EMPOWERING PATIENTS WITH PERSISTENT PAIN USING AN INTERNET-BASED SELF-MANAGEMENT PROGRAM

By

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Abstract

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New strategies are needed to improve care for patients with persistent pain. Biopsychosocial models for pain treatments are effective, yet remain inaccessible, particularly for patients with limited resources and from communities lacking specialized pain services. Prior research suggests that self-management programs can improve pain experiences. Less is known about how programs can be accessed using computer technology and whether patients who receive opioids can engage in them and find benefit.

The purpose of this randomized controlled study was to investigate an 8-week Internet-based self-management program among patients with persistent pain who are prescribed opioid medication. The program, Goalistics Chronic Pain Management Program (CPMP), consists of online self-directed learning modules that focus on cognitive, behavioral, social, and emotional regulation (Ruehlman, Karoly, & Enders, 2011). The intervention was tested within the conceptual framework provided by Ryan and Sawin’s Individual and Family Self-Management Theory (2009). Patients were recruited from primary care clinics and Internet sites, then
randomly assigned to treatment (n = 45) or treatment as usual wait list group (n = 47). The primary aim was to evaluate the effect of the program on self-reported pain intensity and pain interference using the Brief Pain Inventory. Secondary outcomes were measured with the Patient Health Questionnaire (PHQ-8) for depressive symptoms, the Current Opioid Misuse Measure (COMM), the Pain Self-efficacy Questionnaire (PSEQ), and the Patient Global Impression of Change (PGIC). Included were participant reports of nonpharmacologic therapies incorporated and program satisfaction.

Significant improvements were observed for pain self-efficacy and current opioid misuse in the treatment group using data collected from bi-weekly online surveys. Number Needed to Treat analysis found a 2 point decrease in pain intensity achieved by 18% of treatment group members compared to 6% of those in the comparison group. Therefore, 8 people would need to be treated with the CPMP to achieve clinically meaningful improvement in pain intensity within 8 weeks. Depressive symptoms significantly improved for all participants. Program satisfaction was high and most comments suggested increased guidance and instruction to improve future participation. Engagement level varied and was positively associated with improvements in pain intensity, pain interference, and pain self-efficacy.
# TABLE OF CONTENTS

ACKNOWLEDGEMENTS ........................................................................................................ iii

ABSTRACT ............................................................................................................................. v

LIST OF TABLES .................................................................................................................... x

LIST OF FIGURES ................................................................................................................ xii

DEDICATION ........................................................................................................................ xiii

CHAPTER

1. INTRODUCTION ............................................................................................................ 1
   Statement of the Problem ............................................................................................. 3
   Background and Significance ......................................................................................... 4
   Purpose and Specific Aims ............................................................................................. 6
   Summary ......................................................................................................................... 7

2. REVIEW OF THE LITERATURE ................................................................................. 9
   Definitions ......................................................................................................................... 9
   Physiology of Pain ........................................................................................................... 11
   Pain Treatments .............................................................................................................. 15
   Pain Impacts .................................................................................................................... 20
   Theory of Self-efficacy ..................................................................................................... 23
   Theory of Self-management ........................................................................................... 30
   Pilot Study ....................................................................................................................... 37
   Chronic Pain Management Program Intervention ....................................................... 38

3. RESEARCH DESIGN AND METHODS .................................................................. 41
D. INSTRUMENTS........................................................................................................157
   Brief Pain Inventory (BPI)......................................................................................157
   Personal Health Questionnaire (PHQ-9)..............................................................159
   Patient Global Impression of Change (PGIC)....................................................161
   Current Opioid Misuse Measure (COMM).........................................................162
   Pain Self-efficacy Questionnaire (PSEQ)............................................................166
   Demographic Survey ...........................................................................................168
   Medication Inventory 1 and 2.............................................................................169
   Bi-weekly Health Care Utilization Survey ........................................................171
   Computer Usability Satisfaction Survey............................................................173
E. GUIDED SCRIPT FOR STUDY PARTICIPATION .............................................174
F. PERMISSIONS.....................................................................................................178
LIST OF TABLES

1. Measurement Timeline for Treatment and Treatment As Usual Groups ..........56
2. Pain Diagnoses Summary ..............................................................................73
3. Descriptive Statistics for Demographic Characteristics and Baseline Outcomes
   Measurement Scores with Cronbach’s Alpha ..............................................74
4. Most Frequently Prescribed Medications from Participant Baseline Self-report.. 76
5. Mean Scores for Primary and Secondary Outcomes Measurements ..............79
6. Mean and Standard Deviations for BPI Pain Intensity Items at Baseline and
   Posttest for Treatment and Treatment As Usual Groups .................................80
7. Number Needed to Treat Analysis Results for BPI Pain Intensity and Pain
   Interference ......................................................................................................84
8. Highest Rated COMM Items at Baseline and Posttest Indicating Self-reported
   Aberrant Medication-related Behaviors .........................................................89
   Activities .........................................................................................................92
    Program Engagement Levels and Positive Change Scores for Dependent
    Variables .........................................................................................................92
11. Analysis of Engagement Category Levels as a Predictor for Outcomes Variables
    by Linear Regression .......................................................................................93
12. Summary of Bi-weekly Survey Responses Regarding Medication Use and
    Behavioral Changes in Treatment and Treatment As Usual Participants ..........94
13. Most Frequently Reported New Behaviors to Control Pain Reported by Treatment and Treatment As Usual Participants .................................................................96
14. Summative Program Evaluation Survey Results Using the IBM Computer Usability Satisfaction Questionnaire.................................................................97
15. One-way ANOVA Results for Treatment As Usual Group Group after Engaging in the Chronic Pain Management Program.................................................99
LIST OF FIGURES

1. Social Cognitive Theory model of relations between the three classes of determinants in Bandura’s (1986) conception of triadic reciprocity ..................28
3. Sample communication to primary care provider of pain and depressive symptoms at week 8 time point .................................................................58
4. Participant flow diagram ..................................................................................72
5. Brief Pain Inventory pain intensity mean scores for treatment and treatment as usual groups at baseline and posttest .........................................................78
6. Brief Pain Inventory interference mean scores for treatment and treatment as usual groups at baseline and posttest ............................................................82
7. Brief Pain Inventory pain interference with affect and activity mean scores for treatment and treatment as usual groups at baseline and posttest ..................83
8. Patient Health Questionnaire mean depressive symptom severity scores for treatment and treatment as usual groups at baseline and posttest .......................86
9. Patient Self-efficacy Questionnaire mean scores for treatment and treatment as usual groups at baseline and posttest ..........................................................87
10. Current Opioid Misuse Measure mean scores for treatment and treatment as usual groups at baseline and posttest ..............................................................89
11. Patient Global Impression of Change mean scores for treatment and treatment as usual groups at baseline and posttest ......................................................90
Dedication

This dissertation is dedicated to my mother, Tekla Hallanan (1936-2010), who taught that, “If you can read, you can cook.” Her reverence for the written word benefitted me from the first book she taught me to read, through my recent doctoral studies.

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CHAPTER ONE
INTRODUCTION

The annual cost of persistent (or chronic) pain in the U.S. is estimated at $600 billion (Institute of Medicine [IOM], 2011). Poorly managed pain leads to lost income and reduced productivity at work and at home (National Institutes of Health & National Library of Medicine, 2011). On any given day, an estimated 116 million U.S. adults are affected by persistent pain symptoms (IOM, 2011) with one in ten reporting suffering with pain that lasts more than a year (Centers for Disease Control [CDC], 2006). In comparison to other chronic conditions, persistent pain affects more Americans than diabetes, heart disease and cancer combined (American Pain Foundation, 2008).

Persistent pain is defined by the International Association for the Study of Pain as “pain that persists beyond normal tissue healing time, which is assumed to be three months” (Chou et al. and American Pain Society–American Academy of Pain Medicine Opioids Guidelines Panel, 2009a). Poorly managed persistent pain impedes physical and mental functioning, social roles, work productivity, and financial stability for patients and their families (IOM, 2011). Untreated pain drives up health care costs with unplanned emergency and clinic visits. Pain is the leading reason that Americans seek emergency care (CDC, 2010). An estimated 40% of all emergency department (ED) visits for pain have been attributed to the patients with persistent pain (Todd, Cowan, Kelly, & Homel, 2010). Some of these costs might be reduced if pain was better understood and properly treated (Schim & Stang, 2004).

Pain is a complex experience that combines biological, psychological, and environmental components (Turk & Wilson, 2010). Gaps in policy, treatment, education and research have resulted in shortfalls in pain care (IOM, 2011). Behavioral and cognitive therapies have been
well-established as effective components of multidisciplinary pain treatment approaches (Glombiewski, Hartwich-Tersek, & Rief, 2010; Macea, Gajos, Calil, & Fregni, 2010). Yet patients are most often exposed to pharmacological interventions aligning with a biomedical model (Alm & Norbergh, 2010). A biomedical model assumes that disease can be solely explained by measureable biological variables; it aims to correct the malfunction and cure the disease (Engel, 1977). It fails to recognize that numerous psychosocial factors contribute to the experience of pain and disability (Turk & Okifuji, 2002). A biopsychosocial approach to pain care is ideal for addressing the complexity of persistent pain, yet difficult to establish due to organizational, educational, and financial barriers (IOM, 2011). Most medical schools do not include comprehensive pain management instruction and emergency department pain care generally consists of prescribing medicine (Motov & Khan, 2009). Providers are biased towards offering opioids for treatment in the emergency department as the singular intervention, yet pain relief is often inadequate, delayed and does not meet patients’ expectations (Motov & Khan, 2009). Little research evidence supports opioids as providing a lasting solution for patients with persisting pain conditions (Manchikanti et al., 2011).

Significant concern in pain care is the rising use of prescription drugs over the last decade, and also a rise in unintended deaths (CDC, 2011a). Overdose from prescription painkillers has reached an epidemic proportion in the United States according to the CDC. Of 20,044 prescription drug overdose deaths in 2008, about 14,800 (73.8%) involved an opioid analgesic; an increase of more than 300% since 1999 (CDC, 2011a). Rural and impoverished counties are found to have higher prescription drug overdose death rates (CDC,2011a). The rise in deaths parallels the total population sales of opioids that has risen from 98 mg/person in 1999 to 698mg/person in 2007; equating to enough for every American to take 5 mg of Vicodin every
4 hours for a month (CDC, 2011a). Since the mid-1990s, the amount of opioids prescribed has steadily increased and coincides with national efforts to improve the quality of pain control (Pletcher, Kirtesz, Kohn, & Gonzales, 2008).

The increased availability of opioid analgesics has led to increased abuse and misuse (CDC, 2011a). Providers are being cautioned to increase selectivity, screening, and monitoring of patients receiving opioids, all while assuring legitimate access to treatment (CDC, 2011). Written agreements between patients and providers and urine drug screens are implemented in some clinics to decrease risk of aberrant drug-related behaviors (Chou et al., 2009a). ED programs that restrict narcotics for patients have been successful in reducing repetitive visits (Svenson & Meyer, 2007; Masterson & Wilson, 2011). Less is known about how well patients who are engaged in strategies that guard against drug misuse are able to manage their painful conditions. Risk factors for opioid abuse and misuse include comorbidities of depression and nonopioid substance abuse (Birnbaum & White, 2011). More energy will likely be expended in the coming years towards addressing such risks to thwart illegal and inappropriate use of opioids. Comparable tactics are needed to facilitate care options for patients with persistent pain.

**Problem statement**

Prescription pain medications, including opioids, are frequently sought and obtained by patients with persistent pain in emergency department and clinic visits. Nonpharmacologic therapies aimed at long-term management of pain are difficult to apply within these fast-paced settings (Baker, 2005). Depression, substance abuse, and other comorbidites often accompany persistent pain, yet programs to address psychosocial and functional complexities are not widely available to many patients. High cost, limited availability, and lack of insurance coverage limit patients’ access to interdisciplinary approaches to pain management; these are known to be most
effective in treating persistent pain (Chou et al., 2009a). A need exists to examine whether inexpensive, readily-accessible self-management programs can be used to assist patients’ abilities to integrate nonopioid therapies, and at the same time, improve patients’ experiences with pain.

**Background and significance**

How well one manages a chronic condition can be crucial to an individual’s physical and psychological state (Audulv, Norbergh, Asplund, & Hornsten, 2009; Clark et al., 1991). If performed effectively, self-management can reduce the impact of symptoms, assist in coping with psychosocial issues, and affect long-term health outcomes (Audulv et al., 2009; Clark et al., 1991). Programs to aid patients in self-management of chronic conditions have been touted as an effective means to improve quality of life and health functioning while reducing healthcare resource utilization (Bodenheimer, Lorig, Holman, & Grumbach, 2002; Lorig & Holman, 2003; Lorig, Ritter, Laurent, & Plant, 2008). Online and face-to-face group self-management interventions have demonstrated improved outcomes in small, specific populations of patients who suffer with pain (Macea et al., 2010; McGillian et al., 2008). However, no such interventions have been accepted for widespread use in the general population of patients with persistent pain. Little is known about how such nonpharmacologic therapy options may assist these patients in managing and avoiding acute pain crises that often result in additional clinic and ED visits.

Few studies of Internet-based self-management programs have recruited patients with persistent pain from clinical settings such as provider offices and hospitals, specifically targeting those receiving opioid prescriptions; most studies have relied on Internet advertising (Bender, Radhakrishnan, Diorio, Englesakis, & Jadad, 2011). Additionally, few studies to date have
explored the role Internet-based self-management programs may play in decreasing the use of opioid medication and increasing alternative methods of pain control (Bender et al., 2011). Consequently, there is a gap in knowledge about how patients who present to providers and receive opioids would respond to such programs. It remains unknown how effective these interventions may be for patients who might lack the self-motivation to access electronic forms of help without prompting or invitation from a provider.

A significant need exists to address overuse of opioid medications as abuse and unintended deaths from prescription drugs are rising. Studies that measure the effect of self-management programs on persistent pain outcomes will assist researchers in understanding how the learned strategies impact measures of pain intensity, pain interference, and mood. Further development of programs might assist patients in reducing their reliance on opioid medications and in finding more safe and effective solutions to managing painful conditions. The use of opioid medications for persistent pain remains controversial (Chou et al., 2009a; Manchikanti et al., 2011; Stein, Reinecke, & Sorgatz, 2010). Convincing evidence does not exist to support opioids as superior to nonopioids when they are used for long-term treatment in this patient population (Stein et al., 2010). It has been postulated that reducing the demand for opioid prescriptions may be achieved by increasing emphasis on psychosocial interventions and non-pharmacological, nonopioid treatments (Hallinan, Osborn, Cohen, Dobbin, & Wodak, 2011). More research is needed to explore what specific nonpharmacologic therapies patients find useful and whether these therapies result in reduced use of opioids. Such knowledge could lead to greater understanding about how self-management skills can influence patients’ choices and behaviors.
A criticism of self-management programs for chronic disease is that the positive effects have been variable and short-lived (Foster, Taylor, Eldridge, Ramsay, & Griffiths, 2007; Krause, 2005; Weingarten et al., 2002). More input from participants who have engaged in these programs is needed to inform enhancements to existing programs. This may validate the worth of such programs to health care professionals who are in a position to encourage patients’ involvement in self-management of their chronic conditions. To advance the science on interventions for patients with persistent pain, a randomized controlled trial was conducted to measure the effects of an Internet-based self-management program in this patient population. The selected program, Chronic Pain Management Program (CPMP), is based on established principles for treating chronic disease in that it focuses on avoiding or reducing long-term consequences, and addresses interference with mood, cognitive processes, sleep, functionality, and overall quality of life (Fine, 2011). The CPMP is a self-directed, self-paced program consisting of learning modules that fall into four categories: cognitive, behavioral, social, and emotional regulation (Ruehlman, Karoly, & Enders, 2011).

**Purpose and specific aims**

The purpose of this randomized controlled study was to determine whether an Internet-based self-management program impacts pain experiences for participants with a persistent pain diagnosis who are receiving opioid treatment in clinical settings. The primary aim of this study was to evaluate the effect of an Internet-based self-management program on scores of pain intensity (or severity) and pain interference. The study population consists of patients with persistent pain who were prescribed opioid medication from a primary care physician or nurse practitioner. The intervention group was compared to a Treatment as Usual (TAU) wait-list attention control group. Pre-program scores (T1) were compared to those taken every two weeks
(T2-T4) and upon completion of the 8-week program (T5). Outcome measurements were gathered through Internet-delivered surveys using several validated tools. Primary aims were measured using the Brief Pain Inventory (BPI) to capture self-reported pain intensity and pain interference. Secondary outcomes explored additional mood, pain, and quality of life elements using the following measurements: Patient Health Questionnaire (PHQ-8), The Profile of Chronic Pain Assessment, The Patient Global Impression of Change (PGIC), Current Opioid Misuse Measure (COMM), and Pain Self-Efficacy Questionnaire (PSEQ). Diversity of responses and patterns were compared between treatment group and TAU participants. Additionally, participant perceptions about their experience and ability to integrate nonpharmacologic therapies and coping strategies using the self-management program were explored. Information was gathered using a medication inventory and goal-setting questionnaire, a bi-weekly self-report on health care utilization, and a program satisfaction questionnaire.

Summary

The proposed study was necessary to determine expected outcomes for patients with persistent pain after participation in the selected Internet-based self-management program. Findings can be used to promote understanding among health care providers about how this patient population can access and find benefit from such resources. Initial studies on the CPMP have been promising, however, additional research was needed to determine if similar positive results would translate to diverse geographic and patient populations. Specifically, more information was needed to evaluate the effectiveness of Internet-based self-management programs for patients residing in rural regions and from low socioeconomic groups, and from patients receiving opioid prescriptions from clinical settings. Additionally, more study was needed to understand which elements of the program patients find most beneficial, and which
may reduce reliance on opioid medications. Information gained may be used to create enhancements that will improve the CPMP and other self-management programs, thereby boosting the impact and effect sizes of future interventions.

This study also captured information on feasibility of Internet-based programs and program recruitment and completion rates. Such information may help determine enrollment and inclusion criteria in subsequent studies. Future online programs might then be targeted to audiences most likely to successfully complete them. Study findings may lead to greater understanding of how to engage patients with other chronic health conditions in self-management programs and increase the likelihood that patients will successfully participate in Internet-based programs in general.

The long-term goal of this program of research is to improve care of patients with persistent pain by offering effective nonpharmacologic therapy options. This study expands on knowledge that can be used to increase options for patients who currently seek opioid medications as the primary and sole solution to their pain concerns. Subjective feedback from participants provided information on which strategies are most helpful in managing painful symptoms and how they can be incorporated into opioid treatment plans. Findings may be used by ED and clinic staff for developing nonpharmacologic protocols that can assist in acute pain management. More significantly, a greater understanding of self-management tools increases knowledge about interventions that may be effective earlier in the trajectory of a chronic condition. Such knowledge might lead to opportunities to increase treatment options and prevent the devastating consequences of opioid addiction and long-term disability.
CHAPTER TWO

REVIEW OF THE LITERATURE

Pain is “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” (International Association for the Study of Pain [IASP]). The experience of pain is uniquely individual and subjective (IOM, 2011). Chronic non-cancer pain (CNCP) is a term that can be applied to a myriad of pain symptoms that patients experience for a period of time, in the absence of cancer (Dick, Rashiq, Verrier, Ohinmaa, & Zhang, 2011). Generally, persistent (or chronic) pain lasts three to six months beyond the expected recovery time for an acute disease or injury. It can be continuous or recurrent and may or may not be linked to an identifiable pathological condition (Institute for Clinical Systems Improvement [ICSI], 2011).

Persistent pain has been deemed by many pain experts as a “disease in its own right” (IOM, 2011, p. 1-7). A distinction is made from cancer pain, because the goals and implementation of symptom control are thought to be quite different (Dick et al., 2011). A diagnosis of CNCP is unique in that it can occur despite the absence of a universally accepted etiology, or any structural or physiological manifestations (Rashiq & Dick, 2009). Identifiable causes may include an underlying disease or condition, injury, medical treatments (such as surgery), or inflammation (IOM, 2011). Pain associated with a CNCP diagnosis is of sufficient intensity to adversely affect a person’s well-being, functionality, and quality of life (ICSI, 2011).

CNCP is also distinguished from acute pain, which is described as time limited, and ends when a disease or injury heals (ICSI, 2011). Acute pain is a normal, physiological reaction triggered by the nervous system in response to a possible injury. It is the body’s natural response to alert a person to beware or take care of one’s self and is generally accompanied by
disease, inflammation, or tissue injury (National Institute of Neurological Disorders and Stroke [NINDS], 2011). Acute pain is generally thought to be functional. It identifies an injury or signals need for recuperation or rest (Clark, 1999). Acute pain can be recurrent and may alternate with pain-free periods, such as in the case with migraine headaches or sickle cell disease (IOM, 2011).

Persistent pain, conversely, is seen as dysfunctional and without recognized adaptive purpose (Clark, 1999). In CNCP signals of pain continue, even after the injury or in the absence of any detectable damage. Most frequently, CNCP complaints include headache, low back pain, neck pain, and arthritis pain (APF, 2008). Also common are: 1) neurogenic pain, pain resulting from damage to peripheral nerves or to the central nervous system that can persist; and 2) psychogenic pain, “pain not due to past disease or injury or any visible sign of damage inside or outside the nervous system” (NINDS, 2011, para.1). Additionally, certain diagnoses exist that are considered persistent pain conditions, such as chronic fatigue syndrome, endometriosis, fibromyalgia, inflammatory bowel disease, and temporomandibular joint dysfunction (NINDS, 2011). Whether a common cause underlies the chronic nature of these disorders remains unknown.

At the farthest end of the spectrum is chronic pain syndrome (CPS), that represents a significant life role disruption related to persisting pain (ICSI, 2011). Patients experience disability in work or personal roles as a result of their painful conditions. The pain often has no identifiable source and presents with a constellation of symptoms that are poorly defined, difficult to treat, and respond poorly to conventional medical management (Singh, 2012). Exaggerated pain behaviors often seem out of proportion to the objective findings. For example, post-surgical patients with CPS may express high levels of pain long after other patients who
undergo similar procedures, or they may experience pain in a completely different part of the body than their surgical site (Lamacraft, 2012). Anxiety, depression, and long-term opioid use have been identified as risk factors for CPS (Lamacraft, 2012). CPS can affect patients in various ways and may include depressed mood, fatigue, reduced activity, and excessive use of drugs and alcohol (Singh, 2012). Because co-existing psychological disorders may accompany CPS and CNCP, patient assessments should include evaluations of depression, anxiety disorder, somatization, physical or sexual abuse, drug abuse/dependence, and family, marital, or sexual problems (Singh, 2012).

Factors associated with developing CNCP are both modifiable and non-modifiable variables and include: age, female gender, minority ethnicity, low socioeconomic status, obesity, low levels of fitness, surgery, serious illness or injury, childhood physical or sexual abuse, and lack of social support (IOM, 2011). Protective factors include: healthy weight, physical activity, avoiding injuries, monitored pre- and post-surgical analgesia, and personal qualities of positive affect and resilience (IOM, 2011).

**Physiology of pain**

An understanding of pain physiology is necessary to effectively treat pain. The term *nociception* derives from Latin *nocer*, “to hurt,” and it refers to the sensory process that is triggered by painful stimuli. *Pain* refers to the perception of those sensations and can be described in various ways, including aching, sore, irritating, throbbing, or unbearable (Patel, 2010). Nociception can lead to pain, but does not always, and pain can be present without activation of nociception.

Pain can originate from the central nervous system (CNS), the peripheral nervous system (PNS), or both (Jarvis, 2012). Nerve endings, or *nociceptors*, detect stimuli from the periphery
and convert impulses that the brain may then interpret as a pain sensation. Nociceptors are present within the skin, connective tissue, muscle, and viscera. They can be stimulated directly by trauma, or secondarily, by the chemicals (e.g., *neurotransmitters*) released at a site of tissue damage. The message of pain travels from the periphery to the dorsal (posterior) horn of the spinal cord where gray matter composed of nerve cells relay information along sensory fibers. From here, the message is transmitted along the spinal cord to the brain. At this point, the message can be blocked by naturally-occurring, endogenous opiate-like substances (*endorphins*). Transmission of pain signals between nociceptors and dorsal horn neurons are mediated as chemicals are released from the central sensory nerves. Opioid medications work at this stage of pain transmission. An inhibitory process is activated that “gates” pain, or blocks it from ascending along the normal pathway (DeLeo, 2006). If not stopped, the pain impulse moves into higher cortical areas of the brain. Perception occurs when there is conscious awareness of sensations that can now be identified as *pain*. The pain message is inhibited through modulation at this stage; additional neurotransmitters such as serotonin, norepinephrine, and endogenous opioids impede the pain signal to produce an analgesic effect (Jarvis, 2012).

Strategies of pain control aim to either 1) block pain at the periphery, 2) activate inhibitory processes at the spinal cord and brain, or 3) interfere with perceptions of pain (DeLeo, 2006). Treatments aimed at the periphery include nonsteroidal anti-inflammatory drugs that decrease production of sensitizing prostaglandins, the fatty acids responsible for events leading to inflammation. Treatments aimed to block pain at the spinal cord and brain include opioids and tricyclic antidepressants. Opioids are believed to inhibit various nociceptive reflexes by inhibiting the release of neurotransmitters and mimicking the actions of endogenous opioids (DeLeo, 2006). They bind to specific opioid receptors that are located in both central and
Peripheral nervous systems and essentially turn off the neuron so the pain message is not transmitted. These same receptors are responsible for the effects of sedation, slowed respiration and constipation that accompany opioid medications. Interventions targeting the perception of pain include relaxation, biofeedback, and cognitive behavioral therapies.

Both human and animal studies demonstrate that when pain is poorly controlled, gray matter cells within the dorsal horn and brain can become altered in size and function (Chen, Balasubramanyan, Lai, Todd, & Smith, 2009; Rodriguez-Raecke, Niemeier, Ihle, Ruether, & May, 2009). It has been hypothesized that chronic activation of nociceptors in CNCP can lead to reduction of gray matter in the brain areas that regulate pain. The link between CNCP and physiological changes has been strengthened by research. One example finds the brains of patients with chronic osteoarthritis return to normal gray matter composition on magnetic resonance imaging (MRI) after successful surgery (Rodriguez-Raecke et al., 2009). Since the brain is the organ that experiences pain, current models of pain recognize that psychosocial and biological processes are tightly integrated (Lumley et al., 2011). A parallel pathway of neurons accompanies the sensory pathway and is responsible for the emotional responses that react to the unpleasant nature of a pain event.

The Gate Control Theory was the first to suggest that competing influences to pain receptors in the spinal gates of the dorsal horn could determine how pain would be perceived (Melzack & Wall, 1965). Inhibitory nerves in the spinal cord can prevent or block the transmission of the pain message. This explains why electrical stimulation or rubbing an injured area reduce pain sensations. Additionally, the subjective variability in pain was addressed with this theory as it was realized that individual differences in the endogenous opioid system and the modulating system could affect pain experiences (Patel, 2010). Gate Control
Theory explained the connection between pain and emotion, confirming that a person’s thoughts, past experiences and emotions can influence whether pain impulses reach a level of conscious awareness (Melzack & Wall, 1965). This theory laid the foundation for current biopsychosocial models that incorporate physical, psychological and social perspectives in pain management. Melzack and Wall acknowledged the amplifying effect of emotion and role of cognitions in interpreting a painful event (Gatchel, Peng, Peters, Fuchs, & Turk, 2007).

An extension of the Gate Control Theory is the neuromatrix theory that sees pain as generated by the brain’s complex neural network with multiple inputs and outputs; pain need not be directly attached to any sensory input (Melzack, 2005). This theory highlights the role of stress in persistent pain. Pain triggers the stress cascade that includes release of cortisol, norepinephrine, and other physiological responses meant to preserve and protect vital organs; persisting stress responses can result in lasting insults to the body and may explain scenarios of resistant CNCP (Melzack, 2005). Pain is seen as a major stressor under this theory that can profoundly alter homeostasis when it persists. Understanding the impact of stress regulation in pain therapies has led to an increased emphasis on teaching patients how to incorporate pain coping skills (Gatchel et al., 2007). Research confirms that pain experiences can be manipulated by activating brain reward circuits, decreasing anxiety, reducing fear, and eliciting positive emotional states (Lumley et al., 2011). Hypersensitivity and over-reaction to pain can manifest as after effects of persistent pain (IOM, 2011). The relationship between sensory pain, emotions, and cognitions are acknowledged by pain experts, however, are less well appreciated in clinical settings where pain is often treated as a purely sensory experience (Lumley et al., 2011). It is generally agreed that extensive areas of the brain are involved in pain experiences, yet much remains unexplained regarding the pathophysiology underlying persistent pain (Melzack, 2005).
Pain treatments

An estimated 80 percent of all visits to physicians can be attributed to pain (Gatchel, et al., 2007). A large number of patients with CNCP are likely to be treated in primary care settings (Passik, 2009). Most commonly, treatments are offered within a biomedical framework and may include opioid and nonopioid medications or referrals to interventional treatments, such as local electrical or brain stimulation, nerve blocks, steroid or anesthetic injections, or surgery (NINDS, 2011). Multidrug therapies using combinations of analgesics, antidepressants, and/or anticonvulsants are common, although few published clinical trials are available to support this practice (Passik, 2009).

While significant health-related quality of life issues have been identified among patients with CNCP, making improvements in such a heterogeneous population remains a challenge (Dick et al., 2011). Evidence-based prescribing practices are complex, continually evolving, and a lack of standardized training leads to variation in individual practitioners’ pain care knowledge (IOM, 2011; Victor, Alvarez, & Gould, 2009). While primary care settings are generally the first stop for patients with pain, the providers rarely have the time or skills to conduct complete pain assessments or to guide patients in the self-management of their painful conditions (IOM, 2011). Impediments to relieving pain include the limited access most patients have to clinicians with expertise in treating pain (IOM, 2011). General medical education does not lead to pain management competency, and nearly one third of physicians report feeling “somewhat” or “very” unprepared to counsel patients about pain (Pizzo & Clark, 2012). Other barriers include: lack of medical insurance plans that allow for multidisciplinary care, limited access to pain specialists and/or pain clinics, pain guidelines that are impractical for primary care settings, and poor coordination of care among multiple providers (Hallinan et al., 2011). Institutional,
education, organizational, and reimbursement-related practices are all identified as problematic in providing optimal pain care (IOM, 2011).

In addition, the social stigma and judgments often attached to those suffering with CNCP may impact access to adequate treatment (IOM, 2011). Patients with CNCP often feel rejected and blamed by the health care community, or labeled as malingerers and complainers; they often see multiple providers and undergo numerous tests in an effort to resolve their pain (Gatchel et al., 2007). Patients often choose emergency department (ED) services to address pain complaints due to accessibility, convenience, and dissatisfaction with the care offered by their primary care provider (Dixon & Fry, 2011). The common treatment desired and prescribed for acute episodes of pain in the ED is opioid prescription drugs. In addition to the potential misuse and abuse of opioids, problematic physiologic consequences have been identified including hypersensitivity to pain, sexual dysfunction, and side effects (Turk, Swanson, & Gatchel, 2008). The broad spectrum property of opioids produces negative impacts for many organ systems. Sedation, nausea, vomiting, constipation and respiratory depression are common effects and difficult to manage; therefore, patients may require reduced dosages or discontinuation of opioids and receive inadequate analgesia (Benyamin et al., 2008). While efforts to adequately treat pain have led to increased use of prescription medications, ED settings do not allow for the follow-up required to adequately monitor patients receiving opioids.

The American Academy of Pain Management and the American College of Emergency Physicians do not support the routine provision of additional opioids for patients with persistent pain who present in the ED setting (Cantrill et al., 2012; Svenson & Meyer, 2007). Opioids are not universally supported as optimal therapy for chronic non-malignant pain (Fishbain, Cole, Lewis, Rosomoff, & Rosomoff, 2008); despite the increased use of opioids, research continues
to provide evidence of insufficient treatment of pain (Meghani, Wiedemer, Becker, Gracely, & Gallagher, 2009). Up to 50% of patients report they are not satisfied with the pain care they received in an emergency setting; 40% do not have a positive change in their level of pain during the ED encounter (Downey & Zun, 2010). Patients with CNCP who visit EDs for pain relief are often discontented; in one study 47% reported that their ED visit was “poor,” “terrible,” or “the worst experience of my life” (Todd, Cowan, & Kelly, 2006). In a phone survey following up on 500 patients with CNCP who visited the ED, 75% thought they needed more information to manage their symptoms and just 50% reported receiving any information or referrals (Todd et al., 2010). Such findings support the need to provide patients with non-emergent pain care options that may reduce their use of EDs by facilitating pain relief. More research is needed to generate evidence that can guide therapeutic decisions for persistent pain in ED settings (Cantrill et al., 2012).

In primary care settings, providers are challenged to prescribe opioids safely; they must maintain appropriate documentation and are subject to investigations by the Drug Enforcement Administration (Passik, 2009). Widespread under-treatment of pain has been attributed to the reluctance of physicians to prescribe opioids. Risks and benefits must be weighed, along with the worth of nonpharmacologic options. Ideal treatment plans that include opioids will include abuse risk assessment, individualized plans for high-risk patients, and ongoing monitoring with attention to aberrant drug-taking behaviors (Passik, 2009). Prescription monitoring programs that track dispensing of opioids have been used to balance drug diversion risk and management of pain (Fishman, Papazian, Gonzalez, Riches, & Gilson, 2004). Limitations of these programs include the focus on law enforcement priorities and less attention on providing substance abuse interventions. Also of concern are challenges in applying these programs consistently and across
a wide geographic region; states may experience increases in drug diversion activities when neighboring states tighten their regulatory control (Manchikanti, 2007). Yet unknown are the optimal risk screening tools and monitoring systems that are effective and feasible in a primary care setting (Passik, 2009; Turk et al., 2008).

Shortcomings of the traditional, dominating biomedical model were brought to attention by Engle (1977) in recognition that psychosocial factors could impact the reporting of symptoms and responses to medical treatment. This led to growth in the field of behavioral medicine and health psychology, ultimately leading to the biopsychosocial model that has been particularly influential in the treatment of persistent pain (Gatchel et al., 2007). The current consensus is that pain is a complex phenomenon that can only be understood from a biopsychosocial perspective (IOM, 2011; Turk & Okifuji, 2002; Van Damme, Legrain, Vogt, & Crombez, 2009). Pain care under such a framework considers biologic, psychological, and social/family/cultural factors; pain treatments might include psychotherapy, relaxation techniques, biofeedback, and behavior modification (NINDS, 2011). National guidelines concur that a plan of care and treatment goals should be developed using a biopsychosocial model that includes pain self-management strategies (ICSI, 2011). Despite the evidence that multidisciplinary care can be effective in managing pain, these options are not available for the majority of patients who seek pain care in primary care settings (IOM, 2011).

Particularly lacking in primary care settings is access to practitioners who are skilled in applying principles of cognitive behavioral therapy (CBT), such as cognitive restructuring and problem solving. Although these are known evidence-based strategies for managing chronic pain symptoms, they are generally offered after all other forms of therapy have failed. They usually are delivered in the context of specialized pain care, yet this may not be the best approach
When used earlier in the disease trajectory, CBT can address the thoughts, feelings, and behaviors that accompany pain and assist patients in avoiding the interference of symptoms in their lives; this can ultimately reduce their reliance on health care professionals (Macea et al., 2010). Therapeutic interventions for negative mood states can lead to improvements that decrease pain perception, as well as increase tolerance for pain (Gatchel et al., 2007). Additionally, educational interventions that address fear and avoidance beliefs have been found to motivate activity and reduce disability among patients with persistent pain (Gatchel et al., 2007). Therefore, treatment options should address these cognitive and emotional states. If offered earlier, at the first episode of pain, it may change the patient’s relationship with pain and offer freedom from negative impacts (Stannard et al., 2010).

Even with unlimited resources, not every pain can be eliminated (IOM, 2011). Effectiveness of pain treatment depends on the quality of the patient-clinician relationship (IOM, 2011). Patients with CNCP need guided attention and coaching if they are to manage their conditions, yet little reimbursement is available for such activities (IOM, 2011). Ideally, the majority of pain care will be provided in patient-centered primary care settings where patients will learn self-management skills, and more complex cases will be referred to pain centers (IOM, 2011). Health care professionals should offer materials that will teach about self-help strategies to reduce and avoid pain, as well as instruction on benefits and risks of medications. Better and more evidence-based patient educational programs are needed (IOM, 2011).

Individualized treatments designed to consider psychosocial influences that accompany pain are necessary for improving pain experiences. Recent genetics research adds evidence to the individualized nature of pain; genes may influence susceptibility, initiation, maintenance, and aggravation of persistent pain (Gatchel et al., 2007). Other individual variables include a
patient’s belief that they can exert control over the duration, frequency, intensity, or unpleasantness of a painful event (Gatchel et al., 2007). Perceived helplessness has been identified as the strongest contributor to pain disability and pain level (Gatchel et al., 2007). Increasing self-efficacy, or the confidence one has to control pain experiences, has been found to have a positive impact on physical and psychological functioning. Self-management and cognitive behavioral interventions that target self-efficacy have been associated with improvements in pain, and its accompanying functional and psychological states (Keefe, Somers, & Martire, 2008; Marks, Allegrante, & Lorig, 2005). The available interventions vary widely and may include self-instruction, relaxation or biofeedback, changing maladaptive beliefs, and goal setting (Gatchel et al., 2007). Programs may be live or web-based, administered by health professionals or lay persons, and embedded within comprehensive pain management programs or available as stand-alone courses (Foster et al., 2007; Warsi, LaValley, Wang, Avorn, & Solomon, 2004a). No consensus has been reached for these diverse interventions to determine the optimal content, delivery mode, or timing for engagement within the trajectory of a painful condition.

Pain impacts

The IOM report (2011) signifies a formal call to the health care community to address the inadequacies of the current health care system for pain management. At present, the quality of care often depends on the ability of individuals to seek and receive information and assistance, of family members to offer help, and of clinicians to explore options (IOM, 2011). Providers’ bias, knowledge gaps, lack of research, and inadequate systems are all believed to contribute to the current state of expensive and ineffective pain care (IOM, 2011). The most recent estimates reported by the IOM in 2011 are that the annual economic cost of persistent pain in the United
States is at least $560–635 billion; the estimated cost of health care attributed to pain is $261–300 billion, and the cost of lost productivity is $297–336 billion. Approximately 14% of all Medicare costs are spent on medical expenditures for pain (IOM, 2011). These costs are believed to be underestimated because they exclude children, institutionalized elderly and prisoners, military personnel, and caregivers.

The IOM reports pain as a significant public health problem, affecting at least 116 million U.S. adults. Besides monetary costs, pain decreases quality of life, productivity, and affects specific population groups disparately (IOM, 2011). Being born into a minority race or ethnicity increases the risk of developing CNCP, as does female gender, lower socioeconomic status and education levels (IOM, 2011). In a review by Anderson, Green and Payne (2009), disparities were evident in acute, chronic, cancer, and palliative pain care and across all treatment settings and age groups, with minorities receiving lesser quality pain care than non-Hispanic whites. Higher numbers of African Americans, Hispanics and Asians suffer from under-treatment of pain and receive less analgesia (Anderson et al., 2009). Such inequalities in care exist even when sources of pain are clearly apparent, as in the case of long-bone fractures. While non-Caucasians now comprise one third of the U.S. population (Anderson et al., 2009), most pain research does not include sufficient numbers of minorities within the sample to make conclusions about targeted therapies (IOM, 2011). Significant differences have been found between minority groups in perceptions of pain, pain thresholds, and coping with pain, thereby strengthening the case for access to individualized education and personalized care (Anderson et al., 2009).

CNCP is also unevenly distributed among patients with mental health co-morbidities. Research consistently finds that depression and persistent pain conditions co-exist (Bair,
Robinson, Katon, & Kroenke, 2003; Hartman et al., 2006; Wilson et al., 2013). In one international survey, 43.4% of 18,980 participants had co-existing major depressive disorder and persistent pain conditions (Ohayon, 2004). Pain and depression are often entwined and it is difficult to determine whether pain precedes depression or whether depressive symptoms result from pain (Hartman et al., 2006). Less important than causality may be whether the patient who presents with pain symptoms has adequate screening and treatment options for the depressive symptoms. A pilot study conducted to inform this present study found that 41% of 22 ED patients with a CNCP diagnosis reported symptoms indicating moderately severe or severe depression after their ED encounter. None were receiving cognitive behavioral treatment for their depression and just 14% were prescribed antidepressant medicine (Wilson et al., 2013). The interdependency of depression and pain demands a joint approach to treatment (Kroenke et al., 2011). Depression in patients with pain is associated with more pain complaints and greater impairment, such as lower quality of life, decreased work function, and increased health care utilization (Bair et al., 2003). Comorbid mood disorders place patients at higher risk for misuse of prescription opioids (Wasan et al., 2007). A focus on pain may obscure the detection and treatment of depression. Concurrently, this vulnerable population is exposed to potentially lethal medications when opioids are prescribed; this contributes to a heightened risk for suicide (Cheatle, 2011). The risk of death by opioid overdose has been found to be disproportionally increased when one suffers from mental illness (Johnson et al., 2013; Madadi, Hildebrandt, Lauwers, & Koren, 2013). Other identified risks include living in rural areas, unemployment (Johnson et al., 2013), a history of a substance use, and suicide attempt (Johnson et al., 2013; Madadi et al., 2013).

Ideally, pain treatments would attend to the affective distress that accompanies pain. Also
addressed would be co-existing substance abuse issues that strain current health care systems. Patients who repetitively visit EDs with pain complaints often have substance abuse and psychiatric histories, although few if any strategies are employed to detect these comorbid conditions during ED encounters (Curran et al., 2008). Nearly 124 million ED visits were reported in 2009, or 41.4 visits per 100 Americans; of these visitors, 45% present with severe or moderate pain (CDC/National Center for Health Statistics, 2011). Overutilization of the ED for chronic pain contributes to overcrowding, inefficient use of resources, and decreased quality of care for those with emergent needs (Dixon & Fry, 2011). It is generally agreed among health care providers that the ED is not the ideal setting for treating chronic pain (Dixon & Fry, 2011). The percentage of all ED visits that resulted in prescribing an opioid rose from 23% in 1993 to 37% in 2005 (Pletcher et al., 2008). This is a critical issue due to the rising use of prescription drugs over the last decade, and a concomitant rise in unintended deaths (CDC, 2011). The inadequate and complex treatment of pain highlights the need for novel options and systematic changes in the primary care setting to address patients with CNCP. Such focus could reduce the burden that presently strains ED settings. The IOM report (2011) calls for increased education and increased number of health care professionals who have advanced expertise in pain care. Strategies to meet the demands of patients who enter primary care for pain treatment are needed.

**Self-efficacy**

Self-efficacy is confidence in one’s ability to successfully carry out an action (Peterson & Bredow, 2009). Interventions based on this theory aim at obtaining the highest level of functioning and have been useful for patients with a variety of chronic conditions including diabetes, asthma, and cardiac disease (Grey, Knafl, & McCorkle, 2006; Warsi, Wang, LaValley, Avorn, & Solomon, 2004b). Programs based on self-efficacy build confidence in one’s ability to
manage health and maintain active, fulfilling lives. This is accomplished, in part, by setting health-directed goals and achieving them, and watching others do the same (Bodenheimer et al., 2002). Low self-efficacy has been found to interfere with one’s ability to self-manage conditions (Grey et al., 2006).

Self-efficacy arose as a middle-range theory from Bandura’s grand theory: Social Learning Theory of human behavior (Bandura, 1977). Bandura performed hundreds of experiments examining ways behaviors develop and how they can be changed most effectively (Kunkel, 1989). Young children adopted aggressive acts towards a punching bag doll after watching an adult perform these acts. Bandura demonstrated that observational learning (modeling) occurs, and could be used as a mode for mimicking behaviors. The same principles that prompted negative, aggressive behaviors could be applied to increase successful behaviors. Social Learning Theory was renamed Social Cognitive Theory to recognize the complex internal, mental processes that influence behaviors.

In his seminal work, Bandura hypothesized that expectations of personal efficacy can determine “whether coping behaviors will be initiated, how much effort will be expended, and how long it will be sustained in the face of obstacles and aversive behaviors” (Bandura, 1977, p. 191). Bandura’s initial experiments manipulated treatments designed to create differential levels of efficacy expectations in herpetophobics - people with a profound fear of snakes. The research assumption was that a psychological intervention could result in a behavioral change by altering one’s level of self-efficacy (Peterson & Bredow, 2009). By first watching through a window as someone touched a snake (modeling), and gradually increasing actual interactions with snakes, phobias could be reduced. Bandura tested his theory of self-efficacy under the assumption that the confidence built by small, successive steps could lead to positive changes. Helplessness
occurs when people give up trying because they lack a sense of efficacy, or believe their actions will have no impact or will be punished. To overcome helplessness, individuals can engage in experiences that build confidence and support self-efficacy.

Bandura describes four major sources of self-efficacy (1994):

1. Mastery Experiences. Performing a task successfully strengthens one’s sense of self-efficacy.
2. Social Modeling. Vicarious witnessing of others as they successfully complete a task increases the observers' beliefs that they can master comparable activities.
4. Psychological Responses. Moods, emotional states, physical reactions, and stress levels can affect people’s feelings about their ability to perform certain tasks.

Initially, Bandura was able to free his participants of the paralysis and panic they felt around snakes. He then demonstrated that the confidence built from exerting personal control would carry over into confidence for diverse and unrelated behaviors. This theory was not situation-specific and could be tested with many kinds of behaviors. It was an accessible theory and allowed for application in addressing clinical issues. Numerous procedures have been tested and shown to alter levels of self-efficacy.

A strength of Bandura’s theory is that it can be, and has been, applied to many populations and settings. More than 8,600 articles are generated in PubMed when self-efficacy is placed as a search term limited by title and abstract. Self-efficacy has been used in research involving business, athletics, education, computer science, health care, media, political change, psychology, psychiatry, and international affairs (Pajares, 2004). This theory is appropriate to consider within the context of chronic illness, and specifically for CNCP, because
many chronic conditions require some behavior change for optimal outcomes or improved quality of life. Much evidence exists to support a link between health and lifestyle behaviors, yet less is understood about how to influence changes and assist people in sustaining healthy choices (Peterson & Bredow, 2009). By adopting the principles of self-efficacy in research or in practice, new strategies can be developed to assist people in building confidence. This confidence can be applied to managing their chronic conditions, and supporting healthy behaviors that can reduce the impact of these conditions. Even when physical conditions cannot be significantly altered there are still opportunities for people to learn new ways of coping with their situations. Self-efficacy can build confidence in these abilities.

Bandura found that those with low self-efficacy relegate control to others, which in turn limits experiences that would build confidence (Bandura, 1997). Knowing this might inspire health care providers to create opportunities for their clients that will foster confidence and engagement in their plan of care. Bandura (1997) believed that people will not likely approach situations that they believe are outside of their capabilities unless they are externally coerced. Nurses, and all health care providers, can provide this external coaching and engineer opportunities for success.

The concept of self-efficacy has been used as an outcomes measurement in many research studies and has been sensitive to varied interventions. Nursing research has tested the theory of self-efficacy in regards to clinical aspects of care, education, and nursing competency and professionalism (Peterson & Bredow, 2009). Chronic illness has been the focus for the majority of these nursing studies and has allowed for new ideas to come forward and suggest ways to improve care. Research has generated new knowledge on modifying lifestyle choices, such as smoking cessation, exercise behaviors, and weight loss (Peterson & Bredow, 2009).
Health promoting interventions based on increasing self-efficacy have successfully addressed breastfeeding, diabetes management, and chemical dependency (Zulkosky, 2009). The multitude of studies using self-efficacy creates a rich base for comparisons. Evidence is growing to support the use of educational and self-help interventions to increase self-efficacy; a strength of this concept is that it allows patients to focus on their abilities instead of limitations (Keefe et al., 2008).

Self-efficacy can be applied to any culture or ethnicity as it fits within the social cognitive framework based on “triadic reciprocity” that is common amongst humans in all settings (Peterson & Bredow, 2009). This triad is represented in a graphic model (Figure 1) and includes behavior, personal and environmental factors. Self-efficacy is a commonality believed to be part of all personal cognitive experience. There is mutual action or “reciprocal determinism” amongst the model’s three components, yet the strength and direction of the influence has no specific pattern. Therefore, there is fluidity and variation; what determines behavior can vary depending on circumstances, cognitive ability, biological events, and the feedback received. The “person” includes all cognitions, beliefs, attitudes and biological events. In all the world’s diverse settings, this model fits. People are producers as well as products of their circumstances (Pajares, 2004).

![Reciprocal determinism](image-url)
The limitations of self-efficacy include that it does require a level of cognition involving acquisition, organization and use of information. How it applies to persons with dementia or mental illness is less certain. Self-efficacy is sometimes used interchangeably or confused with self-concept, self-perceptions, or self-esteem. This lack of specificity has been named as one drawback to self-efficacy guiding research (Pajares, 1996). To focus solely on self-efficacy, would likely serve to be too limiting when seeking to improve health. It may affect behavioral change, but other considerations are needed when addressing the holistic needs of people with chronic conditions. For example, resources, social support and cultural beliefs can influence choices as well. In addition, because many chronic conditions are complex and multidimensional, it is likely that the solutions for healthier outcomes are also complex. It may be difficult to change more than one behavior at a time using a self-efficacy approach targeting one behavior. For example, a person with CNCP may be able to master exercises to improve muscle strength, but if he has high levels of depression, he may be unable to self-initiate daily exercises. Negative cognitions need to be addressed simultaneously. If the ultimate goal is to improve quality of life, self-efficacy may not be sufficient to make significant gains. Bandura found that treatment results for individuals with snake phobias were long-lasting (Kunkel, 1989), yet less is known about how well effects last in regards to healthy behaviors. Some studies of chronic conditions have found that levels of self-efficacy do not remain stable over time (Bond, Durrant, Digre, Baggley, & Rubingh, 2004; Lorig et al., 2008). Assuming that a one-time boost...
in self-efficacy can have long-term health effects is one that needs further study in a variety of circumstances.

Another limitation of self-efficacy theory in nursing practice is that some self-efficacy gains may be best met using observational learning that is not always available to patients. Although research may show that patients with CNCP learn best when mentored by a like-peer, this is not likely to be feasible for every patient. Systems and programs are needed in order to provide patients with opportunities to develop and master skills. Practical applications have been explored that translate self-efficacy research into practice in order to manage a wide range of chronic conditions including: depression, urinary incontinence, arthritis, epilepsy, HIV, wound healing, asthma, COPD, and cancer (Peterson & Bredow, 2009). Applicability to a wide range and variety of chronic conditions is a great strength of this theory. Yet there exists a gap between research and practice. The language and theory supporting this research have not made their way to routine clinical practice. While clinicians may set goals with their patients, most are probably unaware that they are applying principles of self-efficacy that are grounded in rigorous science. Lack of resources to disseminate new knowledge about self-efficacy may prevent it reaching those who most need this information. Engaging patients as active participants in their health care is one strategy to improve treatment of chronic conditions, yet more research is needed to understand the link between self-efficacy and how patients manage chronic pain.

Self-efficacy outcome measures should be task and domain specific. This creates some inconsistency in measurements, since instruments must be developed for each specific task. Global efficacy beliefs that do not correspond with the specific tasks of interest will reduce predictive accuracy (Pajares, 2004). There are hundreds of different self-efficacy measures with varying degrees of reliability and validity (Peterson & Bredow, 2009). A review by Miles and
colleagues (2011) identified five instruments that may be used to measure self-efficacy among patients with CNCP; however, the authors caution that more research and development of the available instruments is needed. Therefore, although it may be theoretically sound, self-efficacy will have pragmatic limitations as a primary outcome measurement in current pain trials. Gaps in research include the need to test interventions that are specifically designed to enhance self-efficacy in patients who may have low self-motivation and poor confidence in managing pain.

**Self-management**

Historical models of managing disease placed physicians in control of patient’s choices (Bodenheimer et al., 2002). New models of self-management, based on concepts of self-efficacy, suggest that patients can exert control. Self-efficacy is the theory underlying many programs of self-management for chronic conditions. Self-management has been defined as the tasks individuals must undertake to live with chronic health conditions (Lorig & Holman, 2003). It has been utilized to maximize health outcomes by increasing self-efficacy, improving adherence to treatment plans, and enhancing quality of life (Grey et al., 2006). Self-management interventions have been touted as an effective means to improve quality of life and health functioning while reducing health care resource utilization (Bodenheimer et al., 2002; Lorig & Holman, 2003; Lorig et al., 2008). If performed effectively, self-management can reduce the impact of symptoms, assist in coping with psychosocial issues, and affect long-term health outcomes (Audulv et al., 2009; Clark et al., 1991).

In order to address gaps in the current self-management literature, the Individual and Family Self-management Theory (IFSMT) was developed and provides a frame for further studies (Figure 2) (Ryan & Sawin, 2009). The IFSMT is a descriptive, mid-level nursing theory
that allows researchers to incorporate the complexity of the human experience and build on what is known about self-management (Ryan & Sawin, 2009). In the IFSMT, the individual or family assumes responsibility for self-management, and may include health care providers as collaborators in care. Self-management is considered a complex phenomenon involving context, process and outcomes. The IFSMT is a biopsychosocial model that assumes health behavior changes are dynamic and require a desire for change (Ryan, 2009). Within the IFSMT, explorations of self-management can consider risk and protective factors, components of the physical and social environment, and unique characteristics of individuals and family members (Ryan & Sawin, 2009). The IFSMT addresses: (1) context of self-management that can differentiate between acute and chronic illness; (2) process of self-management that can address specifics of interventions, such as those designed to impact self-regulation skills, knowledge and beliefs; and (3) outcomes of self-management, that can be determined using condition-specific measures (Ryan & Sawin, 2009).

Prior research has demonstrated that improving self-efficacy can enhance self-management behaviors and the associated health outcomes, for example, in the case of self-care behaviors in chronic conditions (Aljasem, Peyrot, Wissow, & Rubin, 2001). In other cases, however, the results are conflicting. Specifically, one study found that diabetes self-efficacy scale ratings were associated with some behaviors needed for diabetes disease management (diet, exercise, self-management of blood glucose and foot care), yet not with medication adherence (Sarkar, Fisher, & Schillinger, 2006). External factors such as barriers to resources, patient-provider relationships, social and cultural variations may interfere with the relationship between self-efficacy and performing desired health behaviors (Sarkar et al., 2006). Additionally, while self-management programs hinge on self-efficacy, this psychological construct does not account for individuals who are not responsive to this as motivation to change health behaviors (Willis, Robinson, Wood-Baker, Turner, & Walters, 2011). Patients who are more comfortable with traditional, directive patient-provider relationships may have more difficulty engaging in such programs (Willis et al., 2011). One systematic review of 8,539 participants with persistent musculoskeletal pain found that group-delivered self-management courses with a health care professional’s input had greater effect, and programs with psychological content were more consistently beneficial (Carnes et al., 2012). More understanding is needed about the role of self-efficacy in program outcomes and how benefits can be achieved evenly amongst patients.

For patients with CNCP, more investigations are needed to determine how self-efficacy can be manipulated within a self-management program and how it will influence health behaviors and outcomes. Self-efficacy for people with CNCP includes beliefs about one’s ability to control pain and associated negative emotions, to maintain life activities, and to communicate
needs to health care providers (Miles, Pincus, Carnes, Taylor, & Underwood, 2011). Some evidence exists that patients with higher self-efficacy on these factors have more positive outcomes, better pain control, and better adherence with treatment plans (Miles et al., 2011). Patients vary considerably in their self-efficacy regarding pain symptom management. Higher levels of self-efficacy are associated with lower levels of pain, along with lower levels of psychological distress and negative health outcomes (Keefe, Rumble, Scipio, Giordano & Perri, 2004).

Although the IFSMT has not been tested in patients with acute or persistent pain, it is appropriate to examine it in this context (P. Ryan, personal communication, July 22, 2011). The IFSMT has been applied in more than 20 studies to date; several involved chronic diseases including hypertension, congestive heart failure, and diabetes (P. Ryan, personal communication, April 14, 2013). Testing the process of self-management programs for impact on pain outcome measures fits the intention of this model. It provides an appropriate framework to explore the relationship between interventions for patients with CNCP and chronic pain sequelae. The concepts of pain intensity, pain interference, mood disturbances, and self-efficacy can be tested within this model to determine whether they are sensitive to self-management interventions, and if so, whether the resulting outcomes can have lasting impact.

A literature review was conducted in 2012 and updated in 2013 on the most significant concepts related to the present study. Selection of citations was limited to PubMed, ISI Web of Science, and PsychInfo databases. Articles from 2005-2013 were reviewed along with relevant references from those retrieved articles until saturation was reached. Search terms included self-management, self-efficacy, chronic pain, and chronic disease self-management program. As a result, it was determined that self-management has been explored in the context of many health
conditions, yet research specifically targeting patients with CNCP is lacking. Prior studies of self-management programs have demonstrated improved outcomes in specific pain populations, such as patients with fibromyalgia, headaches, arthritis and angina (Lorig et al., 2008; Macea et al., 2010; McGillion et al., 2008). Few studies can be found that test self-management interventions for the broader population of CNCP, however, the ability to self-manage pain has been recommended as an essential part of evidence-based clinical practice guidelines for rehabilitation of CNCP (ICSI, 2011; Sanders, Harden, & Vincente, 2005). How patients are to accomplish self-management is unclear.

While nearly all patients with a chronic disease must self-manage their condition to some extent, opportunities to prepare patients for these responsibilities are inconsistently and infrequently applied (Redman, 2005). Identified obstacles include literacy, age, availability, and the inequities regarding payment of nonpharmacologic therapies (Redman, 2005). For patients with CNCP, lack of awareness, transportation and cost have been identified as main barriers for accessing self-management resources, and it has been suggested that the role of nursing is to work with other health care professionals to facilitate success (Crowe, Whitehead, Gagan, Baxter, & Panckhurst, 2010). Lack of engagement by clinicians has been identified as an obstacle to widespread implementation of the available self-management programs for chronic disease. More convincing data in specific patient populations is needed, along with dissemination strategies that will ensure programs are available to those in greatest need (Wilson, 2008). Existing programs tend to attract well-educated participants who may already be prone to effective self-care (Wilson, 2008). Recruitment difficulties for self-management programs are reported with rates as low as 11% and males are under-represented; additionally dropout rates are high (Foster et al., 2007). Most recruitment to self-management programs is self-initiated by
relatively healthy participants (Foster et al., 2007). Little is known about how results might be impacted if health care professionals target and invite patients of higher morbidity to participate (Foster et al., 2007). The IFSMT considers access to care and provider relationships as essential elements of “context” that provide risks or protective qualities and can influence outcomes. Within the IFSMT, both physical and social environment are considered. This draws attention to differences in rural and urban settings, ED and clinician offices, and individual and family perspectives. Relationships among contextual dimensions such as literacy, information processing capabilities, and access to care can be tested within this theoretical model (Ryan & Sawin, 2009).

A systematic review evaluating randomized controlled trials involving 2,503 participants of Internet-based pain management programs determined that providing cognitive and behavioral therapy, moderated peer support, and follow-up support can have positive effects on pain, activity, and treatment costs (Bender et al., 2011). Effects on depression and anxiety were inconsistent and the researchers concluded that more rigorous studies are needed to determine the populations best served and the resultant effects. Outcomes are comparable to face-to-face interventions in the few cases where these were tested; additionally, the anonymity afforded by the Internet is believed to be advantageous considering the stigmatization of those with CNCP diagnoses (Bender et al., 2011). Due to the wide variation in program features it remains difficult to determine what aspects of the programs are most beneficial. Also lacking is an understanding of the types and amounts of pain medications used by participants as few studies capture this information.

A limitation of prior research is difficulty in generalizing findings due to heterogeneity of groups, differences in delivery methods, and the complexity of the self-management intervention
(Wilson, 2008). As noted by Dongbo, Ding, McGowan, and Fu (2006), more research is needed to determine whether self-management courses with groups of similar participants are more effective than when engaging dissimilar groups. The IFSMT considers condition-specific context and the complexity of conditions and treatments as part of the overall equation that will determine processes and affect outcomes. Within this framework, a self-management program can be explored as it is applied to the condition of persistent pain. While patients with CNCP may have diverse origins for their symptoms, they share commonalities that can be addressed within a self-management program. For example, in common are the ways in which pain can interfere with life activities, relationships, sleep, work, and mood. Pain intensity, pain interference, and mood are appropriate outcome measurements that can be tested among heterogeneous groups of patients with CNCP. Also in common are patients’ methods for seeking pain relief. These generally include contact with primary care providers who do not have specialized pain management knowledge, or unplanned ED encounters. The IFSMT would consider these common elements that could be contextualized as either protective or risk factors, depending on the quality of these environments in providing essential pain care.

Although individual trials of self-management programs show measurable positive effects, systematic reviews point out that improvements are often short-lived and too small to be clinically significant (Foster et al., 2007; Krause, 2005; Weingarten et al., 2002). The Stanford Chronic Disease Self-Management Program (CDSMP) is one of the most widely used self-management programs in the world (Lorig et al., 2001). Prior studies using the CDSMP found improved functional status and decreased health care utilization among adults with arthritis pain (Lorig et al., 2008). Other self-management programs have been similarly structured and seek to help patients integrate new behaviors and learn to cope successfully with chronic conditions.
More research is needed to determine the effects of self-management programs, and specifically, those that aim to improve outcomes for patients with pain (Warsi et al., 2004b). Qualitative studies regarding the CDSMP are few; exploring what specific patient populations like and dislike about the programs may lead to greater understanding about how the programs translate into different settings, populations, and cultures (Foster et al., 2007). Surveying patients’ about their unique perspectives as participants may yield information that can maximize the utility of these interventions and directly impact the quality of life for patients with persistent pain.

In a pilot study leading up to this present study, the CDSMP was offered to patients with a persistent pain diagnoses who had received an opioid prescription after an ED encounter (Wilson et al., 2013). Participants in the pilot study were invited to fill out pain assessment surveys via the Internet. They were randomly assigned to intervention or wait-list comparison groups. Of those deemed eligible and approached for recruitment, 85% (n =110) expressed interest in participating. Of those, 52 individuals (47%) completed and returned a signed informed consent and were enrolled in the study. Twenty-two (42%) of the consenting 52 participants completed the initial online pretest survey where fourteen distinct pain diagnoses were reported. Ten (45%) participants listed an opioid analgesic among their list of prescribed medications and six (27%) of these ten listed more than one opioid. Although six of 11 in the intervention group (54%) visited the self-management site after completing their pretest survey, only one successfully registered and completed the six-week program.

Because the participation rate was low, the usefulness of the intervention in a general CNCP population remains unknown. The research team concluded that the population served in an ED setting may not be representative of the population of patients with CNCP. Recruited patients were not required to have a connection to a local provider and knowledge of medical
histories was often limited to the subjective reports that were provided at the ED encounter. Subsequently, a pain-specific program was discovered and a proposal developed that would include provider engagement within a primary care setting to test the intervention. Such a plan aligns with IOM recommendations (2011) for strong relationships between patients and providers to maximize pain management outcomes.

The central hypothesis of this research is that a program based on symptom management, education, and social support will improve patients’ experiences with pain, and can specifically target pain intensity, pain interference, and mood. The underlying rationale is that patients are active participants and do not act passively to their pain experiences (Turk, 2004). Building confidence, or self-efficacy, in one’s responses to pain can result in patients who are experts in their own pain management; through mastery experiences they can incorporate strategies, such as relaxation, distraction and self talk to effectively manage their pain (Lorig, 2008). Little is known about the replication of outcomes regarding self-management programs when delivered across various diseases, and to at-risk groups (Grey et al., 2006). Although much research supports self-management programs in general, little is known about the general population of those with persisting pain, and less about how those using opioid medications will respond.

**Chronic Pain Management Program (CPMP)**

An Internet-based pain self-management program was identified to trial in a population of patients with CNCP who were prescribed opioid medications and were recruited from primary care settings. The selected program, Chronic Pain Management Program (CPMP), is based on established principles for treating chronic disease in that it focuses on avoiding or reducing long-term consequences, and addresses interference with mood, cognitive processes, sleep, functionality, and overall quality of life (Fine, 2011). The CPMP is a self-directed, self-paced
program consisting of learning modules that fall into four categories: cognitive, behavioral, social, and emotional regulation (Ruehlman, Karoly, & Enders, 2011). This program was the only Internet-based self-management program that was identified at the start of this study as being available for widespread use and specifically designed for a general population of patients with CNCP.

The program generates an individualized custom plan based on the results of the Profile of Chronic Pain Survey assessment. Scores map onto the four learning modules and the participant receives suggestions for the order of module completion based on their results. The highest priority items for the individual are suggested to be completed first. The modules include didactic materials and interactive activities. Some are to be completed off-line, such as exercises, relaxation, or self-monitoring behaviors. A social networking component invites participants to join an online community and engage in discussions with others who have persistent pain conditions.

The single published study of the CPMP demonstrated its ability to decrease pain severity, pain-related interference, perceived disability, and pain-induced fear. Additionally, program engagement led to significant decreases in depression, anxiety, and stress. Participants also gained knowledge about the principles of chronic pain and its management. An identified limitation of the program is that not everyone with persistent pain is a good candidate for self-initiated, self-paced learning. The study participants were recruited from pain web sites, and therefore may not represent the typical patient who appears in clinical settings or those who are receiving opioid medicines.

Both caution and optimism have been presented in the evaluation of Internet-based self-management programs (Eccleston, 2011). Of concern is that reviews of these programs represent
a small evidence base. One meta-analysis of 22 studies found that Internet-based interventions can have larger impacts than non-Internet-based interventions when used for specified knowledge and/or behavior change (Wantland, Portillo, Holzemer, Slaughter, & McGhee, 2004). Bender and colleagues’ review of Internet-based pain programs (2011) included only 6 studies thought to be of high quality, the populations were widely heterogeneous, and the interventions were poorly defined. None-the-less, to answer the IOM’s call, a new generation of practitioners are needed who will understand the potential of the Internet to deliver on the promise of electronic health interventions (Eccleston, 2011). Young people who are being raised on technology will expect the same quality in health care that they have encountered in all other aspects of their digital lives (Eccleston, 2011). Building on current knowledge regarding Internet-based self-management programs for pain will aid in the development of this vision.
CHAPTER THREE

METHODS

Study design

This prospective, longitudinal study used a nonblind, randomized controlled experimental design with repeated measures of primary outcomes to compare changes between and within groups over time. The randomized controlled trial (RCT) is the “gold standard” and accepted method for determining whether an intervention has a significant effect on participants (Portney & Watkins, 2009). This design can answer research questions about causality and magnitude of effects. This study included randomization to a treatment group trialing the Chronic Pain Management Program (CPMP) and a treatment as usual (TAU) wait-list comparison group. Five time points were used to measure mean scores of pain intensity and pain interference using the Brief Pain Inventory (BPI) during the course of the 8-week program.

Secondary aims were addressed using descriptive methodology. The purpose of descriptive studies is to gain more information and document characteristics of a situation or phenomenon (Norwood, 2010). Generated knowledge can be used for future hypothesis development or to increase understanding about distributions or patterns of disease or disability in a population (Portney & Watkins, 2009). Descriptive methods are appropriate in novel interventions or when trialing tested interventions in a new population, as was the case in this study.

Setting, population, and sample size

Participants were initially selected from primary care medical offices in the Pacific Northwest with physicians and nurse practitioners who agreed to facilitate recruitment and who had access to the targeted population. The population of interest was adult patients diagnosed
with CNCP who were receiving prescriptions for opioid medications. The region served included rural and newly-designated urban areas. The primary initial recruitment site was a federally qualified health center serving a large under- and uninsured population. By doing so, the researchers in this study acknowledged and attempted to address the barriers faced by rural residents and people with lower socioeconomic status with respect to obtaining medical care and health-related information. If access is available, Internet-based self-management programs may be particularly advantageous in rural settings where Americans are more likely to engage in poor health behaviors and suffer from chronic illnesses (Meng et al., 2008).

Inclusion and exclusion criteria for recruitment were adapted from Buhrman, Faltenhag, Strom, and Andersson (2004) after removing items that were related to physical activity interventions. Inclusion criteria included patients with:

- CNCP lasting more than 3 months
- current prescription(s) for an opioid medication
- Internet access with email capability either at home or at a public setting
- more than 18 years of age
- ability to read, speak and write in the English language.

Exclusion criteria were chosen to limit confounding treatment effects and included:

- planned surgical treatment in next 2 months
- pregnancy
- currently enrolled in therapy or support group with counselor, psychologist or psychiatrist for persistent pain or substance abuse.

The target sample size was 120 participants as determined by power analysis to detect a significant small effect ($d = 0.20$), presuming $\alpha = .05$ and $\beta = .20$ (power 80%) for a mixed
analysis of variance based on finding the between x within group interaction. An additional 20% was added to G*Power calculations to account for anticipated attrition. It is reported that moderate effects coincide with clinically meaningful improvements in pain intensity ($d = 0.5$); however, it is also noted that clinical trials for persistent pain are limited by the magnitude of responses that can be expected in the placebo groups, which can be substantial (Dworkin et al., 2008). The sole prior published study on the intervention for this study reported small effects among a population of patients with persistent pain recruited from Internet sites; $d = 0.20$ for pain intensity and $d = 0.30$ for pain interference (Ruehlman et al., 2011). Approximately 20% of Ruehlman et al.’s treatment group did not follow through with the intervention after randomization.

**Sampling technique and recruitment**

The sample was selected from a pool of all patients who met eligibility requirements. Preliminary eligibility screening was determined by providers or their designated office staff using medical records and clinical knowledge. Eligible patients were approached by primary care providers or office staff either during a scheduled office visit or via phone or email to ask if they wished to receive an informational flyer about the study. A standardized script was given to staff to guide this approach and limit coercion that stated: “We are participating in a research study that is testing an Internet-based pain management program for patients with chronic pain. Would you like to hear more about the study?” The primary care office staff were asked to track the number of participants approached, number who receive information, and number who agreed to be contacted by researchers for informed consent procedures (Appendix B). Patients expressing interest could receive a copy of the informed consent to review from the primary care provider or office staff (Appendix C), or an informational flyer that included printed information
on how they could contact the researcher if they chose (Appendix B). In addition, if participants agreed, their name and preferred contact information were collected by office staff or providers and given to the research team for follow up.

Recruitment was anticipated to take approximately 4 months with an estimated 8-10 participants recruited each week. The primary health center selected for recruitment estimated approximately 75-100 eligible patients. Three smaller primary care clinics agreed to participate with estimates of 40 or more eligible patients each. Recruitment began with these pre-identified offices, with the plan to expand to other clinics in the inland northwest region and beyond if targets were not met within the first two months. Flyers were made available for distribution to participating offices for internal communications or to be posted in public view at the discretion of each office administration team. Participating clinics were offered reimbursement at the usual wage rate for office staff time spent assisting recruitment. Participating providers received a $20-$50 gift card at the end of the recruitment phase as a token of appreciation; the amount was dependent on the number of referrals received. Public advertising of the study using the flyer content was planned to begin via the Internet using Facebook and other web pages targeting pain groups if necessary to meet sample size targets. Widespread advertising began after the first 4 months of recruitment were completed and goals for sample size were not met. Any participants who were self-referred and contacted researchers on their own were asked to identify a primary care provider who would support their involvement in the study and could receive study communications.

Potential participants were contacted by a member of the research team via phone or email, depending on their stated preference. The study was described and an opportunity was given for questions to be answered. Once permission was granted, formal eligibility screening
took place guided by a pre-determined script (Appendix B). Those who were deemed eligible were asked if they wished to proceed with informed consent procedures. They were given a copy of the written informed consent agreement, and given the option to review in person with a research team member (for those living within a 100 mile radius) or via phone. In-person meetings were scheduled to take place at the providers’ office, library, or public setting with a computer station. The researcher explained study protocols and demonstrated the Internet-based pain management program to those who wished to view it. Those who consented received verbal and written instructions on how to proceed with the study. For those cases where an in-person informed consent meeting was not feasible or possible, the informed consent process occurred via phone, and the signed consent was obtained via mail or electronic means. In all cases, the participant was offered time to be guided by voice over the phone as an orientation to the pain management program Internet site.

**Primary outcome measurements**

Primary outcome measurements in this study were chosen to align with expert recommendations by IMMPACT, the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (Dworkin et al., 2005). Recognizing the complexity of pain, IMMPACT met in 2003 and the 35 expert participants advised researchers to choose a standard set of outcome measures when conducting pain trials. They underscored the importance of three dimensions in pain management: pain intensity, pain-related functional interference, and emotional burden (Dworkin et al., 2005).

Accurate assessment of pain is important for clinicians managing patients with persistent pain and for evaluation of new treatments (Gendreau, Hufford, & Stone, 2003). Ultimately, it is left to the patient’s self-report to judge pain experiences (Gendreau et al., 2003). Health care
professionals commonly attempt to capture patients’ complex pain experiences using one-dimensional, brief “0-to-10” pain intensity scores (Williams, Davies, & Chadury, 2000; Shugarman et al., 2010). This estimate of magnitude can be simply defined as “how much a person hurts” (Jensen & Karoly, 1993). The concept of pain interference has been identified as an additional measure that can contribute to quality pain management by recognizing pain as a multidimensional experience (Gordon et al., 2010; Wilson, 2011). IMMPACT recommended a 0-to-10 numeric rating scale for pain intensity; the Brief Pain Inventory (BPI) interference items were recommended to measure the impact of pain on physical functioning (Dworkin et al., 2005).

The BPI is a well-validated, reliable instrument that consists of a 4-item pain severity subscale and a 7-item pain interference subscale. Items are rated on 11-point numerical rating scales for intensity (0 = no pain and 10 = pain as bad as you can imagine) and for interference (0 = does not interfere and 10 = completely interferes) (e.g., “Choose the one number that describes how, in the past 24 hours, pain has interfered with your relations with other people”). The BPI is one of the most commonly used instruments in pain trials and has been used in more than 400 studies worldwide (Cleeland, 2009). It has been widely used in research and in cancer care and postoperative settings with coefficient alphas ranging from .70 to .96 (Cleeland, 2009; Lee, 2010). Validity has been established based on comparisons with other pain measurements, and the ability to discriminate among changes in condition over time (Keller et al., 2004). The BPI addresses concerns about recall bias by using multiple recall time frames within one questionnaire; questions are posed about pain “right now” in addition to over the past 24 hours. When captured this way, pain ratings have high correlation with daily ratings (Broderick et al., 2008).
Further studies of the BPI have suggested a three factor structure could divide interference into subscales of functional (activity) and emotional (affect) interference (Wu, Beaton, Smith, & Hagen, 2010). Interference with activities includes walking, work, general activity, and sleep. Interference with affect included mood, relationships, and enjoyment of life (Atkinson et al., 2011). The short form (BPI-SF) is available in 48 foreign-language translations and is the version selected for this study (Appendix D). In order to understand the intervention’s effect on both affect and activity, the three factors were examined in the present study as suggested by Wu et al. (2010).

**Secondary outcome measurements**

Mood states are known to influence the pain experience (Gendreau et al., 2003). For this reason, and to align with recommendations by IMMPACT, an additional measurement was collected to assess the affective component of pain. IMMPACT suggests that all pain trials include a measurement of emotional functioning, and specifically depression. The Beck Depression Inventory is recommended, however, since the IMMPACT consensus meeting many pain researchers and clinics have incorporated the Personal Health Questionnaire Depression Scale (PHQ-9) to measure depression severity due to its short length, simplicity, reliability and validity (Cheatle, 2011). It is important to select instruments that will fit structure and time constraints if they are to be utilized in busy primary care settings (Cheatle, 2001). The internal reliability of the PHQ-9 is .86 to .92 (Kroenke, Spitzer, Williams, & Löwe, 2010).

Studies show that in primary care, the PHQ-9 detects depression with sensitivity between 77% to 88% and specificity ranging from 77% to 92% (Cheatle, 2011; Kroenke et al., 2010). In a review by Kroenke and colleagues (2010) it was determined that the PHQ-9 performance is equal or superior to other depression scales. It has test-retest reliability of .83 to .84 and is
consistent across age, gender, race, and the mode of administration. Scale performance is similar using patient self-report, interviewer-administered either in-person or by telephone, or touch-screen computer. Reliability between self-ratings and interviewer-administered scores are 83% to 84% (Kroenke et al., 2010). The PHQ-9 has been adopted as the scale of choice by numerous large-scale studies and organizations including the United Kingdom National Health Service, U.S. Veterans Administration, U.S. Department of Defense, and the National Health and Nutrition Examination Survey (Kroenke et al., 2010). The instrument has been rated by nurses as superior to other screening tools and as having practical clinical implications in informing care plans and providing insights into patients’ mood (Kroenke et al., 2010). A shortened version, the PHQ-8, was utilized in this study, thereby omitting the final item that asks about thoughts of death or self-harm (Appendix D). This 8-item measurement is generally selected for research when depression is a secondary measure and either 1) it is not feasible to have a back-up system for the rare “suicidal” response to the ninth item, or 2) follow-up to admission of suicidal thoughts would be delayed, such as in mailed or Internet-based screenings (Kroenke et al., 2010). The correlation between the PHQ-9 and PHQ-8 is high (r = .99).

In the pilot to inform this study, the PHQ-9 was used and determined that 54% of participants recruited from the ED had symptoms indicative of a major depressive disorder. Approximately 50% of the participants reported at least occasional thoughts of self-harm or thinking they might be better off dead. The present study sought to evaluate whether those findings would be replicated in a larger population of patients with CNCP who are receiving treatment in primary care settings. The PHQ-9 measurement is designed to ask how often the symptoms were experienced over the past two weeks, thus giving rationale to this study design for bi-weekly measurements.
Additionally, IMMPACT recommends measurements that capture patients’ perceived clinical improvement with treatment. The Patient Global Impression of Change (PGIC) was used to capture this information in this study (Appendix D). Although no formal reliability testing is available for the PGIC, it is commonly used and recommended to measure patients’ perceptions of improvements with pain (Bryce et al., 2007; Dworkin et al., 2005). The PGIC is a 7-point measure of perceived clinical improvement with treatment over a specified time period (Hurst & Bolton, 2004). Respondents were asked to report how their pain condition has changed since they began treatment with their primary care provider. A significant favorable score is considered to be 5 to 7 (Hurst & Bolton, 2004). Respondents were asked to describe changes, if any, in activity limitations, symptoms, or overall quality of life related to their condition on a scale from 0 (no change) to 7 (a great deal better).

For exploratory purposes, an additional measurement was selected to extend what is known about the effects of self-management programs among patients on opioid medications. The rates of opioid misuse and abuse may be underestimated (Turk et al., 2008). Early and accurate identification for misuse is essential to provide effective interventions, yet no consensus exists for optimal methods. Self-reports and clinicians’ appraisals have been found inadequate and unreliable (Chou et al., 2009b; Turk et al., 2008). A review by Turk and colleagues (2008) concluded that the psychometric analyses of existing screening instruments are incomplete. Little is known about how to avoid abuse and addiction among opioid users, therefore more studies are needed to provide evidence of the reliability and validity of existing processes and screening tools. The Current Opioid Misuse Measure (COMM) (Appendix D) is a 17-item self-assessment used to monitor patients on opioid therapy and identify whether patients are currently exhibiting behaviors indicative of misuse. Six key issues are explored: signs and symptoms of intoxication,
emotional volatility, evidence of poor response to medications, addiction, health care use patterns, and problematic medication behavior (Inflexxion, 2008). Construct validity has been demonstrated with positive correlations with urine toxicology results (Wasan et al., 2007). Reported test-retest reliability is .86 and coefficient alpha is .86 (Wasan et al., 2007). Use of the COMM in the current study assists in building the knowledge base regarding opioid misuse measures. Such knowledge may be useful in future studies that address the appropriate use of opioids.

Participants were asked to complete another pain assessment, the Profile of Chronic Pain (PCP) in the first and final weeks as they participated in the self-management program. The timeframe was chosen to align with the planned PCP assessments that are requested as part of the CPMP activities. The PCP has two components: the Screen (PCP-S) and the Extended Assessment (PCP-EA). The 15-item PCP-S has three subscales: pain intensity, pain interference, and emotional burden. Test-retest reliability ranges from .77 to .85 and coefficient alpha from .89 to .91. Convergent and criterion-group validity have been demonstrated (Ruehlman, Karoly, Newton, & Aiken, 2005a). The 95-item PCP-EA has good internal reliability (.74 to .89) and construct validity (Ruehlman et al., 2005b). The PCP-EA assesses pain location and prior diagnoses, pain characteristics, functional limitations, medication use, and health care status. In addition, the PCP-EA includes 13 subscales addressing aspects of coping, catastrophizing, pain attitudes and beliefs.

The Pain Self-Efficacy Questionnaire (PSEQ) is a 10-item instrument to measure the confidence someone has to conduct activities while experiencing persisting pain (Tonkin, 2008) (Appendix D). Since no “gold standard” exists yet in measuring pain self-efficacy, these data were collected to add to the literature on the PSEQ reliability and validity testing; psychometric
properties were determined to be lacking in the one published review of pain self-efficacy scales (Miles et al., 2011). Studies using the PSEQ determined there was high internal consistency (Chronbach’s alpha .92); construct validity was demonstrated by sensitivity to change of condition and correlations with pain-related disability and coping (Tonkin, 2008). Valid and reliable self-efficacy instruments specific to pain may be useful in future studies to test interventions that can assist patients in building and sustaining gains in functioning (Tonkin, 2008). Higher self-efficacy is associated with positive outcomes of pain coping, increased pain thresholds and tolerance, and decreased emotional distress and disability (Keefe et al., 2004). A major weakness in self-efficacy is the variation in testability. Self-efficacy outcome measures should be task and domain specific. Because instruments must be developed for each specific task, there are some inconsistencies in measurement. Global efficacy beliefs that do not correspond with specific tasks of interest will reduce predictive accuracy (Pajares, 2004). Consequently, the ability to generalize findings is limited unless studies measure similar activities. In the review by Miles et al. (2011), the study methods and design in prior investigations of the PSEQ had limitations, therefore, more research is needed to build confidence in this measurement.

Descriptive data was collected in the current study to explore characteristics of enrolled patients. Qualitative description is an appropriate methodology when investigators seek to “understand, represent or explain” (Pyett, 2003). Neither web-based pain management programs nor their application to patients with pain are well-understood. Thus, the purpose of the descriptive analyses was to better understand the participants and their experiences in the CPMP by examining the diversity of responses and identifying categories and trends. Future qualitative analysis may be conducted if a deeper understanding is desired for program development.
A demographic survey was administered with the first pain surveys and included age, level of education, marital status, diagnosis, co-morbidities, and zip code to establish rural or urban residency (Appendix D). Baseline medication use was assessed by a review of all current prescription and over-the-counter medications at the time of informed consent. This assessment included asking participants to state one goal related to their medication and one goal related to their overall health and well-being (Appendix D). A questionnaire adapted from the Stanford University Patient Education Research Center Health Care Utilization survey was distributed bi-weekly to determine how many times in the past two weeks participants visited a health care provider, counselor, clinic, emergency department, or stayed overnight in a hospital (Appendix D). The original scale has test-retest reliability of .76 to .97 and has been validated through chart audits (Lorig et al., 1996). Open-ended questions were added to the scale to ask participants whether they or their providers changed any of their medicines or other therapies in the past week, and specifically, if any changes resulted from their experiences participating in the CPMP. These questions were designed to provide insight on whether the self-management program is able to address the goals that patients identify as most pertinent and allow for hypothesis development in future studies.

Finally, a descriptive survey was administered to explore participants’ perceptions of their experience in the self-management program (Appendix D). Likert-style questions comprised three categories under the broad topic of “satisfaction”:

- Usability/ease of Internet-based program
- Quality of information received through Internet-program
- Usefulness of program for managing and understanding health concerns

The items were adapted from IBM Computer Usability Satisfaction Questionnaires.
(Lewis, 1995). These are validated tools with internal reliability greater than .89 that were developed to collect subjective data on participants’ attitudes and opinions concerning perceptions of use of computer systems. Such measures are considered difficult due to the multidimensional nature of users who perform computer tasks in a variety of environments; adding items to the established questions is permissible (Lewis, 1995). Open-ended survey questions allowed participants to address gaps in knowledge about the usefulness of the CPMP with structured interview items. Participants were asked what, if any, lifestyle, cognitive, or behavioral changes they were able to incorporate as a result of the program. Using the adapted pre-existing and standardized IBM instrument allows results to be compared easily with other programs in the event new pain programs are developed and available. This portion of the study can be replicated inexpensively, and findings communicated easily (Lewis, 1995).

**Procedures**

An equal number of participants were recruited and randomly assigned to either treatment group or treatment as usual (TAU) wait-listed comparison group. Enrollment was ongoing until an acceptable sample size was reached. Participants received their group assignment from a research team member at the time of informed consent using a pre-sealed envelope that contained assignment to group and identification number. It was opened by participants at in-person meetings and over the phone by researchers for those unable to meet in person. Participants were directed to begin with study protocols as soon as they received their group assignment. All participants received an email link to access baseline questionnaires. Once those were completed, they received instructions via email specific to their assigned group. Treatment group participants received their access code to begin the CPMP immediately and free of charge. They were all given the opportunity for additional assistance orienting to the program
if desired. The researcher offered to guide the participant via phone, or in person at a public setting with a computer for those living within a 100 mile radius. TAU group participants were told to expect bi-weekly surveys to obtain data on their pain and mood status, health care utilization and changes to medicines or therapies. TAU participants were informed that after 8 weeks of data collection they would receive information on how to access the CPMP if they chose to participate. They were told that they would be asked to continue with bi-weekly pain and mood assessments if they engaged in the program.

**Data collection and protection**

During the informed consent meeting, participants received verbal and written instructions on data collection procedures. Participants were directed on how to access baseline surveys for data collection using an Internet-based secure survey tool, Qualtrics. A unique participant user identification number was assigned at the time of consent to assure confidentiality with online communications. This identifier was the code used in all data files. Data files were downloaded from the Qualtrics site onto a secure password protected computer and stored for later analysis. A key that attached the participants’ names with their user identification number was stored in a password protected electronic file separate from the survey data file. A paper key was stored in a locked file in the primary investigator’s office. No names were collected with the survey data, however, email addresses are collected and stored on the Qualtrics site. These and all survey data were deleted from the Qualtrics site after the study was completed. Any email communications from participants were deleted after they were read and no longer deemed necessary or pertinent to the study. All data files will be deleted or shredded seven years after the study completion.
Participants were asked to complete baseline surveys at their earliest convenience. This data collection time point (T1) included a demographic survey, the BPI, PHQ-8, COMM, PSEQ, and PGIC. The initial data collection survey was designed to take no more than 30 minutes for most participants to reduce burden and survey fatigue. Baseline data on medications was collected by asking all participants to bring their current medicines or updated list to the informed consent meeting in order to obtain a current and accurate record. Those who provided informed consent via phone were asked to collect their medication containers and read them to the researcher, or share their most current list via email or survey tool. All dosages and usual times of administration were collected. A medication list was generated that was re-distributed at the end of the study with the final survey collection to allow participants to review and adjust if changes occurred during the course of the study. Along with the medication review, the participants were asked to state one goal related to their medication use and one goal related to overall health and well-being. At the study end, they received a reminder of their identified goal(s) and were asked to rate their progress towards that goal.

Scheduled surveys were distributed at time points T2-T5 (Table 1) and data collected via Qualtrics to both treatment and TAU groups. Participants were asked to complete their baseline surveys directly after the informed consent meeting. Those participants assigned to the treatment were guided by the researcher through the CPMP registration process. A user ID and password was assigned and used as the participant’s identity and to log into the program. The participant was informed that the researchers may access their CPMP account to retrieve data for the study. Participants were given the option to choose a private password to keep their specific program activities private if they preferred. The PCP data was collected on the CPMP site as part of the first week’s lessons. Participants were asked to complete the PCP at their earliest convenience
and the researcher used their assigned password to access the results and print out a copy to mail or deliver to the primary care provider, as agreed upon in the informed consent.

Table 1.

*Measurement Timeline for Treatment (TX) and Treatment As Usual (TAU) Groups*

<table>
<thead>
<tr>
<th>Group Assignment</th>
<th>T1</th>
<th>T2</th>
<th>T3</th>
<th>T4</th>
<th>T5</th>
<th>T6</th>
</tr>
</thead>
<tbody>
<tr>
<td>TX/TAU</td>
<td>BPI</td>
<td>BPI</td>
<td>BPI</td>
<td>BPI</td>
<td>BPI</td>
<td>BPI</td>
</tr>
<tr>
<td>TX/TAU</td>
<td>Demographic survey</td>
<td>Health utilization survey</td>
<td>Health utilization survey</td>
<td>Health utilization survey</td>
<td>Medication list with goals</td>
<td></td>
</tr>
<tr>
<td>TX/TAU</td>
<td>PHQ-8</td>
<td>PHQ-8</td>
<td>PHQ-8</td>
<td>PHQ-8</td>
<td>PHQ-8</td>
<td>PHQ-8</td>
</tr>
<tr>
<td>TX/TAU</td>
<td>PSEQ</td>
<td>PSEQ</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TX/TAU</td>
<td>COMM</td>
<td>COMM</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TX/TAU</td>
<td>PGIC</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>PGIC</td>
</tr>
<tr>
<td>TX</td>
<td>PCP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TX</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Computer Usability Satisfaction</td>
</tr>
</tbody>
</table>

Data were collected on both treatment and TAU groups using the BPI, PHQ-8, and Health Care Utilization via Qualtrics approximately 2 weeks after baseline surveys (T2). The researchers communicated via email, text or phone (depending on participants’ stated preference) during the first 4 weeks to ask treatment group participants if they had any questions about the learning activities and to ascertain that they understood how to proceed with the modules. A script was used to guide these contacts to assure intervention fidelity (Appendix E). Each participant received at least one prompt reminding them to engage in CPMP activities and complete their PCP if they had not, and encouraging them to complete more activities if they had shown some engagement. The CPMP directed participants to begin the learning module designed
to address their area of greatest need as identified by their PCP results. Participants were reminded in the communication prompts that they could request more guided assistance over the phone if necessary. Participants finding it too difficult to initiate the program on their own were offered additional meeting time with a member of the research team at a public computer for further instruction if they lived within a 100 mile radius. Data were retrieved from the CPMP regarding the priority order of the learning modules, which activities the participants engaged in, and the ratings they assigned using the site’s 5-item scale for helpfulness (1 = not at all helpful, 5 = extremely helpful).

The only other results that were shared with providers besides the PCP reports were graphic displays of the BPI and PHQ-8 results from both treatment and TAU groups at the end of eight weeks (Figure 3). Additionally, any participants who had PHQ-8 results indicating symptoms of major depression were notified of those findings by a research team member. Participants were contacted by their preferred method (email, text, or phone) at the earliest possible time after the PHQ-8 survey was processed, generally within 24-48 hours of completion. Participants were given a suicide hotline number and advised to consider making an appointment with a mental health services provider or a provider of their choice to determine whether treatment for depression was indicated.
Figure 3. Sample communication to primary care provider of pain and depressive symptoms at week 8 time point

Data collected at T2 was repeated via Qualtrics at two week intervals: T3, T4, T5. Data collected at T5 included the PSEQ, COMM, and PGIC. Additionally, at T5 all participants were asked to review the medicine list the researchers compiled at baseline and report any changes. They were also asked to state their perception of how well they met their identified goals using a Likert-style scale (Appendix D). This communication was delivered via Qualtrics survey system and followed up with a phone call or email if it required further clarification. At T5 for those participants in the treatment group, the adapted IBM Computer Usability Satisfaction Questionnaire was administered via Qualtrics. Participants were reminded to repeat the PCP as directed through the CPMP. The results of these and the initial PCP results were sent from the program administrator in a de-identified data file. A final time point was added for those participants agreeing to be contacted after six months from the posttest survey (T6) to evaluate for lasting effects. Data collection continued for any members of the TAU group who went on to
trial the CPMP as outlined in T2-T6 for the original treatment group. Their initial T5 measures served as a new baseline.

The frequency of data collection was determined to coincide with the anticipated ending date of each of four learning modules that are assigned in the CPMP. Additional rationale for the data collection time points was provided by Broderick et al. (2008) who found that frequent pain assessments are more accurate than those that require patients to remember symptoms beyond several days. Patient reported outcomes involving recall are more likely to suffer from bias, and specifically, may overinflate pain ratings (Broderick, 2008). Bias and inaccuracy due to a reliance on recall is the most significant methodological factor affecting self-reported data (Gendreau, Hufford, & Stone et al., 2003). Bringing pain assessments closer to real time avoids the limitations of memory. Researchers can decrease exaggerated placebo effects that occur due to fading memories of how one felt before treatment, and along with it the weakened evidence of clinical change (Gendreau et al., 2003). Both the BPI and PHQ-9 are commonly used in measurement intervals as close as two weeks. Providing the PHQ-8 at more frequent intervals in this study allowed for greater understanding about how mood is impacted by program involvement, and was thought to provide additional protection to vulnerable patients who may require intervention for severe depression.

Data collection completion and retention of participants was addressed by offering rewards that participants accrued throughout the study. Gift card dollars were earned at a rate of $5 per each survey time point. Completion of all assigned surveys would earn a maximum of $30. An additional $10 was added for any TAU group member who proceeded and engaged in the CPMP and completed the final surveys. Additionally, anyone who completed all assigned surveys earned a chance to be randomly selected by lottery drawing to earn an additional $50 gift
card. Three participants were selected to receive this additional reward; one from the initial treatment group, one from the TAU group, and one from the TAU group after completing the CPMP and final survey. Participants were paid via gift cards that could be delivered either in person, via mail, or electronically once their role in the study was completed. For participants who did not complete their surveys, the researchers initiated contact using a scripted message via phone, text or email when surveys were a week or more overdue to prompt participation (Appendix E). A weekly reminder was delivered electronically until the survey was completed or past due by more than a month.

Electronic surveys are one of the three most significant advances in survey technology in the twentieth century; the other two are random sampling and the telephone (Dillman, 2000). Limitations of paper surveys such as incomplete and missing data, checking wrong box, and errors in transcription can be avoided using electronic versions. The shift of telephone ownership away from household phones towards individual cell phones has made Internet interviewing more desirable from researchers’ perspectives (Dillman, 2000). Email data collection may be particularly well-suited to studies regarding pain as it keeps the audit of the data closer to the participants than a verbal interview because there is no need for transcription (Hamilton & Barrows, 2006). Surveys delivered via Internet are efficient, cost-effective and afford practical advantages. With anonymity provided, participants may be more apt to answer honestly, particularly regarding opioid misuse. The CNCP population often suffer stigma as “drug seekers” so privacy is an important consideration (Todd et al., 2010). Internet-based surveys may be best for sensitive topics (Wantland et al., 2004). Some researchers have suggested that Internet-based formats can allow for equalization to occur among participants in terms of race,
gender, and status; this allows for greater freedom of expression and can shift power from researcher to participant (Hamilton & Barrows, 2006).

**Intervention**

The chosen intervention was the Chronic Pain Management Program (CPMP), an 8-week Internet-based self-management program for patients with persistent pain. The CPMP addresses pain with learning modules that fall into four categories of cognitive, behavioral, social, and emotional regulation: Thinking Better, Feeling Better, Doing More, and Relating Better. The program was created by a team of psychologists based on face-to-face forms of psychosocial intervention for chronic pain that have demonstrated efficacy (Ruehlman et al., 2011). Each learning module offers interactive and didactic lessons with both online and off-line activities designed to address common problems with persistent pain. For example, the “Doing More” module assists in developing an exercise program and “Thinking Better” addresses negative thoughts related to pain. Assignments encourage self-monitoring and practicing new skills.

The results of the PCP are tallied for participants and used to create a custom learning plan that prioritizes needs. Responses are automatically scored within the computer program. They are compared to national age- and gender-based norms, and presented in an online report. Participants scoring higher (“worse”) than 85% of those in his or her norm group in a particular domain will be advised in the online report that this area may be of high priority for attention. For example, low scores on physical activity may suggest a need to focus first on developing an exercise program. Scores that are higher than 75% to 84% of the norm group reflect moderate need for treatment. Scores below this cut point are considered to be of low priority, or within the normal range. The PCP scores map onto the four learning modules and participants are provided direction on which module they should engage in first, based on the highest priority area.
Several tools within the program are available to assist participants in tracking their progress, pacing their activities, and sending reminders via email or text to complete tasks. Data are stored and may be presented graphically to visualize progress. A social networking component of the CPMP allows users to create a profile with privacy options. Participants may send messages to others in the program if they choose. The CPMP has shown promise in improving pain symptoms and emotional distress among participants recruited from the Internet (Ruehlman et al., 2011). It has not been tried among patients recruited from primary care clinical settings, or specifically, among those prescribed opioids.

Although Internet-based programs run the risk of excluding people who cannot or will not participate in computerized communications, online users are increasing and the Internet is considered a valuable tool by many. According to The Harris Poll (Harris Interactive, 2010) of 1,066 Americans, the number of adults who report ever using the Internet to look for health information has increased to an all-time high of 88%. The number of people who go online for any purpose reached 79% and on average, they seek health information six times monthly. This can be compared to the 46% who used the Internet in 1999. Education and income are generally higher among Internet-users, age is lower, and race closely represents the general population distribution (Hamilton & Bowers, 2006). Smartphone ownership has increased to 46% of Americans (Pew Research Center, 2012). It is the growing means of primary communication and Internet access, particularly among minorities, rural and poor populations (Pew Research Center, 2012). The CPMP and Qualtrics surveys can be accessed using smartphones. To increase opportunities for access to this study, participants were encouraged to use whatever means of Internet access they had available; this could be smartphones, or private or public computers.
Analytical plan

The rationale for the analytical plan was guided by what is known about pain and self-management interventions. Data analysis was conducted using SPSS™ software version 18.0 (SPSS, Inc., Chicago, IL, USA). Descriptive statistics, Analysis of Variance (ANOVA), and Number Needed to Treat (NNT) were performed to investigate primary outcomes. Means, standard deviation and ranges were calculated on all quantitative data. Chi-square and independent samples t-tests were used to test for differences between study groups in the distribution of baseline demographic or pain history characteristics including gender, age, educational level, and number of pain diagnoses.

The primary outcomes were analyzed for between and within group interactions to see how each group changed over time. Each participant’s scores on the BPI factors of pain intensity and pain interference measurements were compared by evaluating within and between group differences as well as interaction effects using 2 (between: treatment vs. comparison) x 5 (within: Time 1-5) mixed design ANOVA. The analysis of an interaction effect (between treatment groups and over time) answers the question of whether the intervention works over time of engagement. The 2 x 5 repeated measures ANOVA can determine significance and at what time point a significant effect is detected. Whether that occurs at point T2 after completing the assigned highest priority learning module, or more cumulatively at the endpoint is important to understand and inform future program development. Findings allow conclusions to be drawn about the “dose” of the intervention required to serve some benefit. Patients with CNCP who are prescribed opioids have demonstrated difficulty engaging and sustaining involvement in a chronic disease self-directed web-based application when recruited from ED settings (Wilson et al., 2013). Still unknown at the initiation of this study was the level of participation and effects that can be expected from patients recruited from a primary care setting and who have access to a guided orientation of a pain-specific program. Discovering a time point that yields a significant
effect is important from a pragmatic perspective, and is necessary to address at this state of the science; therefore, sample size calculations for this study were based on the between x within group interaction analysis as it captures the effect of both group assignment and time.

Post hoc sample size calculations were performed using the findings of this study to determine the group size necessary for significant between group effects. Placebo effects are common in pain trials and will result in small differences between groups (Dworkin et al., 2009). Additionally, it is possible that the act of frequent assessments for those in the TAU group for this study results in some benefit from the act of assessment alone, along with any communications with their provider that may result from such assessments. Pain literature suggests that increased assessments will result in improved pain care. This is a well-established assumption that has been responsible for organizations such as The Joint Commission and the American Pain Society to suggest that pain be the fifth vital sign; they recommend this as a means of prompting nurses to reassess and document pain whenever vital signs are obtained (Wells, Pasero, & McCaffery, 2008). Frequent communication, goal setting, and shared knowledge are associated with improvement in pain control (Wells et al., 2008). For this reason the TAU group did not receive any feedback on their assessments or communications to their providers until after the first eight weeks passed and they began the CPMP. One exception was if PHQ-8 results indicated severe or moderately severe depression. For risk reduction, those participants were informed of their results and were encouraged to seek evaluation and treatment for depression as detailed on the informed consent.

Subsequently, TAU group participants were given the opportunity to complete the program, share the PCP results with providers, and continue with bi-weekly measurements. These findings were analyzed separately, evaluating within group differences using a one-way repeated measures ANOVA. This analysis was conducted to see how the findings compare to those from the original treatment group.
In order to guard against Type II error and ensure that clinically significant findings are not overlooked, Number Needed to Treat analysis was employed to determine how many participants did receive clinically significant benefit from the intervention. This type of investigation is considered more relevant to clinicians and patients than group means (Dworkin et al., 2009; Gendreau et al., 2003). Analyzing the data in binary terms will determine whether each patient is a “responder” or a “non-responder”; a responder will have achieved a clinically meaningful benefit (Dworkin et al., 2009; Gendreau et al., 2003). To align with IMMPACT recommendations, two or more different measures should be used to evaluate the clinical importance of improvement or worsening of persistent pain; results of responder analyses were compiled to compare the percentages of participants with clinically important changes on primary outcomes in the two groups (Dworkin et al., 2008; Dworkin et al., 2009). This analysis addresses the variation of responses and can provide information that may be masked by group means. It can also provide ranges that can identify differences on various measures. Clinically important changes in pain scores using 0 to 10 numeric rating scales have been found to be approximately 2.0 points or 30% to 36% on the pain intensity rating (Dworkin et al., 2008; Farrar, Young, Lamoreaux, Werth, & Poole, 2001). Available data suggest that a change of 1 point on the pain interference rating is associated with clinically meaningful improvement (Dworkin et al., 2008). For this study, NNT was calculated by comparing the percentage of “responders” achieving clinically meaningful improvement in each study group for both pain intensity and pain interference. The absolute risk difference was calculated by finding the difference between the incidence proportion of responders in the treatment and control groups. The inverse of this value represents the NNT.

Secondary outcome measures are recommended in pain trials as they can provide important information regarding benefits beyond pain that may impact quality of life (Dworkin
et al., 2009). For this study, the outcomes on PHQ-8, COMM, PSEQ, PCP and PGIC are presented descriptively, and a series of inferential tests were conducted to explore whether effects exist. Cronbach’s alpha was employed for internal reliability on all scales used for this study. For the PHQ-8, measurements were compared looking at within and between group differences as well as interaction effects using 2 (between: treatment vs. comparison) x 5 (within: Time 1-5) mixed design ANOVA. The additional measurements that were collected at baseline and post-intervention were analyzed using 2 (between: treatment vs. comparison) x 2 (within: Time 1-5) mixed design ANOVA. Descriptive statistics were used to summarize characteristic data from the PCP. Because the study’s sample size was not calculated based on secondary outcomes, post hoc analysis was conducted to determine whether absence of effect is due to the study being underpowered for these measures.

It was anticipated that all measurements may not be present during all time points. It was decided *a priori* that missing data would be handled using listwise deletion. It was also anticipated that participants in the treatment group would have varying degrees of involvement with program activities. In order to understand how effects are related to level of participation, a variable of “engagement level” was added to conduct an exploratory analysis to consider intervention “dose” and the varying levels of involvement participants have in the CPMP. Descriptive statistics were used to summarize characteristic of those participants who engaged or did not engage in the CPMP. The covariate “engagement level” was defined *a priori* as any evidence that the participant has entered at least one activity in an assigned learning module. This was determined by the presence of the “star rating” that is required when participants exit an activity. An engagement level of zero was assigned if there was no evidence of any activity within any module. A “1” was assigned if there was no evidence of activity within any learning module, but the PCP had been completed and shared with provider, a “2” was
assigned for evidence of activity within no more than one learning module, a “3” was assigned for evidence of activity within no more than two learning modules, a “4” if no more than three, and a “5” if all four activities showed evidence of activity. The rationale for choosing these categories was that low participation in the learning modules was anticipated and this strategy would provide some measurement of passive engagement as well as activity completion. It was expected that researchers could measure the activities in each learning module that require star ratings upon completion. Yet researchers could not measure whether participants entered a learning module, completed readings and/or watched an educational video; these activities did not require an evaluation rating. Therefore, the categorical measurement of engagement might better measure passive as well as active engagement. Calculating all of the star ratings assigned might indicate high engagement, or could indicate a participant was focused on being a “good patient” and checking off activities without concentrating on content or attempting to learn new behaviors. By assigning categories, researchers hoped to capture whether participants had been exposed to at least some content in each of the four main learning topics. It also allowed a separate category for the exchange of information from a completed PCP, thus allowing measurement of this communication between participant and provider so it can be examined for its impact.

Associations were explored between the level of program engagement and positive changes in BPI, PHQ-8, PSEQ and COMM scores using Pearson’s Correlations Coefficient. Regression models were explored to see if participant engagement levels could predict positive changes on each of the variables that were significantly correlated.

A descriptive approach was employed to study the subjective perceptions and self-reported health behaviors. Most studies of self-management programs have used empirical measurements and little information is available to understand the patient perspective as a participant. Few, if any, self-management programs have prioritized the participants’ experience as central to the
the program; instead, the assumption is that education is paramount (Crowe et al., 2010). Some studies have questioned the impact of self-management programs and identified problems with these interventions, thereby demonstrating a need for further exploration and development (Foster et al., 2007; Redman, 2005). Although individual trials of self-management programs show measureable positive effects, systematic reviews point out that improvements are often short-lived and too small to be clinically significant (Foster et al., 2007). Others argue that effectiveness is not easily determined because the primary benefit for many in these programs is subjective well-being and this is difficult to quantify (Willis et al., 2011). A failure to consider the lived experiences of patients with chronic disease has been identified as a weakness in self-management educational approaches (Protheroe, Rogers, Kennedy, Macdonald, & Lee, 2008). More study is needed to explore how patients engage with and use self-management information.

Milne and Oberle (2005) state that qualitative descriptive research should describe and understand a phenomenon through the lens of participants, and while it stays close to the surface in analyzing data, it should generate insights. For this reason, responses from the bi-weekly health-care utilization survey, medication inventory, and the final usability survey were summarized and categorized as a subjective report of the text data. The numeric data from Likert-style questions were compiled to present a group average perception of satisfaction with the self-management program experience. The numeric scores were used to assist in synthesizing data from the pre-figured topical categories that were established a priori. The open-ended data identified variables that explain how participants viewed their experience in the program. Comparisons between groups were examined and summarized using descriptive statistics. A separate analysis may be performed in addition to the present study in the future if it is determined that the qualitative data merits in-depth attention. Additionally, more investigation of specific activities that participants
engaged in on the program site may be added to the analysis if deemed important to add to
knowledge regarding usability and engagement.

Long-term follow up to six months will be addressed in a future analysis. A 2 x 6 mixed
ANOVA will be conducted to evaluate changes over longer time periods using data from those
participants who complete a final survey at the six month time point. These data will be
examined separately from the initial research as attrition is likely and will need to be analyzed
using accepted methods for missing data.

**Ethical considerations**

Approval for this study was obtained from the Washington State University Institutional
Review Board (IRB), Kootenai Medical Center in Coeur d’Alene, and IRB Spokane prior to
initiation of recruitment from each site. In order to reduce participants’ risk of harm, they were
informed that any information shared that might result in harms to self or others would be
reported to the primary care provider or other appropriate agency at the earliest convenience.
Such information might include reports of suicidal or homicidal thoughts, or other behaviors that
were determined by the study team and/or their medical director to be potentially dangerous to
either the participant or others.

Other potential risks identified included the stress or psychological discomfort associated
with answering personal questions. Participants were encouraged to contact any member of the
study team if they felt they needed counseling, or other support. The risk reduction plan included
making referrals to the appropriate health services if deemed necessary by the medical director.
Those services were pre-identified as the Region 1 Mental Health Services that covers northern
Idaho and has a 24 hour mental health crisis line, and similar services using a suicide hotline for
participants living outside of northern Idaho.

The potential risks of loss of confidentiality and privacy were minimized by using a
secure web site for survey distribution and data collection. No identifying information such as
names or social security numbers were connected to data. Data shared via email between research team members was de-identified and deleted after it was read, and downloaded to secure password protected computers. Emails or text messages between researchers and participants were deleted after necessary information was abstracted and saved in a protected file. The privacy standards of the Qualtrics and Goalistic web-sites were reviewed and presented with IRB applications to assure expected protections were adequate.
CHAPTER FOUR
RESULTS

Sample description

The total number of participants referred for eligibility screening was 283. Of those, 236 responded to researchers and completed eligibility screening either via phone or email. A participant flow diagram consistent with the CONSORT statement (Begg et al., 1996) is depicted in Figure 4. A total of 114 participants consented to join the study; 60 (53%) were referred from their health care provider and 54 (47%) were self-referred from Internet advertising. An equal number, 57, was randomized into the treatment group and the TAU wait-listed attention control group. Ten (6 experimental and 4 control participants) failed to take part in any aspect of the study after randomization. Twelve (6 experimental and 6 control participants) completed baseline data, but did not complete follow-up assessments required for analysis. Therefore, the final sample consisted of 92 participants, with 45 (49%) in the experimental group and 47 (51%) in the control group. Twenty-four potential participants cited computer access or lack of computer abilities as a reason for declining to participate. Eight of those that did not complete the study reported computer utilization issues as a contributing reason.

Participants in this sample were predominantly female (78%). Ages ranged from 24 to 78 years (Mean = 49.33; SD = 11.63) and were assessed to be normally distributed using a histogram. Approximately 65% of the participants were married or living with a significant partner, 9% were single, and the remaining were divorced (20%), separated (3%), or widowed (3%). The majority of the sample had at least some college education (75%); 25% had a high school degree or less, or a General Education Development certificate (GED). Fifteen percent had a two-year college degree, 21% reported a four-year degree, and advanced graduate degrees were reported by 15%. Zip code data showed 41% (n = 38) participants living within the 150 mile radius of the initial recruitment efforts. The remainder lived in 29 different states with
Figure 3. Participant flow diagram
79% (n = 73) from urban areas and 21% (n = 19) from large and small rural communities.

Most participants (73%) reported more than one medical diagnosis related to their painful condition. On average, two pain diagnoses were reported for each participant with a range of 0 to 8 diagnoses. The most common diagnoses were back or spine conditions (45%), fibromyalgia (29%), arthritis/osteoarthritis (26%) and migraine headache (22%). Table 2 depicts the most common diagnoses.

Table 2.

<table>
<thead>
<tr>
<th>Pain Diagnoses Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain source</td>
</tr>
<tr>
<td>Back/spine pain</td>
</tr>
<tr>
<td>Fibromyalgia</td>
</tr>
<tr>
<td>Arthritis/osteoarthritis</td>
</tr>
<tr>
<td>Migraine headache</td>
</tr>
<tr>
<td>Chronic post-surgical pain</td>
</tr>
<tr>
<td>Nerve pain</td>
</tr>
<tr>
<td>Chronic regional pain syndrome</td>
</tr>
<tr>
<td>Facial/jaw pain</td>
</tr>
</tbody>
</table>

Differences between baseline characteristics in treatment and comparison groups were examined with a series of chi-square and independent t-tests (Table 3). The two groups did not differ significantly in the distribution of demographic, baseline pain or depressive symptoms. Characteristics of the 12 participants who completed baseline surveys and did not go on to participate further in the study were compared to the final participant sample using chi-square and independent t-tests. No significant differences were detected in age (t = 0.50, p = .62), gender, (x² = 1.35, p = .25), education level (x² = 0.08, p = .78), or marital status (x² = 0.02,
between the final sample and those who did not complete the study. Those who did not complete were significantly more likely to have been referred from a provider than self-referred ($\chi^2 = 4.6, p = .03$).

Table 3.

Descriptive Statistics for Demographic Characteristics and Baseline Outcomes

Measurement Scores with Cronbach’s Alpha

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>TAU Group</th>
<th>Treatment Group</th>
<th>Test statistic</th>
<th>p value</th>
<th>Cronbach’s alpha</th>
<th>Total combined groups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td></td>
<td></td>
<td>pretest/posttest</td>
<td>N (%)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Females</td>
<td>38 (41)</td>
<td>34 (37)</td>
<td>$x^2 = 0.54$</td>
<td>.54</td>
<td>--</td>
<td>72 (78)</td>
</tr>
<tr>
<td>Males</td>
<td>9 (10)</td>
<td>11 (12)</td>
<td></td>
<td></td>
<td></td>
<td>20 (22)</td>
</tr>
<tr>
<td>Age in Years</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>49.7 (11.3)</td>
<td>49.0 (12.0)</td>
<td>$t = -0.27$</td>
<td>.79</td>
<td>--</td>
<td>49.3 (11.6)</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>29 (31)</td>
<td>29 (32)</td>
<td>$x^2 = .07$</td>
<td>.79</td>
<td>--</td>
<td>58 (63)</td>
</tr>
<tr>
<td>Unmarried</td>
<td>18 (20)</td>
<td>16 (17)</td>
<td></td>
<td></td>
<td></td>
<td>34 (37)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No college</td>
<td>13 (14)</td>
<td>10 (11)</td>
<td></td>
<td></td>
<td></td>
<td>23 (25)</td>
</tr>
<tr>
<td>Some college</td>
<td>34 (37)</td>
<td>35 (38)</td>
<td>$x^2 = .36$</td>
<td>.55</td>
<td></td>
<td>69 (75)</td>
</tr>
<tr>
<td>Referral source</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self</td>
<td>23 (25)</td>
<td>27 (29)</td>
<td>$x^2 = 1.13$</td>
<td>.29</td>
<td>--</td>
<td>50 (54)</td>
</tr>
<tr>
<td>Provider</td>
<td>24 (26)</td>
<td>18 (20)</td>
<td></td>
<td></td>
<td></td>
<td>42 (46)</td>
</tr>
<tr>
<td>Number of pain diagnoses</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>2.4 (1.3)</td>
<td>2.6 (1.7)</td>
<td>$t = -0.86$</td>
<td>.39</td>
<td></td>
<td>2.5 (1.5)</td>
</tr>
<tr>
<td>BPI baseline pain intensity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>5.0 (1.7)</td>
<td>5.6 (1.6)</td>
<td>$t = -1.75$</td>
<td>.08</td>
<td>.89/.90</td>
<td>5.3 (1.7)</td>
</tr>
<tr>
<td>Range</td>
<td>1.0 – 9.3</td>
<td>2.0 – 9.5</td>
<td></td>
<td></td>
<td></td>
<td>1.0 – 9.5</td>
</tr>
<tr>
<td>Measure</td>
<td>BPI baseline pain interference</td>
<td>PHQ-8 baseline depression</td>
<td>PSEQ baseline pain self-efficacy</td>
<td>COMM baseline opioid misuse measure</td>
<td>PGIC baseline impression of change</td>
<td></td>
</tr>
<tr>
<td>---------</td>
<td>-------------------------------</td>
<td>--------------------------</td>
<td>----------------------------------</td>
<td>-----------------------------------</td>
<td>----------------------------------</td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>5.3 (1.8)</td>
<td>5.5 (2.0)</td>
<td>t = -0.38</td>
<td>.70</td>
<td>.87/.92</td>
<td>5.4 (1.9)</td>
</tr>
<tr>
<td>Range</td>
<td>0.3 – 8.7</td>
<td>0.1 – 9</td>
<td></td>
<td></td>
<td></td>
<td>0.1 – 9</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>12.1 (5.6)</td>
<td>13.0 (6.2)</td>
<td>t = -0.69</td>
<td>.49</td>
<td>.87/.90</td>
<td>12.5 (5.9)</td>
</tr>
<tr>
<td>Range</td>
<td>3 – 23</td>
<td>2 – 24</td>
<td></td>
<td></td>
<td></td>
<td>2 – 24</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>22.8 (12.1)</td>
<td>18.9 (10.8)</td>
<td>t = 1.56</td>
<td>.12</td>
<td>.91/.92</td>
<td>20.9 (11.6)</td>
</tr>
<tr>
<td>Range</td>
<td>1 – 2</td>
<td>2 – 43</td>
<td></td>
<td></td>
<td></td>
<td>1 – 52</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>11.1 (6.9)</td>
<td>12.6 (6.9)</td>
<td>t = -1.01</td>
<td>.32</td>
<td>.77/.80</td>
<td>11.8 (6.9)</td>
</tr>
<tr>
<td>Range</td>
<td>0 – 32</td>
<td>2 – 32</td>
<td></td>
<td></td>
<td></td>
<td>0 – 32</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>3.3 (1.9)</td>
<td>3.4 (1.5)</td>
<td>t = -0.16</td>
<td>.87</td>
<td>--</td>
<td>3.3 (1.7)</td>
</tr>
<tr>
<td>Range</td>
<td>1 – 7</td>
<td>1 – 6</td>
<td></td>
<td></td>
<td></td>
<td>1 – 7</td>
</tr>
</tbody>
</table>

Note. BPI = Brief Pain Inventory; PHQ8 = Patient Health Questionnaire; PSEQ = Pain Self-efficacy Questionnaire; COMM = Current Opioid Misuse Measure; PGIC = Patient Global Impression of Change

**Medication summary**

Participants were asked to provide information about their medications at the beginning and end of the study. A summary of the most frequently reported medications is presented in Table 4 from the 86 participants who provided these data. Daily morphine equivalent dose was calculated based on participants’ reported usual dose; the full study sample average was 95.1 mg per day (SD 109.53) and ranged from 5 mg to 640 mg per day. Twenty participants reported
daily morphine equivalency dosages (MED) above 120 mg; Washington State Department of Health requires consultation with a pain specialist for prescriptions greater than 120 mg MED (2013). More than one form of opioid medicine was prescribed for 33 participants. The average number of medications (both over-the-counter and prescription medications) reported by participants was 9 with a range of 1 to 29 distinct medications.

Table 4.

Most Frequently Prescribed Medications from Participant Baseline Self-report (N = 86)

<table>
<thead>
<tr>
<th>Medication category</th>
<th>n</th>
<th>Oral dose range</th>
<th>Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opioid</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>43</td>
<td>5 – 10 mg</td>
<td>Oral</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>20</td>
<td>5 – 80 mg (immediate and extended release)</td>
<td>Oral</td>
</tr>
<tr>
<td>Morphine sulfate</td>
<td>13</td>
<td>15 – 100 mg (immediate and extended release)</td>
<td>Oral, Rectal</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>11</td>
<td>8 – 32 mg (immediate and extended release)</td>
<td>Oral, Intrathecal infusion*</td>
</tr>
<tr>
<td>Tramadol</td>
<td>10</td>
<td>50 – 300 mg (immediate and extended release)</td>
<td>Oral</td>
</tr>
<tr>
<td>Methadone</td>
<td>5</td>
<td>5 – 10 mg</td>
<td>Oral</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>4</td>
<td>25 – 100 mcg</td>
<td>Transdermal</td>
</tr>
<tr>
<td>Antidepressant</td>
<td>45</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sleep aid</td>
<td>40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Muscle relaxant</td>
<td>35</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anticonvulsant</td>
<td>33</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NSAID</td>
<td>30</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antihypertensive</td>
<td>28</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anxiolytic</td>
<td>27</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note. *n = 3; NSAID = non-steroidal anti-inflammatory
Results of primary aims

SPSS output was examined looking at two main effects and one interaction effect for each of the primary outcome variables.

**Pain intensity.** For the BPI measure of pain intensity the assumption of homogeneity of variance was met using Levene’s test. Significance levels were greater than .05 at all five time points; this indicates that the sample was obtained from a population of equal variance. Missing data was handled using listwise deletion. Those participants who did not complete any surveys at a particular time point were removed from the initial ANOVA resulting in a sample of 70. Cell size was not quite equal; 41 remained in the TAU group and 29 in treatment. Missing bi-weekly surveys were observed for 22 participants (23.9%). The BPI can be reported as a composite average intensity score, therefore, those participants who missed a single item could still have a BPI score calculated for any one time point and were included for analysis.

BPI pain intensity scores demonstrated normality using histograms, Q/Q plots, and Kolmogorov-Smirnov statistics. Kurtosis and skewness were within normal range with values of -.27 and -.15 respectively. Mauchly’s test of sphericity was significant suggesting the variance between the sets of scores was unequal and not correlated, therefore, Greenhouse Geisser correction was employed. The 2 x 5 mixed design ANOVA did not result in a significant main effect for time as measured by the BPI composite score for pain intensity ($F(3.43, 272) = 0.97; p = .42; \text{partial eta squared} = 0.014; \text{observed power} 28.1\%$). No significant main effect for group was observed as measured by BPI pain intensity ($F(1,.68) = .24; p = .62; \text{partial eta squared} = 0.004; \text{observed power} 7.8\%$). No significant interaction between group (treatment versus TAU comparison) x time was observed as measured by BPI score for pain intensity ($F(3.43, 272) = 0.38; p = .80; \text{partial eta squared} = 0.005; \text{observed power} 12.7\%$). The partial eta squared values indicated a small effect and the power was below 80%, therefore, the sample size was not
sufficient for discerning differences. Mean BPI pain intensity scores are presented at each time point in Table 5.

Additional ANOVA tests were run on pretest and week eight final posttest scores to allow for analysis of the full sample of 92 participants. A 2 x 2 mixed design ANOVA did not result in a significant main effect for time as measured by BPI pain intensity \( (F(1, 90) = 0.48; p = .49; \text{partial eta squared} = 0.005; \text{observed power} 10.5\%) \). No significant main effect for group was observed as measured by BPI pain intensity \( (F(1, 90) = 1.50; p = .22; \text{partial eta squared} = 0.016; \text{observed power} 22.8\%) \). No significant interaction was observed between group (treatment versus TAU comparison) x time as measured by BPI pain intensity \( (F(1, 90) = 1.54; p = .22; \text{partial eta squared} = 0.017; \text{observed power} 23.3\%) \). Mean BPI pain intensity scores from baseline to posttest are visually depicted in Figure 5.

![Figure 5](image)

*Figure 5.* Brief Pain Inventory pain intensity mean scores for treatment (TX) and treatment as usual (TAU) groups at baseline and posttest (N = 92).
Table 5.

*Mean Scores for Primary and Secondary Outcomes Measurements*

<table>
<thead>
<tr>
<th>Item</th>
<th>Baseline</th>
<th>Week 2</th>
<th>Week 4</th>
<th>Week 6</th>
<th>Week 8</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TX</td>
<td>TAU</td>
<td>TX</td>
<td>TAU</td>
<td>TX</td>
</tr>
<tr>
<td>BPI pain intensity</td>
<td>5.5 (1.4)</td>
<td>5.1 (1.7)</td>
<td>5.2 (1.5)</td>
<td>5.1 (1.6)</td>
<td>5.3 (1.3)</td>
</tr>
<tr>
<td>BPI pain interference</td>
<td>5.4 (2.1)</td>
<td>5.3 (1.9)</td>
<td>5.7 (2.6)</td>
<td>5.7 (2.2)</td>
<td>5.3 (2.1)</td>
</tr>
<tr>
<td>Affect**</td>
<td>5.3 (2.5)</td>
<td>5.0 (2.1)</td>
<td></td>
<td></td>
<td>4.9 (2.7)</td>
</tr>
<tr>
<td>Activity**</td>
<td>5.6 (2.7)</td>
<td>5.4 (2.0)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PHQ-8*</td>
<td>12.4 (6.3)</td>
<td>12.1 (5.6)</td>
<td>11.6 (7.2)</td>
<td>10.7 (6.3)</td>
<td>11.6 (7.2)</td>
</tr>
<tr>
<td>PSEQ**</td>
<td>19.7 (12.2)</td>
<td>23.0 (12.2)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>COMM**</td>
<td>12.4 (6.9)</td>
<td>10.9 (7.0)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PGIC**</td>
<td>3.4 (1.5)</td>
<td>3.3 (1.9)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note. TX = treatment group, TAU = treatment as usual group, M = mean, SD = standard deviation; * N = 70; ** N = 92
The BPI scale authors recommend all four pain severity items be analyzed since validation models included all four. Analysis was performed with the BPI both as a composite average score and individually to assure meaningful findings would not be overlooked. No significant differences were noted on any individual scale item. All but “pain at its least” followed the same trend as the composite scores with non-significant mean score improvements in the treatment group and small effects with insufficient power to detect significant differences between groups as summarized in Table 6.

Table 6.

*Mean and Standard Deviations for BPI Pain Intensity Items at Baseline and Posttest for Treatment (TX) and Treatment As Usual (TAU) Groups*

<table>
<thead>
<tr>
<th>Item</th>
<th>Baseline TAU</th>
<th>Baseline TX</th>
<th>Posttest TAU</th>
<th>Posttest TX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain at worst</td>
<td>6.8 (1.9)</td>
<td>7.2 (1.6)</td>
<td>6.8 (2.1)</td>
<td>6.8 (2.1)</td>
</tr>
<tr>
<td>Pain at least</td>
<td>3.4 (2.0)</td>
<td>4.0 (2.0)</td>
<td>3.5 (2.3)</td>
<td>4.0 (2.2)</td>
</tr>
<tr>
<td>Pain on average</td>
<td>5.1 (1.8)</td>
<td>5.4 (1.6)</td>
<td>5.1 (1.9)</td>
<td>5.2 (1.8)</td>
</tr>
<tr>
<td>Pain right now</td>
<td>5.0 (2.1)</td>
<td>5.9 (2.0)</td>
<td>5.1 (2.2)</td>
<td>5.4 (2.3)</td>
</tr>
</tbody>
</table>

**Pain interference.** BPI pain interference scores are normally based on an average of seven items; therefore, those participants who missed a single item could have a BPI score calculated for any one time point and were included for analysis. Those participants who did not complete any surveys at a particular time point were removed from the 2 x 5 ANOVA resulting in a sample of 70. The assumption of homogeneity of variance was met for BPI pain interference scores using Levene’s test. Significance levels were greater than .05 at all five time points indicating that the sample was obtained from a population of equal variance. The BPI pain interference scores demonstrated normality using histograms, Q/Q plots, and Kolmogorov-Smirnov statistics. Kurtosis and skewness values were within normal ranges with values of .28
and -.42 respectively. Two extreme low values for pain interference were identified as outliers, but were not eliminated from the data as they did not influence the mean. Mauchly’s test of sphericity was significant suggesting the variance between the sets of scores was unequal and not correlated with each other, therefore, Greenhouse Geisser correction was employed.

The 2 x 5 mixed design ANOVA did not result in a significant main effect for time as measured by BPI pain interference \( (F(3.39, 272) = 1.43; p = .23; \text{partial eta squared} = 0.021; \text{observed power} 40.3\%) \). No significant main effect for group was observed as measured by BPI pain interference \( (F(1, 68) = .00; p = .99; \text{partial eta squared} = 0.00; \text{observed power} 5.0\%) \). No significant interaction between group (treatment versus TAU comparison) x time was observed as measured by BPI pain interference \( (F(3.39, 272) = 0.93; p = 0.448; \text{partial eta squared} = 0.013; \text{observed power} 26.8\%) \). The partial eta squared values indicated a small effect and the power was below 80\%, therefore, the sample size was not sufficient for discerning differences. Mean BPI pain interference scores are presented at each time point in Table 5.

Additional ANOVA tests were run on pretest and week eight final posttest scores to allow for analysis of the full sample of 92 participants for pain interference. A 2 x 2 mixed design ANOVA did not result in a significant main effect for time as measured by BPI pain interference \( (F(1, 90) = 0.001; p = .98; \text{partial eta squared} = 0.00; \text{observed power} 5.0\%) \). No significant main effect for group was observed as measured by BPI pain interference \( (F(1, 90) = 0.005; p = .94; \text{partial eta squared} = 0.00; \text{observed power} 5.1\%) \). No significant interaction between group (treatment versus TAU comparison) x time was observed as measured by BPI pain interference \( (F(1, 90) = 0.76; p = 0.39; \text{partial eta squared} = 0.008; \text{observed power} 13.9\%) \). The partial eta squared values indicated a small effect and the power was below 80\%, therefore,
the sample size was not sufficient for discerning differences. Mean BPI pain interference scores from baseline to posttest are visually depicted in Figure 6.

Figure 6. Brief Pain Inventory pain interference mean scores for treatment (TX) and treatment as usual (TAU) groups at baseline and posttest (N = 92).

BPI pain interference items were also analyzed as separate affect and activity factors. The 2 x 2 mixed design ANOVA did not result in a significant main effect for time as measured by BPI pain interference on the three affect items ($F(1, 86) = 0.32; p = .58; \text{partial eta squared} = 0.004; \text{observed power 8.6\%}$). No significant main effect for group was observed as measured by BPI pain interference with affect items ($F(1, 86) = .01; p = .91; \text{partial eta squared} = 0.00; \text{observed power 5.2\%}$). No significant interaction between group (treatment versus TAU comparison) x time as measured by BPI pain interference with affect items ($F(1, 86) = .711; p = 0.40; \text{partial eta squared} = 0.008; \text{observed power 13.3\%}$). The partial eta squared values indicate a small effect with power below 80%.

The 2 x 2 mixed design ANOVA did not result in a significant main effect for time as measured by BPI pain interference on the four activity items ($F(1, 86) = 0.18; p = .67; \text{partial eta}$
squared = 0.002; observed power 7.1%). No significant main effect for group was observed as measured by BPI pain interference with activity items ($F(1, 86) = .00; p = .98; \text{partial } \eta^2 = 0.00; \text{observed power } 5.0\%$). No significant interaction between group (treatment versus TAU comparison) x time as measured by BPI pain interference with activity items ($F(1, 86) = .23; p = 0.633; \text{partial } \eta^2 = 0.003; \text{observed power } 7.6\%$). The partial eta squared values indicate a small effect with power below 80%. The BPI interference with affect and activity scores from baseline to posttest are visually depicted in Figure 7.

![Figure 7](image)

**Figure 7.** Brief Pain Inventory pain interference with affect and activity mean scores for treatment (TX) and treatment as usual (TAU) groups at baseline and posttest (N = 92).

**Clinical significance**

Number Needed to Treat (NNT) analysis was employed to determine the clinical importance of the intervention as evaluated by the BPI measurement. For pain intensity, a clinically meaningful improvement of two points was achieved by 18% of 45 participants in the treatment group and 6% of those in the TAU group when followed over eight weeks time. With an absolute improvement in pain intensity of 12%, on average, eight people would need to be
treated with the CPMP intervention to achieve clinically meaningful improvement in pain intensity within eight weeks. For pain interference, a clinically meaningful improvement of one point was achieved by 28.9% of participants in the treatment group and 29.8% of those in the TAU group. Therefore, no support for a treatment advantage was detected using NNT regarding pain interference outcomes in our study population. Calculations are presented in Table 7.

Table 7.

Number Needed to Treat (NNT) Analysis Results for BPI Pain Intensity and Pain Interference

<table>
<thead>
<tr>
<th>Pain Intensity</th>
<th>Pain Interference</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAU</td>
<td>TX</td>
</tr>
<tr>
<td>Sample size</td>
<td>47</td>
</tr>
<tr>
<td>Positive effect</td>
<td>3</td>
</tr>
<tr>
<td>Incidence of positive effect</td>
<td>6.0%</td>
</tr>
<tr>
<td>Absolute Change</td>
<td>-12%</td>
</tr>
<tr>
<td>NNT</td>
<td>8</td>
</tr>
</tbody>
</table>

Results of secondary outcomes measures

Depressive symptoms. The PHQ-8 was used to evaluate depressive symptom severity. Baseline scores as evaluated by the PHQ-8 were greater than 14 in 37% (n = 34) of the study participants, indicating moderately severe depressive symptoms. Thirteen participants (14%) scored higher than 20 on the PHQ-8 at baseline, indicating severe depressive symptoms. Both 2 x 5 and 2 x 2 ANOVA were conducted to examine whether the reduced sample size for missing bi-weekly survey data would affect results. The assumption of homogeneity of variance was met using Levene’s test. Significance levels were greater than .05 at all five time points for the PHQ-8; this indicates that the sample was obtained from a population of equal variance. Missing data was handled using listwise deletion, as it was with the primary outcomes measures. PHQ-8
scores did not appear normal on a histograms, however, Q/Q plots, and Kolmogorov-Smirnov statistics demonstrated normality. Kurtosis value was -1.12 and skewness value was .06. No outliers were identified and Mauchly’s test did not show significance.

The 2 x 5 mixed design ANOVA run on a reduced sample of 70 participants resulted in a significant main effect for time as measured by PHQ-8 ($F_{(1, 68)} = 5.952; p = .00; \text{partial eta squared} = 0.080; \text{observed power } 98.4\%$). The mean PHQ-8 score decreased significantly for the 70 participants from baseline ($M = 12.48, SD = 5.98$) to posttest ($M = 9.64, SD = 6.11$). No significant main effect for group was observed as measured by the PHQ-8 ($F_{(1, 68)} = 0.049; p = .83; \text{partial eta squared} = 0.001; \text{observed power } 5.6\%$). No significant interaction was observed between group (treatment versus TAU comparison) x time as measured by the PHQ-8 for depression severity ($F_{(1, 68)} = 1.13; p = .34; \text{partial eta squared} = 0.016; \text{observed power } 35.4\%$). The partial eta squared values indicated a small effect and the power was below 80%, therefore, the sample size was not sufficient for discerning differences.

A 2 x 2 mixed design ANOVA run on the full sample of 92 participants resulted in a significant main effect for time as measured by PHQ-8 ($F_{(1, 90)} = 15.26; p = .00; \text{partial eta squared} = 0.145; \text{observed power } 97.2\%$). The mean PHQ-8 score decreased significantly for the 90 participants from baseline ($M = 12.06, SD = 5.89$) to posttest ($M = 10.34, SD = 6.02$). No significant main effect for group was observed as measured by the PHQ-8 ($F_{(1, 90)} = 0.03; p = .86; \text{partial eta squared} = 0.00; \text{observed power } 5.3\%$). No significant interaction was observed between group (treatment versus TAU comparison) x time as measured by the PHQ-8 ($F_{(1, 90)} = 1.37; p = .25; \text{partial eta squared} = 0.015; \text{observed power } 21.2\%$). The partial eta squared values indicated a small effect and the power was below 80%, therefore, the sample size was not
sufficient for discerning differences. The PHQ-8 scores from pretest to posttest are visually depicted in Figure 8.

![Bar graph showing PHQ-8 mean score comparison between TX and TAU groups at baseline and posttest.](attachment:image.png)

Figure 8. Patient Health Questionnaire mean depressive symptom severity scores for treatment (TX) and treatment as usual (TAU) groups at baseline and posttest (N = 92).

**Pain self-efficacy.** The PSEQ was used to evaluate pain self-efficacy at baseline and posttest. The assumption of homogeneity of variance was met using Levene’s test ($p > .05$). Missing data reduced the sample with complete PSEQ scores to 84; 42 participants remained in both TAU and treatment groups. Baseline PSEQ scores appear slightly negatively skewed on a histogram, however, Q/Q plots, and Kolmogorov-Smirnov statistics demonstrated normality as did skewness and kurtosis values that were .30 and -.22 respectively. One outlier was identified; it did not impact the findings if removed so was included in analysis. Mauchly’s test did not show significance. Cronbach’s alpha was examined at baseline and posttest and was .91 and .90 respectively, showing adequate internal reliability at both time points.

The 2 x 2 mixed design ANOVA found a significant main effect for time as measured by PSEQ ($F(1, 82) = 10.7; p = .002$; partial eta squared = 0.116; observed power 89.9%). No significant main effect for group was observed as measured by the PSEQ ($F(1, 82) = 0.321; p = $
A significant interaction was observed between group (treatment versus TAU comparison) \( \times \) time as measured by the PSEQ \( (F_{1.82} = 13.6; p = .00; \text{partial eta squared} = 0.142; \text{observed power} 95.4\%) \). The mean PSEQ score decreased for the TAU group from baseline (\( M = 23.0, \text{SD} = 12.2 \)) to posttest (\( M = 22.5, \text{SD} = 13.4 \)). It increased for the treatment group from baseline (\( M = 19.7, \text{SD} = 12.2 \)) to final posttest (\( M = 28.6, \text{SD} = 12.8 \)). Higher scores reflect stronger self-efficacy beliefs. The partial eta squared values indicate a large effect with power above 80%. The PSEQ scores from baseline to posttest are visually depicted in Figure 9.

\[ \begin{array}{l}
\text{Baseline} & \text{Posttest} \\
\text{TX} & \text{TAU} \\
19.7 & 23.0 \\
28.6 & 22.5 \\
\end{array} \]

\[ \begin{array}{l}
\text{PSEQ Mean Score} \\
0 & 5 & 10 & 15 & 20 & 25 & 30 \\
\text{Baseline} & \text{Posttest} \\
\end{array} \]

**Figure 9.** Patient Self-efficacy Questionnaire mean scores for treatment (TX) and treatment as usual (TAU) groups at baseline and posttest (N = 84).

**Opioid misuse measure.** The COMM was used to evaluate patients’ self-reported aberrant medication-related behaviors at baseline and posttest. The assumption of homogeneity of variance was met using Levene’s test \( (p > .05) \). Missing data reduced the sample with complete COMM scores to 83; 42 participants remained in TAU group and 41 in treatment group. Baseline COMM scores appear slightly negatively skewed on a histogram, and
Kolmogorov-Smirnov statistics did not demonstrate normality \( (p = .005) \), however, Q/Q plots did appear relatively normal. Kurtosis and skewness values were .23 and .62 respectively. Two outliers were identified; the 5\% trimmed mean was unchanged with their removal so they were included in the analysis. Mauchly’s test did not show significance. Cronbach’s alpha was .77 on pretest and .80 on posttest, demonstrating adequate internal reliability at both time points.

The 2 x 2 mixed design ANOVA found a significant main effect for time as measured by COMM \( (F_{1, 81} = 22.65; p = .000; \text{ partial eta squared} = 0.219; \text{ observed power} 99.7\%) \). No significant main effect for group was observed as measured by the COMM \( (F_{1, 81} = 0.129; p = .721; \text{ partial eta squared} = 0.002; \text{ observed power} 6.5\%) \). A significant interaction was observed between group (treatment versus TAU comparison) x time as measured by the COMM \( (F_{1, 81} = 4.097; p = .046; \text{ partial eta squared} = 0.048; \text{ observed power} 51.6\%) \). The mean COMM score decreased for the TAU group from baseline \( (M = 10.90, SD = 6.98) \) to posttest \( (M = 9.55, SD = 6.90) \). It decreased 2.5 times more for the treatment group from baseline \( (M = 12.41, SD = 6.93) \) to final posttest \( (M = 9.05, SD = 6.36) \). Lower scores reflect reduced self-reported aberrant medicine-related behaviors. The partial eta squared values indicate a moderate effect. The COMM considers total scores higher than 9 to be a “positive” for medication misuse behaviors. At baseline 25 participants in the treatment group (59.5\%) were scored “positive” compared to 24 (54.5\%) in the TAU group. At the end of eight weeks, 19 participants in the treatment group (43.2\%) were scored “positive” compared to 21 (45.6\%) in the TAU group, demonstrating a percentage reduction in the treatment group of almost twice that of the TAU group (16.3\% improved versus 8.9\% improved respectively). The COMM scores from pretest to posttest are visually depicted in Figure 10.
Figure 10. Current Opioid Misuse Measure mean scores for treatment (TX) and treatment as usual (TAU) groups at baseline and posttest (N = 83).

Individual items were examined to increase understanding about the most common aberrant behaviors reported by participants. The highest mean scores at both baseline and posttest was for the item “How often have you had trouble with thinking clearly or memory problems?” Mean scores for the five highest rated items are summarized in Table 8.

Table 8.

Highest Rated COMM Items at Baseline and Posttest Indicating Self-reported Aberrant Medication-related Behaviors

<table>
<thead>
<tr>
<th>COMM Item</th>
<th>Baseline Mean (SD)</th>
<th>Posttest Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>How often have you had trouble with thinking clearly or had memory problems?</td>
<td>2.3 (1.2)</td>
<td>2.0 (1.2)</td>
</tr>
<tr>
<td>How much of your time was spent thinking about opioid medications (having enough, taking them, dosing schedule, etc.)?</td>
<td>1.4 (1.1)</td>
<td>1.0 (1.0)</td>
</tr>
<tr>
<td>How often do people complain that you are not completing necessary tasks?</td>
<td>1.3 (1.3)</td>
<td>1.2 (1.2)</td>
</tr>
<tr>
<td>How often have you gotten angry with people?</td>
<td>1.3 (1.1)</td>
<td>1.0 (0.9)</td>
</tr>
<tr>
<td>How often have you been in an argument?</td>
<td>1.2 (1.0)</td>
<td>0.9 (1.0)</td>
</tr>
</tbody>
</table>
**Patient impression of change.** The PGIC was used to evaluate patients’ perception of improvement over time at baseline and posttest. The assumption of homogeneity of variance was not met using Levene’s test ($p = .03$). Missing data reduced the sample with complete PGIC scores to 90; 46 participants remained in TAU group and 44 in treatment group. Baseline PGIC scores appear negatively skewed on a histogram, and Kolmogorov-Smirnov statistics did not demonstrate normality ($p = .000$), however, Q/Q plots did appear normal. Kurtosis and skewness values were -1.07 and .13 respectively. No outliers were identified and Mauchly’s test did not show significance.

The 2 x 2 mixed design ANOVA found no significant main effect for time observed as measured by PGIC ($F(1, 88) = .689; p = .409$; partial eta squared = 0.008; observed power 13.0%). No significant main effect for group was observed as measured by the PGIC ($F(1, 88) = 0.052; p = .821$; partial eta squared = 0.001; observed power 5.6%). No significant interaction between group (treatment versus TAU comparison) x time was observed as measured by the the PGIC ($F(1, 88) = .005; p = .94$; partial eta squared = 0.00; observed power 5.1%). Higher scores reflect perceptions of positive improvement since beginning treatment. The PGIC scores from baseline to posttest are visually depicted in Figure 11.

*Figure 11.* Patient Global Impression of Change mean scores for treatment (TX) and treatment as usual (TAU) groups at baseline and posttest (N = 90).
Profile of Chronic Pain (PCP). The planned paired t-tests were not conducted for the PCP because only three participants completed the survey on posttest. Baseline PCPs were collected from 43 treatment group members and 23 TAU group members after serving as controls. All but five participants requested that the PCP results report be sent to their physician at the end of eight weeks. Demographic data captured that most participants were white (n = 64; 97.0%) and were either on disability due to pain (n = 19; 28.8%) or unemployed due to pain (n = 11; 16.7%). Nearly all (n = 59; 89.4%) participants had been with their health care provider for more than a year and had their current pain condition more than two years (n = 64; 97.0%). Most are somewhat satisfied (n = 19; 28.8%) or very satisfied (n = 19; 28.8%) with their treatment.

About half of the participants reported that they have at least an hour of pain they rate as severe daily (n = 33; 50.0%) and have to give up enjoyable activities, personal goals, usual responsibilities, and enjoyment of relationships several times every week. More than half (n = 46; 69.7%) say they experience constant pain throughout a typical day. Nearly one third of participants reported that thinking clearly, solving problems, concentrating or remembering is an issue every day because of pain. Pain reportedly causes isolation and loneliness, anxiety and sadness “extremely often” for almost one third of participants. Coping methods varied, however, a majority reported high use of trying to “forget about the pain,” focusing on something other than pain, and avoiding activity or movement to get through an episode of pain. The majority said they take a prescription medicine to manage their pain every time they have pain (n = 41; 62.1%). Close to half (n = 27; 40.9%) reported they did not exercise at all over the past month.

Program engagement. Activity levels were evaluated for participants in the CPMP and summarized in Table 9.
Table 9.

*Descriptive Statistics for Engagement in Chronic Pain Management Program (CPMP) Activities.*

<table>
<thead>
<tr>
<th>Engagement level</th>
<th>Frequency (n)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>1</td>
<td>13</td>
<td>29</td>
</tr>
<tr>
<td>2</td>
<td>6</td>
<td>13</td>
</tr>
<tr>
<td>3</td>
<td>7</td>
<td>16</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
<td>11</td>
</tr>
<tr>
<td>5</td>
<td>12</td>
<td>27</td>
</tr>
</tbody>
</table>

Note. (0 = no engagement, 5 = engagement in all four CPMP learning modules).

About 38% of treatment group participants engaged in at least half of the CPMP learning modules. Within those modules, participants varied in how many activities they completed from as few as 1 to all 21 program activities. Only one participant completed all of the possible learning activities in every module, and two did not participate at all in any aspect of the program. Associations were explored between the level of program engagement and positive changes in BPI, PHQ-8, PSEQ and COMM scores using Pearson’s Correlations Coefficient. A summary is presented in Table 10.

Table 10.

*Pearson Correlation Coefficients Between Measures of Chronic Pain Management Program Engagement Levels and Positive Change Scores for Dependent Variables*

<table>
<thead>
<tr>
<th>Scale positive change scores</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Engagement category</td>
<td>-</td>
<td>.297*</td>
<td>.327*</td>
<td>.241</td>
<td>.337*</td>
<td>.090</td>
</tr>
<tr>
<td>2. BPI intensity</td>
<td>-</td>
<td>.618**</td>
<td>.244</td>
<td>.439**</td>
<td>.361*</td>
<td></td>
</tr>
<tr>
<td>3. BPI interference</td>
<td>-</td>
<td>.369*</td>
<td>.335*</td>
<td>.334*</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

92
Regression models were explored to see if participant engagement levels could predict positive changes on each of the variables that were significantly correlated. The five engagement levels determined *apriori* were entered as the continuous independent variable after examining for normal distribution. Kurtosis and skewness were within normal range with values of -1.49 and 0.07 respectively. Three significant models were identified and are summarized in Table 11. A significant and theoretically based regression equation resulted to predict 1) pain intensity $F(1,43) = 4.159, p < .05$, with an $R^2$ of .088; 2) pain interference $F(1, 43) = 5.150, p < .05$, with an $R^2$ of .107; and 3) pain self-efficacy $F(1, 40) = 5.131, p < .05$, with an $R^2$ of .114. Within the three models, between 9-11% of the variance in change scores was explained by program engagement. Future exploration is planned using more advanced statistical techniques. Latent growth modeling has been used for these types of analyses because it is more sophisticated than ANOVA in its handling of missing data and can improve the ability to obtain precise estimates of individual change parameters (Ruehlman et al., 2011).

Table 11.

*Analysis of Engagement Category Levels as a Predictor for Outcomes Variables by Linear Regression*

<table>
<thead>
<tr>
<th>Outcome Variable</th>
<th>n</th>
<th>B</th>
<th>$\beta$</th>
<th>$F$</th>
<th>$R^2$</th>
<th>SE</th>
<th>$p$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model 1 BPI pain intensity</td>
<td>45</td>
<td>.277</td>
<td>.297</td>
<td>4.16</td>
<td>.09</td>
<td>.136</td>
<td>.048</td>
</tr>
<tr>
<td>Model 2 BPI pain</td>
<td>45</td>
<td>.381</td>
<td>.327</td>
<td>5.15</td>
<td>.11</td>
<td>.168</td>
<td>.048</td>
</tr>
</tbody>
</table>
interference

Model 3  PSEQ  42  2.659  .337  5.13  .11  1.174  .029

Note. B = Unstandardized coefficients, \( \beta \) = Standardized coefficients, SE = Standard error

**Healthcare utilization.** Missing data was identified for 36 (39%) of participants on items asking about the number of visits to primary care providers, mental health professionals, emergency departments or hospitals. Zero visits were assumed when no response was given. On average, participants in the TAU group reported 2.2 (SD 2.2) total visits to healthcare providers during the 8-week study period. Treatment group participants reported 2.8 (SD 3.5). Independent \( t \)-tests did not find this to be a statistically significant difference \( t (90) = -.916, p = .36 \) (2-tailed).

The majority of reported visits in both groups were to primary care providers (n = 200), while fewer visits were reported to counselors or psychologists (n = 29), emergency departments (n = 12), or hospital in-patient services (n = 7).

**Treatment changes.** Participants were asked to note on bi-weekly surveys whether they or their provider made any changes to their medicines or pain self-management practices over the prior 2-week period. The responses for each group are summarized in Table 12.

Table 12.

<table>
<thead>
<tr>
<th>Item</th>
<th>Number of “yes” responses from TX group participants</th>
<th>Number of “yes” responses from TAU group participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did your healthcare provider make any changes to your medications?</td>
<td>46</td>
<td>34</td>
</tr>
<tr>
<td>Did you change anything about your use of medications?</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>Did you change anything in your behaviors or activities to help control your pain?</td>
<td>43</td>
<td>34</td>
</tr>
</tbody>
</table>
Where did you receive information to assist with this change?

<table>
<thead>
<tr>
<th>Source</th>
<th>Treatment Group</th>
<th>Control Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare provider</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>Internet site</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Book or magazine</td>
<td>-</td>
<td>4</td>
</tr>
<tr>
<td>Friend or family</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>Goalistics Chronic Pain Management Program</td>
<td>21</td>
<td>-</td>
</tr>
</tbody>
</table>

Bi-weekly surveys asked about medication changes over the last two weeks and a final medication inventory collected data about changes over the 8-week study period. In the treatment group, 9 of 43 (20.9%) participants reported they either decreased or stopped their opioid medicines over the study period compared to 3 of 44 (6.8%) in the TAU group. This was a statistically significant difference between groups ($x^2 = 4.11, p = .04$). In the treatment group, 7 of 43 (16.3%) participants reported they increased their opioid medicines over the study period compared to 9 of 47 (19.1%) in the TAU group. This was not a statistically significant difference between groups ($x^2 = 4.11, p = .13$). The majority of participants in both groups did not report any change in their opioid medication over time; n = 27 (62.8%) in the treatment group and n = 35 (74.5%) in the TAU group. In the treatment group, 8 of 26 (30.8%) participants reported they either added or increased an antidepressant over the 8-week study period compared to 7 of 39 (17.9%) in the TAU group; this was not a statistically significant difference between groups ($x^2 = 1.44, p = .23$).

An independent-samples $t$-test was conducted to compare the total number of behavioral changes reported by participants on their bi-weekly surveys to help control their pain. On
average, participants in the treatment group reported adding more new behaviors (M = 1.6, SD = 1.6) than those in the TAU group, M = 0.9, SD 1.1; \( t (90) = -2.364, \ p = .02 \). The most frequently reported new behaviors were categorized for similar content and summarized in Table 13.

Table 13.

*Most Frequently Reported New Behaviors to Control Pain Reported by Treatment (TX) and Treatment as Usual (TAU) Participants*

<table>
<thead>
<tr>
<th>Behavior</th>
<th>Treatment n = 45</th>
<th>TAU n = 47</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical activity/stretching</td>
<td>21 (47%)</td>
<td>20 (42%)</td>
</tr>
<tr>
<td>Relaxation/breathing/meditation</td>
<td>19 (42%)</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Positive thinking</td>
<td>13 (29%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Pacing activities/rest</td>
<td>12 (27%)</td>
<td>13 (28%)</td>
</tr>
<tr>
<td>Socializing</td>
<td>6 (13%)</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Diet</td>
<td>3 (7%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Hobby/diversional activity</td>
<td>2 (4%)</td>
<td>2 (4%)</td>
</tr>
</tbody>
</table>

**Progress towards goals.** Participants were asked to state two goals at the start of the study and to rate their progress towards meeting the goals at the study end. Posttest data was missing for this item on 22 participants in the treatment group and 12 in the TAU group and was handled using listwise deletion. The most frequently reported goals related to medications were to 1) reduce or eliminate pain medicines \( (n = 24) \), and 2) reduce or eliminate non-specified medicines \( (n = 15) \). The most frequently reported goals related to overall health and well-being were to 1) increase activity, strength or fitness \( (n = 27) \), and 2) to reduce weight \( (n = 9) \). In the treatment group, 17 of 21 \( (81.0\%) \) participants reported they made at least some progress towards their stated medication goal over the 8-week study period compared to 17 of 35 \( (48.6\%) \)
in the TAU group. This was a statistically significant difference between groups ($\chi^2 = 5.77, p = .02$). In the treatment group, 16 of 21 (76.2%) participants reported they made at least some progress towards their stated goal for overall health and well-being compared to 24 of 35 (68.6%) in the TAU group. This was not a statistically significant difference between groups ($\chi^2 = .37, p = .54$).

**Program evaluation.** A summative evaluation was conducted at the end of the 8-week CPMP using the adapted IBM Computer Usability Satisfaction Questionnaire with three additional open-ended items. Forty evaluations were received from the original treatment group members and 25 from those in the TAU group after their wait list period was completed and they had enrolled in the CPMP. Seven items were presented to rate satisfaction with the program’s usability (e.g. “Overall, I am satisfied with how easy it is to use this program”), quality of information (e.g. “The information provided for this program was easy to understand”), and usefulness of the program (e.g. “I could effectively complete the tasks assigned using this program”). Items were evaluated on a seven-point Likert-style scale (from $1 = strongly disagree$ to $7 = strongly agree$). Cronbach’s alpha was .93 showing very good internal reliability. The mean value of the 7 combined evaluation items was 5.17 (SD 1.22). The average responses are displayed in Table 14.

Table 14.

*Summative Program Evaluation Survey Results Using the IBM Computer Usability Satisfaction Questionnaire (N = 65)*

<table>
<thead>
<tr>
<th>Item</th>
<th>Mean (SD)</th>
<th>Mode</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall satisfaction</td>
<td>5.02 (1.55)</td>
<td>6</td>
<td>1 - 7</td>
</tr>
<tr>
<td>Satisfaction with amount of time needed</td>
<td>5.08 (1.37)</td>
<td>6</td>
<td>2 - 7</td>
</tr>
<tr>
<td>Satisfied with available support</td>
<td>5.60 (1.33)</td>
<td>6</td>
<td>2 - 7</td>
</tr>
</tbody>
</table>
Could effectively complete tasks 4.80 (1.54) 6 2 - 7
Felt comfortable using program 5.22 (1.54) 6 1 - 7
Easy to find information needed 4.95 (1.66) 6 1 - 7
Information easy to understand 5.60 (1.26) 6 1 - 7

Qualitative data from the three open-ended items were reviewed for common themes. Three main general categories were assigned after reviewing the comments: positive, negative and neutral. The most frequent positive responses about the CPMP were regarding its influence on 1) stopping negative thoughts and/or focusing on the positive (n = 15), and 2) engaging in healthy activities, such as paced physical exercise, relaxation or socialization (n = 12). The most frequent negative responses about the CPMP were regarding 1) the difficulty navigating program features (n = 16), and 2) the desire for more direction or reminders (n = 12). Responses were regarded as neutral if associated with individual situations and not with the program itself; these included most frequently 1) reports of not using the program as much as they would have liked or planned (n = 10), and 2) reports of external obstacles to engaging in the program, such as computer or Internet issues, lack of time, illness or pain (n = 16).

**Wait list results**

An independent t-test was conducted to compare the engagement level with the CPMP between the 22 participants who chose to enroll after serving for eight weeks in the TAU group and the original 45 treatment group participants. A significantly lower engagement level was observed for the wait-listed group members (M = 1.6, SD = 1.6) than for the original treatment group members, M = 2.8, SD = 1.7; t (65) = -2.75, p = .008 (two-tailed). Sixty percent of the wait-listed participants did not engage in any of the learning modules compared to 30% in the original treatment group.

A series of one-way ANOVA tests were conducted to evaluate within group differences
for the wait-listed participants on all measured outcomes at three time points: baseline scores, week eight scores, and final scores after completing an additional eight weeks enrolled in the CPMP. Mauchly’s test did not show significance for any of the variables. Results are summarized in Table 15.

Table 15.

One-way ANOVA Results for Treatment As Usual (TAU) Group after Engaging in the Chronic Pain Management Program (N = 25)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline Mean (SD)</th>
<th>Posttest Week 8 Mean (SD)</th>
<th>Posttest Week 16 Mean (SD)</th>
<th>df</th>
<th>F</th>
<th>p</th>
<th>Partial eta squared</th>
</tr>
</thead>
<tbody>
<tr>
<td>BPI Pain Intensity</td>
<td>5.3 (1.8)</td>
<td>5.3 (1.9)</td>
<td>5.2 (2.1)</td>
<td>2.48</td>
<td>.069</td>
<td>.93</td>
<td>.003</td>
</tr>
<tr>
<td>BPI Pain Interference</td>
<td>5.2 (1.9)</td>
<td>5.8 (2.3)</td>
<td>5.5 (2.6)</td>
<td>2.48</td>
<td>1.047</td>
<td>.359</td>
<td>.042</td>
</tr>
<tr>
<td>PHQ-8</td>
<td>12.7 (5.6)</td>
<td>11.3 (6.1)</td>
<td>4.7 (5.0)</td>
<td>2.48</td>
<td>39.05</td>
<td>.00*</td>
<td>.619</td>
</tr>
<tr>
<td>PSEQ</td>
<td>24.2 (13.2)</td>
<td>21.9 (15.0)</td>
<td>25.4 (14.6)</td>
<td>2.40</td>
<td>1.761</td>
<td>.19</td>
<td>.081</td>
</tr>
<tr>
<td>COMM</td>
<td>11.2 (4.9)</td>
<td>9.3 (5.1)</td>
<td>10.0 (6.7)</td>
<td>2.42</td>
<td>2.237</td>
<td>.119</td>
<td>.096</td>
</tr>
<tr>
<td>PGIC</td>
<td>3.3 (1.9)</td>
<td>3.5 (2.0)</td>
<td>3.3 (2.2)</td>
<td>2.48</td>
<td>.178</td>
<td>.838</td>
<td>.007</td>
</tr>
</tbody>
</table>

* Significant at the 0.001 level

The one significant effect over time for the wait-listed group was observed on the PHQ-8. No significant change was observed on the mean PHQ-8 score from baseline to week 8 posttest \((p = .22)\). A significant decrease was observed from week 8 to week 16 posttest \((p < .001)\). The partial eta squared value indicates a large effect. The observed power for the one-way ANOVAs was less than 80% for all variables except the PHQ-8 (observed power 100%).
CHAPTER FIVE
DISCUSSION

Interpretation of findings

Patients who receive opioids for persistent pain are capable of engaging in an online self-management program and can have measureable positive effects. Increases in pain self-efficacy can be achieved, along with gains in behaviors associated with aberrant opioid use. The current study was the first to assess the CPMP among a group of patients who were prescribed opioids for persistent pain. The results of this study indicate that engagement in a self-directed program will vary among the targeted population. The level of program participation was positively associated with improvements in pain intensity, pain interference and pain self-efficacy.

Pain intensity and pain interference

A significant difference was not detected on pain intensity or pain interference measurements between treatment and TAU groups. In examining the mean pain intensity scores without regard for significance values, across all time points the values decreased for the treatment group from baseline measurements and were either unchanged or increased for the TAU group. The decreases were small and it is unknown how they may have impacted individuals’ overall experiences and quality of life. Ruehlman et al.’s study (2011) of 305 participants found small, but significant, improvements in pain intensity among those enrolled in the CPMP. The difference in results may have been influenced by their larger sample and their decision to analyze data using a linear growth model rather than ANOVA; this provided better ability to manage missing data and resulted in more precise estimates of individual changes across three time points. Additionally, recruitment eligibility for those participants did not require an opioid prescription, therefore, they may have had less complicated or less severe pain conditions. While the mean group change was not significant in the current study, the NNT
analysis found that for at least 18% of those in the treatment group there was a significant clinical improvement in pain intensity. Therefore, future studies might strive to isolate those individual differences that predispose an individual to respond successfully to the CPMP.

Expected improvements for patients with persistent pain who receive long-term opioid treatment are unknown. Opioid-induced hyperalgesia (OIH) has been recognized as a paradoxical adverse effect, whereby patients receiving opioids experience increased and/or more widespread baseline pain as a result of chronic exposure to opioids (Lee, Silverman, Hansen, Patel, & Manchikanti, 2011). Pain often improves when opioids are discontinued. It is possible that dramatic improvements in pain intensity are not achievable for those who have more painful and resistant conditions, or for patients with OIH unless opioid withdrawal strategies are employed. It is also worth noting that pain intensity ratings have been criticized for oversimplifying a multidimensional experience (Schiavenato & Craig, 2010). Therapists often do not regard pain intensity reduction as a feasible outcome and instead place a high emphasis on health-related quality of life (e.g., Dick et al., 2011). It is possible that those receiving opioids will report higher pain intensity values because of the fear or anxiety related to reducing or eliminating prescriptions. Several participants in this study shared on bi-weekly surveys that their providers were reducing their dosages or that they were having difficulty finding providers willing to continue prescribing opioids. The literature reports that it is a common phenomenon for patients to seek opioid treatment elsewhere if their providers initiate a weaning plan (Lee et al., 2011).

Pain interference scores were also not significantly improved and were more variable than pain intensity scores across all time points for both groups as evidenced by larger standard deviations; this trend has been documented in other studies (Ruehlman et al., 2011; Peleg, Liberman, Press, & Shvartzman, 2011; Wilson et al., 2013). In the TAU group the mean pain interference values were either increased or unchanged, and the treatment group members
increased at time point 2, decreased at time point 3, increased at time point 4, and decreased at the final time point. The variation could be explained by the nature of the measurement; perhaps pain interference is more sensitive to change while pain intensity can be considered more constant in persistent pain conditions. Or perhaps the scores were a function of how much the participants were engaging in the self-management activities at any given time period. Data were not available to correlate actual activities per week, yet exploring this in future work might provide greater understanding about how self-management activities can be utilized and the optimal dose needed to expect results. A spike in pain intensity for all participants and, more dramatically, for pain interference for treatment group members was observed for time point 4. The cause is unknown, however, all participants in the treatment group received an email prompt mid-way reminding them to engage in the CPMP. It is possible that a prompt may have renewed attention to their pain, or added some anxiety about their progress that intensified their pain. Examining the relationship to engagement in the CPMP may yield some clues, as it is also possible that participants were not engaging much in the program by this time point and the prompt focused them back, resulting in an improved final score at time point 5. Several participants sent emails to the researchers after the mid-way prompt asking for reminders about their log in and passwords to access the CPMP, or apologizing for not participating as much as they had planned.

Pain interference scores were explored further with the NNT analysis that found nearly one third of participants in both treatment and TAU had improvements consistent with clinical significance by the end of the study period. Other studies suggest that in the absence of intervention, scores for persistent pain will change little or not at all over time (Ruehlman et al., 2011; Wilson et al., 2013). Finding significant differences between treatment groups in pain trials has often been difficult and has been attributed to strong placebo effects (Dworkin et al., 2008). Placebo effects may have played a role in the current study. It was evident from
comments on final surveys that some participants believed their role in the TAU group was a self-management intervention. Some may have experienced benefit from reflection on their pain management practice in the bi-weekly surveys and this may have impacted self-care behaviors enough to have some positive effect. A large number of those in the TAU group (42%) reported in bi-weekly surveys that they had increased their exercise and activity levels. About one third in the TAU group reported pacing their activities or increasing rest. It is possible that the bi-weekly surveys served as some encouragement or reminder and led to reducing any potential differences that may have been observed between groups on the NNT analysis. It is also possible that pursuing helpful strategies is within the norm of patients with pain, even outside of research enrollment. It cannot be ignored that two-thirds of all participants did not have any clinically significant improvement in pain interference. These results may have been influenced by the fact that the majority of participants did not engage fully in the CPMP, or may provide evidence that the program needs further development if it is to impact measurements of pain among patients receiving opioids. A multitude of studies have consistently found that self-management strategies can assist in the adjustment to painful conditions and limit the impact of pain on people’s lives (Stannard et al., 2010). Due to the placebo effect and the variability and subjectivity in pain reporting, it is important to weigh those historical findings before discounting the potential helpfulness of any intervention.

**Depressive symptoms**

More than half of all study participants had PHQ-8 ratings consistent with moderately severe (37%) and severe (14%) depressive symptoms. This was consistent with the pilot study that informed the current study (Wilson et al., 2013), and many other studies that find depression and pain co-existing (Bair et al., 2013; Hartman et al., 2006; O’Hayon, 2004). No significant differences were detected on the PHQ-8 between treatment and TAU group after eight weeks of program enrollment, unlike findings from Ruehlman et al.’s study (2011). A significant
improvement over time was observed for all participants, however; these results may have resulted from the attention all participants received and the fact that any participant who scored in a severe range for depressive symptoms was given a contact number for mental health treatment resources and suicide prevention. Although it is unknown how many participants may have acted on this information, 15 did report that their antidepressant medications were changed throughout the course of the study (7 from the TAU group and 8 from the treatment group). About one third reported they were receiving psychological counseling in their biweekly surveys. The current study findings reiterate the necessity for clinicians to develop a more systematic approach for screening, referring and treating patients with persistent pain and depression, and perhaps, the need to explore more effective treatments. Nearly half of all participants reported taking anti-depressant medications; it is unknown how many were receiving cognitive behavioral therapies that are an evidence-based and effective approach to treat depression.

For the participants in the wait-listed group, small non-significant improvements were observed on mean PHQ-8 scores during their 8 weeks serving in the comparison arm, while large significant improvements were observed once they completed 8 weeks of enrollment in the CPMP. These results add evidence that the CPMP provided some benefit for depressive symptoms. It is worth noting that every participant who completed the first eight weeks of surveys was given the option to have a report sent to their primary care provider as shown in the example in Figure 3. The Profile of Chronic Pain report sent to providers within the first few weeks of the CPMP also provided information on emotional burden, exercise habits, and negative thought patterns. It is possible that these communications were influential in the
development of treatment plans that were more attentive to depressive symptoms among the study participants.

**Pain self-efficacy**

Treatment group members in the current study had large and significant gains on pain self-efficacy, while the TAU group members remained relatively unchanged on that measure. Higher self-efficacy is associated with positive outcomes of pain coping, increased pain thresholds and tolerance (Keefe et al., 2004), and decreased emotional distress, depressive symptoms, and disability (Keefe et al., 2004; Nicholas et al., 2011). Pain self-efficacy measures the strength of patients’ belief about their ability to accomplish activities despite their pain. Among injured workers, higher self-efficacy scores are found among those workers who return to work and those who maintain functional gain (Nicholas et al., 2011). Therefore, increases in pain self-efficacy could result in improved quality of life for patients, even if they are unable to reduce their pain intensity and interference measurements.

**Opioid misuse measure**

Unique to the current study was the inclusion of the Current Opioid Misuse Measure (COMM) to detect past-month aberrant medication-related behaviors. The research team is not aware of any other published studies using this tool as an outcomes measurement for an online self-management program. The COMM is intended to assess behaviors that are concerning and may indicate addiction, purposeful diversion, or unintended misuse. The instrument has demonstrated accuracy and validity in detecting prescription drug use disorders (Meltzer et al., 2011). The intent of creating the COMM was to promote clinicians’ level of comfort with prescribing opioids (Butler, Budman, & Jamison, 2010). It can be used to track behaviors over time. Misuse is defined as the use of any drug in a manner other than how it is indicated or prescribed; aberrant drug-related behaviors are those behaviors that may suggest substance abuse
or addiction (Butler et al., 2010). While all participants had COMM score improvements over time, greater impact was observed in the treatment group. The mean score decreased from baseline to posttest on all of the 15 COMM scale items except for three. The greatest mean improvement was seen on the item asking how much time was spent thinking about opioid medications (having enough, taking them, dosing schedule, etc.). Items regarding feeling angry and thinking clearly or memory problems also had large mean score improvements.

Few interventions are currently available to limit risks of tolerance, dependence, and addiction that are associated with long term opioid use. If involvement in a self-management program truly affects patients’ use of opioids, perhaps this intervention could be employed earlier in the pain trajectory. Two participants in the treatment group reported being successfully weaned from opioids during their participation in the study. The CPMP may have provided some assistance. Replication studies are needed to build confidence in these findings.

**Patient impression of change**

Results on the PGIC showed that overall, most study participants did not rate their change in condition since beginning treatment with their primary care provider as clinically significant (commonly recognized by a 5-7 rating on the PGIC scale). With an average of about 3.5 at pretest and posttest by both groups (corresponding with “a little better” to “somewhat better”), room for improvement exists for all study participants in their perception of treatment response. The low scores are consistent with the pilot study data for the current study that found no patients reporting higher than a 4 on the PGIC and mean score ratings of a 2 (Wilson et al., 2013). Other intervention studies have found significant improvements and higher percentages of favorable ratings in patients with fibromyalgia (Geisser et al., 2010) and back and neck pain (Hurst & Bolton, 2004). Of note, those patients were not necessarily receiving opioids and this could be an important distinction in severity of condition, and ability to perceive improvements.
Patient reported outcomes like the PGIC are considered important in gaining understanding of disease progress, patient satisfaction and health care utilization, yet they are complex and not consistently associated with other clinical factors (Geisser et al., 2010). More investigation is needed to understand the usefulness of this measurement in the context of pain patients who receive opioids.

**Profile of Chronic Pain (PCP)**

The goal of the PCP assessment is to measure the multiple psychosocial aspects of pain adaptation in a concise format (Ruehlman et al., 2005b). The resulting evaluation can point to difficulties with coping, medication use, catastrophizing, negative pain attitudes and beliefs, and social and functional barriers. When used as part of the CPMP, the assessment is intended to provide guidance to those enrolled in the program; it identifies priorities and can measure progress. No conclusions can be made regarding the present study population’s progress using the PCP, because so few participants completed the posttest at the end of their eight week enrollment. The poor response was likely due to the fact that no reward was offered for completing it, and participants were required to log into the CPMP on the Goalistics’ website and locate the assessment on their own. It is difficult to make any comparisons between the present study population and other populations because the instrument has been revised for online use. Future research might compare PCP scores between study populations and relationships with other outcome measurements.

To align with the IOM’s call for improving expertise in primary care pain treatment (2011), an important step is increasing the quality of pain assessments. The present study did not examine providers’ response to or interpretation of the PCP report. Therefore, future research should determine its effectiveness as a communication tool between patient and provider, and whether treatment planning can be influenced as a result of its use. The PCP has been found to
be reliable and valid when used in a paper-and-pencil version in primary care settings (Karoly, Ruehlman, Aiken, Todd, Newton, 2006). Engaging primary care providers in the measurements may improve participants’ willingness to complete posttests; these can serve as a clinical tool to measure progress.

Theoretical framework

Under Ryan and Sawin’s Individual and Family Self-Management Theory (IFSMT) (2009), studies can be designed to build on the current knowledge regarding self-management programs. The IFSMT allows for the complexity of self-management and serves as a useful framework for testing pain interventions through a biopsychosocial lens. The CPMP is a multi-faceted intervention requiring participants to challenge their beliefs about pain, add knowledge and skills related to self-management activities, regulate emotions, communicate with their health care providers in setting goals and plans, and give and receive social support. That a significant statistical interaction effect (between group x within group) was observed for pain self-efficacy adds confidence for the theoretical structure of the CPMP. The concept of self-efficacy has been tested and validated in hundreds of studies and is based on Bandura’s well-researched Social Cognitive Theory. Self-efficacy is the fundamental concept upon which many self-management programs have been developed and is a central construct incorporated in the “process” stage of the IFSMT. Participants with gains in pain self-efficacy can be expected to master the tasks needed to support healthy behaviors and reduce the impact of their chronic conditions. Self-efficacy scores have been positively associated with a wide range of health promotion behaviors as outlined in Chapter 2. While not the primary focus of the dissertation, the qualitative data from participants adds further evidence that their program involvement led to positive changes such as increasing social activities, seeking vocational training for employment, and changing their perspective to focus on abilities instead of limitations.
Many pain researchers have followed a cognitive-behavioral theoretical foundation and assume that cognitions and beliefs are central to pain management with a focus on coping skills training and cognitive restructuring (Keefe et al., 2004). The IFSMT, however, recognizes that both skill acquisition and social facilitation are important to address in self-management strategies. Outcomes depend not only on patients’ adoption of coping skills, but also on significant collaborations. Therefore, the IFSMT framework provides a more comprehensive model that aligned with the current study design. Communications were sent to providers regarding participants’ Profile of Chronic Pain survey results; this was done in recognition of providers’ influence in their patients’ pain experiences. The significant relationship observed between engagement level and pain and self-efficacy improvements adds confidence that social facilitation may be an important variable for future interventions. The pain assessment and resulting treatment plan often depends upon the interplay between patient and provider (Schiavenato & Craig, 2010). Engagement levels in self-management programs can be manipulated by increasing the influence and support of significant others, as well as increasing motivation within the individual. The results of the current study suggest that the IFSMT is a theoretical framework that is well-suited to pain self-management research. It may be useful in developing future studies that will examine in more detail how providers’ influence and support can impact adoption of self-management skills and overall health outcomes.

**Limitations and strengths of the study**

A wide distribution of ages (from 20s to 70s) was represented in our sample, yet the number of males was less than desired at 22%. This distribution aligns with prior studies that have had as few as 11% males enrolled in self-management programs (Foster et al., 2007). It is possible that males are less likely to accept non-surgical or nonpharmacologic interventions for
their pain conditions, and/or may reflect the demographics of CNCP; females are at higher risk of developing CNCP (IOM, 2011). A strength of the study was that both rural and urban populations were included, however, fewer (21%) were from rural communities. Twenty-one percent of all participants were recruited from a federally-qualified health center. Of those who engaged in the CPMP and completed a Profile of Chronic Pain survey, 31% reported that they were unemployed or receiving disability benefits due to pain or other conditions. Therefore, the study population did represent variety in socioeconomic groups, yet less diversity in ethnicity.

A primary limitation of the study was the lack of ability to precisely measure application of the intervention. Participants assigned to the treatment group had inconsistent engagement in the CPMP and their level of program activity could only be estimated. No measurements were available to determine whether participants had actually engaged in any specific self-management practice; it was only possible to measure whether the participant had entered an activity lesson in the CPMP and rated it. This feature of self-management interventions has been noted in other studies and causes difficulty in knowing exactly which self-management techniques are responsible for positive outcomes (Jensen, Turner, & Romano, 2007). The lack of significant differences on pain measurements should be viewed in light of this gap in knowledge; it is not possible to know how participants would have responded had they engaged in identical doses of program activities. Results showing the relationship between engagement and change scores on pain intensity, pain interference, and pain self-efficacy suggests that those who were more engaged could expect better outcomes. Causality cannot be determined from correlation results, however, so future studies are needed to examine these relationships. Other explanations cannot be ruled out, such as the possibility that more engaged participants had other variables influencing their outcomes, such as higher self-motivation, better social support, or stronger
patient-provider relationships. In our study design, there was no ability to control for the positive impact of receiving contact from researchers with bi-weekly surveys and prompts, as well as the benefit participants may have had from being asked to consider their pain situation in survey questions. This may have contributed to the inability to detect significant differences. While no significant improvements were detected for the wait-listed participants except on depressive symptoms, the group was small and engagement low. All of their mean scores did trend towards improvement and may have been significant in a larger and more engaged group. The fact that two months had passed since their study recruitment may have impacted individual interest and motivation. Some did report significant health changes over that time period that interfered with their intention to participate.

In addition to the limitations of self-efficacy as an outcomes measurement that were outlined in Chapter 2, it should be noted that gains in self-efficacy may be moderated by external barriers. Comorbid conditions such as depression, patient-provider communication problems, and economic barriers have all been mentioned as a threat to successful adoption of self-management techniques (Sarkar et al., 2006). Data was not collected on all of these factors, so it is not possible to know how these influences might affect self-management independent of self-efficacy. Other limitations in analyses were the violations of assumptions for pain interference measurements; conditions of sphericity were not met and significant variation was observed between sets of scores. Missing data for 22 participants makes it difficult to have confidence in the bi-weekly survey results of the 2 x 5 ANOVA. It is unknown how results may have differed if the full sample of 92 participants would have recorded all of their bi-weekly surveys. More frequent assessments were planned for the current study compared to the pilot conducted to inform this study. This strategy was employed, in part, to improve participant engagement in
the study and to reduce attrition. That goal was met. Compared to the pilot study, a much larger percentage of patients remained engaged with the study and completed final posttest surveys. More engagement was demonstrated in the offered self-management program as well. In the pilot study, 80.7% (n = 42) attrition was experienced prior to final posttest survey and only one treatment group member demonstrated full participation in the offered self-management program. Partial program activity was not quantified in the pilot. In the current study, 19.3% (n = 22) attrition was experienced prior to final posttest and 95.5% (n = 43) of those in treatment showed at least some program activity. Some of the differences between the two studies included that gift card reward incentives were offered, primary care providers were included in recruitment efforts, and the population of recruitment was changed from patients seeking care in an emergency department to those with established primary care providers for their opioid prescriptions.

Limitations of the COMM instrument include that patients may not be completely honest, however, it is designed to over-identify risk. False positives are more likely than the risk of not detecting someone with problematic behaviors. The COMM measurement tool was used with one item removed for the current study due to the inability of researchers to intervene immediately to a positive response: “In the past 30 days, how often have you seriously thought about hurting yourself?” Validity testing has not been performed with this item removed and final scores may have under-represented opioid misuse. Comparative validity analyses is planned for the future with the item removed. The COMM has been found in prior studies to have a sensitivity of .77 and specificity of .66, resulting in about 34% of those screened to be false positives (Inflexxion, 2008). Fifty-five percent of our participants had COMM scores placing them in the “positive” category; by conservative estimates after eliminating those who may be
“false positives,” 39 of our 92 participants were identified by the COMM as misusing their opioid medicines. Caution should be noted that the instrument is not intended to withhold pain medicines from people who need them, but rather to assist clinicians in managing their patients who require pain treatment. Patients who are developing addictions or using their medicines in ways other than which they were intended are in need of direct, effective, and compassionate interventions. Providers who prescribe opioids have a responsibility to address these issues.

A strength of the current study was the program evaluation. By asking participants to address what was most helpful and least helpful, our results add to the small literature base about what patients with persistent pain prefer in self-management practices. As clinicians are called to move towards patient-centered care and individualized pain care, these findings may be considered valuable in helping to design programs that patients will find useful. Combinations of effective treatments may exceed the therapeutic effect of any singular pain therapy (Maiers, Westrom, Legendre, & Bronfort, 2010). Due to difficulties applying one consistent intervention, it is worth questioning whether the randomized controlled trial is the best fit for building the types of customized treatments required for patients with persistent pain (Vlaeyen & Morley, 2005).

**Implications for provision of care and policy**

It cannot be overlooked that computer-based programs will not be accessible for everyone. An unexpected hardship for participants was that some of the CPMP was not compatible with certain brands of tablet computers. Another interference was a widespread power outage on the east coast. Although no participants stated that they would have preferred attending an in-person group, several said they would have favored reading materials that could have been used away from the computer or reported difficulty sitting at the computer for long
periods. Additional information on ergonomics, or how to create a comfortable computer work space might be of use. Many stated that they wished they had more contact from the researchers with reminders or instructions. Finding the right balance between the privacy and flexibility of independent, self-guided work and desired interaction could be an important consideration in engaging patients more completely in online self-management programs.

While recognizing the limitations of an Internet-based platform, it is low cost and requires fewer resources than in-person programs. It is also probable that obstacles such as transportation, and the interference of pain on daily activities would limit patient participation in live self-management groups. An Internet-based self-guided program was acceptable to a large number of our participants and at least some had positive gains. Understanding how to better engage patients and assure they adhere to the practices that they find beneficial is an important next step. COMM scores suggested that thinking clearly or memory problems were the most common adverse effect of opioid use among the study participants. Therefore, it is likely that participants on opioids might be better served by a program that provides more guidance.

Despite the evidence of effectiveness in the literature, it is not uncommon for a patient to be reluctant to try psychologically-based treatments that suggest pain is “in my head.” Receptivity to psychological interventions are dependent on patients’ expectations and beliefs about their credibility (Vlaeyen & Morley, 2005). Patients who are wary of self-management and cognitive-behavioral approaches as treatment options will accept them more willingly if they have established a primary trusting relationship with another clinician (Maiers et al., 2010). Learning of others who have been treated successfully with an intervention can influence expectations and outcomes (Vlaeyen & Morley, 2005). Having health insurance companies reimburse for these programs could make a difference in adoption, too. Motivational
interviewing is one therapeutic approach designed to increase the likelihood that patients will enter into and adhere to specific desired changes (Osborne et al., 2006). Increasing motivation and readiness to change may facilitate greater engagement with the behavioral changes needed to self-manage pain care. It is unknown whether participating in the bi-weekly Internet-based surveys served some usefulness and assisted in relieving depressive symptoms; it is possible that the summary reports were seen as helpful or provided some psychological boost to patients because they did not feel they were alone in their pain condition. Primary care providers could initiate similar tracking tools to increase the connection to their patients and monitor progress between clinic visits.

**Recommendations for future research**

It remains unknown how self-management programs like the CPMP translate to different settings and cultures. More research with diverse groups, particularly with more males and non-Caucasian participants is needed. As noted by Nicholas et al. (2011), it is difficult to know which self-management activities participants actually use; most studies have relied on self-report. Studies that can capture accurate data on the frequency of use and adherence to self-management strategies is important to understand what provides the most benefit. Such knowledge can also assist health care providers in making recommendations and encouraging effective strategies. The bi-weekly survey data collected from participants in the current study adds to the literature in understanding which specific strategies were employed. The positive gains in self-efficacy in this sample suggest that the strategies they used most could be beneficial in building confidence in managing symptoms. The largest gaps between treatment and TAU groups were in the reported use of relaxation/breathing/meditation and positive thinking; 19 treatment group members reported adding relaxation/breathing or meditation activities to their pain coping
activities compared to two in the TAU group. Thirteen treatment group participants reported adding positive thinking compared to just one in the TAU group. Future studies might examine the specific impact of these self-management techniques within a multi-faceted self-management program. Similarly, the differences reported by treatment group participants in their use of opioids and achievement of goals related to medicines suggests that self-regulation skills were addressed within the intervention and contributed to the positive findings. Future studies varying specific skills and their impact on personal goals and overall quality of life can be developed using the IFSMT as a conceptual guide.

A key finding by Nicholas et al. (2011) was that the more patients adhere to self-management strategies, the better outcomes they can expect. Therefore, a focus on methods that will assist patients in adhering is an important next step for the science of self-management. Along with developing programs that will be easily accessible and effective, it is equally important to explore how to better engage patients who are often in pain, depressed, and on medicines that interfere with clear thinking and motivation. Prompts for engagement, support and reminders could be tested with any combination of phone, texting, email, in-person, and synchronous or asynchronous Internet-based discussion boards. Future development may address the variability that has been reported in self-management outcomes and strive for more lasting, clinically meaningful results.

A systematic review by Carnes et al. (2011) found that self-management programs led by health care providers have greater benefit. Testing the CPMP with guidance from a care provider might reveal improved engagement and usefulness. Ideally, clinicians who prescribe opioids for pain will suggest or prescribe self-management programs and assure some assistance is available to maximize the effects. The advantage of providers or their support staff leading these offerings
is that patients may be more likely to view it as valid and worthy of their time. The provider’s influence and credibility may be useful in facilitating engagement and thereby impact outcomes; exactly how this is accomplished and how much facilitation is needed is an area for more exploration. A future focus might include determining whether the CPMP benefits those patients who are actively seeking relief from the financial burden, side effects, and social stigma of opioid use. Outcomes could be measured testing the program as a component of an opioid weaning plan. Clinical settings might be examined for the feasibility of providing a computer kiosk where a variety of educational or self-management programs could be assigned to patients, with direction offered as needed. Providers could join together and combine resources within a community to offer Internet-based programs; computer stations in hospital or public libraries, schools, or community centers could be accessed. Within the IFSMT, such strategies can be considered as protective context of the physical and social environment through which self-management programs can be successfully deployed. Many communities are forming coalitions to improve communication among prescribers and reduce the misuse of opioids. These partnership might extend their mission to assuring appropriate treatments are offered. Researchers could study the impacts on law enforcement, mental health, and other societal concerns that are related to opioid misuse when a community approach to pain management is employed.

Conclusion

A fundamental question prior to this study was whether patients who receive opioids for persistent pain are capable of meaningful engagement in online self-management programs. This randomized clinical trial provided evidence that they can, and that measureable increases in pain self-efficacy can be expected. Unique to this study is that significant gains in behaviors associated with aberrant opioid use were observed after engaging in the CPMP. Participants
reported an ability to incorporate new behaviors to assist in their pain management, including relaxation exercises, social activities, and challenging negative thought patterns. Level of program participation was positively associated with improvements in pain intensity, pain interference and pain self-efficacy. Participants reported high satisfaction with the tested program and suggested that more assistance be provided in the form of reminders, prompts and encouragement to remain engaged.

Depressive symptom severity levels at baseline indicated that more than half of all participants were in need of assessment for a Major Depressive Disorder. Depressive symptom severity reduced over time for all study participants, however, remained at levels of moderately severe to severe depressive symptoms for one third of the participants at the study end. Depressed mood can interfere with one’s motivation and ability to engage in activities, therefore, future programs should provide enough guidance and structure to maximize engagement and outcomes. Attention to co-existing mood disorders should be a crucial component of any pain management interventions.

Ultimately, the goal of this research was to raise awareness that patients on opioid medicines are able and willing to participate in programs designed to build confidence and change behaviors that may impact quality of life. More program development and adherence strategies are needed to impact pain experiences more significantly among the studied population. It is hoped that the information gathered from this study generates knowledge that can be used to improve the CPMP and other Internet-based self-management programs. The health care community at large should work towards systems and supports that will assure all patients have access to programs that can assist them as they navigate the challenges of persistent pain. Primary care providers, pain specialists, nurses, policy-makers, insurers, and clinicians from all disciplines should consider that it is within their power and scope of responsibility to advocate for, plan and create more holistic, individualized and patient-
centered pain management treatment options. Such efforts can work to reduce the stigma associated with persistent pain conditions, and create more positive experiences for patients seeking comfort and care.
References


122


MEMORANDUM

TO: John Roll and Marian Wilson
FROM: Malathi Jandhyala (for) Matt Layton, M.D., Chair, WSU Institutional Review Board (3005)
DATE: 6/28/2012
SUBJECT: Approved Human Subjects New, IRB Number #12622-001

Your Human Subjects Review Summary Form and additional information provided for the proposal titled "Empowering Patients with Chronic Pain Using an Internet-Based Self-Management Program", IRB File Number 12622-001 was reviewed for the protection of the subjects participating in the study. Based on the information received from you, the WSU-IRB approved your human subjects protocol on 6/28/2012. This protocol is given Full Board review category.

IRB approval indicates that the study protocol as presented in the Human Subjects Form by the investigator, is designed to adequately protect the subjects participating in the study. This approval does not relieve the investigator from the responsibility of providing continuing attention to ethical considerations involved in the utilization of human subjects participating in the study.

This approval expires on 6/27/2013. If any significant changes are made to the study protocol you must notify the IRB before implementation. Request for modification forms are available online at http://www.irb.wsu.edu/forms.asp.

In accordance with federal regulations, this approval letter and a copy of the approved protocol must be kept with any copies of signed consent forms by the principal investigator for THREE years after completion of the project.

Washington State University is covered under Human Subjects Assurance Number FWA00002946 which is on file with the Office for Human Research Protections.

If you have questions, please contact the Institutional Review Board at (509) 335-3668.
APPENDIX A

INSTITUTIONAL REVIEW BOARD APPROVAL

Any revised materials can be mailed to the Office of Research Assurances (Campus Zip 3005), faxed to (509) 335-6410, or in some cases by electronic mail, to irb@mail.wsu.edu.

Review Type: New
Review Category: Full Board
Date Received: 6/12/2012
OGRD No.: 109212
Agency: N/A

Thank You,

Malathi Jandhyala
Human Subjects Review Coordinator
Office of Research Assurances
Albrook 205
PO Box 643005, Pullman, WA 99164-3005
E-mail: mjandhyala@wsu.edu
Phone: 509-335-3668
Fax: 509-335-6410
Letter of Approval for Amendment

MEMORANDUM
TO: John Roll and Marian Wilson
FROM: Malathi Jandhyala (for) Matt Layton, M.D., Chair, WSU Institutional Review Board (3005)
DATE: 10/10/2012
SUBJECT: Approval of amendment to IRB Number #12622

Your proposal to amend the protocol titled "Empowering Patients with Chronic Pain Using an Internet-Based Self-Management Program" (IRB #12622) was reviewed for the protection of the subjects participating in the study. Based on the information received from you, the IRB has approved your amendment request on 10/10/2012.

This amendment includes:
- Request to expand recruitment from inland northwest region to any U.S. site.
- IRB approval indicates that the amendments described to the previously approved study protocol are designed to adequately protect the subjects participating in the study. This approval does not relieve the investigator from the responsibility of providing continuing attention to ethical considerations involved in the utilization of subjects participating in the study.
- It is important to note that this approval is for the amended research protocol, and does not alter the existing continuing review schedule.
- The approval for this Human Subjects Research Study expires 6/27/2013.
- If any more changes are made to the study protocol you must notify the IRB with an additional Request for Amendment and receive approval before implementation.

If you have questions, please contact the Institutional Review Board at (509) 335-3668. Any revised materials can be mailed to Office of Research Assurances (Campus Zip 3005), faxed to (509) 335-6410, or in some cases by electronic mail, to irb@wsu.edu.

Review Type: Expedited
Review Category: Expedited
Date Received: 10/1/2012
OGRD No.: 109212
Agency: N/A

Sincerely,
Malathi Jandhyala
Human Subjects Review Coordinator
Office of Research Assurances
Albrook 205
PO Box 643005, Pullman, WA 99164-3005
E-mail: mjandhyala@wsu.edu
Phone: 509-335-3668
MEMORANDUM
TO: John Roll, and Marian Wilson
FROM: Malathi Jandhyala (for) Matt Layton, M.D., Chair, WSU Institutional Review Board (3005)
DATE: 5/21/2013
SUBJECT: Approved Continuing Review of Human Subjects Cont Review, IRB Number #12622-004

The information provided for the continuing review of your protocol titled "Empowering Patients with Chronic Pain Using an Internet-Based Self-Management Program", IRB Number 12622-004 was reviewed for the protection of the subjects participating in the study. Based on the information received from you, the IRB has given approval to continue your human subjects protocol for another year starting 5/21/2013.

Approval action:
Approved continuation-the research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects-through 5/20/2014.

The following conditions apply to the project:

a) The IRB approval indicates that the study protocol as presented in the Human Subjects Form by the investigator is designed to adequately protect the subjects participating in the study. This approval does not relieve the investigator from the responsibility of providing continuing attention to ethical considerations involved in the utilization of human subjects participating in the study.

b) In accordance with federal regulations, this approval letter and a copy of the approved protocol must be kept with any copies of signed consent forms by the researcher for THREE years after completion of the research.

c) You are responsible for appropriate reporting of study-activity(amendments, adverse events, close out reports etc..) to the WSU IRB in accordance with the regulations and IRB
APPENDIX A

INSTITUTIONAL REVIEW BOARD APPROVAL

requirements.

d) If any significant changes are anticipated to the study protocol you must notify the IRB and receive approval before implementation. Request for modification forms are available online at http://www.irb.wsu.edu/forms.asp.

This institution has a Human Subjects Assurance Number FWA00002946 which is on file with the Office for Human Research Protections.

If you have questions, please contact the Institutional Review Board at Office of Research Assurances at (509) 335-3668. Any revised materials can be mailed to Office of Research Assurances (Campus Zip 3005), faxed to (509) 335-6410, or in some cases by electronic mail, to irb@wsu.edu. If materials are sent by email attachment, please make sure they are in a standard file type, (i.e., ASCII text [.txt], or Rich Text Format [.rtf]).

Review Type: Expedited
Review Category: Expedited
Date Received: 4/18/2013
OGRD No.: 109212
Agency: N/A
Thank You,

Malathi Jandhyala
Human Subjects Review Coordinator
Office of Research Assurances
Albrook 205
PO Box 643005, Pullman, WA 99164-3005
E-mail: mjandhyala@wsu.edu
Phone: 509-335-3668
Fax: 509-335-6410
APPENDIX A

INSTITUTIONAL REVIEW BOARD APPROVAL

Date: October 29, 2012
To: Marian Wilson, MPH
From: Carmen Brochu, IRB Chairperson
Study Title: Empowering Patients with Chronic Pain Using an Internet-based Self-Management Program.
Submission Type: New Study
Action: Approved
Approval Date: August 1, 2012
Expiration Date: August 1, 2013
Review Type: Full Committee Review

The Kootenai Medical Center Institutional Review Board has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approval submission.

This submission has received full committee review based on the applicable federal regulations.

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and the research participant. Federal regulations require each participant receive a copy of the informed consent document.

Please note that any revision to previously approved materials must be approved by this committee prior to initiation.

All serious and unexpected adverse events must be reported to this committee. All FDA and sponsor reporting requirements should be followed. Please reports all non-compliance issues or complaints regarding this study to the committee. Please note that all research records must be retained for a minimum of seven years.

If you have any questions, please contact Joyce Lesterberg, IRB Coordinator at 208-666-3830 or by e-mail at jlesterberg@kmc.org.
Help test an Internet-based pain management program

☐ Are you an adult with chronic non-cancer pain lasting more than 3 months?

☐ Do you have a current prescription for an opioid medication (like Lortab, Norco, Oxycodone or Morphine)?

☐ Would you like to try an online program to learn more about how to manage the symptoms and stress of your painful condition?

If you answered YES to these questions, you may be eligible to participate in a study to determine the effect of an 8–week program to improve pain symptoms.

Benefits to you include:
• A comprehensive pain and mood evaluation that can be shared with your health care provider
• Free access to the online Goalistics Chronic Pain Management Program.

The program has activities and lessons designed to build skills that can help you manage your pain better. A year’s subscription will be provided and allow you to access the program tools and online support groups after the research study is over.

Participants will also be able to earn gift cards of up to $30 for completing online pain assessments.

This study is being conducted by Washington State University with funding from the Life Sciences Discovery Fund.

Please contact Marian Wilson, MPH, RN at marian.wilson@wsu.edu or (208) 661-2306 or let the clinic staff know you would like more information.

This study has been reviewed and approved for human subject participation by WSU Institutional Review Board.
Pain Management Study

Help test an Internet-based pain management program

Are you an adult with chronic non-cancer pain lasting more than 3 months?

Do you have a current prescription for an opioid medication (like Lortab, Norco, Oxycodone or Morphine)?

Would you like to try an online program to learn more about how to manage the symptoms and stress of your painful condition?

If you answered YES to these questions, you may be eligible to participate in a study to determine the effect of an 8–week program to improve pain symptoms. Benefits to you include:

- A comprehensive pain and mood evaluation that can be shared with your health care provider
- Free access to the online Goalistics Chronic Pain Management Program.

The program has activities and lessons designed to build skills that can help you manage your pain better. A year’s subscription will be provided and allow you to access the program tools and online support groups after the research study is over. Participants will also be able to earn gift cards of up to $30 for completing online pain assessments.

This study is being conducted by Washington State University with funding from the Life Sciences Discovery Fund.

Please contact Marian Wilson, MPH, RN at marian.wilson@wsu.edu or 208-661-2306 or let the clinic staff know you would like more information.

Text message from providers’ office (to be used if email address unavailable): We are participating in a research study that is testing an Internet-based pain management program for patients with chronic pain. Would you like to hear more about the study? Please contact your primary care provider’s office for more information or contact the researchers directly at marian.wilson@wsu.edu or 208-661-2306.

This study has been reviewed and approved for human subjects participation by WSU Institutional Review Board.
Research Study Consent Form

Study Title: Empowering patients with chronic pain using an Internet-based self-management program

Researchers:
Primary Investigator John Roll, PhD
Associate Dean for Research
College of Nursing, Washington State University
509-324-7341
johnroll@wsu.edu

Co-investigator Marian Wilson, MPH, RN
PhD in Nursing Student
College of Nursing, Washington State University
208-661-2306
marian.wilson@wsu.edu

Sponsor: Life Sciences Discovery Fund

You are being asked to take part in a research study to learn about how to improve chronic pain experiences. This study is led by the researchers listed above. This form explains the research study and your part in it if you decide to join the study. Please read the form carefully, taking as much time as you need. Ask the researcher to explain anything you don’t understand.

You can decide not to join the study. If you join the study, you can change your mind later or quit at any time. There will be no penalty or loss of services or benefits if you decide to not take part in the study or quit later. This study has been approved for human subject participation by the Washington State University Institutional Review Board.

What is this study about?

This research study is being done to see if an Internet program can help patients manage their pain. You are being asked to take part because you have been seen by a primary care provider for problems with pain that have lasted more than three months.

The Internet-based pain program was developed by psychologists and has been found helpful for patients with chronic pain conditions. The program consists of education, goal setting, and learning methods to help manage your pain. An online community is available to allow participants to give each other support and feedback about their
APPENDIX C

INFORMED CONSENT TO PARTICIPATE

health concerns. You can read more about this program by visiting http://pain.goalistics.com/

You can take part in this study if you:

- have chronic noncancer pain lasting more than 3 months
- have had contact with a primary care provider in the last 4 weeks
- have a current prescription for an opioid medication
- have Internet access with email capability either at home or at a public setting
- are more than 18 years of age
- are able to read, speak, and write in the English language

You can not take part in this study if you:

- have a surgical treatment planned in the next 2 months
- are pregnant
- are currently enrolled in therapy or support group with counselor, psychologist, or psychiatrist for chronic pain or substance abuse.

What will I be asked to do if I am in this study?

Taking part in the study will take no more than 2 hours every week for 8 weeks. If you wish to take part in the study, you will be asked to meet with a member of the research team either in person or on the phone for a review of this informed consent form. This meeting will last about an hour and include an orientation to the Internet pain management program. If you agree after this orientation to participate, you will be asked to provide information on all of the medications you are currently taking. You will be asked to state one goal you have that is related to your medicines and your health.

You will receive an envelope that will tell you whether you have been assigned to the treatment group that participates in the pain program right away, or to the comparison group that will be invited to participate in the pain program after 8 weeks. This will be decided by a process called randomization—it is like flipping a coin. You have an equal chance of being chosen for the treatment group or for the comparison group. If you are assigned to the treatment group, you will receive a user name and password that will allow you to log in to the secure pain program web site. You will be asked to follow the directions and complete the activities assigned by the program to the best of your ability.

An important part of the Internet program is a detailed pain assessment called the Profile of Chronic Pain. It includes about 100 questions that participants are asked to complete within the first 2 weeks of the program. After you complete this assessment, the computer program generates a report that tells you how your responses compare to others. This report will be printed by the researchers and shared with your primary care provider. The program then suggests what activities you should begin first to help with your pain, based on the results of your profile. You will be asked to begin the program...
activities and complete one learning module every two weeks. The Profile of Chronic Pain will be repeated at the end of 8 weeks and results will be shared with your primary care provider to show your progress.

If you are assigned to the comparison group, you will not be a part of the Internet-based pain management program right away. You will be invited to use it after 8 weeks if you choose. Immediately after consenting for this study, both the comparison group and the treatment group members will be asked to complete a set of about 80 survey questions that ask about pain, mood, use of medications, daily functioning, and medical history. You will be sent an email that links you to a secure website where you will be asked to answer these questions. A secure website is one that protects or disguises your private information while you are using the Internet. You will be asked how your pain and use of medicines interfere with your activities and relationships. You will also be asked your age, education level, and marital status. We will not ask for your name, phone number, or other identifying information on the web site. It will take no more than one hour to complete the initial survey. In addition, every two weeks for 8 weeks a brief survey of about 20 questions will be sent via email to all participants to ask about pain, mood, and visits to the hospital or doctor’s office. This will take no more than 15 minutes.

At the end of 8 weeks, participants in the comparison group and treatment group will receive an email asking them to complete a final survey. This survey will repeat many of the 80 questions that were asked initially to see if there have been any changes. It will take about an hour. Those in the Internet-based pain program will be asked to complete an additional survey of about 10 questions to give feedback on the program. This will take no more than 20 minutes. Those in the comparison group will be asked if they wish to participate in the Internet pain program at this time. If so, they will be asked to continue with the bi-weekly surveys and the final survey that will be sent again via email at the end of the program. In addition, all participants will receive a final survey six months after ending the pain study to see if results are lasting. Along with the Profile of Chronic Pain, the brief bi-weekly pain and mood survey information will be shared with primary care providers to communicate the progress of all participants. All other survey information will remain private and will not be shared with your health care provider.

Participants will receive reminders when surveys are due. These reminders will be sent by the method preferred by each participant, either email, phone, or text. If after 1 month no response is received, the participant will be considered as having withdrawn from the study and the reminders will stop.

Participants have the right to refuse to answer any questions they choose and to drop out from the study if they choose at any time. The results from the study will be available and participants may request them from members of the research team once the study is completed.
Are there any benefits to me if I am in this study?

If you participate in the Internet-based pain management program, there are some potential benefits to you for taking part in this study. You may learn how to manage your pain better and gain understanding about your pain condition. Although this program has been shown to help some people with pain, we do not know how much it helps, or what types of people it helps the most so we cannot know whether you will have any benefit. This is why we are doing this study. By taking part in this study, however, we may learn more about what is needed to improve patients’ experiences. This may help other patients with pain in the future.

If you are chosen for the comparison group, it is likely that you will not have a direct benefit during the first 8 weeks. Once you have completed the final surveys at the end of 8 weeks, however, you will be given directions on how to access the pain program. You may find the program beneficial if you choose to participate.

All participants will have the option of additional meeting time with researchers, either via phone or in person at a public computer station if they need more guidance with the technology needed to participate. Participants will be encouraged to contact researchers for help setting up an email account, accessing a public computer, or navigating the Internet-based pain program or online surveys. Researchers may contact any participant who does not appear to be engaging in the Internet program to ask about their need for additional help.

Are there any risks to me if I am in this study?

It is possible you will feel stress or psychological discomfort when you are answering personal questions. You are encouraged to contact any member of the study team if you feel you need counseling, or other support and we will refer you to the appropriate services. You or your health insurance will be responsible for costs if any additional services are needed. No commitment to pay your bills for additional healthcare needs or for any adverse results from participating in this study is made by the investigators, your primary care provider, or Washington State University.

Will my information be kept private?

A potential risk from taking part in this study is the loss of privacy that comes from giving out personal information and using web-based systems. The research team is reducing this risk by using a secure web site and computer to store all study information and limiting access to your information. We will not store any identifying information like last names or social security numbers with our data file. The information provided on your consent will be kept separate and in a locked file. Any paper copies will be kept in a secured locked box until they are transported to the locked storage file at Washington State University.
APPENDIX C

INFORMED CONSENT TO PARTICIPATE

You will be given a code number to use for any website activity to protect privacy. Any email communications that you send will be permanently deleted by research team members after they are read. You will be shown how to change your password on the Internet-based pain program used for this study if you decide you wish to keep your activities private. We will not notify your healthcare provider of any information that you disclose except for the specific pain and mood assessments that are intended to help in planning your medical treatment. We will let you know what information will be shared with your healthcare provider when you complete your surveys. If you prefer that no information is shared, you may request for the researchers to keep it private. The only exception would be if you share information that our medical director determines would be dangerous to yourself or others. In this case, we will report it to your primary care provider or other appropriate agency if this is believed necessary to protect your safety or the safety of others.

The data for this study will be kept confidential to the extent allowed by federal and state law. No published results will identify you, and your name will not be associated with the findings. Under certain circumstances, information that identifies you may be released for internal and external reviews of this project. The data for this study will be stored on a secure computer kept by the research team and accessible only by protected passwords. The data will only be available to members of the research team, and the Institutional Review Board if requested. A key will be kept that will allow the researchers to connect your survey information with your activity in the Internet-based pain management program. This will allow us to learn what parts of the program you participated in and how beneficial you found them. The Internet-based pain program will inform you of their own privacy standards when you begin their program. The results of this study may be published or presented at professional meetings, but the identities of all research participants will remain anonymous. The data for this study will be kept for 7 years after completion of the study.

Are there any costs or payments for being in this study?

There will be no direct costs to you for taking part in this study. You may be inconvenienced by the time you are asked to spend completing surveys or participating in the Internet program. No compensation will be available for this inconvenience, or for transportation to or from your primary care providers’ office, or other public meeting places you may choose for meeting with researchers.

You will receive $5 for each survey you complete up to a total of $30 for completing all surveys. An additional $10 will be added for any person in the wait-list comparison group who proceeds to participate in the Internet-based pain program and completes the final survey. Also, if you complete all surveys you will be entered in a drawing for an additional $50. Three participants will receive the extra $50 after the study is completed; one from the treatment group, one from the comparison group, and one from the entire group after the final pain surveys are completed. These rewards are meant to thank you for your time, and encourage your participation. They will be available in the form of gift cards that are sent to you after the study is completed. You will have a choice of several
local businesses from which you can request gift cards of your choice. You will also receive a year subscription to the Internet-based pain management program for a full year free of charge. This is a $30 value. You will not receive any other form of compensation for taking part in this study.

The study team members have received funds from Washington State Life Sciences Discovery Fund to conduct this study. Most of these funds are being used to pay for the materials needed for the study. Some funds are being used to pay involved team members and provider partners for their work on the study.

Who can I talk to if I have questions?

If you have questions about this study or the information in this form, please contact the researchers:

Primary Investigator John Roll, PhD  
Associate Dean for Research  
College of Nursing, Washington State University  
P.O. Box 1495  
Spokane, WA  
509-324-723 johnroll@wsu.edu

Co-investigator Marian Wilson, MPH, RN, PhD in Nursing Student  
College of Nursing, Washington State University  
P.O. Box 1495  
Spokane, WA  
208-661-2306 marian.wilson@wsu.edu

If you have questions about your rights as a research participant, or would like to report a concern or complaint about this study, please contact the Washington State University Institutional Review Board at (509) 335-3668, or e-mail irb@wsu.edu, or regular mail at: Albrook 205, PO Box 643005, Pullman, WA 99164-3005.

What are my rights as a research study volunteer?

Your participation in this research study is completely voluntary. You may choose not to be a part of this study. There will be no penalty to you if you choose not to take part. You may choose not to answer specific questions or to stop participating at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study or choosing not to participate will not affect your medical care. You can still get your medical care from your primary care provider. If you agree to voluntarily participate in this research project as described, please indicate your agreement by completing and submitting the consent form to a member of the research team. You may also send a scanned copy via email, an approved electronic consent, or paper copy via U.S. mail to Marian Wilson at the address above. Please retain a copy of this consent form for your reference.
What does my agreement for consenting mean?

If you complete and submit the consent form it means that:
• You understand the information given to you in this form
• You have had the chance to ask the researcher questions and state any concerns
• The researcher has responded to your questions and concerns
• You believe you understand the research study and the potential benefits and risks that are involved.

Your rights as a study participant are included on the last page of this form.
Thank you for your participation in this research.

Statement of Consent

I give my voluntary consent to take part in this study. I will be given a copy of this consent document for my records. Pain and mood survey information may be shared with my primary care provider.

I agree _____ I do not agree ______

My primary care provider is ______________________________

_______________________________ ______________________
Signature of Participant Date

Printed Name of Participant email address (required)

Preferred method of contact

Statement of Person Obtaining Informed Consent

I have carefully explained to the person taking part in the study what he or she can expect. I certify that when this person signs this form, to the best of my knowledge, he or she understands the purpose, procedures, potential benefits, and potential risks of participation. I also certify that he or she:
• Speaks the language used to explain this research
• Reads well enough to understand this form or, if not, this person is able to hear and understand when the form is read to him or her
• Does not have any problems that could make it hard to understand what it means to take part in this research.

_______________________________ ______________________
Signature of Person Obtaining Consent Date

Printed Name of Person Obtaining Consent Role in the Research Study
APPENDIX C

INFORMED CONSENT TO PARTICIPATE

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

The rights below are the rights of every person who is asked to be in a research study. As a clinical study (research) participant, you have the following rights:

• To be told what the study is trying to find out.
• To be told how long the study will last.
• To be told what will happen to you and what procedures will be followed during the study, especially those that are experimental in nature.
• To be told whether any of the procedures, drugs or devices is different from what would be used in standard practices.
• To be told about the frequency and importance of risks, side effects or discomforts that can happen to you during your participation in this study.
• To be told if you can expect any benefit from participating and, if so, what the benefit might be.
• To be told if the study personnel and physician will be compensated for participating in the research.
• To be told the other choices you have and how they may be better or worse than being in the study.
• To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study.
• To be told what sort of medical treatment is available if any complications arise.
• To refuse to participate at all, or to change your mind about participation after study has started. This decision will not affect your right to receive the care you would receive if you were not in the study.
• To be free of pressure when considering whether you wish to agree to participate in the study. To receive a copy of the signed and dated consent form.
• To be told what, if any, financial obligation you will experience.
• To be given a signed copy of this form.
**Brief Pain Inventory (Short Form)**

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<td></td>
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<td>Middle Initial ______</td>
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1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?

1. Yes  
2. No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.

[Diagram showing areas of pain: Right Front, Left Front, Right Back, Left Back]

3. Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.

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<tbody>
<tr>
<td>No Pain</td>
<td>Pain as bad as you can imagine</td>
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4. Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.

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5. Please rate your pain by circling the one number that best describes your pain on the average.

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6. Please rate your pain by circling the one number that tells how much pain you have right now.

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## APPENDIX D
### INSTRUMENTS

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<td>Name:</td>
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**7. What treatments or medications are you receiving for your pain?**

**8. In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.**

- 0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
- No Relief
- Complete Relief

**9. Circle the one number that describes how, during the past 24 hours, pain has interfered with your:**

<table>
<thead>
<tr>
<th>A. General Activity</th>
<th>B. Mood</th>
<th>C. Walking Ability</th>
<th>D. Normal Work (includes both work outside the home and housework)</th>
<th>E. Relations with other people</th>
<th>F. Sleep</th>
<th>G. Enjoyment of life</th>
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</tr>
<tr>
<td>Does not Interfere</td>
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<td>Does not Interfere</td>
<td>Does not Interfere</td>
<td>Does not Interfere</td>
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</tr>
<tr>
<td>Completely Interferes</td>
<td>Completely Interferes</td>
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<td>Completely Interferes</td>
<td>Completely Interferes</td>
<td>Completely Interferes</td>
</tr>
</tbody>
</table>
## PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

**NAME:**

**DATE:**

---

Over the last 2 weeks, how often have you been bothered by any of the following problems? 

(Use "V" to indicate your answer)

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>Several days</th>
<th>More than half the days</th>
<th>Nearly every day</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Little interest or pleasure in doing things</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2. Feeling down, depressed, or hopeless</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3. Trouble falling or staying asleep, or sleeping too much</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4. Feeling tired or having little energy</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5. Poor appetite or overeating</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6. Feeling bad about yourself—or that you are a failure or have let yourself or your family down</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7. Trouble concentrating on things, such as reading the newspaper or watching television</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>8. Moving or speaking so slowly that other people could have noticed. Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>9. Thoughts that you would be better off dead, or of hurting yourself</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

Add columns: [ ] + [ ] = [ ]

(Total:

(Healthcare professional: For interpretation of TOTAL, please refer to accompanying scoring card).

10. If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

<table>
<thead>
<tr>
<th>difficulty</th>
<th>Not difficult at all</th>
<th>Somewhat difficult</th>
<th>Very difficult</th>
<th>Extremely difficult</th>
</tr>
</thead>
</table>

---

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A2631B 10-04-2005
PHQ-9 Patient Depression Questionnaire

For initial diagnosis:

1. Patient completes PHQ-9 Quick Depression Assessment.
2. If there are at least 4 ✅'s in the shaded section (including Questions #1 and #2), consider a depressive disorder. Add score to determine severity.

Consider Major Depressive Disorder
- if there are at least 5 ✅'s in the shaded section (one of which corresponds to Question #1 or #2)

Consider Other Depressive Disorder
- if there are 2-4 ✅'s in the shaded section (one of which corresponds to Question #1 or #2)

Note: Since the questionnaire relies on patient self-report, all responses should be verified by the clinician, and a definitive diagnosis is made on clinical grounds taking into account how well the patient understood the questionnaire, as well as other relevant information from the patient. Diagnoses of Major Depressive Disorder or Other Depressive Disorder also require impairment of social, occupational, or other important areas of functioning (Question #10) and ruling out normal bereavement, a history of a Manic Episode (Bipolar Disorder), and a physical disorder, medication, or other drug as the biological cause of the depressive symptoms.

To monitor severity over time for newly diagnosed patients or patients in current treatment for depression:

1. Patients may complete questionnaires at baseline and at regular intervals (eg, every 2 weeks) at home and bring them in at their next appointment for scoring or they may complete the questionnaire during each scheduled appointment.
2. Add up ✅'s by column. For every ✅: Several days = 1 More than half the days = 2 Nearly every day = 3
3. Add together column scores to get a TOTAL score.
4. Refer to the accompanying PHQ-9 Scoring Box to interpret the TOTAL score.
5. Results may be included in patient files to assist you in setting up a treatment goal, determining degree of response, as well as guiding treatment intervention.

Scoring: add up all checked boxes on PHQ-9

For every ✅: Not at all = 0; Several days = 1; More than half the days = 2; Nearly every day = 3

Interpretation of Total Score

<table>
<thead>
<tr>
<th>Total Score</th>
<th>Depression Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-4</td>
<td>Minimal depression</td>
</tr>
<tr>
<td>5-9</td>
<td>Mild depression</td>
</tr>
<tr>
<td>10-14</td>
<td>Moderate depression</td>
</tr>
<tr>
<td>15-19</td>
<td>Moderately severe depression</td>
</tr>
<tr>
<td>20-27</td>
<td>Severe depression</td>
</tr>
</tbody>
</table>

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A2662B 10-04-2005
### PATIENTS' GLOBAL IMPRESSION OF CHANGE (PGIC) SCALE

**Date:** __________________________

**Name:** __________________________________________________ DOB: __________________________

**Chief Complaint (Presenting Problem):** ____________________________________________________

Since beginning treatment at this clinic, how would you describe the change (if any) in ACTIVITY LIMITATIONS, SYMPTOMS, EMOTIONS, and OVERALL QUALITY OF LIFE, related to your painful condition? Please circle the number below, that matches your degree of change since beginning care at this clinic for the above stated chief complaint.

<table>
<thead>
<tr>
<th>No change</th>
<th>Almost the same</th>
<th>A little better</th>
<th>Somewhat better</th>
<th>Moderately better</th>
<th>Better</th>
<th>A great deal better</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
</tbody>
</table>

**Explanation:**

1 = No change (or condition has got worse)
2 = Almost the same, hardly any change at all
3 = A little better, but no noticeable change
4 = Somewhat better, but the change has not made any real difference
5 = Moderately better, and a slight but noticeable change
6 = Better, and a definite improvement that has made a real and worthwhile difference
7 = A great deal better, and a considerable improvement that has made all the difference

**Patient's signature:** ______________________________________________________________________

---

**NOTE TO HEALTH CARE PROVIDER**

A significant, favorable change is a score of 5-7
No significant change is a 1-4 response.

Note; this a dichotomous scale (5-7 = yes; 1-4 = no).

A 2-point change is significant from their last reported score.

Current Opioid Misuse Measure (COMM)®

The Current Opioid Misuse Measure (COMM)® is a brief patient self-assessment to monitor chronic pain patients on opioid therapy. The COMM was developed with guidance from a group of pain and addiction experts and input from pain management clinicians in the field. Experts and providers identified six key issues to determine if patients already on long-term opioid treatment are exhibiting aberrant medication-related behaviors:
- Signs & Symptoms of Intoxication
- Emotional Volatility
- Evidence of Poor Response to Medications
- Addiction
- Healthcare Use Patterns
- Problematic Medication Behavior

The COMM will help clinicians identify whether a patient, currently on long-term opioid therapy, may be exhibiting aberrant behaviors associated with misuse of opioid medications. In contrast, the Screener and Opioid Assessment for Patients with Pain (SOAPP®) is intended to predict which patients, being considered for long-term opioid therapy, may exhibit aberrant medications behaviors in the future. Since the COMM examines concurrent misuse, it is ideal for helping clinicians monitor patients’ aberrant medication-related behaviors over the course of treatment. The COMM is:

- A quick and easy to administer patient self-assessment
- 17 items
- Simple to score
- Completed in less than 10 minutes
- Validated with a group of approximately 500 chronic pain patients on opioid therapy
- Ideal for documenting decisions about the level of monitoring planned for a particular patient or justifying referrals to specialty pain clinic.
- The COMM is for clinician use only. The tool is not meant for commercial distribution.
- The COMM is NOT a lie detector. Patients determined to misrepresent themselves will still do so. Other clinical information should be used with COMM scores to decide if and when modifications to particular patient’s treatment plan is needed.
- It is important to remember that all chronic pain patients deserve treatment of their pain. Providers who are not comfortable treating certain patients should refer those patients to a specialist.

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Current Opioid Misuse Measure (COMM)®

Please answer each question as honestly as possible. Keep in mind that we are only asking about the past 30 days. There are no right or wrong answers. If you are unsure about how to answer the question, please give the best answer you can.

Please answer the questions using the following scale:

<table>
<thead>
<tr>
<th>Never</th>
<th>Seldom</th>
<th>Sometimes</th>
<th>Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

1. In the past 30 days, how often have you had trouble with thinking clearly or had memory problems?

2. In the past 30 days, how often do people complain that you are not completing necessary tasks? (i.e., doing things that need to be done, such as going to class, work or appointments)

3. In the past 30 days, how often have you had to go to someone other than your prescribing physician to get sufficient pain relief from medications? (i.e., another doctor, the Emergency Room, friends, street sources)

4. In the past 30 days, how often have you taken your medications differently from how they are prescribed?

5. In the past 30 days, how often have you seriously thought about hurting yourself?

6. In the past 30 days, how much of your time was spent thinking about opioid medications (having enough, taking them, dosing schedule, etc.)?

APPENDIX D
INSTRUMENTS

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**APPENDIX D**

**INSTRUMENTS**

<table>
<thead>
<tr>
<th>Please answer the questions using the following scale:</th>
<th>Never</th>
<th>Seldom</th>
<th>Sometimes</th>
<th>Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. In the past 30 days, how often have you been in an argument?</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>8. In the past 30 days, how often have you had trouble controlling your anger (e.g., road rage, screaming, etc.)?</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>9. In the past 30 days, how often have you needed to take pain medications belonging to someone else?</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>10. In the past 30 days, how often have you been worried about how you’re handling your medications?</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>11. In the past 30 days, how often have others been worried about how you’re handling your medications?</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>12. In the past 30 days, how often have you had to make an emergency phone call or show up at the clinic without an appointment?</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>13. In the past 30 days, how often have you gotten angry with people?</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>14. In the past 30 days, how often have you had to take more of your medication than prescribed?</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>15. In the past 30 days, how often have you borrowed pain medication from someone else?</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>16. In the past 30 days, how often have you used your pain medicine for symptoms other than for pain (e.g., to help you sleep, improve your mood, or relieve stress)?</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>17. In the past 30 days, how often have you had to visit the Emergency Room?</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
</tbody>
</table>

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Scoring Instructions for the Current Opioid Misuse Measure (COMM)®

To score the COMM, simply add the rating of all the questions. A score of 9 or higher is considered a positive

<table>
<thead>
<tr>
<th>Sum of Questions</th>
<th>COMM Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; or = 9</td>
<td>+</td>
</tr>
<tr>
<td>&lt; 9</td>
<td>-</td>
</tr>
</tbody>
</table>

As for any scale, the results depend on what cutoff score is chosen. A score that is sensitive in detecting patients who are abusing or misusing their opioid medication will necessarily include a number of patients that are not really abusing or misusing their medication. The COMM was intended to over-identify misuse, rather than to mislabel someone as responsible when they are not. This is why a low cut-off score was accepted. We believe that it is more important to identify patients who have only a possibility of misusing their medications than to fail to identify those who are actually abusing their medication. Thus, it is possible that the COMM will result in false positives – patients identified as misusing their medication when they were not.

The table below presents several statistics that describe how effective the COMM is at different cutoff values. These values suggest that the COMM is a sensitive test. This confirms that the COMM is better at identifying who is misusing their medication than identifying who is not misusing. Clinically, a score of 9 or higher will identify 77% of those who actually turn out to be at high risk. The Negative Predictive Values for a cutoff score of 9 is .95, which means that most people who have a negative COMM are likely not misusing their medication. Finally, the Positive likelihood ratio suggests that a positive COMM score (at a cutoff of 9) is over 2 times (2.26 times) as likely to come from someone who is actually misusing their medication (note that, of these statistics, the likelihood ratio is least affected by prevalence rates). All this implies that by using a cutoff score of 9 will ensure that the provider is least likely to miss someone who is really misusing their prescription opioids. However, one should remember that a low COMM score suggests the patient is really at low-risk, while a high COMM score will contain a larger percentage of false positives (about 34%), while at the same time retaining a large percentage of true positives. This could be improved, so that a positive score has a lower false positive rate, but only at the risk of missing more of those who actually do show aberrant behavior.

<table>
<thead>
<tr>
<th>COMM Cutoff Score</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Positive Predictive Value</th>
<th>Negative Predictive Value</th>
<th>Positive Likelihood Ratio</th>
<th>Negative Likelihood Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score 9 or above</td>
<td>.77</td>
<td>.66</td>
<td>.66</td>
<td>.95</td>
<td>2.26</td>
<td>.35</td>
</tr>
</tbody>
</table>

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PAIN SELF EFFICACY QUESTIONNAIRE (PSEQ)
M.K.Nicholas (1989)

NAME: __________________________________________  DATE: __________________

Please rate how confident you are that you can do the following things at present, despite the pain. To indicate your answer circle one of the numbers on the scale under each item, where 0 = not at all confident and 6 = completely confident.

For example:

0 1 2 3 4 5 6
Not at all Completely
Confident confident

Remember, this questionnaire is not asking whether or not you have been doing these things, but rather how confident you are that you can do them at present, despite the pain.

1. I can enjoy things, despite the pain.

0 1 2 3 4 5 6
Not at all Completely
Confident confident

2. I can do most of the household chores (e.g. tidying-up, washing dishes, etc.), despite the pain.

0 1 2 3 4 5 6
Not at all Completely
Confident confident

3. I can socialise with my friends or family members as often as I used to do, despite the pain.

0 1 2 3 4 5 6
Not at all Completely
Confident confident

4. I can cope with my pain in most situations.

0 1 2 3 4 5 6
Not at all Completely
Confident confident

Turn over
APPENDIX D
INSTRUMENTS

5. I can do some form of work, despite the pain. (“work” includes housework, paid and unpaid work).

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Confident</td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

6. I can still do many of the things I enjoy doing, such as hobbies or leisure activity, despite pain.

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Confident</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

7. I can cope with my pain without medication.

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Confident</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

8. I can still accomplish most of my goals in life, despite the pain.

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Confident</td>
<td></td>
<td></td>
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<td></td>
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</tr>
</tbody>
</table>

9. I can live a normal lifestyle, despite the pain.

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Confident</td>
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</tr>
</tbody>
</table>

10. I can gradually become more active, despite the pain.

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Confident</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

APPENDIX D
INSTRUMENTS

Demographic Survey

What is your age?  

What is your gender?
☐ Male
☐ Female

What is the highest level of education you have completed?
☐ Less than High School
☐ High School / GED
☐ Some College
☐ 2-year College Degree
☐ 4-year College Degree
☐ Masters Degree
☐ Doctoral Degree
☐ Professional Degree (JD, MD)

What is your current status?
☐ Single, never married
☐ Married without children
☐ Married with children
☐ Divorced
☐ Separated
☐ Widowed
☐ Living w/ partner

Please write in your ZIP code.  

What is your medical diagnosis related to your pain condition?

Please write in any other medical conditions.
<table>
<thead>
<tr>
<th>Participant Number</th>
<th>Medication Inventory T1</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>Performed By</td>
<td></td>
<td>Method</td>
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<td>In person</td>
</tr>
<tr>
<td>Medication Name.</td>
<td>Dose</td>
<td>Frequency</td>
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</table>

Please state one goal that you have related to your medications:
______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________

Please state an additional goal related to your overall health and well-being:
______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________
# APPENDIX D

## INSTRUMENTS

<table>
<thead>
<tr>
<th>Participant Number</th>
<th>Medication Inventory T2</th>
<th>Date</th>
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</table>

<table>
<thead>
<tr>
<th>Medication Name</th>
<th>Dose</th>
<th>Frequency</th>
<th>Route</th>
<th>Change in dose or frequency?</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Yes</td>
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<td>No</td>
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</tbody>
</table>

**Change in dose or frequency?**

- Yes
- No

Please rate your progress towards meeting your goal of __________________________

<table>
<thead>
<tr>
<th>No progress</th>
<th>Slight progress</th>
<th>Good progress</th>
<th>Met goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
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<td>6</td>
<td>7</td>
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<tr>
<td>8</td>
<td>9</td>
<td>10</td>
<td></td>
</tr>
</tbody>
</table>

**Comments**

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________
Bi-weekly Health Care Utilization

1. In the past 2 weeks, how many times did you visit a physician? Do not include visits while in the hospital or to a hospital emergency room. Fill in with "0" or another number. ____ times

2. In the past 2 weeks, how many times did you visit a nurse practitioner or physician assistant? Do not include visits while in the hospital or to a hospital emergency room. Fill in with "0" or another number. ____ times

3. In the past 2 weeks, how many times did you visit a counselor or psychologist? Do not include visits while in the hospital or to a hospital emergency room. Fill in with "0" or another number. ____ times

4. In the past 2 weeks, how many times did you go to a hospital emergency room? Fill in with "0" or another number. ____ times

5. How many different times did you stay in a hospital overnight or longer in the past 2 weeks? Fill in with "0" or another number. ____ times

6. How many total nights did you spend in the hospital in the past 2 weeks? Fill in with "0" or another number. ____ nights

7. Did your healthcare provider make any changes to your medications in the past 2 weeks? Yes or No

If you answered yes, please describe the changes made to your medications.

8. Did you change anything about your use of medications in the past 2 weeks? Yes or No

If you answered yes, please describe the changes made to your medications.

9. Did you add or change anything in your behaviors or activities to help control your pain in the past 2 weeks? Yes or No.

If yes, please answer items 10 and 11.

10. Please describe the change you made to help control your pain.

11. Where did you receive information to assist with this change? May select more than one.

- Health care provider
- Internet site

171
APPENDIX D

INSTRUMENTS

- Book or magazine
- Friend/Family
- Goalistic Internet-based Chronic Pain Management Program
- Other (write in)

Adapted from Stanford Patient Education Research Center
APPENDIX D

INSTRUMENTS

Computer Usability Satisfaction Survey

Please provide feedback on your use of the Goalistics Chronic Pain Management Program.

For each of the statements below, circle the rating of your choice.
1. Overall, I am satisfied with how easy it is to use this program.
   STRONGLY DISAGREE 1 2 3 4 5 6 7 AGREE

2. Overall, I am satisfied with the amount of time it took to complete this program.
   STRONGLY DISAGREE 1 2 3 4 5 6 7 AGREE

3. Overall, I am satisfied with the support available (on-line help, email messages) when completing this program.
   STRONGLY DISAGREE 1 2 3 4 5 6 7 AGREE

4. I could effectively complete the tasks assigned using this program.
   STRONGLY DISAGREE 1 2 3 4 5 6 7 AGREE

5. I felt comfortable using this program.
   STRONGLY DISAGREE 1 2 3 4 5 6 7 AGREE

6. It was easy to find the information needed to complete this program.
   STRONGLY DISAGREE 1 2 3 4 5 6 7 AGREE

7. The information provided for this program was easy to understand.
   STRONGLY DISAGREE 1 2 3 4 5 6 7 AGREE

8. Did you find anything about this program especially useful? What would that be?
9. Is there anything you would change about this program if you could? What would that be?
10. What else can you share about your experience participating in this program?

Adapted with permission from the IBM Computer Usability Satisfaction Questionnaires.

173
APPENDIX E

GUIDED SCRIPT FOR STUDY PARTICIPATION

Guided Script for Study Participation

Phone Assessment – Intervention Phase at T2

Participant Number: ________

Date: ________

Assessor: ________________

If leaving a message, state:

Hello. This is (interviewer’s name) from Washington State University calling about our check-in for the research study. I would like to see if you have any questions about the program. You can reach me at (208) xxx-xxxx.

If returning a call, state:

Hi, is this ____ (person’s name)?

If yes, continue. If no, let person on other end of the phone know you’ll call back.

This is (interviewer’s name) from Washington State University calling about our check-in for the pain management study.

Is this a good time for our 10 minute check-in?

If “no” this is not a good time,

When would be a good time for our check-in?

Scheduled Date & Time: ___________________________

Verify Best Phone Number: ________________________

Thank you. I’ll call back on (scheduled date & time).

If “yes”, this is a good time:

Great, thank you. This phone call will include a brief check in about how you are managing with the Chronic Pain Management Internet program.
APPENDIX E

GUIDED SCRIPT FOR STUDY PARTICIPATION

1. First, I’d like to get an idea of your understanding of the program. I see you have/have not completed the Profile of Chronic Pain assessment that is assigned in Lesson One. Can you tell me about any difficulties you are having with the program? *If difficulties are reported, respond to individual concerns related to the program and troubleshoot computer problems. If the Profile of Chronic Pain has not been completed go to question 2.*

2. *If no difficulties reported, and Profile of Chronic Pain has been completed, skip to question 3.*

2. Can I walk you through the steps to complete the assessment? This is the information that I would like to share with your provider to give more information about the difficulties you are having related to your pain. *If participant agrees, guide through site to access the Profile of Chronic Pain. If unable to complete, suggest an appointment to orient to this in person.*

3. Are you able to see in Lesson One the learning module assigned for you to begin first? *If no, offer to guide participant through the site to identify the learning module.*

4. Is there any other help you feel you need to continue with the program?
Phone Contact for Bi-weekly Survey Completion – Intervention and TAU Group

Text or email reminder: (to be sent weekly up to one month past survey due date)

This is just a reminder that we have not received your latest survey for our pain study. Please follow the email link to access it, or contact the research team if you are having problems completing it.

We appreciate your participation!

Marian Wilson, RN, MPH
208-xxx-xxxx
Marian.wilson@wsu.edu

Phone reminder: (to be initiated if survey 2 weeks overdue and no response to text or email)

If leaving a message, state:

Hello. This is (interviewer’s name) from Washington State University calling about our research study. This is just a reminder that we have not received your latest survey for our pain study. Please let me know if you are having problems completing it. You can reach me at (208) xxx-xxxx.

If returning or placing a call, state:

Hi, is this ____ (person’s name)?

If yes, continue. If no, let person on other end of the phone know you’ll call back.

This is (interviewer’s name) from Washington State University calling about our pain study. Is this a good time to ask about your pain survey?

If “no” this is not a good time,

When would be a good time to call back?

Scheduled Date & Time: ___________________________
APPENDIX E

GUIDED SCRIPT FOR STUDY PARTICIPATION

Verify Best Phone Number: ________________________

Thank you. I’ll call back on (scheduled date & time).

If “yes”, this is a good time:

Great, thank you. I noticed you have not completed the latest survey and would like to offer to help you over the phone. May I read the survey questions to you? If yes, read the surveys as presented on the Qualtrics survey site. Thank the participant when they are finished and remind them of the next survey date. If no, continue:

Is there any other way I can help with your participation in the study? Offer to help by resending the surveys, calling at another time, or troubleshooting computer difficulties. Thank the participant if they no longer wish to participate.
APPENDIX F
PERMISSIONS

BPI

“I have attached the BPI-SF as you requested. Please let me know if you have any questions. Thank you for your interest in the BPI. The email that is sent with the tool is the authorization letter for all the non-funded academic research, clinical practice or educational purpose.” Email communication 6/12/13.

Nazim Ali
symptomresearch@mdanderson.org

PHQ-8

“All PHQ, GAD-7 screeners and translations are downloadable from this website and no permission is required to reproduce, translate, display or distribute them.” www.phqscreeners.com

Developed by Drs. Robert L. Spitzer, Janet B. W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc.

PSEQ

“I’m very happy for you to use the PSEQ in your studies and there is no fee (or forms). All I do ask is for the copyright to be acknowledged and a copy of any papers you eventually publish with it.” Email communication 6/09/13

Professor Michael K. Nicholas, PhD
Pain Management Research Institute
Sydney Medical School-Northern
University of Sydney at Royal North Shore Hospital
St Leonards, NSW 2065
Email: michael.nicholas@sydney.edu.au

PGIC

“There is no need to ask for permission to use the PGIC, and no problem with including a copy in an appendix of your thesis. “ Email communication 6/20/13

Jenni Bolton
Anglo European College of Chiropractic
13-15 Parkwood Road
Bournemouth BH52DF
JBolton@aecc.ac.uk
APPENDIX F

PERMISSIONS

IBM Computer Usability Satisfaction Questionnaire


“You definitely have permission to use the questionnaire as you wish” email communication 6/10/13.

James R. (Jim) Lewis, Ph.D., CHFP
Senior Human Factors Engineer
IBM Software Group
8051 Congress Ave., Suite 2088
Boca Raton, FL 33487
Phone: 561-862-2316 (TL: 975-2316)
Fax: 561-862-2316 (TL: 975-2316)
Internet: jimlewis@us.ibm.com

Health Care Utilization

“You may use any of these scales at no cost without permission.”

Funding provided by the National Institute of Nursing Research. Retrieved from Stanford School of Medicine Patient Education Research Center www.patienteducation.edu/research

Permission to reproduce scale for dissertation granted by Dr. Kate Lorig 6/9/13 email communication lorig@stanford.edu.

Profile of Chronic Pain

I am granting permission for Marian Wilson to use the Profile of Chronic Pain instrument for her dissertation work. For information on viewing the instrument in its entirety, please send a request to Linda.Ruehlman@goalistics.com.

Sincerely,

Linda Ruehlman, PhD
Goalistics, LLC
8621 South Maple Avenue
Tempe, Arizona 85284
Phone: 602-751-5433
Linda.Ruehlman@goalistics.com
IFSMT Model

“We have retained the copyright to the model. Yes please use it as described in the Nursing Outlook study.” Email communication 4/14/13.

Polly Ryan, PhD, RN, CNS-BC
Senior Nurse Researcher, Froedtert Health
Research Scientist
University of Wisconsin Milwaukee
College of Nursing
Center Scientist
Self-Management Science Center
Adjunct Associate Professor
Medical College of Wisconsin
ryanpa@uwm.edu
pryan@froedterthealth.com
Gratis

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