCS (Clanton, Rude, & Taylor, 1992; Richards, 1985; Rosenbaum, 1990b; Weisenberg, Wolf, Mittwoch, & Mikulincer, 1990). Rosenbaum (1990b) reports that convergent validity is supported by the low but significant correlations of the SCS with other conceptually-related scales including Rotter's Internal-External Locus of Control Scale, Jones' Irrational Beliefs Test, Fitz's Self-Esteem Scale, Bachman and O'Malley's Self-Esteem Inventory, and Barron's Ego Strength Scale. Rosenbaum (1990b) also found that SCS scores were not related to measures of Type A behaviour. Further supporting the SCS's discriminant validity, Lewinson and Alexander (1990) found that SCS scores were not associated with emotional dependency ratings, rate of occurrence of stressful life events, the frequency of contact with others, or perceived availability of help.

A further assessment of construct validity is provided by theoretical predictions of the SCS and measures of stress and coping. Gintner, West and Zarski (1989) compared

responses on the SCS with those of Folkman and Lazarus' Ways of Coping Scale. Those high in resourcefulness reported using more problem-focussed coping strategies in preparation for an exam than did those who were scored low on the SCS. The low SCS group tended to use more emotion-focussed strategies and to report higher levels of stress symptomatology. In addition, the SCS has been reported not to correlate with the Crowne-Marlow Social Desirability Scale.

The SCS has been used in several laboratory studies of pain (Barrios, 1985; Rosenbaum, 1980; Weisenberg et al., 1990) as well as with samples of chronic pain patients (Krasner, 1990), chronic headache (Rosenbaum, 1990b) and various other chronic illness problems (Aikens, Wallander, Bell, & Cole, 1992; Derry, Chovaz, McLachlan, & Cummings, 1993; Rosenbaum & Palmon, 1984; Rosenbaum & Smira Ben-Ari, 1986). Although most often conceptualized as an enduring personality attribute, learned resourcefulness (as measured by the SCS) has been shown to change over time as a result of cognitive-behavioural interventions with those who have arthritis (Braden, 1990a, 1990b). In these studies, the original 6-point Likert scale format was revised, on the basis of pilot testing, to a 100 mm VAS scale format for each item. Internal consistency reliability was in the high range ($\alpha = 0.86$ to $\alpha = 0.87$) for the VAS format. In addition, the revised SCS continued to perform consistent with theoretical predictions suggesting construct validity of the revised scale. More recently, the VAS version was used in a study of HIV patients with a reported Cronbach's alpha of 0.88 (Grimes & Cole, 1996). In this present investigation, the 100 mm VAS version of the SCS was used (see Appendix S) and internal consistency reliability was $\alpha = 0.84$. A total score was obtained by summing the items and dividing by the number of completed items; higher scores indicate greater resourcefulness. Permission to use the SCS was obtained from the copyright holder (see Appendix T).

Outcome Variables

Braden conceptualizes two important outcomes of the chronic illness experience: (a) the continued involvement in valued life roles which is termed "self-help", and (b) maintenance of life quality. In this study, these were operationalized as self-help and life

satisfaction.

Self-help. Self-help was measured with the 45-item Inventory of Adult Role Behaviours (IARB) (Braden, 1990b). The IARB includes items adapted from Given's (1984) Effect Scale and items developed by Braden (1986) to measure the extent individuals are instrumentally involved in valued family, leisure/recreational, social, work and self-care roles which includes using resources to stay healthy, paying attention to how one's body feels, attempting to eat well and exercise appropriately, etc. The IARB uses 100 mm visual analogue scaling for each item and a total raw score is achieved by summing all items (see Appendix U). In this study, the mean (total score divided by the number of completed items) was used as the total score. Higher scores indicate more involvement in self-help activities.

Given's (1984) 28-item Effect Scale was originally developed to measure the response of ambulatory chronically ill patients to nursing interventions designed to improve patient's care of themselves. The instrument consisted of psychosocial and work performance scales which were developed and tested on a sample of 499 individuals with either hypertension or diabetes. Internal consistency reliabilities ranged from $\alpha = 0.84$ to 0.92. Content and construct validity has been reported by Given (1984).

Braden's expanded IARB instrument has been used in a series of studies of patients with arthritis ($n = 396$) (Braden, 1990b), systemic lupus erythematosus ($n = 291$) (Braden, 1991b) and breast cancer ($n = 307$) (Longman et al.,1996). Internal consistency reliabilities are high across these different chronic illness samples with Cronbach's alphas ranging from 0.92 to 0.94. Criterion-related validity and construct validity has been supported through significant correlation across different data sets and predictive modelling (Braden,1990a, 1990b, 1991b). In addition, the measure appears to be responsive to a variety of nursing interventions (Braden, 1991b; Braden et al., 1990; Longman et al., 1996). In the present investigation, internal consistency reliability was $\alpha = 0.93$. Permission to use the instrument for this study was obtained from the tool developer (see Appendix V).

Life quality. The Satisfaction with Life Domains Scale (Baker, Curbow, & Wingard, 1992; Baker & Intagliata, 1982) measures satisfaction with aspects of life considered to

be important to most individuals. Based on the work of Flanagan (1978), the life domains include: work, leisure, relations with family members, relations with friends, and aspects of self-fulfilment including health. The SLDS was developed to assess satisfaction with these particular life domains, rather than to assess psychological well being which constitutes the other major approach to life quality assessment.

The scale uses the response format of three smiling, one neutral, and three frowning faces developed by Andrews and Withey (1976). Subjects are asked to select the face that best represents their degree of satisfaction with each area of life by choosing one of the seven faces, which range from a "delighted face" with a large upturned smile (scored 7) to a "terrible face" with a deep frown (scored 1). A total score is obtained by summing all items; higher scores indicate greater satisfaction (see Appendix W).

Two versions of the SLDS have been developed, a 15-item version for those with chronic mental illness who live in the community (Baker & Intagliata, 1982), and a 17-item version for long-term survivors of cancer (Baker, Curbow, et al., 1992). The initial version was piloted with a sample of 118 mentally ill adults and then used in a larger study of 729 clients (Baker & Intagliata, 1982; Baker, Jodrey, & Intagliata, 1992). Internal consistency reliability was 0.84, with a mean item-total correlation of 0.47. The second version was developed with a sample of 109 long-term survivors of cancer who had undergone bone marrow transplant (Baker, Curbow, et al., 1991, 1992). A Cronbach's alpha of 0.93 is reported for this sample. Evidence of the concurrent validity of both versions is provided by statistically significant correlations with other more general measures of perceived quality of life, specifically Cantril's Self-Anchoring Ladder of Life and Bradburn's Affect Balance Scale (Baker, Curbow, et al., 1992; Baker, Jodrey, et al., 1992). In addition, construct validity has been supported by the scale's performance consistent with theoretical predictions regarding social support in the samples of mentally ill adults (Baker, Jodrey, et al., 1992) and role retention in cancer survivors (Baker, Curbow, et al., 1991, 1992). The authors of the SLDS provide evidence suggesting that both versions of the scale may be more sensitive to change over time than other more general measures of life quality.

The SLDS was chosen as the measure of life quality in this study because it is one of

the few multi-item instruments that does not include direct assessment of affective states. but rather asks for cognitive judgments about satisfaction with particular life domains. Since measurement of affective state is included as part of the construct "severity of illness", it was thought to be inappropriate to include it as an outcome measure. Although the scale was not developed for a chronic pain population, the items appear generic to many chronic illnesses. A 16-item version, based on the 17-item version for a cancer population, was adapted for use in this study. One item relating to satisfaction with eating was dropped and the second item which asked "How satisfied are you with your bone marrow transplant?" was changed to: "How satisfied are you with your chronic pain problem?" Internal consistency reliability with this present sample of 110 chronic pain patients was $\alpha = 0.94$. Permission was obtained to adapt the tool for this study (personal communication, F. Baker, May 1994). (Also see Appendix X).

Health-Related Quality of Life

In addition to the individual measures which operationalize specific constructs of the Self-Help Model, the Medical Outcomes Study Short-Form 36 (MOS SF - 36), a standardized, psychometrically strong instrument that measures health-related quality of life, was also used in this study. This was done for three reasons. First, it provided an additional test of the impact of a psychoeducational intervention for those with chronic pain independent of the specific relationships predicted in the Self-Help Model. Secondly, although the MOS SF-36 has been used in evaluations of many surgical and pharmacological interventions, it has been used infrequently in evaluations of other types of interventions. Thus, the use of the SF-36 was a test of its responsiveness to an educationally-based nursing intervention. Finally, the instrument was brief and easy to administer.

MOS SF-36. The SF-36 is a generic multi-scale instrument that assesses eight health concepts: limitation in physical activities because of physical health problems (PF – 10 items); limitations in social activities because of physical or emotional problems (SF – 2 items); limitations in usual role activities because of physical health (RP – 4 items); limitations in usual role activities because of emotional problems (RE – 3 items); bodily

pain index which combines a 6-point intensity scale with a rating of perceived interference with normal work (BP – 2 items); general mental health which includes four major dimensions: anxiety, depression, loss of behavioural or emotional control, and psychological well being (MH – 5 items); vitality including both energy and fatigue (VT – 4 items); and, general health perceptions which asks about current health, health outlook and resistance to illness (GH – 5 items). There is also a single-item measure of perceived change in health status over the past month (see Appendix Y).

The MOS SF-36 was constructed as a brief, comprehensive and psychometrically sound measure of health-related quality of life that is sensitive to change over time for use in clinical practice and research, health policy evaluations and general population surveys (Ware & Sherbourne, 1992). A Likert-type method of summated ratings is used to attain scale scores which are then transformed to a 0 to 100 scale using algorithms tested with 24 diverse clinical populations (McHorney, Ware, Lu, & Sherbourne, 1994). All items and scales are scored so that a higher score indicates a better health state. A manual by the Medical Outcomes Trust (Ware, Snow, Kosinski, & Gandek, 1993) that provides detailed information about scoring procedures was used in this study.

Substantial evidence for the reliability and validity of the MOS SF-36 has been published. Reliabilities for all scales are reported to be high (McHorney et al.,1994; McHorney, Ware, Rogers, Raczek, & Rachel, 1992; Stewart, Hays, & Ware, 1988). For example, a study of mixed patient populations ($\underline{n} = 969$) reports reliability estimates of between 0.78 to 0.93 for all scales (McHorney et al., 1992). Considerable support for the construct, convergent and discriminant validity of the scales is also reported in the literature (McHorney et al., 1994; McHorney, Ware, & Raczek, 1993; McHorney et al., 1992; Stewart et al., 1988; Ware & Sherbourne, 1992). The tool developers state that the SF-36 has been used in 260 clinical trials (primarily drug trials and surgical outcome studies) and is becoming widely used internationally. In addition, norms for SF-36 scale scores for male and female adults in six age groups have been estimated from a representative U.S. survey. Permission to use the SF-36 was obtained from the copyright holder (see Appendix Z). Internal consistency reliabilities (using Cronbach's alpha) for the scales in this instrument using data from the 110 subjects in this present study are: PF

(0.88); SF (0.85); RP (0.91); RE (0.85); BP (0.84); MH (0.82); VT (0.85); GH (0.81).

Summary of Instruments

Table 2 summarizes the Self-Help Model constructs, the instruments used to operationalize these constructs, as well as the additional HRQOL measure used in this study. The internal consistency reliability (Cronbach's alpha) of each instrument using the pretest scores of the 110 subjects in this study is also reported.

Pilot Testing of Instruments

Pilot testing of the entire battery of instruments was conducted in November 1994. After receiving ethical approval to pilot test the instruments from McGill University School of Nursing (see Appendix AA), subjects were recruited from two physiotherapy practices and from a chronic pain fitness program. The physiotherapists and fitness instructor gave individuals with chronic pain a copy of a letter that explained the purpose of the pilot (see Appendix BB). Those who were interested in participating allowed their names and phone numbers to be given to the investigator.

The questionnaires were piloted with 7 women and 5 men with idiopathic chronic non-malignant pain. Subjects ranged in age from 35 years to 69 years. Instrument piloting was done to evaluate subjects' comprehension of test items, and to assess subject burden in relation to completing the instruments. The instruments took an average of 48 minutes to complete with a range of 27 minutes to 71 minutes. When asked to provide feedback about the questionnaires, no one stated that the time was too long or overly burdensome, nor did individuals find any of the questions upsetting. Some instructions and formatting of instruments were modified to improve comprehension on the basis of subject feedback.

Table 2
Theoretical Constructs, Measurement Instruments, and Internal Consistency Reliability of Each Instrument Using Pretest Data of 110 Subjects

Model Constructs	Measurement Instrument	Cronbach's α
Perceived Severity of Illness: perception of affliction due to the chronic condition	McGill Pain Questionnaire: SF-MPQ Beck Depression Inventory: SF-BDI Pain Problem Severity Indicator: PPSI	0.79 0.80 n/a
Limitation: perceived restrictions on life and reliance on others	Disability Subscale - Survey of Pain Attitudes: D-SOPA Perceived Level of Dependency: PLD	0.87 n/a
Uncertainty: the inability to determine the meaning of illness- related events	Mishel Uncertainty in Illness Scale Community Form: MUIS-C	0.83
Enabling Skill : the perceived ability to manage day-to-day adversities of a chronic condition	Self Control Schedule: SCS Self-Efficacy Scale: SES	0.84 0.90
Self-help: perceived involvement in valued adult roles	Index of Adult Role Behaviours: IARB	0.93
Life Quality: perceived degree of life satisfaction	Satisfaction with Life Domains Scale: SLDS	0.94
Health-related Quality of Life: additional measure of health-related quality of life	Medical Outcomes Study Short Form 36 MOS SF-36. (8 subscales).	0.81 - 0.91.

Ethical Issues

To protect the rights of eligible subjects for this study, a number of measures were taken including: (a) using an intermediate approach to gain initial permission to interview potential subjects about the nature of the study; (b) using informed consent; (c) ensuring confidentiality; and, (d) proceeding through formal ethical review processes.

The intermediary approach for the initial contact for subject recruitment was previously described in the Procedures section of this chapter. Using this approach provided information about the study to potential subjects who were then free to decide whether they wished to learn more about the study or not. The subsequent telephone contact with the researcher made clear that their decision about participating in the study would not in any way influence any subsequent health care they received.

To protect the rights of subjects, an informed consent was obtained prior to the collection of any data (see Appendix CC). Subjects were given a full verbal and written explanation of the study. The study was presented as one designed to help those with chronic pain learn more about how to cope with their problem on a day-to-day basis. Subjects were told that they would be invited to participate in a 6-week program that involved group meetings of 2 hours in length. However, some subjects would have to wait longer than others for the program, but the wait would be no longer than 3 months. Thus all subjects enrolled in the study were given the opportunity to receive the intervention in a timely fashion. As previously mentioned, the use of a wait-list control rather than a no treatment control was based on ethical considerations as well as pragmatic issues.

Potential subjects were assured that their participation was voluntary, that there were no known hazards to participating in the study, that they could withdraw from the study at any time, and that their questions would be answered. The only costs to the subject related to commuting to the location of group meetings and their time involved in attending the sessions and in data collection. All information was treated with anonymity and confidentiality. All data were kept confidential through use of a subject number and all raw data were stored in a locked file located in the researcher's office. Raw data will be shredded once the data have been entered on computer tape and stored.

There were no known risks to subjects from participation in this psychoeducation intervention. The CPSMP protocol is adapted from the Arthritis Self-Management Program which has been standardized and tested on thousands of individuals.The intervention has subsequently been adapted for other chronic illness populations. There have been no reports of untoward effects after 12 years of program development and testing (Lorig & Holman, 1993). The potential benefits to subjects with chronic pain were thought to include improved ability to manage their pain problem and thus to enhance their ability to engage in life activities.

The study protocol was presented for ethical approval to three ethical review committees: the Ethical Review Committee of the School of Nursing, McGill University (see Appendix DD); the Human Subjects Review Committee of Memorial University of Newfoundland (see Appendix EE); and to the Ethical Review Committee of the Salvation Army Grace General Hospital in St. John's, Newfoundland (see Appendix FF).

Data Analysis

The data analysis consisted of procedures to 1) describe the characteristics of the sample and assess the comparability of the treatment and control groups at pretest, 2) describe study attrition and confirm comparability of groups with subjects who completed the study, 3) assess reliability of the dependent measures with the study sample, 4) assess the effects of the treatment program, and 5) test the hypothesized pathways in Braden's Self-Help Model.

First, data were screened to detect missing data and possible outliers prior to running all analyses. Specifics of this procedure are explained in Chapter 4. Reliability assessment of instruments using Cronbach's alpha was presented in the instrumentation section of this chapter. Background demographic and pain-related characteristics of subjects randomized to the treatment and control groups were described and compared using chi-square analysis for categorical data and independent groups t-tests for continuous level data. Between-groups comparisons of the dependent variable scores at pretest were done to further assess the comparability of groups at baseline. Similar comparisons of these variables were conducted between subjects who dropped out of the study after

randomization and subjects who completed the study. An alpha level of $p \leq 0.05$ was chosen as the level of statistical significance for these comparisons.

Results of the intervention were assessed by separate analysis of covariance (ANCOVA) procedures of the posttest variables using the pretest levels of each measure as the covariate. ANCOVA was chosen as the method of analysis because of its ability to reduce unaccounted-for variance and hence its greater power to detect treatment effects compared to other approaches (Frison & Pocock, 1992; Maxwell & Delaney, 1990). Data transformations were applied to four variables (BDI-SF, D-SOPA, PPSI, and IARB) to achieve normality of skewed data for the analysis of covariance (Ferketich & Verran, 1994). Assumptions for parametric statistical analysis including independence, normality, homogeneity of variance, linearity, and homogeneity of regression were checked and were met by all except one dependent variable. The RP scale of the MOS SF-36 violated the normality assumptions and did not respond to data transformation. Therefore, the treatment effect for this variable was assessed using the distribution-free Mann-Whitney U test. Because 18 statistical tests were done, the Bonferroni correction was applied to protect against Type 1 error. An alpha level of 0.003 (0.05/18) was chosen as the level of statistical significance for between-groups treatment comparisons.

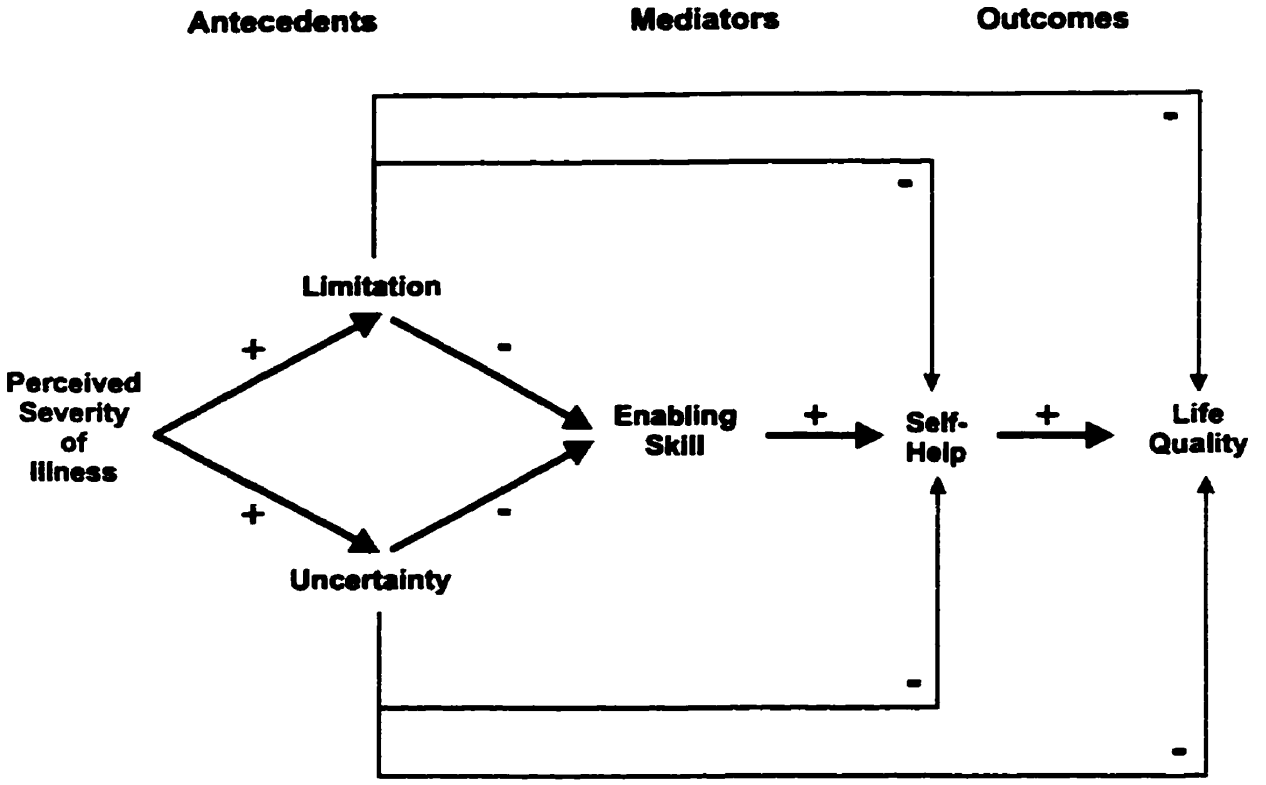
Model testing was conducted in three distinct steps. First, the correlation matrices of the Self-Help Model variables at pretest and posttest were examined for possible multi-collinearity using the criterion level of bivariate $r = 0.70$ as suggested by Tabachnick and Fidell (1989) and inspection of tolerance for each variable (Munro, 1997; Pedhazur, 1997). Assumptions related to causal modelling analysis were tested including graphic and statistical examination of residuals (Verran & Ferketich, 1987). No violation of assumptions was detected. The final selection of variables to include in the model testing was made based on both theoretical and statistical grounds.

Second, the hypothesized paths among variables of the Self-Help Model were tested using path analysis techniques based on least squares multiple regression (Pedhazur, 1997). The purpose was to examine whether the hypothesized paths, initially developed and tested with those suffering from arthritis-related conditions, were supported by data collected at two points in time from individuals with mixed idiopathic chronic pain

conditions. For purposes of this analysis, data were treated as cross sectional at pretest and at posttest. For each time period (pretest and posttest), the independent variables that operationalized the constructs of the Self-Help Model were regressed on the dependent variable in a series of simultaneous multiple regressions. Based on Braden's (1990b) original model testing and subsequent model refinement (Braden, 1993b), five structural equations were developed to test Braden's theoretical model (see Figure 2). For the model test using the posttest data, a dichotomous dummy variable indicating group assignment (treatment = 1, control = 0) was also added to the regression equations. Tabachnick and Fidell (1989) recommend no less than 20 subjects per independent variable and overall no fewer than 100 subjects in multiple regression analyses. Since no regression equation had more than 5 independent variables, the sample size of 110 at pretest and 102 at posttest was sufficient for this model testing. The significance level of $p \leq 0.05$ was used for the standardized beta regression coefficients and for the adjusted R^2s which indicated the amount of explained variance for each of the dependent variables. The multiple regression analyses were done using the Statistical Package for the Social Sciences (SPSS for Windows, 1995).

The final approach to model testing assessed the overall fit of the model to the data at pretest and at posttest. The EQS for Windows statistical software program by Bentler and Wu (1995) calculates a number of indicators of the extent to which the *a priori* model is consistent with the data. Therefore, the set of regression equations for the pretest and posttest data were submitted to the EQS program. Four indices of fit were provided: the chi-square goodness-of-fit statistic and three comparative goodness-of-fit indices [i.e., the Bentler-Bonett normed fit index (NFI); the Bentler-Bonett nonnormed fit index (NNFI); and the comparative fit index (CFI)]. Indicators of good or adequate fit are a non-significant chi-square statistic and values between 0.90 and 1.00 for the three other indices (Bentler, 1995).

Because assessing the adequacy of a model is seldom a straightforward process, Bentler (1995) suggests that all indicators be examined but recommends the CFI as the preferred index since it avoids underestimation due to sample size and sampling variability which may occur with the other indices. In addition, the chi-square statistic is



Regression equations:

Limitation = (Beta) Perceived Severity of Illness + e

Uncertainty = (Beta) Perceived Severity of Illness + e

Enabling Skill = (Beta) Limitation + (Beta) Uncertainty + e

Self Help = (Beta) Enabling Skill + (Beta) Limitation + (Beta) Uncertainty + e

Life Quality = (Beta) Self Help + (Beta) Limitation + (Beta) Uncertainty + e

Note: Beta = Standardized regression coefficient ; e = error.

Figure 2. Self-Help Model Constructs with Regression Equations

inflated by larger sample sizes ($n \geq 100$) and therefore a model may be rejected (achieve significance) even if only trivially false (Bentler, 1995; Norris, 1997; Wheaton, 1987). For these reasons, the major indicator of fit used in this study was the Comparative Fit Index (CFI) but all indices are reported and discussed.

Summary

Chapter 3 presented the methodology of this study. A randomized clinical trial was used to evaluate the impact of a standardized psychoeducation program for individuals with chronic non-malignant pain. The development and description of the experimental intervention, the Chronic Pain Self-Management Program (CPSMP), was provided. Subject inclusion criteria and procedures used to recruit as representative a community sample of the population of interest as possible were described. Reliability and validity information of the instruments used in the study was provided and the pilot testing of the instruments was discussed. Ethical considerations related to the study were also described and discussed. The data analysis procedures to evaluate the impact of the intervention and to test the hypothesized relationships in Braden's Self-Help Model were described.

CHAPTER 4

Results

Results of this study are presented in three sections. First, data about the study sample are presented as follows: description and comparison of the sociodemographic and pain-related characteristics of subjects randomly allocated to the treatment and wait-list control groups; description and comparison of the pretest scores of the dependent variables between the two groups; and, description of background characteristics and study variables of subjects who dropped out of the study after randomization compared to those who completed the study. The second section presents the results of the intention-to-treat analysis of covariance (ANCOVA) that tested the effect of the Chronic Pain Self-Management Program on the dependent variables. The last section presents the results of the path analyses used to test the hypothesized relationships in the Self-Help Model and to test the overall fit of the model to the pretest and the posttest data .

Sample Characteristics and Comparability of Groups

Sociodemographic and Pain-related Characteristics

One hundred and ten individuals who met the inclusion criteria voluntarily consented to participate in the study. Fifty-seven subjects were randomly assigned to the treatment group and 53 to the wait-list control group. Selected sociodemographic and pain-related characteristics of the two groups are presented in Tables 3 and 4. The only missing data were related to age (control group, $\underline{n} = 1$) and pain duration (treatment group, $\underline{n} = 1$). The groups were not significantly different on any of the background characteristics using chi-square analysis for categorical data and two-tailed independent groups t-tests for continuous level data ($\underline{p} > 0.05$).

This young to middle-aged sample were Caucasian except for one subject of east Indian origin. Most were graduates of high school and two thirds had some post secondary education. There was an equal gender balance with women outnumbering men 3 to 1 in both groups. Most of the subjects were married and living with family or friends.

Table 3

Selected Sociodemographic Characteristics of all Study Subjects (N=110) by Group

Variable	Treatment Group n = 57		Control Group n = 53	
Continuous Variable				
Age (in years)				
Mean ± Standard Deviation	39.23 (9.36)		40.42 (8.67)[a]	
Range	24 - 57		26 - 60	
Categorical Variable	**n**	**%**	**n**	**%**
Gender				
Female	42	74	40	75
Male	15	26	13	25
Marital Status				
Married/partnered	41	72	43	81
Single	8	14	5	9
Divorced/Separated	8	14	4	8
Widowed	0	0	1	2
Living Arrangements				
Live with family/friends	50	88	48	91
Live alone	7	12	5	9
Education Level				
High school or less	14	25	18	34
Some post-secondary school	37	64	26	49
University graduate	6	11	9	17
Employment Status				
Employed and working	21	37	18	34
Employed but unable to work	11	19	8	15
Unemployed due to pain	13	23	19	36
Unemployed for other reasons	4	7	1	2
Other (homemaker / retired)	8	14	7	13
Receiving Financial Benefits				
Workers Compensation benefits	7	12	9	17
Other disability benefits	13	23	13	25

[a] $n = 52$

Only one third of the sample were employed and working while another third were receiving either Worker's Compensation or other disability benefits.

As Table 4 indicates, the average pain duration was 5.6 years for the control group and 6.6 years for the treatment group. While the vast majority had multiple pain sites, the most common being the low back (75%) and neck/shoulder (64%), eight individuals had complaints confined to one area of the body such as headache, orofacial pain, non-specific abdominal pain or non-arthritic knee pain. Over 40% attributed their pain to one or more motor vehicle accidents. Others attributed their pain to lifting, falls, "just happened" or to other causes such as surgery. Most people (83%) were taking various medications for their pain including non-steroidal anti-inflammatory drugs (Nsaids), narcotic combinations, muscle relaxants, tricyclic antidepressants, and sedatives/ hypnotics. Over 64% had visited their family doctor and 34% a medical specialist within the past month for their pain. Also, many were receiving adjunctive therapy of some kind

Table 4

Selected Pain-related Characteristics of all Study Subjects (N=110) by Group

Variable	Treatment Group n = 57		Control Group n = 53	
Continuous variable				
Pain duration (in years)				
Mean ± Standard Deviation	6.57 (6.34)[a]		5.57 (4.42)	
Range	1 - 28		1 - 20	
Number of painful body sites (1 - 20)				
Mean ± Standard Deviation	6.89 (4.99)		6.96 (4.24)	
Range	1 - 20		1 - 17	
Categorical variable	**n**	**%**	**n**	**%**
Common pain sites				
Low back	39	68	43	81
Neck/shoulders	35	61	35	66
Upper/mid back	25	44	25	47
Leg/knee	24	42	22	42
Head/face	16	28	15	28

Table 4 (cont.)

Variable	Treatment Group n = 57		Control Group n = 53	
Categorical variable	**n**	**%**	**n**	**%**
Perceived cause of pain				
Motor vehicle accident	23	40	22	42
Lifting	12	21	6	11
Fall	3	5	6	11
Twisting	0	0	4	8
Just happened/other	19	34	15	28
Surgery for pain				
Yes	18	32	17	32
Taking any medications for pain				
Yes	48	84	43	81
Medications currently taken for pain				
Acetaminophen	8	14	9	17
Nsaid (including ASA)	17	30	20	38
Narcotic combinations	25	44	24	45
Muscle relaxants	11	19	12	23
Tricyclics/antidepressants	8	14	12	23
Sedatives/hypnotics	7	12	5	9
Anti-ulcer (to counteract Nsaids)	4	7	2	4
Visit to heath practitioners in past month				
Family doctor	37	65	34	64
Medical specialist	22	39	15	28
Physiotherapist	21	37	19	36
Chiropractor	12	21	7	13
Registered massage therapist	7	12	5	9
Acupuncturist	5	9	1	2
Other chronic illnesses				
Gastrointestinal	9	16	4	8
Cardiovascular	7	12	5	9
Respiratory	4	7	1	2
Neurological	1	2	4	8
Depression	2	4	4	8
Other varied illnesses	12	21	14	26

[a] $n = 56$

including physiotherapy, chiropractic, acupuncture, or massage. Chi-square analysis revealed no differences between the two groups on these aspects of service utilization ($p > 0.05$).

Dependent Variables at Pretest

To further assess the equivalence of groups at baseline, the pretest scores of the dependent variables in the study were compared. Prior to doing this comparison, all pretest data were cleaned and checked for missing values and outliers, and were investigated to be certain they met the assumptions of parametric statistical analysis.

For the Self-Help Model variables, three measures were found to have missing data that precluded the calculation of a total score. One subject did not complete the pain problem severity indicator (PPSI) and the dependency item (PDI), and another subject completed just half the items on the self-efficacy scale (SES). Both these subjects were in the control group and these values were left as missing. Missing data in four multi-item instruments including MUIS-C (uncertainty), SCS (resourcefulness), IARB (self-help role behaviours) and SLDS (life satisfaction), ranged from less than two percent to ten percent of the items in any given instrument. For these variables, total scores could still be reliably calculated for all subjects based on criteria regarding missing data (F. Baker, personal communication, June 9, 1994; Braden, 1986; Mishel, 1990). Complete data sets were found for the remaining three measures of pain rating (MPQ-SF), depression (BDI-SF) and disability (D-SOPA). For the Medical Outcomes Study SF-36, only one subject in the treatment group had missing data on the Physical Function Scale that precluded the calculation of a total PF score. This was left as missing. Only three other subjects had one or two items missing from the SF-36 and total scales could be calculated for all scales (Ware et al., 1993). Overall, missing data of the dependent variables at pretest constituted less than one half of one percent of the total possible responses on all scales combined.

All of the dependent variables were examined for outliers or extreme values defined as scores that were greater than three standard deviation units above or below the mean. No extreme values were found for any variable except for the Role Physical (RP) Scale of the SF-36. The outlying values were checked for accuracy and were found to be correct. On

examination, the RP scale has only 5 possible values: 0, 25, 50, 75 or 100. At pretest, 86% of subjects ($n = 94$) scored zero on this scale, hence all other values were outliers. However, eliminating the outliers would have resulted in a variable with a mean and standard deviation of zero and no variability. Because this problem with floor/ceiling effects has previously been noted in the scale (McHorney et al., 1994), it was decided not to eliminate cases but to use distribution free (non-parametric) statistical analysis for this one variable since the assumption of normality was violated.

Pretest scores of all other dependent variables were normally distributed except for four Self-Help Model variables. Depression (BDI-SF) and adult role behaviours (IARB) were skewed significantly to the right ($p < 0.05$) with skewness values of 0.62 and 0.59 respectively. Square root transformations as recommended by Ferketich and Verran (1994) reduced the skewness to non-significant levels of -0.10 for the BDI and 0.22 for the IARB ($p > 0.05$). Disability (D-SOPA) and the pain problem severity indicator (PPSI) were skewed significantly to the left ($p < 0.05$) with values of -0.52 and -0.60 respectively. A power transformation resulted in normal distributions with skewness values of 0.12 for the D-SOPA and 0.10 for the PPSI ($p > 0.05$). The transformed values for these variables were used for all subsequent statistical analyses however raw scores are reported in tables for clarity.

Comparison of Dependent Variables at Pretest By Group. Table 5 presents the pretest mean scores on the Self-Help Model variables and Table 6 presents pretest mean scores for the eight scales of the Medical Outcomes Study SF-36 for both treatment and control groups. Between-group differences for all dependent variables except for the Role Physical (RP) Scale of the SF-36 were analysed using two-tailed independent groups t-tests. No significant differences were found on any of these variables ($p > 0.05$). Differences for the RP Scale of the SF-36 were assessed using the two-tailed Mann-Whitney U test. There was no significant difference in mean rankings for this variable (treatment group, 55.04; control group, 55.99; $p = 0.80$). These results provide additional evidence that the randomization procedure had successfully produced equivalent treatment and control groups.

Table 5

Pretest Scores on Self-Help Model Variables for all Subjects (N=110) by Group

	Treatment Group n = 57		Control Group n = 53	
Variable	**Mean**	**SD**	**Mean**	**SD**
Antecedent variables				
Pain rating (MPQ-SF)	19.04	8.11	19.02	8.45
Depression (BDI-SF)	8.11	5.19	7.92	5.16
Disability (D-SOPA)	2.56	0.85	2.84	0.77
Problem Severity (PPSI)	73.84	18.33	73.58 [a]	17.67 [a]
Dependency (PDI)	55.14	25.86	55.21 [a]	30.03 [a]
Uncertainty (MUIS-C)	68.65	11.93	65.19	11.94
Mediating variables				
Self-efficacy (SES)	48.08	16.75	48.55 [a]	17.98 [a]
Resourcefulness (SCS)	64.64	10.49	65.03	11.54
Outcome variables				
Self-help (IARB)	54.89	11.63	52.42	12.96
Life satisfaction (SLDS)	67.28	19.80	66.32	19.18

[a] $n = 52$.

Table 6

Pretest Scores on Scales of the MOS SF-36 for all Subjects (N=110) by Group

	Treatment Group n = 57		Control Group n = 53	
Variable	**Mean**	**SD**	**Mean**	**SD**
MOS SF - 36 Scales				
Physical function (PF)	40.75[a]	24.25 [a]	37.65	20.48
Role - physical (RP)	7.89	22.24	11.32	29.65
Bodily pain (BP)	26.53	16.20	28.89	18.34
Role - emotional (RE)	39.77	43.39	43.40	41.65
Social function (SF)	46.71	25.83	47.17	25.90
Vitality (VT)	30.56	19.80	35.19	21.09
Mental health (MH)	58.81	21.04	57.36	20.29
General health (GH)	44.12	20.36	47.61	22.56

[a] $n = 56$.

Study Attrition

Of the 110 subjects randomized to the trial, eight subjects (treatment group, n = 5; control group, n = 3) subsequently did not complete the posttest measures and were considered dropouts, a rate of 7%. Of the treatment group dropouts, one became ineligible after randomization, one was admitted to hospital for an extended period for a serious acute illness, and three individuals who had attended one or no classes declined to complete the questionnaire booklet at posttest. All three dropouts in the control group were subjects who could not be contacted at 3-month follow-up despite three phone call attempts and a follow-up letter. Figure 3 depicts a summary of group allocation, the dropouts, and the final number of subjects who completed the posttest instruments.

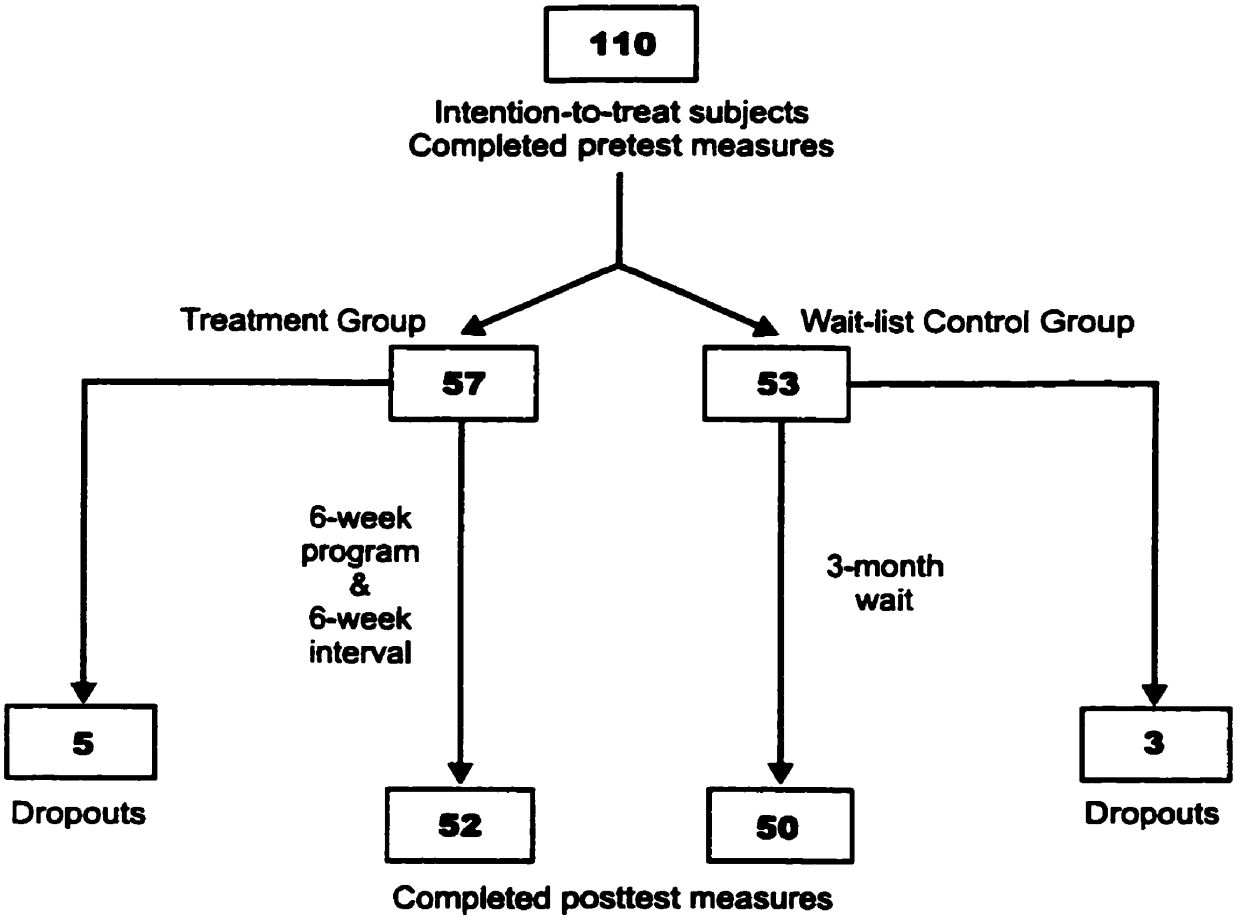


Figure 3. Summary of Group Allocation of Subjects, Dropouts and Subjects Completing the Study.

Comparison of Dropouts and those Completing the Study. To investigate the differences between those who dropped out of the study ($n = 8$) and those who completed the study ($n = 102$), statistical comparisons of all background characteristics and the pretest dependent variables were done. Table 7 presents the frequencies and percentages of five background characteristics that were significantly different between the two groups using chi-square analysis ($p \leq 0.05$). The data indicate none of the dropouts were working compared to 38% of those completing the study and significantly more dropouts were receiving disability benefits compared to completers. Interestingly, 100 % of the dropouts reported neck pain compared to 61% of completers. All dropout subjects had visited their family doctor within the past month compared to 63% of completers, and more of the dropouts than expected were taking sedatives/ hypnotics, however the number of subjects was small. Although not statistically significant, all dropouts were female. All other background characteristics were not significantly different between the two groups ($p > 0.05$).

Table 8 presents the pretest means, standard deviations and t-test results of 10 dependent variables that were significantly different between those completing the study and the dropouts ($p \leq 0.05$). As a group, the dropouts had significantly higher pain rating scores (MPQ-SF), felt themselves to be more disabled (D-SOPA), were more depressed (BDI-SF) and had poorer general mental health (MH) scores, felt more dependent on others (PDI), and perceived themselves to have poorer general health (GH), less vitality (VT), and poorer social functioning (SF). They also had lower levels of self-efficacy (SES) and were less satisfied with their lives (SLDS). From these data, it appears that those who dropped out of the study were more severely affected by their pain condition compared to those who completed the study.

Table 7

Comparison of Significant Background Characteristics between the Dropouts (n=8) and Subjects who Completed the Study (n=102)

	Completers n=102		Dropouts n = 8			
Variable	**n**	**%**	**n**	**%**	χ^2 (df)	**p**
Employment status						
Employed and working	39	38	0	0	15.55	.016*
Employed, unable to work	18	18	1	12	(6)	
Unemployed due to pain	25	24	7	88		
Unemployed other reason	5	5	0	0		
Other (homemaker, etc.)	15	15	0	0		
Receiving financial benefits						
Workers' Compensation	15	15	1	12	0.94	n.s.
Other disability benefits	21	21	5	63	7.53 (2)	.023*
Common pain locations						
Neck/shoulder	62	61	8	100	4.93 (1)	.026*
Medications taken for pain						
Sedatives/hypnotics	9	9	3	38	6.28 (1)	.012*
Visits to health professionals in past month						
Family physician	63	63	8	100	4.74 (1)	.029*

* $p \leq 0.05$

n.s. = non- significant ($p > 0.05$)

Table 8

Comparison of Significant Pretest Variables between the Dropouts (n=8) and Subjects who Completed the Study (n=102)

	Completers n = 102		Dropouts n = 8			
Variable	**Mean**	**SD**	**Mean**	**SD**	**t**	**p**
Self-Help Model						
Antecedent variable						
MPQ - SF	18.48	7.94	26.00	9.32	2.55	.012*
BDI - SF	7.55	4.75	13.63	7.00	3.36	.006*
D - SOPA	2.62	0.80	3.59	0.44	3.37	.001*
PDI	53.04[a]	27.49[a]	82.13	15.19	4.83[b]	.001*
Mediating variable						
SES	49.27[a]	16.78[a]	36.15	18.82	-2.11	.037*
Outcome variable						
SLDS	68.49	18.97	51.5	12.32	-2.49	.014*
MOS - SF 36						
SF	34.22	20.25	14.58	14.11	-2.69	.008*
VT	48.41	25.65	28.13	19.76	-2.18	.031*
MH	47.10	21.08	29.00	22.92	-2.32	.022*
GH	59.29	19.41	43.00	29.84	-2.19	.031*

two-tail independent groups t-test

[a] $n = 101$

[b] Levene's Test for Equality of Variances violated; unequal variance estimate reported.

* $p \leq 0.05$

To be certain that the treatment subjects (n = 52) and control subjects (n = 50) who completed the trial were comparable on background characteristics at baseline, statistical analysis using chi-square and t-tests were repeated on the sociodemographic and pain-related characteristics (see Appendix GG). No significant between-group differences were found ($p > 0.05$).

Posttest Measures of Dependent Variables

The posttest scores of the 102 subjects who completed the trial were checked for missing values and outliers, and were assessed to evaluate whether scores approximated a normal distribution. Only two measures had missing data that prohibited the calculation of a total score: pain rating (MPQ-SF) (treatment group, $n = 3$), and dependency (PDI) (control group, $n = 1$). These data were left as missing. The pattern of missing data in the multi-item instruments at posttest was similar to that previously described with the pretest measures. Missing data for four multi-item instruments (MUIS-C, SCS, IARB, SLDS) ranged from less than two percent to ten percent of items in a given instrument. For these variables, total scores could still be reliably calculated for all subjects based on instructions of the tool developer (F. Baker, personal communication, June 9, 1994; Braden, 1986; Mishel, 1990). Seven subjects had one or two missing items on the MOS SF-36. Again, total scores could be reliably calculated for all SF-36 scales (Ware et al., 1993). Overall, the total amount of missing data was very small. All dependent variables at posttest were examined for extreme outliers but none were detected except for the Role Physical (RP) Scale of the SF-36 as expected from the pretest scores. These data violated normality assumptions and non-parametric analysis was again used to assess group differences (Munro, 1997).

All other variables were normally distributed except for four Self-Help Model variables. Depression (BDI-SF) and self-help role behaviours (IARB) were skewed significantly to the right ($p < 0.05$) with values of 0.94 and 0.50 respectively. Square root transformations reduced the skewness to non-significant levels of -0.02 for the BDI-SF and 0.19 for the IARB. ($p > 0.05$) Uncertainty (MUIS-C) and the pain problem severity indicator (PPSI) were skewed significantly to the left ($p < 0.05$) with values of -0.56 and -0.65 respectively. A power transformation resulted in normal distributions with skewness values of -0.03 for the MUIS-C and 0.11 for the PPSI ($p > 0.05$). The transformed values for these variables were used for all subsequent statistical analysis but raw scores are presented in tables for clarity.

Effects of the Treatment: Between-Group Differences

This section specifically addresses two research questions posed in this study. First, does participation in the CPSMP significantly improve scores of the variables defined by the Self-Help Model including antecedent variables (pain rating, depression, pain problem severity, disability and uncertainty), mediating variables (self-efficacy and resourcefulness) and outcome variables (self-help and life satisfaction) compared to wait-list controls? Second, does participation in the CPSMP significantly improve health-related quality of life as measured by the MOS SF-36 compared to wait-list controls? Mean scores and standard deviations for the Self-Help Model variables at pretest and 3 months later for the treatment and control groups are presented in Table 9. The results of the separate analysis of covariance (ANCOVA) for each variable are also presented. Comparisons of posttest means using the pretest levels as the covariate indicated that those in the treatment group had statistically significant improvement ($p \leq 0.003$) in six of the ten variables compared to the control group. The treatment group reported significantly less dependency on others (PDI), reduced severity of the pain problem on their lives (PPSI), greater involvement in self-help roles including valued family, community, work and self-care activities (IARB), greater life satisfaction (SLDS) and reported higher levels of self-efficacy (SES) and resourcefulness (SCS) compared to the control group. In addition, there were positive trends to improvement in measures of disability (D-SOPA) ($p = 0.008$) and pain rating (MPQ-SF) ($p = 0.039$) compared to the controls. By contrast, scores of depression (BDI-SF) and uncertainty (MUIS-C) did not improve in the treatment group compared to the control group.

The mean scores, standard deviations and ANCOVA results for seven of the eight scales of the MOS SF-36 are presented in Table 10. Comparisons of posttest means using the pretest levels as the covariate show that the treatment group had statistically significant improvement ($p \leq 0.003$) in two scales compared to the controls. As a group, treatment subjects had reduced bodily pain (BP: a measure of intensity and interference) and increased vitality (VT) at 6-weeks post intervention when compared to controls. Also, there were positive trends to improvement in the treatment group in general mental

Table 9

Between-groups Comparison (n=102) of Ten Self-Help Model Variables

Variable (possible range)	Treatment Group n = 52		Control Group n = 50		ANCOVA	
	Pretest mean (SD)	Posttest mean (SD)	Pretest mean (SD)	Posttest mean (SD)	F (df)	p
Antecedent variables						
Pain rating	18.94[a]	17.27[a]	18.32	20.14	4.38	.039
MPQ-SF (0 - 45)‡	(8.13)	(9.16)	(7.94)	(8.93)	(2, 96)	
Depression	7.67	6.83	7.48	7.68	2.83	.096
BDI-SF (0 - 39)‡	(4.91)	(5.63)	(4.63)	(4.75)	(2, 99)	
Disability	2.51	2.29	2.79	2.81	7.33	.008
D-SOPA (0 - 4)‡	(0.84)	(0.78)	(0.76)	(0.72)	(2, 99)	
Problem Severity	72.67	60.98	73.02[b]	71.22[b]	9.83	.002*
PPSI (0 - 100)‡	(18.44)	(21.26)	(17.61)	(15.83)	(2, 98)	
Dependency	52.44	45.67	54.52[c]	59.77[c]	12.39	.001*
PDI (0 - 100)‡	(25.24)	(26.08)	(29.66)	(23.00)	(2, 97)	
Uncertainty	68.25	66.12	64.54	64.60	.002	.960
MUIS-C (23 - 115)‡	(12.22)	(11.14)	(11.84)	(9.07)	(2, 99)	
Mediating variables						
Self-efficacy	49.52	59.66	49.00[b]	46.94[b]	21.74	.000*
SES (10 - 100)	(15.86)	(18.12)	(18.04)	(17.17)	(2, 98)	
Resourcefulness	64.48	67.77	64.81	62.52	17.27	.000*
SCS (0 - 100)	(10.69)	(9.78)	(11.71)	(11.47)	(2, 99)	
Outcome variables						
Self-Help	55.32	60.41	52.76	51.22	22.47	.000*
IARB (0 - 100)	(11.92)	(13.15)	(12.94)	(12.44)	(2, 99)	
Life Satisfaction	68.85	76.19	67.16	64.28	20.21	.000*
SLDS (0 - 119)	(19.57)	(19.87)	(19.39)	(17.31)	(2, 99)	

[a] n = 49; [b] n = 49; [c] n = 48; * $p \leq .003$.

‡ Lower scores are more positive; for all other variables, higher scores are more positive.

Note: All parametric statistical assumptions met including homogeneity of regression.

Table 10

Between-groups Comparison (n=102) of Seven Scales from the MOS SF-36

Variable (possible range)	Treatment Group n = 52 Pretest mean (SD)	Treatment Group n = 52 Posttest mean (SD)	Control Group n = 50 Pretest mean (SD)	Control Group n = 50 Posttest mean (SD)	ANCOVA F (df)	ANCOVA p
SF-36 (0 - 100)‡						
Physical function: PF	41.68 (24.70)	44.64 (25.07)	38.41 (20.22)	38.30 (21.63)	1.62 (2, 99)	.206
Bodily pain: BP	27.23 (16.39)	35.0 (18.65)	29.74 (18.37)	27.60 (17.89)	10.35 (2, 99)	.002*
Role - emotional: RE	41.03 (43.59)	59.62 (42.95)	44.67 (42.38)	56.00 (43.35)	0.33 (2, 99)	.570
Social function: SF	47.84 (26.16)	55.05 (27.48)	49.00 (25.36)	48.50 (24.83)	3.90 (2, 99)	.051
Vitality: VT	31.83 (19.73)	43.33 (22.16)	36.70 (20.69)	33.27 (19.74)	20.99 (2, 99)	.000*
Mental health: MH	60.46 (19.67)	68.15 (18.37)	58.08 (19.27)	60.84 (19.93)	4.07 (2, 99)	.046
General health: GH	45.35 (19.64)	48.69 (20.28)	48.93 (22.54)	48.86 (21.91)	0.99 (2, 99)	.323

‡ Higher scores are more positive for all scales.
* $p \leq 0.003$
Note: All parametric statistical assumptions met including homogeneity of regression.

health (MH) ($p = 0.046$) and social functioning (SF) ($p = 0.051$) compared to controls. There were no significant between-group differences in scores of physical functioning (PF), general health perceptions (GH), and role emotional functioning (RE).

The assessment of the treatment effect on the remaining Role Physical (RP) Scale of the SF-36 was done in two steps. First, a two-tailed Mann Whitney U test was used to assess the pretest scores of the 102 subjects who completed the study to confirm group equivalence at baseline. Mean rankings (treatment group, 51.15; control group, 51.86) were not significantly different ($p > 0.05$). The Mann-Whitney U test on the posttest measures found that mean rankings (treatment group, 58.33; control group, 44.40) were significantly different ($p \leq 0.003$) indicating that the treatment group had significant improvement in role physical functioning compared to controls. See Table 11 for pre- and posttest means and standard deviations of the RP Scale for both groups and the results of the Mann-Whitney U test.

Table 11

Between-groups Comparison (n=102) of Pretest and Posttest Mean Scores on the Role Physical Scale of the SF-36

	Treatment Group n = 52		Control Group n = 50		Mann-Whitney U	
Variable	**Mean**	**SD**	**Mean**	**SD**	**Z**	**p**
Pretest						
Role Physical: RP1	8.65	23.16	12	30.41	-0.19	0.849
Posttest						
Role Physical: RP2	24.52	33.39	9	23.56	-2.945	.003*

* $p \leq 0.003$

As a further test of the effectiveness of the intervention, the 20 subjects with the most improved scores from pretest to posttest for each statistically significant variable ($p \leq 0.003$) were classified according to group allocation. Fourteen to 18 of the 20 most improved subjects were in the treatment group providing more supportive evidence that the positive outcomes were due to treatment (see Table 12).

Table 12

Group Allocation of 20 Subjects with most Improved Scores on Statistically Significant Variables

Variable	Treatment Group	Control Group
Self-Help Model		
Problem Severity: PPSI	15	5
Dependency: PDI	14	6
Self-help: IARB	17	3
Life satisfaction: SLDS	16	4
Self-efficacy: SES	15	5
Resourcefulness: SCS	16	4
MOS SF-36		
Role Physical: RP	16	4
Bodily Pain: BP	15	5
Vitality: VT	18	2

Finally, as a form of process evaluation an attendance record was kept to track the number of classes attended by treatment subjects. Of the 6 program sessions, 44 subjects attended 4 or more sessions indicating that 85% of those randomized to the treatment group received two thirds or more of the course content (see Table 13). The average number of sessions attended was 4.7

Table 13

Number of Sessions Attended by Subjects in the Treatment Group

Sessions Attended (Maximum of 6)	Treatment Subjects n = 52
0	1 (1.9 %)
1	2 (3.8 %)
2	2 (3.8 %)
3	3 (5.8 %)
4	7 (13.5 %)
5	21 (40.4 %)
6	16 (30.8 %)

Model Testing: Path Analyses

The final section of this chapter addresses the third research question of this study: Do chronic pain subjects' scores on variables that operationalize the constructs in Braden's Self-Help Model support the predicted relationships in the Model? For purposes of model testing, the six constructs in the Model were operationalized using 7 variables. Figure 4 depicts the theoretical constructs (upper and lower case script), the variable(s) used to operationalize the constructs (upper case script), and the hypothesized relationships that were tested.

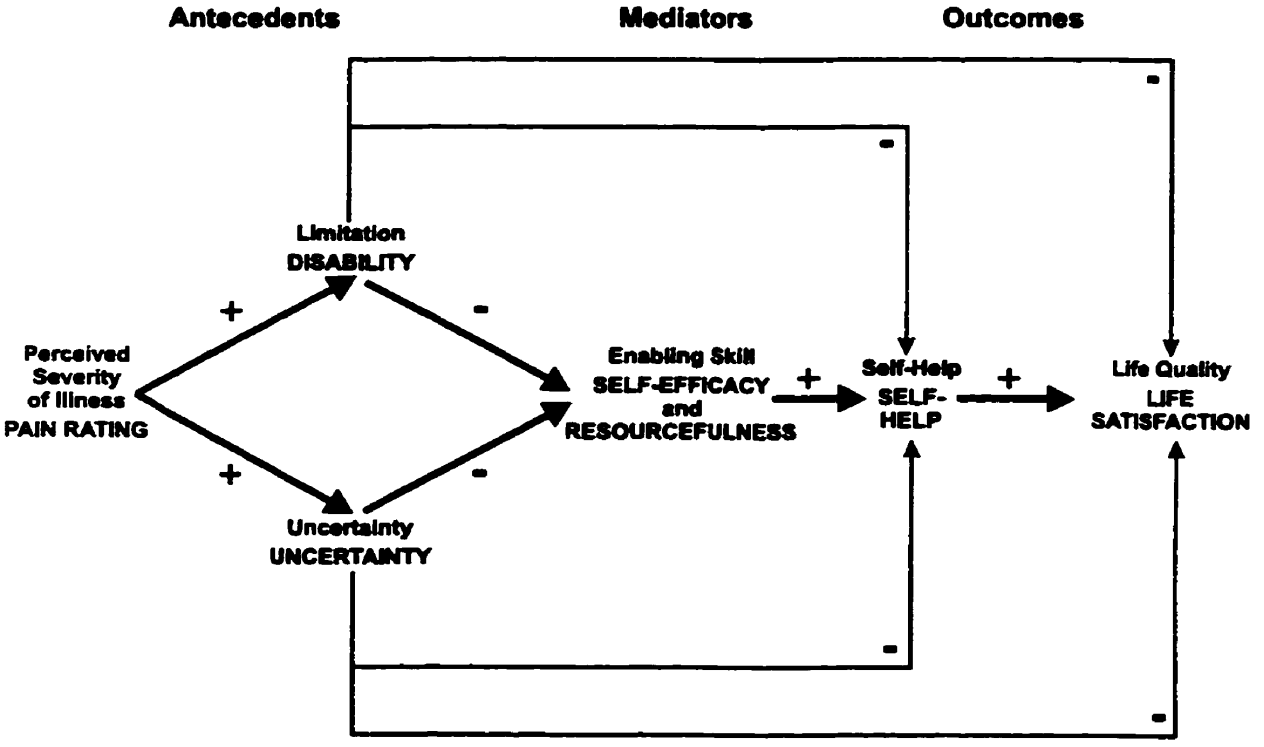


Figure 4. Self-Help Model Constructs, Variables, and Hypothesized Relationships

Three variables were excluded from model testing on statistical grounds. One of the assumptions of path analysis is that the variables in the model are measured without error and measurement error is assumed to be zero (Pedhazur, 1997). Although in reality this assumption cannot be met, it underscores the importance of having reliable measures of

variables in the path model. The variables selected for model testing had demonstrated reliability and validity and had high internal consistency reliability in this study sample as reported in Chapter 3. Because the two single-item indicators, PPSI (perceived severity of the pain problem) and PDI (perceived dependency indicator), could not be thoroughly assessed for reliability, they were not included in the model testing. In addition, a decision was made to exclude depression from this model testing because of its high negative correlation with life satisfaction at pretest and posttest ($r \geq 0.70$). The correlation matrix of the pretest scores of the 7 variables used in the Model testing as well as depression are presented in Table 14 and the correlation matrix of the posttest scores are presented in Table 15. Other than the high negative correlations between depression and life satisfaction, no other evidence of multi-collinearity was found using both the correlation matrix ($r \geq 0.70$) and by inspection of tolerance for each variable (Munro, 1997; Pedhazur, 1997; Tabachnick & Fidell, 1989).

Table 14

Intercorrelations of Selected Self-Help Model Variables at Pretest (N = 110)

Variable	1	2	3	4	5[a]	6	7
1. Pain rating							
2. Depression	. 59***						
3. Disability	.41***	.43***					
4. Uncertainty	.29 **	.45***	.20*				
5. Self-efficacy [a]	-.32 ***	-.50***	-.58***	-.34***			
6. Resourceful	-.20*	-.28**	0.05	-.24**	0.13		
7. Self-help	-.45***	-.55***	-.57***	-.22*	.56***	.22 **	
8. Life Satisfaction	-.56***	-.80***	-.46***	-.40***	.50***	0.08	.64***

* $p \leq .05$; ** $p \leq .01$; *** $p \leq .001$

[a] $n = 109$

Table 15

Intercorrelations of Selected Self-Help Model Variables at Posttest (n = 102)

Variable	1[a]	2	3	4	5[b]	6	7
1. Pain rating							
2. Depression	.46***						
3. Disability	.49***	.42***					
4. Uncertainty	.21**	.45***	.22*				
5. Self-efficacy[b]	-.35***	-.47***	-.61***	-.22*			
6. Resourceful	-0.12	-.33 ***	-0.03	-.23*	.25**		
7. Self-help	-.45***	-.52 ***	-.63***	-.27**	.62***	.35***	
8. Life Satisfaction	-.55***	-.78 ***	-.56***	-.36***	.48***	.21*	.62***

* $p \leq .05$; ** $p \leq .01$; $p \leq .001$

[a] $n = 99$; [b] $n = 101$.

Testing Hypotheses of the Self-Help Model

Model Test 1: Pretest Data. Six hypotheses related to the Self-Help Model were tested. These hypotheses, numbered 3 to 8, are listed at the end of Chapter 2. Table 16 presents a summary of the results of the regression analyses that tested these hypotheses using the cross-sectional data at pretest ($N = 110$). Results of the goodness-of-fit indicators are also presented at the bottom of Table 16.

Hypothesis 3 stated that perceived severity of illness (pain rating) would be significantly positively associated with two adversities of chronic illness, limitation (disability) and uncertainty. To test this hypothesis, pain was regressed separately on disability and on uncertainty. The first regression procedure, with disability as the dependent variable, resulted in a significant beta of 0.41 for pain (the relative predictive strength of pain on disability) and explained 16% of the variance (adjusted R^2) in disability. Therefore, individuals with higher levels of pain had higher disability. In the second regression, pain with a significant beta of 0.29 explained 8% of the variance in

Table 16

Multiple Regression Analysis: Pretest Scores of Self-Help Model Variables (N=110)

Independent Variable	B	95% CI	Beta	p
On Disability (0-4)*				
Pain (0-45)	0 .21	0.12 to 0.30	0.41	0.001
R^2 = 0.17; **Adjusted** R^2 = 0.16; F(1,108) = 22.23, p ≤ 0.001				
On Uncertainty (23-115)				
Pain (0-45)	0.42	0.16 to 0.67	0.29	0.002
R^2 = 0.08; **Adjusted** R^2 = 0.08; F(1,108) = 9.88, p ≤ 0.01				
On Self-efficacy (10-100)				
Disability (0-4)*	-2.23	-2.86 to -1.59	-0.54	0.001
Uncertainty (23-115)	-0.33	-0.55 to -0.11	-0.23	0.004
R^2 = 0.39; **Adjusted** R^2 = 0.38; F(2,106) = 34.0, p ≤ 0.001				
On Resourcefulness (0-100)				
Disability (0-4)*	0.26	-0.24 to 0.76	0.10	0.30
Uncertainty (23-115)	-0.23	-0.41 to -0.06	-0.26	0.01
R^2 = 0.07; **Adjusted** R^2 = 0.05 F(2,107) = 3.73 , p ≤ 0.05				
On Self-help (0-100)*				
Self-efficacy (10-100)	0.10	0.04 to 0.16	0.31	0.002
Resourcefulness (0-100)	0.10	0.03 to 0.18	0.21	0.01
Disability (0-4)*	-0.53	-0.77 to -0.29	-0.40	0.001
Uncertainty (23-115)	0.01	-0.07 to 0.08	0.01	0.89
R^2 = 0.44; **Adjusted** R^2 = 0.42; F(4,104) = 20.80, p ≤ 0.001				
On Life Satisfaction (0-119)				
Self-help (0-100)*	1.80	1.21 to 2.40	0.51	0.001
Disability (0-4)*	-0.56	-1.35 to 0.22	-0.12	0.16
Uncertainty (23-115)	-0.42	-0.65 to -0.20	-0.26	0.001
R^2 = 0.49; **Adjusted** R^2 = 0.47; F(3,106) = 33.77, p ≤ 0.001				

* Transformed scores.

Model fit indices: CFI = 0.91; NFI = 0.89; NNFI = 0.76; $\chi^2(8) = 29.71$, p = 0.000

uncertainty. Therefore, individuals with higher levels of pain had higher levels of perceived disability and to a lesser extent higher levels of uncertainty. These results support Hypothesis 3.

Hypothesis 4 stated that disability and uncertainty would be significantly negatively associated with enabling skill (self-efficacy and resourcefulness). This was tested by two separate regression equations; the first regressed disability and uncertainty on self-efficacy, and the second regressed disability and uncertainty on resourcefulness. Thirty eight percent (38%) of the variance in self-efficacy was explained by these two variables. Higher belief in disability had a significant negative association with self-efficacy (beta = -0.54) as did uncertainty (beta = -0.23). Uncertainty also had a significant negative association with resourcefulness (beta = -0.26) as predicted but disability did not significantly impact on resourcefulness. Only 5% of the variance in resourcefulness was explained by uncertainty. Thus, individuals who had higher disability and who had more uncertainty had lower levels of self-efficacy. In addition, those with more uncertainty also had lower levels of resourcefulness. These results partially support hypothesis 4.

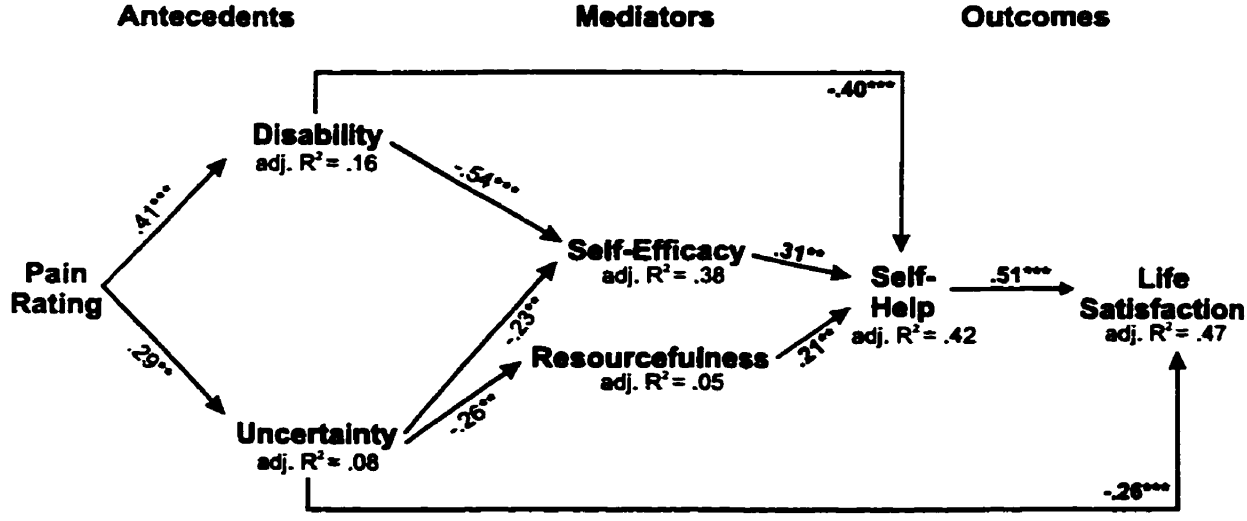
Hypothesis 5 stated that self-efficacy and resourcefulness would have a significant positive association with self-help, while hypothesis 6 stated that disability and uncertainty would have a significant negative association with self-help. These two hypotheses were tested in one regression equation that entered all the independent variables simultaneously. As predicted both self-efficacy and resourcefulness were significantly positively associated with self-help with betas of 0.31 and 0.21 respectively, and disability was negatively associated with self-help with a significant beta of -0.40. However, uncertainty was not significantly associated with self-help. Forty two percent (42%) of the variance in self-help was explained by self-efficacy, resourcefulness and disability. These results suggest that the greater the enabling skill as measured by self-efficacy and resourcefulness, the greater the involvement in self-help behaviours or, conversely the less the enabling skill, the less self-help involvement. In addition, there was a strong negative impact of disability on self-help. These results support hypothesis 5 and partially support hypothesis 6.

Hypotheses 7 and 8 were tested together. Hypothesis 7 stated that self-help would be

significantly positively associated with life quality (measured by life satisfaction) and hypothesis 8 stated that disability and uncertainty would be negatively associated with life satisfaction. Forty seven percent (47%) of the variance in life satisfaction was explained by self-help with a significant beta of 0.51 and uncertainty with a significant beta of -0.26 as predicted. As self-help behaviour increased, so did life satisfaction; however, higher levels of uncertainty reduced life satisfaction to some extent. Contrary to theoretical prediction, disability did not have a significant direct impact on life satisfaction. These results support hypothesis 7 and partially support hypothesis 8.

In summary, hypotheses 3, 5, and 7 were fully supported and hypotheses 4, 6, and 8 were partially supported by the data. These 6 hypotheses depict 13 paths or relationships among the variables in the Self-Help Model. Ten of the 13 paths were supported by this model test. Figure 5 depicts the variables, the path coefficients, and the amount of variance accounted for (adjusted R^2) by the significant relationships that emerged from this first test of the Self-Help Model using pretest data.

The fit of Braden's *a priori* Model to the data was assessed via the EQS statistical



* $p < 0.05$
** $p < 0.01$
*** $p < 0.001$

Figure 5. Model Test 1: Path Coefficients and Adjusted R^2 for Significant Relationships at Pretest

software program. Five structural equations depicting the relationships hypothesized in the Self-Help Model were submitted to the EQS program with no problems encountered during optimization. Thirteen parameters were estimated. Sample size for this analysis (N = 110) was adequate based on Bentler's (1995) criteria of 5 to 10 subjects per parameter. Results of the goodness-of-fit analysis were as follows. First, Bentler's comparative fit index (CFI) was 0.91. Since a perfect fit is 1.00, this result was indicative of low level but adequate fit of the model to the data. The normed fit index (NFI) was 0.89 and the nonnormed fit index (NNFI) was 0.76. For this data set, chi-square yielded a significant statistic of 29.7 with 8 degrees of freedom. However, Bentler (1995), Wheaton (1987) and others (Norris, 1997, Youngblut, 1994) state that a non-significant chi-square is difficult to obtain in many studies due to inflated values with large n's (n >100). For this reason, Bentler (1995) has suggested that the CFI is a more precise population-based indicator of fit. In summary, there appears to be some support for the adequacy of the Self-Help Model to explain the pattern of relationships in the pretest data.

Model Test 2: Posttest Data. A second test of the Self-Help Model was done using data from the 102 subjects who completed the measures at posttest. This second path analysis addressed the question: "How consistent or reproducible is the hypothesized pattern of relationships in the Self-Help Model at a second point in time (3 months after pretest), under different conditions (half the sample exposed to an intervention), in a group of individuals with chronic pain?" A modification was made to the second model test by including the variable "group" that took treatment effect into account. "Group" depicted group assignment (i.e., those in the treatment group were scored as 1 while those in the control group were scored 0). Table 17 presents a summary of the results of the regression analyses using the cross-sectional data at posttest as well as the goodness-of- fit indicators.

Table 17

Multiple Regression Analysis: Posttest Scores of Self-Help Model Variables (n=102)

Independent Variable	B	95% CI	Beta	p
On Pain (0-45)				
Group	-2.87	-6.48 to 0.73	-0.16	0.117
R^2 = 0.03; **Adjusted** R^2 = 0.02; F(1,97) = 2.50, p = 0.117				
On Disability (0-4)				
Pain (0-45)	0.04	0.02 to 0.05	0.45	0.000
Group	-0.40	-0.67 to -0.13	-0.25	0.004
R^2 = 0.30; **Adjusted** R^2 = 0.29; F(2,96) = 20.59, p = 0.000				
On Uncertainty (23-115)				
Pain (0-45)	0.25	0.03 to 0.46	0.23	0.027
Group	2.37	-1.57 to 6.32	0.12	0.240
R^2 = 0.06; **Adjusted** R^2 = 0.04; F(2,96) = 2.88, p = 0.061				
On Self-efficacy (10-100)				
Disability (0-4)	-12.50	-16.54 to -8.46	-0.52	0.000
Uncertainty (23-115)	-0.22	-0.52 to 0.07	-0.12	0.139
Group	6.77	0.60 to 12.94	0.18	0.032
R^2 = .41; **Adjusted** R^2 = .39; F(3,97) = 22.38, p = 0.000				
On Resourcefulness (0-100)				
Disability (0-4)	1.99	-0.82 to 4.80	0.14	0.163
Uncertainty (23-115)	-0.33	-0.54 to -0.12	-0.31	0.002
Group	6.78	2.46 to 11.09	0.31	0.002
R^2 = 0.15; **Adjusted** R^2 = 0.12; F(3,98) = 5.69, p =0.001				
On Self-help (0-100)*				
Self-efficacy (10-100)	0.09	0.03 to 0.14	0.27	0.004
Resourcefulness (0-100)	0.13	0.05 to 0.22	0.25	0.002
Disability (0-4)	-3.19	-4.56 to -1.82	-0.42	0.000
Uncertainty (23-115)	-0.04	-0.12 to 0.05	-0.06	0.425
Group	0.71	-1.12 to 2.54	0.06	0.443
R^2 = 0.55; **Adjusted** R^2 = 0.53; F(5,95) = 23.56, p = .000				

Table 17 (cont.)

Independent Variable	B	95% CI	Beta	p
On Life Satisfaction (0-119)				
Self-help (0-100)*	1.20	0.56 to 1.85	0.37	0.003
Disability (0-4)	-5.86	-10.59 to -1.14	-0.24	0.016
Uncertainty (23-115)	-0.43	-0.73 to -0.13	-0.22	0.005
Group	4.53	-1.72 to 10.77	0.12	0.154
$R^2 = 0.48$; **Adjusted** $R^2 = 0.45$; $F(4,97) = 21.98$, $p = 0.000$				

* Transformed score.
Model fit indices: CFI = 0.96; NFI = 0.95; NNFI = 0.86; $\chi^2(8)=35.20$, $p=0.001$.

Table 18 provides a comparison of Model 1 and Model 2 hypotheses testing results. Results of this second path analysis fully supported hypotheses 3, 5, 7 and 8 and partially supported hypotheses 4 and 6 of Braden's Self-Help Model. Hypotheses 4 predicted a significant negative association between the adversities of illness (disability and

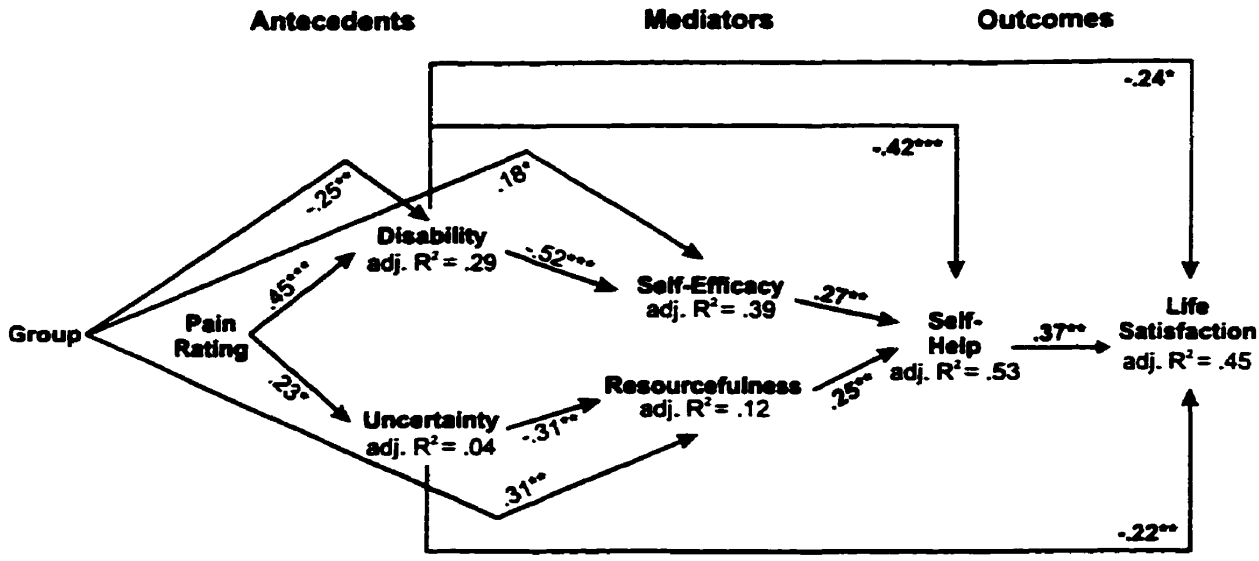
Table 18
Comparison of Results: Model 1 and Model 2 Hypotheses Testing

Hypotheses (Self-Help Model Variables)		Model 1	Model 2
3.	Pain rating + disability / + uncertainty	Supported	Supported
4.	Disability / Uncertainty - self-efficacy / - resourcefulness	Partially Supported	Partially Supported
5.	Self-help + self-efficacy / + resourcefulness	Supported	Supported
6.	Disability / Uncertainty - self-help	Partially Supported	Partially Supported
7.	Self-help + life satisfaction	Supported	Supported
8.	Disability / Uncertainty - life satisfaction	Partially Supported	Supported

uncertainty) and enabling skill (self-efficacy and resourcefulness). Consistent with Model Test 1, disability was significantly associated with self-efficacy (beta = -0.52) but not resourcefulness. However, uncertainty which had been negatively associated with both self-efficacy and resourcefulness in Model Test 1 was significantly associated only with resourcefulness (beta = -0.31) in this second model test. Regarding hypothesis 6 (disability and uncertainty would be significantly negatively associated with self-help), disability was significantly associated with self-help (beta = -0.42) as predicted but uncertainty was not significantly associated with self-help consistent with Model Test 1. The significant negative relationship between disability and life satisfaction proposed in hypotheses 8 was not supported by the first model test but was supported in this second model test (beta = -0.24). As in the first model test, 10 of 13 hypothesized paths were supported by the posttest data.

In terms of the amount of variance explained, the largest change occurred in self-help with 53% of the variance accounted for in this second model test compared to 42% in the first test. The reason for the stronger effect of disability, self-efficacy and resourcefulness on self-help may be due to the addition of group assignment to the model. Being assigned to the treatment group had a significant direct impact on disability (beta = -0.25), self-efficacy (beta = 0.18) and resourcefulness (beta = 0.31). Therefore, being in the treatment group decreased levels of perceived disability, and increased levels of self-efficacy and resourcefulness leading to higher levels of self-help consistent with theoretical predictions. The variable 'group' increased the amount of variance explained in disability from 23% in the first test to 29% in this second model test. It also increased the variance explained in resourcefulness from 5% in the first test to 12% in this second test.

Figure 6 provides a summary of the variables, the path coefficients, and the amount of variance explained (adjusted R^2) by the significant relationships that emerged from this second test of the Self-Help Model with 102 individuals at posttest. The fit of the Self-Help Model to the posttest data was assessed using the EQS statistical software program as previously described in the first model test. Fifteen parameters were estimated with no problems encountered during optimization. Overall, the results of the goodness-of-fit



* $p < 0.05$
** $p < 0.01$
*** $p < 0.001$

Figure 6. Model Test 2: Path Coefficients and Adjusted R^2 for Significant Relationships at Posttest

analysis were improved in this second model test. Bentler's comparative fit index (CFI) was 0.96 and the normed fit index (NFI) was 0.95 indicating adequate fit of the model to the data. The nonnormed fit index (NNFI) was 0.86 and the chi-square yielded a significant statistic of 35.2 with 8 degrees of freedom. Although these last two indicators did not indicate good fit, they are considered to be more sensitive to sampling variability and sample size and so may be underestimating the fit of the model to the data (Bentler, 1995; Wheaton, 1987). In summary, there appears to be support for the adequacy of the Self-Help Model to explain the pattern of relationships in these data from a sample of individuals with chronic pain. This is not to say, however, that the causal model was proved to be true, but rather that it was not disconfirmed (Pedhazur, 1997).

Summary

There were three research questions and eight related research hypotheses posed in this study. The first question asked whether participation in the CPSMP would significantly improve scores at 6-weeks post-intervention in variables guided by Braden's Self-Help Model including antecedent, mediating and outcome variables. The results of the intention-to-treat ANCOVA analyses indicated that those in the treatment group (n = 52) had significant improvement or trends to improvement in four of six antecedent variables (pain quality rating, pain problem severity, disability and dependency), in both mediating variables (self-efficacy and resourcefulness), and in both outcome variables (self-help and life satisfaction) as compared to those in the wait-list control group (n =50). Two antecedent variables (depression and uncertainty) did not show significant change in the treatment group.

The second research question asked whether participants in the CPSMP would achieve statistically significant short-term improvement in health-related quality of life as measured by a standardized, norm-referenced, psychometrically strong instrument. Results of the intention-to-treat ANCOVA analyses of the Medical Outcomes Study Short Form-36 indicated that those in the treatment group (n = 52) had significant improvement or trends to improvement in five of the eight SF-36 scales including bodily pain, role-physical function, social function, vitality and mental health as compared to those in the wait-list control group (n =50). Physical function, role-emotional function and general health perceptions were not significantly different between the two groups.

The third research question addressed whether data from individuals with chronic pain supported the predicted relationships in the Self-Help Model. Two tests of the model were conducted via path analysis techniques. Of the six research hypotheses related to the model testing, three hypotheses were fully supported and three were partially supported by the first model test using pretest data (N = 110). The second model test using posttest data (n =102) provided full support to four research hypotheses and partial support to two hypotheses. The Self-Help Model explained a significant portion of the variance in the two

major outcomes: between 42% and 53% of the variance in self-help and between 45% and 47% of the variance in life satisfaction. Model fit indices suggested that the model provided an adequate fit to the data, particularly the posttest data.

CHAPTER 5
Discussion

This chapter is divided into five sections. The first discusses the results of the randomized clinical trial of the Chronic Pain Self-Management Program (CPSMP). Comparisons of the results of this present study are made with results of the Arthritis Self-Management Program (ASMP) and with results of other comparable chronic pain interventions. The second section discusses the results of the path analyses that tested the Self-Help Model. The third and fourth sections discuss the implications for nursing practice and recommendations for future research. The final section of this chapter reviews the strengths and limitations of the present investigation. The chapter concludes with a summary.

Outcomes of the Randomized Clinical Trial

This randomized controlled trial examined the effect of a community-based, 12-hour, group psychoeducation program on a sample of young to middle-aged individuals with mixed idiopathic chronic pain problems. The findings present a picture of statistically reliable short-term improvement in those who were enrolled in the CPSMP ($n = 52$) as compared to those in the wait-list control group ($n = 50$) on multiple theory-guided self-report measures and on a number of health-related quality of life scales. At 6-weeks post-intervention, treatment subjects who attended a mean of 4.7 of the six CPSMP classes had statistically significant improvement ($p \leq 0.003$) in measures of pain intensity and impact, perceived severity of the pain problem as a whole, dependency, vitality, physical role functioning, self-help role behaviours, and life satisfaction as well as in two hypothesized mediating variables, self-efficacy and resourcefulness. The percent improvement on all but one of these variables in the treatment group as compared to the control group ranged from 9% to 47%. The high rate of improvement in one measure, the physical role functioning scale of the SF-36 (217%), may have been due to the floor/ ceiling effects of this scale

(McHorney et al., 1994). Although outcomes such as pain quality rating measured by the short-form of the MPQ, perceived disability, mental health, and social functioning did not reach statistical significance at the 0.003 level, there were positive trends to improvement ($p \leq 0.05$) in the treatment over the control group. By contrast, those in the control group either remained the same or deteriorated on most measures over the 3-month wait period. (See Appendix GG for published results).

The evidence from this study strongly suggests that increasing perceived self-efficacy and enhancing resourcefulness skills are effective strategies that strengthen self-help and self-care behaviours which then impact on life satisfaction. Bandura's (1986) self-efficacy theory proposes that self-efficacy will influence what people choose to do, and how persistent they will be in the face of difficulties; increased efficacy will also influence thought patterns to be more positive, and decrease stress and despondency. Likewise, learned resourcefulness theory suggests that increasing enabling skill (i.e., problem solving skills, cognitive reframing, delay in immediate gratification, and a general belief in self) not only buffers stress but also prompts people to initiate self change (Rosenbaum, 1990a). Rosenbaum states that people who are more resourceful not only cope better with adversity but also are more capable of adopting health-promoting behaviours and attitudes. Braden's Self-Help Model applies Rosenbaum's theory to the situation of chronic illness by specifying the critical aversive variables that induce stress, and by suggesting that educational interventions should specifically target enabling skill in order to reduce or mediate the negative impact of aversive aspects of chronic illness and increase positive self-help responses that will also improve life satisfaction.

These theoretical explanations are supported by a substantial body of work from theories of stress and coping (Lazarus & Folkman, 1984), learned helplessness theory (Seligman, 1975), as well as from broad frameworks such as the cognitive-behavioural perspective of learning and behavioural change (Turk & Meichenbaum, 1994), and from nursing models such as the McGill Model of Nursing (Gottlieb & Rowat, 1987). These perspectives all support strategies that were part of content and process of the CPSMP including specific strategies aimed at increasing self-efficacy, enhancing problem-solving ability, helping people cognitively reframe events, providing opportunities for increasing

belief in their own abilities to successfully manage problems by building on inherent strengths, etc. Such strategies appear to have a consistently positive impact on a wide range of quality of life outcomes.

The results reported in this present study of the CPSMP appear comparable to results of the Arthritis Self-Management Program (ASMP) studies. Lorig and Holman (1993) reported statistically significant short-term improvement ($p \leq 0.05$) in pain intensity (22%) and self-efficacy (14%), and non-significant positive trends in disability (6%) and depression (14%) in treatment subjects ($n=77$) who attended an average of 4.5 of six "efficacy-enhanced" ASMP classes over wait-list control subjects ($n=50$). The efficacy-enriched ASMP (which served as the prototype for the CPSMP) incorporated features known to effect self-efficacy: exercises to increase skills mastery, feedback about accomplishments, modelling by leaders and participants, symptom reinterpretation, examples of how to change one's beliefs, and persuasion (Goeppinger & Lorig, 1997). Increases in health status obtained with this efficacy enriched program were 1.5 to 12 times greater than in the original course (Lorig & Gonzalez, 1992). This evidence along with previous findings of the lack of association between health status change and behaviour change has led Lorig to conclude that improvements in health status are due to changes in self-efficacy (Goeppinger & Lorig, 1997; Lorig, Seleznick, et al., 1989).

Findings of this present study also appear to compare favourably with short-term outcomes of somewhat analogous outpatient pain clinic treatment programs with similar chronic pain populations. Four studies of broadly-based educational group interventions which were based on cognitive-behavioural principles that emphasized self-management and coping skills were located in the recent literature (Peters & Large, 1990; Philips, 1987; Skinner et al.,1990; Williams et al., 1996). Because there were differences in methodology including research design, sampling procedures, attrition rates, use of different outcome measures as well as program differences, direct comparisons of the results of this set of studies with the results of the CPSMP should be viewed with caution. However, despite the noted differences, subject characteristics were remarkably similar across studies including this study sample and the results of these interventions were relatively consistent with findings in this study. In general, those who participated in these

outpatient programs reported significant improvements in self-report measures of depression/mental health (11 - 31%) (Peters & Large, 1990; Philips, 1987; Skinner et al.,1990; Williams et al., 1996), aspects of functioning (18 - 40%) (Peters & Large, 1990; Philips, 1987; Skinner et al.,1990; Williams et al., 1996), and self-efficacy/perceived control over pain (25 - 34%) (Philips, 1987; Williams et al., 1996). Improvement in measures of physical performance such as walking and stair climbing was reported in only one study (Williams et al., 1996). Of note, only two of the four studies reported significant improvements in self-report measures of pain (8 - 25%) (Philips, 1987; Skinner et al., 1990) suggesting that improvements in psychosocial, functional and other outcomes are not necessarily linked to changes in perceived pain intensity and quality ratings. Although some variables showed larger rates of improvement in these studies compared to results of this CPSMP intervention, the methodological rigour of this present study including low attrition rates and intention-to-treat statistical analyses may have led to more conservative estimates of improvement in this study.

Since theoretically one would have predicted improvement in all variables, it is instructive to examine in greater detail those variables that did not change in the treatment group compared to the control group. Depression, uncertainty, and three of the eight scales of the SF-36 (i.e., physical functioning, role-emotional functioning, and general health perceptions), did not demonstrate significant change or positive trends to improvement at posttest.

Depression as measured by the short-form Beck Depression Inventory (SF-BDI) (Beck & Beck, 1972) did not change significantly. In part, the lack of statistically significant improvement may be because group mean scores for both treatment and control groups were not in the depressed range at pretest when a score of 8 or above is used to indicate mild clinical depression (Turner & Romano, 1984). Since group means were not in the depressed range at baseline, improvements in this variable would be less likely to occur. Although depression did not exhibit significant change, the mental health scale of the SF-36 did show a trend to improvement ($p \leq 0.05$) in the treatment compared to the control group. Four mental health concepts including anxiety, depression, loss of behavioural or emotional control, and psychological well-being are measured in this scale (Ware &

Sherbourne, 1992).

There was no significant change in uncertainty as a result of this intervention. The sample of individuals with chronic pain in this study scored in the mid-range for uncertainty which was similar to other chronic illness conditions including systemic lupus erythematosus, multiple sclerosis, and coronary heart disease but lower than conditions such as epilepsy (Mishel, 1991). Although strategies which might reduce uncertainty were included in the CPSMP (e.g., providing information, enhancing the positive and maintaining hope, promoting self-advocacy, and helping specify controllable circumstances), these strategies may not have been explicit enough or strong enough in terms of time spent teaching these components to effect change in this population with mid-level uncertainty (Mishel, 1993). Alternately, the 6-week follow-up period may have been too early to detect a change in this variable. Another plausible explanation of why uncertainty did not improve may be due to the particularly amorphous nature of chronic pain itself (Hilbert, 1984; Hitchcock, Ferrell, & McCaffery, 1994; Rowat & Knafl, 1985; Seers & Friedli, 1996).

The lack of change in physical functioning in the SF-36 may be related to issues of measurement. For example, the physical functioning scale uses three response categories ('limited a lot', 'limited a little', and 'not limited at all') to measure ten areas of perceived physical performance. Although aspects of physical performance related to exercise, walking, etc. are included in the CPSMP, finer gradations of performance (eg., 5 to 7 response categories) would probably be necessary to detect smaller degrees of change as a result of a psychoeducation intervention (Streiner & Norman, 1989).

There was no significant change in general health perceptions as a result of the intervention. There are a number of plausible explanations for this finding. First, it is possible that perceptions of one's general health are not easily or quickly altered and consequently data collection at 6 weeks post-intervention may be too short a time frame to detect change. Health ratings might have improved over time if the positive changes gained as a result of the intervention were able to be maintained over the long term. Secondly, the general health perceptions scale asks people to rate their present health, future health, and to compare themselves to others in terms of health and sickness. Many

subjects in this study sample had exhausted most available treatment options for their pain and they understood that the intent of the CPSMP was self-management and not cure. Being able to better 'manage' a condition may not be viewed as leading to improved health in the future or to decreasing a perceived gap in health between themselves and others. Lastly, the fact that just under 50% of study subjects (n = 50) reported at least one other ongoing health problem including hypertension, gastrointestinal problems (e.g., irritable bowel), long standing respiratory problems, or a variety of other illnesses in addition to their chronic pain problem may be an important contributing factor to the non-significant results in general health perceptions.

Interestingly, role-emotional functioning (i.e., the degree to which emotional problems have interfered with work and other accomplishments) improved substantially in both groups. However, there was no statistically significant difference between the groups at posttest. Why the control group would have improved on the role-emotional functioning scale while demonstrating few other improvements is not clear except that this scale, like the role-physical scale, has been demonstrated to have significant floor/ ceiling effects (McHorney et al., 1994). Because both measures of role functioning (i.e., physical and emotional) are measured with dichotomous response categories (presence/absence), McHorney and colleagues (1994) have suggested that finer gradations in scaling are probably needed to improve the sensitivity of these two scales.

The Self-Help Model: Discussion of Model Testing

The last research question in this study addressed whether the predicted relationships in Braden's (1990a) Self-Help Model would be supported by data collected at pretest and at posttest from a sample of individuals with idiopathic chronic pain. Six hypotheses were tested using causal modelling via path analyses techniques. In brief, the hypotheses stated that: (a) perceived severity of illness (pain rating) would be significantly positively associated with the adversities of illness (perceived disability and uncertainty); (b) perceived disability and uncertainty would be negatively associated with enabling skill (self-efficacy and resourcefulness), with self-help, and with life quality (life satisfaction); (c) self-efficacy and resourcefulness would be positively associated with self-help; and, (d)

self-help would be positively associated with life satisfaction.

Before discussing the path analysis results in detail, a comment needs to be made about the role of causal modelling approaches in theory development. First of all, the term causal modelling is somewhat misleading since modelling techniques such as path analysis cannot uncover causes or prove directionality (i.e., that x leads to y). A causal model is a theoretical conception of the pattern of relations among a set of variables or constructs. As a method, path analysis is intended not to elucidate causes per se, but rather to shed light on the feasibility of a causal model that a researcher has formulated *a priori* on the basis of knowledge, theoretical understandings, creativity and insight (Pedhazur, 1997; Pedhazur & Schmelkin, 1991). Thus, path analysis tests how well an *a priori* theoretical model is consistent with the data. If the model is inconsistent with the data, doubts are cast about the theory from which the model was derived (Norris, 1997; Pedhazur, 1997). Consistency of the model with the data, however, does not constitute proof of the theory; at best, it lends support to the theory's feasibility to explain or predict phenomena. It is possible for other competing explanations of phenomena (i.e., other causal models) to be consistent with the same data. The decision of which model is more tenable, then, does not rest on the data but on theoretical considerations.

The Self-Help Model, initially formulated from theory and insight (Braden, 1986), has been tested with various chronic illness groups, most recently those with HIV disease (Grimes & Cole, 1996). Because the evidence suggested that the original conceptual-ization of the Self-Help Model was robust in different populations, model testing was conducted in this present study to evaluate its' explanatory power regarding learned response to the experience of chronic pain.

The results of the two separate model testing procedures using the pre- and posttest data in this study supported the overall hypothesized pattern of relationships among variables in the Self-Help Model. These data, then, lend further support to the underlying theory of learned response to chronic illness experience. Of particular significance was the amount of variance explained in the two outcomes of the Model, self-help and life quality. In the baseline model test, variance explained in self-help was 42% and in life quality was 47%. At posttest, with the intervention effect included in the model test, amount of

variance explained in self-help rose to 53% and in life quality was 45%. These posttest results are remarkably similar to the results in the arthritis studies in which Braden found that the Self-Help Model explained 52% to 55% of the variance in self-help and 47% to 49% of the variance in life quality with over 50% of subjects in her samples having attended an arthritis self-help education program (Braden, 1990a, 1990b). The consistency in amount of variance explained by both the arthritis studies and the present study is particularly noteworthy given that different measures were used to operationalize some of the Model constructs. Measures of uncertainty, resourcefulness and self-help were the same in the arthritis studies and in this present study, however different measures of limitation and life quality were used in this present study. As well, self-efficacy was an additional measure of enabling skill used in this study. Therefore, despite some differences in measurement across the two study samples, the pattern of relationships among the essential constructs in the Model and the predictive power of the Model appears stable.

The recent model test conducted by Grimes and Cole (1996) in a sample of 83 individuals with HIV disease who had not received a self-help intervention found that the Self-Help Model explained 31% of the variance in self-help and 35% of the variance in life quality. These results, although explaining a smaller amount of variance in the outcomes, was consistent with the hypothesized pattern of relationships in the model and adds additional support to the robustness of the Self-Help Model constructs in chronic illness experiences of various kinds.

As predicted in the Self-Help Model, the adversities of illness – perceived disability and uncertainty – were important variables influencing outcomes in this present study with disability having a greater negative impact than uncertainty. In both Model tests using pre- and posttest data, perceived disability was a significant strong negative predictor of self-efficacy and of self-help. It also had a small but significant negative impact on life satisfaction in the posttest model results. These data support a growing body of research findings in the chronic pain and other chronic illness literature that higher levels of *perceived* disability (as opposed to objectively-rated disability) are significantly associated with poorer physical and psychosocial outcomes including life satisfaction (Browne et al.,

1990; Dolce, 1987; Jensen & Karoly, 1991, 1992; Jensen, Turner, & Romano, 1994; Jensen, Turner, Romano, & Lawlor, 1994; Strong et al., 1990; Weir et al., 1992). Although evidence supports the link between 'perceptions' and outcomes, there has been little investigation about what factors influence one's perception of being disabled by pain (Jensen, Turner & Romano, 1994). In this study, pain rating explained only 16% of the variance in disability at pretest; this increased to 29% at posttest with the addition of the intervention variable 'group'. This leaves over 70% of the variance in perceived disability unexplained. Given the substantial negative impact of perceived disability on Self-Help Model variables, further investigation about perceived disability – both antecedent factors and strategies that successfully change perceptions – is warranted.

As noted earlier, uncertainty – the other adversity of illness in the Self-Help Model – had a small but significant negative predictive effect on resourcefulness and on life satisfaction similar to results in the model tests in the arthritis studies (Braden, 1990a, 1990b). However, unlike Braden's results, uncertainty was not associated with self-help in the present study. Reasons for this are not completely apparent. However, in the arthritis studies, the impact of uncertainty on self-help was small (Braden, 1990a). Although uncertainty has been identified as an important contributor to the distress experienced by those with chronic pain in qualitative studies (Hitchcock, Ferrell, & McCaffery, 1994; Rowat & Knafl, 1985; Seers & Friedli, 1996), uncertainty has not been studied in quantitative studies of chronic pain populations to any extent. In this present study, pain rating explained only 4 to 8% of the variance in uncertainty, a finding which stands in sharp contrast to the 40% variance explained in uncertainty in the arthritis studies. In one study, additional sociodemographic, and illness-related variables explained more of the variance in uncertainty than perceived severity of illness alone (Braden, 1990a).

In the Self-Help Model, enabling skill is hypothesized to mediate the adversities of illness. The theory proposes that if enabling skills can be enhanced, the negative impact of the adversities of illness will be minimized and outcomes related to self-help and life satisfaction will be improved. Unlike previous Self-Help Model studies, this present

study expanded the concept of enabling skill beyond learned resourcefulness to include self-efficacy. Model test results found that both self-efficacy and resourcefulness were significantly positively associated with self-help as predicted. Because self-efficacy and resourcefulness were uncorrelated at pretest ($r = 0.13$, $p > 0.05$) and had a low correlation at posttest ($r = 0.23$, $p < 0.05$), each variable was exerting a unique effect on self-help. This was expected because the two variables reflect different aspects of enabling skills: self-efficacy is domain specific with respect to perceived ability to successfully manage pain and other-related symptoms (Bandura, 1977a) while learned resourcefulness is reflective of general tendencies to use particular coping skills when dealing with any stressful circumstance (Rosenbaum, 1990). Thus, Braden's proposal that enabling skill may lessen the impact of the adversities of illness by its direct positive impact on self-help was supported by the findings in this present study.

The importance of a construct like enabling skill to explain outcomes is also supported by findings in the chronic pain literature. In a study of 94 chronic pain patients 3 to 6 months after an inpatient pain program, Jensen, Turner and Romano (1994) found that improvement in physical and psychosocial functioning and reduced health care utilization were associated with changes in perceptions/beliefs about pain and the use of cognitive coping strategies and were unrelated to changes in behaviour (eg., increased exercise, practice of relaxation, etc.) as operant conditioning theory would claim. Rather, Jensen and colleagues (1994) concluded that improvement appeared to be more closely linked with changes in what people think about their pain and the cognitive strategies they employ than with changes in what they do in terms of specific behaviours. Although self-efficacy beliefs were not measured in the Jensen et al. study, their conclusions are consistent with Bandura's Self-Efficacy Theory (Bandura 1977a, 1986) and Lorig's thesis regarding the importance of efficacy-enhancing interventions to improve outcomes (Lorig, Chastain, et al., 1989; Lorig, Seleznick, et al., 1989). This is also consistent with Learned Resourcefulness Theory (Rosenbaum, 1990) in that the enabling skills highlighted as mediating the negative impact of adversities are: problem solving, cognitive reframing, belief in self, and delay in gratification, a cognitively-based skill set.

Alternate or competing explanations to the mediating effects of enabling skill are also

of interest. In a recent study, Braden, Mishel and Longman (1998) found that resourcefulness acts as a moderator rather than a mediator between the adversities of illness and self-help. (A mediator is a variable that accounts for the relationship between a predictor and outcome whereas a moderator affects the direction or strength of the relationship) (Baron & Kenny, 1986). To test for moderator effects, scores are subjected to a median split with individual scores dichotomized into high or low resourcefulness. Learned resourcefulness theory would suggest that being high in resourcefulness in a general sense sets the stage for additional learning. Hence, those in the high range may increase their sense of efficacy more readily when exposed to an efficacy-enhancing intervention, thus influencing outcomes. By contrast, those low in resourcefulness at pretest may have higher levels of perceived disability and uncertainty and respond to the intervention by first increasing resourcefulness skills and through increasing those skills enhance self-help. Further model testing of mediator/moderator effects would need to be done to test these additional hypotheses in this population of individuals with chronic pain.

The Self-Help Model may not be the only explanation for how people respond to the experience of chronic illness, but it has continued to be supported by data from samples of patients with arthritis, systematic lupus erythematosus, HIV disease, breast cancer and in this present study of mixed idiopathic chronic pain (Braden, 1990a, 1990b, 1991b; Braden et al., 1990, 1993, 1998; Grimes & Cole, 1996) . Overall, the hypothesized pattern of relationships in the Self-Help Model was supported by the data collected in this study and was consistent with findings in the chronic pain literature.

Implications for Clinical Practice

The important role of education-based interventions as an adjunct to traditional medical and physical therapies for the management of chronic pain is now well-established (Allegrante, 1996). Results of the CPSMP were within the range of outcomes reported by four somewhat comparable outpatient chronic pain programs (Peters & Large, 1990; Philips, 1987; Skinner et al.,1990; Williams et al., 1996). Admittedly, the results of these hospital-based programs were stronger on some variables. However, their

programs ranged from 13.5 to 28 hours and involved members of a multidisciplinary team. which although ideal, adds to the cost of programs and decreases portability to other settings. By contrast, the low-cost CPSMP is 12 hours in length, and utilizes one facilitator. Because of its standard protocol, it can be reliably delivered by generalist health care providers in a variety of community settings such as local service clubs, churches, schools , etc. (Lorig, 1986; Goeppinger & Lorig, 1997). Hence, the more moderate effects of the CPSMP may be offset by the potential for broad dissemination and greater accessibility by those with chronic pain than is currently the case with more specialized pain clinic services (Turk, Rudy, & Sorkin, 1993). The caveat to this generalization is that individuals such as the eight drop-outs in this study who had high levels of pain and depression and poorer levels of functioning may not have the motivation to engage in a program of this type. They may need more specialized treatment that is more appropriately available at a pain treatment centre.

Given the current shift of health services away from acute care institutions to the community, it would appear that community-based nurses are well placed to deliver, evaluate and help with further refinement and modification of the CPSMP. However, even after additional evaluation of the long-term impact of the CPSMP is completed, dissemination of a program such as the CPSMP will likely be a difficult task. As Lorig (1995) has eloquently argued, effective research-based educational treatments are largely denied to clients because patient education does not fit cleanly within the present structure of professional health care delivery systems or within health care financing. Issues around program delivery, accessibility, and financing will be barriers to the dissemination of community-based programs of this type unless policy level changes relating to these issues are made. Nurses need to be involved in clearly articulating the importance of educational treatments that enhance self-management and self-care for clients not only suffering from chronic pain, but for the wider population of community-based clients with various chronic health problems. This approach is in keeping with a series of Canadian health policy initiatives outlined in documents such as the Lalonde Report (1974), the Epp Framework (1986) and the most recent strategies for population health (Health Canada, 1994). All these reports have emphasized the need for broader health promotion strategies

within the community and the importance of enhancing coping skills that enable people to be self-reliant, solve problems, and make informed choices that promote health.

Another practice implication relates to the usefulness of the ASMP as a prototype program for interventions with other chronic illness populations. The original arthritis program was successfully 'cloned' for use with the chronic pain sample in this study. Because the successful ingredients of the intervention appear to relate to the process components that enhance self-efficacy and resourcefulness, the ASMP content has the potential to be modified for any number of other chronic health problems. In addition, Braden's Self-Help Model has been shown to be a useful organizing framework for nursing interventions by highlighting important antecedent variables, by suggesting the process through which change may occur and therefore what strategies should be specifically taught, and by identifying the outcomes that should be expected to improve as a result of nursing psychoeducational interventions whether delivered at the group or at the individual level. Both the ASMP and hence the CPSMP and Bradens' Self-Help Model are based on a health promotion orientation that builds on innate strengths and abilities of people and engages them in an active process of change. This is consistent with the view that health is a resource for everyday living and that self-help interventions provide learning opportunities for people to find healthy and satisfying ways of living in the face of chronic illness experience.

Recommendations for Further Research

Several recommendations for future research are suggested based on the findings in this study. First, this CPSMP intervention needs to be replicated using multiple facilitators located in both urban and rural areas, with follow-up at 3, 6 and 12 months (minimum) and with the addition of variables that monitor employment status, health care utilization and cost. Such research would provide evidence of the long-term impact of the CPSMP and the cost-benefit aspects of the intervention. Long-term follow-up studies of the ASMP have reported that treatment gains in health status variables translated into cost savings to the health care system with 40% reduction in number of physician visits in the treatment

over a comparison group at 4 years (Lorig, Mazonson, & Holman, 1993). Based on the similarity of short-term results in trials of the ASMP and this randomized controlled trial of the CPSMP, it is possible that cost savings to the health care system may result from the CPSMP over the long-term. Research documenting long-term treatment effects and associated costs would support nursing's claim that well-designed, theory-based psychoeducation interventions make an important contribution to the overall well-being of those with chronic health problems as well as impact on health care costs.

This study used the MOS SF-36 as an additional measure of health-related quality of life. Given the almost "gold standard" respect that the instrument now garners, it was used in this study as a test of the instrument's responsiveness to a nursing psychoeducation intervention. Although five scales out of eight appeared sensitive to change as a result of this intervention, both role functioning scales appeared to have significant floor/ceiling effects, which the tool developers themselves have acknowledged (McHorney et al., 1994). Of greater concern is the 10-item physical functioning scale. The use of three response categories may be sensitive enough to detect change as a result of a major surgical or even pharmacological intervention, but the restricted number of response categories are unlikely to be responsive to nursing interventions. Because of the potential importance of the SF-36 in evaluating patient outcomes in the health care system overall, nurse researchers need to include this measure in other nursing outcome studies to evaluate its responsiveness. Both the strengths and limitations of this instrument, including its' theoretical base, needs to be carefully examined to evaluate its usefulness for nursing and whether it is congruent with nursing's broad conceptualization of health-related quality of life.

Lastly, there are also recommendations for further testing of the Self-Help Model in this population. Using the data collected in this study, additional model testing could be conducted by testing mediator/moderator effects of the enabling skill variables – resourcefulness and self-efficacy – and then conducting competitive tests of the models to determine the best fit. Additionally, after data is collected in a replication study, a larger sample would allow for more sophisticated structural equation modelling that could test the bidirectional influences of variables, investigate cause and effect relationships over

time, and allow for the addition of other antecedent variables such as sociodemographic, pain-related, and other variables such as social support that may explain more variance in perceived disability and uncertainty. Because of the particularly aversive effects of perceived disability in this chronic pain sample, further research investigating related antecedent factors and strategies that successfully change perceptions about disability is warranted. Given that the Self-Help Model has been used and/or tested with a wide variety of chronic illness conditions, a meta-analysis of model testing results might be warranted at this time to evaluate the general applicability of the model to chronic illness.

Study Strengths and Limitations

The major strength of this study is the methodology which addressed weaknesses noted in previous work particularly regarding selection bias, failure to enter treatment, and attrition (Crombie & Davis, 1998; Turk & Rudy, 1990). This study randomly allocated subjects to treatment. It had a low rate of subject refusal to enter the study and had a low and equal rate of attrition in both the treatment and wait-list control groups. It used both theory-guided and standardized, norm-referenced measures that were valid and reliable. The study used a tested intervention as a prototype program, used a standard protocol to deliver the program, had blind assessors at post-treatment to reduce the likelihood of bias, and used intention-to-treat statistical analyses. In addition, the study used a sample that was as representative as possible of those with idiopathic chronic pain in the community who use a variety of health care services. It included a broad referral base as well as a pain clinic group. In addition, because most of the study participants were referred, there is no reason to think that these individuals were an extraordinarily motivated group. However, referral/selection bias cannot be completely ruled out.

There are, however, a number of methodological and other limitations to this study. This study used self-report measures only and social desirability response bias cannot be discounted. However, random assignment should have equally distributed those individuals prone to give more socially desirable responses to both the treatment and the control group. For the most part, data collection procedures were well controlled. However, a small proportion of subjects (less than 15%) took the instrument booklet

home with them to complete. Although all subjects were given instructions to complete the questionnaires by themselves, the investigator had no control over who may have influenced responses in their home environment.

Because this study was designed to evaluate the short-term impact of the CPSMP, it is not known whether treatment effects will be maintained over the long term. Although results from the ASMP suggest that improvements are maintained, this cannot be assumed in this study population. In addition, all programs were delivered by a single facilitator. The use of multiple facilitators would have strengthened the hypothesis that the content and process of the CPSMP rather than the personal attributes of the facilitator were the effective ingredients in this intervention.

There were also limitations to the model testing procedures. These data were treated as cross-sectional data and hence no definitive statements about cause and effect relationships can be made. More advanced techniques are available for modelling data over time, however, a larger sample size would be required. Another limitation is that this model testing only tested the hypotheses as stated in the Self-Help Model. No other approaches to improving the fit of the model to the data were done such as theory trimming or conducting a competitive test of different models. Hence, a better fitting model than the model tested in this study may exist for these data.

Conclusion

The primary purpose of this study was to evaluate the effectiveness of a community-based psychoeducation program for the self-management of chronic pain. The results of the randomized clinical trial of the CPSMP demonstrated the overall positive impact of the program on a number of pain-related and other quality of life variables. The second purpose of the study was to test whether the hypotheses in the Self-Help Model were sup ported by data from this study. Overall, the two model tests conducted in this study supported the overall constructs and hypothesized pattern of relationships of the Self-Help Model. The findings of this study were discussed, implications for clinical practice and recommendations for future research were presented and the strengths and limitations of the study were reviewed.

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Appendix A

Sample Size Calculations

$$N = [(1/q_1 + 1/q_2)\, S^2\, (z_\alpha + z_\beta)^2] \div E^2$$

q_1 = proportion of subjects in group 1
q_2 = proportion of subjects in group 2
S = standard deviation of the mean change score
z_α = standard normal deviate for alpha (1.96 when $\alpha = 0.05$)
z_β = standard normal deviate for beta (0.84 when $\beta = 0.20$)
E = mean change attributable to the intervention

Pain Rating Scale (0 - 10 scale)*: 4-month mean change = -0.98 with a standard deviation of 2.085

$N = 4 \times (2.085)^2 \times (1.96 + .84)^2 \div (.98)^2$
$N = 142$

Depression SF-BDI (0-39)*: 4-month mean change = -1.23 with a standard deviation of 2.88

$N = 4 \times (2.88)^2 \times (1.96 + .84)^2 \div (-1.23)^2$
$N = 172$

* Scores taken from: Lorig, K., Chastain, R., Ung, E., Shoor, S. & Holman, H. (1989). Development and evaluation of a scale to measure perceived self- efficacy in people with arthritis. *Arthritis and Rheumatism, 32*, 37-44.

Appendix B
Letter to Health Professionals for Recruitment of Subjects

Dear Colleague:

This is a formal request to ask your assistance in recruiting clients for a research study entitled: A Randomized Clinical Trial of a Community-Based Nursing Intervention for Persons Experiencing Chronic Non-Malignant Pain. The study is being conducted by me, Sandra LeFort, as part of Ph.D. studies at McGill University.

As part of the study, a 6-week education program (2 hours a week) is being offered to people living with a chronic pain problem. The education program is meant to complement ongoing therapy, not to replace therapy. All program participants receive a packet of information that includes a 150-page Pain Management Workbook, an audio relaxation tape, and other information about nutrition and fitness. There is no charge to patients for attending the program.

Individuals are eligible for the study if they meet the following criteria:

1. Men and women over 18 years of age.

2. Have had an idiopathic pain problem for more than 3 months. By idiopathic, I mean any chronic pain condition where there is no identified disease or pathological process causing the pain. For example, those with arthritis or arthritis-related conditions would be in-eligible because arthritis is a progressive disease process. Those with chronic pain due to an injury of some sort or unknown specific cause would be eligible. Therefore, most individuals with chronic back or neck pain, headache, reflex sympathetic dystrophy, or a variety of other non-specific pain problems would be eligible. The only reason I am excluding the arthritis group is because an education program is already in place for them (The Arthritis Self-Management Program through the Arthritis Society).

3. Be able to read and speak English. There are a number of questionnaires to complete that are written at about the grade 8 level (takes about 45 minutes). Therefore, subjects need to be literate. In addition, the education program involves readings, so it is important that people can read.

4. Must be free of major psychiatric or cognitive disorder.

5. Is not currently attending a structured education program for pain management. Those attending a support group would be eligible.

A brief summary of the project is enclosed. Ethical approval for the study has been received from three institutions: McGill University School of Nursing Human Ethics Committee; Memorial University Faculty of Medicine Human Ethics Committee; Grace General Hospital Human Ethics Committees. The study is also funded by Health and Welfare Canada (NHRDP).

Potential subjects for the study are being recruited from hospital chronic pain outpatient clinics, and from various physician, physiotherapy, and other health-related clinics in the city. At present, the education sessions are being held in a comfortable, easily accessible room at the Grace Hospital. There will be both evening and day classes and there is lots of parking. Because over 100 subjects are needed for the study, the study will be ongoing for a least the next year.

If you are interested in letting some of your patients know about the study, here is a suggested approach:

1. Give eligible, interested clients the enclosed letter entitled "Explanation of Nursing Research Study".

2. If they are interested in knowing more about the study and if they agree, you can take their name and phone number and pass this on to me at at the School of Nursing or at at home. Or, alternately they can call me themselves.

When patients phone, the study is explained in more detail and if they are interested, an appointment is scheduled at the Grace. At this initial interview, they complete the informed consent and the questionnaires. They are then assigned to one of the groups.

Thanks very much for your attention to this request. If you have other suggestions for recruitment or if you wish to talk with Sandra or Dr. Kamra, please call anytime.

Sincerely

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Appendix B (Cont.)

Explanation of Nursing Research Study

Hello!

We wanted to let you know that a nurse who has worked with people who have a persistent pain problem is conducting a research study. The nurse's name is Sandra LeFort and she is doing this research as part of her work for a doctoral degree from McGill University. Her project involves offering an education program called The Chronic Pain Self-Management Program for 2 hours a week for 6 weeks. The program is held at the Grace Hospital and there are both day and evening classes. The purpose of the study is to examine whether participating in the program helps people learn how to better manage their pain problem on a day-to-day basis. The program is free of charge and you will receive a pain management workbook, a relaxation audiotape as well as other information.

If you are interested in hearing more about this project, we need your permission to give her your name and phone number so that she can call you. Or, if you prefer you can call her yourself at and leave a message. She will get right back to you to explain the study and the chronic pain program in detail to you, and then you can decide if you are interested in participating. We want to let you know that you are under no obligation to to allow us to release your name and phone number. However, your participation would be greatly appreciated. Thank you for your attention.

Appendix C

Telephone Protocol for Pain Clinic Nurse
Permission for Researcher to Contact Subjects

Hello!

I am calling from Dr. Kamra's office at the Pain Clinic of the Grace General Hospital. He wanted to let you know that a nurse who has worked with people who have a persistent pain problem is conducting a research study. The nurse's name is Sandra LeFort and she is doing this research as part of her work for a doctoral degree from McGill University. Her project involves offering a group education program called The Chronic Pain Self-Management Program for 2 hours a week for 6 weeks. The program is held at the Grace Hospital and there are both day and evening classes. The purpose of the program is to help people learn how to better manage their pain problem day-to-day. The program is free of charge and you will receive a pain management workbook, a relaxation audiotape as well as other information.

If you are interested in hearing more about this project, we need your permission to give her your name and phone number so that she can call you. She will explain the study and the pain program in detail to you, and then you can decide if you are interested in participating.

We want to let you know that you are under no obligation to allow us to release your name and phone number. However, your participation would be greatly appreciated. Thank you for your attention.

Appendix D

Follow-up Letter to Encourage Completion of Posttest Instruments

Dear

Because we have been unable to contact you by phone to arrange an appointment, I have enclosed a copy of the questionnaires that you completed three months ago for the Chronic Pain Study. Although I realize that this will take you some time to complete, I cannot stress how important it is for you to complete and then send it back to me in the stamped self-addressed envelope provided. From a scientific point of view, it is extremely important to have follow-up information about how you have been doing, whether or not you were in the Program or whether you attended any or just some of the sessions. If there is a problem with completing the questionnaires, please do not hesitate to contact one of my research assistants (Creina or Anne) at . If you have any other concerns, please contact me directly at .

I wish to thank you for your participation in the study thus far. Your contribution will help us better understand whether education programs like the Chronic Pain Self-Management Program are helpful for people.

Warmest regards,

Sandra M. LeFort, M.N., R.N.
Associate Professor, School of Nursing
Memorial University of Newfoundland

Appendix E

Letter of Permission to Adapt ASMP Program and Adapt SES Tool

Stanford Patient Education Research Center

Stanford University School of Medicine
Department of Medicine

1000 Welch Road, Suite 204
Palo Alto, California 94304
(415) 723-7935
(415) 723-9656 FAX

December 21, 1993

Sandra LeFort, PhD
111 Strawberry Marsh Road
St. John's, Newfoundland
Canada, A1B 2V7

Dear Sandra:

It certainly looks like you have done your homework. First, please feel free to change the ASM course in any way you see fit. I would like a copy of the revised course.

In making changes, I would urge you to maintain and enhance where possible the efficacy enhancing portions of the course. From all of our research, the enhancement of self-efficacy is probably more important than any content you may teach. Along this same vain I hope that you will measure changes in self-efficacy in your study. I think that you can make some wording changes to the arthritis self-efficacy pain scale to make it specific to pain and not arthritis. I am enclosing our article on that scale.

I would also urge you to look at one more sub study. We know that the Melzack, visual analogue and MOS scales all measure pain. What we do not know is how sensitive these scales are to change. This is especially true of the MOS pain scale. I would urge you to use several pain measures so that we can better learn the comparative qualities of these scales when used for behavioral interventions. I am sure that Dr. Melzack will have much more to say about this. For all of us who are doing behavioral pain research, this is a very important question and one that you can help answer.

Please let me know if there are any other ways in which I can help with your study. It sounds exciting. Best of luck. May the new year be one of joy and productivity.

Sincerely,

Kate Lorig , RN, DrPH
Sr. Research Scientist

Appendix F

CPSMP Workbook Acknowledgements and Table of Contents

Acknowledgements

Thanks to both Kate Lorig, R.N., Dr. P.H. who developed the Arthritis Self-Management Program and the Arthritis Foundation, Atlanta, Georgia for their permission to adapt the program for those with chronic pain.

Thanks to Kim Doyle, O.T., Jill Seviour, O.T., P.T., Ken Pike, and Sharon Fraser who all had a hand in helping me understand the Arthritis Self-Management Program.

Thanks to Chander Kamra, M.D., Kathleen Matthews, R.N., M.N., Lorraine Vardy, P.T., Jill Seviour, O.T., P.T., Kim Doyle, O.T., and Cathy Simmonds, P.T. who discussed ideas about the content of a program for people with chronic pain.

Many thanks to my husband, John W. Doyle, for his patience and expertise with the layout and graphics of this workbook.

A special thanks to the authors and publishers who gave permission to reprint and adapt chapters from existing publications:

Margaret Baim, R.N., M.S. and Loretta LaRoche, B.A. Jest 'n Joy (pp.266-283). In Herbert Benson, M. D. and Eileen M. Stuart, R.N., C., M.S. (Eds). *The Wellness Book. The Comprehensive Guide to Maintaining Health and Treating Stress-Related Illness.* © 1993 by Fireside. Reprinted by permission of the publisher.

Margaret A. Caudill, M.D., Ph.D. *Managing Pain Before It Manages You* (pp.18-37).© 1995 by The Guilford Press. Reprinted by permission of the publisher.

Penney Cowan. American Chronic Pain Association Workbook Manual (pp.109-113).© 1990 by ACPA, Inc. Reprinted by permission of the publisher.

Diane Harlowe M.S., O.T.R. and Patricia Beadles Yu, M.A. ROM Dance: A Range of Motion Exercise and Relaxation Program Second Edition (pp.92-109).© 1992 by St. Mary's Hospital Medical Center, Madison, WI. Reprinted with permission of the publisher.

Kate Lorig, R.N., Dr. P.H. and James Fries, M.D. *The Arthritis Helpbook Third Edition* (pp.27-34 & pp. 85-96). © 1990 by Addison- Wesley Publishing Company Inc. Reprinted by permission of the publisher.

Kate Reves, Ph.D. Getting a Good Night's Sleep. A self-Help Guide to Overcoming Difficulties in Sleeping. 1990 by Pain Clinic, West Wales General Hospital, Glangwili, Carmarthen, Dyfed, Wales. Reprinted with permission of the author.

Appendix F (Cont.)

Contents

Appendix G
Verification of Attendance at ASMP Leader Training Program

May 10, 1994

Dear Sandy,

Thank you for attending the ASMP Leader Training session. I hope that you enjoyed the three day blitz! I know that you won't be delivering the program as an ASMP Leader but I am quite sure that you will be a great advocate of it.

If, at any time, you have any questions about the program please do not hesitate to call me. By the way, I read somewhere that ...

Sincerely,

Sharon Fraser
Education Coordinator

P.S. If anyone that you are speaking to is interested in taking the ASMP have them call Pat Samson at The Arthritis Society (368-8190) and she will put their names on a waiting list.

5516 Spring Garden Rd. Halifax Nova Scotia B3J 1G6 Ph: (902) 429-7025

Appendix H

Study Participant No:____ Date: _____

General Information Questionnaire

Directions: For each of the following questions, please check (√) or write in the answers which best describe yourself. This information is confidential and will not be personally identified with you.

1. What is your age? _____ Years

2. What is your gender? Female_____ Male _____

3. What is your marital status? (Please check one)

_____ Married _____ Separated

_____ Cohabiting with a partner _____ Divorced

_____ Single _____ Widowed

4. Who are the others in your household? Select as many answers as apply to you.

_____ Spouse/Partner
_____ Child/Children Ages of children:_____
_____ Adult relative(s) or friend(s)
_____ Live alone
_____ Other. Please specify _____

5. What is your level of education? (Please check one).

_____ 8th grade or less
_____ Some high school
_____ High school graduate
_____ Trade/business school
_____ Some university
_____ University graduate

6. What is your occupation?

7. What is your current employment status? Check only one answer.

___ Employed full-time and working
___ Employed part-time and working
___ Employed full-time but unable to work due to chronic pain problem
___ Employed part-time but unable to work due to chronic pain problem
___ Unemployed due to chronic pain
___ Unemployed due to other reasons
___ Other. Please specify: _____

8. If you are not presently working at a job, are you receiving:

(a) .... Worker's Compensation Benefits? ___ Yes ___ No

(b) .... Other disability benefits? ___ Yes ___No

9. How long have you had your chronic pain problem? Please state in months or years.

10. Where in your body is your chronic pain located most of the time? Check as many body areas as apply to you.

_____ Head _____ Face _____ Neck _____ Shoulder(s)

_____ Upper arm(s) _____ Elbow(s) _____ Lower arm(s)

_____ Wrist(s) _____ Hand(s) _____ Finger(s)

_____ Upper back _____ Mid-back _____ Lower Back

_____ Buttocks _____ Upper leg (above the knee)

_____ Knee(s) _____ Lower legs (below the knee)

_____ Ankle(s) _____ Feet

_____ Other. Please specify:

11. What do you think first caused your pain problem?

_____ Lifting something

_____ A fall

_____ Struck by or against an object

_____ Twisting your body

_____ Just happened. Please explain.

_____ Other reason. Please explain.

12. Do you have any other medical conditions besides your chronic pain problem? Please specify.

13. (a) Do you currently take medication for your chronic pain problem?

_____ Yes _____ No

(b) If yes, please list the medications you take for your chronic pain and how often you take them:

Medication	How often

14(a). Have you ever had surgery for your chronic pain problem?
_____ Yes _____ No

(b). If yes, how many surgeries have you had?
_____ surgeries

(c). If yes, what kind of surgery did you have?

15. Have you visited a health professional in the past 30 days because of your chronic pain problem? Please specify the number of visits you made to each of the following health professionals.

_____ Family Doctor
_____ Medical Specialist
_____ Physiotherapist
_____ Occupational Therapist
_____ Registered Massage Therapist
_____ Chiropractor
_____ Acupuncturist
_____ Nurse
_____ Psychologist
_____ Other Please specify:

Appendix I

SF-MPQ

Instructions: This questionnaire asks about your TYPICAL pain over the past week. Below is a list of words that describe pain. Please read each word. If the word does not describe your typical pain in the past week, circle 0 under Does Not Apply. If the word does describe your typical pain in the past week, then place circle (1) for Mild, (2) for Moderate or (3) for Severe. Try not to skip any words.

	DOES NOT APPLY	MILD	MODERATE	SEVERE
THROBBING	0	1	2	3
SHOOTING	0	1	2	3
STABBING	0	1	2	3
SHARP	0	1	2	3
CRAMPING	0	1	2	3
GNAWING	0	1	2	3
HOT-BURNING	0	1	2	3
ACHING	0	1	2	3
HEAVY	0	1	2	3
TENDER	0	1	2	3
SPLITTING	0	1	2	3
TIRING/EXHAUSTING	0	1	2	3
SICKENING	0	1	2	3
FEARFUL	0	1	2	3
PUNISHING-CRUEL	0	1	2	3

Appendix J
Letter of Permission for SF-MPQ

111 Strawberry Marsh Road
St. John's, NF
A1B 2V7, Canada
Phone: (709) 753-2405
Fax: (709) 753-6266
E-Mail: SLeFort@kean.ucs.mun.ca

Feb. 16, 1995

Ronald Melzack, Ph.D.
Department of Psychology
1205 Dr. Penfield Ave., Room W8-1
Montreal, Quebec
H3A 1B1

Dear Dr. Melzack:

Greetings of the New Year, even if it is a bit late.

Now that my study is through the three ethical review committees, I am now writing to everyone to ask for formal permission to use and reprint their measures in my study. As you know, I will be using the Short Form MPQ originally published in Pain, Volume 30, in 1987. Could you kindly send a letter indicating your permission for me to do so for purposes of my study entitled:

"A Randomized Clinical Trial of a Community-Based Nursing Intervention for Persons Experiencing Chronic Non-Malignant Pain".

Thanks a lot!

Warmest Regards,

Sandra.
Sandra M. LeFort, M.N., R.N.
Doctoral Candidate, School of Nursing, McGill University

Feb 28, 1995

Dear Sandra:
It's always a pleasure to hear from you! And it's a pleasure too to give you permission to use the SF-MPQ for your research.

With warmest wishes
Ron Melzack

Appendix K

BDI-SF

Instructions: This questionnaire contains groups of statements. Please read the entire group of statements in each category. then pick out the one statement in that group which best describes the way you feel today, that is, right now! Circle the number beside the statement you have chosen. If several statements in the group seem to apply equally well, circle each one.

Be sure to read all the statements in the group before making your choice.

A. (Sadness)

3 I am so sad or unhappy that I can't stand it.

2 I am blue or sad all the time and I can't snap out of it.

1 I feel sad or blue.

0 I do not feel sad.

B. (Pessimism)

3 I feel that the future is hopeless and that things cannot mprove.

2 I feel I have nothing to look forward to.

1 I feel discouraged about the future.

0 I am not particularly pessimistic about the future.

C. (Sense of failure)

3 I feel I am a complete failure as a person.

2 As I look back on my life, all I can see is a lot of failures.

1 I feel I have failed more than the average person.

0 I do not feel like a failure.

D. (Dissatisfaction)

3 I am dissatisfied with everything.

2 I don't get satisfaction out of anything anymore.

1 I don't enjoy things the way I used to.

0 I am not particularly dissatisfied.

BDI - SF (cont.)

E. (Guilt)

3 I feel as though I am very bad or worthless.

2 I feel quite guilty.

1 I feel bad or unworthy a good part of the time.

0 I don't feel particularly guilty.

F. (Self-dislike)

3 I hate myself.

2 I am disgusted with myself.

1 I am disappointed in myself.

0 I don't feel disappointed in myself.

G. (Self-harm)

3 I would kill myself if I had the chance.

2 I have definite plans about committing suicide.

1 I feel I would be better off dead.

0 I don't have any thoughts of harming myself.

H. (Social withdrawal)

3 I have lost all of my interest in other people and don't care about them at all.

2 I have lost most of my interest in other people and have little feeling for them.

1 I am less interested in other people than I used to be.

0 I have not lost interest in other people.

I. (Indecisiveness)

3 I can't make any decisions at all anymore.

2 I have great difficulty in making decisions.

1 I try to put off making decisions.

0 I make decisions about as well as ever.

BDI - SF (cont.)

J. (Self-image change)

3 I feel that I am ugly or repulsive-looking.

2 I feel that there are permanent changes in my appearance and they make me look unattractive.

1 I am worried that I am looking old or unattractive.

0 I don't feel that I look any worse than I used to.

K. (Work difficulty)

3 I can't do any work at all.

2 I have to pushc myself very hard to do anything.

1 It takes extra effort to get started at doing something.

0 I can work as well as before.

L. (Fatigability)

3 I get too tired to do anything.

2 I get tired from doing anything.

1 I get tired more easily than I used to.

0 I don't get any more tired than usual.

M. (Anorexia)

3 I have no appetite at all anymore.

2 My appetite is much worse now.

1 My appetite is not as good as it used to be.

0 My appetite is no worse than usual.

Letter of Permission for BDI - SF

FEB 1995

111 Strawberry Marsh Road
St. John's, NF
A1B 2V7
Phone: (709)
Fax: (709)
E-Mail: SLeFort@kean.ucs.mun.ca

Feb. 16, 1995

McGraw Hill Health Care Publications
Editoral and Advertising Offices
Permissions Editor
4530 West 77th Street
Minneapolis, MINN
55435

Dear Permissions Editor:

This letter is to formally request your permission to use and reprint the short-form version of the Beck Depression Inventory developed by Arron T. Beck and R. W. Beck (Postgraduate Medicine, December, 1972, pp. 81-85). I will be using the inventory in my PhD study entitled: A Randomized Clinical Trial of Community-Based Nursing Intervention for Persons Experiencing Chronic Non-Malignant Pain. I am a Ph.D. student at the School of Nursing, McGill University.

I have also written to Dr. Arron Beck directly to solicit his permission as well.

Thank you for your attention to this matter.

Sincerely,

Sandra M. LeFort

Sandra M. LeFort, M.N., R.N.
Doctoral Candidate, School of Nursing, McGill University

March 1, 1995

Permission is granted for your request stated above.

Sincerely,

Geri Hoag

Geri Hoag, Permissions Editor
for POSTGRADUATE MEDICINE

Appendix M

PPSI & PDI

Here is a list of questions about your pain. Please read each question carefully including the words at the beginning and end of each line. Then draw a mark at the point on the line that indicates where you see yourself between two end points. Your mark can be any place on the line.

Here is an example:

How happy are you with the weather?

NOT HAPPY AT ALL ——————————————— HAPPIEST POSSIBLE

If you put your line where we did, this indicates that you are not very happy about the weather (about 25% happy).

Answer each question as best you can. There are NO right or wrong answers.

---

1. How severe a problem is chronic pain in your life?

NOT a Problem AT ALL ——————————————— MAJOR INCAPACITATING PROBLEM

2. As a result of your chronic pain problem, how much do you have to depend or rely on others in your daily life?

NOT AT ALL DEPENDENT ON OTHERS ——————————————— EXTREMELY DEPENDENT ON OTHERS

Appendix N
D-SOPA

Instructions: Please read each statement. Take your time and think about what each statement says. Place an "X" under the column that best indicates how much you agree or disagree with each statement TODAY.

1. I do not consider my pain to be a disability.

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
(4)	(3)	(2)	(1)	(0)
____	____	____	____	____

2. If my pain continues at its present level, I will be unable to do my work.

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
(0)	(1)	(2)	(3)	(4)
____	____	____	____	____

3. My pain problem does not need to interfere with my activity level.

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
(4)	(3)	(2)	(1)	(0)
____	____	____	____	____

4. I will get a job to earn money regardless of how much pain I feel.

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
(4)	(3)	(2)	(1)	(0)
____	____	____	____	____

5. I consider myself to be disabled.

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
(0)	(1)	(2)	(3)	(4)
____	____	____	____	____

6. My pain does not stop me from leading a physically active life.

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
(4)	(3)	(2)	(1)	(0)
_____	_____	_____	_____	_____

7. I can do nearly everything as well as I could before I had a pain problem.

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
(4)	(3)	(2)	(1)	(0)
_____	_____	_____	_____	_____

8. Pain will never stop me from doing what I really want to do.

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
(4)	(3)	(2)	(1)	(0)
_____	_____	_____	_____	_____

9. Whether or not a person is disabled by pain depends more on your attitude than the pain itself.

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
(4)	(3)	(2)	(1)	(0)
_____	_____	_____	_____	_____

10. My pain would stop anyone from leading an active life.

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
(0)	(1)	(2)	(3)	(4)
_____	_____	_____	_____	_____

Appendix O

Permission to use SOPA

UNIVERSITY OF WASHINGTON
SEATTLE, WASHINGTON 98195

School of Medicine
Department of Rehabilitation Medicine, RJ-30

February 14, 1994

Sandra M. LeFort, M.N., R.N.
Ph.D. Candidate
School of Nursing
McGill University
111 Strawberry Marsh Road
St. John's, Newfoundland
CANADA A1B 2V7

Dear Sandra M. LeFort:

Enclosed please find the most recent version of the SOPA.

As indicated in the description of the SOPA, if you do collect responses to a number of SOPAs, have descriptive information concerning the patients/clients you use the measure with, and are willing to share that information, I would appreciate being able to see those data and possibly use them in future descriptions/manuals of the measure. Certainly if you publish any articles in which you use the measure, I would appreciate a preprint/reprint of the paper.

Good luck, and I hope you find the SOPA helpful.

Sincerely,

Mark P. Jensen, Ph.D.
Assistant Professor

BB919 Health Sciences Building

Appendix P

MUIS-Community Form

Instructions: Please read each statement. Take your time and think about what each statement says. Then place an "X" under the column that most closely measures how you are feeling TODAY. If you agree with a statement, then you would mark under either "Strongly Agree" or "Agree". If you disagree with a statement, then mark under either "Strongly Disagree" or "Disagree". If you are undecided about how you feel, then mark under "Undecided" for that statement. Please respond to every statement.

1. I don't know what is wrong with me.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)
____	____	____	____	____

2. I have a lot of questions without answers.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)
____	____	____	____	____

3. I am unsure if my condition is getting better or worse.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)
____	____	____	____	____

4. It is unclear how bad my pain will be.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)
____	____	____	____	____

5. The explanations they give me about my condition seem hazy to me.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)
____	____	____	____	____

6. The purpose of each treatment is clear to me.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)
____	____	____	____	____

7. My symptoms continue to change unpredictably.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)
____	____	____	____	____

8. I understand everything explained to me.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)
____	____	____	____	____

9. The doctors say things to me that could have many meanings.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)
____	____	____	____	____

10. My treatment is too complex to figure out.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)
____	____	____	____	____

11. It is difficult to know if the treatments or medications I am getting are helping.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)
____	____	____	____	____

12. Because of the unpredictability of my condition, I cannot plan for the future.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)
____	____	____	____	____

13. The course of my chronic pain keeps changing. I have good days and bad days.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)
____	____	____	____	____

14. I have been given many different opinions about what is wrong with me.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)
____	____	____	____	____

15. It is not clear what is going to happen to me.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)
____	____	____	____	____

16. The results of my tests are inconsistent.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)
____	____	____	____	____

17. The effectiveness of the treatment is undetermined.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)
____	____	____	____	____

18. Because of my condition, what I can do and cannot do keeps changing.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)
____	____	____	____	____

19. I'm certain they will not find anything else wrong with me.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)
____	____	____	____	____

20. The treatment I am receiving has a known probability of success.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)
____	____	____	____	____

21. They have not given me a specific diagnosis.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)
____	____	____	____	____

22. The seriousness of my condition has been determined.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)
____	____	____	____	____

23. The doctors and nurses use everyday language so I can understand what they are saying.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)
____	____	____	____	____

Appendix Q

Permission to use MUIS-C

Request Form
MUIS-C

I request permission to copy the Mishel Uncertainty in Illness Scale Community Form for use in my research entitled, A Randomized Clinical Trial of a Community-Based Nursing Intervention for those Experiencing Chronic Non-Malignant Pain

In exchange for this permission, I agree to submit to Dr. Mishel a printout of the uncertainty data or a 5¼ inch disk containing the data with a data dictionary. The data must contain information in each subject's age, sex, education, and diagnosis, along with the raw data on the uncertainty scale. This data will be used to establish a normative data base for clinical populations. No other use will be made of the data submitted. Credit will be given to me in reports of normative statistics that make use of the data I submitted for pooled analyses. I also agree to send Dr. Mishel a copy of my findings. I understand that my report will be used to compile information on the theory of uncertainty in illness. Credit will be given to me in any reports referring to my findings.

Linda L Fox
(Signature)

March 4, 1994.
(Date)

Position and Full Address of Investigator.

Doctoral Candidate
School of Nursing
McGill University
c/o 111 Strawberry Marsh Rd., St. John's, NFLD. Canada A1B 2V7

Permission is hereby granted to copy the MUIS for use in the research described above.

Merle Mishel
Merle H. Mishel

3/24/94
(Date)

Please send two signed copies of this form to Merle H. Mishel, Ph.D., College of Nursing, University

Merle H. Mishel, PhD, FAAN
School of Nursing
CB #4760, Carrington Hall
University of North Carolina
Chapel Hill, NC 27599-7460

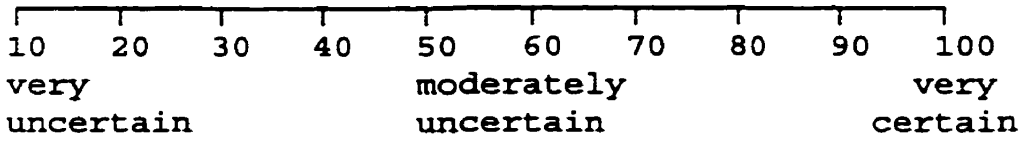
MHM:pw
revised 1/89

Appendix R

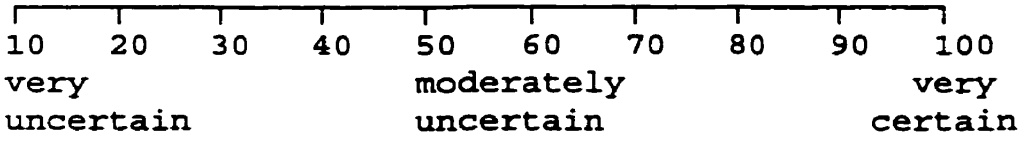
SES

In the following questions, we'd like to know how much control you feel you have over your pain and other symptoms. For each of the following questions, please circle the number which corresponds to how certain you are that you can now perform the following tasks.

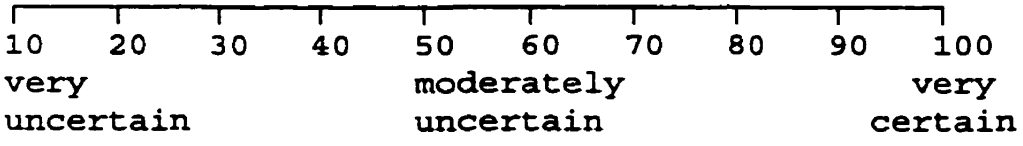
1. How certain are you that you can decrease your pain quite a bit?



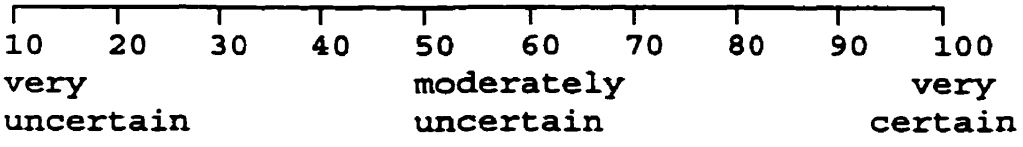
2. How certain are you that you can continue most of your daily activities?



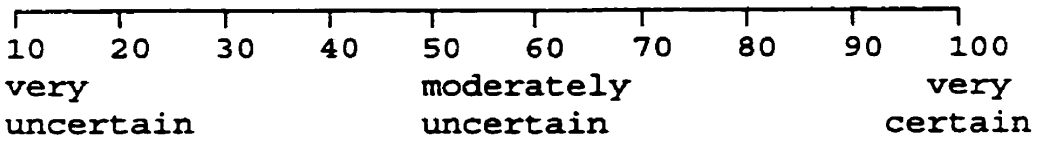
3. How certain are you that you can keep your chronic pain from interfering with your sleep?



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

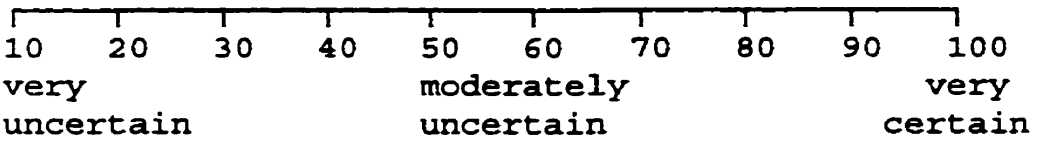


5. How certain are you that you can make a large reduction in your chronic pain by using methods other than taking extra medication?

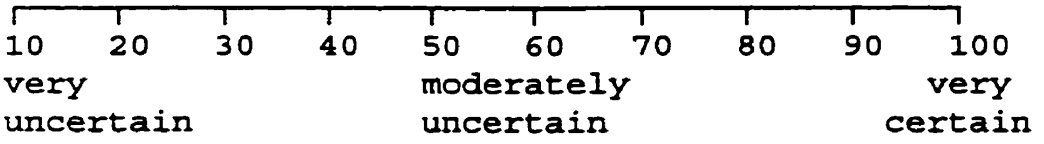


SES (Cont.)

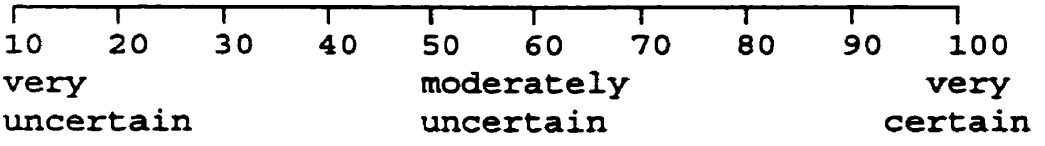
6. How certain are you that you can control your fatigue?



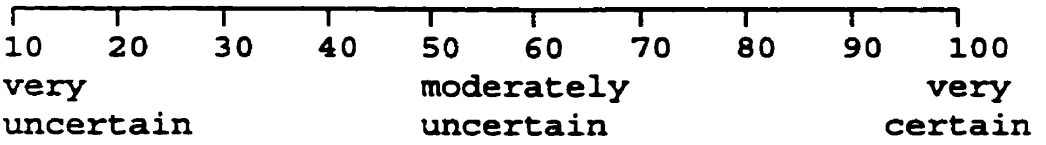
7. How certain are you that you can regulate your activity so as to be active without aggravating your chronic pain?



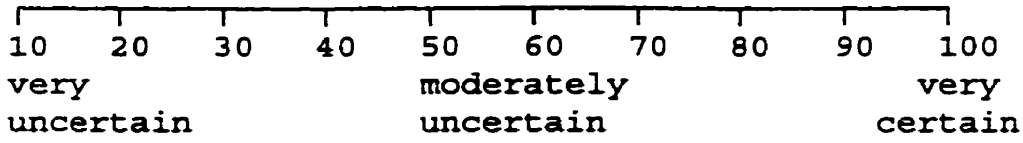
8. How certain are you that you can do something to help yourself feel better if you are feeling blue?



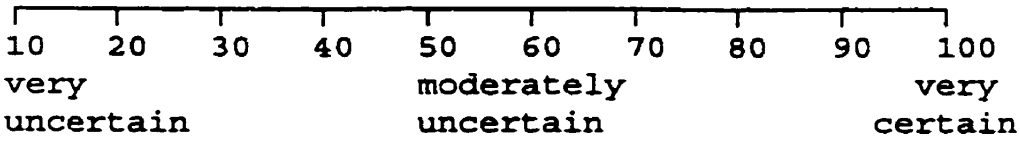
9. As compared to other people with chronic pain like yours, how certain are you that you can manage chronic pain during your daily activities?



10. How certain are you that you can manage your chronic pain symptoms so that you can do the things you enjoy doing?



11. How certain are you that you can deal with the frustration of chronic pain?



Appendix S
SCS

Instructions: The following statements are designed to find out how different people view their thinking and their behavior. Read each of the following statements and place a mark at a point on the line that indicates how much you feel the statement applies to you. A statement may range from "Not true about me" to "True about me".

Here is an example:

I tend to rush into things, rather than stop and think carefully about what I am doing.

NOT TRUE About Me ——————————————— TRUE About Me

If you put a mark where we did, it means that the statement applies to you <u>to a certain extent</u>, but not completely. Over half the time (about 70%), you rush into things, but sometimes you do stop and think before acting. Answer each item as best you can. If some statements do not apply directly to you, try to put yourself in the situation and then answer on that basis. There are no right or wrong answers.

---

1. When I do a boring job, I think about the less boring parts of the job and the reward I will receive once I am finished.

NOT TRUE About Me ——————————————— TRUE About Me

2. When I have to do something that makes me anxious, I try to visualize how I will overcome my anxiety while doing it.

NOT TRUE About Me ——————————————— TRUE About Me

3. Often by changing my way of thinking, I am often able to change my feelings about almost anything.

NOT TRUE About Me ——————————————— TRUE About Me

4. I often find it difficult to overcome my feelings of nervousness and tension without any outside help.

NOT TRUE About Me ——————————————— TRUE About Me

5. When I am feeling depressed. I try to think about pleasant things.

NOT TRUE About Me ——— TRUE About Me

6. I cannot help thinking about mistakes I have made in the past.

NOT TRUE About Me ——— TRUE About Me

7. When I am faced with a difficult problem. I try to approach its solution in a systematic way.

NOT TRUE About Me ——— TRUE About Me

8. I usually do my duties quicker when someone is pressuring me.

NOT TRUE About Me ——— TRUE About Me

9. When I am faced with a difficult decision. I prefer to postpone making a decision even if I know all the facts.

NOT TRUE About Me ——— TRUE About Me

10. When I have difficulty concentrating. I look for ways to increase my concentration.

NOT TRUE About Me ——— TRUE About Me

11. When I plan to work. I first remove all the things from my workspace that are not relevant to the task.

NOT TRUE About Me ——— TRUE About Me

12. When I try to get rid of a bad habit. I first try to find out all the reasons why I have the habit.

NOT TRUE About Me ——— TRUE About Me

13. When an unpleasant thought is bothering me. I try to think about something pleasant.

NOT TRUE About Me ——— TRUE About Me

14. If I smoked two packs of cigarettes a day. I probably would need outside help to stop smoking.

NOT TRUE About Me ——— TRUE About Me

15. When I feel down. I try to act cheerful so that my mood will change.

NOT TRUE About Me ——— TRUE About Me

16. If they were available. I would take a tranquilizer whenever I felt tense and nervous.

NOT TRUE About Me ——— TRUE About Me

17. When I am depressed. I try to keep myself busy with things I like.

NOT TRUE About Me ——— TRUE About Me

18. I tend to postpone unpleasant tasks or duties even if I could perform them immediately.

NOT TRUE About Me ——— TRUE About Me

19. I need outside help to get rid of some of my bad habits.

NOT TRUE About Me ——— TRUE About Me

20. When I find it difficult to settle down and do a certain job. I look for ways to help me settle down.

NOT TRUE About Me ——— TRUE About Me

21. Although it makes me feel bad. I cannot help thinking about all sorts of possible catastrophies in the future.

NOT TRUE About Me ——— TRUE About Me

22. First of all I prefer to finish a job that I have to do and then start doing the things I really like.

NOT TRUE About Me ——————————————— TRUE About Me

23. When I feel physical pain in a certain part of my body, I try not to think about it.

NOT TRUE About Me ——————————————— TRUE About Me

24. My self-esteem increases once I am able to overcome a bad habit.

NOT TRUE About Me ——————————————— TRUE About Me

25. In order to overcome bad feelings that accompany failure, I often tell myself that things are not so bad and that I can do something about it.

NOT TRUE About Me ——————————————— TRUE About Me

26. When I feel that I am too impulsive and rush into things, I tell myself to stop and think before I do anything.

NOT TRUE About Me ——————————————— TRUE About Me

27. Even when I am terribly angry at someone, I consider my actions very carefully.

NOT TRUE About Me ——————————————— TRUE About Me

28. Facing the need to make a decision, I usually find out all the alternatives instead of deciding quickly and spontaneously without thought.

NOT TRUE About Me ——————————————— TRUE About Me

29. Usually I first do the things I really like to do even if there are more urgent things to do.

NOT TRUE About Me ——— TRUE About Me

30. When I realize that I cannot help but be late for an important meeting, I tell myself to keep calm.

NOT TRUE About Me ——— TRUE About Me

31. When I feel pain in my body, I try to divert my thoughts from it.

NOT TRUE About Me ——— TRUE About Me

32. I usually plan my work when faced with a number of things to do.

NOT TRUE About Me ——— TRUE About Me

33. When I am short of money, I decide to record all my expenses in order to budget carefully in the future.

NOT TRUE About Me ——— TRUE About Me

34. If I find it difficult to concentrate on a certain job, I divide it into smaller sections.

NOT TRUE About Me ——— TRUE About Me

35. Quite often, I cannot overcome unpleasant thoughts that bother me.

NOT TRUE About Me ——— TRUE About Me

36. When I am hungry and have no opportunity to eat, I try to divert my thoughts from my stomach or try to imagine that I am satisfied.

NOT TRUE About Me ——— TRUE About Me

Association for Advancement of Behavior Therapy
Publications Department
305 Seventh Avenue, New York, NY 10001 (212) 647-1890 FAX (212) 647-1865

Linette Peterson, Ph.D.
Publications Coordinator

David Teisler, CAE
Director of Publications

February 17, 1995

Sandra M. LeFort
McGill University
111 Strawberry Marsh Road
St. John's NF
ALB 2V7
CANADA

Re: Permission

SOURCE: Michael Rosenbaum, A Schedule for Assessing Self-Control Behaviors: Preliminary Findings, from Behavior Therapy, Volume 11 (1980) Materials: pages 109-121

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David Teisler, CAE
Director of Communications

dd/permiss

Appendix U
IARB

The purpose of this questionnaire is to find out about changes in your usual activities as a result of your chronic pain. Please read each statement carefully, including the words at the beginning and end of each statement. Then draw a mark at the place on the line that indicates where you see yourself between the two end points. Your mark can be put any place on the line.

Here is an example:

My chronic pain interferes with my sleep to the

GREATEST extent possible ——————————————— LEAST extent possible

When judging your answer to this statement, you must consider the degree to which your chronic pain affects your sleep. The above mark which is closer to "Least extent possible" indicates that sleep is a little bit affected by pain, about 10%.

Here is another example:

I spend time looking after myself.

NOT TRUE about me ——————————————— TRUE about me

The above mark is about mid-way between the two end point. So the statement is true about 50% true about me.

Please respond to every statement according to how you feel TODAY. There are NO right or wrong answers.

---

1. Because of my chronic pain, I go out to social events

LESS than I used to ——————————————— SAME or MORE than I used to

2. Because of my chronic pain, I am doing shopping and errands

LESS than I used to ——————————————— SAME or MORE than I used to

3. I am able to participate in the social activities that I want to do

LESS than I used to ——————————— SAME or MORE than I used to

4. I am doing the community activities that I want to do

LESS than I used to ——————————— SAME or MORE than I used to

5. I am doing the recreational activities that I like to do

LESS than I used to ——————————— SAME or MORE than I used to

6. I stay home

MORE than I used to ——————————— SAME or LESS than I used to

7. My chronic pain has disrupted my friendships to the

HIGHEST degree possible ——————————— LEAST degree possible

8. Because of my chronic pain, I stay away from the rest of my family to the

HIGHEST degree possible ——————————— LEAST degree possible

9. I act irritable toward family members (for example, snap at them, criticize them, pick fights) to the

GREATEST extent possible ——————————— LEAST extent possible

10. My chronic pain interferes with the regular daily work around the house I usually do (for example, yard work, repairs, cooking, cleaning, etc.)

HIGHEST degree possible ——————————— LEAST degree possible

11. When I go out, I stay away from home for the shortest period of time possible.

TRUE about me ——————————————— NOT TRUE about me

12. My chronic pain interferes with the length of visits with my friends to the

GREATEST extent possible ——————————————— LEAST extent possible

13. My chronic pain interferes with the things I usually do for fun to the

GREATEST extent possible ——————————————— LEAST extent possible

14. My chronic pain interferes with the things I usually do to take care of my children or family to the

GREATEST extent possible ——————————————— LEAST extent possible

15. I have influence in my family appropriate to my place in the family (for example, as a wife, husband, parent, son, daughter) to the

LEAST extent possible ——————————————— GREATEST extent possible

16. I am involved in a variety of rewarding social activities to the

LEAST extent possible ——————————————— GREATEST extent possible

17. My leisure time is occupied with a variety of rewarding activities to the

LEAST extent possible ——————————————— GREATEST extent possible

18. My chronic pain problem has affected my sexual activity to the

GREATEST extent possible ——————————————— LEAST extent possible

19. Since my chronic pain problem, I am now involved in only inactive recreational activities (for example, watching T.V. or videos, playing cards, reading).

TRUE about me ——————————————— NOT TRUE about me

20. Because of my chronic pain I ask others in the family to do my usual work around the house to the

GREATEST extent possible ——————————————— LEAST extent possible

21. My chronic pain makes my work (at my job, at home, at school or where I volunteer) difficult to the

HIGHEST degree possible ——————————————— LEAST degree possible

22. Because of my chronic pain, I am absent from my job or am unable to do my work (at home, at school, or where I volunteer) to the

GREATEST extent possible ——————————————— LEAST extent possible

23. In spite of my chronic pain, I do my work carefully and accurately.

NOT TRUE about me ——————————————— TRUE about me

24. Because of my chronic pain, making the extra effort to excel at work or home activities occurs to the

LEAST extent possible ——————————————— GREATEST extent possible

25. Because of my chronic pain, I act irritable towards people at work, school, neighbours, and others (for example, I snap at them, give short answers, criticize them easily) to the

GREATEST extent possible ——————————————— LEAST extent possible

26. My chronic pain interferes with my work (job, school, volunteer work) to the

GREATEST extent possible ——————————————— LEAST extent possible

27. Every day I do extra things to keep myself well.

NOT TRUE about me ——————————————— TRUE about me

28. Health care professionals are my only source of help for staying well.

TRUE about me ——————————————— NOT TRUE about me

29. I keep track of how well a treatment works for me.

NOT TRUE about me ——————————————— TRUE about me

30. I ignore my health.

TRUE about me ——————————————— NOT TRUE about me

31. I follow guidelines for exercise that are suitable for me.

NOT TRUE about me ——————————————— TRUE about me

32. I do nothing to keep well.

TRUE about me ——————————————— NOT TRUE about me

33. I make use of a number of resources besides health care professionals to keep myself well (for example, books, classes, sharing with others).

NOT TRUE about me ——————————————— TRUE about me

34. I seldom follow guidelines for good nutrition.

TRUE about me ——————————————— NOT TRUE about me

35. I pay attention to how my body feels.

NOT TRUE about me ——————————————— TRUE about me

36. I don't read about what to do to stay well.

TRUE about me ——————————————— NOT TRUE about me

37. I find ways in addition to what health care professionals advise to keep myself in the best possible health.

NOT TRUE about me ——————————————— TRUE about me

38. I take medication not prescribed by my doctor.

TRUE about me ——————————————— NOT TRUE about me

39. I attempt to keep myself well.

NOT TRUE about me ——————————————— TRUE about me

40. I spend time on everything except trying to stay well.

TRUE about me ——————————————— NOT TRUE about me

41. I make time to get enough exercise.

NOT TRUE about me ——— TRUE about me

42. I seldom make the effort to eat foods that are good for me (eg.. foods that are low in fat and salt. fresh fruits and vegetables. etc.).

TRUE about me ——— NOT TRUE about me

43. I spend time keeping myself well.

NOT TRUE about me ——— TRUE about me

44. I make my own adjustments in how much medication I take.

TRUE about me ——— NOT TRUE about me

45. I keep up to date on ways to stay well.

TRUE about me ——— NOT TRUE about me

College of Nursing

THE UNIVERSITY OF
ARIZONA.
HEALTH SCIENCES CENTER

Tucson, Arizona 85721
(602) 626-6154

February 28, 1995

Sandra M. LeFort, MN, RN
Doctoral Candidate
School of Nursing
McGill University
111 Strawberry Marsh Road
St. John's, Newfoundland
CANADA A1B 2V7

Dear Ms LeFort:

This letter is to provide permission for your use of the 46-item Inventory of Adult Role Behavior (IARB) measure I have developed as a measure of self-help. I am very interested in your study, "A Randomized Clinical Trial of a Community-Based Nursing Intervention for Persons Experiencing Chronic Non-Malignant Pain," and am looking forward to hearing about your findings. Best wishes for the completion of your study. Please feel free to contact me should you require any additional information.

Sincerely,

Carrie Jo Braden

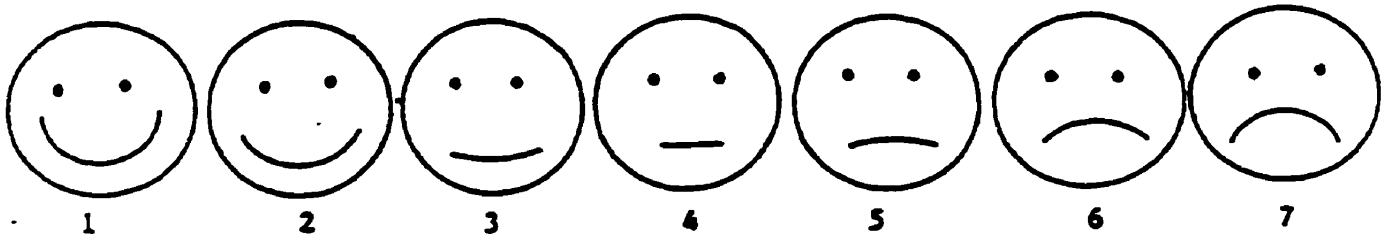
Carrie Jo Braden, PhD, FAAN
Associate Professor

CJB/rf

Appendix W

SLDS

Below are some faces expressing various feelings of satisfaction or dissatisfaction. Below each is a number. Indicate how you feel about different parts of your life by writing the number indicating your current feelings.



Which Face Comes Closest To Expressing How You Feel Today About:

A) **Your health?** ..... _____

B) **Your relations with your wife, husband, or partner (boyfriend or girlfriend)?** ..... _____

C) **Your relations with other relatives?** ..... _____

D) **Your relations with friends?** ..... _____

E) **Your body?** ..... _____

F) **Your ability to go about your daily activities?** .. _____

G) **Your job/school/household work?** ..... _____

H) **The way you spend your leisure time?** ..... _____

I) **Your appearance?** ..... _____

J) **How much physical strength you have?** ..... _____

K) **How comfortable overall you feel?** ..... _____

L) **Your chronic pain problem?** ..... _____

M) **Your ability to attain sexual satisfaction?** ..... _____

N) **Your ability to control your personal circumstances?** ..... _____

O) **The quality of your life?** ..... _____

P) **Your future?** ..... _____

Q) **How satisfied you feel with your life as a whole?** ..... _____

Appendix X
Corresponding regarding SLDS

JOHNS HOPKINS
UNIVERSITY

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Baltimore MD 21205
(410) 955-4074 / FAX (410) 955-1811
Department of Environmental Health Sciences
Division of Occupational Health
Health Psychology Program

April 26, 1994

Sandra M. LeFort, M.N., R.N.
McGill University School of Nursing
111 Strawberry Marsh Road
St. John's, Newfoundland
Canada A1B 2V7

Dear Ms. LeFort:

Thank you for your interest in my research on quality of life. I am enclosing reprint of my papers that deal with the various versions of the Satisfaction with Life Domains Scale (SLDS). Copies of the SLDS for mental patients and for BMT patients are also enclosed. I am not aware of any other papers on "role retention, and wondered if you had a reference to a publication describing Dr. Braden's theory or could give me her address.

I would be interested in hearing about the results of your research and ask that you keep me informed.

Sincerely,

Frank Baker

Frank Baker, Ph.D.
Professor

FB:cmb
Enclosures

Appendix Y

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 one)

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

(circle one number on each line)

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

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

(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 past 4 weeks, 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 3

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 2

Mild 3

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 3

Quite a bit 4

Extremely 5

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

(circle one number on each line)

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

10. During the 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.)?

(circle one)

All of the time 1

Most of the time 2

Some of the time 3

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 False	Definitely False
a. I seem to get sick a little easier than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

Appendix BB

Letter of Explanation for Pilot Study

HELLO!

I am a registered nurse and will soon be starting a research project with people who have a persistent pain problem here in St. John's. Before I begin the project, I need to have a group of volunteers fill out a number of questionnaires that I plan to use in the study. The questionnaires concern aspects of how pain affects your everyday life.

The reason why I am asking people living with pain to fill out these questionniares is to find out if there are any problems with the questionnaires. For example, some of the things I need to know are: Are the instructions explaining how to fill out the questionnaires clear? Are the questions easy to understand? Do the questions "make sense"? How long do the questionnaires take to fill out? Is it too tiring to fill them all out at once?

In order to answer these questions, I need 12 to 15 volunteers who have a persistent pain problem who are willing to give about 1 to 1½ hours of their time. I want to assure you that the information obtained from the questionniares will be completely confidential and anonymous. Your name will not appear on the forms at all. The information will only be used to improve the questionnaires so that the research study will be a better one.

If you have a persistent pain problem and are interested in volunteering let your physiotherapist or fitness instructor know. We will arrange for a group meeting after one of your sessions. Some of you may prefer to fill out the questionnaires at another more convenient time and place. That's O.K., too. I'm willing to go where ever is best for you.

Thank you for your consideration of this request. I really appreciate any time you could give to this project.

Sincerely,

Sandra LeFort, R.N., M.N.
Ph.D. Student in Nursing
McGill University

Appendix CC

CONSENT TO PARTICIPATE IN A NURSING RESEARCH STUDY

Title of Research Study
Evaluation of the Chronic Pain Self-Management Program

Investigators
Sandra LeFort, R.N., M.N., Associate Professor, School of Nursing, Memorial University of Newfoundland, St. John's, NF. Phone: (709)-
Dr. Kathleen Rowat, Associate Professor, School of Nursing, McGill University, Montreal, QC. Phone: (514)-
Katherine Gray-Donald, Associate Professor, School of Dietetics and Human Nutrition, McGill University, Montreal, QC. Phone: (514) -

Purpose and Background
People who experience chronic non-malignant pain sometimes have difficulty coping with the effects of pain on their everyday lives. The purpose of this study is to examine whether participating in the Chronic Pain Self-Management Program helps people learn how to better manage their pain problem on a day-to-day basis.

Procedures
If I agree to participate in this study, I understand that the following things will happen:

1. I will be asked to complete a series of questionnaires that relate to how I feel about my pain and its effects on my life. These questionnaires will take about 1 to 1½ hours to complete. If I find this too long, I do not have to answer all questionnaires at one sitting, but may complete the questionnaires over two sittings. While encouraged to answer all the questions, I am under no obligation to to do so. In addition, I will be asked to fill out these same questionnaires in 3 months.

2. I will attend the Chronic Pain Self-Management Program which consists of meeting with a nurse and 7 or 8 other people who have chronic pain for 2 hours each week for 6 weeks. One group of participants will begin the program in the next few weeks, and a second group will start 3 months from now. I will be assigned to one of these two groups. This will be determined by chance (random assignment). If I wish to bring a family member or friend with me to the program, I may do so.

3. I understand that the Chronic Pain Self-Management Program is an educational program. It emphasizes ways in which I may help myself to better handle my pain problem day to day. The classes include both discussion and practice. Topics include different ways to manage pain and fatigue, dealing with feelings, fitness and nutrition, medications, communicating with my family, and learning to set realistic goals.

Relaxation exercises will be practised in the class.

4. I understand that my attendance at the Chronic Pain Self-Management Program is not meant to replace my regular ongoing treatment. I should not change any aspect of my regular treatment without first talking to my doctor.

Potential Benefits
There are two potential benefits of participating in this study. By attending the Chronic Pain Self-Management Program, you may learn different ways of managing your pain problem, and feel more able to be involved in everyday activities. Secondly, the results of the study might help health care professionals better understand ways to help people with chronic pain in the future.

Potential Risks
There are no known risks to participating in the study and attending the Chronic Pain Self-Management Program. You might find, however, that some topics you hadn't thought about before may upset you. If this happens, you can call the nurse, the researchers who are conducting this study, or your doctor to discuss these concerns.

Cost
There is no charge for attending the Chronic Pain Self-Management Program.

Confidentiality
Information about specific individuals in this study will be kept strictly confidential, and will not be available to anyone except the researchers. Only an identification number will appear on the questionnaires, and therefore responses will remain anonymous. One copy of your name and your study identification number will be kept in a locked file drawer in the researcher's office. No one but the nurse investigator will have access to the file. All information obtained in this study will be used for research purposes only. If you wish, the investigator will send you a copy of the results of the study when it is completed.

Questions
You may contact the nurse researchers at the phone numbers on the front page of this consent at any time to answer any questions you may have about the study or the Chronic Pain Self-Management Program.

Right to Refuse or Withdraw
Your participation in this study is entirely voluntary and you are free to refuse to take part in the study or to withdraw at any time without affecting or jeopardizing your health and medical care.

Liability Statement

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the investigators, sponsors, or involved institutions from their legal and professional responsibilities.

Consent

I,_____, the undersigned agree to my participation in the research study described. Any questions have been answered and I understand what is involved in the study. I realise that participation is voluntary and that there is no guarantee that I will benefit from my involvement. I acknowledge that a copy of this form has been offered to me.

_____ _____
(Signature of Participant) (Date)

_____ _____
(Signature of Witness) (Date)

To be signed by the primary investigator:

To the best of my ability I have fully explained to the subject the nature of this research study. I have invited questions and provided answers. I believe that the subject fully understands the implications and voluntary nature of the study.

_____ _____
(Signature of Primary Investigator) (Date)

Phone Number: _____

Appendix GG

Published Results of the Randomized Controlled Trial

LeFort, S.M., Gray-Donald, K., Rowat, K,M, & Jeans, M.E. (1998). Randomized controlled trial of a community-based psychoeducation program for the self-management of chronic pain. *Pain, 74* (2,3), 297-306,

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Pain 74 (1998) 297–306

Randomized controlled trial of a community-based psychoeducation program for the self-management of chronic pain

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Abstract

Although chronic pain is a frequent cause of suffering and disability and is costly to society, there continues to be limited access to specialty pain clinic services. Hence, there is a need for cost-effective, accessible interventions that will help people find ways to better manage this difficult problem. This randomized controlled trial examined the effect of a low-cost, community-based, nurse-delivered, group psychoeducation program entitled the Chronic Pain Self-Management Program (CPSMP). It has a standard protocol that was modified from the successful Arthritis Self-Management Program (ASMP). One hundred and ten individuals with mixed idiopathic chronic pain conditions were enrolled in the study (75% female; mean age 40 years; mean chronicity 6 years) and were randomly assigned to one of two conditions: the 12-h (CPSMP) intervention group, or the 3-month wait-list control group. Self-report measures of pain-related and other quality of life variables as well as two hypothesized mediating variables were collected pre-treatment and 3 months later by assessors blind to group allocation. One hundred and two subjects completed the study. Results of intention-to-treat analysis indicated that the treatment group made significant short-term improvements in pain, dependency, vitality, aspects of role functioning, life satisfaction and in self-efficacy and resourcefulness as compared to the wait-list control group. Because it has a standard protocol, this intervention has the potential to be reliably delivered at low cost in varied urban and rural community settings and hence be more widely accessible to a greater number of people suffering from chronic pain than is currently the case with more specialized pain clinic services. Based on the results of this study, further research evaluating the long-term impact and potential cost savings to the individual and to the health care system is warranted. © 1998 International Association for the Study of Pain. Published by Elsevier Science B.V.

Keywords: Chronic pain; Psychoeducation; Cognitive/behavioral strategies; Quality of life; Nursing; SF-36

1. Introduction

Chronic non-malignant pain is a frequent cause of suffering and disability. It is estimated that at least one in 10 adults live with a chronic pain problem most often located in the back, head or joints (Crook et al., 1984; Millar, 1996; Smith et al., 1996). While some have pain as a result of a recognized disease process, an estimated 64% have pain of undefined pathology that is idiopathic in nature (Bonica, 1990). Many of these pain sufferers are either partially or totally disabled for periods of days, weeks, months or permanently. Poorly managed chronic pain frequently generates feelings of deep distress, hopelessness and despair, and may ultimately result in tremendous disruption to individual and family functioning (Craig, 1994; Rowat et al., 1994).

The economic impact of chronic pain to industry, the health care system and to society as a whole is considerable, an estimated $79 billion in the United States alone (Bonica, 1990). Chronic pain complaints, particularly of musculoskeletal origin, are among the most frequent reasons for visits to physicians (Schappert, 1994; Millar, 1996) and require, on average, more time per visit than any other type of health problem (Koch, 1986). The increased need to counsel patients about treatment and to help them cope with pain-related psychosocial, work and family problems is cited as

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the primary reason for this extra contact time. In addition to physician services, persons with chronic pain also spend more time in hospital and use a broad range of other health services (Crook et al., 1984; Millar, 1996).

Over the past two decades there has been a proliferation of specialty pain treatment centers, many of which use a multidisciplinary approach (Bonica, 1990; Health and Welfare Canada, 1990). However, access to these programs is limited by the nature of the referral process, by geographic location, and by cost and resource issues (Turk and Rudy, 1990; Weir et al., 1992). In the UK for example, only 1% of those with chronic pain are thought to reach a specialty pain clinic (Smith et al., 1996).

Given the scope and cost of chronic pain as well as the personal suffering, there is a need for low-cost, accessible and effective interventions that will help people find ways to better manage this difficult problem. One example of an accessible, community-based approach is the Arthritis Self-Management Program (ASMP). It is a standardized 12-h psychoeducation group program and uses a detailed protocol that has been widely disseminated through national Arthritis Societies/Foundations in the United States, Canada, Great Britain, Australia and New Zealand (Lorig, 1992). The program has been delivered by both generalist health care providers and by trained lay leaders at a cost ranging from $0 to $600 (US) per course as compared to $3000 (US) for a short-term outpatient group program at a pain clinic (Turk et al., 1993). The ASMP has been evaluated in four randomized clinical trials and has demonstrated efficacy in improving aspects of health status such as pain, depression and disability, and resulted in a reduction in health care costs up to 4 years post intervention (Lorig and Holman, 1993; Lorig et al., 1993). The evidence suggests that the ASMP may be a practical, cost-effective prototype on which to base educational programs for those with other types of chronic non-malignant pain.

Therefore, the objective of this randomized controlled trial was to examine the effect of a low-cost, community-based, psychoeducation program entitled the Chronic Pain Self-Management Program (CPSMP) on pain-related and other quality of life variables in a sample of individuals with mixed idiopathic chronic pain conditions. Since we were interested in assessing possible mediators of change, measures of two process variables were collected as well.

2. Methods

2.1. Design

Our study design was a randomized controlled trial in which eligible and consenting adults were randomly allocated to one of two conditions: the 12-h Chronic Pain Self-Management Program (CPSMP) intervention group, or the 3-month wait-list control group. Pre-treatment measures were administered prior to randomization and post-treatment measures were collected approximately 3 months later. Ethical approval for the study was received from two university-based and one hospital-based ethics review committees.

2.2. Study population and procedure

The study was conducted in St. John's, Newfoundland, Canada over a 16-month period. Subjects were drawn from a target population of men and women suffering from a chronic non-malignant pain problem that was idiopathic in nature. Chronic pain is defined as pain lasting longer than expected healing time (>3–6 months) (Mersky and Bogduk, 1994). Idiopathic refers to any pain condition where there is no readily identifiable pathology, such as with many soft tissue and musculoskeletal chronic pains. Eligibility criteria were: 18 years of age or older, idiopathic pain of longer than 3 months duration, able to speak and read English, free of major cognitive or psychiatric disorder, not currently participating in other educational or supportive interventions for their pain problem, and not awaiting surgical intervention.

Subjects entered the study in one of three ways. First, the most recent 2-year patient roster of a hospital-based 'anesthesia block' pain clinic was used to identify patients with the help of the clinic anesthetist. In all, 116 patients were listed, 84 of whom lived within 80 km of the city. Of these, 22 were unable to be contacted (two were deceased and 20 had moved). Nineteen were ineligible (10 no longer had a pain problem, three were currently enrolled in a educationally-based rehabilitation program, two were cognitively impaired due to head injuries, and four were scheduled for back surgery). Twenty-one refused (five had problems with scheduling or transportation, two were unable to sit for long periods and felt unable to participate, and 14 were not interested at this time). The number of study participants from this source was 22 or 51% of eligible subjects.

The second recruiting technique involved contacting a wide spectrum of health professionals who treat chronic pain patients in the community. Patients were referred by medical and dental specialists ($n = 18$), family physicians ($n = 17$), physiotherapists ($n = 24$), registered massage therapists ($n = 4$), chiropractors ($n = 4$), occupational health nurses ($n = 10$), rehabilitation specialists ($n = 3$), and psychologists ($n = 2$). Of these 82 referrals, 75 agreed to participate and seven refused. Finally, 14 people were self-referred having heard about the program through 'word of mouth'. Thirteen agreed to participate and one was ineligible.

Subject eligibility was initially assessed by telephone. The principal investigator then interviewed subjects individually to confirm eligibility, to obtain informed consent, and to administer the pre-treatment measures. In most cases, subjects completed the instruments in one sitting; some subjects (less than 15%) completed it in two sittings or took the

booklet home (completed within 48 h). Once pre-treatment measures were completed, subjects were randomly allocated to either the treatment or the wait-list control group. Randomization was stratified on the basis of gender using opaque, sealed, numbered envelopes using block randomization. Those randomized to the treatment condition were invited to participate in the next available program (within 3 weeks of the initial interview). The intervention lasted 12 h spread over 6 weeks and post-treatment measures were taken 6 weeks later for both treatment and control subjects. The time between pre- and post-treatment data collection ranged from 12 to 15 weeks. Every effort was made to obtain post-treatment measures on all individuals enrolled in the study (e.g., three phone calls and a follow-up letter). A research assistant who was blind to group allocation of subjects administered the post-treatment questionnaires. Once post-testing was completed, those in the wait-list control group were offered enrollment in the next available program, however they did not become treatment subjects.

2.3. The intervention

The CPSMP is a standardized, psychoeducation program (2 h per week for 6 weeks) developed for group presentation in community settings. The course is designed to maximize discussion and group problem solving, encourage individual participation and experimentation with various cognitive/behavioral self-management techniques, and facilitate mutual support. Consequently, didactic presentation is kept to a minimum and the process components are emphasized. The content of the program, although similar to the ASMP, was adapted with permission to be more directly applicable to those with various idiopathic chronic pains. Content areas were validated by six health professionals who work with chronic pain patients. Program materials were given to every participant and included a 150-page workbook and relaxation tape developed for the CPSMP and a variety of current pamphlets on chronic pain, nutrition, and walking. The intervention was delivered by the first author after participating in a 3-day intensive training workshop for ASMP course leaders and after having attended the 6-week ASMP program to become familiar with all aspects of the course. In all, 11 programs with six to ten participants per group were taught by the first author using a detailed treatment protocol developed from the ASMP Leader's Manual (Lorig, 1992) that specified content and process to ensure consistency across every session of all programs (see Table 1 for course content overview).

2.4. Self-report measures

The variables measured in this trial were guided by Braden's Self-Help Model of Learned Response to Chronic Illness Experience (Braden, 1990, 1993) and are conceptualized as antecedent variables (perceived severity of illness, dependency, uncertainty), mediating variables (enabling skill), and outcome variables (self-help activities and life satisfaction). In addition to these theory-guided measures, a norm-referenced, health-related quality of life instrument was used as a further measure of outcome. Sociodemographic and pain history data were obtained by a questionnaire developed for the study. The complete battery of instruments was pilot tested prior to the initiation of the study with 15 people with chronic pain to assess acceptability; no difficulties were noted.

2.4.1. Antecedent variables: perceived severity of illness, dependency and uncertainty

Data regarding perceived severity of illness were measured in four areas: pain quality, depression, disability and a

Table 1
Chronic Pain Self-Management Program course overview[a]

Topic	Session					
	1	2	3	4	5	6
Self-help principles	✔					
Myths about chronic pain	✔					
What is chronic pain?	✔					
Balancing rest/activity	✔			✔		
Exercise for health		✔	✔	✔	✔	✔
Pain management strategies (physical/cognitive/behavioral)		✔	✔	✔	✔	✔
Depression			✔			
Nutrition				✔		
Evaluating non-traditional treatments					✔	
Communication skills					✔	
Medications						✔
Fatigue						✔
Problem-solving	✔	✔	✔	✔	✔	✔
Contracting/feedback	✔	✔	✔	✔	✔	✔

[a]Course adapted with permission from: Lorig, K., Arthritis Self-Help Course, Leader's Manual and Reference Materials,Arthritis Foundation, Atlanta, GA, 1992.

global measure of perceived severity of the pain problem. The Pain Rating Index of the Short Form-McGill Pain Questionnaire (SF-MPQ) measured pain quality (Melzack, 1987). Depression was measured using the short version of the Beck Depression Inventory (SF-BDI) (Beck and Beck, 1972; Beck et al., 1988). Perceived level of disability was measured by the 10-item disability subscale of the Survey of Pain Attitudes (SOPA-D) (Jensen et al., 1994). A global judgment of the perceived severity of the pain problem was assessed by a single item visual analogue scale (VAS) that asks: 'How severe a problem is chronic pain in your life?' with anchors: '0 = Not a problem at all' and '100 = Major incapacitating problem'. Evidence of the item's reliability and validity is provided by Philips (1987).

Dependency was measured by a single item 100 mm VAS developed for this study based on the work of Philips (1987) and others (Wewers and Lowe, 1990; Youngblut and Casper, 1993). It asks: 'As a result of your chronic pain, how much do you have to depend or rely on others in your daily life?' with anchors '0 = Not at All Dependent on Others' and '100 = Extremely Dependent on Others'. Uncertainty was measured with the 23-item community version of Mishel's Uncertainty in Illness Scale (MUIS-C) (Mishel, 1981). Using a 5-point scale, individuals indicate how much they agree or disagree with items relating to the ambiguity, complexity, inconsistency and unpredictability of their symptoms and treatment. Evidence supports the reliability ($r = 0.75–0.90$) and validity of the instrument with various chronic illness groups including chronic low back pain (Mishel, 1981, 1983). Internal consistency reliability in the present study sample was 0.83.

2.4.2. Mediating or process variables: enabling skill

Enabling skill, defined as the ability to manage day-to-day adversities of illness, was assessed using measures of self-efficacy and resourcefulness. A modified 11-item version of the Self-Efficacy Scale (SES), originally developed for the ASMP studies, was used to measure perceived self-efficacy to successfully manage pain and other associated symptoms. Subjects respond to each item using a 10-point graphic rating scale from 10 (very uncertain) to 100 (very certain). References to 'arthritis pain' were changed to 'chronic pain'. Evidence of reliability ($r = 0.87$) and validity of the SES is provided by Lorig et al. (1989). In this study, internal consistency reliability of this modified scale was 0.90. Resourcefulness was measured using the 100 mm VAS version of the Self Control Schedule (SCS) (Rosenbaum, 1980). This 36-item instrument assesses individual tendencies to use complex cognitive, problem-solving, and behavioral skills when dealing with stressful circumstances. Reliability ($r = 0.96$) and validity are reported (Rosenbaum, 1980; Redden et al., 1983) and the instrument has been used in studies of both acute and chronic pain (Braden, 1990; Rosenbaum, 1990; Toomey et al., 1995). Items were summed and divided by the number of completed items to obtain the final score. The internal consistency reliability coefficient for the SCS in this study was 0.84.

2.4.3. Outcome variables: self-help and life satisfaction

Self-help was measured by Braden's (1990) 45-item Inventory of Adult Role Behaviors (IARB) which is based on the work of Given (1984). The IARB uses 100 mm visual analogue scales to measure the extent individuals are instrumentally involved in valued activities related to family, leisure/recreational, social, work and self-care roles such as the use of resources to stay well, paying attention to how one's body feels, attempting to eat well and exercise appropriately, etc. Items were summed and divided by the number of completed items for a total score. The instrument has been used with various chronic illness groups including arthritis and has demonstrated reliability ($r = 0.84–0.92$) and validity (Given, 1984; Braden, 1990, 1991). In this study, internal consistency reliability was 0.93. Life satisfaction was measured by the modified 17-item Satisfaction with Life Domains Scale (SLDS) (Baker et al., 1992), that is based on the work of Flanagan (1978). Using a 7-point faces scale, individuals select their degree of satisfaction with six life domains: work, leisure, relations with family members, relations with friends, and aspects of self-fulfillment including health. Evidence of reliability ($\alpha = 0.93$) and validity are reported (Baker and Intagliata, 1982; Baker et al., 1991, 1992). The internal consistency reliability coefficient for the SLDS in this study was 0.94.

2.4.4. Health-related quality of life

The Medical Outcomes Study Short Form-36 (SF-36) was administered as an additional outcome measure because of its strong psychometric properties, its increasing use as an outcome measure in clinical trials, and its brevity and ease of administration (Ware et al., 1993). The SF-36 assesses eight health concepts: physical functioning (PF-10 items); role functioning related to physical (RP-4) and emotional problems (RE-3); social functioning related to physical or emotional problems (SF-2); pain index which combines a 6-point intensity scale with a rating of perceived interference with normal work (BP-2); general mental health (MH-5); vitality (VT-4); and, general health (GH-5). Scores for each health concept range from 0 to 100 with higher scores indicating better health. Data supporting its reliability ($r = 0.78–0.93$) and validity are reported (Ware and Sherbourne, 1992; McHorney et al., 1993; Ware et al., 1993; McHorney et al., 1994). In this study sample, internal consistency reliabilities for the eight scales ranged from 0.81 to 0.91.

2.5. Data analysis

Treatment and control group data were compared using chi-square analysis for discrete level data and independent *t*-tests for continuous level data on demographic, pain history, and pre-treatment variables to assess the comparability of

groups at baseline. Results of the intervention were assessed by separate analysis of covariance (ANCOVA) procedures of each post-treatment measure using the pre-treatment levels of each variable as the covariate. All data were cleaned and checked; power or square root transformations were applied to four variables to achieve adequate normality of skewed data for the analysis of covariance. Raw means for all variables are reported here for clarity. All assumptions for parametric statistical analysis including homogeneity of regression were met. Because of the large number of statistical tests, the Bonferroni correction was applied to protect against Type 1 error. An alpha level of 0.003 (0.05/18) was chosen as the level of statistical significance for analysis of covariance results. An alpha of 0.05 was the chosen level of significance for all other analyses.

The intention-to-treat principle was maintained in this study (Newell,-1992). Thus, for purposes of statistical analyses, individuals randomized to the intervention group were considered to be in this group even if they did not attend the program, or attended only a few sessions.

3. Results

3.1. Subjects and comparability of groups

Of the 110 individuals initially recruited into the study, 57 were randomly assigned to the treatment and 53 to the control group. Demographic and pain-related questionnaire data of the two groups are presented in Table 2. The subjects in both groups were not significantly different on any of these characteristics. In addition, pre-treatment scores of the study variables did not differ significantly between groups indicating that the randomization procedure was successful in producing comparable groups.

This young to middle-aged sample was Caucasian except for one subject of east Indian origin. Most were graduates of high school with women out numbering men 3:1. The average pain duration was 5–6 years. While the vast majority had multiple pain sites, the most common being the lower back and neck, some individuals had complaints confined to one area of the body such as headache, orofacial pain, non-specific abdominal pain or non-arthritic knee pain. Over 40% attributed their pain to one or more car accidents. Others attributed their pain to lifting, falls, surgery or 'just happened'. Most people were taking various medications for their pain including NSAIDS, narcotic combinations, antidepressants, sedatives/hypnotics and muscle relaxants. Over 60% had visited their family doctor and over 30% a medical specialist within the past month for their pain problem. In addition, many were receiving adjunctive therapy of some kind including physiotherapy, chiropractic treatment, massage or acupuncture. Chi-square analysis revealed no significant differences between the two groups on these aspects of service utilization ($P > 0.05$).

Of the 110 subjects who were randomized to the trial, eight subjects (five from the treatment and three from the control group) subsequently did not complete the post-treatment measures and were considered drop-outs, a rate of 7%. Of the treatment group drop-outs, one became ineligible after randomization, one was admitted to hospital for an extended period for a serious acute illness, and three sub-

Table 2
Baseline sociodemographic and pain-related characteristics for all subjects randomized to treatment and control groups

Characteristics	Treatment ($n = 57$)	Control ($n = 53$)
Age, mean (SD)	39 (24–57)	40 (26–60)
Gender, female (%)	42 (74)	40 (75)
Married (%)	37 (65)	37 (70)
Living alone (%)	7 (12)	5 (9)
Less than 11 years formal education (%)	10 (18)	4 (8)
Post-secondary education (%)	43 (75)	35 (66)
Working full/part-time (%)	21 (37)	18 (34)
Not working due to pain (%)	24 (42)	27 (51)
Receiving disability income (%)	20 (35)	22 (42)
Pain duration in years, mean (SD)	6.5 (1–28)	5.6 (1–20)
Number of pain locations, mean (SD)	6.7 (1–20)	7.0 (1–17)
Pain in lower back (%)	39 (68)	43 (81)
Pain in neck (%)	35 (61)	35 (66)
Cause of pain, motor vehicle accident (%)	23 (40)	22 (42)
Surgery for pain problem (%)	18 (32)	17 (32)
Any medications for pain (%)	48 (84)	43 (81)
Narcotic use (%)	25 (44)	24 (45)
In past month, visited the following for pain		
Family physician (%)	37 (65)	34 (64)
Medical specialist (%)	22 (39)	15 (28)
Physiotherapist/occupational therapist (%)	23 (40)	20 (38)
Other adjunctive therapist[a] (%)	21 (37)	19 (36)

[a]Includes registered massage therapist, chiropractor, acupuncturist, and others.

jects who had attended one or no classes declined to complete the questionnaire booklet at post-treatment. All three drop-outs in the control group were subjects who could not be contacted at 3-month follow-up.

A comparison of demographic, pain history, and pre-treatment mean scores of all variables for drop-outs ($n = 8$) versus those who completed the study ($n = 102$) was done. Although similar in demographic and most pain-history variables, the drop-outs as a group had higher pain quality scores ($P \leq 0.01$), were more depressed ($P \leq 0.001$) and had poorer general mental health scores ($P \leq 0.05$), felt more dependent on others ($P \leq 0.001$), had poorer general health perceptions ($P \leq 0.05$), had less vitality ($P \leq 0.01$), felt themselves to be more disabled ($P \leq 0.001$), had less self- efficacy ($P \leq 0.05$), had poorer social functioning ($P \leq 0.05$) and were less satisfied with their lives ($P \leq 0.05$). In addition, all of the drop-outs were female, none of them were working compared to 38% of 'completers', and 75% of them were receiving disability benefits of some kind compared to 35% of 'completers'. From these data, it appears that those who dropped out were more severely affected by their pain condition compared to those who completed the study.

To be certain that the treatment ($n = 52$) and control ($n = 50$) subjects who completed the trial comprised equivalent groups at baseline, statistical analysis using chi-square and t-tests of demographic, pain history, and all pre-treatment scores was repeated. No significant between-group differences were found ($P > 0.05$).

3.2. Effects of the treatment: between-group differences

The mean scores on all antecedent, mediating and outcome variables at pre-treatment and 3 months later (6-week follow-up) as well as the within-group mean change scores are presented in Table 3 for the two groups. Comparisons of post-treatment means using the pre-treatment levels as the covariate indicated that those in the treatment group had statistically significant improvement ($P \leq 0.003$) in six of the ten variables compared to the control group. At 6-week follow-up, those in the treatment group reported less dependency on others, reduced severity of the pain problem on their lives, had higher levels of self-efficacy and resourcefulness, reported greater involvement in valued adult role activities and had greater life satisfaction compared to the control group. In addition, there were strong positive trends to improvement in measures of pain quality ($P \leq 0.05$), and disability ($P \leq 0.01$) compared to the controls.

The mean scores on the SF-36 scales at pre-treatment, post-treatment and the within-group change are presented in Table 4. Comparisons of post-treatment means using the pre-treatment levels as the covariate show that the treatment group had statistically significant improvement ($P \leq 0.003$) in three of the eight scales compared to the controls. As a

Table 3

Pre-treatment mean, post-treatment mean and within-group change on antecedent, mediating and outcome variables

Variable (possible range)	Treatment ($n = 52$)			Control ($n = 50$)			ANCOVA		
	Pre-treatment, mean (SD)	Post-treatment, mean (SD)	Change, mean (SD)[a]	Pre-treatment, mean (SD)	Post-treatment, mean (SD)[a]	Change, mean (SD)[a]	df	F	P
Antecedent variables									
Pain quality, SF-MPQ (0–45)	18.94 (8.13)	17.27 (9.16)	1.67 (9.61)	18.32 (7.94)	20.14 (8.93)	−1.82 (6.83)	96	4.38	0.039
Pain problem severity (0–100)	72.67 (18.44)	60.98 (21.26)	11.69 (18.51)	73.02 (17.61)	71.22 (15.83)	1.80 (17.41)	98	9.83	0.002*
Depression, SF-BDI (0–39)	7.67 (4.91)	6.83 (5.63)	0.85 (4.71)	7.48 (4.63)	7.68 (4.75)	−0.20 (3.21)	99	2.83	0.096
Disability, D-SOPA (0–4)	2.51 (0.84)	2.29 (0.78)	0.21 (0.59)	2.79 (0.76)	2.81 (0.72)	−0.02 (0.55)	99	7.33	0.008
Dependency (0–100)	52.44 (25.24)	45.67 (26.08)	6.77 (19.50)	54.52 (29.66)	59.77 (23.00)	−5.25 (22.60)	99	12.39	0.001*
Uncertainty, MUIS-C (23–115)	68.25 (12.22)	66.12 (11.14)	2.14 (9.68)	64.54 (11.84)	64.60 (9.07)	−0.06 (9.73)	99	0.002	0.960
Mediating variables									
Self-efficacy, SES (10–100)	49.52 (15.86)	59.66 (18.12)	10.14 (13.75)	49.00 (18.04)	46.94 (17.17)	−2.06 (14.79)	98	21.74	0.000*
Resourcefulness, SCS (0–100)	64.48 (10.69)	67.77 (9.78)	3.29 (8.12)	64.81 (11.71)	62.52 (11.47)	−2.28 (6.18)	99	17.27	0.000*
Outcome variables									
Role behaviors, IARB (0–100)	55.32 (11.92)	60.41 (13.15)	5.09 (8.37)	52.76 (12.94)	51.22 (12.44)	−1.55 (7.26)	99	22.47	0.000*
Life satisfaction, SLDS (0–119)	68.85 (19.57)	76.19 (19.87)	7.35 (14.01)	67.16 (19.39)	64.28 (17.31)	−2.88 (11.78)	99	20.21	0.000*

[a]Positive change score indicates improvement from pre- to post-treatment. Negative change scores indicate deterioration from pre- to post-treatment.
*Statistically significant at $P \leq 0.003$.

Table 4

Pre-treatment mean, post-treatment mean and within-group change on Medical Outcomes Study SF-36

Scale (0–100)	Treatment (n = 52)			Control (n = 50)			ANCOVA		
	Pre-treatment, mean (SD)	Post-treatment, mean (SD)	Change, mean (SD)[a]	Pre-treatment, mean (SD)	Post-treatment, mean (SD)	Change, mean (SD)[a]	df	F	P
Physical function (PF)	41.68 (24.70)	44.64 (25.07)	2.96 (14.87)	38.41 (20.22)	38.30 (21.63)	−0.11 (15.21)	99	1.62	0.206
Role-physical (RP)	8.65 (23.16)	24.52 (33.39)	15.87 (29.30)	12.00 (30.41)	9.00 (23.56)	−3.0 (27.96)	99	11.51	0.001*
Bodily pain (BP)	27.23 (16.39)	35.0 (18.65)	7.77 (14.59)	29.74 (18.37)	27.60 (17.89)	−2.14 (15.95)	99	10.35	0.002*
General health (GH)	45.35 (19.64)	48.69 (20.28)	3.62 (16.27)	48.93 (22.54)	48.86 (21.91)	−0.07 (14.87)	99	0.99	0.323
Vitality (VT)	31.83 (19.73)	43.33 (22.16)	11.51 (16.32)	36.70 (20.69)	33.27 (19.74)	−3.43 (15.22)	99	20.99	0.000*
Social function (SF)	47.84 (26.16)	55.05 (27.48)	7.21 (20.76)	49.00 (25.36)	48.50 (24.83)	−0.50 (19.55)	99	3.90	0.051
Role emotional (RE)	41.03 (43.59)	59.62 (42.95)	18.59 (53.79)	44.67 (42.38)	56.00 (43.35)	11.33 (48.38)	99	0.325	0.570
Mental health (MH)	60.46 (19.67)	68.15 (18.37)	7.69 (16.71)	58.08 (19.27)	60.84 (19.93)	2.76 (14.87)	99	4.07	0.046

[a]Positive change score indicates improvement from pre- to post-treatment. Negative change scores indicate deterioration from pre- to post-treatment.
*Statistically significant at $P \leq 0.003$.

group, treatment subjects had reduced bodily pain (a measure of intensity and interference), improved physical role functioning, and increased vitality, when compared to controls. In addition, there were positive trends to improvement in general mental health ($P \leq 0.05$) and in social functioning ($P = 0.051$).

As a further test of the effectiveness of the intervention, the 20 subjects with the most improved scores from pre- to post-treatment for each statistically significant variable were classified according to group allocation. Fourteen to 18 of the 20 most improved subjects were in the treatment group providing more supportive evidence that the positive outcomes were due to treatment (Table 5). Lastly, as a form of process evaluation an attendance record was kept to track the number of classes attended by treatment subjects. Of the six program sessions, 44 subjects attended four or more sessions indicating that 85% of those randomized to the treatment group received two-thirds or more of the course content (Table 6). The average number of sessions attended was 4.7.

4. Discussion

This randomized controlled trial investigated the impact of a nurse-delivered, community-based, 12-h group psychoeducation program on a sample of young to middle-aged individuals with mixed idiopathic chronic pain problems. The findings present a picture of statistically reliable short-term improvement in those who were enrolled in the CPSMP as compared to a group of wait-list controls on multiple self-report measures including pain severity and impact, dependency, vitality, physical role functioning, increased involvement in valued adult roles, life satisfaction and in the two hypothesized mediating variables, self-efficacy and resourcefulness. The percent improvement on all but one of these variables in the treatment over and above changes in the control group ranged from 9% to 47%, with most in the modest range. The high rate of improvement in physical role functioning (217%) may be due to the floor/ceiling effects of this subscale (McHorney et al., 1994). Even outcomes such as pain quality measured by the short form of the MPQ, perceived disability, mental health, and social functioning which did not reach statistical significance at the 0.003 alpha level showed positive trends ($P \leq 0.05$) in the treatment over the control group. Depression as measured by the short form of the Beck Depression Inventory did not change significantly, although there was a weak positive trend to improvement. In part, this may be because most study subjects in both groups were not in the depressed range when 8 is used as the cut-off score for clinical depression (Turner and Romano, 1984). Uncertainty was the only variable that stayed virtually unchanged. This may be explained in part by the amorphous nature of chronic pain itself and the lack of clear communication about chronic pain by many health professionals.

The results of this study appear comparable to and in some outcomes showed a larger effect than the results of the Arthritis Self-Management Program studies. Lorig and Holman (1993) report statistically significant short-term improvement in pain (22%) and self-efficacy (14%), and non-significant positive trends in disability (6%) and depression (14%) in treatment subjects who attended an average of 4.5 of the six ASMP sessions over wait-list control subjects. Although these changes were modest, they were maintained

Table 5

Group allocation of 20 subjects with most improved scores on statistically significant variables

	Treatment (n = 52)	Control (n = 50)
Pain problem severity	15	5
Dependency	14	6
Role behaviors	17	3
Life satisfaction	16	4
Self-efficacy	15	5
Resourcefulness	16	4
SF-36		
Role physical (RP)	16	4
Bodily pain (BP)	15	5
Vitality (VT)	18	2

Table 6

Number of sessions attended by those in the treatment group

Sessions attended (maximum of 6)	Treatment subjects (%) (n = 52)
0	1 (1.9)
1	2 (3.8)
2	2 (3.8)
3	3 (5.8)
4	7 (13.5)
5	21 (40.4)
6	16 (30.8)

at 20 months and 4 years post-intervention and translated into cost savings to the health care system with 40% reduction in number of physician visits in the treatment over a comparison group (Lorig et al., 1993).

Our findings also appear to compare favorably with short-term outcomes of somewhat analogous pain clinic outpatient programs with similar patient populations (Philips, 1987; Peters and Large, 1990; Skinner et al., 1990; Peters et al., 1992; Williams et al., 1996), however comparisons should be viewed with caution due to differences in methodology across studies including research design, sampling procedures, and use of different outcome measures. In general, these outpatient programs report significant improvements in self-report measures of pain (8–25%), depression (11–31%), and aspects of functioning (18–40%) as well as improvement in some measures of physical performance. The programs range from 13.5 h to 28 h and involve members of a multidisciplinary team, which although ideal, adds to the cost of the program and decreases portability to other settings. By contrast the CPSMP, with outcomes that are in the lower end of this range, is 12 h in length, utilizes one facilitator, and can be delivered in a variety of community settings such as local service clubs, churches, schools, etc. (Lorig, 1986). An additional caveat is that results of our study are conservative because intention-to-treat analyses may dilute the effect of treatment (Newell, 1992).

Similar to other trials of chronic pain interventions, we measured a large number of variables to be certain to capture the full effect of the program. Our intention was to utilize the most responsive self-report instruments to small but potentially important change. We used a combination of established pain-related measures as well as instruments guided by a theoretical framework that views the broad range of self-help role behaviors and client perception of life satisfaction as important outcomes. To our knowledge, this is the first report of the SF-36 used in a randomized trial of a psychoeducation program. In part, it was a test of the instrument's responsiveness to change as a result of a non-medical/surgical intervention although the instrument has been used with other pain populations (Patrick et al., 1995; Jhingran et al., 1996). In addition to outcome measures, we were also interested in investigating hypothesized mechanisms responsible for change. The 24% improvement in self-efficacy in the treatment over the control group adds to a growing body of evidence supporting the critical role of perceived control and efficacy beliefs in the management of chronic pain (Philips, 1987; Spinhoven and Linsson, 1991; Lorig and Holman, 1993). The clinical importance of the small (9%) but significant improvement in resourcefulness (i.e., use of various coping skills) is more equivocal and requires further investigation. In general, the trend to improvement in the treatment group on most variables measured in this study supports the overall positive impact of the program.

A strength of this study is the methodology including random allocation of subjects, the low and equal rate of attrition in both groups, blind assessors at post-treatment to reduce the likelihood of bias, the use of a standard protocol to deliver the program, and intention-to-treat statistical analysis. In addition, the study used a sample that was as representative as possible of those with idiopathic chronic pain in the community who use a variety of health care services. It included a broad referral base as well as a pain clinic group. Because most of the subjects were referred, there is no reason to think that these individuals were an extraordinarily motivated group. However, baseline scores of the eight drop-outs compared to those who completed the study suggest that those with higher levels of pain and depression, and poorer functioning may not have enough motivation to engage in a program of this type. They may need more specialized treatment that is more appropriately available at a pain treatment center.

This study also has limitations. Because this study was designed to evaluate the short-term impact of the CPSMP, it is not known whether treatment effects are maintained over the long term. In addition, all programs were delivered by a single facilitator. The use of multiple facilitators would have strengthened our hypothesis that the content and process of the CPSMP rather than the personal attributes of the facilitator are the effective ingredient in this intervention. Future studies of this intervention need to use multiple facilitators, include long-term follow up at 6 months and 1 year, and monitor potential cost savings to both the individual and the health care system.

The important role of psychoeducation as an adjunct to traditional medical and physical therapies for the management of chronic pain is now well-established (Allegrante, 1996). The Chronic Pain Self-Management Program has been shown to have a demonstrable effect on a variety of pain-related and quality of life variables at 6 weeks post intervention. Because it has a standard protocol, this intervention has the potential to be reliably delivered at low cost in varied urban and rural community settings and hence be more widely accessible to a greater number of people suffering from chronic pain than is currently the case with more specialized pain clinic services. Based on the results of this study, further research of this community-based approach to chronic pain management is warranted.

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