An Evaluation of the Long-Term Treatment Outcomes of a Multidisciplinary Chronic Pain Centre Program

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ABSTRACT

The Chronic Pain Center (CPC) in Saskatoon offers a multidisciplinary treatment program whose goals are to facilitate improved coping skills, function and well-being, and to promote self-reliant lifestyles. They have documented a statistically significant improvement on several measures of physical and social functioning at the completion of the six week program, but to date have no formal evaluation of the long term effects.

The purpose of this study was to re-evaluate the CPC clients (treatment group) at least one year following their completion of the treatment program to determine if they had maintained those improvements and also to compare them to the group of clients (control group) who underwent initial multidisciplinary assessment at the Centre, but did not attend the six week treatment program. Evaluation by mail out questionnaires assessed several important aspects of chronic pain. A 34% response rate resulted in 142 participants for this study.

Data analyses involved a multi-stage process of univariate, bivariate and multivariate analyses. For the first goal, evaluating changes in the treatment group over time, the outcome variables considered had been administered at three points in time: admission to the CPC program, discharge from the six week program, and at study follow-up. For the second goal, the treatment and control groups were compared at one point in time; the study follow-up.

The study demonstrated that the scores on all outcome variables used in the follow-up study improved significantly from the time of assessment to the time of discharge for the clients who attended the CPC treatment program. These improvements declined over time, but remained significantly improved from the admission scores. (Wilks' Λ=.501, $F(1,48)=4.788$, $p=.000$) However, the study was unable to demonstrate any significant differences between the treatment and control groups on any of the outcome measures at the time of the study follow-up. (Wilks' Λ=.930, $F(1,107) = 1.014$, $p=.430$) There were several limitations to this study, including the use of a non-randomized control group and the method of recruitment, which may have introduced bias into the study and affected the ability to effectively explain this finding.

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Chapter 1

Introduction

1.1 Background

Chronic pain, defined as pain that has been present three to six months or more, (1-3) is common and costly. Surveys have indicated that between 17% and 29% of Canadians suffer from moderate to severe chronic pain, (1,2,4) and a report based on Statistics Canada 2001 Canadian Community Health Survey (CCHS-1.1) found 27.1% of men and 38.4% of women reported having at least one chronic pain condition.(5) The cost of medical expenses, lost income, and lost productivity in Canada is estimated at over $10 billion annually. (6) This is not only a financial burden, but a difficult personal and social burden for many Canadians.

Although no currently available treatment eliminates pain for the majority of patients, multidisciplinary pain rehabilitation programs have been shown in the literature to be beneficial and cost-effective for reduction of pain and improving functional outcomes. (7-11) However, important gaps in the literature remain. There has been little research looking at the stability of improvement over time (12,13) and few studies have utilized comparison groups. Those studies that did include a comparison group generally used individuals who were “drop-outs” of a program (14) or lacked insurance or the ability to pay for the program, (7,15) as the “no treatment” group. The lack of clear outcome measures to determine success, (3,8,9,16) and poor response rates in follow-up have also been identified as problematic. (15,17)

1.2 Purpose and Research Questions

The Chronic Pain Centre (CPC) in Saskatoon was established in 2004 as a publicly funded provider of multidisciplinary assessment and treatment for persons with chronic pain in Saskatchewan. Of the 400 to 500 referrals received by the CPC each year, approximately 100 have been accepted annually for assessment, and of these, approximately 50 clients annually have attended the six week treatment program. The goals of treatment are to facilitate improved coping skills, function and well-being, and to promote self-reliant lifestyles. Preliminary findings, documented in a CPC internal report[1], suggested that following this six week program, clients demonstrated statistically significant improvements on several measures of physical and social functioning. These improvements appeared to be sustained when clients were re-evaluated three months after discharge from the program. To date however, apart from internal statistical reviews, there has been no formal, more methodologically rigorous evaluation of the potential longer-term benefits of the CPC's treatment program.

The purpose of this study was to re-evaluate the CPC clients at least one year following their completion of the treatment program to determine if they had maintained improvements in function and social well-being and to compare them to the group of clients who underwent initial multidisciplinary assessment at the Centre, but did not attend the six week treatment program. The specific research questions were:

[1] Personal communication: Kate Fast, Saskatoon Chronic Pain Centre, internal statistical review: 2007

1) Are improvements in clients physical and social functioning, observed at completion of the six week program, maintained over time?

2) Is there a significant difference in these outcomes, on evaluation at least one year after assessment, of those clients who completed the six week program compared to those who underwent the initial assessment, but did not attend the program?

Chapter 2:

Literature Review

2.1 Definition of Chronic Pain and Associated Features

Pain is a complex, multi-dimensional experience that is difficult to describe or evaluate. Chronic pain is defined as pain that has been present three to six months or more. (1-3) Although chronic pain may originate from an injury, in some individuals the pain persists beyond resolution of the underlying disorder and reaches a point where it interferes with normal function and everyday activity. Chronic pain, though, includes factors other than just the defined duration of pain. The pain is often more intense than the underlying process would predict (18) and it interferes with appetite, the ability to work, physical activity and sleep. The pain becomes a preoccupation and can lead to fatigue, irritability and depression. Fear of pain, fear of movement, and fear of re-injury can add to and complicate the perception of pain. (19)

There is a large body of neuroscience research on chronic pain that is ongoing, and many experimental pain models have been proposed. These models attempt to describe and delineate the components of chronic pain, including the nociception (the actual stimulation of nerves that conduct pain impulses), and the subjective response to pain which is filtered through an individual's genetic composition, prior learning, psychological status, and sociocultural influences. (19) These psychosocial factors involve both emotion - the immediate response to nociception, and cognition - the meaning attached to the emotional experience. These emotional and cognitive factors can trigger

additional emotional reactions that amplify the experience of pain and perpetuate the vicious circle of nociception, pain, distress and disability. (19)

Pain is ultimately a subjective experience, described in terms of sensory properties but incorporating many different emotions, primarily negative ones. Depression, anxiety, emotional distress and anger are common emotions in chronic pain patients. (19) For example, in a recent Canadian study, the prevalence of depression was twice as high among those reporting chronic pain compared to those who did not report chronic pain. Depression was also related to pain intensity for both men and women, with higher levels of pain intensity being associated with higher prevalence of depression. (1) Pain and emotion interact in many different ways and "emotional distress may predispose people to experience pain, be a precipitant of symptoms, be a modulating factor amplifying or inhibiting the severity of pain, be a consequence of persistent pain, or be a perpetuating factor. Moreover, these potential roles are not mutually exclusive." (19)

A Canadian study (20) reported in 2008 that pain interfered with physical activity, recreation, family responsibilities and self-care, as well as impacted on the happiness and self-perceived health of pain sufferers. Another study recently conducted at the University of Alberta's Multidisciplinary Pain Centre in Edmonton reported a "significant disruption of attention and memory in two thirds of participants with chronic pain."(21) Death by suicide appears to be at least doubled in chronic pain patients (22) and it has been demonstrated in laboratory experiments "that uncontrolled pain compromises immune function, promotes tumour growth and can compromise healing. (23) Not only does chronic pain

affect the individual, but also has consequences for the patients' partner and family. A study from the Netherlands demonstrated that chronic disease that involved pain and fatigue significantly impacted their partners' personal life and social relations. (24) Chronic pain patients experience nociceptive dysfunction, anxiety, depression, anger, maladaptive behaviors such as catastrophizing and poor coping, as well as functional deficits and physical deconditioning. These symptoms may also be interdependent, so treatment cannot simply address one of them. Effective treatment programs need to address all these components and rely on appropriate and realistic goal setting and a collaborative interdisciplinary [2] treatment approach. (19,25,26)

2.2 Epidemiology of Chronic Pain in Canada

In Canada, chronic pain is more prevalent than other well-known chronic illnesses such as diabetes or asthma, affecting between 17% and 29% of Canadians.(27) Another Canadian study found the average duration of pain was 10.7 years, with an average intensity of 6.3 on a scale of 1 to 10. (2) A study by the Alberta Ministry of Health and Welfare, based on data from the Alberta sample of the National Population Health Survey (NPHS) projected a 70% increase over the next 25 years in the number of Albertans suffering from chronic pain, primarily due to an aging population. (28)

[2] The term interdisciplinary is often used interchangeably with multidisciplinary, although they do have slightly different meanings. Multidisciplinary team members work more independently and often sequentially and the primary means of communication may be the medical record. Interdisciplinary teams are seen to work more collaboratively with frequent communication to discuss patient status and the evolving treatment as an integral part of the teams functioning. Having said that, these distinctions are not always adhered to in the literature and the terms are sometimes used interchangeably. (25)

According to data from the Canadian Community Health Survey, chronic pain is more prevalent in women (38.4%) than in men (27.4%), though the prevalence increases with age for both genders. (1,5) Chronic pain is also associated with household income and marital status, with a higher prevalence among people in lower income categories and those who are divorced or separated.(1) A recent report based on Statistics Canada National Population Health Survey (1994/1995 through 2002/2003) and 2005 Canadian Community Health Survey Data examined chronic pain specifically in Canadian seniors. (20) The authors concluded that chronic pain is a “major health concern for seniors”, affecting 27% of seniors living in households and 38% of those in health care institutions. Similar to the general population of Canadians, older women are more likely to report chronic pain than older men, as are those with lower socioeconomic status.

Estimating the economic burden of chronic pain is not straightforward. There are both direct and indirect costs to society. (29) The direct costs include medical costs, labour of health professionals, equipment and supplies used in the assessment and treatment of chronic pain. The indirect costs include loss of potential productivity, both at home and at work (reduced work performance, absenteeism, unemployment) and reduction in health related quality of life. In the United States, Turk et al estimated that the combined direct and indirect cost of chronic pain to be in excess of $125 billion US per year. (30) The exact cost of chronic pain in Canada is not known, but it is “believed to be enormous.” (31) The Chronic Pain Association of Canada estimates the annual cost to exceed $10 billion. (6)

2.3 Treatment of Chronic Pain

The etiology of chronic pain is largely unknown, and as a result, treatment efforts have consisted of a wide variety of methods. Because pain is a multi-dimensional problem, and involves biological processes as well as cognitive, emotional and social components, (1,19,26) there is no single or quick solution.

Chronic pain was first described as a disease in 1939 and following WWII the concept of multidisciplinary treatment was developed. The first interdisciplinary pain centers were established by the 1950's and rapidly expanded over the next 20 years. (32) Having said that, multidisciplinary pain management is still "often introduced at a very late stage" (3) or considered as a last resort when all other medical interventions have been tried and failed.(3,16) Initial efforts are generally aimed at eliminating the cause of pain, and when this fails, treatments including medication and physical modalities such as heat or cold are undertaken to palliate the symptoms or interrupt the transmission of pain signals.(10) Physical therapy is often used in an effort to build or recondition muscles and improve functional mobility. Other interventions may include TENS (transcutaneous electrical nerve stimulation), biofeedback, acupuncture, or therapeutic nerve blocks, which are local anesthetic injections administered to block the transmission of pain. All of these interventions typically achieve only temporary pain relief with chronic pain patients.(9) During the course of this treatment, patients may be expecting a "cure", and as their pain continues through these various approaches they may develop unhelpful coping strategies and maladaptive behaviors.(16,33)

Although there is considerable variation in the content of multidisciplinary or interdisciplinary programs in the treatment of chronic pain, they generally have at least three different medical specialists or health care providers involved. (3,27) Interdisciplinary team members usually include a physician, nurse, psychologist, physical therapist, and an occupational therapist. Communication and collaboration among the team members is a vital part of this treatment method. The goal of treatment is not necessarily to improve the pain, but rather, to improve the coping skills and function of someone living with chronic pain. (34,35) The focus of an interdisciplinary program is on addressing barriers specifically related to pain – fear of re-injury, catastrophizing, poor sleep and lack of understanding about safe and necessary reactivation. This is in contrast to "Functional Restoration" programs, which tend to focus on physical conditioning and work hardening (reconditioning to specific job tasks to transition from treatment to return to work). As commented by Stanos, "Interdisciplinary pain programs provide outcome-focused, coordinated, goal-oriented interdisciplinary services." (25)

While the actual reduction in intensity of pain may be minimal, (7) it is apparent that other criteria are important in the evaluation of effectiveness of treatment. Which is considered the most important change may depend on the perspective of the individual client. (17) Over the past 20 years, research has provided a substantial body of evidence supporting the effectiveness of a multidisciplinary approach to treatment of chronic pain. (7,8,10,14,16,36) These studies have reported improvement in function and lifestyle, and at the very least,

chronic pain clients broaden their range of coping strategies and recognize that they are not alone.

Due to the rapidly increasing number of pain clinics, the question of effectiveness of multi-disciplinary treatment approaches has been studied extensively. Flor et al (7) conducted a meta-analysis of many of the early studies, looking at 65 studies published from 1960 to 1990. They found multidisciplinary treatments superior to no treatment, being on a waiting list and single discipline treatments. The study identified numerous benefits of multidisciplinary treatment including improvements in pain, mood, pain interference (interfering with activity and daily living), return to work and decreased use of the health care system, and these benefits appeared to be stable over time, although they defined long-term as over six months. Flor et al was one of early authors to establish the effectiveness of a multi-disciplinary approach to chronic pain management, and this finding has been supported by more recent literature as well. In 1999, Morley et al, (8) looked at published reports of randomized controlled trials of cognitive behavior therapy for chronic pain, and found “good evidence” for its effectiveness, and Turk et al (9) in a 2002 literature review, examined published studies to compare the clinical effectiveness and cost effectiveness of treatments for chronic pain. Turk found that pain rehabilitation programs demonstrated comparable reduction in pain to alternative treatments (including medication, conservative care, surgery, spinal cord stimulators and implantable drug delivery systems) but “with significantly better outcomes for medication use, health care utilization, functional activities, return to work, and closure of disability claims.” They also found “substantially

fewer iatrogenic consequences and adverse events." These studies have provided a strong basis for the use of multidisciplinary pain management programs as the best therapeutic option for treatment chronic pain patients.

There has continued to be great interest in evaluation of not only the effectiveness of this approach to managing chronic pain but also examining various aspects and components of treatment. Robbins et al (14), in their study examining the efficacy of treatment in an interdisciplinary pain management centre, made comparisons between treatment program completers and treatment dropouts. They showed no statistically significant difference between these two groups at pre-treatment but found that patients who completed the interdisciplinary pain management program "demonstrated significant improvement on the majority of outcome measures", and maintained these gains at one-year follow-up. A study evaluating the effects of a multidisciplinary pain management program on coping, health related quality of life and pain intensity (34) found significant improvements related to coping, avoidance, pain intensity, global mental health as well as social and physical functioning. Mead et al (16) did pre-test and 6 week follow-up evaluation on participants of a Pain Coping Strategies Program and reported statistically significant decreases in anxiety, improvement on the physical tests and improvement on their perceived performance and perceived satisfaction of activities of daily living. Recently a study conducted in Norway (37) compared the outcomes of a chronic pain rehabilitation program to an age-matched comparison group from the general population in the same geographic area. They found significant improvement in

function, although the participants still reported significantly lower function on all core aspects of functional health status compared to the normative sample.

This body of research suggests that multidisciplinary programs may be the most effective treatment for chronic pain. However, several limitations in studying chronic pain management have been discussed in the literature: the unsystematic use of outcome measures, lack of control or comparison groups, poor response rates to follow-up and lack of long-term evaluation (ie. over 18 months). (10,13) These issues are discussed in the sections that follow.

2.3.1 Unsystematic Use of Treatment Outcomes

One of the challenges identified in the literature is that there are no clear outcome measures to determine success in the treatment of chronic pain. (3,8,9,16) In a systematic review of 25 studies, there were a total of 221 outcome measures used, the majority being self-reported. (8) On the one hand, there is a need for use of measures which accurately reflect the multifaceted nature of pain. As Turk states, “pain is not a monolithic entity…Since there are many facets to pain, it should be obvious that no single outcome measure captures all of the relevant issues. For this reason, outcome assessment must look at a variety of criteria to adequately describe the effects of any treatment.”(9) But on the other hand, the wide variety of measures makes integration of the research on treatment effectiveness a challenging task. Use of a standard set of outcome measures for chronic pain would facilitate comparisons of the effectiveness of chronic pain treatment programs.

To address these challenges, systematic reviews have grouped the most commonly used outcome measures into “domains”. (3,8,10) In 2002, in an effort to standardize the domains, a consortium of 27 professionals with expertise relevant to evaluation of chronic pain treatment outcomes met in the U.S. Those involved in this “Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials” (IMMPACT) (38) were selected to represent health care disciplines, academia, governmental agencies and the pharmaceutical industry. Their goal was to make recommendations for which core outcome domains should be considered by investigators conducting clinical trials of the efficacy and effectiveness of treatments for chronic pain. They identified six core domains: pain intensity, physical functioning, emotional functioning, participant ratings of improvement, symptoms or adverse events, and participant disposition (adherence or withdrawal). They recommended that each of the six domains should be considered in the design of all clinical trials of the efficacy and effectiveness of treatments for chronic pain, and if one or more are not included the reasons for exclusion should be justified a priori. IMMPACT met again in 2003 to recommend core outcome measures for each of these domains.(39) In 2006, IMMPACT met, this time with 40 participants from universities, government agencies, a patient self-help organization and the pharmaceutical industry to determine the clinical importance of changes in each of the specific outcome measures previously recommended.(40) The core domains suggested by IMMPACT are consistent with the OMERACT-III (41) (Outcome Measures in Rheumatoid Arthritis Clinical Trials) which have been adopted by the World

Health Organization /International Leagues of Associations for Rheumatology (WHO/ILAR). (42)

2.3.2 Inadequate Control Groups and Poor Response Rates

A second limitation identified in the literature is that few studies utilized comparison groups. (3,7,15,16,43) A suggested justification for this was that since the subjects had long histories of pain, a change following the short interval of treatment could logically be attributed to the treatment.(17) In studies that did use a comparison group it has been suggested that they were rarely appropriate. (7,8,43) Robbins et al (14) used "program drop-outs" as a control group finding that those who completed the interdisciplinary pain management program demonstrated significant improvements on the majority of outcome measures relative to the "drop-outs." 127 subjects completed the program and 74 dropped out for various reasons including noncompliance (78.4%). Deardorff et al (15) used lack of insurance authorization for the treatment program as the "no treatment" group. They found positive outcomes of increased physical functioning, decreased medication use, and increased return to work rate for the treatment group compared to the no-treatment group. They did note that as well as the lack of insurance, the no-treatment group was "significantly older" than the treatment group and had a greater proportion of males than females. Roberts and Reinhardt (44) used a comparison group made up of patients who had been rejected for treatment, or refused to attend. Reasons for rejection included such things as unwillingness to cooperate, severe medical problem, severe mental disorder or chemical dependency as the primary problem. Guck et al (45) used a

no-treatment group made up of patients who had been accepted for treatment but lacked the financial ability or insurance coverage to pay for the treatment program. Several studies used wait-lists, but these were short term, as ethically a wait list can only be maintained until a place opens up in the treatment program. (8)

In those studies that did use a comparison group they were not randomly assigned, and often were self-selected. The importance of a control or comparison group, and random assignment, is in the ability to show a causal relationship. (46) The use of a randomized control group allows the researcher to conclude, with more confidence, that any change observed in the treatment group can be attributed to the treatment itself and not to some extraneous factors. An important assumption is that the treatment and comparison group are alike on all factors which may be associated with the outcome of interest, except for the treatment itself. Therefore, a systematic difference, such as the ability to pay or the reason for a patient or group of patients dropping out or being excluded, may introduce bias into the findings.(3) The difficulty in designing suitable controls has been discussed in many articles. (8,16,47) Hildebrandt (47) states that “a randomized control group would have been very difficult, if not impossible” and Morley, (8) in his systematic review, states that “the variety of control conditions reflect the difficulty in designing suitable controls.” He goes on to state that “being allocated to a control would have different psychological consequences to being allocated to an active treatment.”

Poor response rates to follow-up have been identified as a problem issue as well, (15,17) and it has been reported that “it is not unusual for follow-up

evaluation to be based on less than 30% of the original population." (17) This is a difficult population to engage. Low response rates can introduce bias into a study if "responders" differ in a systematic way from the "non-responders." (48) For example if they differ with respect to their sex, age, medical characteristics, or even a factor that is not obvious or assessed. Nonresponse bias can lower the statistical power of the study and mask statistically significant relationships, which "truly" exist. (49) Nonresponse can also limit the generalizability of the findings.

Turk (17) goes on to say that outcome research in this area is a "daunting task" and the "perfect treatment outcome study is not only inconceivable, but it would surely be impossible to execute," but that we should not be deterred from continuing to evaluate the effectiveness of treatment in chronic pain. Gamsa adds that the problems are complex and difficult to solve and it "may be necessary to accept limits in a field of study defined by multiple interacting variables." (43)

2.3.3 Lack of Long Term Follow-up

In reviewing the literature, it is noted that there is very little data on long term effects of these programs. In fact, there is no standard definition of what long term means, and in an early meta-analysis, Flor et al (7) divided the 65 studies reviewed into "short term", which was up to six months after completion of treatment, and "long term" which was defined as longer than six months post treatment. Turk and Rudy (50) conducted a literature review of "many studies", the majority citing a one year follow-up period. McCracken and Turk (10)

conducted a literature review, which included several meta-analyses, and concluded that “there was little data beyond 18 months.”

Many studies look at immediate effects following the intervention. A 2004 study (34) evaluating the effectiveness of a multidisciplinary pain management program used data collected only before and immediately after the treatment program, and Mead et al, (16) in 2007, used data from pre-treatment and six weeks post program. Moss-Morris et al (36) used a longitudinal design evaluating patients at the end of a four week treatment program and at one, three and six months. It is common in the literature to use six and/or twelve month follow-up periods for evaluation of outcomes. (14,34,47,51,52)

There is considerable evidence that improvements are maintained for up to one year. In a 1991 study, Deardorff (15) compared a group of patients treated in a multidisciplinary pain program to a group of patients who were evaluated by the program, but not included in the treatment program due to lack of insurance coverage. The average time to follow-up was approximately 10 months for the treatment group and approximately 13 months for the non-treatment group. The findings supported the effectiveness of the treatment program showing increased physical functioning, decreased medication use, and an increased return to work rate for the treatment group. Robbins et al (14) conducted a prospective one-year outcome study of interdisciplinary chronic pain management. Patients were compared pre and post treatment as well as at one year follow-up evaluation. Comparisons were made between “treatment program completers and treatment dropouts.” Their results “clearly show” that patients who completed the interdisciplinary program demonstrated significant

improvements on the majority of outcome measures and maintained these gains at follow-up, relative to the treatment dropouts.

A recent study evaluated patients before, after and at 12 months following treatment to determine how treatment expectancy affects the outcomes of treatment. In this study they defined long-term outcomes as 12 months. (51) All of these studies supported the effectiveness of a multidisciplinary approach to management.

However, there has been some suggestion that the positive effects of a treatment decline over time. Harkapaa, in a 1990 study from Finland, (53) showed positive results three months after a multidisciplinary program for chronic low back pain, but found these effects had "faded out" in many of the measured parameters after one year. They found a "refresher" program offered one and a half years after the initial program was effective in restoring the improvements. Lanes et al (12) contacted patients whom had completed a multidisciplinary rehabilitation program for chronic back pain within a previous ten year period and interviewed 52.9% of these patients. The length of time since completion of the program ranged from .2 to 9.7 years, the average being 3.1 years. Although their findings supported the effectiveness of this approach to treatment in terms of return to work, they found a general decline in the percentage of patients reporting feeling better than before treatment as they moved to longer term. (75% of those less than six months post treatment compared to 38% of those who were more than three years reported feeling better or much better than before treatment) Bendix et al (54) investigated four different types of back pain treatments over a five year period. They found positive results related to return

to work, less sick time, less health care usage, and coping better in daily activities in the treatment group compared to a control group after four months and one year, but also found that some of these positive benefits had “faded out” at the two year evaluation. These longer term follow-up studies, all finding support for a multidisciplinary approach to treatment but some decline in positive effects over time, were specifically for chronic back pain programs.

Moss-Morris et al (36) examined the patients’ perceptions of their pain across a multidisciplinary pain management program, evaluating them at the beginning and end of the four-week treatment program and at one, three and six months follow-up. They showed that a multidisciplinary pain program is successful in improving pain-related disability and reported gains in both mental and physical wellbeing, but also found a small loss in treatment gains over the 6 month follow-up period. A prospective study from Norway (55) used data from a one year follow-up evaluation, and suggested that future studies should “clarify the long-term effect of multidisciplinary rehabilitation programs for individuals with chronic musculoskeletal pain in terms of function in daily life.”

2.4 Implication of Literature Review for the Present Study

In the present study, an attempt was made to contact all clients who were assessed at the Saskatoon Chronic Pain Centre (CPC) for follow-up at least one year after their final contact with the CPC, and for some this was over three years following their contact with the CPC. This is a longer follow-up time than is generally found in the literature.

In order to facilitate integration with the literature, the follow-up evaluation in this study addressed the domains recommended by the IMMPACT group and included a measure of pain intensity, physical functioning, emotional functioning and overall improvement. [3] The goals of the treatment program – improved coping skills, function and well-being and the promotion of self-reliant lifestyles are captured in the domains of physical and emotional functioning and overall improvement. Although actual reduction of pain is not necessarily a goal of treatment, it is important to monitor and has been included in the evaluation. Outcome measures that were recommended for each domain included: a pain severity visual analogue scale (VAS), the Multidimensional Pain Inventory (MPI), the Beck Depression Inventory (BDI-II) and the Patient Global Impression of Change (PGIC). The first three of these had previously been used by the CPC for evaluation of the treatment group during the six week CPC program, and thus provided a basis for comparison for this group in the follow-up evaluation.

As identified in the literature, comparison groups are difficult to establish effectively in this population. Although randomization is considered the "gold standard", when it is not deemed possible, a non-random control group may be used, although this offers less compelling support for causation. (46) By definition, a quasi-experimental design lacks random assignment, with assignment to conditions being by means of self-selection. (46) Because of this, the investigator must rely on other design options to reduce internal validity threats. (46) This study used a non-randomized control group (for the second

[3] The other two recommended domains; symptoms or adverse events, and participant disposition (ie. withdrawal) are specific to drug clinical trials and not applicable to this study.

research question) which is a stronger design than many previous studies, and was further strengthened with additional study design considerations. In an effort to improve postal response rates for this study, a number of strategies reported in the literature were employed including reminder letters and the use of colored questionnaire paper.

Chapter 3:

Methodology

3.1 Background

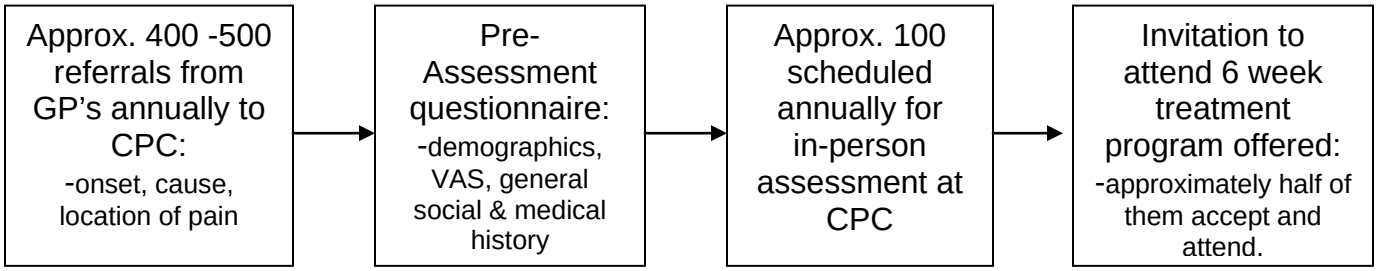
The Chronic Pain Centre (CPC) was established in Saskatoon in May 2004, and the goal of this six week program is to facilitate improved coping skills, function and well-being, and to promote self-reliant lifestyles. Data collected by the CPC at the pre-assessment and assessment stages were made available for this study in addition to the data collected by questionnaire specifically for the study.

3.1.1 Data Source

Between its inception in 2004 and October 2007, the CPC had conducted approximately 400 multidisciplinary assessments and provided treatment for approximately 200 clients. Approximately 400 to 500 initial referrals are received each year at the CPC from family practitioners. (Figure 3.I) These referrals are screened and those patients who would be better managed by an alternate resource are re-directed. (ie palliative, frail geriatric, acute pain, cancer) Once past the initial screening, clients are asked to complete a pre-assessment questionnaire recording demographic characteristics, pain information, medical and social history, basic psychosocial information and self-reported functional status. (Appendix 7.1) Approximately 100 of these clients are scheduled annually for an in-person multidisciplinary assessment session. Following this assessment, clients are invited to attend the six week chronic pain management

program. In this study, the clients who were assessed and attended the six week treatment program (described below) constitute the "treatment group", and the clients who were assessed but did not attend the program are the "control group".

Figure 3.1: Referral Process for the CPC:



3.1.2 The Saskatoon CPC Treatment Program

The Saskatoon CPC treatment program is based on a cognitive-behavioral approach and consists of education sessions, discussion/support groups, physical activity and individual and group sessions with a psychologist, physical therapist, occupational therapist, nurse and physician. Although all clients participate in the complete program and all services, the treatment program is tailored to meet each individual's needs in order to reach their treatment goals.

The assessment team is comprised of a medical consultant, a psychologist and a registered nurse. A physical therapist and occupational therapist are available to take part in the assessment when appropriate. Their findings are combined and summarized in an "Assessment Report" that identifies

medical and psychological barriers to recovery and makes recommendations for both pain medication optimization and rehabilitation.

The six week program includes daily attendance at the CPC for 3 1/2 hours for the first four weeks, and then a one week break to provide an opportunity to practice the pain management skills at home and assess problems that the clients may encounter. This is followed by a return week to review and problem solve with the treatment team to promote success after discharge. The six week program is focused on teaching skills that enhance self-management of pain. Typically a client would receive ten sessions of physical therapy, five sessions with the occupational therapist, and five with the psychologist, as well as weekly group activity and discussions. Regular physical activity is encouraged in the program. Additionally, clients are taught specific coping strategies, such as rational self-analysis, diaphragmatic breathing, relaxation techniques and pacing. Interdisciplinary case conferences are held weekly, and typically each client's case is discussed in this conference on three occasions. The first meeting is held immediately following the initial evaluation by the assessment team to discuss if the client is a good candidate for the program and to identify preliminary treatment goals. The remaining meetings are held at the mid-point of the program and at discharge to discuss client progress.

During the course of the program, the clients complete a number of psychosocial and functional measures, both at the beginning and at the completion of the six week program. These measures include: the Beck Depression Inventory (BDI-II), the Multidimensional Pain Inventory (MPI), Tampa Scale (fear of movement), Pain Catastrophizing Scale, and the Chronic Pain

Acceptance Questionnaire (CPAQ-R). Following discharge, there is a voluntary three month review in which clients are asked to complete the same measures for a third time. The CPC also conducts annual focus groups with clients, as well as satisfaction surveys of clients and family physicians and reports that based on a 100% response rate of the client satisfaction survey, 90% of clients felt “more capable and confident” of managing their condition and 95% of the physicians who have referred a client to the CPC were satisfied with the program.

3.2 Recruitment Procedure for Follow-up in This Study:

Clients were considered eligible for the study if they had undergone the assessment at the CPC prior to October 2007. Due to “privacy” concerns, the initial contact with all CPC clients was done by personnel hired by the Saskatoon Health Region who contacted eligible clients by phone to explain the study, ask if they would be willing to participate and obtain consent. Attempts were made to contact all clients who had been assessed at the CPC between its inception in 2004 and October 2007. Unfortunately, virtually all of the contact phone calls were made during regular working hours. (8:00 A.M. to 6:00 P.M.) Questionnaires were mailed out to all clients who agreed to participate and a number of strategies were used that have been identified in the literature as effective in increasing response rates to postal questionnaires. (49,56-59) These strategies included a pre-mail out telephone call, stamped return envelope, and the questionnaire printed on pink colored paper. The main questionnaire, including a cover letter, (Appendix 7.2) was followed with a reminder letter one month later, and in another month, non-responders were sent a reminder letter

with a second copy of the questionnaire and a pen. A third wave was a second reminder letter for non-responders.

Finally, an incentive for participation was offered. To ensure that subject responses remained anonymous, the entry form was completed by the client and sealed in an envelope prior to being returned with the questionnaire. On receipt of the completed questionnaire, the sealed envelope containing the name of that client was removed and entered into the draw box for a participation prize.

3.3 Instrumentation and Study Variables

Following the guidelines recommended by the IMMPACT consensus, and to reflect the goals of the treatment program, the follow-up evaluation for this study included measures to address the domains of pain intensity, physical functioning, emotional functioning and overall improvement. The IMMPACT group had also made recommendations for the core outcome measures to be used to determine the effectiveness of treatments for chronic pain. In this study, for each domain evaluated, one of the recommended outcome measures was selected. To provide an opportunity for further comparison for the treatment group, the outcome measures selected were those which had previously been used by the CPC with the clients who had attended the six week program. An additional consideration in instrument selection for the study was participant burden, especially in light of the fact that response rates are already an identified challenge. Please refer to Appendix 7.2 for the complete questionnaire used in this study.

3.3.1 Dependent Variables

Pain intensity was measured with a visual analogue scale (VAS) which consists of a 10-cm horizontal line with hash marks at one-centimeter intervals. Clients were asked to indicate where on the scale, from “No Pain” (0 cm) to “Worst Possible Pain” (10 cm) best described their level of pain in the last 24 hours. Scores can range from 0 to 10, with higher scores indicating worse perceived pain. The VAS has been found to be a valid and reliable instrument (60,61) and well established in the chronic pain population with test-retest reliability correlations between .75 and .83. (37)

The Multidimensional Pain Inventory (MPI) is a comprehensive 60-item self-report inventory, designed to measure several important aspects of the subjective experience of chronic pain, including pain intensity, emotional distress and cognitive and functional adaptation in response to their condition. (62) The MPI was developed as a multidimensional assessment instrument, theoretically linked to the cognitive-behavioral perspective of pain, and specifically for use with chronic pain patients. (62) In its entirety the MPI consists of 12 scales, grouped into 3 sections: 1) pain and its impact, 2) responses by significant others, and 3) activities. Sample items include: “In general, how much does your pain interfere with your day-to-day activities?” and “How much control do you feel that you have over your pain?” Clients are asked to respond to questions based on a scale from 0 to 6, with 0 being “Never” or “Not at all” and 6 being “Very Much”, “Very Often” or “Extreme”. The scores are computed by the MPI computer program into a raw score and a t-score for each of the scales. To be consistent with the data already collected by the CPC, five MPI scales were used in this

follow-up: Pain Severity, Interference, Life Control, Affective Distress and Support, as well as the scale for General Activity. For Pain Severity, Interference and Affective Distress, a higher score indicates increased symptoms or more difficulty related to these scales as opposed to Life Control, Support and General Activity where a higher score would indicate improved status or less difficulty. The MPI is reported to be psychometrically sound; the reliability (internal consistency) estimates for all scales ranging from .70 to .90. (62) The MPI has been widely used as an outcome measure and its psychometric adequacy has been demonstrated in diverse types of chronic pain. (40) It provides a reliable and valid measure of the interference of pain with physical functioning. (39)

The Beck Depression Inventory (BDI-II) (63-65) is a 21 item self-report scale assessing severity of symptoms of depressive disorders. The BDI consists of items with four statements rated from 0 to 3 in terms of intensity. Clients are instructed to select the statement which best describes their own feelings. For example, the statements related to “Sadness” are 0 = I do not feel sad, 1 = I feel sad much of the time, 2 = I am sad all the time, and 3 = I am so sad or unhappy that I can’t stand it. Total scores range from 0 to 63, with higher scores indicating increased symptoms of depression. Estimates of the BDI’s internal consistency reliability (Cronbach’s alpha) range from .73 to .95, (40,66) and test-retest reliability (Pearson) at .80 to .90. (40) The brevity and low reading level requirements are considered additional strengths of this instrument. (40)

The Patient Global Impression of Change scale (PGIC) is a single-item rating for overall assessment of change. (67) Respondents select one statement from a seven point scale ranging from 0 (“very much improved”) to 7 (“very much

worse"). The PGIC has shown sensitivity to change and is "extensively used by pain researchers as a standard outcome measure and for comparison to other outcome measures." (68) This measure is intended to provide an indication of the clients' overall impression of change, and the meaningfulness of this change, or the personal importance that the change has for participants. (38) There is widespread use of the PGIC in clinical trials, and the data has been reported to provide "a responsive and readily interpretable measure of participants' assessments of the clinical importance of their improvement or worsening over the course of a clinical trial." (39,40) The measure has been criticized due to the reliance on the client recalling their initial state and mentally comparing it to the present, but in spite of this it is thought to be valuable to include one rating of global improvement to assess the client's personal perspective. (38)

3.3.2 Other Variables

Several variables were used from the pre-admission data provided by the CPC. Age, gender, educational status, pre-admission VAS and area of pain information were available for both study participants and non-participants. For the pre-admission VAS, all clients had been asked during the CPC pre-admission assessment to rate the level of pain during the past 24 hours. The area of pain, self reported as the primary complaint, was defined as musculoskeletal, neuropathic, abdominal, headache, incisional, pelvic, other and unknown. Information was also available to construct two additional variables: 1) time since assessment at CPC (the time in months between the initial assessment at CPC and contact for the study follow-up) and 2) time since treatment start (the time

between the actual start date of CPC treatment program and follow-up contact for those clients who attended the program).

An additional two questions were included in the study questionnaire, the first regarding employment status and the second asking about any other treatments that have been sought since the CPC visit.

3.4 Ethical Approval

Ethical approval was obtained from both the Behavioural Research Ethics Board (Beh-REB) of the University of Saskatchewan and Ethics Committee of the Saskatoon Health Region. (Appendix 7.3) Verbal consent was obtained from each participant at the time of phone contact, when they agreed to participate in the study. Two copies of the consent form (Appendix 7.4) were also sent out with the questionnaire package; one for their reference and one returned signed with the questionnaires.

3.5 Analysis

Data analyses involved a multi-stage process consisting of univariate, bivariate, and multivariate analyses using SPSS 17.0 for Windows. The particular variables used in the analysis varied according to the research question. (Table 3.1)

Table 3.1: Summary of Variables used in Follow-up Questionnaire, by Research Question.

	Research Question 1	Research Question 2
Dependent Variables		
Visual Analogue Scale (VAS)		■
Multidimensional Pain Inventory (MPI)		
Pain Severity	■	■
Interference	■	■
Life Control	■	■
Affective Distress	■	■
General Activity		■
Beck Depression Inventory (BDI-II)	■	■
Patient Global Impression of Change Scale (PGIC)		■
Other variables		
Age	■	■
Gender	■	■
Education level	■	■
Employment status[4]	—	—
Pre-admission VAS	■	■
Area of pain	■	■
Time since assessment at CPC[5]		■
Time since treatment at CPC	■	
Further treatment sought after CPC	■	■

3.5.1 Preliminary Analysis

Preliminary data analysis included data screening and the testing of statistical assumptions. Any outliers were checked in the raw data, and were corrected if found to be data entry errors. When testing basic assumptions, it was found that some of the outcome variables were not normally distributed. These variables were subsequently transformed (squared or cubed to reduce a

[4] Subsequent to data collection, it was found that data related to the question about employment were not specific enough to be useful, and therefore were not used in the analysis.

[5] time since assessment categorized by less than the median/more than the median of 32 months

negative skew and square root transformed for a positive skew)(69) and rechecked for normality.

The data on the total group of clients that were eligible for the study were examined, and comparisons were made between those clients that participated in the study and those that did not participate in this study. Differences between these groups were tested using chi-square tests for categorical variables and t-tests for continuous measures.

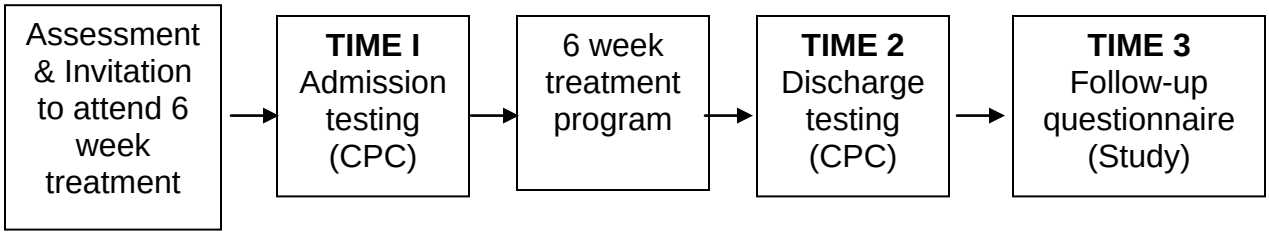
3.5.2 Analysis for Research Question 1

Are improvements in clients physical and social functioning, observed at completion of the six week program, maintained over time?

To evaluate changes in the treatment group over time, the outcome variables uses for analysis were the BDI and four MPI[6] scales: Pain Intensity, Interference, Life Control and Affective Distress. These variables had been collected at three points in time (Figure 3.2): admission to CPC treatment program (Time 1), discharge from CPC program (Time 2) and at data collection for follow-up for this study (Time 3). Although the Time 3 follow-up questionnaires were collected at one point in time, the actual length of time between Time 2 and Time 3 varied for individual participants from one to three years.

[6] In review of the data collected, it was noted that one of the scales within the MPI (Support) had a considerable amount of missing information. This scale was questioning whether or not the client had support of a spouse or significant other, and in the questionnaire there was an opportunity to select a "not applicable" answer. In addition there were also several "missing" answers in these questions. As a result this scale was not included in the analysis.

Figure 3.2: Question 1: Treatment Group Testing Times.



In preliminary examination of the data, paired samples t-tests were used to examine changes in the scores over the three points of time by comparing the means of each variable for Time1 to Time 2 (admission to discharge), Time 2 to Time 3 (discharge to follow-up) and Time 1 to Time 3 (admission to follow-up). The paired t-test compares the means of two variables by computing the difference between the two variables for each case, and testing to see if the average difference is significantly different from zero.

To take into account multiple dependent variables, a multivariate analysis of covariance (MANCOVA) was then conducted to examine the treatment groups' scores on the various outcome measures at the three points in time. The MANCOVA compares the differences in the means between the different time points, therefore, "difference scores" were computed and comparisons were done looking at Time 1 to Time 2 (admission to discharge), and Time 1 to Time 3 (admission to follow-up). The MANCOVA was repeated using an alternate method, with the Time 1 scores entered as covariates rather than using the difference scores.

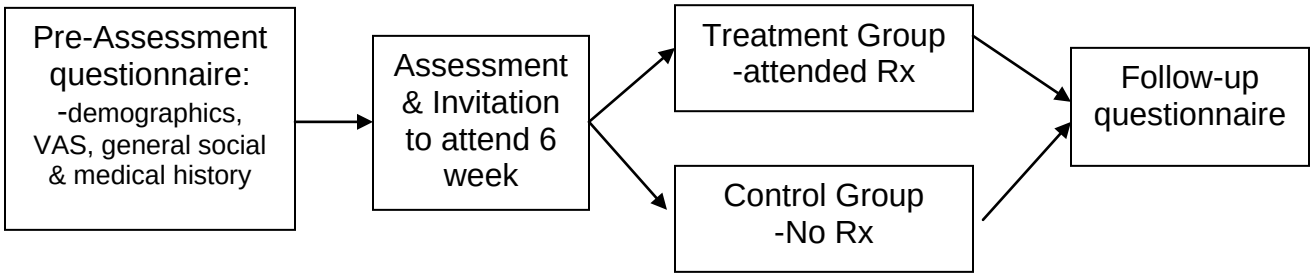
Results of the univariate tests were then examined to provide additional information about the significant multivariate result and how it affected the dependent variables.

3.5.3 Analysis for Research Question 2

Is there a significant difference in these outcomes, on evaluation at least one year after assessment, of those clients who completed the six week program (treatment group) compared to those who underwent the initial assessment, but did not attend the program (control group)?

To address the second research question, both the treatment and control groups were considered at one point in time - the study follow-up period of at least one year since assessment. (Figure 3.3)

Figure 3.3: Question 2: Comparison of Treatment and Control Groups.



The treatment and control groups were compared on the eight outcome measures: the VAS, BDI, the PGIC (Global Change), and five scales of the MPI; Pain Severity, Interference, Life Control, Affective Distress and General Activity.

Given the lack of random assignment to treatment condition, it is important to establish that the treatment and control groups are alike as possible on characteristics which may potentially impact the outcomes of interest in this study. To that end preliminary analysis for Research Question 2 involved comparing the treatment and control groups on demographic information, CPC pre-admission data and time since assessment. Differences between the treatment group and control group were tested using chi-square tests for categorical variables and t-tests for continuous measures.

In preliminary examination of the data a series of one-way ANOVA's was conducted, to examine the means and standard deviations of the treatment and control groups on each outcome variable. The next step was a multivariate analysis of covariance (MANCOVA), which is designed to look at several dependent variables simultaneously, include covariates and also look at interactions between independent variables. In addition to considering main effects, particularly treatment group status, the MANCOVA is also able to test whether treatment status interacted with other variables (e.g. time since initial assessment, gender, etc) to influence any of the dependent variables. Results of the univariate tests were then examined to provide additional information about the significant multivariate result and how it affected the dependent variables.

The VAS had been measured at the pre-assessment stage as well as the follow-up for all study participants; therefore an exploratory analysis, using paired t-tests, was conducted separately for the treatment and control groups to examine changes in this pain severity rating; an ANOVA was then used to

examine the difference scores, representing the change in the VAS over time, based on treatment status. To further compare the treatment and control groups on the follow-up VAS, a univariate analysis of covariance (ANCOVA) was conducted, using the pre-assessment VAS as a covariate, which controls for the effect of a covariate and decreases the error.

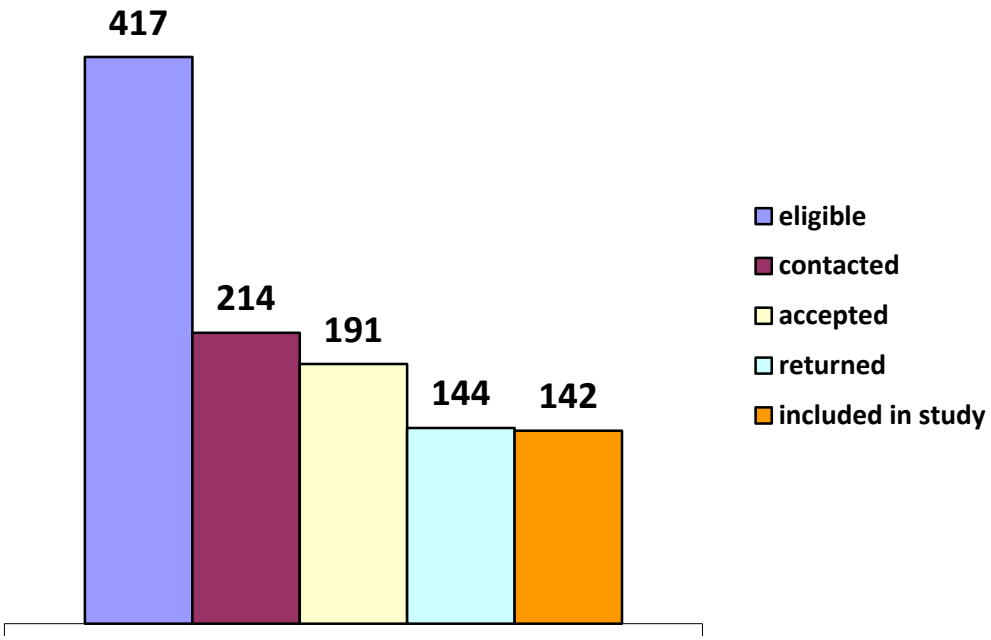
Chapter 4:

Results

4.1 Participants:

From the inception of the Saskatoon Chronic Pain Centre in Saskatoon in May, 2004, to the study cutoff date of October 2007, there were 417 clients considered eligible for this study. (Figure 4.1) The research assistant, hired by the Saskatoon Health Region to make the initial phone calls, was able to contact 214 of the 417 clients; 18 of those contacted declined the invitation to participate, 5 were reported as deceased and 191 agreed to participate in the study. Of the remaining 203 clients, 39 had moved with no new contact information and 164 had no answer at the contact phone number on file.

Figure 4.1: CPC Population.



The total return response for the questionnaire package was 144, although one subject stated that he was refusing to complete the questionnaires and one subject was deemed ineligible as she had actually only completed the six week program one month prior to the study. (the assessment date had been several months previous to this). The sample considered for this study included 142 clients. (34%) It is worth noting, though, that from those 214 clients that were contacted 144 of them returned the questionnaire package. (67%)

Based on data provided by the CPC on various characteristics, comparisons between the study participants and those not participating in the study are shown in Table 4.1 below. Compared to the clients not included in the study, study participants were older and more likely to have attended the CPC treatment program. There were no significant differences between participants and those not participating in the study based on gender, education level, area of pain or in the pre-admission VAS.

Table 4.1: Characteristics of Study Participants and Study Nonparticipants.

	Study Participants (n=142)		Clients not Participating in Study (n=275)		
	Mean	**SD**	**Mean**	**SD**	**p**
Age	49.46	10.65	46.05	12.25	.005
Range	20 - 79		18 - 81		
Pre-Admission VAS	6.34	1.58	6.62	1.55	.101
Time since assessment (mo)	33.04	13.24	33.38	14.79	.878
	Number	**%**	**Number**	**%**	**p**
Gender:					
Male	53	37.32	99	36.00	
Female	89	62.68	176	64.00	.790
Education level:					
High School or less	51	35.92	101	36.73	
College/technical/ other course	54	38.03	116	42.18	
University /grad degree	25	17.60	40	14.55	
missing	12	8.45	18	6.55	.623
Area of Pain					
Musculo-skeletal	105	73.94	212	77.09	
Neuropathic	21	14.79	37	13.45	
Other (combined)	16	11.27	26	9.45	.364
CPC Treatment					
Yes	88	61.97	135	49.09	
No	54	38.03	140	50.90	.012

4.2 Research Question I

Are improvements in clients physical and social functioning, observed at completion of the six week program, maintained over time?

This question pertains only to the treatment group; those clients participating in the study who had attended the six week CPC treatment program. (n=88) The outcome variables used for this analysis had been collected at three points in time, and Table 4.2 shows the mean scores and standard deviation for

the relevant dependent measures at each time point. Improvement is demonstrated by decreased scores for the BDI, Pain Intensity, Interference, and Affective Distress, and increased scores for Life Control.

Table 4.2: Mean Scores on Outcome Variables for Treatment Group. (n=88)

Outcome Variable	Admission (CPC) scores Time 1		Discharge CPC) scores Time 2		Follow-up (Study) scores Time 3	
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**
BDI	22.88	10.38	15.43	10.30	19.90	11.91
Pain Intensity	49.64	7.16	45.34	9.25	46.06	10.03
Interference	52.72	6.20	49.14	7.73	51.04	8.26
Life Control	49.27	8.16	55.58	8.74	52.24	9.37
Affective Distress	50.43	8.43	45.54	8.72	46.61	8.89

Results of the paired t-test are shown in Table 4.3. There was a statistically significant improvement for all dependent variables, between Time 1 and Time 2, followed by a statistically significant decline in scores between Time 2 and Time 3 for three of the five outcome variables; BDI, Interference, and Life Control. However, despite this decline between Time 2 and Time 3, the scores for all of the outcome variables still demonstrated an overall statistically significant improvement from Time 1 to Time 3 (from admission to follow-up).

Table 4.3: Treatment Group: Changes in Mean Scores.[7] (n=88)

	Time 1 - 2	p	Time 2 – 3	p	Time 1 – 3	p
BDI	Improved	.001	Declined	.011	Improved	.001
Pain Severity	Improved	.001	Declined	.775	Improved	.001
Interference	Improved	.000	Declined	.046	Improved	.009
Life Control	Improved	.001	Declined	.002	Improved	.004
Affect Distress	Improved	.001	Declined	.151	Improved	.007

The next step in analysis was multivariate analysis of covariance (MANCOVA), using the "difference scores" for Time 1 to Time 2 and Time 1 to Time 3. Box's test of Equality of Covariance Matrices was nonsignificant (Box's M=97.79, p=.475), demonstrating that there was homogeneity of covariance of the dependent variables across all independent groups. The results of the MANCOVA were consistent with the results of the paired t-test, demonstrating that the differences seen in the means at these levels were statistically significant. (Wilks' Λ=.501, F(1,48)=4.788, p=.000). This indicates that when looking at all the outcome variables simultaneously, the improvement in scores from admission to discharge, and from admission to study were statistically significant. Other factors included in the analysis were Gender, Education Level, Area of Pain, and Further Treatment and the covariates examined were Age, Time Since Treatment and Pre-Admission VAS. There were no statistically significant main effects for any of these variables. The MANCOVA was repeated using the Time 1 scores as covariates rather than the "difference scores", and produced consistent results.

[7] Outcome variables that were found to violate the assumption of normality in at least one level (Time1, Time 2 or Time 3) were transformed at all levels prior to analysis.

The MANCOVA did demonstrate a statistically significant interaction between gender and education level. (Wilks' Λ=.544, F(2,96)=1.709, p=.045). The univariate results show the interaction between gender and education level affecting only the Interference Time 1 to Time 2 scores. (F(2,57)=7.161, p=.002) Looking at the changes in scores between Time 1 and Time 2, for males the most change occurred for those with a high school or less education, while for females the largest change occurred for those with a university or graduate degree.

4.3 Research Question 2

Is there a significant difference in these outcomes, on evaluation at least one year after assessment, of those clients who completed the six week program (treatment group) compared to those who underwent the initial assessment, but did not attend the program (control group)?

Demographics and pain-related assessment information for study participants, by treatment status, is shown in Table 4.4. There were no statistically significant differences between the treatment and control groups based on Age, Gender, Education Level, Area of Pain, Pre-Admission VAS, additional treatment or time since assessment at the CPC. Further examination of the information regarding additional treatment sought since contact with the CPC also did not demonstrate any significant differences between the treatment and control groups in the kinds of treatment that were reported. (acupuncture, biofeedback, chiropractic, physical therapy and other)

Table 4.4: Comparison of Treatment and Control Groups on Demographic and Assessment Data.

	Treatment Group (n=88)		Control Group (n=54)		
	Mean	**SD**	**Mean**	**SD**	**p**
Age	49.16	10.03	49.94	11.66	.671
range	23-74		20-79		
Pre-Admission VAS	6.26	1.60	6.48	1.50	.481
Time since assessment at CPC(mos)	32.99	13.41	33.11	13.10	.958
	Number	**%**	**Number**	**%**	**p**
Gender					
Male	32	36.36	21	38.89	
Female	56	63.64	33	61.11	.763
Education level					
High School or less	30	34.09	21	38.89	
College/technical/other course	32	36.36	22	40.74	
University degree/grad degree	18	20.45	7	12.96	
Missing	8	9.09	4	7.41	.488
Area of Pain					
Musculo-skeletal	66	75.00	39	72.22	
Neuropathic	12	13.64	9	16.67	
Other (combined)	10	11.36	6	11.11	.181
Treatment since CPC					
Yes	61	69.32	42	77.78	
No	27	30.68	12	22.22	.319

Note: the Pre-Admission VAS scores were transformed prior to analysis to correct for negative skew of scores.

Preliminary data analysis included a series of one way ANOVA's (Table 4.5) to examine the means and standard deviations of the eight outcome measures, (outcome variables for this question as listed in Table 3.1).for both the treatment and control groups. No statistically significant differences emerged between the treatment and control groups for any of the variables.

Table 4.5: Means and Standard Deviation of Variables by Treatment Status.

	Treatment Group (n=88)		Control Group (n=54)		
	Mean	**SD**	**Mean**	**SD**	**p**
VAS (pain rating)	5.64	2.28	5.63	2.53	.975
BDI – total score	19.95	12.07	19.66	11.80	.888
MPI – Pain Severity	45.55	9.48	46.95	10.98	.296
MPI – Interference	50.95	7.69	51.11	9.26	.641
MPI – Life Control	51.58	9.33	53.33	9.51	.284
MPI– Affective Distress	47.07	8.31	45.71	9.81	.377
MPI – General Activity	52.16	9.54	52.05	12.62	.953
Global Change	3.27	1.50	3.77	1.63	.070

Note: actual score values are reported here, although transformed scores were used for analysis and establishing significance.

Because there are eight dependent variables for research question 2, a multivariate analysis of covariance (MANCOVA) was undertaken. Box's test was nonsignificant (Box's M=130.84, p=.547), indicating that the assumption of homogeneity of covariance matrices had not been violated. No main effect was demonstrated for treatment condition, (Wilks' Λ=.930, F (1,107) = 1.014, p=.430). There was also no interaction of treatment condition with any of the factors examined including Gender, Education Level, and Area of Pain or with any of the covariates which included Age, Time Since Assessment, Pre-Assessment VAS,. However, main effects did emerge for Pre-Assessment VAS (Wilks' Λ=.756, F(1,107)=4.314, p=.000), Area of Pain (Wilks' Λ=.692, F(2.214)=2.701, p=.001) and Education Level (Wilks' Λ=.868, F(1,107)=2.030, p=.050).

The univariate tests demonstrated the effect of Pre-Assessment VAS on all of the outcome variables except Affective Distress. (Table 4.6)

Table 4.6: Between Subject Effects for Pre-Assessment VAS.

	df	Mean Square	F	p
VAS (follow-up)	1	113.686	28.04	.000
BDI (total)	1	10.609	5.37	.022
Pain Severity	1	1.675 E7	28.13	.000
Interference	1	3.885E10	12.69	.001
Life Control	1	354.777	4.29	.041
Affective Distress	1	168.498	2.16	.144
General Activity	1	452.497	4.58	.035
Global Change	1	2.192	14.14	.000

To understand the effect that the Pre-Assessment VAS had on the scores for the outcome variables, a correlation matrix, presented in Table 4.7, was computed. The Pre-Assessment VAS scores are positively correlated with the BDI, Pain Severity, Interference and Global Change, and negatively correlated with Life Control and General Activity. Thus, a higher Pre-Assessment VAS was associated with poorer outcomes at the time of the study.

Table 4.7: Correlation Matrix: Pre-Assessment VAS and Outcome Variables.

	VAS (study)	BDI	Pain Severity	Interf.	Life Control	Affect. Distress	General Activity	Global Change
Pearson Correlation	.43	.28	.47	.37	-.23	.18	-.25	.35
Sig (2-tail)	.000	.001	.000	.000	.008	.036	.004	.000
N	130	132	133	133	133	133	133	131

For Area of Pain and Education, looking at the between subject effects, both factors were seen to have an effect only on the Follow-up VAS scores.[8] As shown in Table 4.8, those with musculoskeletal pain were highest, on average, on the VAS, and those with "other" scored lowest. In regard to Education,[9] VAS scores were higher for those participants with less formal education. Although this is statistically significant, it is less than 1.0 point (1 cm on VAS) difference, which does not reach the level of minimally important clinical change. (40)

Table 4.8: Effect of Area of Pain and Education Category on VAS.

	n	Mean VAS	SD	Standard error	Mean square	F	p
Area of Pain							
Musc-skeletal	102	5.83	2.27	.22			
Neuropathic	21	5.38	2.25	.49			
Other	16	4.69	2.96	.74	25.53	6.30	.003
Education Category							
H.S/tech	81	5.75	2.33	.26			
Univ/diploma	58	5.47	2.44	.32	16.23	4.00	.048

The VAS is the only variable that had been measured at the pre-assessment stage as well as the follow-up for all study participants. In an exploratory analysis, results of paired t-tests, (Table 4.9) conducted separately for the treatment and control groups revealed that both groups experienced a

[8] The test for homogeneity of variance for the outcome variable VAS was not met, (Levene's p=.028) therefore, the results for this variable should be interpreted with caution. Because ANOVA is quite robust, though, the results will be examined.

[9] The Education levels had been collapsed into two categories: 1) high school or less, some college, or technical school and 2) University degree, other diploma or certificate or Graduate degree.

statistically significant improvement in pain severity between pre-assessment and the time of the study.

Table 4.9: Mean Change of VAS Scores by Treatment Status.

	Mean pre-assessment VAS	Mean follow-up VAS	Mean change	p
Treatment Group	6.25	5.53	.72	.004
Control Group	6.44	5.53	.91	.007

However, additional analysis, using an ANOVA to examine the difference scores, revealed no statistically significant difference in these scores, representing change over time, according to treatment status.(p=.646)

To further compare the treatment and control groups on the Follow-up VAS, a univariate analysis of covariance (ANCOVA) was conducted. Because the Pre-Assessment VAS is known to have an effect on the VAS, entering it as a covariate in the ANCOVA controls for its effect on the VAS, reducing error. Again, this test did not demonstrate any significant difference between the treatment and control groups based on the VAS. (p=.795)

Further analysis then considered the question of Global Change. Although the mean Global Change score was 3.46 and there was no statistical difference found between treatment and control groups, it is important for the reporting of the results to examine the data by percentage breakdown, as well. The results presented in Table 4.10 demonstrate that, overall, 59.3% reported feeling some degree of improvement, compared to 14.3% reporting no change and 26.4% stating that they were minimally, much or very much worse.

Table 4.10: Results of Global Change Question.

	1 =very much improved	2 =much improved	3 =min. improved	4 =no change	5 =min. worse	6 =much worse	7 =very much worse
Treatment Group							
n (n=88)	**7**	**25**	**25**	**9**	**13**	**8**	**1**
%	**8.00**	**28.4**	**28.4**	**10.2**	**14.8**	**9.1**	**1.1**
Control Group							
n (n=52)	**2**	**11**	**13**	**11**	**4**	**8**	**3**
%	**3.7**	**20.4**	**24.1**	**20.4**	**7.4**	**14.8**	**5.6**
Total (n=140)							
n	**9**	**36**	**38**	**20**	**17**	**16**	**4**
percent	**6.4**	**25.7**	**27.1**	**14.4**	**12.1**	**11.4**	**2.9**

Finally, to more carefully examine the change in scores on some selected outcomes, the difference, or change in scores were computed for the variables and the mean changes are reported in Table 4.11.

Table 4.11: Mean Changes in Selected Outcome Scores.

	n	Mean Change Time 1 - 3
VAS	130	0.79
Interference (treatment group only)	73	1.89
BDI (treatment group only)	73	2.95

The selected outcomes were chosen and discussed by the IMMPACT paper and the mean change in a variable is important in the determination of

clinically important change, which will be discussed in more detail in the next section.

Chapter 5:

Discussion

Chronic pain is a common and important cause of reduced function in daily life. Multidisciplinary treatment programs, although found to be the best choice of management, do not provide all the answers. The goal of these treatment programs is not necessarily to improve the pain, but rather, to improve the coping skills and function of someone living with chronic pain. (34,35) Research has supported the effectiveness of a multidisciplinary approach to treatment of chronic pain, (7,8,10,14,16,36) and have reported improvement in function and lifestyle and improved coping strategies following treatment. Multidisciplinary treatment for chronic pain has been studied extensively, but questions remain about its long-term effectiveness. The literature also clearly states that there are many issues related to the study of chronic pain; the lack of standard outcomes, difficulty in using adequate control groups and poor response rates which make it difficult to compare the different studies. The lack of follow-up longer than one year has also been identified as an issue that needs more investigation to determine effectiveness.

This study was specifically designed to re-evaluate the CPC clients at least one year following their completion of the treatment program to determine if they had maintained improvements in function and social well-being observed at the completion of the six week program. A second goal was to examine how they compared to the group of clients who had undergone initial multidisciplinary assessment at the Centre, but did not attend the six week treatment program. The main findings of this study were:

1) The scores on the outcome measures for the treatment group did improve significantly during the six week treatment period, and although there was some decline in the scores, they remained significantly improved at the time of this follow-up study (between one and three years since treatment) compared to admission; and

2) There were no statistically significant differences on any of the outcome measures between the treatment and control groups at the time of the follow-up study.

With respect to the first research goal of this study, the data confirmed that the clients who had attended the six week treatment program demonstrated a statistically significant improvement in all the outcome variables following the program. This is supported by the CPC's internal report and in the literature by several other studies. Dysvik (34) looked at data immediately following a multidisciplinary treatment program; Mead et al (16) used data from six weeks post program, and Moss-Morris et al (36) evaluated patients at the end of a treatment program as well as a one, three and six months. These authors all found participation in a multidisciplinary treatment program to be associated with significant improvement in various measures of physical and social well-being. In the present study, since there is no control group for this period, we must be cautious suggesting causation, as alternate explanations may be possible for the findings. For example, measurement bias- if clients as part of the study tend to give more socially acceptable answers or perhaps *a*ttention bias – if clients who are part of the study give more favourable responses as a result of the attention received. However, the significant improvement in all measures over such a

short period of time does suggest a positive impact of the treatment program. Although scores did decline over time they did not return to the pre-treatment level and the improvement remained statistically significant. This decline over time has been observed and discussed in the literature as well. A study conducted in Finland in 1990 (53) found that improvements noted at three months after a treatment program had “faded out” in many of the measured parameters after one year. Lanes et al (12) and Bendix et al, (54) in evaluating chronic back pain treatment programs, found a decline in improvement as they moved to longer term, and Moss-Morris et al (36) showed losses in treatment gains over a six month follow-up period. In fact, it has been suggested that a “booster” treatment might be effective in an effort to counter the decline in scores over time. (12,53,54)

Regarding the second goal, it was surprising, given the significant improvement of the treatment group on all outcome measures, to see no significant differences between the treatment and control groups on any of the variables at the time of the study follow-up. It is difficult to compare these findings to other studies due to the issues discussed previously. However, Deardorff, (15) did find that both treatment and control groups showed significant improvement in pain ratings and the “interference with activities ratings” at a follow-up period averaging 11 months, but they also found that the treatment group showed significant improvement compared to the controls on several other measures as well. There are few studies that look at follow-up longer than 12 months, and those that do have used a wide variety of measures and few have used control groups. McCracken and Turk (10) conducted a literature review,

which included several meta-analyses, and concluded that “there was little data beyond 18 months.” There are some longer term studies that look specifically at back pain treatment. Bendix et al (54) did a 5 year review of subjects and found positive results in the treatment group compared to the control group related to sick time use and health care usage, but no differences for all other parameters studied. A systematic review done in 1999 looking at multidisciplinary rehabilitation in fibromyalgia and widespread musculoskeletal pain (70) found limited research-based evidence favouring multidisciplinary rehabilitation. They stated “Despite an extensive search we were able to select only seven relevant trials to include in this systematic review” and that “the methodological quality of the selected studies was low.” These authors go on to report that they found “no quantifiable benefit of multidisciplinary rehabilitation for fibromyalgia. However, behavioural treatment and stress management appear to be important components of multidisciplinary rehabilitation. Education combined with physical training produced some positive effects in long-term follow-up.”

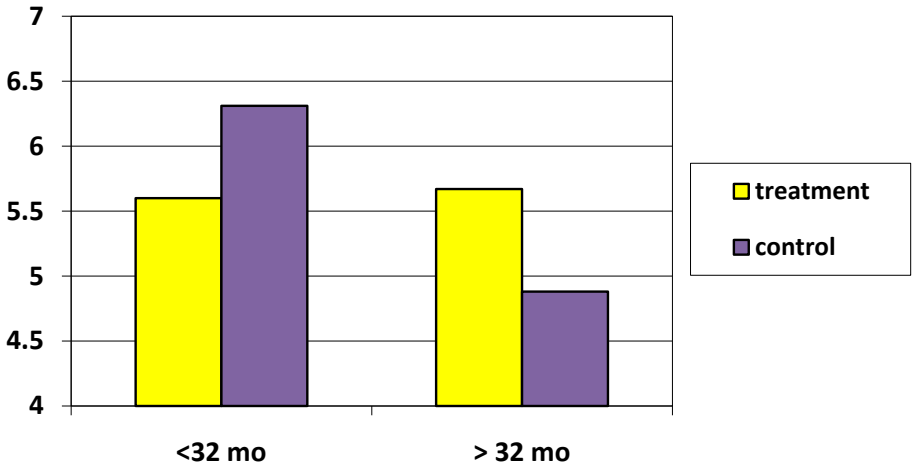
Due to methodological constraints, the lack of difference between the treatment and control groups in our study is not easily explained. That is, although we were able to follow the treatment group over time, we had no equivalent information for the control group; thus, the comparison between the treatment and control groups was based on data collected at only one point in time.

The only exception was the VAS, which was administered to both control and treatment participants at two points in time (CPC Pre-Assessment and the Follow-up questionnaire). As reported in Table 4.4, there was no statistically

significant difference between the treatment and control group in Pre-Admission VAS or in the Follow-up VAS (Table 4.5). Analysis revealed that both groups experienced a statistically significant improvement in pain severity (Table 4.9) and there was no statistically significant difference in the change over time according to treatment status. This would suggest that both the treatment and control groups demonstrated a similar degree of improvement between these two points in time.

Examination of the average scores the VAS at different lengths of time since assessment also suggests that the control group may have gradually improved over time. The graph below (Figure 5.1) shows the average scores for the treatment and control groups on the Follow-up VAS categorized by time since assessment. (those less than and greater than the median time of 32 months.) For those in the treatment group, there was no statistically significant association between time since assessment and study VAS scores. For the control group however, participants reporting at a longer time since assessment had significantly better VAS scores than those reporting less time since assessment (p. = .04). While the treatment group demonstrated rapid improvement between admission and discharge, which was largely maintained to the time of the study, (Research Question 1) the improvement of the control group may have been more gradual over time.

Figure 5.1: VAS Average Scores by Time Since Assessment.



As there are no pre-assessment data for the control group for any of the other variables, there is no baseline to establish whether they improved over time or not. A similar pattern of scores presented for the VAS, based on length of time from assessment, was observed for the Pain Severity (difference in control group scores: p=.003) and for Interference scales of the MPI (difference in control group scores: p=.01). (Data not shown) It is important to note these results do not illustrate changes over time, but rather cross-sectional differences based on length of time since assessment. However, they do represent significant differences, and illustrate a trend that may assist in the interpretation of results. Although it cannot be stated that this represents improvement in scores over time, the trend observed in multiple outcome measures may suggest such. This would support the findings of Deardorff, (15) who reported significant improvement in pain ratings and "interference with activity ratings" for both the treatment and control groups. On the other hand, as these are not repeated measures, the "greater than 32 months" group of clients may have had

significantly better scores from the beginning, and rather than improving over time, may have merely maintained these scores.

An important issue to consider is the clinical importance or meaningfulness of the change in scores that is being analyzed.(40) Although many studies demonstrate statistically significant changes, there has been very little work done on determining what reflects a clinically important change. The IMMPACT consensus meeting developed recommendations for determining clinical change for chronic pain outcome measures and noted that “patients, clinicians, third-party payors and others may have very different perspectives regarding what benefits constitute clinically important improvement.”(40) The group also stated that clinically important change in individuals cannot be directly applied to the evaluation of group differences, but do go on to propose “provisional benchmarks” for comparing different treatment groups within trials. For the VAS they suggest that a reduction of at least 10%-20% (1-2 cm.) reflects minimally important change. As reported previously in Table 4.9, the mean difference in VAS scores is less than 1 cm for both the treatment and controls, which may mean that the changes demonstrated, although statistically significant, may not represent a meaningful clinical change. Having said that, it is important to remember that the primary goal of treatment is not necessarily to reduce the pain, but rather, to improve the coping skills and functioning of those living with chronic pain, so changes in the VAS alone cannot be used to evaluate improvement.

In discussion of clinical importance for the domains of physical and emotional functioning, the IMMPACT discussion used the MPI Interference scale

and the BDI respectively, both of which were used in this study for analysis of changes in the treatment group over time. The IMMPACT paper suggests a change of 0.6 points on the Interference scale and 5 points on the BDI could be considered a reasonable estimate of a clinically important change. (40) Looking at the mean change in the Interference and BDI scores presented in Table 4.11, a clinically important change is noted for Interference (mean change=1.89), but the change in the BDI score (mean change = 2.95) does not quite meet the suggested level for minimal clinical change.

Due to the low response rate and issues with method of recruitment (recruitment issues discussed under limitations) these results need to be interpreted with caution, but it does highlight the need to examine clinical relevance in future studies.

The only measure of whether or not the subjects feel they have improved or not is the Global Change question, which provides an indication of clients overall impression of change. (38) The measure has been criticized due to reliance on the participant recalling their initial state and mentally comparing it to the present, which, for some subjects was three years, but it does offer a measure of the participant's personal perspective. (38) Although on a 0 to 7 scale, the mean score for Global Change was 3.46 (SD 1.56) which corresponds to the descriptor "No Change", the actual percentage of responses in the categories is important to note. The results demonstrate that, overall, 59.3% reported feeling minimally, much or very much improved, compared to 14.3% reporting no change and 26.4% stating that they were minimally, much or very much worse.

5.1: Other findings:

The present study did demonstrate that the Pre-Admission VAS was a statistically significant predictor for all the outcome variables, except for Affective Distress. A higher Pre-Assessment VAS was associated with poorer outcomes at the time of the follow-up. Therefore, those experiencing more severe pain at pre-admission reported higher levels of depression, more intense pain, increased symptoms of depression, less sense of life control, lower general activity and more interference of pain with everyday activities at the time of the study. Using the Pre-Admission VAS score could provide an additional tool for the CPC to allow for modification or stratification of the treatment program based on this predictor.

5.2 Study Strengths and Limitations

The purpose of this study was to evaluate the long term outcomes of the Saskatoon CPC treatment program, and an effort was made to address a number of methodological gaps identified in the literature. The outcome measures used in this study were those that were previously used by the CPC as well as having been recommended by IMMPACT (39), which will provide easier integration with other studies using these standardized measures. Although other measures might better capture certain aspects of chronic pain such as self efficacy, it was felt that an important part of this study was the effort to utilize the standardized assessment tools recommended by IMMPACT.

A control group, although not randomized, was used to provide comparison for the treatment group, and comparison of these groups was done

on several pre-assessment factors. In addition, a number of recommended techniques were employed to improve the response rate. To address the issue of longer term follow-up, this study looked at clients at least one year after their final contact with the CPC. This provided data over a three year follow-up period, as opposed to the more common six to twelve month reviews. The longer period of follow-up may have contributed, though, to the difficulty in contacting subjects, as no effort had been made by the CPC to maintain current contact information.

There are limitations of this study. The first limitation is the fact that the treatment and control groups were not randomized. The clients self-selected whether to attend the treatment program, and although comparison between the treatment and control groups on a number of characteristics was possible and revealed few differences, there is still a risk of selection bias. It is possible that the groups differed on factors that were not measured which may have impacted the outcomes of interest in the study.

The second limitation is the lack of “pre-test” scores. Given that the program was not designed to collect the test variables prior to the start of the treatment, there was a limited amount of comparative data for the treatment and control groups. The data available did not demonstrate any significant differences in demographics, area of pain or pre-admission VAS levels of pain, but comparison on complete “pre-test” information was not possible. Even given these limitations, there are a number of factors which suggests that the treatment and control groups were likely similar on key factors. First, all CPC clients had been screened at 3 levels: by a family physician, by the CPC at the referral stage and again at the pre-assessment stage. At each of these stages, those clients

who were not compatible for the program were re-directed elsewhere. This screening process would increase the likelihood that the group of clients as a whole (both those who completed the program and those who did not) were similar on characteristics potentially related to the outcomes of interest. Secondly, for all clients, there is a considerable amount of data gathered during the pre-assessment and assessment period. To address the lack of a "pre-test" score for the control group on key outcome measures, the two groups were compared on a number of variables collected at the pre-assessment and assessment stage to establish similarity in these populations. This comparison not only included Age, Gender and Educational Status but also, Pain Severity (Pre-Admission VAS) and Area of Pain. Thirdly, to respond to a concern about the differences in populations that could result in self-selection to a particular group, a survey conducted by the CPC[10] asked the question why clients did not attend the treatment program and found that the primary reason was travel distance, time, and costs involved in hotel, food, travel, etc. for the six week treatment period. Because the Saskatoon CPC is a publicly funded program, there is no cost to the client for the treatment program itself. This likely introduces less bias than the control groups used in the literature that were based on drop-outs, or lack of insurance or ability to pay for treatment programs.

A third limitation was response rate, which has been discussed as a problem with chronic pain research as it is a difficult population to engage. It is not uncommon to see studies based on less than 30 % of the original population. (17) Nonresponse bias can lower statistical power, mask statistically significant

[10] Saskatoon Chronic Pain Centre, internal review. 2006

relationships which “truly” exist and limit the generalizability of the findings. (49) In this study, from the 417 clients determined to be eligible for this study, data was collected for 142 of them (34%), although it is worth noting that 144 of the 214 clients that were contacted (67%) did respond to the questionnaires. Because nonresponse bias is a risk, comparison was done between those who participated in the study with those who did not. It showed that at the time of their pre-admission assessment by the CPC, they did not significantly differ in Gender, Education Level, Area of Pain or Pre-Admission rating of pain intensity. They also did not differ on the average Length of Time since contact with the CPC. However, study participants and clients who did not participate in the study did differ significantly on Age, with the study participants being older, and on treatment status, with a higher percentage of the study participants having attended the six week treatment program

A fourth limitation is related to the method of recruitment. Due to “privacy” concerns, the initial contact with all CPC clients was done by personnel hired by the Saskatoon Health Region. Because virtually all of the contact phone calls were made during regular working hours (8:00 A.M. to 6:00 P.M.) there may have been an impact on the response, as those who were working would be unavailable and therefore not invited to participate in the study. This may have significantly skewed the results if those clients whom they were unable to reach were, in fact, the clients who had made the most improvement and had returned to work, leaving those who were retired, or not at work as a larger part of our study population. Response rates could potentially be improved by continued tracking of clients by the CPC, to maintain current contact information as well as

ensuring that contact phone calls, to recruit participants, were made at various times throughout the day as well as on weekends.

And finally, due to time and financial constraints, the study was cross-sectional rather than longitudinal which limited the ability to examine the changes in scores over time. Although the study data was collected for all participants at least one year since contact with CPC, the time period varied by participant between one and three years. Data was available for three different time periods for the treatment group, the first two being admission and discharge of the treatment program, but the third, at the point of follow-up data collection, also varied from one to three years.

5.3 Significance of the Study

The findings of this study contribute to the chronic pain treatment literature by examining longer term outcomes than have generally been the case and by the use of a control group. Although this study lacked standardized pre-test scores it was demonstrated that the treatment and control groups were similar by comparison on multiple factors at the pre-treatment stage. Although the quasi-experimental design does not allow for causal inferences to be made, demonstrating a statistically significant improvement over a short time period among treatment participants, which is largely maintained over time, does strengthen the inference that the treatment program has a positive impact. Statistically significant improvements, however, need to be studied in more depth to determine clinical importance. The fact that there was no difference between the treatment and control groups at follow-up is more difficult to interpret and

supports the need for more long-term studies using a control group that is followed over time. Even given the limitations, this study provides valuable information both to the research literature and to the agency, which is interested in to having some indication of the long-term effects of their program.

5.4 Conclusions

This study demonstrates that the scores on all the outcome variables did, in fact, improve significantly from the time of assessment to the time of discharge for the clients who had attended the CPC program. These improvements were seen to decline for all variables over time, although not significantly for the scales of Pain Severity and Affective Distress. Even with the decline in scores, the study scores remained significantly improved from the admission scores.

Having said that, the study also found that overall there were no significant differences between the treatment group and the control group at the time of follow-up on any of the outcome measures. Although this is difficult to explain, especially given the limitations of this study, it is possible that there may be a gradual improvement over time, especially evident in the pain intensity scores, in those clients who did not attend the treatment program. Whether or not these improvements demonstrate clinical importance is also unclear. The Global Change question also suggests improvement in both the treatment and control groups as the results demonstrate that 59.3% of the study participants reported feeling minimally, much or very much improved. The findings in this study may have been affected by the recruitment process, in that clients who had

demonstrated more improvement may have been at work and therefore not contacted or included in this study.

Time from assessment or treatment to follow-up may be an important factor, but as this study was a cross-sectional rather than a longitudinal design, the effects of time were not captured effectively. Further study needs to look at changes in scores over time in a longitudinal design. As well, the IMMPACT recommendations for evaluation focuses on outcomes but examination of treatment processes might assist in explaining outcome findings. Process-orientated measures such as self-efficacy and active vs. passive coping might add depth in capturing the goals of the CPC treatment program.

In terms of the Saskatoon CPC program, the study confirmed that the clients did improve significantly over the six week treatment period, which does suggest a positive impact of the program. Further study needs to be done to examine clinical importance. It is also clear that the Pre-Admission VAS is, statistically, a predictor of outcome, and perhaps could be used to modify or stratify the treatment program to address various levels of pain intensity. The suggestion of a "booster" program should be considered in light of the finding that the scores on the outcome measures for the treatment group did decline over time. Finally, maintaining current contact information for clients for follow-up and inclusion of some or all of the assessment battery at the time of pre-admission would greatly enhance future evaluation as it would potentially improve the response rate as well as provide additional information for comparison for the control group

6. References

(1) Meana M, Cho R, DesMeules M. Chronic Pain: The Extra Burden on Canadian Women. BMC Womens Health 2004 Aug 25;4 Suppl 1:S17.

(2) Moulin DE, Clark AJ, Speechley M, Morley-Forster PK. Chronic pain in Canada-prevalence, treatment, impact and the role of opioid analgesia. Pain Res Manag 2002;7(4).

(3) Thomsen AB, Sorensen J, Sjogren P, Eriksen J. Economic evaluation of multidisciplinary pain management in chronic pain patients: a qualitative systematic review. J.Pain Symptom Manage. 2001 Aug;22(2):688-698.

(4) Chronic pain affects 1 in 3 Canadians: poll. Available at: http://www.cbc.ca/health/story/2007/11/07/chronicpain-study.html. Accessed 1/12/2008, 2008.

(5) Munce SE, Stewart DE. Gender differences in depression and chronic pain conditions in a national epidemiologic survey. Psychosomatics 2007 Sep-Oct;48(5):394-399.

(6) Chronic Pain. Available at: http://www.chronicpaincanada.com/. Accessed 12/28/2007, 2007.

(7) Flor H, Fydrich T, Turk DC. Efficacy of multidisciplinary pain treatment centers: a meta-analytic review. Pain 1992 May;49(2):221-230.

(8) Morley S, Eccleston C, Williams A. Systematic review and meta-analysis of randomized controlled trials of cognitive behaviour therapy and behaviour therapy for chronic pain in adults, excluding headache. Pain 1999 Mar;80(1-2):1-13.

(9) Turk DC, Ph, D. Clinical Effectiveness and Cost-Effectiveness of Treatments for Patients With Chronic Pain. Clin.J.Pain 2002 November/December;18(6):355-365.

(10) McCracken LM, Turk DC. Behavioral and cognitive-behavioral treatment for chronic pain: outcome, predictors of outcome, and treatment process. Spine 2002 Nov 15;27(22):2564-2573.

(11) Guzman J, Esmail R, Karjalainen K, Malmivaara A, Irvin E, Bombardier C. Multidisciplinary bio-psycho-social rehabilitation for chronic low back pain. Cochrane Database Syst.Rev. 2002;(1)(1):CD000963.

(12) Lanes TC, Gauron EF, Spratt KF, Wernimont TJ, Found EM, Weinstein JN. Long-term follow-up of patients with chronic back pain treated in a multidisciplinary rehabilitation program. Spine 1995 Apr 1;20(7):801-806.

(13) Patrick LE, Altmaier EM, Found EM. Long-term outcomes in multidisciplinary treatment of chronic low back pain: results of a 13-year follow-up. Spine 2004 Apr 15;29(8):850-855.

(14) Robbins H, Gatchel RJ, Noe C, Gajraj N, Polatin P, Deschner M, et al. A prospective one-year outcome study of interdisciplinary chronic pain management: compromising its efficacy by managed care policies. Anesth.Analg. 2003 table of contents; Jul;97(1):156-162.

(15) Deardorff WW, Rubin HS, Scott DW. Comprehensive multidisciplinary treatment of chronic pain: a follow-up study of treated and non-treated groups. Pain 1991 Apr;45(1):35-43.

(16) Mead K, Theadom A, Byron K, Dupont S. Pilot study of a 4-week Pain Coping Strategies (PCS) programme for the chronic pain patient. Disabil.Rehabil. 2007 Feb 15;29(3):199-203.

(17) Turk DC, Rudy TE, Sorkin BA. Neglected topics in chronic pain treatment outcome studies: determination of success. Pain 1993 Apr;53(1):3-16.

(18) Hassinger DD, Hayes D. A Consistent Lexicon for Chronic Pain: Defining Etiologies and Mechanisms. The Neuroscience Institute 2004;6(3).

(19) Gatchel RJ, Peng YB, Peters ML, Fuchs PN, Turk DC. The biopsychosocial approach to chronic pain: scientific advances and future directions. Psychol.Bull. 2007 Jul;133(4):581-624.

(20) Ramage-Morin PL. Chronic pain in Canadian seniors. Health Reports, Satistics Canada 2008 02-21;19(1):Feb 28, 2008.

(21) University of Alberta. Chronic Pain can Impair Memory. Science Daily 2007 May 18.

(22) Tang NK, Crane C. Suicidality in chronic pain: a review of the prevalence, risk factors and psychological links. Psychol.Med. 2006 May;36(5):575-586.

(23) Liebeskind JC. Pain can kill. Pain 1991;44:3-4.

(24) Baanders AN, Heijmans MJ. The impact of chronic diseases: the partner's perspective. Fam.Community Health 2007 Oct-Dec;30(4):305-317.

(25) Stanos S, Houle TT. Multidisciplinary and interdisciplinary management of chronic pain. Phys.Med.Rehabil.Clin.N.Am. 2006 May;17(2):435-50, vii.

(26) Scascighini L, Sprott H. Chronic nonmalignant pain: a challenge for patients and clinicians. Nat.Clin.Pract.Rheumatol. 2008 Feb;4(2):74-81.

(27) Peng P, Choiniere M, Dion D, Intrater H, Lefort S, Lynch M, et al. Challenges in accessing multidisciplinary pain treatment facilities in Canada. Can.J.Anaesth. 2007 Dec;54(12):977-984.

(28) Health Surveillance AH. Chronic pain in Alberta: a portrait from the 1996 National Population Health Survey and the 2001 Canadian Community Health Survey. 2003 May 2003.

(29) Baldwin ML. Reducing the costs of work-related musculoskeletal disorders: targeting strategies to chronic disability cases. J.Electromyogr.Kinesiol. 2004 Feb;14(1):33-41.

(30) Turk DC, Melzack R editors. Handbook of Pain Assessment. 2nd ed.; 2001.

(31) Veillette Y, Dion D, Altier N, Choiniere M. The treatment of chronic pain in Quebec: a study of hospital-based services offered within anesthesia departments. Can.J.Anaesth. 2005 Jun-Jul;52(6):600-606.

(32) Ashburn MA. Interdisciplinary chronic pain management programs. J Pharm Care Pain Synp Control 2007 Aug 10;2(3):Feb 10, 2008.

(33) Justins DM. Management strategies for chronic pain. Ann.Rheum.Dis. 1996 Sep;55(9):588-596.

(34) Dysvik E, Vinsnes AG, Eikeland OJ. The effectiveness of a multidisciplinary pain management programme managing chronic pain. Int.J.Nurs.Pract. 2004 Oct;10(5):224-234.

(35) van Geen JW, Edelaar MJ, Janssen M, van Eijk JT. The long-term effect of multidisciplinary back training: a systematic review. Spine 2007 Jan 15;32(2):249-255.

(36) Moss-Morris R,. Patients' Perceptions of Their Pain Condition Across a Multidisciplinary Pain Management Program: Do They Change and if So Does It Matter? The Clinical journal of pain 2007;23(7):558.

(37) Lillefjell M, Krokstad S, Espnes GA. Prediction of function in daily life following multidisciplinary rehabilitation for individuals with chronic musculoskeletal pain; a prospective study. BMC Musculoskelet.Disord. 2007 Jul 10;8:65.

(38) Turk DC, Dworkin RH, Allen RR, Bellamy N, Brandenburg N, Carr DB, et al. Core outcome domains for chronic pain clinical trials: IMMPACT recommendations. Pain 2003 Dec;106(3):337-345.

(39) Dworkin RH, Turk DC, Farrar JT, Haythornthwaite JA, Jensen MP, Katz NP, et al. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. Pain 2005 Jan;113(1-2):9-19.

(40) Dworkin RH, Turk DC, Wyrwich KW, Beaton D, Cleeland CS, Farrar JT, et al. Interpreting the Clinical Importance of Treatment Outcomes in Chronic Pain Clinical Trials: IMMPACT Recommendations. J.Pain 2007 Dec 4.

(41) Bellamy N, Kirwan J, Boers M, Brooks P, Strand V, Tugwell P, et al. Recommendations for a core set of outcome measures for future phase III clinical trials in knee, hip, and hand osteoarthritis. Consensus development at OMERACT III. J.Rheumatol. 1997 Apr;24(4):799-802.

(42) Turk DC, Dworkin RH. What should be the core outcomes in chronic pain clinical trials? Arthritis Res.Ther. 2004;6(4):151-154.

(43) Gamsa A. The role of psychological factors in chronic pain. II. A critical appraisal. Pain, 1994 4;57(1):17-29.

(44) Roberts AH, Reinhardt L. The behavioral management of chronic pain: long-term follow-up with comparison groups. Pain 1980 Apr;8(2):151-162.

(45) Guck TP, Skultety FM, Meilman PW, Dowd ET. Multidisciplinary pain center follow-up study: evaluation with a no-treatment control group. Pain 1985 Mar;21(3):295-306.

(46) Shadish WR, Cook TD, Campbell DT. Experimental and Quai-Experimental Designs for Generalized Causal Inference. Boston, USA: Houghton Mifflin Company; 2002.

(47) Hildebrandt J, Pfingsten M, Saur P, Jansen J. Prediction of success from a multidisciplinary treatment program for chronic low back pain. Spine 1997 May 1;22(9):990-1001.

(48) Gordis L. Epidemiology. Philadelphia, Pennsylvania: Elsevier Saunders; 2004.

(49) Harrison RA, Cock D. Increasing response to a postal survey of sedentary patients - a randomised controlled trial [ISRCTN45665423]. BMC Health Serv.Res. 2004 Nov 10;4(1):31.

(50) Turk DC, Rudy TE. Neglected topics in the treatment of chronic pain patients--relapse, noncompliance, and adherence enhancement. Pain 1991 Jan;44(1):5-28.

(51) Goossens ME, Vlaeyen JW, Hidding A, Kole-Snijders A, Evers SM. Treatment expectancy affects the outcome of cognitive-behavioral interventions in chronic pain. Clin.J.Pain 2005 Jan-Feb;21(1):18-26; discussion 69-72.

(52) Lang E, Liebig K, Kastner S, Neundörfer B, Heuschmann P. Multidisciplinary rehabilitation versus usual care for chronic low back pain in the community: effects on quality of life. The Spine Journal, 2003 0;3(4):270-276.

(53) Harkapaa K, Mellin G, Jarvikoski A, Hurri H. A controlled study on the outcome of inpatient and outpatient treatment of low back pain. Part III. Long-term follow-up of pain, disability, and compliance. Scand.J.Rehabil.Med. 1990;22(4):181-188.

(54) Bendix AE, Bendix T, Haestrup C, Busch E. A prospective, randomized 5-year follow-up study of functional restoration in chronic low back pain patients. Eur.Spine J. 1998;7(2):111-119.

(55) Lillefjell M, Krokstad S, Espnes GA. Factors predicting work ability following multidisciplinary rehabilitation for chronic musculoskeletal pain. J.Occup.Rehabil. 2006 Dec;16(4):543-555.

(56) Edwards P, Roberts I, Clarke M, DiGuiseppi C, Pratap S, Wentz R, et al. Increasing response rates to postal questionnaires: systematic review. BMJ 2002 May 18;324(7347):1183.

(57) Edwards P, Roberts I, Clarke M, DiGuiseppi C, Pratap S, Wentz R, et al. Methods to increase response rates to postal questionnaires. Cochrane Database Syst.Rev. 2007 Apr 18;(2)(2):MR000008.

(58) Nakash RA, Hutton JL, Jorstad-Stein EC, Gates S, Lamb SE. Maximising response to postal questionnaires--a systematic review of randomised trials in health research. BMC Med.Res.Methodol. 2006 Feb 23;6:5.

(59) Paul CL, Walsh RA, Tzelepis F. A monetary incentive increases postal survey response rates for pharmacists. J.Epidemiol.Community Health 2005 Dec;59(12):1099-1101.

(60) Gallagher EJ, Bijur PE, Latimer C, Silver W. Reliability and validity of a visual analog scale for acute abdominal pain in the ED. Am.J.Emerg.Med. 2002 Jul;20(4):287-290.

(61) Million R, Hall W, Nilsen KH, Baker RD, Jayson MI. Assessment of the progress of the back-pain patient 1981 Volvo Award in Clinical Science. Spine 1982 May-Jun;7(3):204-212.

(62) Kerns RD, Turk DC, Rudy TE. The West Haven-Yale Multidimensional Pain Inventory (WHYMPI). Pain 1985 Dec;23(4):345-356.

(63) Beck AT, Ward CH, Mendelson M, Mock J, Erbaugh J. An inventory for measuring depression. Arch.Gen.Psychiatry 1961 Jun;4:561-571.

(64) Beck AT, Steer RA, Brown GK. Manual for the Beck Depression Inventory-II. 1996.

(65) Harris CA, D'Eon JL. Psychometric properties of the Beck Depression Inventory-Second Edition (BDI-II) in individuals with chronic pain. Pain 2008 7/31;137(3):609-622.

(66) De Gagne TA, Mikail SF, D'Eon JL. Confirmatory factor analysis of a 4-factor model of chronic pain evaluation. Pain 1995 Feb;60(2):195-202.

(67) Hurst H, Bolton J. Assessing the clinical significance of change scores recorded on subjective outcome measures. J.Manipulative Physiol.Ther. 2004 Jan;27(1):26-35.

(68) Farrar JT, Young JP, LaMoreaux L, Werth JL, Poole RM. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. Pain, 2001 11;94(2):149-158.

(69) Field A. Discovering Statistics Using SPSS. second edition ed. London: SAGE Publications Ltd; 2005.

(70) Karjalainen K, Malmivaara A, van Tulder MW, Roine R, Jauhiainen M, Hurri H, et al. Multidisciplinary rehabilitation for fibromyalgia and musculoskeletal pain in working age adults.(Review). Cochrane database of systematic reviews (Online) 1999(3).

Appendix 7.1

Pre-Assessment and Assessment information:

Demographic Data:
- Age
- Sex
- Education level
- Employment status
- Income level
- Income source (ie salary, WCB, pension)

Past Medical history
- Past medical/surgical history
- Other symptoms (ie nausea, dizziness, memory difficulties)

Social history:
- Lives alone/with partner/children
- Alcohol/"street" drug use
- Smoker/non-smoker

Pain history:
- Date of onset
- Cause of pain
- Pain rating on scale of 0 to 10. (VAS)
- Other treatments sought for relief of pain

Emotional Functioning:
- Anxiety / Depression
- Change in relationship with partner (scale of 0 to 10)

Physical Functioning / Interference:
- Sleep disturbance
- Fatigue
- Memory/concentration
- Sitting/standing/walking tolerance
- Sexual difficulties

Appendix 7.2

Saskatoon Chronic Pain Centre Study
Return Address
Date
Re: **An Evaluation of the Long-Term Treatment Outcomes of a Multidisciplinary Chronic Pain Centre Program.**

Dear_____;

You are being invited to participate in this research project because you were assessed at the Saskatoon Chronic Pain Centre in the past. You may or may not have attended the six week program offered there.

We are interested in knowing how you have changed, over time, in both the intensity of pain you are experiencing and your ability to cope and manage activities in daily life. The purpose of this study is to compare the changes in the group of clients who attended the program to the changes in those who were assessed but did not attend the program. We are hoping to gain information about what the effects are of attending the six week pain management program offered at the Saskatoon Chronic Pain Centre.

Your participation is completely voluntary; you are not obliged to participate. If you do agree to participate, you may choose to have your name entered into a draw for one of four digital cameras, as a token of our appreciation. If you wish to enter the draw, please complete the attached entry form, seal it in the enclosed envelope, and return it with the completed questionnaires. The entry envelope will be removed from the questionnaire when we receive them, and entered into the draw box. Your questionnaire information will remain confidential.

The following questions will help us to evaluate any changes, from your perspective, in your pain and ability to manage daily activities. It will take approximately 15 to 20 minutes to complete these questions. Some of these questionnaires you may have seen or completed in the past.

Please read the instructions for each section and indicate how that specific question applies to you. Please do not write your name or any identifying information on the questionnaire sheets.

Thank you for taking the time to assist us with this project.
Yours truly,

Flo Wagner

Flo Wagner
Masters Candidate,
Community Health & Epidemiology
University of Saskatchewan
(306) 966-2110

ID # _____

1) Select the number below that best describes your pain during the past 24 hours:

0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
No Pain										**worst pain possible**

2) Have you received any treatment for your pain since attending the Saskatoon Chronic Pain Centre? No ☐ Yes ☐ (if yes, please check all that apply)

Acupuncture ☐

Biofeedback ☐

Chiropractic ☐

Physiotherapy ☐

Other ☐

Please list other treatment:_____

_____

_____

3) Since your assessment at the Saskatoon Chronic Pain Centre, how would you describe the change (if any) in ACTIVITY LIMITATIONS, SYMPTOMS, EMOTIONS and OVERALL QUALITY OF LIFE, related to your painful condition? (check **ONE** box)

Very much improved ☐1

Much improved ☐2

Minimally Improved ☐3

No change ☐4

Minimally worse ☐5

Much worse ☐6

Very much worse ☐7

4) Employment and Income Information:

What is your current occupation?_____

Are you currently working? ☐ Full time ☐ Part-time ☐ Not currently working.

If not currently working, for how long have you been unable to work?

_____years and _____months

5) Household Income (OPTIONAL): (please circle one response)

< $5,000	$20,000-$29,000	$50,000-$59,999
$5,000-$9,999	$30,000-$39,999	>$60,000
$10,000-$19,000	$40,000-$49,999	not provided

6) Income Source (Please circle all that apply)

Salary	Worker's Compensation	Support for Independence (Social Assistance)
Employment Insurance	Disability Pension (employer)	
Work Pension	Canada Pension Disability	

Other_____

ID # _____

MULTIDIMENSIONAL PAIN INVENTORY (MPI)

Instructions: An important part of our evaluation includes examination of pain from your perspective because you know your pain better than anyone else. The following questions are designed to help us learn more about your pain and how it affects your life. Under each question is a scale to mark your answer. Read each question carefully and then **circle a number** on the scale under that question to indicate how that specific question applies to you. An example may help you to better understand how you should answer these questions.

Example- How nervous are you when you ride in a car when the traffic is heavy?

0	1	2	3	4	5	6
Not at all Nervous						**Extremely Nervous**

If you are not at all nervous when riding in a car in heavy traffic, you would want to **circle** the number 0. If you are very nervous when riding in a car in heavy traffic, you would then circle the number 6. Lower numbers would be used for less nervousness, and higher numbers for more nervousness.

Section I

1. Rate the level of your pain at the **present moment.**

0	1	2	3	4	5	6
No pain						**Very intense Pain**

2. In general, how much does your pain interfere with your day-to-day activities?

0	1	2	3	4	5	6
No interference						**Extreme interference**

3. Since the time your pain began, how much has your pain changed your ability to work?

(____ Check here if you have retired for reasons other than your pain.)

0	1	2	3	4	5	6
No change						**Extreme change**

4. How much has your pain changed the amount of satisfaction or enjoyment you get from taking part in social and recreational activities?

0	1	2	3	4	5	6
No change						**Extreme change**

5. How supportive or helpful is your spouse (significant other) to you in relation to your pain?

0	1	2	3	4	5	6
Not at all supportive						**Extremely supportive**

6. Rate your overall mood during the **past week.**

0	1	2	3	4	5	6
Extremely low						**Extremely high**

7. How much has your pain interfered with your ability to get enough sleep?

0	1	2	3	4	5	6
No interference						**Extreme interference**

8. On the average, how severe has your pain been during the **last week?**

0	1	2	3	4	5	6
Not at all severe						**Extremely severe**

9. How able are you to predict when your pain will start, get better, or get worse?

0	1	2	3	4	5	6
Not at all able to predict						**Very able to predict**

10. How much has your pain changed your ability to take part in recreation and other social activities?

0	1	2	3	4	5	6
No change						**Extreme change**

11. How much do you limit your activities in order to keep your pain from getting worse?

0	1	2	3	4	5	6
Not at all						**Very much**

12. How much has your pain changed the amount of satisfaction or enjoyment you get from family-related activities?

0	1	2	3	4	5	6
No change						**Extreme change**

13. How worried is your spouse (significant other) about you because of your pain?

0 1 2 3 4 5 6
Not at all worried Extremely worried

14. During the **past week**, how much control do you feel that you have had over your life?

0 1 2 3 4 5 6
No control Extreme control

15. On an average day, how much does your pain vary (increase or decrease)?

0 1 2 3 4 5 6
Remains the same Changes a lot

16. How much suffering do you experience because of your pain?

0 1 2 3 4 5 6
No suffering Extreme suffering

17. How often are you able to do something that helps to reduce your pain?

0 1 2 3 4 5 6
Never Very often

18. How much has your pain changed your relationship with your spouse, family, or significant other?

0 1 2 3 4 5 6
No change Extreme change

19. How much has your pain changed the amount of satisfaction or enjoyment you get from work? (____ Check here, if you are not presently working.)

0 1 2 3 4 5 6
No change Extreme change

20. How attentive is your spouse (significant other) to you because of your pain?

0 1 2 3 4 5 6
Not at all attentive Extremely attentive

21. During the **past week** how much do you feel that you've been able to deal with your problems?

0 1 2 3 4 5 6
Not at all Extremely well

22. How much control do you feel that you have over your pain?

0 1 2 3 4 5 6
No control at all A great deal of control

23. How much has your pain changed your ability to do household chores?

0 1 2 3 4 5 6
No change Extreme change

24. During the **past week** how successful were you in coping with stressful situations in your life?

0 1 2 3 4 5 6
Not at all successful Extremely successful

25. How much has your pain interfered with your ability to plan activities?

0 1 2 3 4 5 6
No change Extreme change

26. During the **past week** how irritable have you been?

0 1 2 3 4 5 6
Not at all irritable Extremely irritable

27. How much has your pain changed or interfered with your friendships with people other than your family?

0 1 2 3 4 5 6
No change Extreme change

28. During the **past week** how tense or anxious have you been?

0 1 2 3 4 5 6
Not at all tense or anxious Extremely tense and anxious

Section II

Listed below are 19 common daily activities. Please indicate **how often** you do each of these activities by **circling a number** on the scale listed below each activity. Please complete all 19 questions.
1. Wash dishes.

0 1 2 3 4 5 6
Never Very often

2. Mow the lawn. (____ Check here if you do not have a lawn to mow.)

0 1 2 3 4 5 6
Never Very often

3. Go out to eat.

0 1 2 3 4 5 6
Never Very often

4. Play cards or other games.

0 1 2 3 4 5 6
Never Very often

5. Go grocery shopping.

0 1 2 3 4 5 6
Never Very often

6. Work in the garden. (____ Check here if you do not have a garden)

0 1 2 3 4 5 6
Never Very often

7. Go to a movie.

0 1 2 3 4 5 6
Never Very often

8. Visit friends.

0 1 2 3 4 5 6
Never Very often

9. Help with the house cleaning.

0 1 2 3 4 5 6
Never Very often

10. Work on the car. (____ Check here if you do not have a car.)

0 1 2 3 4 5 6
Never Very often

11. Take a ride in a car or bus.

0	1	2	3	4	5	6
Never						**Very often**

12. Visit relatives. (____ Check here if you do not have relatives within 160 km.)

0	1	2	3	4	5	6
Never						**Very often**

13. Prepare a meal.

0	1	2	3	4	5	6
Never						**Very often**

14. Wash the car. (____ Check here if you do have a car.)

0	1	2	3	4	5	6
Never						**Very often**

15. Take a trip.

0	1	2	3	4	5	6
Never						**Very often**

16. Go to a park or beach.

0	1	2	3	4	5	6
Never						**Very often**

17. Do the laundry.

0	1	2	3	4	5	6
Never						**Very often**

18. Work on a needed household repair.

0	1	2	3	4	5	6
Never						**Very often**

19. Engage in sexual activities.

0	1	2	3	4	5	6
Never						**Very often**

BECK DEPRESSION INVENTORY***

APPENDIX 7.3 ETHICS APPROVAL

Saskatoon Health Region

Research Services Unit
Strategic Health Information & Planning Services (SHIPS)
Joanne Franko, Manager
Suite 300 Saskatoon Square
410 22nd St E
Saskatoon, SK S7K 5T6
Phone: 306.655.3356 Fax: 306.655.3373

DATE: **August 15, 2008**

TO: **Dr. Bonnie Janzen**
Community Health & Epidemiology
University of Saskatchewan

FROM: **Joanne Franko**
Manager, Research Services Unit

RE: **RESEARCH PROJECT ETHICS COMMITTEE (EC)#: B2008-116**
PROJECT NAME: An evaluation of the long-term treatment outcomes of a multidisciplinary chronic pain program
PROTOCOL #: N/A

Saskatoon Health Region is pleased to provide you with operational approval of the above-mentioned research project.

Please advise me when the data collection phase of the research project is completed. I would also appreciate receiving a summary of the results for this research project. As well, any publications or presentations that result from this research should include a statement acknowledging the assistance of Saskatoon Health Region.

I would like to wish you every success with your project. If you have any questions, please contact our office at 655-3351.

Yours truly,

Laurel Duczek, Director, SHIPS, for
Joanne Franko, M.Sc.
Manager, Research Services Unit

cc: Kate Fast, Manager, Chronic Pain Centre, Buckwold Building

UNIVERSITY OF SASKATCHEWAN

Behavioural Research Ethics Board (Beh-REB)

Certificate of Approval

PRINCIPAL INVESTIGATOR	DEPARTMENT	BEH#
Bonnie Janzen	Community Health and Epidemiology	08-116

INSTITUTION(S) WHERE RESEARCH WILL BE CONDUCTED
University of Saskatchewan
Saskatoon SK

SPONSOR
UNFUNDED

TITLE
An Evaluation of the Long-Term Treatment Outcomes of a Multidisciplinary Chronic Pain Centre Program

ORIGINAL REVIEW DATE	APPROVAL ON	APPROVAL OF:	EXPIRY DATE
05-May-2008	21-Jul-2008	Ethics Application Consent Protocol	20-Jul-2009

Full Board Meeting ☐ Date of Full Board Meeting:

Delegated Review ☒

CERTIFICATION

The University of Saskatchewan Behavioural Research Ethics Board has reviewed the above-named research project. The proposal was found to be acceptable on ethical grounds. The principal investigator has the responsibility for any other administrative or regulatory approvals that may pertain to this research project, and for ensuring that the authorized research is carried out according to the conditions outlined in the original protocol submitted for ethics review. This Certificate of Approval is valid for the above time period provided there is no change in experimental protocol or consent process or documents.

Any significant changes to your proposed method, or your consent and recruitment procedures should be reported to the Chair for Research Ethics Board consideration in advance of its implementation.

ONGOING REVIEW REQUIREMENTS

In order to receive annual renewal, a status report must be submitted to the REB Chair for Board consideration within one month of the current expiry date each year the study remains open, and upon study completion. Please refer to the following website for further instructions: *http://www.usask.ca/research/ethics_review/*

John Rigby, Chair
University of Saskatchewan
Behavioural Research Ethics Board

Please send all correspondence to:

Ethics Office
University of Saskatchewan
Room 302 Kirk Hall, 117 Science Place
Saskatoon SK S7N 5C8
Telephone: (306) 966-2975 Fax: (306) 966-2069

APPENDIX 7.4 RESEARCH PARTICIPANT INFORMATION and CONSENT FORM

You are invited to participate in a research project entitled: **An Evaluation of the Long-Term Treatment Outcomes of a Multidisciplinary Chronic Pain Centre Program.**

Purpose: The purpose of this study is to evaluate what effect, if any, the six week program offered at the Saskatoon Chronic Pain Center has on levels of pain and ability to manage activities of daily living over a period of time. You are being invited to take part in this research study because you have been assessed at the Chronic Pain Centre in the past, and may or may not have attended the six week program. We would like to compare the responses of those who did attend with those who did not attend this six week program to see what differences there are in the way you have managed your chronic pain condition.

Procedures: If you agree to be part of this study, you will be asked to complete several questionnaires that will be sent to you by mail. Some of these questionnaires you will have seen before as part of your assessment at the Chronic Pain Centre. It will take approximately 15 to 20 minutes of your time to complete these. There will be a stamped envelope included for you to return the questionnaires.

Some of the information you provide may be compared to the answers you gave during your initial assessment at the Chronic Pain Centre to determine if there has been any change in your condition. This information will only be identified and linked by using your ID number, not your name.

If you agree to participate, I will date and sign a consent form noting that I have read and explained the contents to you.

Potential Benefits: We hope that the information learned from this study can be used in the future to benefit other people with chronic pain. If you wish to have a written summary of the results of the study, a summary will be mailed to you after the study if finished.

As a token of appreciation for your participation, on receipt of your completed questionnaires, your name will be entered into a draw for one of four digital cameras. An entry form and envelope will be provided and to ensure your response remains confidential, the sealed envelope will be removed from the returned questionnaires on receipt and entered into the draw box.

Potential Risks: There are no known risks that are associated with the procedures described above. Some of the questions are personal in nature. You may refuse to answer any individual question.

Storage of Data: All study results and materials will be safeguarded and securely stored by the researcher in secure location and a locked file cabinet. All results will be identified only by the ID number and the ID numbers will be stored separately from the master list of names to safeguard the identification of any individuals. Once data

collection is complete, the master list will be destroyed. Data will be kept for five years and then destroyed in a secure manner.

Confidentiality: Your name will not be attached to any information, nor mentioned in any study report, nor be made available to anyone except the researcher. The information that you provide will be entered into a database along with all other participants, and reports will be based on the summary of these findings. What we learn from this study may be published or presented at conferences; but will be reported in summary form and no names will be used, so that it will not be possible to identify any individuals. Also the Consent Forms will be stored separately from the questionnaires so that it will not be possible to associate a name with any given set of responses. Please do not put your name or other identifying information on the questionnaires.

Right to Withdraw: Your participation is voluntary, and you can answer only those questions that you are comfortable with. If you agree to participate in this study, you are still free to withdraw at any time and without giving any reasons for your decision. There will be no penalty or loss of benefits to which you are otherwise entitled, and your future medical care will not be affected.

Questions: If you have any questions concerning the research project, please feel free to ask at any point; you are also free to contact the researcher at the number provided if you have other questions. This research project has been approved on ethical grounds by the University of Saskatchewan Behavioural Research Ethics Board on (*insert date*). Any questions regarding your rights as a participant may be addressed to that committee through the Ethics Office (306 966-2084). Out of town participants may call collect.

Consent to Participate:

I read and explained this Consent Form to the participant before receiving the participant's consent, and the participant had knowledge of its contents and appeared to understand it.

A copy of this consent form will be mailed to the participant.

_____
(Name of Participant)

_____ _____ _____
(Signature of Researcher) (Date) (Time)

☐ Please mail a written summary of the results of this study.

Researcher: **Flo Wagner**
Masters Candidate,
Community Health & Epidemiology
University of Saskatchewan **(306) 966-2110**