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Self-Efficacy in Headache Management: A Quasi-Experiment

by

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Abstract

The goal of this research was to measure the effectiveness of a headache selfmanagement workshop offered in relative isolation from other headache treatments. Headache Management Self-Efficacy scores (HMSE) were compaired from baseline, to post-test after participation in the headache Self-Management Workshop. Baseline measurement occurred during the Assessment and Education (A and E) session where lifestyle and medication information were taught. The pre-test, post-test questionnaires included the HMSE, CESD-R, HDI, and HIT-6. Data were collected on 231 subjects, 23 in the intervention and 208 in the comparision group. Self-efficacy improved for the entire sample (p = 0.041), headache frequency decreased (p = 0.048), quality of life improved (p = 0.003) and disability improved for the comparison group but not the intervention group (p = 0.041). Unfortunately the small sample size in the intervention group did not allow for meaningful comparisons therefore few differences between groups were found. Benefits seen may have been related to A and E session attendance rather than the intervention itself.

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Dedication

To Grant, Holly and Toban whose love, patience and support will always be cherished and will be returned in kind as you stretch for success in your own endeavours.

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Abbreviation	Definition
A and E Session	Program Assessment and Education Session
ANOVA	Two-way Repeated Measures Analysis of Variance
ASA	Acetyl Salicylic Acid
ASMP	Arthritis Self Management Program
BDI	Beck Depression Inventory
CBT	Cognitive Behavioural Therapy
CDSMP	Chronic Disease Self Management Program
CESD-R	Centre for Epidemiologic Studies Depression Scale-Revised
CHR	Calgary Health Region
CPSMP	Chronic Pain Self Management Program
EMG	Electromyography
HDI	Headache Disability Inventory
HIT-6	Headache Impact Test
НМО	Health Maintenance Organization
HMSE	Headache Management Self-efficacy Scale
HSE	Headache Self-efficacy Scale
McNemar	"A nonparametric test for comparing differences in proportions when the values are derived from paired (non-independent) groups." (Pg. 452) (Polit, 1996)
MIDAS	Migraine Disability Assessment Scale
NP	Nurse Practitioner
NSAID	Non-steroidal Anti-inflammatory drug

List of Symbols, Abbreviations and Nomenclature

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OTC	Over-The-Counter
SF-36	Short Form-36 Health Survey
SMW	Self Management Workshop
SPSS	Statistical Package for Social Sciences

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CHAPTER ONE: INTRODUCTION

Background

At the time of writing the proposal for this study, the Calgary Headache Assessment and Management Program (CHAMP) operated within the Calgary Health Region, one of nine health regions in the province of Alberta. In the later part of 2008, all of the nine health regions were merged to create Alberta Health Services. CHAMP and all other provincial health services in Calgary now operate under the umbrella of Alberta Health Services.

Chronic headache is a painful and often disabling neurological condition that has had unwavering prevalence in North America over the last 20 years. In the United States of America, migraine (the most common and disabling of headache types) occurs with a prevalence ranging from 7-8% for males and 17-18% for females (Diamond et al., 2007; Lipton, Stewart, Diamond, Diamond, & Reed, 2001b). The prevalence rates in Lipton et al. (2001b) include adolescents as well as adults; 5% of boys and 7% of girls between the ages of 12 and 17 report migraine. In Canada, the prevalence of migraine in the adult population has been recorded at 6-8% in males and 15-25% in females (McIntyre et al., 2006; O'Brien, Goeree, & Streiner, 1994). Chronic tension-type headache is less intense than migraine but can also be disabling when headaches are frequent. It has been reported that 38% to 88% of adults in the U.S. suffer from episodic tension-type headache therefore it is a common occurrence that often impacts ability to function (Schwartz, Stewart, Simon, & Lipton, 1998; Strine, Chapman, & Balluz, 2006).

Migraine most often affects people at a time in their lives when they need to be at their most productive. Women, between the ages of 30 and 50 years suffer the highest

occurrence of migraine with 27-33% reporting migraine in the past year (Lipton et al., 2001b). For men, migraine prevalence peaks earlier, between the ages of 18 and 40 years at 9-11% (O'Brien et al., 1994). Unfortunately, a large number of individuals suffering chronic headache go undiagnosed and untreated. It is estimated that only 56% of those who suffer migraine have been given an accurate medical diagnosis (Diamond et al., 2007). Failure to seek and obtain an accurate headache diagnosis may be due to the complex nature of headache and the lack of time family physicians are able to spend establishing an adequate headache history and treatment plan with their clients (Bond, Digre, Rubingh, Durrant, & Baggaley, 2004).

Migraine and tension-type headache are the two most common primary headache disorders (Strine et al., 2006) and while much of the pathophysiology of these disorders is understood, the cause of these disorders is yet unknown. The International Headache Society (Headache Classification Committee of the International Headache Society, 2004) has documented dozens of primary and secondary headache types that can be diagnosed, ranging from mild and intermittent to disabling daily headaches, therefore determining a client's diagnosis is not always a straight forward task.

Family physicians treat the majority of clients complaining of headache despite having little education in chronic pain (Morley-Forster, Clark, Speechley, & Moulin, 2003). The difficulty of managing lifelong disorders such as migraine is a common source of frustration for physicians. The ability of physicians to provide adequate headache management strategies is often met with limited success. When the family physician runs out of treatment options, the next step for many headache sufferers is to seek specialist care. The problem however, is that the wait-time to see a neurologist

specializing in headache management is usually several months and this wait can lead to feelings of helplessness and hopelessness in clients, especially when they feel that their primary care physician is no longer able to or interested in treating their headaches (Peters, Huijer Abu-Saad, Vydelingum, Dawson, & Murphy, 2004).

In the Calgary Health Region, the wait-time to receive a consultation from a headache specialist has ranged from at minimum, three months to as long as two years (personal communication, I. O'Callaghan, RN, headache program clinical coordinator, November 23, 2005). In response to the issue of long wait-times, the staff of the Calgary Headache Assessment and Management Program (CHAMP) at the Foothills Hospital has initiated an early access program for their clients.

Context

As soon as the CHAMP nurse receives a new referral, the client is contacted and invited to attend one of the weekly Program Assessment and Education (A and E) Sessions. Referrals range from 60-90 each month and are generally received from family practitioners and physician specialists. All clients referred to CHAMP (typically those who suffer from 5-15 headache days per month) that live in the Calgary area, are required to attend the two-hour A and E Session before their referral is processed further. During the A and E Session, clients are made aware of the multidisciplinary aspects of the clinic, given advice about appropriate medication usage and offered general lifestyle education as it relates to headache management. Each A and E session is attended by between 10 and 40 clients. Clients who attend the A and E Session are invited to have a personal lifestyle assessment done by an occupational therapist or a registered nurse (RN) and are asked to invest some time focusing on one or two lifestyle changes. For example, clients might attend to diet by making sure that they do not skip meals, a common headache trigger (Pikoff, 2004).

The wait-time between attending the A and E Session and obtaining an appointment to see a neurologist is typically between three and six months. While clients are waiting for the neurologist's appointment they are also invited to attend the Self-Management Workshop (SMW). This workshop consists of headache self-management education that is designed to teach behavioural skills that enhance headache prevention and management (Sauro & Becker, 2008). Participants attend for two hours weekly over five weeks for a total of 10 hours of education and facilitated discussion held at the Foothills Medical Centre.

The SMW is a cognitive behavioral group-based treatment that was developed based on the chronic pain self-management program that is taught at the Calgary Health Region (CHR), Chronic Pain Centre. The chronic pain self-management program at the Chronic Pain Centre consists of general chronic pain self-management education (McLean et al., 2005). It was developed to address the educational needs of clients suffering from neuropathic, musculoskeletal, pelvic, or headache pain and was offered in two-hour sessions over eight weeks (16 hours total). The headache clients that are referred to the CHR, Chronic Pain Centre typically suffer from chronic daily headache (15-30 headache days per month) or severe refractory headaches and are generally more disabled than clients who are referred to CHAMP (See Figure 1.1).



Figure 1.1: Headache referral algorithm at CHAMP

At CHAMP, the SMW is not compulsory and only certain clients choose to participate. In addition to the SWM, CHAMP clients can also participate in a lifestyle assessment, sleep workshop, body-works workshop and lecture series upon admission to CHAMP. These workshops and lectures all focus on headache self-management activities and do not include medical interventions such as changing the client's medications or giving analgesic injections.

Self-Management

Headache has long been considered a psychophysiological condition amenable not only to medical treatment but also to behavioural therapies. Clients can learn to identify and modify their headache triggers and learn to prevent headache occurrences using therapies such as biofeedback, relaxation training, and cognitive behavioural therapy (stress management). These modalities have been the mainstay of behavioural therapy in headache for many years (Holroyd & Andrasik, 1982; Penzien, Andrasik et al., 2005; Penzien, Rains, & Andrasik, 2002; Rains, Penzien, McCrory, & Gray, 2005). Cognitive behavioural therapy in particular is typically used to help clients learn about headache triggers and exacerbating factors, emotional impact of pain, and appropriate use of medical therapies such as prescription or over the counter medications (Pikoff, 2004).

Self-management refers to the adoption of health habits that one participates in with the intent of reducing the impact and/or progression of a disease process in the context of collaboration between healthcare professionals and the client (Bandura, 2005). All clients self-manage disease through their daily decisions about activities to pursue, medication to use, and what foods to eat, but they do not necessarily manage *well*. The self-management model promotes collaborative relationships with caregivers where clients are given the opportunity to learn and practice effective self-management skills (Bodenheimer, Lorig, Holman, & Grumbach, 2002). By recognizing maladaptive health habits and replacing them with effective coping strategies, individuals can suffer less pain and live longer and more productive lives (Bandura, 2005).

Purpose of Study

This study represents the first formal evaluation of the CHAMP program's Self-Management Workshop (SMW) when taken *before* consult with a CHAMP neurologist. Sauro and Becker (2008) evaluated the SMW as an integral part of the CHAMP clinic's non-medical treatment program where clients who participated in the SMW at any time during their care were evaluated (recruited from 2004-2005).

CHAMP clients, who choose to enrol, often complete the SMW before having their first consultation with the headache neurologist and multidisciplinary team. Individual treatment by the multidisciplinary team does not begin until after the initial neurologist consultation. In this study, it is possible to avoid the potential impact that individual, multidisciplinary treatments offered at CHAMP (e.g. medication changes or physical therapy), may have on the measurement of change in headache management self-efficacy. The hope is that the effect of the SMW on headache management selfefficacy can be singled out from other treatments offered after the neurologist consultation has been completed. Many clients referred to CHAMP have seen a neurologist in the past and my not need or want further medical assessment or treatment if non-pharmacological treatments are effective. Measuring self-efficacy in this way does not however, control for treatment activities that clients participate in, that are outside of the CHAMP program, therefore clients were asked to report headache treatments that occurred outside of CHAMP.

Research Question, Objectives and Hypothesis

Research Question

The major research question in this study is:

• Does participation in a headache self-management program (the SMW) make a difference in headache management self-efficacy?

Objectives

The primary research objective is to compare headache management self-efficacy scores for clients at baseline, to post-test scores after participation in the headache selfmanagement program (SMW). There will be a comparison group of headache sufferers that do not receive the intervention. Secondary research objectives include describing demographic characteristics of headache clients attending the CHAMP A and E session, and measuring quality of life, depression and headache disability.

Primary Research Hypothesis

Attendance in a headache self-management program (SMW) will increase headache self-efficacy scores. The primary outcome variable is headache self-efficacy score as measured by the Headache Management Self-Efficacy scale (French et al., 2000).

Key Terms

Self-efficacy

Alberta Bandura has done extensive work on human motivation and defines selfefficacy as; belief in one's ability to organize and perform the tasks needed to attain one's goals (Bandura, 1997).

Self-management

Self-management refers to the adoption of health behaviours that one participates in with the intent of reducing the impact and/or progression of a disease process in the context of collaboration between healthcare professionals and the client (Bandura, 2005).

Significance of Study

Individuals suffering from chronic headaches are managing their headaches on a daily basis, sometimes effectively, sometimes not. Better pain management techniques, coping skills, health practices, all require behaviour change that does not occur with traditional patient education alone (Bodenheimer et al., 2002). Clients need to take part in goal setting, attempt activities that they can succeed in, and learn new pain coping skills before they gain confidence in their ability to succeed in performing new behaviours (Maes & Karoly, 2005). Self-management programs provide the structure and process necessary for behaviour change to occur and be maintained provided that clients are willing to participate. The success of self-management programs has been documented in client groups with arthritis, (Barlow, Williams, & Wright, 1999; Lorig, Lubeck, Krianes, Seleznick, & Holman, 1985) musculoskeletal pain (Rahman, Ambler, Underwood, & Shipley, 2004; Von Korff et al., 1998), chronic pain (LeFort, Gray-Donald, Rowat, & Jeans, 1998) and chronic disease (Bodenheimer et al., 2002; Lorig et al., 1999).

A model of health care that focuses on the cure of chronic illness through purely medical means cannot be sustained as our population ages and demand increases (Bandura, 2005). Primary care providers and hospitals struggle to keep up with the demands of our aging population as seen by long wait times for elective surgeries such as hip and knee replacement (De Coster, McMillan, Brant, McGurran, & Noseworthy, 2007). The shortage of nurses reported in most of Canadian centre also contributes to patient access to care for chronic illness (Tarjan, 2008). Albert Bandura (2005) proposes that our aging population will force a shift to demand-side remedies for chronic illness and that the collaborative self-management model is key to this movement. Bandura states that self-management programs will help reduce the demand by promoting better health practices and reducing the burden of illness. Bandura's belief in the potential of self-management programs is illustrated in his statement "Self-management is good medicine. If the huge benefits of these few habits were put into a pill it would be declared a scientific milestone in the field of medicine" (p. 245). While this may be an exaggeration, the shift toward more personal responsibility for health maintenance is becoming more prevalent in Canadian society. Helping clients to become more self-responsible has become an important role for community nurses and other healthcare providers as guided by the Chronic Care Model (Coleman, Austin, Brach, & Wagner, 2009) and the Flinders Model of self-management support (Battersby et al., 2007).

Nurses must understand self-management models and how to engage clients to become more responsible for health in order to help reduce the demand for healthcare services (Newman, 2006). It starts by using this important theoretical learning when listening to clients who live with chronic headache and hearing how they continue to manage despite pain, fear and the other ravages of chronic disease. By recognizing a client's readiness to change behaviour and coaching them to find their own solutions (Jensen, Nielson, & Kerns, 2003), solutions that work for them, nurses can help move clients toward becoming better self-managers. The opportunity to work with specific populations of headache clients to develop and promote headache self-management models now exists; CHAMP is an excellent example of such an opportunity. Self-management programs succeed partly because clients gain a sense of control over their chronic condition or in other word their sense of self-efficacy is enhanced (Marks, Allegrante, & Lorig, 2005a). Self-efficacy in individuals for specific tasks is amenable to change (Bandura, 1997) therefore self-management models for headache, that are self-efficacy based, should be successful in changing headache coping behaviors.

Headache is a prevalent, psychophysiological disorder that impacts ability to function socially and productively. The inability to control headaches is costly in terms of absence from work, the expense of acute medications, and emergency room visits (Blumenfeld & Tischio, 2003). These factors make headache a natural fit for selfmanagement approaches (Penzien, Rains, Lipchik, & Creer, 2004). As yet, a headache self-management model that can address all the needs of headache sufferers, has not been adequately tested and perfected (Penzien, Rains et al., 2005).

Summary

Headache clients referred to the CHAMP program have early access to medical advice, lifestyle counselling and multidisciplinary care by attending a two-hour program Assessment and Education Session (A and E). At this session, they are introduced to the concept of self-management then given the opportunity to sign up for the Self-Management Workshop (SMW). The SMW consists of 10 hours of small group, selfefficacy based education. The primary research hypothesis that attending the SMW will increase headache management self-efficacy scores will be tested in this study. This study also represents one of the first formal evaluations of the SMW in the Calgary Health Region.

Outline of Thesis

In Chapter Two, the investigator provides a review of the literature and discussion on various headache management programs, the development of current self-management models and a review of several quantitative research studies that are similar, or have relevance to this study. The investigator will articulate the limitations of these studies and the gap in knowledge regarding headache self-management self-efficacy that exists. In Chapter Three the investigator will describe the research method and protocol for this study. In Chapter Four, the investigator presents the analysis and results of this study. Finally in Chapter Five, findings, conclusions, limitations, recommendations for nursing and future research are presented.

CHAPTER TWO: REVIEW OF THE LITERATURE

This chapter will focus on providing support for the psychophysiological view of headache in comparison to a biomedical view of headache as primarily a physical disorder. As well, the most common behavioural therapies used in headache will be described with a focus on cognitive behavioural therapy, as it is the treatment approach that is used by the Calgary Headache Assessment and Management Program (CHAMP) in their Self-Management Workshop (SMW). Patient education programs that use cognitive behavioral treatment techniques and have a self-efficacy focus have been shown to impact chronic disease self-management self-efficacy (Marks, Allegrante, & Lorig, 2005b). Only two articles were found in the literature that described and/or tested a self-management model for headache (based on searches in CINAHL, 1982 to present, PsycINFO, 1967 to present, and Medline, 1966 to present) therefore many of the articles included in this review are related to other chronic conditions and were included to support the notion that an effective headache self-management model would be of benefit to headache sufferers.

Psychophysiological View of Headache

There has been a growing trend toward behavioural approaches to headache management as an adjunct or alternative to pharmacological management. In the last 30 years, behavioural headache research has suggested that relaxation training, biofeedback, cognitive behavioural therapy and stress management are at least as effective as headache preventative medication (Penzien, Rains et al., 2005). All of these treatments are anchored to the belief that headache is a psychophysiological disorder. Rains et al (2005) in their review of headache behavioural treatment, define psychophysiological disorder as

the notion of headache as a physical disorder that is impacted significantly by environmental, social and psychological stressors.

These stressors often lead to negative emotional states in headache sufferers such as depression and anxiety. In fact, headache sufferers are more likely to suffer from depression and/or anxiety than the general population (Molgat & Patten, 2005; Nicholson, Houle, Rhudy, & Norton, 2007). Molgat and Patten (2005) in a Canadian study found that major depression was reported in 17.6% of migraine sufferers compared to 7.4% in the general public and 7.8% in participants with other chronic conditions. These results suggest that management of negative emotional states such as depression must be included in a headache treatment plan. The use of passive coping styles during painful episodes (such as lying down and withdrawal from socialization) by migraine sufferers has been associated with greater feelings of helplessness and more intense experience of pain (Siniatchkin, Riabus, & Hasenburg, 1999).

The research on behavioural approaches to headache has been extensive and has explored general efficacy, comparisons between pharmacological and behavioural approaches, maintenance and durability of effect, cost effectiveness and the mechanisms that underlie treatment (Andrasik, 1996). As well, a large amount of the research done in headache revolves around the beliefs and cognitions that impact headache management (Martin, Holroyd, & Penzien, 1990; Scharff, Turk, & Marcus, 1995). Research has shown that locus of control and self-efficacy are key factors client ability to prevent and control headaches (Nicholson et al., 2007). Locus of control refers to an individual's perception of whether certain events are under the individual's control or are influenced more by the actions of others (French et al., 2000). Locus of control is not explored

further in this literature review as it is beyond the scope of this research project. Selfefficacy theory is discussed in detail in the theoretical framework section of this chapter.

Pharmacological Versus Non-Pharmacological Headache Treatment

In the pharmacological management of headaches, medications are used to treat acute headache attacks and to prevent future attacks. Acute medications used in headache vary from inexpensive over the counter (OTC) medications such as acetyl salicylic acid (ASA), ibuprofen and acetaminophen, to costly prescription medications such as the triptans (e.g. sumatriptan/Imitrex) used in migraine. Potent non-steroidal anti-inflammatory drugs (NSAID's), ergotamines and at times opioids are also used to treat severe headache occurrences.

There are several issues associated with acute headache treatment. First, in a recent study of migraine prevalence in the United States, only about half (56.2%) of all migraine sufferers reported having sought medical treatment for headache and received an accurate diagnosis of migraine (Diamond et al., 2007). The more potent triptans, which are specific to migraine treatment, are therefore underused due to the fact that many patients have not received a migraine diagnosis. Even with a migraine diagnosis, 49% of sufferers treat their attacks primarily with OTC medications (Diamond et al., 2007). Less expensive OTC medications do not often help to manage the severe pain associated with migraine and are frequently overused in an effort to gain control of pain. Chronic daily headache is often associated with medication overuse; however, it is still not understood whether medication overuse is the cause or the result of suffering daily headache pain (Bigal, Rapoport, Sheftell, Tepper, & Lipton, 2004). The cost of prescription medications is often prohibitive for patients and poor understanding of their

effects creates adherence issues with acute treatment. Gallagher and Kunkel (2003) reported that 11% of migraine sufferers in their study did not even fill their prescription citing high costs and concerns about adverse effects. As well 71% delayed taking their prescription medication, for fear of side effects.

Medications are also used to reduce the frequency and intensity of headache attacks. There are several classes of preventative medications including, tricyclic antidepressants, beta-blockers, and antiepileptics. These medications must be taken on a daily basis and may not show any clinically significant improvement for weeks or months. Rains and colleagues (2006a) in their review of headache compliance literature suggest that the more obstacles to adherence (e.g. long term medication use, complicated dosing schedules, side effects and costs) the less likely that clients will continue to use headache medications appropriately or at all. To add to the adherence issue, no preventative medication has been shown to be effective in more than about 30% of individuals; therefore, several trials of different medication may be necessary before any benefits are seen (W. J. Becker, 1999).

While headache medications are often effective, effective headache management is not as simple as just taking a pill. Behaviour change is required to initiate and maintain the behaviour of buying the medication and consuming it at the right time, in the right dose. Clients do not simply carry out the "doctor's orders", nor should they, instead they weigh the advantages and disadvantages of any given treatment and make decisions based on their own risk/benefit analysis (Rains, Penzien, & Lipchik, 2006b). In a Canadian study (Ivers, McGrath, Purdy, Hennigar, & Campbell, 2000) that explored decision-making in patients taking sumatriptan, it was found that clients first considered

several personal and environmental cues to determine if the headache they were experiencing would become a migraine. Clients then considered several other factors for example, past effectiveness of sumatriptan or severity of migraine, before making the decision to take sumatriptan.

While preventative medications may have beneficial effects on client mood as well as pain, headache sufferers do not always make the connection between the psychological, social and environmental stressors that they live with and the pain they suffer. The biomedical model that sees headache as a physical disorder provides only a one-dimensional approach to headache management. When behavioural aspects of care are also considered, clients will have more information and more choices so that they can make appropriate risk/benefit analyses and finally a treatment decision that they can carry out. The opposite situation, where the client is left with the impression that headaches are purely psychological, can also occur. All too often, in the investigator's experience, family members and/or health care providers tell headache sufferers that it is "all in their head", leaving clients with the feeling of not being heard.

In shifting views of headache from a purely biological or purely psychogenic disorder to a psychophysiological disorder, it is possible to provide clients with alternatives to medication to treat acute symptoms, and to address the depression, anxiety and anger that are associated with suffering chronic headache pain. Behavioural therapies used in headache management generally include strategies to recognize and avoid headache triggers and learning self-management skills that help to prevent headache occurrences. The most commonly used interventions are relaxation training, biofeedback and cognitive behavioural therapy (Rains et al., 2005). Relaxation training is thought to reduce headache by enabling headache sufferers to change their physiological responses to stress that lead to headache and by decreasing sympathetic arousal (Hoodin, Brines, Lake, Wilson, & Saper, 2000). Progressive muscle relaxation, autogenic training, and meditative relaxation are the most common forms of relaxation used in headache management and are usually combined with cognitive behavioural therapy (Bigal & Lipton, 2006).

Biofeedback is the use of technology, usually electromyography (EMG) or thermal monitoring, to monitor a client's physiological state so that the client is able to focus on that state and may be able to modify it (Holroyd & Andrasik, 1982). Electromyography is often used to monitor muscle tension responses in the neck and shoulders and had long been employed to treat tension-type headache (Holroyd, Frank, & Westbrook, 1977). Thermal biofeedback, in which clients learn to increase the warmth of their hands, has been used primarily in migraine. Relaxation training is done in conjunction with biofeedback so that clients learn techniques to modify their physiological responses to stress and pain, gradually decreasing their reliance on the technology through practice and skill acquisition (Rains et al., 2005).

Cognitive behavioural therapy (CBT) is the most involved of the three behavioural techniques discussed above. In this method, the role of thoughts and emotions that arise in response to stressful or painful events are examined so that they can be linked to behaviours (Holroyd & Andrasik, 1982). Behaviours that lead to headache are replaced with better coping strategies and stress reduction. This relationship between headaches, stress and coping is explored while skills in cognitive restructuring, communication, self-talk, pacing of activities and relaxation are taught (McLean et al., 2005). Cognitive behavioural therapy can be administered one on one but is most often and most economically presented in a group format. The selfmanagement treatment group offered through CHAMP is based on CBT processes.

The effectiveness of behavioural therapies is well documented in the headache literature (Penzien, Andrasik et al., 2005). In a review of 30 years worth of research (Penzien et al., 2002), it was found that migraine and tension-type headache activity was reduced from 35-50% through the use of behavioural therapies. Despite their effectiveness, there are drawbacks to administering these therapies. Behavioural therapies aimed at reducing headache are often taught in the clinician's office over an average of 5-10 sessions (more if psychological issues are present), and, even when taught in a group setting, still require several hours of clinician time to conduct the group intervention (Rains et al., 2005). The length of therapy, the scarcity of resources and the location of treatment in the clinician's office, make behavioural therapies inaccessible to a large number of potential clients (Haddock et al., 1997). In response to access issues, many providers have explored approaches that reduce therapist contact.

Minimal Therapist Contact

In response to issues of cost, clinician time and accessibility to clients, minimal therapist contact or home-based formats have been developed and tested (Rowan & Andrasik, 1996). In minimal therapist contact, the same treatment that is usually provided in a clinic setting is modified with written, videotaped or audiotaped materials so that clients can access the information at home (Haddock et al., 1997). The therapist in the clinic introduces the skills then clients rely on the take home materials to practice and learn. While the information is more accessible to clients and they have more

freedom in terms of learning at their own pace, in their own style, there are risks to presenting material with little supervision. Adherence to treatment and understanding of treatment principals may be jeopardized with the minimal contact method. Nonetheless, a comprehensive meta-analysis of 13 minimal therapist contact headache programs has shown this treatment modality is equal or superior in effectiveness to clinic-based treatment (Haddock et al., 1997). Furthermore, this method of service delivery demonstrated these results while less therapist time was used (161.1 minutes compared with 483.8 minutes) and cost was reduced to 1/5 of that of clinic-based treatment.

Headache Management Programs

Despite the benefits of minimal contact treatment, not all headache clinics are experienced in providing behavioural therapies and not all clients respond well to this form of treatment, especially clients with disabling headache (Nash, Park, Walker, Gordon, & Nicholson, 2004). Many versions of headache treatment programs have emerged. In the U.S., headache programs have been developed, primarily in health maintenance organizations (HMO's) as a response to high numbers of headache referrals to neurology and the high number visits required to treat headaches effectively (Harpole et al., 2003). In Canada, several multidisciplinary pain clinics have been developed which treat headache among other pain conditions(Magnusson, Riess, & Becker, 2004; Sauro & Becker, 2008). A review of the literature now follows that reveals a wide range of headache programs currently in use, from nurse practitioner managed clinics to multidisciplinary inpatient programs.

Several nurse practitioner led headache management programs are described in the literature, all of them originating from Kaiser Permanente, an HMO in California, U.S.A. (Blumenfeld & Tischio, 2003; Harpole et al., 2003; Maizels, Saenz, & Wirjo, 2003). These programs were all established in response to large numbers of neurologist referrals for headache, as well as client dissatisfaction with the previous model of care. Other commonalities among these programs include: use of a disease management model and referral by primary care physicians. The client population that was treated tended to suffer from headaches that were moderate to severe in intensity and were often disabling. As well, all programs included a group intake and education session where clients were taught about headache biogenesis, triggers, medications and other treatment options. The nurse practitioners in the headache programs performed histories and physical exams on the majority of clients, which were then reviewed by a general practitioner or neurologist. The program physician followed complex cases, such as clients with high narcotic use, significant comorbidity, or multiple treatment failures.

Where these NP led headache management programs differed was in the focus of their evaluation. Harpole and colleagues (2003) measured, quality of life using the Short Form-36 Health Survey (SF-36), headache related disability using the Migraine Disability Assessment (MIDAS), and satisfaction with care, in 55 participants with "problem headaches" (Harpole et al., 2003, p. 217). Fifty-four consecutive patients enrolled in the program were followed for six months. Headaches suffered were not further defined by diagnosis in this article. Statistically significant improvement in disability (p < 0.005) from baseline to 6-month follow-up (21.1 points on the MIDAS scale) however a large standard deviation (26.3) in MIDAS scores was seen suggesting a wide range of responses. In 6 of the 8 subscales of the SF-36 (p < 0.005) and patient satisfaction (p < 0.001) was noted.

Blumenfeld and Tischio (2003) undertook a pilot study of adult patients with primary headaches and were also concerned about quality of life using two scales to measure outcomes (SF-36 and Migraine-specific Quality of Life Questionnaire). Significant improvements at 6 months (p < 0.001) were found for both scales. Clinic visits were also decreased, and 97% of participants reported headache improvement; however, these self-reports were not supported with headache diary data (a more accurate measure of improvement).

Maizels (2003) and colleagues enrolled 264 participants in their prospective, observational study which was focused on the cost savings realized by their NP program. Triptan use (abortive medications including sumatriptan and dihydroergotamine) and visits to the clinic or emergency department at baseline and 6 months were measured. The authors recorded a 19% increase in triptan costs related to higher usage of this acute migraine medication, 32% reduction in clinic visits and 49% reduction in emergency room visits. While clients used more triptans, the reduction in medical visits within the treatment group more than offset the added cost of these medications by \$19,000 U.S. for the entire sample. No p values were cited in this study; however, the authors stated that clinical significance was achieved. Lack of control or comparison groups in all three of these research studies, is an important limitation that makes it difficult to draw conclusions about the effectiveness of the interventions used in these headache programs.

A neurologist led headache treatment program, that included layperson education for clients (Rothrock et al., 2006) reported on 100 clients who were assessed and treated by a neurologist, given written material on migraine biogenesis, treatment options and medication overuse. Clients were randomized to headache school or to no school and

neurologists were blinded as to study group allocation. Headache school was defined as a group intervention that consisted of three 90-minute classes, led by a layperson that suffered migraine. The layperson/leader reviewed and expanded upon the written material topics given to all clients. MIDAS disability scores were the primary outcome variable and statistically significant improvement in mean MIDAS scores (p < 0.05) were seen in the treatment group compared to controls (15 compared to 54) using paired *t*-tests (Rothrock et al., 2006). However, the analysis of data in this study showed the treatment group had significantly lower MIDAS scores at baseline than the comparison group (39 compared to 68). The authors were therefore cautious in drawing conclusions about the effectiveness of the intervention. A larger sample size may have been indicated; there were no power or effect size calculations provided to evaluate this study further.

Providing headache clients with basic education about their condition, treatment and lifestyle options appears to be beneficial in terms of improved disability and quality of life. However the four studies described above lacked the rigour and/or the sample size to allow for confident conclusions about nurse practitioner led headache programs or about lay migraineur led education in a neurology practice. Further randomized, controlled research studies with larger sample sizes are necessary to determine the effectiveness and cost-efficiency of nurse practitioner and neurologist-led headache management programs.

Several studies in the literature are representative of multidisciplinary, tertiary care programs in Canada and the U.S. In 2004, Magnusson, Reiss and Becker of Calgary, Alberta, Canada published a comparison of chronic daily headache sufferers treated in the neurologist's office compared with a multidisciplinary treatment centre
(Magnusson et al., 2004). The main outcome variables in this study were disability measured by the HDI and quality of life measured by the SF-36. This was not a randomized trial; rather, it was an outcome cohort study of chronic daily headache sufferers treated in two different settings by the same neurologist lead team. Data was collected by retrospective chart review. Therefore the outcomes must be viewed with some reservation. The group treated in the neurologist office (n = 75) received primarily pharmacological treatment, education about medications and handouts regarding lifestyle modifications. The multidisciplinary group (n = 52) received the same pharmacological management as the first group but also received psychologist counselling, physical therapy and group education in chronic pain self-management. The self-management group had a cognitive behavioral treatment focus and consisted of eight weekly sessions of two hours in length. The group membership included musculoskeletal and pelvic pain patients in addition to the headache patients that were selected for this study. Other group treatments such as relaxation training and sleep hygiene were also provided to many of these participants.

Magnusson, Reiss and Becker (2004) found that disability, measured by the HDI (range 0-100) was moderate, 53.4 at baseline and remained unchanged at 51.5 at the oneyear follow-up period for the headache patients in the neurologist office group; while, the multidisciplinary group showed statistically significant improvement in disability over a similar time frame (51.1 baseline versus 34.0 at follow-up, p < 0.001). Similarly, quality of life measured by the SF-36 was unchanged in the neurologist office group; while the multidisciplinary group showed statistically significant improvements in all eight subscales (p < 0.05). Also of note was that while headache pain, measured in days per month, was significantly reduced in frequency for the neurologist office group from 23.4 at baseline to 19.2 at follow-up (p < 0.0001). Headache intensity remained unchanged from 4.6/10 at baseline to 4.5/10 at study exit, suggesting that intensity, rather than frequency, may be a more important determinant of headache related disability in daily headache sufferers. In the multidisciplinary group, pain intensity showed a downward trend (30% decrease in pain ratings on a 0-10 point scale) but did not reach statistical significance.

Magnusson and Becker (2002) substantiated the importance of headache intensity in a separate study in which they compared participants with episodic migraine (range of 1-18 days with headache in the last four weeks) to participants with transformed migraine, one form of chronic daily headache, (range of 22-28 days with headache in the last four weeks). Of 121 patients in a neurologist led headache clinic who completed all questionnaires, 87 met study criteria, 50 with migraine and 37 with transformed migraine. The groups were compared using *t*-tests and no differences in terms of pain intensity, disability, depression or anxiety were found between the episodic and chronic daily headache groups. The similarity in the outcomes for these two groups was unexpected; as practitioners generally believe that chronic daily headache is a more disabling condition. This was an observational study therefore it is limited by the lack of randomization and a control group.

There are headache sufferers whose disability and pain are severe enough to necessitate admission to hospital. The use of CBT as a method of headache management in a hospital setting is described in the following study. Hoodin and colleagues (Hoodin et al., 2000) evaluated the impact of a self-management program on inpatients of the

Head Pain Treatment Unit in Chelsea, Michigan, U.S. In this retrospective chart review, data from 221 clients who attended daily cognitive behavioral therapy in a group setting that included relaxation training, pacing of activity, and self-monitoring were used. Intensive medical therapy and individual psychological counselling focusing on lifestyle modifications was also given to all clients. Adherence to self-management behaviors was measured using a seven-day retrospective self-report and affective distress was measured using the Beck Depression Inventory (BDI) in the 221 clients (77% female) suffering from intractable chronic daily headaches or chronic posttraumatic headaches.

When baseline measures were compared to six-month follow-up, a statistically significant increase in the use of relaxation strategies during headache (mean number of days in the past seven = 2.8 at baseline versus 4.7 at six months), during stress (1.8 versus 3.9) and in the prevention of headache (2.3 versus 4.7) was found. Depression scores dropped from 16.2 at baseline to 8.1 at six-month follow-up (p < 0.001).

Interestingly, the clients in this treatment program who used relaxation the most were those with the highest depression scores (p = 0.05). These clients also experienced the greatest drop in depression scores at follow-up (p = 0.05). Improvement in headache pain did not correlate with depression scores (p = 0.137).

One important limitation of this study is that reductions in depression, and treatment adherence cannot be linked directly to the group self-management program as medical and psychological interventions may also have been contributing factors. In the current study, the CHAMP Self-management Workshop and other educational workshops are offered prior to client involvement with the neurologist or psychologist allowing for measurement of self-management group impact in greater isolation from other treatments.

Hoodin et al. (2000) also note that the percentage of clients using relaxation techniques on at least five days per week was still less than ideal (55% of clients used during headache, 45% during stress, and 59% to prevent headache occurrence). The sample for this study appears to represent the most significantly affected of headache sufferers, those requiring hospitalization, and more time may have been needed to see ideal treatment adherence results. However an improvement of 50% in the use of relaxation techniques does appear to be substantial for this population and it may not have been realistic for the investigators to expect ideal results.

Supporting the notion that some headache sufferers, especially those with chronic daily headache, may not benefit from CBT in a multidisciplinary setting, Barton and Blanchard (2001) published the following study. They completed a prospective trial of 16 chronic daily headache participants who were treated for up to 20 sessions, using not only CBT but also relaxation training and thermal biofeedback training. In comparison, all other CBT headache offerings, in the literature reviewed here, consisted of 10 or fewer sessions. Only 12 participants completed the treatment and of those only two (17%) achieved greater than 50% reduction in headache index scores (a calculation of pain intensity and frequency together). Barton and Blanchard (2001) did not separate CBT from other forms of therapy therefore it is difficult to determine what part of the treatment failed for the participants.

Nash et al., (2004) offered their CBT group to 80 patients with migraine, tensiontype headache or both, with moderate to severe disability. The trial was designed so that

CBT would be offered in the absence of medical, psychological or physical therapies. Outcome measures for headache pain (frequency measured in headaches experienced the last month and intensity measured on a 0-10 point Likert-type scale), medication use (total days per month using acute medications) and quality of life (SF-36) were collected pre-treatment and at one month after completion of the treatment group.

The CBT group consisted of 10 weekly sessions of 90 minutes duration that focused on headache pathophysiology, lifestyle modifications, relaxation, stress, and pain coping. In the analysis, statistically significant changes were seen in all domains. Headache frequency decreased from 21 days per month to 13 days (p < 0.001). Headache intensity decreased from 6.9/10 to 5.8/10, which was statistically significant (p < 0.01) however it is doubtful that a one-point decrease would feel clinically significant to participants. Number of days per month taking acute medication was reduced from 21 to 12 (p < 0.001). Quality of life was improved on the SF-36 subscales of social functioning, physical role, mental health, vitality, pain (all at p < 0.001) and general health (p < 0.05). Only the subscales of physical functioning and emotional role were unchanged.

Nash et al., (2004) did a more controlled study that singled out the benefits of CBT from other treatments; however, no control or comparison group were used, weakening the strength of the findings. The disability metric used did not allow for post-treatment follow-up within six months, therefore outcome data on disability were not collected. Addressing two of the weaknesses in the Nash (2004) study, the current study has included a comparison group and employs the HDI to measure disability both before and after the CHAMP Self-Management Workshop.

Several examples of headache management programs have been reviewed, revealing a variety of approaches and treatment models. However, the headache selfmanagement model is new compared to other chronic conditions. Self-management programs for conditions such as childhood asthma, were first introduced in the 1960's (Lorig & Holman, 2003). Dr. Kate Lorig began her work developing arthritis patient education programs in the 1970's and 80's (Lorig et al., 1985) which eventually lead to the development of the Stanford Model of self-management. The Stanford Model and its application to arthritis, heart disease, lung disease, stroke and chronic pain will be reviewed in the next section.

Self-Management Programs in Chronic Disease

Lorig and Holman (2003) define self-management as the health-related behaviors, either passive or active, that individuals with chronic disease decide to engage in. All individuals with chronic disease manage their condition, just not always in ways that promote better health and reduced disability. Patient education programs, such as the Arthritis Self-Management Program (ASMP), developed by Lorig and colleagues (1985), were established to help clients manage medical, role and emotional tasks, and teach the following self-management skills: problem solving, decision-making, utilization of resources, development of constructive partnerships with health care providers, action planning and goal setting.

The ASMP is used by volunteer arthritis organizations in North America (Lorig et al., 1985), Australia (Prior & Bond, 2004), the United Kingdom (Barlow et al., 1999) and others, to provide education and support to individuals suffering from osteoarthritis, rheumatoid arthritis, fibromyalgia as well as other forms of arthritis. The ASMP is taught

in community settings by lay leaders, who often suffer from arthritis themselves, and consists of six weekly two-hour sessions that follow a strict protocol outlined in the Arthritis Helpbook (Lorig, 2000), which is provided to all participants.

The ASMP has been shown to reduce pain, and increase exercise at both four (p < 0.01) and 20 months (p < 0.05) post treatment (Lorig et al., 1985). Support for the hypothesis that self-efficacy is associated with changes in health status was found (Lorig, Chastain, Ung, Shoor, & Holman, 1989) and has been replicated in several other studies (Lorig & Holman, 2003). In a four-year follow-up study (Lorig & Holman, 1993), pain was reduced by 19%, self-efficacy scores increased by 17% and health care utilization measured by physician visits was reduced by 43% (p < 0.05).

In a study conducted in Calgary, Rankin (1998), compared participants suffering from rheumatoid arthritis who wanted to participate in the ASMP to a control group who *did not want* to participate in the ASMP (n = 146). Rather than using wait-list controls (Lorig et al., 1985), Rankin sought a control group who were true non-participants in the ASMP. Using both interviews and self-administered instruments, Rankin concluded that participants interested in attending the ASMP did not differ significantly from the control group in terms of self-efficacy (p = 0.076), the primary research hypothesis. In fact both groups were very similar in terms of illness-related stress, depression and well being, differing only on the measure of social desirability (p = 0.003). This study brings into question whether arthritis sufferers who participate in an ASMP really differ in terms of self-efficacy from arthritis sufferers who choose not to participate in a self-management program.

Following the success of the ASMP, Lorig explored the effectiveness of the Stanford University model of self-management in chronic disease in general. The Chronic Disease Self-Management Program (CDSMP) was developed and tested in participants diagnosed with heart disease, lung disease, stroke or arthritis (Lorig et al., 1999). Using wait-list controls, where the control group was given the intervention after a six-month wait, Lorig and colleagues examined the data from 952 participants. The intervention group demonstrated statistically significant improvements (p < 0.01) in the amount of time spent exercising, health distress and communication with physicians. Two years later, these participants demonstrated statistically significant reductions in health distress (p = 0.0001), physician and emergency room visits (p = 0.036), and an increase in self-efficacy scores (p = 0.009) compared to baseline (Lorig et al., 2001). Studies of the CDSMP have also revealed the tasks that clients with chronic disease need to be able to perform to become good self-managers (e.g. lose weight, use medications appropriately) and the types of education strategies that enhance self-efficacy in chronic disease sufferers (Marks et al., 2005b). The CDSMP is based on self-efficacy theory and uses skills mastery modeling as well as decision-making and problem solving. The use of self-efficacy as a valid theoretical framework for understanding chronic disease selfmanagement has also been studied and described throughout Lorig's work (Marks et al., 2005a). A version of the CDSMP is taught in Calgary, Alberta under the name "Row Your Own Boat".

A common design in Lorig's work is the use of wait-list controls. Wait-list controls by definition are individuals who are interested in participating in the study intervention, a self-management program, however were randomized to no treatment for a specified period of time. After waiting, the controls participate in the intervention and outcomes are evaluated. Using individuals who are interested in, and have chosen to participate in a self-management program as controls introduces a potential source of bias to Lorig's research.

Controls in research are usually individuals who are observed because they are similar to the intervention group but do not receive the intervention. When control group subjects know that they will eventually have the intervention, outcome expectations may be affected by the wait. Their condition (arthritis) may progress, or they may spend the wait time seeking more information about the intervention. All of these possible situations could bias control group member responses when evaluated at the end of the study. The current study uses a comparison group of individuals who have chosen not to participate in the Self-Management Workshop during the timeframe of this study. It is not known if they chose to participate in the SMW at a later time.

In order to extend the reach of the CDSMP to a broader audience, an Internetbased version was created and tested in comparison to the established small group format described above. In this study (Lorig, Ritter, Laurent, & Plant, 2006), 958 participants were randomized to the intervention or usual-care control. The findings at one year postintervention were similar to the small group format in that health distress, fatigue and pain were improved. In contrast however, the only statistically significant change in health behavior was for exercise (p = 0.023) and no significant change in healthcare utilization was found in the Internet intervention group. Despite the differences between the Internet and small-group based programs the Internet appears to be a viable mode of delivery for the CDSMP.

The Stanford University model of self-management education has also been adapted for use in chronic pain. In a Canadian study, LeFort and colleagues (LeFort et al., 1998) randomized participants with idiopathic pain (defined as musculoskeletal pain with no known pathology) to Chronic Pain Self-Management Program (CPSMP) (n = 57)or three-month wait-list control (n = 53). The CPSMP also consisted of six two-hour sessions held weekly and included a workbook developed for the chronic pain program. The content was similar to the ASMP and the leader, a registered nurse, was trained in the ASMP standardized leadership course. The treatment group demonstrated improvements in pain severity (p = 0.002), disability (p = 0.008), self-efficacy, resourcefulness, role behaviors and life satisfaction (p < 0.003 for all four variables). The variables measured in this study were based on Braden's theoretical model of self-help (LeFort, 2000), a nursing theory which hypothesizes that client's perceive the severity of their illness in relationship to limitation and uncertainty (antecedents), enabling skill and self-help (mediators), and quality of life (outcomes). Analysis of the relationship between all of the variables in Braden's model demonstrated support for the validity of the model (p values varied from < 0.05 to < 0.001).

Von Korff and colleagues (Von Korff et al., 1998) were interested in improving the management of low back pain in primary care and developed a four-session, layperson-led patient education program based on the Stanford University model. Problem solving, goal setting and action planning skills were applied to back pain management skills such as posture and body mechanics, pacing exercise and managing flare-ups. Randomization of 255 participants to self-management or usual care was conducted and data were collected at baseline, 3, 6 and 12 months. The self-management group demonstrated statistically significant reductions in worries about back pain (p < 0.022), and in disability (p = 0.007) at the six and 12-month follow-ups. Little difference was found in activity limitation or in pain reduction and while self-management participants demonstrated improvements in their self-care confidence at three (p = 0.47) and six months (p = 0.032), by 12 months the differences no longer reached statistical significance (p = 0.10). Self-efficacy for low back pain management was not measured in this study and the results of other measures in general were not as impressive as other self-management programs using the Stanford University model. The intervention was only four sessions compared to the usual six and therefore may not have provided enough guidance, peer support and information necessary for low back pain sufferers to change their behavior.

The ASMP, CDSMP, CPSMP and low back pain program are all excellent examples of patient education programs that use cognitive behavioral therapies in an attempt to change health-related behaviors. The importance of enhanced self-efficacy as a mediator for health behavior change has also been explored and supported throughout the development of the Stanford University model of self-management (Marks et al., 2005b).

In the previous section, headache management programs were reviewed demonstrating a variety of approaches to treatment of chronic headaches, primarily of the migraine and tension-type diagnosis. In the next section, the need for a model of headache self-management is explored followed by a review of the limited research found which uses a headache-specific tool to measure headache management selfefficacy.

Self-Management Model for Headache

The HMO-based, nurse-led headache management programs described earlier in this chapter included many important elements of a headache self-management model. In their early research of headache self-management, Mitchell and White (1977) measured several components of self-management separately, then in combination. They found that the combination of self-monitoring, self-recording of headache patterns, and acquisition of relaxation, problem solving, goal setting and other skills was the most effective in reducing headache (3.7% headache reduction for one method of headache management, versus 83% using all methods listed above). While the sample size was very small (n = 12), the findings of this study, along with the HMO studies, support the development of a multifaceted and intensive model of headache self-management.

Donald Penzien and colleagues (Penzien et al., 2004) suggest that a multifaceted headache self-management model is warranted in the treatment of tension-type headache and should, as in the case of Lorig's Stanford model (Lorig, 1993) include goal-setting, decision-making, self-monitoring, action planning, and self-efficacy enhancing strategies. Penzien (2004) also lists the process components of a comprehensive headache selfmanagement program including; a patient registry, out-come tracking, and algorithms for identifying program candidates. The specific skills that should be targeted in headache self-management include; acceptance of headache as a chronic condition, identification of triggers, correct use of medications and ability to strategize trigger avoidance and reduction. The characteristics of clients that are most likely to benefit from selfmanagement are also explored and for example include significant headache frequency,

significant health care usage, and an ability to process and respond to information about their responses to their headache condition.

Further testing of this model for tension-type headache self-management is warranted to validate the model and to encourage expansion of this model to all primary headache types (e.g. migraine, cervicogenic headache) (Penzien, Rains et al., 2005). The importance of self-efficacy for headache self-management is also worthy of further research because self-efficacy is so contextual in nature and can therefore be enhanced through a variety of techniques (Bandura, 1997). The limited research studies found in the literature to date that have explored self-efficacy in headache will now be reviewed.

Self-Efficacy in Headache Management

To date, there has not been one study reported in the literature (based on searches in CINAHL, 1982 to present, PsycINFO, 1967 to present, and Medline, 1966 to present) in which the researchers evaluate the effectiveness of a headache self-management program on self-efficacy beliefs. There has however, been a headache specific selfefficacy tool developed, tested (French et al., 2000), and subsequently used in a number of headache studies (Lee, Park, & Kim, 2005; Nash, Williams, Nicholson, & Trask, 2006; Nicholson, Nash, & Andrasik, 2005).

The Headache Management Self-Efficacy Scale (HMSE) was developed by French and colleagues (2000) in order to provide a brief (25 item), headache-specific measure of beliefs about ability to prevent, manage and control headaches. A previously developed scale, the Headache Self-Efficacy Scale (HSE) developed by Martin and colleagues (Martin, Holroyd, & Rokicki, 1993), was found to be too long (51 items), difficult to score and focused only on perception of ability to prevent headache attacks. As a result, it was not often used. The goal of French and his team (2000) was the development of a tool that would also capture other dimensions of headache self-efficacy such as ability to manage headache pain and headache-related disability.

French et al., (2000) conducted a randomized controlled trial in which participants (n = 262, 77% women) were placed into one of four 8-week treatment groups or a control group (n in each group was not stated): 1. tricyclic medication (for headache prevention) and clinical management, 2. placebo and clinical management, 3. tricyclic medication and stress management (relaxation, cognitive coping and problem-solving), 4. placebo and stress management. Participants in the four treatment samples were found to be demographically similar. They suffered from chronic tension-type headache, and were recruited from two headache clinics (serving Ohio and West Virginia, U.S.A.). Participants were excluded if they used antidepressant, antianxiety or other prophylactic headache medications, or if they reported a primary pain complaint other than headache.

Participants completed the HMSE developed by the researchers as well as the Headache-Specific Locus of Control Scale, Beck Depression Inventory (BDI), Headache Disability Inventory (HDI), Interview of Coping Efforts – Headache Version, and Trait Anxiety Inventory. Participants also completed daily recordings of headache frequency and severity, which were used to calculate the Headache Index, an average of weekly headache ratings. The HMSE is comprised of 25 items measured on a 7-point Likert scale with 1 = "strongly agree to 7 = "strongly disagree", generated by experienced headache practitioners. HMSE scores can range from a minimum of 25 to a maximum of 175. Lower scores indicate lower headache self-efficacy and higher scores, higher self-

efficacy. All measures were collected at baseline and one month after completion of the 8-week intervention.

The results of this study (French et al., 2000) supported four hypotheses: 1. Selfefficacy beliefs correlate with but are different from locus of control beliefs (p < 0.001). 2. Higher self-efficacy beliefs correlated with lower disability (p < 0.001). 3. Higher selfefficacy correlated with higher use of positive coping strategies (p < 0.05), although interestingly, only 9% of clients used positive coping to prevent headaches and only 14% use positive coping to manage headaches. 4. Self-efficacy and locus of control beliefs accounted for additional variance in headache-related disability beyond that explained by headache severity.

The researchers felt that the HMSE appeared to be a psychometrically sound tool for measuring belief in one's ability to participate in actions that will prevent or manage headache. The internal consistency of the HMSE in this study was considered excellent by the authors (Cronbach's $\alpha = .90$). Three subsequent headache studies that used the HMSE were found in the literature.

The first of those studies was by Nicholson, Nash and Andrasik (2005) who conducted an 8-week, self-administered behavioural intervention. The aim of this study was to show that adding tailored messages to a minimal therapist contact program for headache could improve outcomes and participant retention (91% completed the intervention). The intervention consisted of an education component (written materials), self-management skills (audio tapes) and computer generated messages that were tailored to each participant's clinical picture. Twenty-one out of 23 participants who were eligible completed the intervention. No control or comparison group was used. The results were significantly increased scores (p < 0.01) on the HMSE (pretest M = 102, SD = 16, posttest M = 124, SD = 23), fewer headache days per month (p < 0.001), reduced stress (p < 0.01), improved sleep (p < 0.01), and fewer skipped meals (p < 0.001).

In a randomized double-blind controlled trial, Lee, Park and Kim (2005) compared buspirone hydrochloride (n = 31) with placebo (n = 43) in the treatment of migraine and co-morbid anxiety. The HMSE was administered to both treatment and placebo groups at baseline and every two weeks for six weeks. Improvement was noted in HMSE scores for the treatment group (18.1%) versus the placebo group (9.1%), however this change was not statistically significant (p = 0.271). The sample size for this study is an issue because of insufficient power to correctly detect a statistically significant difference (power = 0.22) (Brant, 2009). The fact that instruments were repeatedly used in a short period of time (four times in eight weeks) may have been a threat to the internal validity of this study.

In an effort to determine the impact of pain-related anxiety on headache-related disability, Nash and colleagues (Nash et al., 2006) administered the HMSE as well as the Headache-Specific Locus of Control Scale (HSLC) (Martin et al., 1990), Migraine Disability Assessment Scale (MIDAS), Pain Anxiety Symptom Scale (PASS), and SF-36 to 96 participants (85% women). In the hierarchical linear regression analysis, pain, self-efficacy and locus of control together accounted for 32% (p < 0.001) of the variance in headache-related disability; however, self-efficacy for headache management was itself, not a statistically significant predictor of disability (Nash et al., 2006). Self-efficacy was a strong predictor of disability in previous research (French et al., 2000), therefore, the non-significant impact in this study was unexpected. When all other factors were

controlled for, pain-related anxiety was found to account for 14% (p < 0.01) of the unique variance in disability (Nash et al., 2006). Based on the contradictory nature of these findings, continued research with larger numbers of headache participants is warranted to more fully understand the role that self-efficacy plays in headache management.

The HMSE was chosen as the primary outcome measure for the current study on CHAMP participants as a measure of the effectiveness of the Self-management Workshop to increase headache management self-efficacy. Self-efficacy was not previously measured in the CHAMP client population and may be an important metric to evaluate progress for headache clients in this setting based on the literature findings discussed above. The HMSE adds a headache-specific self-efficacy instrument to the questionnaire that all CHAMP participants are required to complete on admission to the program. Instruments in the CHAMP questionnaire also measured the constructs of depression, quality of life and disability.

Implications for Advanced Practice Nursing

French et al., (2000) and LeFort et al., (1998) chose experimental methods and randomized participants into either a self-management intervention group or control group. There have been no studies found to date, that have compared headache-specific self-efficacy in subjects who *choose* to participate in a self-management program, to those who choose not to participate. The reality for clients who are offered treatment at a multidisciplinary chronic pain centre is that social, cultural, and economic factors effect treatment decisions. There are several modes of treatment available to headache clients including medical management, physical therapy, occupational therapy, psychology, exercise and cognitive behavioural therapy. Therefore, it is important to consider selfefficacy for headache management in the context of the choices that clients face when entering treatment.

The role of the nurse in the multidisciplinary pain centre is to provide information and encouragement to clients regarding participation in the most appropriate modes of treatment, including participation in a self-management program as appropriate. Self-management education can be a very effective tool in enhancing self-efficacy in pain management (Marks et al., 2005a). However, clients will make their own decisions based on perception of ability to participate and their own beliefs about pain.

The aim of the present study is to address some of the gaps that have been identified in the current literature. Firstly, there is a need to evaluate the effectiveness of headache-specific self-management programs, using an adequate sample size to allow for reliable results. Secondly, it is important to uncover the differences, if they exist, between clients who choose to participate in headache self-management programs and clients who do not. Penzien et al., (2005) agree that the self-management model is appropriate in the advancement of headache treatment and that it has been underutilized and under researched in the headache population. Thirdly, the benefit of this research will be to provide a better understanding of the social and cognitive factors that influence decision-making in this population. The advanced practice nurse must consider client perceptions of efficacy in order to implement interventions that are timely, appropriate, and limit the progression of chronic headache conditions. Accessing appropriate resources at the appropriate time may also help to reduce the burden of pain and chronicity for headache clients.

Theoretical Framework

The construct of self-efficacy is central to the framework of this study. In selfefficacy theory (Bandura, 1997), which is based on social cognitive theory, it is recognized that behavior, person and environment are all intertwined and interact with each other in complex ways. Bandura refers to this triadic relationship as reciprocal determinism (Bandura, 1978). In order to have some control over their environment, individuals need to organize cognitive, social and behavioral skills in a way that leads them to action. Bandura proposed two kinds of expectations in self-efficacy theory: efficacy expectations and outcome expectations. Efficacy expectations relate to beliefs about one's ability to successfully perform a particular behaviour that will lead to a particular outcome. If a headache sufferer believes in her ability to exercise without worsening pain, she will be more likely to try an exercise activity. *Outcome expectations* refer to a person's belief that a specific behavior will result in a particular outcome. If a headache sufferer is successful in reducing the severity of a painful attack using deep breathing, she will expect deep breathing to work again with future headache attacks. Outcome expectations are highly dependent upon efficacy expectations. Figure 2.1 represents the relationship between person, behavior, environment and efficacy and outcome expectations.



Figure 2.1: Schematic representation of Bandura's efficacy and outcome expectations.

Adapted from: van der Bijl, J., & Shortridge-Baggett, L. M. (2002). The theory and measurement of the self-efficacy construct. In E. R. Lenz & L. M. Shortridge-Baggett (Eds.), *Self-efficacy in nursing: Research and measurement perspectives* (pp. 9-27). New York, NY: Springer Publishing Company, Inc.

**Efficacy expectations* relate to beliefs about one's ability to successfully perform a particular behaviour that will lead to a particular outcome. ** *Outcome expectations* refer to a person's belief that a specific behavior will result in a particular outcome.

People are motivated to perform behaviors when they believe that the desired

outcome of those behaviors is likely to occur. Bandura (1997) outlined the four most

effective information sources that create a strong sense of self-efficacy as:

• *Performance accomplishments*: mastering part or all of an activity that

was once thought difficult or impossible.

- *Vicarious experiences*: seeing other people successfully perform the target activity.
- *Social persuasion*: the act of encouraging, coaching or telling an individual that they are capable of performing the activity.
- *Reinterpretation of physiological/emotional states*: relying on information from one's emotions or health functioning to determine capability in performing an activity.

The CHAMP program provides strategies to enhance self-efficacy beliefs through the headache self-management group using all four of Bandura's (1997) information sources. Knowing which clients will benefit from self-management interventions and which clients will find their own way to increase control over their headache pain is the challenge for nurses and other professionals involved in chronic pain management.

Also important to the exploration of self-efficacy for headache management is a discussion of the stages of change that headache sufferers must move through in order to accept some level of pain or disability in their endeavor to maximize functioning and quality of life. Prochaska, DiClemente and Norcross (1992) have described the stages through which clients pass in order to accept and embrace change.

Pre-contemplation and contemplation are stages in which clients have not yet, or are just beginning to consider changing their behavior but are unlikely to do so in the near future (Prochaska et al., 1992). A resistance to consider the self-management group was apparent in clients at this stage. The preparation stage of change involves active consideration of behavioral change that will likely occur in the near future. The action and maintenance stages describe individuals who are already participating in new

behaviors and are actively engaged in trying to prevent a return to their old ways and habits. Jensen and colleagues (2003), in their review of research into stages of change, found encouraging evidence that self-management programs contribute to forward movement through the stages of change.

Advanced practice nurses have been embracing the frameworks of Bandura and Prochaska et al to promote healthy behavior and advance nursing knowledge for some time. Nursing theorist Nola Pender, in her Health Promotion Model (Tillett, 1998) endorses the themes of self-efficacy and change behavior as key components for nurses to consider when developing plans of care. With these two key frameworks in mind, self-management of chronic headaches will be explored in this thesis.

Summary

The psychophysiological approach to chronic headache treatment not only includes appropriate acute and preventive medications but also provides modalities to treat the negative emotional states inherent in this condition (Molgat & Patten, 2005). Behavioral therapies such as relaxation training, biofeedback and cognitive behavioral therapy are valuable tools that help headache clients to recognize and avoid headache triggers, manage stress and learn self-management skills (Rains et al., 2005).

Many headache sufferers require intensive individual treatment to overcome their pain and suffering. Behavioral approaches to headache are important components of tertiary multidisciplinary care in both ambulatory and in-patient settings. However, multidisciplinary care is generally not accessible to a large number of headache clients nor is it always necessary. Therefore many different approaches have been tried to increase access to behavioral therapies. Minimal therapist contact approaches, group education programs and nurse led clinics have all had varied success in providing headache clients with a better understanding of the pathophysiology of headache and with access to behavioral therapies.

A multifaceted self-management model for headache has not yet been realized and tested however Lorig's work with chronic disease and chronic pain self-management programs has provided abundant data to suggest that this approach can be successful (Marks et al., 2005a). Goal setting, decision-making, self-monitoring, action planning and self-efficacy enhancing strategies are the hallmarks of Lorig's Stanford Model (Lorig & Holman, 1993) and are all appropriate components of headache self-management. Penzien et al. (2004) suggest that specific skills such as acceptance of headache as a chronic condition, development of strategies to avoid triggers and correct use of medications are also key components of a headache self-management model.

The HMSE is a tool that measures self-efficacy for headache management and prevention. It has been shown to have excellent internal consistency reliability with a Cronbach's α of 0.90, yet the HMSE has only been tested in three subsequent studies. Small sample size, lack of comparison/control group and insufficient power to detect change were issues in the studies found in the literature that used the HMSE.

The HMSE was selected for use in the current research so that self-efficacy could be measured for participants in the CHAMP program comparing those who attend a selfmanagement program (SMW) to those who do not. The CHAMP program represents one example of a headache self-management model that has not yet been fully evaluated. In order to evaluate and improve interventions such as the SMW offered by CHAMP, we need to understand how headache sufferers gain a sense of control over their headaches

and how (and when) they adopt new behaviors that improve their headache condition. The theoretical frameworks of self-efficacy (Bandura, 1997) and stages of change (Prochaska et al., 1992) are key to this research.

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CHAPTER THREE: METHOD

Chapter three includes a description of the research method, sample, recruitment, data collection, instruments, sample size calculations, data analysis and ethical considerations for this research study. The steps taken in data collection will be summarized in the research protocol section.

Research Method

This research was a quasi-experiment. Participants who chose to participate in the Self-Management Workshop SMW, a headache self-management program while awaiting the neurologist consult, constituted the intervention group. Participants who did not participate in the SMW constituted the comparison group. Participants who completed the SMW were compared at baseline and post intervention. Participants who completed the SMW were also compared to participants who did not participate in the intervention (comparison group).

Sample and Recruitment

Sampling Method

The subjects taking part in this quasi-experiment were a convenience sample of consecutive headache clients referred to the Calgary Headache Assessment and Management Program (CHAMP), who attended an intake class referred to as the Assessment and Education (A and E) Session. At the CHAMP Program A and E Session, pathophysiology of headache and the proper use of medications were presented by a neurologist in the first hour, and then an occupational therapist presented lifestyle information in the second hour. Just prior to the lifestyle presentation, the investigator presented a description of the research protocol and clients were given the opportunity to consent to participation in this study. Clients were all given the option of signing up to participate in the SMW. Lifestyle assessment, sleep workshop, body-works workshop and the lecture series were also offered to participants. Clients were informed that an appointment would be made for them to see the neurologist in approximately three months time, but they could explore lifestyle changes and participate in the workshops in the interim.

Recruitment

The CHAMP clinic receives, on average, 60-90 new referrals each month from family physicians and other specialists. A small number of CHAMP referrals are forwarded to other specialty clinics (e.g. CHR, Chronic Pain Centre) or are determined urgent and given an expedited neurologist consult. Referred clients who live in Calgary or in the surrounding area (within a one-hour drive) were required to attend the two-hour Program A and E Session, held at the Foothills Medical Centre. These sessions occurred three times each month at varying times of day to accommodate the access needs of⁻ clients. There was no limit to the number of clients who could attend each session. The researcher attended all A and E Sessions held by CHAMP from December 2006 to November 2007 in order to recruit study participants. The investigator attended a total of 26 sessions with 348 registered clients and recruited 231 (67%) participants for the current research study.

Based on clinical experience with headache clients in a multidisciplinary pain treatment program and on discussion with CHAMP clinic registered nurses, it was estimated that a recruitment rate of approximately 65-70% could be expected. The actual recruitment response rate achieved was 67%. Attendance at the Program A and E

Session was mandatory for all local clients (Calgary and surrounding area). All study participants were recruited at the Foothills Hospital. Pretest questionnaires were completed during the A and E session and posttest questionnaires were completed in the CHAMP clinic just prior to neurologist consult.

Inclusion Criteria

All study participants met the following inclusion criteria:

- Attendance at a CHAMP Program A and E Session
- Able to read and speak English fluently

Exclusion Criteria

The following exclusion criteria were applied:

- Living more than a one-hour drive from Calgary (out of town referrals). (A small number of clients chose to travel and attend the A and E session. Those clients were allowed to participate in this study.)
- Expedited referrals (i.e. clients in need of urgent care)
- Children under the age of 18
- Cognitive impairment
- Established psychiatric disorders
- Previous exposure to self-management programs

Data Collection

All attendees at each A and E Session completed the pre-test instruments together at the end of the presentation then handed them in. Clients who agreed to participate in the study also handed in a signed consent form and were given a copy of the consent form for their records. A coloured label with the study name and assigned participant number was placed on the pre-test instrument. The researcher then photocopied the instruments and removed the participants' names from all pages (originals were retained by CHAMP for clinic use).

Two corresponding labels were attached to the client's referral form to be used later on the chart and the post-test instrument. The post-test label was clearly marked "POST-TEST" to prevent being mistaken for the pre-test. Post-tests were placed in the participants' charts. When study clients arrived for their neurologist appointment, several months later, the receptionists were able to identify study participants by the label on the chart and asked them to complete the post-test instrument while in the waiting room. Completed instruments were either returned to the chart or given to the CHAMP clinic nurse. The researcher picked up post-tests weekly, removed participant names and entered the data into the study database. The Statistical Package for Social Sciences (SPSS) version 15.0 was used for data entry and analysis (SPSS Inc., Chicago, IL).

The Intervention

The SMW is a closed group (all members start and complete the group together) composed of five to eight clients. The group is lead by a registered nurse, occupational therapist or psychologist. The role of the SMW is to improve control over headaches, explore and practice stress management, develop new coping skills and reduce the negative effects of headache. Clients are encouraged to support each other and share headache management strategies. Topics covered in the workshop include stress management, relaxation techniques, pacing, coping skills and cognitive restructuring. CHAMP considers clients who are interested in making changes to improve headache

management, lack support in coping efforts and want to actively participate in improving their health, as most likely to benefit from the SMW.

Two Self-Management Workshops are run each month. Each workshop consists of five, weekly, two-hour sessions. Clients are expected to attend, practice skills at home and actively participate in all five sessions. Completion of SMW was, for the purposes of the current research, defined as attendance in at least three of the five sessions. Study participants who completed three or more sessions of SMW were included in the intervention group. All others composed the comparison group.

Instruments

In this study four instruments were used: the Headache Management Self-Efficacy Scale (HSME), Centre for Epidemiological Studies Depression Scale Revised (CESD-R), Headache Disability Inventory (HDI), and Headache Impact Test (HIT-6) were used to collect the data. All instruments used were self-administered pen and paper tests. The score on the HMSE was the primary outcome variable. The CHAMP program was already using the CESD-R, HDI and HIT-6 instruments therefore only the HMSE was added to the regular questionnaire completed by CHAMP clients.

The HMSE is a 25-item instrument scored on a seven-point Likert scale (strongly disagree = 1 to strongly agree = 7). The scoring of the HMSE was not stated by the authors in the published literature (French et al., 2000) however, scoring was confirmed by personal communication with the author (personal communication, Dr. Douglas French, Professeur agrégé, École de psychologie, Université de Moncton, July 18, 2006). Based on direct scoring from the seven-point scale, (i.e. strongly disagree = 1, strongly

agree = 7) the total possible score can range from 25-175. Lower scores indicate lower headache self-efficacy and higher scores indicate higher headache self-efficacy.

French et al., (2000) tested the HMSE with a sample (n = 329) of headache sufferers and found strong internal consistency and construct validity (Cronbach's α = 0.90). The HMSE was chosen for the current study because it measures self-efficacy for headache prevention and management. Strategies to improve headache prevention and management are both explored in the intervention, the SMW. See Appendix A for the HMSE instrument.

The Centre for Epidemiological Studies Depression Scale Revised (CESD-R) is a 20-item instrument scored on a five-point Likert scale (0-4) in which participants indicate their feelings or behaviors for the last two weeks (not at all or less than one day, one to two days, three to four days, five to seven days, nearly everyday for two weeks) (Eaton, Muntaner, Smith, Tien, & Ybarra, 2004). The possible range of scores is from 0-80. In general, lower scores indicate fewer depressive symptoms while higher scores indicate a greater number of depressive symptoms. The CESD-R is appropriate for use in the present study as it was developed primarily to screen the general population for the presence of depressive symptoms (Eaton et al., 2004). The CESD was revised in response to the adoption of the DSM-IV in 1994. An algorithm has been established to interpret the CESD-R, based on participant responses to certain groups of items. The algorithm categorizes individuals as unlikely depressed, sub-threshold, possible or probable depressive disorder (Eaton et al., 2004). Cronbach's alpha for the CESD-R ranged from 0.88 to 0.93. The CESD-R was collected in this study to determine if study participants have a similar rate of depression to other headache study participants.

Molgat and Patten (2005), in a Canadian study, demonstrated that migraine sufferers had a higher incidence of depression than the general population. The CHAMP program was using a shortened version of the CESD-R previously; therefore the full version was implemented, with the CHAMP director's permission, and used with all CHAMP clients from the study onset onward. See Appendix B for the CESD-R instrument.

The Headache Disability Inventory (HDI) is a 25-item instrument designed to measure the functional and emotional impact of headache on subjects (Jacobson, Ramadan, Aggarwal, & Newman, 1994). A three-point scale is used for scoring the HDI instrument (yes, sometimes, no). For each item, "yes" is scored at four points, "sometimes" is scored at two points and "no" is scored at zero points for a possible range in scores of 0-100. Scores are interpreted such that lower scores indicate mild disability, and higher scores indicate more severe disability. Good long-term (60-day retesting, r =(0.83) (Jacobson et al., 1994) and short-term reliability (7-day retesting, r = 0.78) (Jacobson, Ramadan, Norris, & Newman, 1995) were found with the HDI. The HDI was included as it has been used in research conducted on a similar sample of the Calgary, Alberta headache population (Magnusson & Becker, 2002; Magnusson et al., 2004). Disability was significantly improved in participants of a multidisciplinary headache program that included a self-management workshop (HDI scores were 51.1 baseline versus 34.0 at follow-up, p < 0.001) (Magnusson et al., 2004). The aim of using the HDI this study was to determine if the SMW impacts headache related disability. See Appendix C for the HDI instrument.

The Headache Impact Test (HIT-6) is a 6-item instrument designed to measure the impact of headache on functional ability and health-related quality of life (Kosinski et

al., 2003). Headache impact refers to the effects pain severity, limitations on daily activities, ability to concentrate, and ability to cope with headaches. The HIT-6 is the short form of the 55-item HIT instrument. A five-point scale is used for scoring (never = 6 points, rarely = 8, sometimes = 10, very often = 11, always = 13) for a possible range in scores of 36-78. Scores are interpreted such that a score of 49 or less indicates little or no headache impact, 50-55 indicates some headache impact, 56-59 indicates substantial headache impact, 60 or more indicates severe headache impact (The GlaxoSmithKline Group of Companies, 2001). When tested in a headache-specialty neurology practice (n = 309) the HIT-6 was shown to have high reliability (Cronbach's α = 0.87) (Kawata et al., 2005). Kawata et al., (2005) suggest that the HIT-6 is appropriate for determining headache impact in clients that are seeking specialist care for their headache condition. The HIT-6 was included to determine if the SMW impacted quality of life for participants. See Appendix D for the HIT-6 instrument.

The investigator also collected demographic, work status, headache frequency and intensity data from a number of tools that CHAMP had developed and were completed by clients during the referral process and the Program A and E Session. As well, in order to determine past experience with self-management programs, participants were asked on the pre-test questionnaire to indicate if they had ever attended a health-related selfmanagement program. Clients having past experience with self-management programs were excluded from this study. On the post-test questionnaire, participants were asked to list any changes made to their headache management routine by their family physician. Participants were also asked to record attendance in a CHAMP workshop (Self-Management, Sleep or Bodyworks) or a competing self-management program (e.g. Living Well) since attending the A and E session and completing the pretest questionnaire. See Appendix E for the headache pain, pain and work, and workshop attendance instruments.

Sample Size

The sample size calculation was anchored in the primary outcome variable of the difference in headache self-efficacy score from pre to post intervention. A review of the literature was done to obtain estimates of pre-test and post-test mean HMSE scores, standard deviations, and effect size. Nicholson et al., (2005) reported statistically significant differences between pre-test and post-test HMSE scores (p < 0.01) in their evaluation of a self-help program with a sample size of n = 21. Participants met International Headache Society (Headache Classification Committee of the International Headache Society, 2004) criteria for a migraine disorder and were 95% female (n = 20), 90% Caucasian (n = 19) and had a mean age of 45 (range 22 to 65 years). Despite the small sample size, the statistical power was determined to be 0.71 in this study based on the following calculations. The mean HMSE scores for Nicholson's et al., (2005) study (pre-test M = 102, SD = 16, post-test M = 124, SD = 23) were used as estimates to calculate a pooled standard deviation (SD pooled = 19.8) and effect size (ES = 22) and were inserted into an online sample size calculator (Brant, 2009) with power and alpha set at 0.80 and 0.05 respectively. The standard deviation of change in HMSE scores was not cited by Nicholson et al. (2005) therefore it was decided to use the pooled standard deviation of the pre and post-test scores that were published as the best estimate available. Other investigators of chronic headache sufferers, who used a pre-test, posttest intervention design reported differences in HMSE scores of 14 (Lee et al., 2005), 13

and 10 (French et al., 2000). Based on reviewing the existing research literature and from the investigator's own clinical experience it was expected that the pre-test, post-test difference in the intervention group's HMSE score would be *at least* 10 (See Table 3.1). A mean score on the HMSE was computed from the pre and post-test instruments for both the experimental and comparison groups

Several power calculations were performed using the SD pooled calculated from the data presented by Nicholson et al., (2005). As may be seen from Table 3.1, the power calculations provide sample size estimates ranging from 13 to 62. Following discussion with the investigator's thesis committee and in consideration of the feasibility of obtaining an adequate sample size, within a reasonable timeframe, it was decided to obtain a total sample size of 124 patients (i.e. 62 in *each* group).

Tab	le 3.	1: (Sampl	e sizes	estimates	anchored	in	differences	in	HMSE sco	ores
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α	1-β (power)	Effect size	SD pooled	n	Source
0.05	0.80	22	19.8	13	Nicholson et al. (2005)
0.05	0.80	14	19.8	30	Lee et al. (2005)
0.05	0.80	13	19.8	37	French et al. (2000)
0.05	0.80	10	19.8	62	French et al. (2000)
0.05	0.80	10	19.8	62	Present Study

Sample size estimates were determined using an online calculator (Brant, 2009). Effect sizes were calculated from the difference in mean HMSE scores from pre and post-tests of chronic headache sufferers (French et al., 2000; Lee et al., 2005; Nicholson et al., 2005).

Data Analysis

Data analysis was computed using the Statistical Package for Social Sciences (SPSS) version 15.0. The analysis consisted of computing descriptive statistics (means, standard deviations, cross tabulations, and bar charts) to describe the sample demographics (age, gender, pain frequency and intensity, employment status, smoking, alcohol and caffeine use). Chi-square analysis, and Fishers Exact on 2x2 tables were done comparing the intervention and comparison groups on several dichotomous nominal variables. t-tests were used on the continuous variables, age, age of headache onset, waittime and rates of smoking, alcohol and caffeine use. The instruments (HMSE, CESD-R, HDI, and HIT-6) were collected at the A and E session and on the day of the participant's first CHAMP neurologist consult. The primary outcome of interest was change in efficacy scores between and within groups therefore, a two-way repeated measures ANOVA was done in order to control for group effect, time effect, and group by time interaction. ANOVA calculations were also completed on the CESD-R, HDI, and HIT-6. Alpha was set at 0.05 for tests of statistical significance, all tests were two-tailed and 95% confidence intervals were computed.

Ethical Considerations

Ethics Approval

The research protocol and consent form were forwarded to the Centre for Advancement of Health for scientific review and to the Conjoint Health Research Ethics Board at the University of Calgary, Calgary, Alberta for ethical approval and consent, which was received. See Appendix F for ethical approval letter.

Informed Consent and Confidentiality

Permission for the investigator to approach clients during the A and E session was obtained in writing from CHAMP director, Dr. Werner. J. Becker (see Appendix G). All clients were given approximately one hour to review and complete the consent form (see Appendix H) during the CHAMP Program A and E Session, and were encouraged to ask questions of the investigator who was present for the last hour of the A and E Session. The investigator provided phone contact information via the consent form and encouraged clients to call if they had any questions or concerns. Clients were informed that participation in this study would consist of completing a pre-test instrument at the CHAMP Program A and E Session, and a post-test instrument administered on the same day as the client's scheduled CHAMP neurologist consult. Permission to access demographic, work status headache frequency and intensity data, collected from various CHAMP tools, was included in the consent. A copy of the consent form was given to each client.

In order to maintain anonymity and confidentiality, questionnaires were stripped of names and other personal identifiers except for the assigned study number. No names were included on any of the questionnaires and no names or other personal identifiers will be included in any future publications. The identifying study number was placed on the front each study participant's chart, and on the pre-test and post-test instruments. The assignment of a study number was necessary so that pre-test and post-test questionnaires could be paired for data analysis.

Completed questionnaires were kept initially in the CHAMP nursing office locked file cabinet, then moved to the University of Calgary, for analysis and locked in the
research office of Dr. Karen Then (the author's thesis supervisor). Access to the study data was limited to the researcher and the supervisory committee members. Questionnaires will be stored for five years from study completion, and then shredded. All computer files were password protected accessible by the investigator and the graduate student's supervisor on a computer in the locked research office. All electronic files will be erased after five years.

Potential Risks

The instruments used included a variety of questions about depression, coping, disability and perception of ability to manage headache. The risk of arousing emotional responses in clients while answering these questions was considered. Study participants were informed at the A and E Sessions that the investigator and CHAMP psychologist would be available for consultation should a participant request that service. Scores on the CESD-R instrument that indicated severe depressive symptoms or suicidal ideation in the last week were flagged by CHAMP staff, clarified with the client, and consultation with the CHAMP psychologist was offered.

Protocol

The following protocol was adhered to in this study:

- 1. Ethical approval received from Conjoint Health Research Ethics Board.
- 2. Study protocol reviewed with CHAMP administrators and staff.
- Participants were recruited from the two-hour CHAMP Program A and E Sessions, held at the Foothills Medical Centre, three times per month.

- 4. Participants were given the study consent form and heard a 5-10 minute explanation of the study and consent process presented by the researcher.
- Participants completed and returned the pre-test instruments during the A and E Session.
- A coloured label with the study name and assigned number was placed on the pre-test instruments. Corresponding labels were place on the post-test and clinic chart.
- 7. The researcher photocopied the instruments and removed the participant's name from all pages.
- 8. Participants were informed that a neurologist appointment would be made for them in approximately three months.
- 9. When participants returned for the neurologist consult, they completed the post-test instruments in the clinic waiting room prior to seeing the neurologist. If participants chose not to be assessed, post-tests were mailed out.
- 10. CHAMP clinic nurses removed the post-test instruments from the chart after the neurologist consult and filed the instruments in a marked study folder in the CHAMP clinic office. The researcher picked up completed forms weekly.
- The researcher entered all pre-test and post-test data into a Statistical
 Package for Social Sciences (SPSS) database program, version 15.0
 (SPSS Inc., Chicago, IL).

12. Data was analyzed using SPSS functions.

Summary

This study was a quasi-experiment in which participants who completed the SMW prior to having a consult with the CHAMP neurologist were considered the intervention group; all other participants comprised the comparison group. Following a power calculation, it was decided that at least 62 participants were required in each group (124 total). Pre-test data were collected from participants at the A and E session and post-test data was collected on the day of consult with the CHAMP neurologist.

Demographic information and pain measures were collected using CHAMP instruments. The primary outcome variable, self-efficacy was measured using the HMSE. The HMSE was a new instrument added to the regular CHAMP admission questionnaire. Depression (CESD-R), disability (HDI), and quality of life (HIT-6) data were also collected. Upon the granting of ethical approval, recruitment began in December 2006 and was completed in November of 2007. The established study protocol was adhered to through the duration of the study.

CHAPTER FOUR: RESULTS

In this chapter the author will present the results of data analysis. It will be recalled, the following objectives guided the analysis of data for this study:

- Describe the sample of headache sufferers participating in the current research by computing descriptive statistics on demographic data, and comparing demographics between the treatment and comparison groups.
- 2. Describe the results from instruments used:
 - a. Pre and post-test mean, median, standard deviation of pain measures, Headache Management Self-Efficacy Scale (HMSE), Centre for Epidemiologic Study Depression Scale-Revised (CESD-R), Headache Disability Index (HDI) and Headache Impact Test-6 (HIT-6). Comparisons were made between and within groups controlling for group effect, time effect and group by time interaction.
 - b. It was initially planned that an analysis of the primary outcome variable of self-efficacy (HMSE) would be done, statistically controlling for differences in depression (CESD-R), disability (HDI) and quality of life (HIT-6). It was also planned to stratify test scores by age and gender. These analyses were not done because of a large discrepancy between the size of the intervention group (n = 23) and the comparison group (n = 208). Given the small cell sizes that would have been obtained by stratifying on age and gender, meaningful statistical results would not have been achieved.

3. Compile and analyze qualitative data on changes made in headache management routine that occurred after participants attended the Calgary Headache Assessment and Management Program (CHAMP), Assessment and Education (A and E) session and before their first consult visit to the CHAMP neurologist (to account for treatment other than CHAMP workshops occurring in this time period).

Research Objective 1: Description of the Sample

Study participants were recruited between December 4, 2006 and November 5, 2007 from 26 separate A and E sessions held at CHAMP. A total of 412 participants were booked into A and E sessions, 348 participants actually attended and 64 cancelled or were "no shows" (see Table 4.1).

 Table 4.1: Assessment and Education Session attendance

A and E session attendance	n (%)
Total clients booked	412
Cancelled or did not show	64 (15.5)
Actual attendance	348 (84.5)

Only CHAMP clients living within one hour of Calgary were required to attend the A and E session. Clients who travelled a further distance were booked for consultation with the neurologist and given the opportunity to meet with other CHAMP staff on that same day.

By the time of study completion, 234 study participants (67.0% of A and E attendees) had been recruited. Recruitment details are reported in Table 4.2. Data from 234 study participants were entered into SPSS version 15.0 (SPSS Inc., Chicago, IL).

Three participants were excluded from the analysis leaving a total of 231: one reported silent/pain-free migraines, one was diagnosed with seizures and did not have headache, and one did not complete the pre-test.

 Table 4.2: Recruitment of participants from the Assessment and Education Sessions

Recruitment	n (%)*
Attended A and E session	348
Did not consent	81 (23.3)
Consented but did not return pre-test	5 (1.4)
Did not meet inclusion/exclusion	28 (8.0)
criteria	
Recruited into study	234 (67.2)
Excluded from analysis	3 (0.8)
- 1 silent/pain-free migraines	
- 1 seizures not headache	
- 1 did not complete pre-test	
Total included in analysis	231 (66.4)
Intervention Group	23 (6.6)
Comparison Group	208 (59.8)
Comparison Group	208 (59.8)

* % of 348 who attended the A and E session

Pre-tests were reviewed by the investigator after the A and E session. Only those participants who met the study inclusion and exclusion criteria were recruited into the study. Of the 234 who signed the consent form, 28 did not meet criteria. Table 4.3 is a representation of the inclusion/exclusion criteria that were not met.

Inclusion/exclusion criteria not met	n (%)
Age under 18	3 (0.8)
Self-management experience	19 (5.5)
Language barrier	1 (0.3)
Not a CHAMP client*	4 (1.1)
Withdrew consent	1 (0.3)
Total that were excluded	28 (8.0)

Table 4.3: Participants who consented but did not meet study criteria

*Several CHR, Chronic Pain Centre patients attended the A and E session

Clients who had participated in a health related self-management workshop in the past made up the largest group that were excluded (n = 19). These individuals were not accepted into the study as it was felt that the changes in self-efficacy, which this study was designed to measure, might have already occurred.

There were only 23 (10.0%) study participants that completed the Self-Management Workshop (SMW) before having their CHAMP neurologist consult visit. Those 23 participants chose to participate in the SMW and constituted the intervention group. A shorter than anticipated wait time for neurologist assessment and lack of availability for SMW sessions may have contributed to the small intervention group. Normally, approximately 10-16 CHAMP clients complete the SMW per month. The remaining 208 (90.0%) participants constituted the comparison group. The post-test was completed by a total of 190 (82.3%) participants: all 23 from the intervention group and 167 from the comparison group (n = 41 of the comparison group participants did not complete the post-test despite reminders). Figure 4.1 represents the numbers of participants who were eligible for this study by attending the A and E session, those who consented, met criteria and constituted the intervention and comparison groups. 348 Attended A and E session

81 No consent

5 No pre-test returned

28 Did not meet inclusion/exclusion criteria

234 Recruited into study (67%)	
23 Intervention Group	211 Comparison Group
0 Excluded from analysis	3 Excluded from analysis
0 No Post-test completed	41 No Post-test completed
23 Final Intervention Group n	167 Final Comparison Group r
190 Final Sa	ample n

Figure 4.1: Recruitment and sample size

The following descriptive statistics were computed on the entire sample (n = 231)

then on the intervention group (n = 23) and control group (n = 208) separately.

- Mean, median, standard deviation, and 95% confidence intervals
- Box plots, bar charts
- Cross tabulations
- T-tests
- Fishers Exact Tests

Demographic variables collected at the time of neurologist consult were: age, gender, occupation, age of headache onset, smoking, alcohol, caffeine use, attendance at CHAMP workshops and lectures. The wait time to see the CHAMP neurologist was also

calculated (defined as the number of days from pre-test to post-test).

Table 4.4 outlines the reasons for failure to complete the post-test. Since the post-test was administered at the CHAMP neurologist consult appointment, participants who never attended the consult did not receive the post-test. As well, several post-tests were either not given to participants in error (Total n = 12, 23.5% of the sample who did not complete the post-test, 2 in the intervention group and 10 in the comparison group) or went home with participants and were subsequently lost (n = 5, 9.8%).

Reason for no post-test	Total Sample	Intervention	Comparison
	n = 51/231 (%)	n = 5/23 (%)	n = 46/208 (%)
Appointment cancelled	18 (35.5)	1 (20.0)	17 (37.0)
No show	10 (19.6)	2 (40.0)	8 (17.4)
Headaches improved	3 (5.9)	0	3 (6.5)
Participant moved	3 (5.9)	0	3 (6.5)
Post-test missed	12 (23.5)	2 (40.0)	10 (21.7)
Post-test lost	5 (9.8)	0	5 (10.9)

Table 4.4: Reasons post-test data were not collected at neurologist consult

A total of 51 post-tests were not collected on schedule, at the time of consultation with the neurologist. The most common reasons the post-test was not collected were because the participant cancelled their appointment (n = 18), did not show (n = 10) or the CHAMP clerks missed giving the post-test instruments to the participant (n = 12). Five participants were from the intervention group and 46 were from the comparison group.

When possible, post-tests were mailed out to participants who cancelled, did not show for their appointment, or missed receiving the post-test in error. As seen in Table 4.5, of the 51 post-tests that were not collected at the time of CHAMP neurologist consult, 37 (72.5%) were mailed out to the study participants with a self-addressed stamped envelope. Participants were phoned once and reminded to return their completed post-test. Ten post-tests (19.6%) were subsequently returned in the mail thus reducing the number of uncompleted post-tests to 41.

Mailed post-tests	Total Sample	Intervention	Comparison
	n (%)*	<u>n</u>	n
Total originally missed	51	5	46
Total mailed out	37 (72.5)	5	32
Not returned	27 (52.9)	0	27
Returned	10 (19.6)	5	5
	. ,		

Table 4.5: Rate of return on mailed post-tests

* % of total originally missed (51)

Of the 10 post-tests that were returned in the mail, five were from intervention group participants (50%) and five were from the comparison group (50%). Of the 37 tests that were mailed out, 10 were mailed back by participants for a return-rate of 27%.

The participants of this study were predominantly female (n = 192, 83.1%), and employed (n = 142, 61.5%). Smoking data were missing on 57 (24.7%) participants however of those that responded, 64.5% were non-smokers (n = 149). Ninety-four (40.7%) stated that they abstained from any alcohol intake (data missing on 58 or 25.1%). The SMW (intervention) group did not differ from the comparison group in terms of gender, smoking or alcohol use (see Table 4.6).

Variables	Total Sample	Intervention	Comparison	χ^2 (df)
	n = 231 (%)	n = 23 (%)	n = 208 (%)*	p value
Gender				
Male	39 (16.9)	6 (26.1)	33 (15.9)	0.243¥
Female	192 (83.1)	17 (73.9)	175 (84.1)	
Employed				
Yes	142 (61.5)	16 (69.6)	126 (60.6)	0.588¥
No	41 (17.7)	6 (26.1)	35 (16.8)	
Missing	48 (20.8)	1 (4.3)	47 (22.6)	
Smoking				
Yes	25 (10.8)	3 (13.0)	22 (10.6)	1.000¥
No	149 (64.5)	17 (74.0)	132 (63.5)	
Missing	57 (24.7)	3 (13.0)	54 (25.9)	
Alcohol use				
Yes	79 (34.2)	7 (30.5)	72 (34.6)	1.037 (1)
No	94 (40.7)	13 (56.5)	81 (38.9)	0.309
Missing	58 (25.1)	3 (13.0)	55 (26.4)	

Table 4.6: Chi square comparisons of gender, employment status, smoking and
alcohol use

¥Fisher's Exact Test

*Only gender and age available for the 41 participants who did not complete post-test.

Only age and gender were available on the 41 participants who did not complete the post-test as demographic data were only collected at the time of the CHAMP neurologist consult appointment. For these 41 participants, the CHAMP clinic database was used to collect age and gender data.

As seen in Table 4.7, the average age of all participants was 38.3 (SD = 12.6)years of age with a range of 18-74 years. The age at which participants first experienced the headache for which they were seeking treatment ranged from 4-59 years (mean = 21.8). Smoking rate was 7-8 cigarettes/day for the 25 smokers (SD = 5.6). Caffeine containing beverages were consumed by 168 (70.6%) participants at an average rate of 1.5 beverages per day. The wait-time between attendance at the A and E session, where participants completed the pre-test, and the CHAMP neurologist consult appointment where the post-test was completed, was on average 108 days (SD = 39.7). There were no statistically significant differences between the self-management and comparison groups on any of the above-mentioned measures.

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Variables	Total Sample Mean (SD) n = 231	Intervention Mean (SD) n = 23	Comparison Mean (SD) n = 208	<i>t</i> (df)	p value
Age in years n (missing)	38.3 (12.6) 225 (6)	40.7 (15.7) 22 (1)	38.4 (12.1) 160 (48)	0.802 (180)	0.424
Age of headache onset n (missing)	21.8 (12.6) 191 (40)	21.2 (11.3) 19 (4)	21.9 (12.9) 153 (55)	-0.209 (170)	0.835
Smoke rate/day n (missing)	7.7 (5.6) 25 (0)	7.3 (6.8)	7.7 (5.8)	-0.103 (20)	0.910
Caffeine cups/day n (missing)	1.5 (1.5) 163 (68)	1.5 (1.0) 19 (4)	1.5 (1.5) 129 (79)	0.066 (146)	0.947
Wait-time in days n (missing)	108.1 (39.7) 190 (41)	108.8 (34.7) 23 (0)	108.0 (41.0) 162 (46)	0.089 (183)	0.929

Table 4.7: Participant age, headache onset, smoking, caffeine use and wait-time for
neurologist consultation

Study participants were also invited to attend the relaxation, body-works and sleep workshops offered at CHAMP. As seen in Table 4.8 the SMW participants were more likely to have attended the relaxation (p < 0.001), body-works (p = 0.008), and sleep workshops (p < 0.001).

CHAMP	Total Sample	Intervention	Comparison	Fisher's
Workshops	n = 231 (%)	n = 23 (%)	n = 208 (%)	Exact
				p value
Missing n (%)	46 (19.9)	0	46 (22.1)	
	·			
Relaxation				
Yes	7 (3.0)	5 (21.7)	2 (1.0)	<0.001***
No	178 (77.1)	18 (78.3)	160 (76.9)	
Body-works				
Yes	12 (5.2)	5 (21.7)	7 (3.4)	<0.01**
No	173 (74.9)	18 (78.3)	155 (74.5)	
Sleep				
Yes	4 (1.7)	4 (17.4)	0	<0.001***
No	181 (78.4)	19 (82.6)	162 (77.9)	
Other workshop				
(not CHAMP)				
Yes	3 (1.3)	0	3(1.4)	1.000
No	182 (78.8)	23(1000)	159 (76 4)	
		·	I	l

Table 4.8: CHAMP workshop attendance

p<0.01, *p<0.001.

As seen in Table 4.9, the SMW participants were also more likely to have attended lectures about stress and health (p = 0.006), supporting those with headache (p = 0.014), pacing of activities (p = 0.006), and headache triggers (p = 0.009). It should be noted however that the number of attendees in all of the workshops (Table 4.8) and lectures was very low. Therefore the statistics reported on group comparisons must be viewed with caution.

CHAMP Lectures	Total Sample	Intervention	Comparison	Fisher's Exact
	n = 231 (%)	n = 23 (%)	n = 208 (%)	p value
Managing headaches Yes No	8 (4.3) 177 (95.7)	3 (13.0) 20 (87.0)	5 (2.4) 157 (74.5)	0.062
Ergonomics Yes No	4 (1.7) 181 (78.4)	2 (8.7) 21 (91.3)	2 (1.0) 160 (76.9)	0.076
Stress and Health Yes No	4 (1.7) 181 (78.4)	3 (13.0) 20 (87.0)	1 (0.5) 161 (77.4)	0.006**
Supporting those with Headache Yes No	5 (2.7) 180 (97.3)	3 (13.0) 20 (87.0)	2 (1.0) 160 (76.9)	0.014*
Pacing Activity Yes No	4 (1.7) 181 (78.4)	3 (13.0) 20 (87.0)	1 (0.5) 161 (77.4)	0.006**
Headache Triggers Yes No	17 (9.2) 168 (90.8)	6 (26.1) 17 (73.9)	11 (5.2) 151 (72.6)	0.009**
Other Lectures Yes No	1 (0.5) 184 (99.5)	1 (4.3) 22 (95.7)	0 162 (77.9)	0.124
Missing n (%)	46 (19.9)	0	46 (22.1)	,

Table 4.9: CHAMP lecture attendance

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*p < .05, **p < 0.01

Gender, employment status, smoking, alcohol use, age in years and age of headache onset were also compared between study completers and non-completers using a Chi-square test. No statistically significant differences were found except in employment status; study completers were more likely to be working than noncompleters (p = 0.022). See Table 4.10. No significant differences in age of participants or age of headache onset were found on *t*-test.

Variable	Completers	Non-completers	γ^2 (df)	p
	n (%)	n (%)	// (/	1
Gender				
Male	33 (17.4)	6 (14.6)	0.180(1)	0.672
Female	157 (82.6)	35 (85.4)		
Employment	· r			
status (pre-test)				
Working	152 (80.0)	26 (63.0)	5.247(1)	0.022*
Not working	38 (20.0)	15 (36.6)		
Smoking				
Yes	25 (14.0)	4 (23.5)		0.290¥
No	153 (86.0)	13 (76.7)		
Alcohol use				
Yes	80 (45.2)	9 (52.9)	0.375(1)	0.541
No	97 (54.8)	8 (47.1)		
Variable	Mean (SD)	Mean (SD)	<i>t</i> (df)	р
			1.001(000)	0.010
Age in years	38.7 (12.8)	36.4 (11.9)	1.001(223)	0.318
Age of h/a onset	21.8 (12.6)	22.4 (12.8)	-0.187(189)	0.852
L	I	<u> </u>	l	I

Table 4.10: Study completers versus non-completers

*p < 0.05. ¥Fisher's Exact Test.

Employment status was collected on the post-test as well as the pre-test, therefore a McNemar test was done to determine if this nominal variable changed over time. The differences in employment status from pre-test to post-test for the total sample (n = 187, p = 0.481), the SMW group (n = 22, p = 1.000) and the comparison group (n = 161, p = 0.302) were not statistically significant. An item requiring participants to list their occupation was added to the CHAMP questionnaire by CHAMP staff after the start of this study therefore pre-test data were incomplete. More data on occupation were available on the post-test (missing = 85, the 41 who did not complete post-tests plus another 44 who did not answer the question), therefore only post-test data is reported here (Table 4.11). Participants reporting occupations in business and clerical positions were the most highly represented at 16.0% (n = 37), followed by sales (10.8%), health (7.4%) and education positions (6.9%). It is important to remember that the sample was predominantly female (83.1%) when considering occupational data.

Occupation Category	n (%)
Business/clerical	37 (16.0)
Sales	25 (10.8)
Health occupations	17 (7.4)
Education or social services	16 (6.9)
Service	15 (6.5)
Management	14 (6.1)
Sciences	12 (5.2)
Art, recreation or sport	5 (2.2)
Student	4 (1.7)
Trades	1 (0.4)
Total reporting occupation	146 (63.2)
Missino	85 (36 8)
TTI SOUR	05 (50.0)
Total sample	231
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	Table	4.11:	Occu	pation
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In summary, 231 participants were recruited for this study, 23 in the intervention group and 208 in the comparison group. The sample was comprised of females primarily (83%) with an average age of 38 (SD = 12.6) and 62% were working. Smoking rate

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(11%) and alcohol (41%) and caffeine (71%, 1.5 cups/day) consumption rates were collected and did not differ between groups. No significant differences between study completers (n = 190) and non-completers (n = 41) were found.

Research Objective 2: Instruments

The study data were collected at two time intervals. The first collection time (pre) was at the A and E session, the second collection time (post) was on the day of participant's CHAMP neurologist consultation appointment. The following variables were collected: headache days per month, average pain, worst pain, least pain, level of suffering, headache interference with work, days of work missed, HMSE, CESD-R, HDI and HIT-6.

Pain Measures

The pain measures analysed in this study consisted of headache frequency, severity, suffering, interference with work and days missed from work. These data were collected using questions developed by the CHAMP team. Tables 4.12-4.24 are a summary of the findings of the pain measures that were of interest to the researcher. Mean, median, mode, SD and confidence intervals were computed for the pain measures. Two-way repeated measure analysis of variance (ANOVA) tests were done in order to control for group effect, time effect, and group by time interaction. It will be noted that the total n possible for the ANOVA calculations is 190 as the pre-tests for the 41 participants who did not complete post-tests, were excluded from the calculation. It was also decided to exclude any instruments with missing values rather than insert average scores in place of missing values to allow for proper scoring of the instruments (Polit, 1996). It is noted that for all tables in the "Instruments" section, the n for the intervention and comparison groups is the same for the pre and post-tests as the 41 cases with no posttest data were removed from the analysis along with any other cases missing data. However, the n for the total sample includes all valid cases.

Participants reported headache frequency as the number of days in the last month that they suffered from headache pain. Participants estimated number of days per month by recall or used headache diary data. Headache diaries were mailed to all CHAMP clients along with their invitation to attend the A and E session. As seen in Table 4.12, the average number of headache days at pre-test for the total sample was 18.0 and at posttest was 14.5 however the standard deviation was large for both time intervals (pre = 9.3 and post = 9.5). This decrease in the number of headaches recorded per month was significant (p < 0.001) however the improvement occurred in the comparison group (p < 0.001) not the intervention group (p = 0.863). The distribution of headache days reported at pre-test is negatively skewed due to the large number of participants who reported frequent and daily headache (mode = 30 days). At study completion the median had dropped from 17 to 13 days per month, however the mode remained the same at 30 days.

Table 4.12: He	adache days i	the past month	, descriptive statistics :	and paired t-tests
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Headache days per month	Total Sample Mean (SD) n = 231	Intervention Mean (SD) n = 23	Comparison Mean (SD) n = 208	Median	Mode	Intervention 95% CI	Comparison 95% CI
Pre Post t (df) p value	18.0 (9.3) 14.5 (9.5) 4.977 (180) <0.001***	18.4 (9.7) 18.2 (9.7) 0.174 (21) 0.863	16.9 (8.8) 13.9 (9.5) 5.161 (154) <0.001***	17.0 13.0	30.0 30.0	14.6-22.2 14.2-22.2	15.5-18.3 12.4-15.4
Pre- n (missing) Post- n (missing)	226 (5) 185 (46)	22 (1)	155 (53)				•

***p < 0.001

A significant time effect, (p = 0.048) was found on the two-way ANOVA analysis for headache frequency (Table 4.13). In other words, headache frequency decreased between baseline and the post-test. Interaction between time and group in which the intervention and comparison groups changed in different directions over time, was approaching significance (p = 0.088).

Source of variation	Sum of	Degrees of	Mean	F	p value
	Squares	Freedom	Square		
Time	101.94	1	101.94	3.790	0.048*
Time by Group (Interaction term)	75.44	1	75.44	2.938	0.088
Error (time)	4493.88	175	25.68		
Group	318.01	1	318.01	2.210	0.139
Error (group)	25178.80	175	143.88		

Table 4.13: Two-way analysis of variance for headache days in the last month

*p < 0.05

Figure 4.2 is a representation of headache frequency, which changed significantly over the course of the study (p = 0.048) and was approaching significance for time by group interaction (p = 0.088).



Figure 4.2: Number of headache days per month at baseline and post-test

Headache severity, as well as suffering due to headaches, was measured on a 0-10 scale (0 = no pain/suffering to 10 = worst pain/suffering possible). The distribution of pain intensity and suffering scores is detailed in Tables 4.14-4.21.

As seen in Table 4.14, participants reported an average pain severity of 5.5/10 or moderate (SD = 1.9) at baseline, which was unchanged at study completion.

Average headache severity	Total Sample Mean (SD)	Intervention Mean (SD)	Comparison Mean (SD)	Median	Mode	Intervention 95% CI	Comparison 95% CI
(0-10 scale)	n = 231	n = 23	n = 208				
Pre Post t (df) p value	5.5 (1.9) 5.5 (2.0) -0.532 (184) 0.595	6.1 (1.8) 5.8 (2.1) 0.923 (21) 0.367	5.3 (1.8) 5.4 (2.0) -0.934 (158) 0.352	6.0 6.0	7.0 5.0	5.3-6.8 4.9-6.6	5.0-5.6 5.1-5.7
Pre- n (missing) Post- n (missing)	227 (4) 187 (44)	22 (1)	159 (49)				

Table 4.14: Average headache severity for the last month descriptive statistics and paired t-tests

As seen in Table 4.15, the average headache severity was not significantly

different between groups (p = 0.165) and did not improve over time (p = 0.698) in the

ANOVA analysis.

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Source of variation	Sum of Squares	Degrees of Freedom	Mean Square	F	p value
Time	0.21	1	0.21	0.151	0.698
Time by Group (Interaction term)	1.54	1	1.54	1.108	0.294
Error (time)	247.92	179	1.39		
Group	11.45	1	11.45	1.946	0.165
Error (group)	1053.32	179	5.88		

The most severe headaches suffered for this sample were on average 8.1 out of 10 at baseline and only slightly lower (7.8) at the post-test (Table 4.16).

Severity of worst headache	Total Sample Mean (SD)	Intervention Mean (SD)	Comparison Mean (SD)	Median	Mode	Intervention 95% CI	Comparison 95% CI
(0-10 scale)	n = 231	n = 23	n = 208				
Pre Post t (df) p value	8.1 (1.8) 7.8 (2.0) 1.443 (185) 0.151	8.3 (1.5) 8.5 (1.0) -0.568 (21) 0.576	8.0 (1.8) 7.7 (2.1) 1.665 (158) 0.098	8.0 8.0	8.0 8.0	7.6-9.1 7.6-9.3	7.7-8.2 7.4-8.0
Pre- n (missing) Post- n (missing)	228 (3) 187 (44)	22 (1)	160 (48)				

Table 4.16: Severity of worst headaches over the last month, descriptive statistics and paired t-tests

The level of worst headaches suffered by participants did not change over time (p

= 0.761) or differ between groups (p = 0.120). See Table 4.17.

Table 4.17: Two	-way analysis o	of variance fo	r severity of	worst headache
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Source of variation	Sum of Squares	Degrees of Freedom	Mean Square	F	p value
Time	0.19	1	0.19	0.093	0.761
Time by Group (Interaction term)	1.64	1	1.64	0.818	0.367
Error (time)	360.25	180	2.00		
Group	12.74	1	12.74	2.438	0.120
Error (group)	940.68	180	5.23		
	1				

Study participants experienced mild headaches (<2/10) as well as severe and many participants reported headache-free days when reporting least amount of pain in the last month (median = 0, mode = 0). Least headache reports did not change during the study period (p = 0.389). See Table 4.18.

Least amount of	Total Sample	Intervention	Comparison	Median	Mode	Intervention	Comparison
pain	Mean (SD)	Mean (SD)	Mean (SD)			95% CI	95% CI
(0-10 scale)	n = 231	n = 23	n = 208				
Pre	1.2 (1.8)	1.6 (1.8)	1.0 (1.6)	0.0	0.0	0.9-2.3	0.7-1.2
Post	0.9 (1.6)	1.9 (1.9)	0.8 (1.5)	0.0	0.0	1.0-2.3	0.6-1.1
t (df)	0.864 (184)	-0.098 (21)	1.223 (158)				
p value	0.389	0.923	0.223				
Pre- n (missing)	227 (4)	22 (1)	159 (49)			·	
Post- n (missing)	187 (44)						

Table 4.18: Least amount of pain for the last month, descriptive statistics and pairedt-tests

The least amount of pain experienced by participants did not change over time for the sample; however there was a statistically significant difference (p = 0.026) between the intervention group and the comparison group. The comparison group reported lower pain levels at both baseline and post-test.

Table 4.19: Two-way analysis of variance for least amount of pain

Source of variation	Sum of Squares	Degrees of Freedom	Mean Square	F	p value
Time	0.10	1	0.10	0.076	0.784
Time by Group (Interaction term)	0.35	1	0.35	0.277	0.599
Error (time)	225.31	179	1.26		
Group	19.20	1	19.20	5.071	0.026*
Error (group)	677.79	179	3.79		

*p < 0.05

Suffering from headache pain was rated as moderate with averages ranging from 5.5 to 6.0/10 and did not change over the course of this study. See Table 4.20.

Amount of suffering	Total Sample Mean (SD) n = 231	Intervention Mean (SD) n = 23	Comparison Mean (SD) n = 208	Median	Mode	Intervention 95% CI	Comparison 95% CI
Pre Post t (df) p value	5.8 (2.1) 5.5 (2.3) 1.162 (183) 0.247	6.0 (2.3) 5.7 (2.2) 0.646 (21) 0.525	5.6 (2.1) 5.5 (2.3) 0.746 (157) 0.457	6.0 6.0	5.0 4.0	5.1-6.8 4.7-6.6	5.3-5.9 5.1-5.8
Pre- n (missing) Post- n (missing)	226 (5) 187 (44)	22 (1)	158 (50)				

 Table 4.20: Amount of suffering for the last month, descriptive statistics and paired t-tests

Suffering did not change for participants over time (p = 0.421), and no significant

difference between groups or interaction was found (0.534). See Table 4.21.

Table 4.21: Two-way analysis of variance for amount of suffering

Source of variation	Sum of	Degrees of	Mean	F	p value
	Squares	Freedom	Square		
Time	1.59	1	1.59	0.650	0.421
Time by Group (Interaction term)	0.19	1	0.19	0.077	0.781
Error (time)	435.29	178	2.44.		
Group	2.83	1	2.83	0.388	0.534
Error (group)	1298.33	178	7.29		

Those participants who were employed were asked to report on a 5-point scale (never = 1, rarely = 2, occasionally = 3, frequently = 4, or always = 5) how often headache interfered with their ability to do their work. Participants were also asked to report how many days of work they missed in the last month. As seen in Table 4.22, the

average baseline interference score for this sample was 3.4 (occasionally to frequently).

Participants in both the intervention and comparison groups missed on average 2-3 days

of work each month.

Table 4.22:	Headache	interference	with wo	rk and	l _. days o	of work	missed,	descriptiv	/e
		statisti	cs and p	aired t	-tests				

Variable	Total Sample Mean (SD) n = 231	Intervention Mean (SD) n = 23	Comparison Mean (SD) n = 208	Median	Mode	Intervention 95% CI	Comparison 95% CI
Interfered with work Pre Post t (df) p value	3.4 (0.8) 3.3 (0.8) 1.164 (138) 0.146	3.4 (0.9) 3.2 (0.6) 0.898 (13) 0.385	3.4 (0.7) 3.4 (0.8) 0.896 (120) 0.372	3.0 3.0	3.0 3.0	3.0-3.8 2.8-3.6	3.3-3.6 3.2-3.5
Pre- n (missing) Post- n (missing)	179 (52) 145 (86)	14 (9)	121 (87)				
Days missed per month Pre Post t (df) p value	2.6 (2.2) 2.4 (2.4) 0.638 (133) 0.524	2.8 (1.6) 1.8 (1.0) -0.354 (12) 0.730	2.3 (1.6) 2.3 (2.0) 0.773 (116) 0.441	2.0 2.0	2.0 1.0	1.5-4.2 0.2-3.4	1.9-2.7 1.8-2.7
Pre- n (missing) Post- n (missing)	121 (110) 90 (141)	6 (17)	67 (141)				

The level of work interference did not change at the post-test (p = 0.189) nor did

it differ between groups (p = 0.706). See Table 4.23.

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Source of variation	Sum of Squares	Degrees of Freedom	Mean Square	F	p value
Time	0.47	1	0.47	1.742	0.189
Time by Group (Interaction term)	0.15	1	0.15	0.576	0.449
Error (time)	35.48	133	0.27		
Group	0.13	1	0.13	0.143	0.706
Error (group)	117.81	133	0.89		
	1	1			1

 Table 4.23: Two-way analysis of variance for headache interference with work

There was no statistically significant change in the days of work missed over the course of the study. See Table 4.24.

Table 4.24: Two-way analysis of variance for days of work missed due to headaches

Source of variation	Sum of Squares	Degrees of Freedom	Mean Square	F.	p value
Time	3.31	1	3.31	1.650	0.203
Time by Group (Interaction term)	2.25	1	2.25	1.118	0.294
Error (time)	142.56	71	2.01		
Group	0.02	1	0.02	0.004	0.952
Error (group)	319.90	71	4.51		

Self-efficacy

The psychometric instruments (HMSE, CESD-R, HDI, and HIT-6) were also collected at baseline and study completion. Mean, median, mode, SD and 95%

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confidence intervals were computed for the psychometric instruments pre and post. Twoway repeated measure ANOVAs were done in order to control for group effect, time effect, and group by time interaction.

The HMSE is a 25-item instrument and scores can range from 25-175. Lower scores indicate a lower sense of control over headache management and higher scores indicate a higher sense of control.

As seen in Table 4.25, the mean HMSE score for the sample at baseline was 91.3 (SD = 24.3) and at completion was 96.0 (SD = 25.5) for significance at the 0.01 level. The intervention group however did not change significantly (p = 0.242). HMSE scores for this sample ranged from 30-168.

HMSE	Total Sample Mean (SD) n = 231	Intervention Mean (SD) n = 23	Comparison Mean (SD) n = 208	Median	Mode	Intervention 95% CI	Comparison 95% CI
Pre Post t (df) p value Pre- n (missing) Post- n (missing)	91.3 (24.3) 96.0 (25.5) -2.604 (172) 0.010* 221 (10) 179 (52)	89.7 (26.2) 95.4 (26.3) -1.204 (21) 0.242 22 (1)	92.9 (24.0) 96.2 (25.6) -2.147 (147) 0.033* 148 (60)	94.0 97.0	76.0 81.0	79.5-99.9 84.6-106.2	89.0-96.8 92.0-100.3

 Table 4.25: Headache Management Self-efficacy Scale descriptive statistics and paired t-tests

*p < 0.05

Effect size and sample size needed to detect a difference in mean scores were calculated using an online calculator (L. A. Becker, 2009; Brant, 2009). The mean differences between groups in the pre-test (3.2) and post-test (0.8) were very small and standard deviations of the means were large. As a result the number of subjects needed

to show a statistically significant difference in mean scores is very high (see Table

4.25A).

 Table 4.25A: Effect size calculations for primary outcome variable, Headache

 Management Self-Efficacy Scale

Mean difference in self-	SD	Effect	n in sample needed	Comments
efficacy scores	pooled	Size	to detect a difference	
Pre-test Intervention vs. Comparison = 3.2	24.3	0.13	906	Due to large SD and small ES power is low.
Post-test Intervention vs. Comparison = 0.8	25.7	0.03	16, 201	For n = 208, power = 0.27. For n = 23, power = 0.07.

Sample size calculations based on $\alpha = 0.05$, $\beta = 0.20$, Power = 0.80

As seen in Table 4.26, in the ANOVA analysis, HMSE scores rose significantly for the entire sample during the study (p = 0.041), however the intervention group did not differ significantly from the comparison group (p = 0.703). The large difference in sample sizes between the intervention and comparison groups may be a factor in these results.

Source of variation	Sum of Squares	Degrees of Freedom	Mean Square	F	p value
Time	769.78	1	769.78	4.229	0.041*
Time by Group (Interaction term)	55.07	1	55.07	0.303	0.583
Error (time)	30583.43	169	182.04		
Group	155.97	1	155.97	0.146	0.703
Error (group)	179045.99	169	1065.75		
*p < 0.05.					ł

 Table 4.26: Two-way analysis of variance Headache Management Self-efficacy Scale

Boxplots representing the HMSE pre and post-test scores are shown in Figure 4.3. The HMSE pre-test scores ranged from 30-168 with a median score of 94 and mean of 91.3 (SD = 24.3). The interquartile range was 31.5 and there was one extreme outlier (case number 70 had a score of 168 which was confirmed against the raw data). On the post-test, scores ranged from 36-161 with a median score of 97. The interquartile range was 35.5 and there were no outliers.



Figure 4.3: Boxplots of Headache Management Self-Efficacy pre-test and post-test scores for the total sample

As seen in Figure 4.4, HMSE scores are stratified by group. The intervention

group had lower median and mean scores than the comparison group at baseline and post-

test however the range in scores was similar.



Figure 4.4: Boxplots of Headache Management Self-Efficacy pre-test and post-test scores for the intervention and comparison groups

Depression

The CESD-R is a 20-item instrument with a possible range in scores of 0-80. The higher the CESD-R score, the greater the likelihood of depression. As seen in table 4.27 the mean CESD-R score at baseline was 17.3 (SD = 12.7) and at completion was 15.2 (SD = 13.6), a significant decrease for the total sample (p = 0.021). The comparison group changed significantly over time (p = 0.009) while the intervention group did not. The median score at baseline was 15.0 and dropped to 10.0 at the post-test.

CESD-R	Total Sample Mean (SD) n = 231	Intervention Mean (SD) n = 23	Comparison Mean (SD) n = 208	Median	Mode	Intervention 95% CI	Comparison 95% CI
Pre Post t (df) p value Pre- n (missing)	17.3 (12.7) 15.2 (13.6) 2.336 (162) 0.021* 214 (17)	20.2 (17.0) 19.8 (17.9) 0.160 (20) 0.875 21 (2)	16.8 (11.9) 14.7 (13.0) 2.646 (138) 0.009** 139 (69)	15.0 10.0	17.0 5.0	14.8-25.6 13.9-25.7	14.7-18.9 12.4-17.0
Post- n (missing)	174 (57)	· · · · · · · · · · · · · · · · · · ·					

Table 4.27: Centre for Epidemiologic Study Depression Scale-Revised, descriptive statistics and paired t-tests

*p < 0.05, **p < 0.01

However in the ANOVA analysis (Table 4.28), the change in CESD-R scores did

not reach significance (p = 0.270) and no difference between groups was seen (p = 0.270)

0.142). The large discrepancy between group sizes and large standard deviations in the

intervention group (17.0 and 17.9) contributed to null findings on ANOVA. When

groups were compared to each other over time, no significant differences were found.

Table 4.28: Two-way analysis of variance Centre for Epidemiologic StudyDepression Scale-Revised

Source of variation	Sum of Squares	Degrees of Freedom	Mean Square	F,	p value
Time	55.85	1	55.85	1.226	0.270
Time by Group (Interaction term)	26.75	1	26.75	0.587	0.445
Error (time)	7199.37	158	45.57		
Group	658.50	1	658.50	2.180	0.142
Error (group)	47716.37	158	302.00		

Disability

The HDI is a 25-item instrument with a possible range in scores of 0-100. In this study HDI scores were reported as a total score (HDI-T) as well as stratified into the emotional (HDI-E) and functional (HDI-F) subscales. Higher scores indicate greater headache related disability. As seen in Table 4.29 the average total HDI score at baseline was 54.0 (SD = 20.1) and at completion was 48.5 (SD = 23.0), a significant improvement occurring only in the comparison group (p < 0.001). Median and mode scores on the functional subscale (HDI-F) were slightly higher than on the emotional subscale (HDI-E).

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HDI	Total Sample Mean (SD) n = 231	Intervention Mean (SD) n = 23	Comparison Mean (SD) n = 208	Median	Mode	Intervention 95% CI	Comparison 95% CI
HDI-T Pre Post t (df) p value	54.0 (20.1) 48.5 (23.0) 4.019 (150) <0.001***	59.3 (23.8) 61.1 (25.0) -0.553 (15) 0.588	52.2 (19.7) 46.3 (22.3) 4.407 (131) <0.001***	54.0 46.0	46.0 36.0	49.3-69.2 50.0-72.3	48.7-55.6 42.4-50.2
Pre- n (missing) Post- n (missing)	206 (25) 167 (64)	16 (17)	132 (76)				
HDI-E Pre Post	26.4 (11.4) 23.0 (13.0)	29.5 (15.3) 29.7 (15.2)	26.1 (11.2) 21.9 (12.7)	26.0 22.0	18.0 16.0	24.2-34.8 23.8-35.6	24.2-28.0 19.8-24.1
Pre- n (missing) Post- n (missing)	219 (12) 177 (54)	16 (17)	132 (76)				
HDI-F Pre Post	28.0 (10.4) 25.2 (11.4)	27.5 (10.3) 29.3 (11.8)	27.2 (10.3) 24.6 (11.4)	28.0 24.0	24.0 26.0	22.8-32.1 24.1-34.4	25.5-28.9 22.7-26.5
Pre- n (missing) Post- n (missing)	215 (16) 171 (60)	16 (17)	132 (76)				

***p < 0.001

The HDI was analyzed for change in total score (HDI-T) and for changes in the emotional (HDI-E) and functional (HDI-F) subscales using three two-way ANOVAs. As seen in Table 4.30, the intervention group reported more disability than the comparison group (p = 0.041). The HDI total score was approaching statistical significance for group and time interaction (p = 0.055).

Source of variation	Sum of Squares	Degrees of Freedom	Mean Square	F	p value
Time	112.65	1	112.65	0.990	0.321
Time by Group (Interaction term)	425.63	1	425.63	3.742	0.055
Error (time)	16608.36	146	113.76		
Group	3409.55	1	3409.55	4.270	0.041*
Error (group)	116587.36	146	798.54		

*p < 0.05

Figure 4.5 is a representation of the significant difference between the

intervention and comparison group (p = 0.041) and the time and group interaction which was approaching significance (p = 0.055).

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Figure 4.5: Headache Disability Index total score

As seen in Table 4.31, a significant group difference was found for the emotional subscale (p = 0.048). HDI emotional subscale scores were approaching significance for a time (p = 0.080) and interaction effect as well (p = 0.053).

Source of variation	Sum of	Degrees of	Mean	F	p value
	Squares	Freedom	eedom Square		
Time	129.56	1	129.56	3.107	0.080
Time by Group (Interaction term)	158.83	1	158.83	3.809	0.053
Error (time)	6754.20	162	41.69		
Group	1045.71	1	1045.71	3.959	0.048*
Error (group)	42789.26	162	264.13		

Table 4.31: Two-way analysis of variance Headache Disability Index, emotionalsubscale

*p < 0.05

Two-way analysis of variance of the HDI, functional scale was also computed. A time by group interaction was seen on the functional subscale (p = 0.035). In other words, functional disability scores changed in different directions for each group, they increased for the intervention group but decreased for the comparison group. See Table 4.32.

Table 4.32: Two-way analysis of variance Headache Disability Index, functionalsubscale

Source of variation	Sum of Squares	Degrees of Freedom	Mean Square	F	p value
Time	5.36	1	5.36	0.151	0.698
Time by Group (Interaction term)	160.29	1	160.29	4.522	0.035*
Error (time)	5539.39	156	35.45		
Group	199.09	1	199.09	0.992	0.321
Error (group)	31307.40	156	200.69		

*p < 0.05

Figure 4.6 is a representation of the significant time by group interaction (p = 0.035) that was found on the HDI, functional subscale.



Figure 4.6: Headache Disability Index functional subscale

As illustrated in Figure 4.7, the SMW intervention group scores for the HDI were higher than the comparison group but did not change significantly from pre-test to posttest.


Figure 4.7: Headache Disability Index, bar graph of total and subscale scores

Quality of Life

The HIT-6 is a six-item instrument with a range in scores from 36-78. Lower scores indicate less impact of headaches on quality of life and higher scores indicate greater impact. As seen in Table 4.33, the mean HIT-6 score at baseline was 64.0 (SD = 5.0) and at completion was 62.7 (SD = 5.6). This change was significant for both groups.

HIT-6	Total Sample Mean (SD) n = 231	Intervention Mean (SD) n = 23	Comparison Mean (SD) n = 208	Median	Mode	Intervention 95% CI	Comparison 95% CI
Pre Post t (df) p value	64.0 (5.0) 62.7 (5.6) 3.895 (182) <0.001***	64.5 (5.5) 62.7 (5.1) 2.130 (20) 0.046*	63.9 (4.9) 62.7 (5.6) 3.331 (157) 0.001**	64.0 63.0	66.0 63.0	62.4-66.7 60.3-65.1	63.1-64.6 61.8-63.6
Pre- n (missing) Post- n (missing)	229 (2) 185 (46)	21 (2)	158 (50)				

 Table 4.33: Headache Impact Test-6 descriptive statistics and paired t-tests

*p < 0.05, **p < 0.01, ***p < 0.001

As seen in Table 4.34, there was a significant time effect on the HIT-6 (p = 0.003)

with scores for the whole sample dropping over time. No between group or time by

group differences were seen in the ANOVA analysis.

Table 4.34: Two-way	v analysis of variance	Headache Impact Test-6
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Source of variation	Sum of Squares	Degrees of Freedom	Mean Square	F	p value
Time	80.24	1	80.24	8.951	0.003**
Time by Group (Interaction term)	4.24	1	4.24	0.473	0.492
Error (time)	1586.72	177	8.97		
Group	4.24	1	4.21	0.090	0.765
Error (group)	8335.34	177	47.09		

**p < 0.01

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As seen in Table 4.35, the majority of participants (85.6%) were severely impacted by their headache pain at baseline. While more participants scored in lower pain impact categories at the post-test, most remained severely impacted by pain (77.8%).

HIT-6 Groupings	Category Range	n (%)
Little or no impact Pre Post	36-49	2 (0.9) 4 (2.2)
Some impact Pre Post	50-55	9 (3.9) 12 (6.5)
Substantial impact Pre Post	56-59	22 (9.6) 25 (13.5)
Severe impact Pre Post	60-78	196 (85.6) 144 (77.8)
Total Pre Post		229 185

Table 4.35: Degree of headache impact based on HIT-6

Internal Consistency Reliability

Cronbach's alpha was computed for the HMSE, CESD-R, HDI and HIT-6 instruments to determine how well the items in each instrument measured self-efficacy, depression, disability and quality of life respectively in this sample of headache sufferers. As seen in Table 4.36, all the instruments scored 0.80 or higher which is desirable for group-level comparisons (Polit & Beck, 2004).

Instruments	Cronbach's α	Cronbach's α	Cronbach's α	# of items
	reported in the	Pre-test	Post-test	in each
	literature	n = 231	n = 190	instrument
HMSE	0.90	0.91	0.92	25
CESD-R	0.88-0.93	0.91	0.93	20
HDI	0.83	0.91	0.94	27
HIT-6	0.87	0.80	0.80	6

Table 4.36: Cronbach's alpha for the HMSE, CESD-R, HDI and HIT-6 instruments

Research Objective 3: Qualitative Data Analysis

Changes to participant's treatment or behaviour other than the intervention, attending the SMW, needed to be accounted for as each could contribute to changes in self-efficacy scores. The open-ended question that was included in the post-test was: *Please list any changes that may have been made to your headache management routine since attending the* A *and* E *session (e.g. any medication changes made by your family physician, visits to other medical specialists, or initiation of physical therapy).* It was hoped that by answering this question, participants would give some indication as to how active they were in seeking help for their headaches during the waiting time, which was on average 108 days.

Of the 190 participants that completed a post-test, 79 (41.6%) wrote comments about changes to their headache management routine. These statements were transcribed verbatim into an Excel spreadsheet. Some participants made several changes to their management therefore each change was recorded separately. A total of 162 statements were entered. Participants mostly wrote about treatments that they had started or lifestyle changes they had made. These statements were read then given primary codes. The primary codes were: complementary/alternative medicine (CAM), CBT, chiropractor, massage, medication, physio, relaxation, sleep, specialist care, stopping medication over use, treatment of psychiatric issues and control of headache triggers. The topics of medication and control of headache triggers were further broken down into secondary codes as they occurred most frequently (see Table 4.37).

The most common changes made by all participants were the use of headache preventative medications, dietary changes and stopping the overuse of acute headache medications. On observation (data not entered into SPSS), there were some notable differences between groups. The self-management group did not endorse the use of complementary and alternative medicine (CAM) or vitamins/herbs while the comparison group did. The SMW group made several statements about the cognitive behavioral therapy techniques that they learned while participating in the Self-Management Workshop. The use of trigger management techniques and medications appeared to be similar between both groups.

Primary Codes	Total Respondents	SMW	Comparison	
Secondary Codes	n = 79/190 (%)*	n = 12/23 (%)	n = 67/167 (%)	
Relaxation	13 (16.5)	5 (41.7)	8 (11.9)	
Stopped overuse	13 (16.5)	2 (16.7)	11 (16.4)	
Chiropractor	9 (11.4)	1 (8.3)	8 (11.9)	
CAM	8 (10.1)	0	8 (11.9)	
Physio	7 (8.9)	1 (8.3)	6 (8.9)	
Massage	6 (7.6)	1 (8.3)	6 (8.9)	
Sleep	6 (7.6)	1 (8.3)	5 (7.5)	
CBT	5 (6.3)	5 (41.7)	0	
Specialist visit	3 (3.8)	1 (8.3)	2 (3.0)	
Other treatments	3 (3.8)	1 (8.3)	2 (3.0)	
Treat psych	1 (1.3)	0	1 (1.5)	
Medication				
Preventative	24 (30.4)	5 (41.7)	19 (28.4)	
Vitamins/herbs	7 (8.9)	0	7 (10.4)	
Acute	5 (6.3)	1 (8.3)	4 (6.0)	
BCP	4 (5.1)	0	4 (6.0)	
Other meds	3 (3.8)	0	3 (4.5)	
Trigger control				
Diet	15 (19.0)	2 (16.7)	13 (19.4)	
Exercise	10 (12.7)	1 (8.3)	9 (13.4)	
Caffeine	8 (10.0)	0	8 (11.9)	
Other triggers	4 (5.1)	2 (16.7)	2 (3.0)	
Posture	2 (2.5)	2 (16.7)	0	
Smoking	2 (2.5)	0	2 (3.0)	
Alcohol	1 (1.3)	0	1 (1.5)	
Stress	1 (1.3)	0	1 (1.5)	
Total statements	162	30	132	

Table 4.37: Treatment activity during the wait-time for consult with CHAMPneurologist

CAM = Complementary alternative medicine

CBT = Cognitive behavioural therapy

BCP = Birth control pills

% of Total respondents (n = 79), of SMW (n = 12) and of Comparison (n = 67)

Summary

In summary, 23 (10%) participants completed the Self-Management Workshop (SMW) comprising the intervention group and the remaining 208 (90%) participants formed the comparison group for a total of 231 participants. Forty-one comparison group members did not complete the post-test resulting in their pre-test data not being used in the paired t-test and ANOVA analyses. The sample was predominantly female (n = 192, 83.1%) and non-smoking (n = 149, 64.5%) with an average age of 38.3 years (SD = 12.6). SMW completers were more likely to participate in other CHAMP workshops and many of the lectures, than the comparison group (p < 0.001 to 0.009).

In the pain measures analysis, headache frequency was reduced from 18.0 to 14.5 days per month from baseline to study completion for the total sample (p = 0.048) but there was not a statistically significant difference between the groups (p = 0.139) however group and time interaction was approaching significance (p = 0.088). Average severity of headache pain was 5.5/10 (SD = 1.9) for both groups and it did not change significantly over the course of the study. The comparison group reported significantly lower pain on their "least pain" reports (p = 0.026) than the SMW group on the ANOVA. In other words, they had more pain-free days than participants in the SMW group. Both groups reported that headaches interfered with their ability to work occasionally to frequently and missed on average 2-3 days of work each month due to headaches.

The primary outcome variable was self-efficacy measured by the HMSE. Scores improved significantly from pre-test to post-test for the entire sample (p = 0.041) but

there were no statistically significant differences noted between the SMW intervention and comparison groups.

Improvement in depression (CESD-R) scores was detected for the comparison group on paired t-test (p = 0.009) however no time effect (p = 0.270) or difference between groups (p = 0.142) was seen in the ANOVA analysis. In terms of disability (HDI), both groups scored in the moderate range for disability (46.3-61.1/100) however, on the ANOVA analysis, the intervention group scored higher than the comparison group (p = 0.041). The group and time interaction only reached statistical significance on the functional subscale (p = 0.035) but were approaching statistical significance on the emotional subscale (p = 0.053) and on total score (p = 0.055). Quality of life (HIT-6) scores did improve for the whole sample, reaching statistical significance (p = 0.003), but the majority of participants scored in the "severe impact" range both at baseline (n = 196, 85.6%) and at study completion (n = 144, 77.8%) suggesting the change was not clinically significant or the grouping category was too broad.

There was one qualitative or open-ended question in this research, in which participants were asked to report treatment changes that occurred between attending the A and E session and seeing the CHAMP neurologist. Many participants changed or started headache preventative medications, reduced their pain killer use and made dietary changes. Comparison group members endorsed the use of complementary alternative medicine approaches while SMW group members did not. SMW participants made several comments about using the cognitive behavioural therapy techniques they had learned during the study intervention.

CHAPTER 5: DISCUSSION

Health-related self-management programs are becoming more commonplace in Canada. The Stanford Model of self-management education is used widely in Canada and the U.S.A. by clients diagnosed with arthritis (Lorig et al., 1985), idiopathic chronic pain (LeFort et al., 1998) and chronic disease in general (Lorig et al., 1999). The Stanford Model uses trained layperson leaders to guide participants through a standardized set of educational exercises and discussions designed to improve selfefficacy for disease management. In Calgary, clients diagnosed with chronic illnesses such as diabetes, chronic obstructive pulmonary disease, and arthritis are able to attend a Stanford-based program called "Row Your Own Boat". Row Your Own Boat is offered in all quadrants of the city of Calgary, often in culturally sensitive settings and in Punjabi and Chinese, as well as English.

The Calgary Health Region also supports several professionally facilitated selfmanagement workshops, through the Regional Pain Program, that are designed to help clients with chronic headache, pelvic, neuropathic and musculoskeletal pain. This study sought to determine if the CHAMP Self-management Workshop (SMW), a professionally facilitated program, is effective in improving headache management self-efficacy.

This chapter includes a discussion of the demographic and pain characteristics of the study participants. The study hypothesis, *attendance in a headache self-management program (the Self-management Workshop) will increase headache self-efficacy scores*, was tested using the HMSE. The results of self-efficacy testing and of depression, disability and quality of life testing are reviewed and discussed. Qualitative data regarding headache management activities occurring outside of CHAMP are also explored. This chapter concludes with an exploration of the limitations of this study, the implications and recommendations for nursing practice and directions for future research.

Demographic Characteristics

The prevalence of migraine headaches for women in Canada is three times that of men (25% versus 8%) (O'Brien et al., 1994), therefore it was expected that the majority of study participants would be female. Females made up 83% of the participants. The average age of participants was 38.3 years which gives support to previous research that found women aged 30-50 in the U.S. and Canada suffered the highest occurrence of migraine headache (Lipton et al., 2001b; O'Brien et al., 1994). With this age range, it can be assumed that this sample is composed of individuals who are in the prime of their family and working lives. Therefore they are being affected by pain at a time in their lives when they need to be the most productive. It is vital that these individuals have access to appropriate and accessible interventions to manage their pain.

Looking at substance use, the rate of cigarette smoking for Canadians aged 35-44 is 19.2% and for women in that age range is 17.5% (men = 20.8%) ("Canadian tobacco use monitoring survey (CTUMS)"). The smoking rate in this study is lower than the national average (25% of participants however did not report their smoking status) suggesting that smoking was not a common coping mechanism or stress reliever for this sample.

In the current study, one third (34.2%) of participants stated that they used alcohol and 70.6% used caffeinated beverages (average1.5 beverages/day). The amount of alcohol consumed by individuals was not reported however, as consumption rate was only available on a very small number of participants (n = 25). The data were insufficient to make any generalizations about this sample in terms of consumption.

Alcohol and caffeine are well-known headache triggers. Clients who attend CHAMP are often counselled to reduce intake of alcohol and caffeine, during the optional lifestyle assessment, as a way to reduce headache frequency. Headache sufferers who overuse caffeine often experience caffeine withdrawal headaches if they miss or delay their usual morning coffee for example. This information has implications for primary care. If disease specific education, such as that provided to CHAMP clients in the A and E session, was more readily available to headache sufferers while they were in primary care, then potentially significant lifestyle changes such as alcohol and caffeine reduction could be addressed earlier.

In this study, it was found that participants who completed the SMW were more likely to attend the relaxation, body-works and sleep workshops also offered by CHAMP. The SMW group was also more likely to attend the CHAMP lecture series to learn about stress management, pacing, headache triggers, and emotional support for those with headache. It is possible that participants, who were inclined to attend a group-based intervention such as the SMW, also had the same inclination and the time to attend other workshops and lectures related to headaches. However, the numbers in each of the groups was so small that the statistical results cannot be meaningfully interpreted. Aside from group and lecture attendance, there were no demographic differences noted between the SMW and comparison groups or between study completers and non-completers. Again, this lack of difference may be related to the small number of participants in the interaction group.

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Hypothesis Testing

Pain Measures

In the current study, no group differences were found on any of the pain measures (frequency, intensity, suffering, impact of pain on work, and days of work missed) except for reports of least amount of pain in the last month (p = 0.026). The comparison group was more likely to have reported a headache free day in the last month suggesting that headache intensity was lower in the comparison group. It is possible that participants with lower pain intensity saw less need to attend the SMW, and that a selection bias occurred in this study as a result.

Headache Frequency and Intensity

As a whole, the participants of this study had a statistically significant reduction in headache frequency from 18 days to 14.5 days per month (p < 0.001) however this change occurred in the comparison group (p < 0.001), not in the intervention group (p = 0.863). While the ANOVA analysis of headache frequency was only approaching significance (p = 0.088) for group by time interaction, least amount of pain results support the hypothesis that headache frequency was lower in the comparison group. Headache intensity, suffering, impact of pain on work, and days of work missed did not change significantly from baseline to study completion.

Magnusson, Becker and Reiss (2004) found similar reduction in frequency of headaches without change in headache intensity, in headache clients who were treated in the neurologist office, and noted that disability measured by the HDI also did not change for this group. They hypothesized that headache intensity was a more powerful predictor of disability than headache frequency and supported this finding with further research comparing intermittent migraine sufferers to those with daily headache (Magnusson & Becker, 2002). Similarly, HDI scores did not change over time in the current study, despite reduced headache frequency, supporting the conclusions of this prior research.

The CHAMP program's mandate is to treat clients with 5-15 days of headache per month. Clients with more headaches are supposed to be referred to the CHR Chronic Pain Centre. In this study, 107 (47%) participants reported having headache on more than 15 days in the month prior to the A and E session and of those, 61 (27%) participants reported having daily headaches. Therefore, only about half (53%) of study participants fell into the category of having 15 or fewer headache days per month. The severity of the headache problems seen in this sample was considered a typical finding by CHAMP staff, so was not unexpected.

CHAMP versus CHR Chronic Pain Centre

The similarity in headache severity between many of CHAMP's clients and clients of the CHR Chronic Pain Centre suggests that clients and family physicians may not see these two programs as being different from each other. Or perhaps, early access to education through the A and E session was an attractive component for physicians and their clients. Referring physicians may have chosen to send daily headache clients to CHAMP so that they could begin learning management strategies and have a shorter wait-time before seeing the specialist. The CHR Chronic Pain Centre has only recently, in the spring of 2008, adopted a model similar to that of CHAMP. The CHR Chronic Pain Centre and is now offering several education sessions to their clients, at the time of referral, so that learning can occur while clients wait for specialist treatment. As well, many CHR Chronic Pain Centre headache clients attend CHAMP's A and E session to

learn more about lifestyle management in headache. Therefore there is already significant crossover occurring between these two programs for many headache clients.

As the treatment approaches of these two pain clinics become more similar, it may become feasible to combine these two programs, but maintain separate treatment streams for moderate frequency headache sufferers (8-15 headache days/month) and severe frequency headache sufferers (15-30 headache days/month). Clients with more severe headaches would then have access to the more intense eight-session self management program provided at the CHR Chronic Pain Centre as well as the wider array of multidisciplinary workshops offered at the Pain Centre. Access to appropriate specialized headache services could be made more streamlined and more efficient with a single point of entry to headache services in Calgary.

Impact of Headache on Work

In terms of headache impact, the participants in this study missed work/school on average 2-3 days per month. This statistic also speaks to the severity of headache problems endured by study participants. In order to illustrate the difference between CHAMP participants and the general population of headache sufferers, prevalence data was reviewed. In the American Migraine Study of the general population (Lipton et al., 2001b), the authors found that of the approximately 30,000 respondents, 18% (n = 2818) of females and 6.5% (n = 920) of males reported migraine. Of these migraine sufferers, 53% reported significant impairment from their severe headaches and approximately 30% had missed at least one day of work/school in the last three months. The specialistseeking sample in the current study is significantly more disabled, as can be expected, in terms of impact on ability to work than the migraine sufferers in the American study. It is possible that fear of losing employment was one of the factors that led CHAMP participants to seeking specialist help for their headaches. The headache management information that participants learned in the A and E session and in the SMW improved participants self-efficacy but was not helpful in reducing the impact of headaches on ability to function at work. It may be that medical management of severe headaches is a more important headache management strategy, for changing work-related headache disability, than self-management strategies. Many migraine-specific medications exist that can alleviate severe headaches to the degree that clients can attain enough relief to remain at work (e.g., sumatriptan/Imitrex).

Psychometric Instruments

Self-Efficacy

The study hypothesis, attendance in a headache self-management program (the Self-Management Workshop) will increase headache self-efficacy scores, was tested using the HMSE (p = 0.242). There was insufficient evidence to support this hypothesis due to the intervention group size (n = 23). It will be recalled that the HMSE is a 25-item instrument used to measure headache management and prevention self-efficacy. The possible range in scores is from 25-175 with higher scores indicating higher self-efficacy.

A wide range of HMSE scores were obtained (30-168) indicating a large variation in levels of perceived self-efficacy in this sample. For the entire sample pre-test scores averaged 92.5 (SD = 24.2) and increased only 3.6 points to 96.1 (SD = 25.6) reaching statistical significance (p = 0.041). For the intervention group (only 22 had complete HMSE data) the change in scores was slightly higher with baseline scores averaging 89.7 (SD = 26.2) and post-test 95.4 (SD = 26.3) for an increase of 5.7 points. It is doubtful that this small increase in HMSE scores is clinically significant as the predicted increase was estimated as at least 10 and this was a conservative estimate.

Therefore, self-efficacy improved for the whole sample but the groups did not differ from each other statistically (p = 0.703). A larger intervention group may have provided the evidence to support a difference in the intervention and control groups, as the SMW group scores are lower at baseline than the comparison group. It may be that CHAMP clients who attend the SMW do so because they feel less in control of their headache conditions. If future research bears this out to be true, it will be important that the SMW include strategies that are targeted at raising the self-efficacy beliefs of participants. At the time of this study the SMW content was designed in general to improve headache management self-efficacy however self-efficacy theory was not taught directly.

In the literature, only one study was found that used the HMSE to measure response to a self-management program. Nicholson, Nash and Andrasik (2005) followed 21 participants through an eight-week headache self-management program. This homebased program included individually tailored messages that were generated based on pretest scores for the self-efficacy, depression and other psychometric tests that were used. Mean baseline HMSE score was 102, and the post-intervention scores averaged 124, for a change of 22 points. The limited data that was collected on the CHAMP Selfmanagement Workshop participants did not come close to this success.

When determining the sample size for the current study, the effect size and pooled standard deviation calculated for the Nicholson, et al. (2005) were used. See Table 5.1.

The large standard deviations in HMSE scores and the small intervention group (n = 23) contributed to the lack of power seen in the current study.

Source	Mean difference	Pooled Standard	n	Power
	in scores	Deviation		
Pre-test, intervention vs. comparison	3.2	24.3	I = 23 C = 208	0.07 0.27
Post-test, intervention vs. comparison	0.08	25.7	I = 23 $C = 208$	0.03 0.05
Nicholson et al. (2005)	22	19.8	21	0.71

Table 5.1: Power given the sample sizes in the intervention and comparison groups

There were however other differences between the CHAMP and Nicholson et al. (2005) interventions. The CHAMP Self-management Workshop is a five-week program run in a small-group learning format, which included facilitated discussion about selfmanagement topics. Participants in the current study attended the SMW, in the CHAMP clinic, prior to specialist assessment, diagnosis and other potential treatments. Participants in the Nicholson et al. (2005) study had been interviewed by a psychologist to ensure they met I.H.S. (Headache Classification Committee of the International Headache Society, 2004) criteria for migraine diagnosis before embarking on eight weeks of home study with weekly mail-outs of individually tailored headache information. It is possible that the psychologist interview and knowledge of diagnosis had a treatment effect that impacted HMSE scores in the Nicholson et al. (2005) study. The current study included a comparison group so that extraneous variables such as those mentioned above could be monitored. The participants in the current study did not have confirmation of their headache diagnosis until after completing the post-test. Knowledge of headache pathogenesis may have contributed to the increased sense of control reported by participants in the Nicholson et al., (2005) study. This possibility could be tested in future research on the SMW by providing the intervention participants with information about their most likely diagnosis. Waiting until after participants were assessed by the neurologist and given a diagnosis, then randomizing to SMW or usual care might address this potential bias in the results of this study.

If HMSE scores for the current study are looked at for all participants together, the statistically significant, although small increase in self-efficacy scores, could be attributed in part to attendance at the A and E session. The A and E session provided two hours of headache pathophysiology, pharmacology and lifestyle information. Participants were given time to ask questions and talk with presenters afterward about their specific headache issues. Presenters prepared for the A and E session by reviewing the referral documents of all the scheduled participants and therefore tailored the presentation to include the most relevant information for those present.

It was not the aim of this study to measure the effectiveness of the A and E session however this two-hour educational offering may have contributed to the improved sense of control that participants felt over their headache conditions. It may be appropriate to increase the amount of self-efficacy based information offered at the A and E session. As well, future research should include an instrument with questions regarding participant impressions and learning from the A and E session.

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The mean wait-time between attending the A and E session and the neurologist appointment was 108 days. It is possible that participants in the SMW intervention did not have had enough time to trial and incorporate new self-management skills by the time of their CHAMP neurologist appointment and the post-test. When this research was proposed, the wait-time for neurologist consult was closer to 6 months (180 days), which would have allowed more time for both attendance in the SMW and for the practice of new skills. It was certainly better for clients to have a shorter wait time to see the neurologist, however it was believed that the longer wait time would be a motivating factor for clients to participate in the SMW. The current study was designed to capture wait time client activity in participating in a non-physician treatment approach, the SMW.

In terms of headache frequency, a large proportion of this sample (47%) had more that 15 days of headache per month. The severity of headaches seen in this sample may also have contributed to the lower HMSE scores and the small effect size seen in this study compared to what was found in the literature (Nicholson et al., 2005).

Depression, disability and quality of life measurements were included in this study to help identify differences between the intervention and control groups. It is difficult to determine if real differences between groups were found, as the groups were not of equal size, which is one of the assumptions of the statistical tests performed in this study. However, it is worthwhile commenting on the depression, disability and quality of life findings and how they relate to the published research.

Depression

Depression was measured using the CESD-R, which ranges in score from 0-80 with higher scores indicating greater likelihood of depression. Overall, the participants of

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this study scored on average 17.3 at baseline and 15.2 at the post-test, therefore indicating that depression was not a major issue for most of them. Nicholson et al., (2005) measured depression using a different tool, the Beck Depression Inventory. The findings however were similar. The participants in Nicholson's research (2005) reported depression scores in the moderate range and although their scores improved post-intervention, this change was not statistically significant. It is possible that significantly depressed CHAMP clients chose not to participate in this study or did not attend the A and E session leaving a biased sample to recruit from.

While the intervention group was not statistically different from the comparison group in the ANOVA analysis (p = 0.142), baseline depression scores were generally higher and had a larger variance (SD = 17.0 versus 11.9) in the intervention group. Therefore a larger intervention group may have been able to demonstrate a greater tendency toward depression in participants who choose to attend the SMW. If participants in self-management programs are more depressed than those who do not attend, recognizing this difference could be an important step toward improving the intervention so that facilitators can attempt to address the needs of depressed individuals. Disability

Disability was measured in this study using the HDI. Total scores were compared as well as scores on the emotional and functional subscales. The range of scores on the HDI is 0-100 with higher scores indicating more disability. Overall, the sample scored in the moderate range for disability with an average of 54.0 at baseline. The post-test scores for the sample were reduced at 48.5 (p < 0.001) however this change occurred only in the comparison group (p < 0.001), not in the intervention group (p = 0.588). This group difference was supported in the ANOVA analysis for the total HDI score (p = 0.041) and on the emotional subscale (p = 0.048). In conclusion, HDI scores did not improve with the SMW intervention. In contrast, Nicholson et al., (2005) used the MIDAS to measure disability and found that disability was significantly reduced following their selfmanagement intervention. That study however, was limited by the lack of a control or comparison group.

The SMW group participants in the current study were more disabled (and potentially more depressed) than the comparison group. These findings suggest that perceived disability and depression could be important factors in the decision to attend the SMW. While in the time frame of this study the SMW did not have an impact on disability or depression, these two constructs should be measured again in several months time to determine if they changed over a greater length of time.

Quality of Life

Quality of life was measured using the HIT-6, a 6-item instrument. No group differences were found however HIT-6 scores improved for the whole sample, reaching statistical significance. While scores improved, the majority of participants remained in the severe impact range. This may suggest that the changes seen in the HIT-6 were not clinically significant. However, neither depression nor disability changed over time so either quality of life changed despite lack of progress in depression and disability or the HIT-6 instrument was more sensitive to the changes that occurred between the pre and post-tests. When looking at post-test results, the n in the severe category decreased by 52 while the lower categories combined only increased in n by a total of eight. Therefore it is possible that the 41 participants who did not complete the post-test were all in the

severe impact range and these missing data are responsible for the significant decrease in HIT-6 scores.

It is also possible that the criteria for severe impact are too broad and many moderately impaired participants are wrongly included in this category as suggested by Kawata et al. (2005). The range of possible scores is 36-78. Participants who scored 60-78 fell into the severe category, a range of 19 points. The range for substantial impact was 56-59 (4 point range), for some impact is 50-55 (6 point range). The range of scores possible for being categorized as having severe impact is much broader than for the lesser categories of impact. Therefore it is possible that these categorizations are not valid for this sample of headache sufferers. A different break down of scores may reveal that some of the participants in this study were perhaps wrongly grouped into the severe headache impact category.

Cronbach's alpha for the HIT-6 was 0.80, which is the minimum value for reliability validity in group-level comparisons. Therefore HIT-6 validity in this sample was adequate but not tremendous, meaning that 20% of participant responses were random and did not reveal true differences between individuals (Polit & Beck, 2004). The HMSE, CESD-R and HDI had excellent reliability validity (Cronbach's α ranged from 0.91 to 0.94). The HMSE, CESD-R and HDI therefore should be used in future research on CHAMP clients however another quality of life measure might be worthy of a trial in this population and could demonstrate greater internal consistency.

Depression, disability and quality of life did not appear to change dramatically over the time frame of this study. While the A and E session may have accounted for improvement in self-efficacy scores, and perhaps quality of life, it had no impact on the constructs of depression and disability. These results support Bandura's (1997) claim that self-efficacy is more easily impacted than the more complex psychological constructs of depression, disability. Having a metric that accurately reports changes in perceived health status could be useful in the future evaluation and funding of headache self-management programs.

Qualitative Results

Participants were asked to list any changes made to their headache management during the waiting time (mean = 108 days) between attending the A and E session and seeing the CHAMP neurologist. Less than half (41%) of post-test completers answered this question and it was assumed that no response to this question meant that nothing had changed. It is also possible that there were too many tools in the questionnaire and it took too much time and effort for participants to complete an additional open-ended question.

The most common activities reported were; starting a headache preventative medication, stopping analgesic medication over use, using relaxation techniques, and trigger management around caffeine reduction, dietary changes and increased exercise. All of these topics had been discussed in detail at the A and E session, therefore suggesting that the A and E session alone may have contributed to healthy behaviour change in some study participants. This also supports the belief that clients are more likely to change their behaviour when a health care provider presents basic lifestyle information to them.

Intervention group participants appeared to differ from the comparison group in their use of complementary and alternative medicine approaches to headache management (CAM). This also held true for the use of massage therapy and vitamins or herbs, which could also have been categorized as CAM activities. This difference may be explained by the fact that this group showed interest in physician recommended and system supported treatment options by choosing the Self-management Workshop rather than exploring treatment opportunities beyond the scope of western medicine.

Participants in the intervention group also wrote several statements related to the use of strategies they had learning in the Self-management Workshop, such as pacing of activities and monitoring self-talk. These statements reveal that the self-management strategies learned, were of importance and were being used to help manage headaches. For these participants it would be important for their primary care providers to acknowledge the skills these clients have learned and encourage further development of headache self-management strategies.

In summary, qualitative differences were found between the intervention and comparison groups in terms of the use of CAM treatment options. Many of the treatments and activities listed had been suggested in the A and E session and in the SWM and may have contributed to higher self-efficacy ratings in these individuals. As previously proposed, these qualitative data suggest that attendance at the A and E session was an important first step for many of the study participants to consider exploring their lifestyles and current headache management routines. The changes that participants made on their own and in conjunction with their primary care physician may have contributed to the improved sense of self-efficacy that participants reported. In order to improve the quality of data collected on lifestyle changes, clients could be asked to complete an instrument that includes several headache management behaviours. Clients

would indicate on the instrument whether they were contemplating, changing or maintaining change in any of the listed or other headache self-management behaviours.

Limitations

Recruitment

The recruitment rate for participation is this study was 67%. It was predicted that approximately 65% of A and E participants would enroll, so this goal was met. In order to meet statistical power of 0.80, the required sample size was estimated at 62 in each group for a total of 124 participants. This goal was determined to be attainable within a reasonable timeframe by the investigator and supervisor. Unfortunately, far fewer participants completed the Self-management Workshop than predicted despite continuing recruitment to 231 participants. The small intervention group (n = 23) did not allow for meaningful computations to be made with the much larger comparison group. In-depth statistical analysis stratifying for gender, age, depression, disability and quality of life and comparing against the HMSE was not undertaken because of the difference in the size of the groups. As a result it was not possible to determine the potential impact of age or gender on self-efficacy in this study.

Participation in the Self-management Workshop may have been hampered by several factors. One of the workshop facilitators took a leave of absence and one nurse left the clinic during the study period and neither was replaced leaving one occupational therapist and one registered nurse to lead workshops. As a result, CHAMP clients who had indicated interest in the Self-management Workshop had a limited number of classes available to them. Only about 40% of clients responded to letters from CHAMP inviting them to attend specific workshop dates (personal communication, A. McLean, CHAMP occupational therapist, June, 2007). Near the completion of study recruitment, two additional Self-management Workshops per month were offered to participants as staffing had improved, but this did not translate into more intervention group numbers. Changes to CHAMP administrative staff intended to improve communication with clients and recruitment into workshops occurred, but again toward the end of the study period and did not appear to benefit recruitment. Recruitment began in December 2006 and concluded in November 2007.

It is notable that the waiting time between attending the A and E session and visit to a CHAMP neurologist was on average 108 days. Prior to the start of this study waittimes had consistently been around six months. However, neurologists had been added to this service and a concerted effort had been made by CHAMP administrators to reduce that wait-time. Unfortunately for this study, but fortunately for CHAMP clients, those efforts began to be successful. This reduced the time participants had to, first consider, then enrol and complete the Self-management Workshop before seeing the CHAMP neurologist.

The Intervention

At the conclusion of each A and E session, participants were reminded to sign up for the Self-Management Workshop (SMW) before leaving. Participants in this study were allowed to self-select whether they would or would not participate in the intervention. Participants were very willing to put their name on a waiting list for the SMW, however this did not translate into participation. Most participants waited weeks before CHAMP staff phoned them and offered a spot in the workshop. The choice of time slots for SMW groups was also limited in number and by time of day. Many participants were unwilling or unable to attend at the scheduled times or weekdays and as a result remained on the waitlist until the next month's workshops were offered. As a result, even though participants indicated an interest in attending the SMW, scheduling barriers may have limited their ability to participate. Therefore, the process of registering participants into the SMW may have biased their decision to attend.

In discussions with CHAMP staff, it was felt that some participants lost that momentum and enthusiasm about the workshop as a result of waiting long periods of time before hearing more about it. It was decided to take scheduling information into account when planning further educational offerings and try to link registration in to SMW more closely with the A and E session. Having the opportunity for immediate action would benefit those participants who were in the preparation or action stage of change (Prochaska et al., 1992) by providing an intervention they could readily participate in. It is important to recognize that many participants will be precontemplative; not yet ready to see their own role in managing headaches. Therefore, CHAMP staff must recognize the need to continue to offer information regarding workshops and support to clients as they progress through the program.

It was not reasonable to monitor participants while they were attending the Selfmanagement Workshop therefore it is difficult to know exactly what they were taught, how it was presented and how participants responded to this learning opportunity. Participants self-reported attendance but did not indicate the timing of the group within their waiting period to see the CHAMP neurologist. Group satisfaction data was not accessed. Therefore, lack of control and measurement of the intervention itself is another limitation of this study. As well, with the shortened wait-time, participants did not have much time to practice self-management skills or incorporate them into daily life prior to completing the post-test. It may take more time than was available in this study for headache management self-efficacy to change and be measured accurately.

The SMW was a five-session self-management program that was developed based on the eight-session Chronic Pain Self-Management program offered at the CHR, Chronic Pain Centre. Both programs were based on the book "Managing Pain Before It Manages You" (Caudill, 2002), a workbook for clients with pain, and were developed by a multidisciplinary team experienced in pain management. The workbook's author, Caudill, has participated in extensive research about pain, self-management and selfefficacy (Arnstein, Caudill, Mandle, Norris, & Beasley, 1999; Arnstein, Caudill, & Wells-Federman, 2000; Arnstein, Vidal, Wells-Federman, Morgan, & Caudill, 2002; Wells-Federman, Arnstein, & Caudill, 2002). Therefore one can assume that the components of the SMW are self-efficacy based. However, this program was designed to help headache clients become better self-managers, it was not designed specifically to increase self-efficacy. Therefore it may not have been reasonable to expect significant changes in headache management self-efficacy for participants in this program.

The A and E Session

The two-hour A and E session includes a physician presentation on headache pathophysiology and medication use followed by a nurse, psychologist or occupational therapist presenting on lifestyle modification and CHAMP program offerings. The nature and quality of these presentations varied depending on the physician presenting and the discipline presenting the lifestyle information. These variations may have biased study recruitment and the self-efficacy benefits participants gained from attending the A and E

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session. As well, in March of 2007, four months into study recruitment, the lifestyle portion of the session was rewritten and the information presented was significantly modified. It took time for CHAMP presenters to become comfortable with the new material and present it in a confident manner. The change in presentation represents a secular trend that occurred during recruitment and could be a threat to the validity of study results. However the new information had a greater focus on self-efficacy and client involvement in care, thereby supporting the construct that this study was trying to measure. While the change in A and E information could also have biased recruitment to SMW and self-efficacy, the effect may not have been negative. No noticeable change in recruitment rate was identified with the new presentation.

As is typical in health care, a large number of clients referred to CHAMP declined to attend the A and E session or did not show (15.5%) up when booked. This reduced the potential number of study recruits. As well, some CHAMP clients were seen on an expedited basis if their headache treatment needs were considered urgent or emergent. Other clients from outside of Calgary were routed directly to a neurologist consult without attending the A and E session as traveling long distances was considered a hardship and it was not feasible for those clients to attend weekly education sessions, such as the SMW. As a result several clients referred to CHAMP were not available for recruitment in this study. It was not possible, within the limits of this study, to gather any demographic or psychometric information on clients who did not attend the A and E session, to see if they differed in any way from the study sample.

The headache diagnosis of study participants was largely unknown at the time of the A and E session. Diagnosis was determined at the neurologist consult, which

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occurred after participants completed the post-test therefore this data was not collected in the current study. It is possible that other types of headache were over-represented in this sample versus migraine and tension-type, making it difficult to compare our findings to the literature as most headache studies begin with the determination of headache diagnosis. In future studies of headache self-management programs, headache diagnosis should be collected and analysed to further define the sample's characteristics and to provide data that can be generalized to a larger population of headache sufferers.

Process and Method

CHAMP participants are asked to complete a large package of psychometric tests, history and demographic forms. In order to avoid additional paperwork burden, the investigator chose to follow the CHAMP program protocol for collecting data, adding only the HMSE and one other page of questions. Participants handed in different forms at different stages of their participation, often forgetting or losing their history and demographic documents. This added to the complexity of data collection and resulted in lost data. As well, the CHAMP booking clerk, who was well trained in the protocol for this study, was unexpectedly away for several months. During this time, many post-tests were not given out and were subsequently mailed to participants. The rate of return for mailed post-tests was only 27%. In conclusion, several limitations hampered this study however adequate data were collected to provide direction for future research.

Implications and Recommendations for Nursing Practice

1. Nurses can have an impact on when and where their clients choose to pursue selfmanagement interventions. The philosophy of health-related self-management is based on the belief that clients have inner strengths and abilities, which help them to change their health behaviors. The belief that nurses can help clients learn skills to care for themselves is not new. There are nursing models that promote self-efficacy in health management. Braden's Self-Help Model: Learned Responses to Illness Experience (Braden, Mishel, & Longman, 1998) and Pender's Health Promotion Model (Tillett, 1998) are excellent examples of a self-efficacy based approach to client care.

The difficulties seen in this study, where participants showed interest in attending the SMW but did not follow through with this action, suggests that we do not yet understand how to engage headache sufferers into intensive self-management activities. Khara Sauro, a member CHAMP's research staff initiated a survey of 198 of the program's clients in 2006 and found that several reasons were given for not attending CHAMP workshops or lectures. Distance to travel (24%), location of activities on a busy hospital site (20%), the timing of sessions (16%) and the time commitment required (17%) were reported as the most common reasons for non-attendance (unpublished data; by Khara Sauro, MSc., CHAMP researcher, used with permission). It is reasonable to suggest that costs related to parking, time off of work and childcare might have also been considerations for the primarily female participants in this study.

As nurses seek to develop appropriate self-management programs and activities for their clients, barriers to attendance must be taken into account. The answer may be to provide a wider variety of self-management options for clients such as home-based educational modules that can be tailored to client needs (Nicholson et al., 2005). Other approaches like the minimal contact model (Rowan & Andrasik, 1996) and web-based learning could be made available and potentially reach a wider audience of headache clients. Minimal contact and web-based treatments are also less costly in the long run for the specialist program to provide. The initial set up of a web-based treatment would involve significant effort and cost. The ability to develop, promote and manage these types of programs are within the skills and knowledge of ambulatory care nurses who work in the community with chronic headache clients.

Promoting self-management opportunities for headache clients to primary care physicians and other allied health workers is another important role that nurses who work with the headache population can play. Often, physicians are not aware of the existence of health education opportunities like the A and E session and CHAMP workshops. CHAMP and the CHR Chronic Pain Centre also provide valuable information in the form of public lectures, which require less time and commitment from clients. "Row Your Own Boat" is a self-management program offered in the community that clients could attend without physician referral. Educating primary care providers regarding headache management approaches and community resources is important to reducing the frustration that can occur when physicians deal with chronic conditions such as headache.

2. Nurses can use self-efficacy enhancing approaches in their encounters with clients.

Lev et al., (2002) showed in their experience with breast cancer patients that nurses can address all four sources of self-efficacy enhancing strategies in everyday encounters with their clients. It will be recalled that the four self-efficacy enhancing strategies are:

- *Performance accomplishments*: mastering part or all of an activity that was once thought difficult or impossible.
- *Vicarious experiences*: seeing other people successfully perform the target activity.
- *Social persuasion*: the act of encouraging, coaching or telling an individual that they are capable of performing the activity.
- *Re-interpretation of physiological/emotional states*: relying on information from one's emotions or health functioning to determine capability in performing an activity.

In headache management, the self-efficacy enhancing interventions might include positive feedback for recognition of, and behaviour change with headache triggers such as no longer skipping meals (a *performance accomplishment*). Encouraging interaction with other clients or peers that have had similar successes in headache management through adopting and exercise program would provide *vicarious experiences*. Providing support and reinforcing the client's ability to initiate a walking program to increase fitness and reduce stress would be an example of *social persuasion*. Helping clients to interpret headache worsening during exercise, as a sign to slow down and pace activity rather than stopping completely in fear of causing further harm is an example of *reinterpretation of physiological or emotional states*.

The further exploration of self-efficacy could provide valuable information to nurses as they develop new headache management programs and reinforce attendance in existing ones. Translating the knowledge of self-efficacy theory into practice with headache clients may be an important approach to help move clients toward behaviour change. The goal is to insure that clients are supported in their self-management efforts so they might reach the highest possible level of health (van der Bijl & Shortridge-Baggett, 2002). Nurses in advanced practice need to collaborate with clients to understand their perceptions of health and create a meaningful plan of care with the client.

3. Nursing knowledge and care can impact the client's clarity of headache diagnosis and appropriate headache management strategies.

Chronic headache clients need to know they are safe from harm before they can attend to headache management issues. While most primary care physicians rule out dangerous organic causes of headache before referring their clients to specialist care, clients need reassurance that their ongoing pain does not equate with harm.

The recording of headache frequency, severity and triggers is valuable information for both clients and their healthcare providers. Diary data can help with the formulation of a headache diagnosis and provide clues as to the most appropriate treatments. Treatment can also be evaluated using headache diary data if responses to pharmacological and non-pharmacological treatments are tracked. Nurses can provide guidance, support and positive feedback so that clients keep adequate records of their headache patterns and then learn from the data that they collect.

 Nurses can use behaviour change theory to help reinforce the messages from the A and E session and help clients to set realistic goals for behaviour change.

Nurses can play a role in teaching and reinforcing the lifestyle changes that are presented in the CHAMP's A and E session. They can provide encouragement and support when change is attempted and praise when behaviors change. Nurses can also assist headache clients to decide what they hope to achieve when they seek specialized care. Clients need to take part in goal setting, attempt activities that they can succeed in, and learn new pain coping skills before they gain confidence in their ability to succeed in performing new behaviours (Maes & Karoly, 2005). Nurses, armed with the knowledge of change theory (Prochaska et al., 1992), can assess readiness for change then offer the appropriate level of information based on stage of readiness. Headaches are often a lifelong issue therefore clients will need help and understanding to maintain the lifestyle changes they enact, and support when relapse occurs.

Future Research

HMSE scores changed over the course of this study, as did scores on the CESDR, HDI and HIT-6, therefore it may provide a good metric of the benefits that participants gain from attending the CHAMP program. CHAMP workshops use some self-efficacy based educational tools therefore continuing to collect HMSE data at the A and E session then comparing results with data collected after clients complete any of the workshops could provide valuable data. Self-efficacy scores may increase more when clients attend one, two or more workshops. The HMSE could be collected at discharge from CHAMP and at intervals post discharge to obtain ongoing data as to whether or not control over headaches is improved or achieved over time. Depression, disability and quality of life should also be measured at later intervals in client treatment to determine if the SMW and other CHAMP workshops and treatments have an impact on these constructs. These data may be useful in deciding in how to best sequence client care and in the planning of future workshops. Maintenance programs that help clients to revisit self-management concepts and share in peer support may be indicated and prove helpful. The current format of the Self-management Workshop may be difficult for clients to attend, as evidenced by the low recruitment to the intervention group in this study and in the research conducted by CHAMP staff on non-attendance to workshops. Focus groups of clients should be done where clients are asked about the format of selfmanagement offering they would most likely attend. If minimal contact or web-based headache self-management programs are developed, those will require thoughtful evaluation. The HMSE may be a useful tool for that evaluation as well.

It is possible that the CHAMP Lifestyle Assessment may be a more valuable intervention for clients than the SMW. During the Lifestyle Assessment clients review their current life activities with the CHAMP OT or nurse and try to identify possible headache triggers and areas where change may be of benefit. This session builds on the information provided in the A and E session and moves clients toward setting realistic goals for behaviour change. If offered in a group setting, the Lifestyle Assessment could be more cost effective and reach a larger audience. As well clients would have the opportunity to share their experiences with others and learn from their peer's experiences. The HMSE would be a good evaluation tool for this intervention as well as clients will need to feel confident in their ability to change habits (e.g. smoking cessation) in order to improve the management of their headache conditions. Many of the participants in this study underwent a lifestyle assessment however this intervention was not directly measured.

After attending the A and E session, a large number of participants were lost to follow-up (n = 51/231). Many cancelled or refused the neurologist consult appointment. Only a few stated their headaches improved (n = 3). Therefore, these headache sufferers

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are still in the healthcare system and are likely seeking care from their primary care providers and other health care facilities. It would be valuable to track these individuals to understand why they left the program or refused the neurologist consult. Was the program not what they had expected or did they lack confidence in the self-management and lifestyle approaches proposed by CHAMP staff. In future programs could be developed that better suit the headache management needs of individuals who do not currently see CHAMP as the appropriate resource for them.

Conclusions

This investigator measured the impact of the CHAMP Self-management Workshop on headache management self-efficacy in clients who choose to participate in this program. Self-efficacy had not previously been measured in individuals suffering with headache comparing an intervention and comparison group.

Unfortunately, very few participants chose (or were able) to take part in the Selfmanagement Workshop making it difficult to make reliable comparisons between the intervention and comparison groups. However, the average self-efficacy scores and quality of life scores did improve over time for both groups, while depression, disability did not change. The HMSE tool may have been measuring the benefits of attending the A and E session as well as the SMW in this study. All participants were required to attend the A and E session to be included in this research.

The HMSE looks to be a useful tool to measure self-efficacy in this headache population however more research is needed to adequately measure the impact of the A and E session and the SMW independently. The qualitative data collected in this study revealed that many clients returned to their physicians and changed their medication routines. Many others initiated trigger management, exercise and diet changes suggesting that the A and E session gave them adequate information to make changes in their headache management routine. It is important to further investigate the impact of attending the A and E session so that this intervention can be evaluated and improved as needed.

Recruitment and access to the SMW were an issue in this study. The CHAMP program organizers will need to look at providing better access to this intervention for their clients and may want to consider home or web-based educational offerings as well as community versus hospital-based classes. Readiness of clients to participate in cognitive behavioural therapy-based treatment may be an important assessment for nurses in the CHAMP clinic to make. Clients may need further information and encouragement to participate in this time-consuming intervention. Nurses also need to recognize that not everyone requires a self-management program to improve their sense of control over their headaches. Self-efficacy can also be enhanced by providing pertinent information, such as that provided in the CHAMP A and E session.

The literature reviewed for this study shows that self-management interventions are effective additions to medical treatment for clients living with chronic conditions (Marks et al., 2005a). Minimal therapist contact interventions, that are mainly homebased, are also effective and may be more appropriate for CHAMP clients than the SMW as they are more easily accessed in terms of cost, time and transportation.

Nurse-led headache management programs (HMO based) that offered headache education, usually two hours of professional instruction focused on headache pathophysiology and lifestyle change, also had positive outcomes for their clients (Blumenfeld & Tischio, 2003; Harpole et al., 2003; Maizels et al., 2003). The A and E session content is similar to that offered in the HMO programs and has been shown in this study to benefit the self-efficacy of CHAMP clients. Therefore, some self-management skills can be learned, in some clients, with very minimal attention, in large groups, over a very short period of time. This is important information for future program development in headache care but also in other types of chronic pain. A broader spectrum of learning paradigms needs to be explored and researched before chronic pain care can be optimized in Calgary, and in Canada.

Research in the field of chronic pain self-management in Canada has been expanding. McGillion, LeFort, & Stinson (2008) have initiated many research projects in chronic pain, but have also written on the importance of changing health policy to make self-management a priority for governments. The authors presented evidence of how self-management interventions can improve self-efficacy and acceptance of chronic illness and also create positive behaviour change.

Questions around access to care, readiness to participate in lifestyle change, and knowledge translation need to be addressed nation-wide so that more people, in more settings, can learn chronic pain self-management skills. Collaborative relationships between clients and health care professionals are promoted through self-management education. These collaborations are necessary so that care is anchored to the client's goals and outcomes are achieved in ways that also empower the client to continue managing as independently as possible.

If self-management really is the "magic pill" that clients and healthcare providers have been looking for (Bandura, 2005), then pain centres across Canada will have to work together to ensure this knowledge is made more available to all who need it. However, not everyone needs to learn self-management skills in classrooms or specialty clinics. Appropriate public education about chronic headache management, and the management of many other chronic conditions that is easily accessed, for example on the internet or in community settings, could go a long way toward enhancing health related self-efficacy. In many Canadian cities it is already possible to learn self-management skills from lay-people, nurses and primary care physicians in the community. Political will and funding are still needed however to support sustainable, client-centred, population-based healthcare that encourages active engagement in care and collaborative relationships with healthcare providers.

REFERENCES

- Andrasik, F. (1996). Behavioral management of migraine [Electronic version]. Biomedicine and Pharmacotherapy, 50, 52-57.
- Arnstein, P., Caudill, M., Mandle, C. L., Norris, A., & Beasley, R. (1999). Self efficacy as a mediator of the relationship between pain intensity, disability and depression in chronic pain patients [Electronic Version]. *Pain, 80*, 483-491.
- Arnstein, P., Caudill, M., & Wells-Federman, C. (2000). Self-efficacy as a mediator of depression and pain-related disability in chronic pain. In M. Devor, M. C.
 Rowbotham & Z. Wiesenfeld-Hallin (Eds.), *Proceedings of the 9th world congress on pain: Progress in pain research and management* (Vol. 16). Seattle, WA: IASP Press.
- Arnstein, P., Vidal, M., Wells-Federman, C., Morgan, B., & Caudill, M. (2002). From chronic pain patient to peer: Benefits and risks of volunteering. *Pain Management Nursing*, 3(3), 94-103.
- Bandura, A. (1978). The self system in reciprocal determinism. *American Psychologist*, 33(3), 344-357.
- Bandura, A. (1997). Self-efficacy: The exercise of control. New York: Freeman.
- Bandura, A. (2005). The primacy of self-regulation in health promotion [Electronic version]. *Applied Psychology: An International Review*, 54(2), 245-254.
- Barlow, J. H., Williams, B., & Wright, C. C. (1999). 'Instilling the strength to fight the pain and get on with life': Learning to become an arthritis self-manager through an adult education programme [Electronic Version]. *Health Education Research*, 14, 533-544.

- Barton, K. A., & Blanchard, E. B. (2001). The failure of intensive self-regulatory treatment with chronic daily headache: A prospective study [Electronic Version]. *Applied Psychophysiology and Biofeedback, 26*, 311-318.
- Battersby, M., Harvey, P., Mills, P. D., Kalucy, E., Pols, R. G., Frith, P. A., et al. (2007).
 SA HealthPlus: A controlled trial of a statewide application of a generic model of chronic illness care [Electronic version]. *Milbank Quarterly*, 85(1), 37-67.
- Becker, L. A. (2009). Effect size calculator. Retrieved February 26, 2009, from http://web.uccs.edu/lbecker/Psy590/es.htm#III
- Becker, W. J. (1999). Evidence based migraine prophylactic drug therapy [Electronic version]. Canadian Journal of Neurological Science, 26(Supp 3), S27-S32.
- Bigal, M. E., & Lipton, R. B. (2006). Modifiable risk factors for migraine progression [Electronic Version]. *Headache: The Journal of Head and Face Pain, 46*(9), 1334-1343.
- Bigal, M. E., Rapoport, A. M., Sheftell, F. D., Tepper, S. J., & Lipton, R. B. (2004).
 Transformed migraine and medication overuse in a tertiary headache centre clinical characteristics and treatment outcomes [Electronic Version]. *Cephalalgia*, 24, 483-490.
- Blumenfeld, A., & Tischio, M. (2003). Centre of excellence for headache care: Group
 model at Kaiser Permanente [Electronic version]. *Headache: The Journal of Head*& Face Pain, 43, 431-440.
- Bodenheimer, T., Lorig, K., Holman, H., & Grumbach, K. (2002). Patient Self-Management of Chronic Disease in Primary Care [Electronic Version]. *Journal of the American Medical Association*, 288, 2469-2475.

- Bond, D. S., Digre, K. B., Rubingh, C., Durrant, L., & Baggaley, S. K. (2004). Impact of a self-help intervention on performance of headache management behaviors: A self-efficacy approach. *Internet Journal of Allied Health Sciences and Practice* Retrieved September 25, 2005, from http://ijahsp.nova.edu/articles/Vol2num1/dale_bond_phd.htm
- Braden, C. J., Mishel, M. H., & Longman, A. J. (1998). Self-help intervention project [Electronic Version]. *Cancer practice*, *6*, 87-98.
- Brant, R. (2009). Rollin Brant's home page: Power and sample size calculator. Retrieved February 26, 2009, from <u>http://newton.stat.ubc.ca/~rollin/stats/ssize/</u>
- Canadian tobacco use monitoring survey (CTUMS). (January 19, 2009). Retrieved April 17, 2009, from <u>http://www.hc-sc.gc.ca/hl-vs/tobac-tabac/research-</u>recherche/stat/_ctums-esutc_2008/wave-phase-1_table1-eng.php
- Caudill, M. A. (2002). *Managing pain before it manages you* (Revised ed.). New York: Guilford Press.
- Coleman, K., Austin, B. T., Brach, C., & Wagner, E. H. (2009). Evidence on the Chronic
 Care Model in the new millennium [Electronic version]. *Health Affairs*, 28(1), 75-85.
- De Coster, C., McMillan, S., Brant, R., McGurran, J., & Noseworthy, T. (2007). The western Canada waiting list project: Development of a priority referral score for hip and knee arthroplasty [Electronic version]. *Journal of Evaluation in Clinical Practice*, 13(2), 192-197.
- Diamond, S., Bigal, M. E., Silberstein, S., Loder, E., Reed, M., & Lipton, R. B. (2007). Patterns of diagnosis and acute and preventive treatment for migraine in the

United States: Results from the American migraine prevalence and prevention study. CME [Electronic Version]. *Headache: The Journal of Head and Face Pain, 47*(3), 355-363.

- Eaton, W. W., Muntaner, C., Smith, C., Tien, A., & Ybarra, M. (2004). Centre for
 Epidemiological Studies Depression Scale: Review and revision (CESD and
 CESDR) [Electronic Version]. In M. E. Maruish (Ed.), *The use of psychological testing for treatment planning and outcomes assessment* (Third ed., Vol. 3).
 Mahwah, NJ: Lawrence Erlbaum Associates, Retrieved on July 18, 2006 from
 <u>http://www.mdlogix.com/cesdrpaper.pdf</u>
- French, D. F., Holroyd, K. A., Pinell, C., Malinoski, P. T., O'Donnell, F., & Hill, K. R. (2000). Perceived self-efficacy and headache-related disability [Electronic version]. *Headache: The Journal of Head and Face Pain, 40*, 647-657.
- Gallagher, R., & Kunkel, R. (2003). Migraine medication attributes important for patient compliance: Concerns about side effects may delay treatment [Electronic version]. *Headache: The Journal of Head & Face Pain, 43*, 36-43.
- Haddock, C. K., Rowan, A. B., Andrasik, F., Wilson, P. G., Talcott, G. W., & Stein, R. J. (1997). Home-based behavioral treatments for chronic benign headache: a metaanalysis of controlled trials. *Cephalalgia*, 17(2), 113-118.

Harpole, L. H., Samsa, G. P., Jurgelski, A. E., Shipley, J. L., Bernstein, A., & Matchar,
D. B. (2003). Headache Management Program Improves Outcome for Chronic
Headache [Electronic version]. *Headache: The Journal of Head and Face Pain,*43, 715-724.

- Headache Classification Committee of the International Headache Society. (2004). Classification and diagnostic criteria for headache disorders, cranial neuralgias, and facial pain. *Cephalalgia*, 24(Suppl 1).
- Holroyd, K. A., & Andrasik, F. (1982). Do the effects of cognitive therapy endure? A two-year follow-up of tension headache sufferers treated with cognitive therapy or biofeedback. *Cognitive Therapy and Research*, 6(3), 325-333.
- Holroyd, K. A., Frank, A., & Westbrook, T. (1977). Cognitive control of tension headache. *Cognitive Therapy and Research*, 1, 121-133.
- Hoodin, F., Brines, B. J., Lake, A. E., Wilson, J., & Saper, J. R. (2000). Behavioral selfmanagement in an inpatient headache treatment unit: Increasing adherence and relationship to changes in affective distress [Electronic Version]. *Headache: The Journal of Head and Face Pain, 40*, 377-383.
- Ivers, H., McGrath, P. J., Purdy, R. A., Hennigar, A. W., & Campbell, M.-A. (2000). Decision making in migraine patients taking sumatriptan: An exploratory study [Electronic version]. *Headache: The Journal of Head and Face Pain, 40*, 129-136.
- Jacobson, G. P., Ramadan, N. M., Aggarwal, S. K., & Newman, C. W. (1994). The Henry Ford Hospital headache disability inventory (HDI) [Electronic Version]. *Neurology*, 44, 837-842.
- Jacobson, G. P., Ramadan, N. M., Norris, L., & Newman, C. W. (1995). Headache disability inventory (HDI): Short-term test-retest reliability and spouse perceptions [Electronic Version]. *Headache: The Journal of Head and Face Pain,* 53, 534-539.

- Jensen, M. P., Nielson, W. R., & Kerns, R. D. (2003). Toward the development of a motivational model of pain self-management [Electronic version]. *The Journal of Pain, 4*, 477-492.
- Kawata, A. K., Coeytaux, R. R., DeVellis, R. F., Finkel, A. G., Mann, J. D., & Kahn, K.
 (2005). Psychometric properties of the HIT-6 among patients in a headachespecialty practice. *Headache: The Journal of Head and Face Pain, 45*, 638-643.
- Kosinski, M., Bayliss, M. S., Bjorner, J. B., Ware, J. E., Garber, W. H., Batenhorst, A., et al. (2003). A six-item short-form survey for measuring headache impact: The HIT-6 (TM) [Electronic Version]. *Quality of Life Research*, 12, 963-974.
- Lee, S.-T., Park, J.-H., & Kim, M. (2005). Efficacy of the 5-HT1A agonist, buspirone hydrochloride, in migraineurs with anxiety: A randomized, prospective, parallel group, double-blind, placebo-controlled study. *Headache: The Journal of Head and Face Pain, 45*, 1004-1011.
- LeFort, S. M. (2000). A test of Braden's self-help model in adults with chronic pain [Electronic Version]. *Journal of Nursing Scholarship*, 32, 153-160.
- LeFort, S. M., Gray-Donald, K., Rowat, K. M., & Jeans, M. E. (1998). Randomized controlled trial of a community-based psychoeducational program for the selfmanagement of chronic pain [Electronic Version]. *Pain, 74*, 297-306.
- Lev, E. L., Daley, K. M., Conner, N. E., Reith, M., Fernandez, C., & Owen, S. V. (2002). An intervention to increase quality of life and self-care self-efficacy and decrease symptoms in breast cancer patients. In E. R. Lenz & L. M. Shortridge-Baggett (Eds.), *Self-efficacy in nursing: Research and measurement perspectives* (pp. 95-111). New York, NY: Springer Publishing Company.

- Lipton, R. B., Stewart, W. F., Diamond, S., Diamond, M. L., & Reed, M. (2001b).
 Prevalence and burden of migraine in the United States: Data from the American Migraine Study II [Electronic version]. *Headache: The Journal of Head & Face Pain, 41*, 646-657.
- Lorig, K. (1993). Self-management of chronic illness: A model for the future [Electronic Version]. *Generations*, 17(3), 11-15.
- Lorig, K. (2000). The arthritis helpbook : a tested self-management program for coping with arthritis and fibromyalgia (5th ed.). Cambridge, Mass.: Perseus Books.
- Lorig, K., Chastain, R. L., Ung, E., Shoor, S., & Holman, H. R. (1989). Development and evaluation of a scale to measure perceived self-efficacy in people with arthritis [Electronic version]. Arthritis and Rheumatism, 32, 37-44.
- Lorig, K., & Holman, H. (1993). Arthritis self-management studies: A twelve year review [Electronic version]. *Health Education Quarterly*, 20, 17-28.
- Lorig, K., & Holman, H. (2003). Self-management education: History, definition, outcomes and mechanisms [Electronic version]. Annals of Behavioral Medicine, 26(1), 1-7.
- Lorig, K., Lubeck, D., Krianes, R. G., Seleznick, M., & Holman, H. (1985). Outcomes of self-help education for patients with arthritis [Electronic version]. Arthritis and Rheumatism, 28(6), 680-685.
- Lorig, K., Ritter, P., Laurent, D. D., & Plant, K. (2006). Internet-based chronic disease self-management: A randomized trial [Electronic version]. *Medical Care*, 44, 964-971.

- Lorig, K., Ritter, P., Stewart, A. L., Sobel, D. S., Brown, B. W., Jr., Bandura, A., et al. (2001). Chronic disease self-management program: Two-year health status and health care utilization outcomes [Electronic version]. *Medical Care, 39*, 1217-1223.
- Lorig, K., Sobel, D. S., Stewart, A. L., Brown, B. W., Jr., Bandura, A., Ritter, P., et al. (1999). Evidence suggesting that a chronic disease self-management program can improve health status while reducing hospitalization: A randomized trial [Electronic version]. *Medical Care, 37*(1), 5-14.
- Maes, S., & Karoly, P. (2005). Self-regulation assessment and intervention in physical health and illness: A review [Electronic version]. Applied Psychology: An International Review, 54(2), 267-299.
- Magnusson, J. E., & Becker, W. J. (2002). A comparison of disability and psychological factors in migraine and transformed migraine. *Cephalalgia*, 22, 172-178.
- Magnusson, J. E., Riess, C. M., & Becker, W. J. (2004). Effectiveness of a multidisciplinary treatment program for chronic daily headache. *Canadian Journal of Neurological Science*, 31, 72-79.
- Maizels, M., Saenz, V., & Wirjo, J. (2003). Impact of a group-based model of disease management for headache [Electronic Version]. *Headache: The Journal of Head and Face Pain, 43*, 621-627.
- Marks, R., Allegrante, J. P., & Lorig, K. (2005a). A review and synthesis of research evidence for self-efficacy enhancing interventions for reducing chronic disability:
 Implications for health education practice (Part I) [Electronic Version]. *Health Promotion Practice*, *6*, 37-43.

- Marks, R., Allegrante, J. P., & Lorig, K. (2005b). A review and synthesis of research evidence for self-efficacy enhancing interventions for reducing chronic disability:
 Implications for health education practice (Part II) [Electronic Version]. *Health Promotion Practice*, 6, 148-156.
- Martin, N. J., Holroyd, K. A., & Penzien, D. B. (1990). The headache-specific locus of control scale: Adaptation to recurrent headaches [Electronic version]. *Headache: The Journal of Head and Face Pain, 30*, 729-734.
- Martin, N. J., Holroyd, K. A., & Rokicki, L. A. (1993). The headache self-efficacy scale: Adaptation to recurrent headaches [Electronic version]. *Headache: The Journal of Head and Face Pain, 33*, 244-248.
- McGillion, M. H., LeFort, S. M., & Stinson, J. (2008). Chronic pain self-management. In
 S. Rashiq, D. Schopflocher, P. Taenzer & E. Jonsson (Eds.), *Chronic pain: A health policy perspective*. Edmonton, Alberta, Canada: Wiley-Blackwell.
- McIntyre, R. S., Konarski, J. Z., Wilkins, K., Bouffard, B., Soczynska, J. K., & Kennedy,
 S. H. (2006). The prevalence and impact of migraine headache in bipolar
 disorder: Results from the Canadian Community Health Survey [Electronic
 version]. *Headache: The Journal of Head & Face Pain, 46*(6), 973-982.
- McLean, A., Miller, C., Thompson, D., Schultz, G., Magnusson, J. E., Kinsella, M., et al. (2005). Chronic pain self management group: Calgary Health Region.
- Mitchell, K. R., & White, R. G. (1977). Behavioral self-management: An application to the problem of migraine headaches [Electronic Version]. *Behavior Therapy*, 8, 213-221.

- Molgat, C. V., & Patten, S. B. (2005). Cormobidity of major depression and migraine: A Canadian population-based study [Electronic Version]. *Canadian Journal of Psychiatry*, 50(13), 832-837.
- Morley-Forster, P. K., Clark, A. J., Speechley, M., & Moulin, D. E. (2003). Attitudes toward opioid use for chronic pain: A Canadian physician survey. *Pain Research & Management.*, 8(4), 189-194.
- Nash, J. M., Park, E. R., Walker, B. B., Gordon, N., & Nicholson, R. A. (2004).
 Cognitive-behavioral group treatment for disabling headache [Electronic version].
 Pain Medicine, 5, 178-186.
- Nash, J. M., Williams, D. M., Nicholson, R. A., & Trask, P. C. (2006). The contribution of pain-related anxiety to disability from headache [Electronic version]. *Journal* of Behavioral Medicine, 29(1), 61-67.
- Newman, A. M. (2006). Self-Efficacy. In I. M. Lubkin & P. D. Larson (Eds.), Chronic illness: Impact and interventions (Vol. 6, pp. 105-120). Sudbury, MA: Jones and Bartlett.
- Nicholson, R. A., Houle, T. T., Rhudy, J. L., & Norton, P. J. (2007). Psychological risk factors in headache. CME [Electronic Version]. *Headache: The Journal of Head and Face Pain, 47*, 413-426.
- Nicholson, R. A., Nash, J., & Andrasik, F. (2005). A self-administered behavioural intervention using tailored messages for migraine [Electronic version]. *Headache: The Journal of Head and Face Pain, 45*, 1124-1139.

- O'Brien, B., Goeree, R., & Streiner, D. (1994). Prevalence of migraine headache in Canada: A population-based survey [Electronic version]. International Journal of Epidemiology, 23, 1020-1026.
- Penzien, D. B., Andrasik, F., Freidenberg, B. M., Houle, T. T., Lake, A. E., Lipchik, G.
 L., et al. (2005). Guidelines for trials of behavioural treatments for recurrent headache, first edition: American headache society behavioral clinical trials workgroup [Electronic Version]. *Headache: The Journal of Head and Face Pain,* 45(s2), S110-S132.
- Penzien, D. B., Rains, J. C., & Andrasik, F. (2002). Behavioural management of recurrent headache: Three decades of experience and empiricism. *Applied Psychophysiology and Biofeedback*, 27, 163-181.
- Penzien, D. B., Rains, J. C., Lipchik, G. L., & Creer, T. L. (2004). Behavioral interventions for tension-type headache: Overview of current therapies and recommendation for a self-management model for chronic headache [Electronic version]. Current Pain and Headache Reports, 8, 489-499.
- Penzien, D. B., Rains, J. C., Lipchik, G. L., Nicholson, R. A., Lake, A. E., & Hursey, K.
 G. (2005). Future directions in behavioural headache research: Applications for an evolving health care environment [Electronic version]. *Headache*, 45(5), 526-534.

Peters, M., Huijer Abu-Saad, H., Vydelingum, V., Dawson, A., & Murphy, M. (2004).
Migraine and chronic daily headache management: A qualitative study of patients' perceptions [Electronic Version]. *Scandinavian Journal of Caring Science, 18*, 294-303.

- Pikoff, H. B. (2004). Complementary headache therapy: A closer look at the treatments and the evidence. Buffalo, NY: Data for Decisions.
- Polit, D. (1996). *Data analysis and statistics for nursing research*. Upper Saddle River: Prentice Hall.
- Polit, D., & Beck, C. T. (2004). Nursing research: Principles and Methods (7 ed.).Philadelphia: Lippincott, Williams and Wilkins.
- Prior, K. N., & Bond, M. J. (2004). The roles of self-efficacy and abnormal illness behavior in osteoarthritis self-management [Electronic version]. *Psychology Health and Medicine*, 9(2), 177-192.
- Prochaska, J. O., DiClemente, C. C., & Norcross, J. C. (1992). In search of how people change: Applications to addictive behaviors [Electronic version]. American Psychologist, 47, 1102-1114.
- Rahman, A., Ambler, G., Underwood, M. R., & Shipley, M. E. (2004). Important determinants of self-efficacy in patients with chronic musculoskeletal pain [Electronic Version]. *The Journal of Rheumatology*, *31*, 1187-1192.
- Rains, J. C., Lipchik, G. L., & Penzien, D. B. (2006a). Behavioral facilitation of medical treatment for headache-Part I: Review of headache treatment compliance
 [Electronic Version]. *Headache: The Journal of Head and Face Pain, 46*(9), 1387-1394.
- Rains, J. C., Penzien, D. B., & Lipchik, G. L. (2006b). Behavioral facilitation of medical treatment for headache-Part II: Theoretical models and behavioral strategies for improving adherence [Electronic Version]. *Headache: The Journal of Head and Face Pain, 46*(9), 1395-1403.

- Rains, J. C., Penzien, D. B., McCrory, D. C., & Gray, R. N. (2005). Behavioral headache treatment: History, review of the empirical literature, and methodological critique [Electronic Version]. *Headache: The Journal of Head and Face Pain, 45*(s2), S92-S109.
- Rankin, J. A. (1998). Determinants of participation in an arthritis self management program. University of Calgary, Calgary.
- Rothrock, J. F., Parada, V. A., Sims, C., Key, K., Walters, N. S., & Zweifler, R. M.
 (2006). The impact of intensive patient education on clinical outcome in a clinicbased migraine population [Electronic Version]. *Headache: The Journal of Head* and Face Pain, 46(5), 726-731.
- Rowan, A. B., & Andrasik, F. (1996). Efficacy and cost-effectiveness of minimal therapist contact treatments of chronic headaches: A review [Electronic version]. *Behavior Therapy*, 27, 207-234.
- Sauro, K., & Becker, W. J. (2008). Multidisciplinary treatment for headache in a Canadian healthcare setting [Electronic version]. *Canadian Journal of Neurological Science*, 35, 46-56.
- Scharff, L., Turk, D. C., & Marcus, D. A. (1995). The relationship of locus of control and psychosocial-behavioral response in chronic headache [Electronic version]. *Headache: The Journal of Head and Face Pain, 35*, 527-533.
- Schwartz, B. S., Stewart, W. F., Simon, D., & Lipton, R. B. (1998). Epidemiology of tension-type headache [Electronic version]. JAMA, 279, 381-383.
- Siniatchkin, M., Riabus, M., & Hasenburg, M. (1999). Coping styles of headache sufferers [Electronic Version]. *Cephalalgia*, 19, 165-173.

Strine, T. W., Chapman, D. P., & Balluz, L. S. (2006). Population-based U.S. study of severe headaches in adults: Psychological distress and comorbidities. CME [Electronic Version]. *Headache: The Journal of Head and Face Pain, 46*(2), 223-232.

Tarjan, R. (2008). Crunching the numbers. Info Nursing, 39(2), 5-5.

The GlaxoSmithKline Group of Companies. (2001). Headache impact test: How much are headaches disrupting your life? [Pamphlet]: QualityMetric Inc.

Tillett, L. A. (1998). The health promotion model. In A. M. Tomey & M. R. Alligood (Eds.), *Nursing theorists and their work* (4th ed., pp. 529-537). St. Louis: Mosby.

- van der Bijl, J., & Shortridge-Baggett, L. M. (2002). The theory and measurement of the self-efficacy construct. In E. R. Lenz & L. M. Shortridge-Baggett (Eds.), Selfefficacy in nursing: Research and measurement perspectives (pp. 9-27). New York, NY: Springer Publishing Company, Inc.
- Von Korff, M., Moore, J., Lorig, K., Cherkin, D., Saunders, K., Gonzalez, V., et al.
 (1998). A randomized trial of a lay person-led self-management group intervention for back pain patients in primary care [Electronic version]. *Spine, 23*, 2608-2615.
- Wells-Federman, C., Arnstein, P., & Caudill, M. (2002). Nurse-led pain management program: Effect on self-efficacy, pain intensity, pain-related disability, and depressive symptoms in chronic pain patients. *Pain Management Nursing*, 3(4), 131-140.

APPENDIX A: HMSE

Instructions: You will find below a number of statements related to headaches. Please read each statement carefully and indicate how much you agree or disagree with the statement by circling a number next to it. Use the following scale as a guide:

.

	Strongly Disagree	Moderately Disagree	Slightly Disagree	Neither Agree Nor Disagree	Slightly Agree	Moderately Agree	Stron Agr	igly ee
	1	2	3	4	5	6	7	
•	<u></u> , , , , , ,, ,,,,							
	1) I can keep	o even a <i>bad</i> he	adache from	disrupting my day				
	by changi	ng the way I re	spond to the I	pain.		12	3 4 5	67
	2) When I'm	n in some situat	tions, nothing	I do will prevent h	eadaches.	1 2	3 4 5	67
	3) I can redu	ice the intensity	y of a headach	e by relaxing.		12	345	67
	4) There are	things I can do	to reduce he	adache pain.		1 2	345	67
	5) I can prevent headaches by recognizing headache triggers.					12	345	67
	6) Once I ha	ive a headache	there is nothin	ng I can do to contr	ol it.	1 2	345	67
	7) When I'm tense, I can prevent headaches by controlling the tension.						345	67
	8) Nothing I do reduces the pain of a headache.					1 2	345	67
	9) If I do cer	rtain things eve	ry day,					
	I can redu	ice the number	of headaches	I will have.		1 2	345	67
	10) If I can	catch a headach	ie before it be	gins, I often can sto	op it.	1 2	345	67
	11) Nothing	I do will keep	a mild headad	the from turning int	to a bad hea	dache. 12	345	67
	12) I can pre	event headache	s by changing	how I respond to s	tress.	1 2	345	67
	13) I can do	things to contr	ol how much	my headaches inter	fere with m	y life. 1 2	345	67
	14) I cannot	control the ten	sion that caus	es my headaches.		12	345	67
	15) I can do	things that wil	l control how	long a headache la	sts.	12	345	67
	16) Nothing	I do will keep	a bad headacl	ne from disrupting	my day.	12	345	67
	17) When I'	m not under a l	lot of stress, I	can prevent many l	headaches.	12	345	67

1	2	3	4	5	6	7
1	2	3	4	5	6	7
1	2	3	4	5	6	7
1	2	3	4	5	6	7
1	2	3	4	5	6	7
1	2	3	4	5	6	7
1	2	3	4	5	6	7
1	2	3	4	5	б	7
	1 1 1 1 1 1 1	1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2	1 2 3 1 2 3	1 2 3 4 1 2 3 4	1 2 3 4 5 $1 2 3 4 5$ $1 2 3 4 5$ $1 2 3 4 5$ $1 2 3 4 5$ $1 2 3 4 5$ $1 2 3 4 5$ $1 2 3 4 5$ $1 2 3 4 5$ $1 2 3 4 5$	1 2 3 4 5 6 1 2 3 4 5 6 1 2 3 4 5 6 1 2 3 4 5 6 1 2 3 4 5 6 1 2 3 4 5 6 1 2 3 4 5 6 1 2 3 4 5 6 1 2 3 4 5 6 1 2 3 4 5 6 1 2 3 4 5 6

Scoring and Interpretation

The total possible score on the HMSE can range from 25-175. Lower scores indicate lower headache self-efficacy and higher scores indicate higher headache self-efficacy. Items 2, 6, 8, 11, 14, 16, 18, 20, 23 are reverse scored.

APPENDIX B: CESD-R

Below is a list of the ways you might have felt or behaved. Please fill in the circles to tell us how often you have felt this way in the past week or so.

this way in the past week or so.	LAST WEEK				NEARLY EVERY	
My appetite was poor	Not at all OR Less than 1 day	days	3-4 days	5-7 days	DAY FOR 2 WEEKS	
I could not shake off the blues	O	0	0	0	0	
I had trouble keeping my mind on what I was doing	O	0	0	0	0	
I felt depressed	0	0	0	0	0	
My sleep was restless	0	0	0	0	0	
I felt sad	0	0	0	0	0	
I could not get going	0	0	0	0	0	
Nothing made me happy	O	0	0	0	0	
I felt like a bad person	O	0	0	0	0	
I lost interest in my usual activities	O	0	0	0	0	
I slept much more than usual	0	0	0	0	0	
I felt like I was moving too slowly	O	0	0	0	0	
I felt fidgety	0	0	0	0	0	
I wished I were dead	0	0	0	0	0	
I wanted to hurt myself	0	0	0	0	0	
I was tired all the time	O	0	0	0	0	
I did not like myself	0	0	0	0	0	
I lost a lot of weight without trying to	O	0	0	0	0	
I had trouble getting to sleep	O	0	0	0	0	
I could not focus on important things	0	0	0	0	0	

Scoring and Interpretation

Scoring for the CESD-R; zero for answers in the first column, one for answers in the second column, two for answers in the third column, three for answers in the fourth column, four for answers in the fifth column. The possible range of scores is from 0-80, with the higher scores indicating the presence of more symptomatology.

.

APPENDIX C: HDI

HDI

Please fill in the most appropriate response:

		1 time per month	More than 1 time but less than 4 times per month	More than 1 per week
•	I have a headache	0	0	0
		Mild	Moderate	Severe
•	My headache is	0	0	0

The purpose of these questions is to identify difficulties that you may be experiencing because of your headaches. Please answer "Yes", "Sometimes", or "No" to each item (do not fill in responses in shaded areas) as it pertains to your headaches only.

	Yes	Emotional Sometime	l s No	Yes	Functiona	al Is No
Because of my headaches I feel handicapped.	0	0	0			
Because of my headaches I feel restricted in performing my routine daily activities.				0	0	0
No one understands the effect my headaches have on my life.	0	0	0			
I restrict my recreational activities (e.g. sports, hobbies) because of my headaches.				0	0	0
My headaches make me angry.	0	0	0			
Sometimes I feel that I am going to lose control because of my headaches.	0	0	0			
Because of my headaches I am less likely to socialize.				0	0	0

· · ·



My headaches make me feel frustrated.	0	0	Ο			
I find it difficult to read because of my headaches.				0	0	0
I find it difficult to focus my attention away from my headaches and on to other things.				0	0	0

Scoring and Interpretation

For each item, "yes" is scored at four points, "sometimes" is scored at two points and "no" is scored at zero points for a possible range in scores of 0-100. Scores are interpreted such that lower scores indicate mild disability, and higher scores indicate more severe disability.

APPENDIX D: HIT-6

HIT6	***********	

1. When you have headaches, how often is the pain severe?

0	0	0	0	0
Never	Rarely	Sometimes	Very often	Always

2. How often do headaches limit your ability to do usual daily activities including household work, work, school, or social activities?

0	0	0	0	0
Never	Rarely	Sometimes	Very often	Always

3. When you have a headache, how often do you wish you could lie down?

0 0		0	0	0
Never	Rarely	Sometimes	Very often	Always

4. In the past 4 weeks, how often have you felt too tired to do work or daily activities because of your headaches?

0 0		0	0	0
Never	Rarely	Sometimes	Very often	Always

5. In the past 4 weeks, how often have you felt fed up or irritated because of your headaches?

0	0	0	0	0
Never	Rarely	Sometimes	Very often	Always

6. In the past 4 weeks, how often did headaches limit your ability to concentrate on work or daily activities?

0	0	0	0	0
Never	Rarely	Sometimes	Very often	Always

Scoring and Interpretation

A five-point scale is used for scoring (never = 6 points, rarely = 8, sometimes = 10, very often = 11, always = 13). The possible range in total scores is 36-78. Scores are interpreted such that a score of 49 or less indicates little or no headache impact, 50-55 indicates some headache impact, 56-59 indicates substantial headache impact, and 60 or more indicates severe headache impact.

APPENDIX E: HEADACHE PAIN, PAIN AND WORK, AND WORKSHOP

ATTENDANCE

					P	ain				
* if yo pain.	u have	only fa	ace or n	ieck pai	n, answ	ver the o	questio	ns with	regar	ds to that
In the	past m	onth, or	n how m	any day	rs did yc	u have	a heada	che? →		
On av	erage,	how sev	vere we	re these	headad	nes? (0	=No Pa	in; 10=S	severe	Pain)
O 0 No Pain	O 1	0 2	O 3	O 4	O 5	0 6	0 7	0 8	0 9	O 10 Worst Possible
In the	past m	ionth, h	ow seve	ere was	the WO	RST he	adache	you had	? (0=N	lo Pain;
O 0 No Pain	O 1	0 2	O 3	O 4	O 5	O 6	0 7	O 8	0 9	O 10 Worst Possible F
In the	past m	i onth , w	/hat is th	ne LEAS	ST amou	unt of he	adache (<i>0=No F</i>	you ha∖ Pain: 10=	ve had =Seve	? (If you h re <i>Pain</i>)
O 0 No Pain	0 1	0 2	0 3	0 4	0 5	0 6	0 7	0 8	0 9	O 10 Worst Possible F
How n	nuch h	eadache	e are yo	u having	y right r	10w? (0	=No Pai	n; 10=S	evere	Pain)
O 0 No Pain	0 1	0 2	0 3	0 4	0 5	0 6	0 7	0 8	9 9	O 10 Worst Possible F
In the	past m	onth, h	ow muc	h suffer	ing did y	vou expe	erience I	pecause	of you	ur headacl
0 No Suffer	O 1 ina	0 2	O 3	O 4	O 5	O 6	0 7	0 8	0 9 Pos	O 10 Worst ssible Suff

			Pain and W	/ork		
1. Are you	currently wo	rking? *lf	you answer NO ,	please proceed	to question 6	
	0 0)				
if VES nia	Ves N see indicate:	0				
n 123 , pie			Hours worke	d ner week:		
	Full-time		riours worke	d per week.		
	0		Hours worke	d per week:		
	Part-time					
What type	of work do y	ou do?				
2. Do vou (do shift work	?				
- ,	0 ()				
	Yes N	10				
lf YES , brie	efly describe	your usua	al shift schedule:			
3. If you a your ability O Never	re currently to do your w O Rare	working ork to you	, how often does ur satisfaction (w O Occasionally	your headache hile at work)? O Frequently	e disorder interfe O Always	ere with
4. If you headaches	are curren ?	tly worki	ng , do you mi	ss time from v	work because	of you
	0 ()				
	Yes N	10				
If Yes , plea headache	ase estimate ->	the numb	per of days per m	ionth of work yo	u miss because	of you
5. Are ther	re/where the	re factors	in your work en	vironment that y	vou feel contribu	te(d) to
your neade	$\bigcap^{1} \mathcal{O} $	7				
	Yes N	J0				
lf Yes , plea	ase list contri	buting fac	ctors:			
lf Yes , plea	Yes N Ase list contri) lo buting fac	stors:			
6. If you ar	e currently i Unable to wo	n ot worki ork and/or	ng, please indication on disability bec	ate the reason: ause of beadach	165	
	Inable to we	ork and/or	on disability bec	ause of other he	alth condition	,
	Dotirod		on disability bec			
(pla	UNUER Dase indicate					١
7. Please i	ndicate wher	ı you last	worked:		Month	/ Year

	Work Shops Attended						
1. Which of the following workshops have you attended to date in the CHAMP program?							
	O Self-Management O Relaxation O Body Works	O Sleep O None					
Other							
2. Which of the following lectures have you attended?							
	 O Managing Migraines in the Workplace O Ergonomics 101 O Stress and Health O Supporting Those with Migraine 	O Pace Yourself O Migraine Triggers: A Close O None	r Look				
Other							

3. Have you attended a self-management program outside of CHAMP (i.e. Row Your Own Boat or Chronic Pain Self-Management Group, at the Living Well Program) since completing the first study questionnaire at the Assessment and Education Session?

O O Yes No

11. Please list any changes that may have been made to your headache management routine since attending the A and E session (e.g. any medication changes made by your family physician, visits to other medical specialists, or initiation of physical therapy).



APPENDIX F: ETHICAL APPROVAL LETTER



2006-11-21

For Katon L. Then Faculty of Nursing PF 2228. Curvanity of Calgary Calgary, Alberta

Dear Dr. Thea:

RE: Solf-Efficacy in Hendeche Management: A Queal-Experiment

.....

Effics 1D; E-20384

Student: Suzanne M Baslak

The above-noted preprical including the Research Proposal, Consent Form (Version 1 dated July 08, 2006) has been submitted for Board review and found to be efficiently acceptable.

Ploase note that this appreval is subject to the following conditions:

- Please note that a the apprevants surgered to the removing conditions: (1) appropriate procedures for rought for access to identifier health information have been approved; (2) a copy of the university outside turn must have been given to each research subject, if required for this study; (3) a Progress Report must be substitled by howember **21, 2007**, containing the following information:
- the number of subjects (continuity

 - iii a description of any previousl modificance;
 - ary unisual and/or severo complications, advorse events or onansicipated problems in volving risks to subjects or others, withdrawal of subjects fingt the research, or ecuplaints about the research;
 - a commany of any recent literature, finding, we sher relevant information, especially information about risks associated with the iv) research: v)
 - a copy of the current informed consent form;
- vi) the superior date of termination of this project,
 4) a Final Report must be submitted at the termination of the project.

Please note that you have been assured as the principal collaborator on this study because subjects are not permitted to surve as principal investigators light account & Board's best wishes for success in your research.

YOURS SPACE

Menze-Gordförlich, BACHousi, LI N, PhD Chan, Comjoint Health Research Ethios Board

GGioucy e.c. Arhilt Research Committee សារដែល Office of Information & Privacy Commissioner

Rescards Services

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Dr. .S. Evons(leformation)

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OFFICE OF MEDICAL BIOETHICS Room 93, Heritage Modical Rasearch Bldg

3330 Hospital Crive NW

Calgary, AB, Canada IVN 4N1 Telephone: (403) 220-7390 Fax: (403) 269-6524 Email: omb@ucelgary.ca

APPENDIX G: PERMISSION LETTER





Calgary Headache Assessment and Management Program (CHAMP) Part of the Regional Pain Program Foothills Medical Centre 12th Floor, Ambulatory Neurosciences 1403 – 29th Street N.W. Calgary, Alberta T2N 2T9 403-944-2826 Phone: 403-283-2270 Fax:

Neurologists W. J. Becker* A. G. Eloff K. D. Busche J. Kohli * *denotes professional corporation*

August 1st, 2006

602 South Tower

Foothills Medical Centre 1403 – 29th Street N.W.

Calgary, Alberta T2N 2T9

Fellow

L. J. Cooke Clerk

Nurse Coordinator I. O'Callaghan

Nurse P. Barnes

I. Hayden

To Whom It May Concern:

access to instruments collected by CHAMP.

Centre for Advancement of Health

Self-Efficacy in Headache Management: A Quasi-experiment Re:

I grant Suzanne Basiuk permission to approach CHAMP clients at the Program

Assessment and Education Session to participate in thesis research and to have

Occupational Therapists A. McLean K. Coutts

Psychologist J. Cathcart

Secretary M, Debnam

J. Berke

Research Coordinator **B.** Kelly-Besler

W.J. Becker, M.D., FRCPC

WJB/mad

Yours truly,

cc: Suzanne Basiuk

APPENDIX G: PERMISSION LETTER

Calgary Headache Assessment and Management Program (CHAMP) NURSITY OF Part of the Regional Pain Program 🖌 calgary health region Foothills Medical Centre 12th Floor, Ambulatory Neurosciences 1403 – 29th Street N.W. Calgary, Alberta T2N 2T9 Phone: 403-944-2826 Fax: 403-283-2.270 Neurologists W. J. Becker* A. G. Eloff K. D. Busche J. Kohli * *denotes professional* August 1st, 2006 corporation Centre for Advancement of Health 602 South Tower Fellow L. J. Cooke **Foothills Medical Centre** 1403 – 29th Street N.W. Calgary, Alberta T2N 2T9 Clerk 1. Hayden Nurse Coordinator I, O'Calfaghan To Whom It May Concern: Nurse Re: Self-Efficacy in Headache Management: A Quasi-experiment P. Barnes Occupational Therapists A. McLean K. Coutts I grant Suzanne Basiuk permission to approach CHAMP clients at the Program Assessment and Education Session to participate in thesis research and to have access to instruments collected by CHAMP. Psychologist J. Cathcart Yours truly, Secretary M. Debnam . **Research** Coordinator W.J. Becker, M.D., FRCPC B. Kelly-Besler WJB/mad cc: Suzanne Basiuk

APPENDIX H: CONSENT FORM

TITLE: Self-Efficacy in Headache Management: A Quasi-experiment

SPONSOR: University of Calgary

INVESTIGATORS: Dr. Karen Then, ACNP, PhD, CCN(C) (Supervisor) Ms. Suzanne Basiuk, RN, BN, CNN(C) (Master's Thesis Student)

This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information. You will receive a copy of this form.

BACKGROUND

This study is part of the investigator's master's thesis in nursing. The goal of this research is to gain a better understanding of what headache sufferers do to manage their pain, while they are waiting to see a headache neurologist.

The Calgary Headache Assessment and Management Program (CHAMP) has created a treatment program that encourages clients to learn more about headache management, and consider making lifestyle changes, while waiting for the neurologist appointment. Some clients are able to make important changes that improve headache pain and reduce headache disability during this time period.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to gain a better understanding of how and why headache sufferers decide to participate in headache self-management behaviors. Self-management behaviors might include, paying attention to your headache triggers, initiating an exercise program or changing how you think about the headaches.

WHAT WOULD I HAVE TO DO?

You will be asked to complete two questionnaires.

- The first questionnaire will be given to you to complete at the CHAMP Program Assessment and Education Session
- The second questionnaire will be given to you to complete on the same day as your first visit with the CHAMP neurologist.

Each questionnaire will take about 30 minutes to complete and will ask you several questions about the ways in which you think about and manage your headaches.

APPENDIX H: CONSENT FORM

RISKS AND BENEFITS

Some of the items in the questionnaire related to coping with pain can bring on an emotional reaction in some clients. If you feel you need to discuss your responses to any of the questions, or if you feel you are at risk, the researcher and/or the CHAMP psychologist will be available to talk with you.

If you agree to participate in this study there may or may not be a direct benefit to you. Your headaches may be improved during the study but there is no guarantee that this research will help you. The information we get from this study will help us in the future for patients with chronic headache.

WHAT DOES MY PARTICIPATION INVOLVE?

Participation in this study is completely voluntary and you may withdraw from the study at any time without jeopardizing your health care.

If new information becomes available that might affect your willingness to participate in the study, you will be informed as soon as possible.

Your participation is limited to completing the two questionnaires mentioned earlier. The investigator will also be using demographic and headache data from a number of tools already collected by CHAMP at the Program Assessment and Education Session.

There is <u>no payment</u> or <u>cost</u> involved in participation in this study. Questionnaires will be completed on the same day that you will be attending other CHAMP appointments.

WILL MY RECORDS BE KEPT PRIVATE?

The data collected will be stored in an electronic format that will have no names or personal identification numbers attached. Electronic files will be on a secure computer at the University of Calgary, accessible only to Dr. Karen Then and Ms. Suzanne Basiuk.

APPENDIX H: CONSENT FORM

SIGNATURES

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the investigators, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care. If you have further questions concerning matters related to this research, please contact:

Dr. Karen Then (403) 220-8542

Or

Ms. Suzanne Basiuk (403) 560-9677

If you have any questions concerning your rights as a possible participant in this research, please contact the Associate Director, Internal Awards, Research Services, University of Calgary, at 220-3782.

Participant's Name

Signature and Date

Investigator/Delegate's Name

Signature and Date

Witness' Name

Signature and Date

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

A signed copy of this consent form has been given to you to keep for your records and reference.