The Role of Acceptance and Pain Intensity in Chronic Pain Disability and Physical Functioning

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THE ROLE OF ACCEPTANCE AND PAIN INTENSITY IN CHRONIC PAIN DISABILITY AND PHYSICAL FUNCTIONING

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THE ROLE OF ACCEPTANCE AND PAIN INTENSITY IN CHRONIC PAIN DISABILITY AND PHYSICAL FUNCTIONING

LISA LUKWINSKI FERGUSON

ABSTRACT

Chronic pain is a wide spread, debilitating disorder. With the development of Relational Frame Theory, the pathological nature of avoidance behaviors has been brought to the forefront of chronic pain research and acceptance based therapies are being extensively studied. Although interdisciplinary chronic pain rehabilitation programs draw from a variety of disciplines, they incorporate many components of acceptance therapy.

The purpose of the present study was to examine the relationship between chronic pain acceptance, pain intensity, disability, and physical functioning. This study sought to answer the following questions: 1) Do patients who complete an interdisciplinary chronic pain rehabilitation program differ from those who drop out by demographics or outcome measures?, 2) Is an interdisciplinary chronic pain rehabilitation program effective in promoting acceptance of chronic pain and physical functioning while decreasing disability?, 3) What is the relationship between chronic pain acceptance, pain intensity, disability, and physical functioning?, and 4) Will changing levels of acceptance interact with changes in disability and physical functioning independent of pain intensity?

Of the 487 patients admitted into a Cleveland area chronic pain program between 2006 and 2007, 393 patients completed the program and were included in the main analyses. Pre- and post-treatment measures included pain intensity, CPAQ, UAB, PDI,
and a six-minute treadmill test. Chi-square and independent sample t-tests were performed to compare completers and non-completers, paired sample t-tests were used to determine the effectiveness of the program, and Pearson correlations and hierarchal multiple regression were used to examine the relationship of the outcome variables. The tests were considered significant at the .05 level.

Program completers differed significantly from non-completers in age, primary complaint, and marital status. Program completers significantly improved across all outcome measures. Greater acceptance and lower pain intensity correlated with lower disability and fewer pain behaviors, but there was no significant relationships between physical functioning and either acceptance or pain intensity. While both acceptance and pain intensity predicted both disability and pain behaviors, changing in acceptance was the strongest predictor of both. These results support previous research indicating the importance of chronic pain acceptance and its independence from pain intensity.
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CHAPTER I
REVIEW OF THE LITERATURE

Chronic pain affects every aspect of life; it is a private experience that can affect one’s physical abilities, psychological health, and daily functioning. A comprehensive literature review of chronic pain epidemiology reported 15% of the adult population in western countries experiences chronic benign pain in their lifetime (Verhaak, Kerssens, Dekker, Sorbi, & Bensing, 1998). This percentage has been closely replicated in more recent populations including Australia (Blyth et al., 2001), France (Bouhassira, Lanteriminey, Attal, Laurent, & Touboul, 2008), various European countries and Israel (Breivik, Collett, Ventafridda, Cohen, & Gallacher, 2006), Scotland (Smith et al., 2001), and Canada (Tripp, VanDenKerkhof, & McAlister, 2006). With such high rates of occurrence in today’s society, it is not surprising that chronic pain is one of the most cited reasons individuals seek health care, particularly when the pain limits the individual’s activity level (Jacobson & Mariano, 2001; von Korff, Wagner, Dworkin, & Saunders, 1991). The annual cost of chronic pain is estimated to be more than $100 billion and includes alternative therapies, lost work productivity, unemployment, pain-related disability income, medication, and other medical expenses (Burgoyne, 2007; Chen, 2005;
Despite its high prevalence, chronic pain is difficult to define and assess.

1.1 Chronic Pain Defined

The complex and subjective nature of pain makes it difficult to define. The International Association for the Study of Pain (IASP) describes pain as an unpleasant, subjective “sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” (Merskey & Bogduk, 1994, p. 209). Loeser (as cited in Gatchel, Peng, Peters, Fuchs, & Turk, 2007) identified four facets of pain: nociception (nerve stimulation), pain (subjective experience of nociception), suffering (emotional response), and pain behavior (overt actions indicating the experience of pain). Although the IASP does not clarify the difference between acute and chronic pain, chronic pain is traditionally described as pain that persists for three to six months or beyond the expected time of healing. An exploration of the literature provides further distinctions between acute and chronic pain.

Turk and Okifuji (2001) define acute pain as being “elicited by the injury of body tissue and activation of nociceptive transducers at the site of local tissue damage…The state of acute pain lasts for a relatively limited time and generally remits when the underlying pathology resolves” (p. 17). Acute pain tends to come and go with external stimuli. When pain is caused by a more serious tissue injury, such a sprain, minor burn, or surgery it can be classified as subacute pain (Niv & Devor, 1999). With acute and subacute pain, the location, pattern, and description of the pain may lead to the diagnosis of the underlying cause of the pain symptom (Gatchel & Epker, 1999). However, there are instances when people report pain in the absence of bodily damage, such as imagining...
biting down on a piece of aluminum foil. (Mersky & Bogduk, 1994). Acute and subacute pain can play a role in recovery from injury or illness and may be part of the adaptive process of learning to avoid dangerous environmental stressors (Wiertelak et al., 1994). Acute and sub-acute pains are easily treated in a medical model, often with medication and/or surgical procedures (Niv & Devor, 1999). While there is some degree of suffering and disability, physical as well as emotional, associated with acute pain, no definable moment classifies the transition to chronic pain. The only indication of chronic pain is a gradual realization that pain is not subsiding (Niv & Devor, 1999).

The complex experience of chronic pain not only differs from acute pain in duration but also in its ability to be treated, its association with disability, and the psychological, social, and economic impact it has on an individual and society. Turk and Okifuji (2001) define chronic pain as multidimensional:

Elicited by an injury but may be perpetuated by factors that are both pathogenetically and physically remote from the original cause. Chronic pain extends for a long period of time, represents low levels of underlying pathology that does not explain the presence and extent of pain, or both. This type of pain prompts patients frequently to seek health care, and it is rarely effectively treated. Because the pain persists, it is likely that environmental and affective factors eventually interact with the tissue damage, contributing to the persistence of pain and illness behaviors. (p. 17)

Not limiting the pain experience to pathological causes, this definition highlights the role of psychological, socioeconomic, and environmental factors in the transition of acute pain to chronic pain as well as the role of pain behaviors. Pre-existing personality characteristics, conditioning factors, secondary gain, individual coping styles, social support, the type of physical disease or injury, behavior of the individual, and quality of medical care all play an important role in the development of chronic pain (Gatchel &
Epker, 1999; Niv & Devor, 1999; Turk & Flor, 1999). An increased likelihood of other disorders and emotional/cognitive responses can reinforce disability, change mood, and increase one’s pain perception (Niv & Devor, 1999). Pain’s subjective nature, its frequent co-morbidity with mood disorders (especially depression) (Tunks, Crook, & Weir, 2008), sleep disorders (Burgoyne, 2007; Latham & Davis, 1994), other psychological illnesses (Hansen & Streltzer, 2005; Tunks et al., 2008), and the reinforcement produced by pain behaviors complicate the diagnosis and treatment of chronic pain. Because preventing the transition from acute to chronic pain may be the key to preventing the escalation of pain and its disabling nature (Gatchel et al., 2003), studying trends and risk factors associated with the development of chronic pain is vital.

The vast majority of epidemiological research on chronic pain distinguishes pain based on its cause and body location and/or body system. The most commonly reported causes of nonmalignant chronic pain are arthritic conditions, deteriorated/herniated discs and degeneration/fractures of the spine, and trauma/surgery (Breivik et al., 2006; Elliott, Smith, Penny, Smith, & Chambers, 1999; Eriksen, Jensen, Sjogren, Ekholm, & Rasmussen, 2003). The most frequently reported site of chronic pain is the musculoskeletal system – including joints (particularly the knees), head/neck, abdominal, the lower extremities, and the back/lower back (Breivik et al., 2006; Burgoyne, 2007; Elliot et al., 1999; Miro et al., 2007; Verhaak et al., 1998). Other common chronic pain conditions include headache, fibromyalgia (Chen, 2005) and neuropathic pain (Bouhassira et al., 2008; Chen, 2005). The identification of the most prevalent sites of chronic pain as well as the identification of possible risk factors for the development of chronic pain is imperative in implementing early intervention procedures.
The identification of risk factors associated with acute pain progressing to chronic pain can increase the effectiveness of early intervention treatment of acute pain and aid in the assessment, treatment, and study of chronic pain. Three psychosocial variables are prominent in research; gender, age, and employment status. Gender is an important yet complicated psychosocial risk factor. The influence of gender on chronic pain can be due to biological factors, cultural influences, pain behaviors (behaviors that signal the experience of pain), or coping mechanisms (Miaskowski, 1999). Women, tend to report chronic pain conditions more frequently (Bouhassira et al., 2008; Eriksen et al., 2003; Verhaak et al., 1998), have higher levels of pain and pain-related disability, display more pain behaviors (Keefe et al., 2000), and experience pain syndromes more frequently than men (Berkley, 1997; Unruh, 1996). Gender has been found to be a predictor of chronic pain disability as more females develop disability from acute pain (Gatchel, Polatin, & Mayer, 1995). Miaskowski (1999) presents data showing women exhibit lower tolerance and pain threshold than males, but women are perceived by both sexes as being able to cope with pain more efficiently. Theories about these pain-related gender differences range from social to biological in nature. The way males and females are socialized, respond to emotion, and the different expectations of their social roles may explain the overrepresentation of women with different chronic pain conditions (Fillingim, 2000; Unruh, 1996). Others propose that differences in hormone levels between males and females play a role in pain perception. It is hypothesized that the fluctuation of hormone levels during the menstrual cycle (Berkley, 1997; Heitkemper & Jarrett, 2001) as well as the effects of sex hormones on nervous systems and their different concentrations in
males and females (Berkley, 1997; Fillingim & Ness, 2000) may play a role in greater pain sensitivity in females which especially those with chronic pain conditions.

Age is a second psychosocial factor associated with chronic pain. Studies show that reports of chronic pain increase with age with peak prevalence between ages 45 and 65 years (Bouhassira et al., 2008; Breivik et al., 2006; Verhaak et al., 1998). In Denmark, those 67 years or older reported higher incidences of chronic pain (Eriksen et al., 2003). Finally, with 25% of chronic pain patients indicating that pain impacts employment, work status is a third important factor in chronic pain (Breivik et al., 2006; reviewed in Tunks et al., 2008). In a community sample, those who are retired or unemployed individuals are more likely to report chronic pain than those who are employed (Elliot et al. 1999). Workers with highly physical jobs have been found to report chronic pain more than those with sedentary jobs (Erikson, 2003). The presence of workers’ compensation has also been found to be a predictor of the development of chronic pain disability (Gatchel, Polatin, & Mayer, 1995) as well as less successful treatment outcomes (Blyth, March, Nicholas, & Cousins, 2005; Burns, Sherman, Devine, Mahoney, & Pawl, 1995; Dworkin, Handlin, Richlin, Brand, & Vannucci, 1985). When patients from a spine rehabilitation center with chronic low back pain and/or sciatica where compared based on financial compensation, the group receiving financial compensation reported greater pain, depression, and disability than the non-compensated group (Rainville, Sobel, Hartigan, & Alexander, 1997). While gender, age, and employment are the most frequently cited factors in chronic pain development and occurrence, other factors that may promote chronic pain include psychosocial factors (Linton, 2000), depression (Hansen & Strelter, 2005; Linton, 2000), lack of social
support, unhealthy lifestyle, substance abuse (Hansen & Streltzer, 2005), divorce, and low education levels (Eriksen, 2003). Since chronic pain mainly affects the working age population and their work status, the cost of pain-related disability is enormous.

1.2 Chronic Pain and Disability

Whereas pain is a symptom, disability is a restriction in everyday functioning. Chronic lower back pain, the most common and disabling type of chronic pain, permanently disables approximated 1% of the working age population. Chronic lower back pain is the number one cause of disability in people under the age of 45 years and the third cause of disability in people over the age of 45 years (Burgoyne, 2007; Gatchel, Polatin, & Mayer, 1995). Pollard (1984) defines pain disability as “the extent to which chronic pain interferes with a person’s ability to engage in various life activities” (p. 974). This interference involves interplay among variables such as pain severity (Von Korff, Dworkin, & Le Resche, 1990), the extent and duration of pain, (Tait, Pollard, Margolis, Duckro, & Krause, 1987), pain beliefs (Geisser, Haig, & Theisen, 2000; Young Casey, Greenberg, Nicassio, Harpin, & Hubbard, 2008), and depressive symptoms (Young Casey et al., 2008). Although disability is a hallmark of chronic pain, observed relationships between disability and pain severity are often weak.

Studies find the relationship between pain intensity and subjective ratings of disability to be complex with a moderate to weak relationship between the two variables (Crombez, Vlaeyen, Heuts, & Lysens, 1999; Geisser, Robinson, Miller, & Bade, 2003; Gronblad et al., 1993; Gronblad, Hurri, & Kouri, 1997). To add confusion, self-rated disability has been found to predict persisting pain intensity, but pain intensity does not predict persisting subjective disability (Epping-Jordan et al., 1998). Although some
research shows an insignificant relationship between these constructs, other research supports a significant relationship between pain intensity and self-reported disability. When there is a significant relationship, higher subjective pain disability relates to greater pain severity (Gauntlett-Gilbert & Eccleston, 2007; Turk, Okifuji, Sinclair, & Starz, 1996; Soares, Sundin, & Grossi, 2003; Weiner, Rudy, Kim, & Golla, 2004). When comparing an older pain population to a younger pain population, increased pain intensity becomes more related to subjective pain disability in the older population (Edwards, 2006; Turk, Okifuji, & Scharff, 1995). The lack of a clear linear relationship between subjective pain disability and pain intensity has prompted researchers to explore variables that mediate the relationship between pain intensity and self-reported disability, including depression (Epping-Jordan et al., 1998; Gauntlett-Gilbert & Eccleston, 2007; Holzberg, Robinson, Geisser, & Gremillion, 1996; Young Casey et al., 2008), anxiety (Holzberg et al., 1996; Meredith, Strong, & Feeney, 2006), self-efficacy (Arnstein, 2000; Arnstein, Caudill, Mandle, Norris, & Beasley, 1999; Meredith et al., 2006), pain-related fear (Crombez et al., 1999), catastrophizing (Keefe et al., 2000), and quantity of symptoms (Millard, Wells, & Thebarge, 1991).

When assessing disability in pain patients, it is important to look not only at the subjective pain experience but also objective limitations in activity. Many treatment programs take into account self-reported levels of pain severity and observable manifestations of functioning, but again the relationship is generally not clear. Two widely used forms of objective functioning include pain-related illness behaviors and physical functioning. Fordyce (as cited in Turk & Flor, 1987) first described pain-related illness behaviors, or pain behaviors, and their importance in categorizing pain as chronic.
Pain behaviors are observable, reinforceable actions that indicate to others the experience of pain; pain behaviors include verbal complaints, non-verbal sounds and gestures, body posturing, displaying functional limitations, and actions taken to reduce pain. Increased pain behaviors have been correlated with greater pain intensity (Dickens, Jayson, & Creed, 2002; Grambling & Elliot, 1992; Keefe & Block, 1982; McDaniel et al., 1986). The reduction of pain behaviors also relates to the reduction of pain severity (Hansen & Streltzer, 2005; Sator-Katzenschlager et al., 2003). Research has also found a link between pain intensity and physical performance; higher pain intensity significantly correlates with lower objective physical performance (McCracken, Gross, & Eccleston, 2002; Turk et al., 1996) and recovery from pain is associated with increased physical performance (Bryant, Grigsby, Swenson, Scarbro, & Baxter, 2007). Tests of physical performance included such exercises as time to stand up from a sitting position, walking, amount weight lifted, and bicycle riding. Similar to pain intensity and subjective disability, some research suggests mediating factors are important to understanding the relationship between pain intensity and observable manifestations. Mediating factors can include pain-related fear (Crombez et al., 1999; Geisser, Haig, & Theisen, 2000), anxiety (McCracken et al., 2002), neuropsychological functioning (Weiner, Rudy, Morrow, Slaboda, & Lieber, 2006), as well as stimuli that reinforce symptom presentation or pain behaviors (Richards et al., 1982). The generally insignificant or moderate relationship between pain behaviors and pain intensity (Ahles et al., 1990; McCahon, Strong, Sharry, & Cramond, 2005; Monina, Falzetti, Firetto, Mariani, & Caputi, 2006; Richards, Nepomuceno, Riles, & Suer, 1982; Romano et al., 1988) indicates that subjective pain ratings and pain behaviors are different aspects of the pain experience. Although there
tends to be a discrepancy between pain severity and objective disability, a decrease in pain behaviors and improved physical functioning are still considered core outcomes in clinical trials of pain treatment (Turk & Dworkin, 2004).

What patients believe they can do and what they are actually capable of doing may be relatively independent and the relationship between subjective and observed disability may vary. In a study involving fibromyalgia patients, self-reported disability and physical functioning were not significantly related (Turk et al., 1996). But when the same group of fibromyalgia patients was classified as dysfunctional, interpersonally distressed, or adaptive coper using the Multidimensional Pain Inventory, a significant correlation between increased disability and decreased physical functioning was found in the group classified as adaptive copers (Turk et al., 1996). A higher number of observed pain behaviors strongly correlates to greater self-reported disability (Dickens et al., 2002; McCahon et al., 2005; Prkachin, Schultz, & Hughes, 2007), with greater subjective pain disability predicting greater number of pain behaviors (McCahon et al., 2005). When determining the level of pain-related disability, objective manifestations of functioning may be more sensitive then self-report measures of disability in discerning functional limitations (Brach, VanSwearingen, Newman, & Kriska, 2002). On the other hand, conflicting results between objective and subjective ratings of disability may indicate the presence of two distinct constructs (Reuben, Valle, Hays, & Siu, 1995). The use of both types of measures seems necessary to get a complete picture of pain-related disability.

1.3 Biopsychosocial Model of Pain

Not all pain develops into chronic pain and not all people who develop chronic pain become disabled. The subjective nature and assessment of pain makes it difficult to
ascertain what portion of disability can be attributed to actual physical impairment and
what portion can be attributed to other factors such as emotional and cognitive responses
and environmental contingencies (Tait et al., 1987). Since the relationship between
chronic pain and disability is so complex, it is helpful to look at it within a
multidimensional schema. Moving away from a strictly medical model towards a
multidimensional pain model has opened new avenues in theories of chronic pain and the
development of pain-related disability. In the multidimensional biopsychosocial model
(Gatchel et al., 2007) of chronic pain, body and mind are connected and pain has multiple
causes and perpetuations. The nociception process, the subjective experience of pain,
along with personal attitudes, emotions, and cognitions, and social context play a role in
the development of chronic pain and disability. The complex interaction between these
biological, psychological and social factors leads to a diverse range of pain behaviors,
pain beliefs, and coping strategies (Turk & Flor, 1999; Waddell and Main 1998). If
maladaptive pain beliefs and passive coping styles are established, greater pain
interference (Cipher, Clifford, & Schumacker, 2002; Raichle, Hanley, Jensen, &
Cardenas, 2007), more psychological distress (Keefe, Crisson, Urban, Williams, 1990;
Walker, Smith, Garber, & Claar, 2005), increased pain severity (Carroll et al., 2002;
Cipher et al., 2002; Turk & Okifuji, 2002), lowered pain threshold (Turk & Flor, 1999;
Waddell and Main 1998), and greater disability (Linton, 2000) may be consequences.
Family, work, and social networks can reinforce pain behaviors and aid in the
perpetuation of disability.

Fordyce (as cited in Turk & Flor, 1987) first proposed that learned behaviors
perpetuate disability even after the damage that initiated pain is not present. Operant
conditioning principles can lead to an increased amount of observed pain behaviors. In operant conditioning, positive reinforcement increases pain behaviors when followed by positive consequences such as spousal attention and medication prescription. Negative reinforcement increases pain behaviors through the removal of aversive consequences, including the avoidance of activities that induce pain (Fordyce, Shelton, & Dundore, 1982; Turk & Flor, 1987; Turk, Swanson, & Tunks, 2008). Spousal behavior has been shown to be a strong reinforcer. Chronic pain sufferers are more likely than controls to have spouses who are attentive to displays of pain behaviors (Romano et al., 1992). Chronic pain patients with spouses solicitous to the pain experience display a greater number of pain behaviors (Paulsen & Altmaier, 1995), report greater pain, and lower activity levels (Flor, Kerns, & Turk, 1987; Flor, Turk, & Rudy, 1989) than pain patients with spouses inattentive to pain behaviors. Romano and colleagues (1995) found depressive symptoms mediate the relationship between solicitous spouses and impaired functioning. The same study also found pain intensity mediates the relationship between solicitous spouses and the number of displayed pain behaviors. Avoidance of certain activities may occur simply because of a potential increase in pain or re-injury.

1.4 Avoidance

From psychoanalytic to cognitive-behavioral models, many psychological theories recognize the problematic nature of avoidance (Hayes, Wilson, Gifford, Follette, & Strosahl, 1996). Robustly dubbed experiential avoidance by Hayes and colleagues (1996), avoidance becomes any attempt to “alter the form or frequency” of private experiences (such as pain) as well as “the contexts that occasion them” (p. 1154). Experiential avoidance helps maintain dysfunctional processes in many disorders such as
obsessive-compulsive disorder, borderline personality disorder, and chronic pain. The process of experiential avoidance can be understood through Relational Frame Theory (RFT) (Hayes, 2004). In RFT, the thoughts and language of a person create a “relational frame” in which events become related and alter the meaning of other events. Hayes (2004) lays out the three processes of relational learning; bidirectionality (A relates to B), combinatorial entailment (if A relates to B and B relates to C, then C relates to A), and transformation of stimulus functions among related stimuli (language and cognition relate two seemingly unrelated groups of stimuli).

Experiential avoidance is a key pathological factor in RFT. During the transformation of stimulus functions process, as events that cause suffering become related to other arbitrary events humans begin to avoid these events. As avoidance behaviors increase, they too can become associated with the avoided event further strengthening the relational frame (Hayes, 2004). Most times one is unaware of the multiple transformations of stimulus functions; this is termed cognitive fusion. Experiential avoidance and cognitive fusion can help explain the development of chronic pain. As pain is experienced, it becomes associated with different movements and activities. Although avoidance behaviors (i.e. resting) may actually reduce acute pain, excessive avoidance may lead those avoidance behaviors to actually be associated with increased chronic pain, help sustain disability, and distort the pain experience in chronic pain patients.

The Fear-Avoidance Model of Chronic Pain (Lethem, Slade, Troup, & Bentley, 1983) incorporates the ideas of Fordyce and RFT to explain the disabling effect of chronic pain. In this model, chronic pain can either be confronted or avoided; those who
avoid pain can enter into a cycle where fearing pain and re-injury and avoidance behaviors perpetuate disability.

Multiple steps are at play in the Fear-Avoidance Model (Crombez et al., 1999; Vlaeyen & Linton, 2000). The fear of pain or re-injury encourages avoidance behaviors. Kazdin (as cited in Vlaeyen, Kole-Snijders, Boeren, & can Eek, 1995) defines avoidance as the “performance of a behavior which postpones or averts the presentation of an adverse event” (p. 364). In the scope of chronic pain, avoidance entails any attempt to reduce pain including but not limited to avoiding activity, treatment seeking, and taking medication (McCracken, 1998). As avoidance and pain-related fear intensifies, withdrawal from situations that reinforce well behaviors occurs. This withdrawal can further exacerbate mood disturbances (Boersma & Linton, 2006; McCracken, Zayfert, & Gross, 1992). As opportunities diminish to correct the erroneous notion that activity causes pain, avoidance becomes self-perpetuating (Crombez et al., 1999; Gatchel et al., 2007; McCracken, 1998) and the performance of pain behaviors becomes more likely (Fordyce et al., 1982). Along with the possible disabling effects of pain behaviors described previously, increased avoidance and pain related fear can lead to physical deterioration, which further promotes disability, enhances the pain experience, decreases pain tolerance (Hansen & Streltzer; McCracken, 1998; McCracken, Zayfert, & Gross, 1992; Vlaeyen & Linton, 2000), increases the likeliness of mood disturbances (McCracken, Zayfert, & Gross, 1992), and perpetuates the fear-avoidance cycle of chronic pain. All these factors make the extinction of pain behaviors and the reinforcement of well-behaviors difficult (Turk et al., 2008).
Although increased avoidance is correlated with increased fear (Boersma & Linton, 2006), neither are strongly related to pain intensity (Al-Obaidi, Nelson, Al-Awadhi, & Al-Shuwaie, 2000; Crombez et al., 1999; Vlaeyen, Kole-Snijders, Boeren, & van Eek, 1995). Higher rates of avoidance predict greater disability (Al-Obaidi et al., 2000; Crombez et al., 1999; Geisser et al., 2000; Linton, 2000; Vlaeyen, Kole-Snijders, Boeren, & von Eek, 1995), diminished physical capacity (Crombez et al., 1999; Geisser et al., 2000; Vlaeyen, Kole-Snijders, Rotteveel, Ruesink, & Heuts, 1995), and lower pain tolerance (McCracken 1998). Fear of movement or injury is a better predictor of physical functioning than pain severity or pain duration (Crombez et al., 1999; Vlaeyen, Kole-Snijders, Rotteveel, Ruesink, & Heuts, 1995). Pain related fear also aggravates pain symptoms (Vlaeyen, Kole-Snijders, Boeren, & van Eek, 1995). While both avoidance and fear are related to impaired functioning, activity avoidance has been found to be the stronger predictor (Geisser, Haig, & Theisen, 2000).

The fear-avoidance model explains the inadequacy of pain behaviors and avoidance as pain management techniques. As pain behaviors are reinforced and avoidance is used to control pain, quality of life quickly diminishes. Since there is a strong relationship between meaningful life functioning and perceived control over the effects of pain, but a weak relationship between life functioning and perceived control over actual feeling of pain (Tan, Jensen, Robinson-Whelen, Thorncy, & Monga, 2003), there is a clear need for cognitive-behavioral therapies that help the patient reframe the pain experience.
1.5 Chronic Pain Acceptance

Through the evolution of cognitive and behavioral orientations, a rise in different forms of therapies has occurred. One such therapy is Acceptance and Commitment Therapy (ACT). Based in RFT, ACT aims to rework language and cognitions that define avoidance behaviors by identifying values and supporting patients as they act in line with their values despite the presence of difficult private events (Hayes, 2004). Through exercises, exposure, and metaphors, ACT helps patients rework the context in which they think about their problems and solution sets, realize that attempts to control private events do not work, outline personal values from which actions and goals can be defined, learn cognitive defusion techniques, actively experience events in the present through acceptance, and commit to these changes (Hayes, 2004).

ACT views chronic pain as an experiential avoidance disorder and focuses on patient values and the function of behaviors (Hayes & Duckworth, 2006). In chronic pain populations, avoidance is related to lower levels of activity as well as greater disability and anxiety (McCracken & Samuel, 2007) whereas acceptance, a key component of ACT, is associated with better mood, lower levels of physical and psychosocial disability, greater globally rated daily activity, less avoidance behavior, and greater well-being (McCracken, 1998; McCracken & Eccleston, 2003; McCracken & Vowles, 2006).

In line with RFT, McCracken and Vowles (2006) define the acceptance of pain as “willingness to have uncomfortable experiences when the actions that bring about those experiences serve important purposes for the individual…It is a careful discrimination of what to control and what to leave as is based on the purposes served by these actions”
In chronic pain, acceptance involves engaging in experiences despite pain sensation or fear of pain.

Most medical models of pain treatment are aimed solely at pain reduction. When these methods of treatment are insufficient, ACT works to restore meaningful function to the life of a patient despite persistent pain. When undergoing the process of acceptance one must admit to the experience of pain, stop unproductive attempts to control pain, know that pain does not have to imply disability, and remain committed to living life with pain while pursuing meaningful life activities (McCracken, 1998; McCracken, 2004; McCracken, Vowles, & Eccleston, 2004). Acceptance based therapy has been shown to be an effective form of chronic pain treatment in improving mood, disability, physical performance, and even pain severity (McCracken, Vowles, & Eccleston, 2005; Vowles & McCracken, 2008; Wicksell, Dahl, Magnusson, & Olsson, 2005). ACT was also shown to be more effective that regular medical treatment in reducing sick days and healthcare use (Dahl, Wilson, & Nilsson, 2004).

Acceptance is not another form of coping, ignoring pain, or increasing behavioral activity for purposes of pain management (McCracken, & Eccleston, 2003; McCracken & Vowles, 2006). In fact it has been found that acceptance may have more utility than active coping methods in the adjustment to chronic pain (McCracken & Eccleston, 2003). Greater acceptance is not merely a function of lower pain levels (McCracken, 1998) and is also distinct from diverting attention from pain or reinterpreting pain (McCracken & Eccleston, 2003). Acceptance related processes reliably predict important aspects of emotional, physical, and social functioning, including health care use and work status in people with chronic pain (McCracken & Vowles, 2006).
1.6 Interdisciplinary Chronic Pain Rehabilitation Programs

Based directly in a biopsychosocial model, interdisciplinary chronic pain rehabilitation programs (ICPR) incorporate ideas from ACT, especially the role of acceptance. The effectiveness of ICPR has been thoroughly studied and repeatedly shown (Cassisi, Sypert, Salamon, & Kapel, 1989; Cutler et al., 1994; Flor, Fydrich, & Turk, 1992; Gatchel & Okifuji, 2006; Guzman et al., 2007; Hooten, Townsend, Sletten, Bruce, & Rome, 2007; Rome et al., 2004; Scheman, Janotta, Burleson, & Covington, 2006; Skouen, Grasdal, Haldorsen, & Ursin, 2002; Stanos & Houle, 2006; Turk, 2002) and such programs are considered to be among the most therapeutic and cost effective treatments available (Gatchel & Okifuji, 2006).

Since drugs only decrease pain about 30% in less than 50% of the patients (Turk, 2002), the primary concern of interdisciplinary chronic pain rehabilitation programs are functional restoration and effective self-management after leaving treatment. Functional restoration emphasizes the acceptance of pain and its fluctuations along with the return to a more productive and active lifestyle precedes the elimination of pain. Treatment focuses on modifying negative thinking particularly thoughts of helplessness and hopelessness, increasing the use of positive coping strategies, and promoting increased activity and productive functioning (Turk et al., 2008). When assessing pain and other outcomes of treatment programs, attention should be focused on physical, emotional, and social functioning and include pain intensity, disability, and physical and emotional impairment (Turk & Dworkin, 2004; Waddell & Turk, 2001).
1.7 Purpose of Study

The mentally and physically disabling nature and great expense in health care, disability benefits, and loss of productivity that comes with chronic pain, makes finding effective ways to manage the problems associated with chronic pain imperative. If the fear-avoidance model describes how pain decreases activities and promotes disability, focusing treatment on the acceptance of chronic pain may lead to better and more productive lives through improved physical functioning and decreased disability. While the usefulness of interdisciplinary chronic pain rehabilitation programs (ICPR) in reducing disability and mood disturbances has been repeatedly demonstrated, their role in changing acceptance has been the subject of little research. The purpose of this study is to look at the effectiveness of ICPR in changing acceptance and explore the impact of change in acceptance on disability and physical functioning.

Research Questions

1. Do patients who complete an interdisciplinary chronic pain rehabilitation program differ from those who drop out by demographics, pain severity, level of disability, physical functioning, or acceptance of pain?

2. Is an interdisciplinary chronic pain rehabilitation program effective in promoting acceptance of chronic pain and physical functioning while decreasing disability?

3. What is the relationship between chronic pain acceptance, pain intensity, disability, and physical functioning?

4. Will changing levels of acceptance interact with changes in disability and physical functioning independent of pain intensity?
Hypothesis

1. Completers and non-completers will not differ by demographic information, pain severity, or level of disability, physical functioning, and acceptance.

2. The interdisciplinary chronic pain program will help patients learn to accept their chronic pain, lower their perceived disability and increase their physical functioning. Admission scores of acceptance and physical function will be lower than discharge scores while admission scores of disability rating will be higher than discharge scores. Scores of pain intensity will remain relatively the same.

3. Higher ratings of acceptance and lower pain intensity scores will be related to lower ratings of disability and higher ratings of physical functioning. Acceptance and pain intensity will not be related.

4. Changes in the acceptance of chronic pain will predict changes in pain-related disability and physical functioning. As patients come to accept their chronic pain, they will perceive themselves to be less disabled and perform better on ratings of physical functioning. Acceptance will contribute more to disability and physical functioning than pain intensity.
CHAPTER II

METHODS

2.1 Participants

During the years 2006 and 2007, 487 patients were admitted into the Cleveland Clinic Chronic Pain Rehabilitation Program (CPRP). Ninety-four (19.3%) of the patients did not complete the program and were not included in the post treatment analyses. Most patients are referred to the CPRP by their local physician and suffer from chronic non-malignant pain that could not be eased by other medical or surgical methods. Patients provided informed consent at the beginning of treatment and IRB approval for the study was obtained (See Appendix A).

Demographics and pain related information were obtained throughout the CPRP and documented in a discharge summary. Of the 487 patients who were enrolled in the program, the majority were female (65.9%), married (57.5%) and disabled due to pain (71.0%). The mean age and duration of pain were 45.86 years (13.24) and 10.96 years (9.60), respectively. Primary pain complaints included lower back (35.7%), fibromyalgia (15.0%), neck (7.2%), neuropathy (7.0%), and complex regional pain syndrome (6.2%).
2.2 Measures

*The Pain Disability Index (PDI)*

The PDI (Tait, Pollard, Margolis, Duckro, & Krause, 1987) is a self-report inventory that measures subjective pain-related disability and function. It contains seven items that assess the extent which chronic pain interferes with a patient’s functioning across seven broad domains: family/home responsibility, recreation, social activity, occupation, sexual behavior, self-care, and life support activity. Individuals must select the level of overall impact pain plays in each domain. Scores on each domain range from 0 (no disability) to 10 (total disability). The total score of all seven domains (ranging from 0 –70) indicates the level of general disability. The higher the scores on this inventory, the more an individual’s pain interferes with his/her functioning.

Preliminary validity tests of the PDI showed its effectiveness in distinguishing high and low disability groups (Pollard, 1984). Tait and colleagues (1987) where able to further strengthen the measure’s validity by showing that inpatients scored significantly higher on the PDI than outpatients. The instrument’s construct validity has also been shown (Jerome & Gross, 1991; Tait, Chibnall, & Krause, 1990).

Gronblad and colleagues (1993) looked at the inter-correlations between the PDI and the Oswestry Disability Questionnaire (ODQ), a widely used reliable and valid method for assessment of disability. Correlations were high across corresponding raw score values \((r = .83)\), factor scores \((r = .84)\), and percentage scores \((r = .82)\) (Gronblad et al., 1993).

Tait and colleagues (1987) reported a two factor structure to the PDI. They found family/home responsibilities, recreation, social activity, occupation, and sexual behavior
to load on the first factor which seemingly represents voluntary or discretionary activities. The second factor includes self-care and life-support activities, representing obligatory functions that are essential for living. Although this study supports a two-factor structure, others determined that the PDI only has a one-factor structure (Chibnall & Tait, 1994; Tait, Chibnall, & Krause, 1990). Despite the possibility of a two-factor structure of the PDI, its alpha reliabilities range from 0.85 (Chibnall & Tait, 1994) to 0.87 (Tait et al., 1987, Tait et al., 1990), indicating internal consistency.

**Chronic Pain Acceptance Questionnaire (CPAQ)**

The CPAQ (McCracken, Vowles, & Eccleston, 2004) is a 20-item self-report measure designed to quantify acceptance in pain populations. Each item is rated on a 7-point Likert-type scale, 0 = never true to 6 = always true. The sum of all items, including nine reverse-scored items, indicates level of acceptance with higher scores representing greater acceptance.

The CPAQ originally contained 34 items in a four-factor structure (McCracken, 1999). This factor structure was replicated by McCracken, Vowles, & Eccleston (2004), but they also found two of the factors to have marginal reliabilities and therefore suggested a 20-item questionnaire with the two factors of activity engagement and pain willingness. The original 34-item CPAQ had a reliability coefficient of $\alpha = 0.85$ and a 24-item CPAQ showed good internal consistency with $\alpha = 0.84$ (McCracken, 1998). The total score and subscales of the final 20-item questionnaire have adequate reliability ($\alpha = 0.78-0.82$) (McCracken & Eccleston, 2006). Acceptance, as measured by the CPAQ, has been shown to be a separate construct from coping (McCracken & Eccleston, 2006) and not related to pain intensity (McCracken, 1998).
The UAB Pain Behavior Scale (UAB)

The UAB (Richards, Nepomuceno, Riles, & Suer, 1982) is used to measure the frequency of pain behaviors. The scale consists of 10 items rated on frequency of occurrence. Each item is rated as 0, ½, or 1 allowing for a range of scores from 0-10. Trained observers rate a patient on the frequency or intensity of verbal and non-verbal vocal complaints, length of down-time, facial grimaces, standing posture, mobility, body language, use of visible supportive equipment, stationary movement, and medication. Richards et al. (1982) demonstrated satisfactory inter rater reliability (0.95, P<0.01), test-retest reliability (0.89, P<0.01), and temporal stability. They also were able to demonstrate the ease and efficiency in using this measure with little training. The UAB has good inter-rater reliability and a significant correlation with self-reported disability (Tait, 1999). However, it does not appear to be related to reports of pain intensity (Richards et al., 1982).

Numerical Rating Scale (NRS)

A NRS was used to measure pain intensity. This is a ratio scale measurement on which the patients are asked to rate their current level of pain from 0 to 10. A score of 0 indicates no pain and a score of 10 indicates the worst possible pain you could imagine. Not only is this easy and quick to administer, but also allows for comparisons of different levels of pain and the calculation of percent change in intensity (Gramling & Elliott, 1992).

Six-Minute Treadmill Test

A six-minute treadmill test was used as an objective performance measure of disability and restoration of function. This variable was picked because it assesses a
patient’s ability to perform an important everyday activity. The treadmill test was performed within a series of exercises during admission and discharge physical therapy sessions. Harding et al. (1994) found a timed walk test to have excellent inter-rater and test-retest reliability (0.994 and 0.944 respectively). They also found that 5-minute and 10-minute walk times where highly correlated ($r=0.985$).

2.3 Procedures

The CPRP is an interdisciplinary, 3-4 week outpatient program designed to reduce pain and suffering, optimize functioning, reduce physical and psychological dependence, promote social and vocational reintegration, eliminate inappropriate sick role behaviors, eliminate unnecessary or habituating medication, including opioids and benzodiazepines, and restore productivity. These goals correspond with the aims of other interdisciplinary programs (Gatchel & Okifuji, 2006; Stanos & Houle, 2006). During the CPRP, patients may participate in some or all of the following treatments: pharmacological, physical, and occupational therapy; individualized case management services; psychophysiological training (biofeedback); behavior modification; weaning of opioids and sedatives when appropriate; chemical dependency assessment; individual and group psychotherapy; coping skills training; family therapy and education; vocational assessment and work reconditioning; education about the causes of pain and methods of coping with pain; and dietary consultations as needed.

All data were collected as part of treatment evaluation. Self-report measures were completed at admission and discharge as part of a battery of questionnaires. The treadmill and UAB data were obtained as part of the regular physical therapy sessions.
2.4 Data Analysis

The Statistical Program for Social Sciences was used to analyze the data. A $p \leq 0.05$ was used in all analysis. To compare patients who completed the CPRP with non-completers, ANOVAs were used for continuous variables and chi-square analyses were used for categorical variables. To determine the effectiveness of the CPRP to improve pain, disability, physical functioning, and acceptance admission and discharge scores were compared with repeated-measure $t$-Tests. Correlation and regression analyses were used to assess the relationship between acceptance and disability and physical functioning. Change scores of outcome variables were obtained by subtracting discharge scores from admission scores.
CHAPTER III
RESULTS

3.1 Hypothesis 1

The first hypothesis predicted that program completers would not differ from program non-completers in demographic data, pain severity, level of disability, physical functioning, and acceptance of pain. To test this hypothesis completers and non-completers were compared by gender, work status, marital status, and primary complaint using chi-square analyses (see Table 1). Patients who completed the interdisciplinary chronic pain rehabilitation program (CPRP) did not differ significantly from non-completers on gender or work status. Significantly more patients who completed the CPRP were married while significantly more non-completers were single [$\chi^2(1) = 7.04, p < .01$]. A 2x7 chi-square indicated an association between program completion and primary complaint [$\chi^2(6) = 14.01, p < .05$]. A higher percentage of completers had back pain, headache, or neck pain whereas more non-completers had fibromyalgia, neuropathic pain, CRPS, or other primary complaints.

Independent sample t-tests were utilized to test whether program completers differed from non-completers in age, duration of pain, hours rest, or admission outcome scores (see Table 1). Program completers were significantly older than non-completers.
Table 1.  
Differences between Program Completers and Non-Completers

<table>
<thead>
<tr>
<th></th>
<th>Non-Completers</th>
<th>Program Completers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (% Female)</td>
<td>66.3%</td>
<td>65.8%</td>
</tr>
<tr>
<td>Work Status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unemployed/Disabled</td>
<td>77.7%</td>
<td>70.8%</td>
</tr>
<tr>
<td>Working/Student</td>
<td>16.0%</td>
<td>18.9%</td>
</tr>
<tr>
<td>Retired/Homemaker</td>
<td>6.4%</td>
<td>10.2%</td>
</tr>
<tr>
<td>Marital Status (% Married)**</td>
<td>48.4%</td>
<td>63.3%</td>
</tr>
<tr>
<td>Primary Complaint (%)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Back Pain</td>
<td>28.4%</td>
<td>37.5%</td>
</tr>
<tr>
<td>Fibromyalgia</td>
<td>18.9%</td>
<td>14.0%</td>
</tr>
<tr>
<td>Headache</td>
<td>2.1%</td>
<td>9.2%</td>
</tr>
<tr>
<td>Neck</td>
<td>5.3%</td>
<td>7.7%</td>
</tr>
<tr>
<td>Neuropathic Pain</td>
<td>8.4%</td>
<td>6.6%</td>
</tr>
<tr>
<td>CRPS</td>
<td>10.5%</td>
<td>5.1%</td>
</tr>
<tr>
<td>Other</td>
<td>26.3%</td>
<td>19.9%</td>
</tr>
<tr>
<td>Mean Age in Years (SD)*</td>
<td>43.02 (11.88)</td>
<td>46.55 (13.47)</td>
</tr>
<tr>
<td>Mean Pain Duration in Years(SD)</td>
<td>10.14 (9.64)</td>
<td>11.16 (9.59)</td>
</tr>
<tr>
<td>Hours of Rest</td>
<td>16.72 (5.52)</td>
<td>16.63 (4.81)</td>
</tr>
<tr>
<td>Mean Admission Acceptance (SD)</td>
<td>44.54 (18.95)</td>
<td>42.69 (17.14)</td>
</tr>
<tr>
<td>Mean Admission Pain Severity (SD)</td>
<td>7.26 (2.03)</td>
<td>6.95 (3.41)</td>
</tr>
<tr>
<td>Mean Admission Disability (SD)</td>
<td>45.82 (11.82)</td>
<td>45.15 (12.10)</td>
</tr>
<tr>
<td>Mean Admission Pain Behaviors (SD)</td>
<td>5.43 (2.05)</td>
<td>5.07 (2.00)</td>
</tr>
<tr>
<td>Mean Admission Physical Function (SD)</td>
<td>.16 (.09)</td>
<td>.21 (.66)</td>
</tr>
</tbody>
</table>

*p ≤ .05  
**p ≤ .01  

Note. Acceptance was measured with the Chronic Pain Acceptance Questionnaire, pain severity with a 0-10 numerical rating scale, disability with the Pain Disability Index, pain behaviors with the UAB Pain Behavior Scale, and physical function with the 6 minute treadmill test.
There were no significant differences in the two groups for duration of pain, hours rest, and level of admission acceptance, pain severity, self-rated disability, pain behaviors, or physical functioning.

3.2 Hypothesis 2

The second hypothesis predicted that scores of pain intensity, chronic pain acceptance, disability and physical function would improve from admission to discharge. For patients who completed the CPRP, a series of paired sample t-tests were employed to determine if pre-treatment scores of acceptance and physical functioning were significantly lower than post-treatment scores and pre-treatment scores of pain severity, disability, and pain behaviors were significantly higher than post-treatment scores. Repeated measure analyses are displayed in Table 2. All measures showed significant change in the predicted direction. Significant decreases in pain intensity \[ t(357) = 18.57, p < .001 \], pain behaviors \[ t(278) = 30.09, p < .001 \], and self-rated disability \[ t(385) = 32.07, p < .001 \] occurred from pre-treatment to post-treatment as well as significant increases in acceptance \[ t(235) = -22.33, p < .001 \] and physical functioning \[ t(269) = -2.03, p < .05 \].

Table 2.

<table>
<thead>
<tr>
<th>Outcome Variable</th>
<th>Mean Pre-Treatment (SD)</th>
<th>Mean Post-Treatment (SD)</th>
<th>Mean Change in Score Pre-Treatment – Post-Treatment (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acceptance**</td>
<td>43.01 (16.48)</td>
<td>73.34 (16.90)</td>
<td>-30.33 (20.86)</td>
</tr>
<tr>
<td>Pain Severity**</td>
<td>6.94 (3.44)</td>
<td>3.69 (3.58)</td>
<td>3.25 (3.31)</td>
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<td>Disability**</td>
<td>45.11 (12.12)</td>
<td>18.82 (14.17)</td>
<td>26.29 (16.11)</td>
</tr>
<tr>
<td>Pain Behaviors*</td>
<td>5.04 (1.95)</td>
<td>1.57 (1.23)</td>
<td>3.47 (1.92)</td>
</tr>
<tr>
<td>Physical Function*</td>
<td>0.17 (0.16)</td>
<td>0.25 (0.65)</td>
<td>-0.08 (0.63)</td>
</tr>
</tbody>
</table>

* \[ p \leq .05 \]
** \[ p \leq .01 \]
3.3 Hypothesis 3

The third hypothesis predicted that acceptance would be negatively correlated with disability and positively correlated with physical function while pain intensity would be positively correlated with disability and negatively correlated with physical function. To test this hypothesis, Pearson correlations were performed for all admission, discharge, and change scores; the matrices are presented in Table 3.

Correlations between Admission Scores

While greater acceptance and less pain severity were both significantly correlated with lower self-rated disability ($r = -.30, p < .01, N = 293$ and $r = .20, p < .01, N = 366$ respectively), acceptance had a slightly stronger association. Ratings of pain behaviors were correlated with pain intensity ($r = .18, p < .01, N = 352$) but not acceptance. Finally, neither acceptance nor pain intensity were correlated with physical functioning.

Correlations between Discharge Scores

Acceptance had significant negative correlations with pain intensity ($r = -.26, p < .01, N = 300$), self-rated disability ($r = -.46, p < .01, N = 303$), and pain behaviors ($r = -.17, p < .05, N = 219$). At discharge, higher scores of acceptances were associated with lower pain intensity, lower self-rated disability, and less observed pain behaviors. Pain intensity had significant positive correlations with self-rated disability ($r = .48, p < .01, N = 381$) and pain behaviors ($r = .26, p < .01, N = 278$). Lower pain intensity was associated with lower self-rated disability and less observed pain behaviors. Neither acceptance nor pain intensity were correlated with physical performance.
Table 3:

Correlation Matrix

<table>
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<tr>
<th></th>
<th>Admission</th>
<th></th>
<th></th>
<th></th>
<th>Discharge</th>
<th></th>
<th></th>
<th></th>
<th>Change</th>
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<tr>
<td>Pain Severity (PS)</td>
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<td>.20**</td>
<td>.18**</td>
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<td>.28**</td>
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<td>.02</td>
<td>-.01</td>
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<tr>
<td>Acceptance (AC)</td>
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<td>.04</td>
<td>-.18**</td>
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<td>.03</td>
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</table>

*p ≤ .05  
**p ≤ .01
**Correlations between Change Scores**

Change in acceptance was negatively correlated with change in disability ($r = -.43, p < .01, N = 236$) and change in pain behaviors ($r = -.19, p < .05, N = 171$). Patients who showed greater increases in acceptance also showed greater decreases in disability and observed pain behaviors. Change in pain intensity was positively correlated with change in disability ($r = .36, p < .01, N = 356$) and change in pain behaviors ($r = .15, p < .05, N = 263$). This indicates that greater decreases in reported pain intensity are associated with greater decreases in disability and observed pain behaviors. Change in acceptance and change in pain intensity were not associated with change in physical function. Change in acceptance was not correlated with change in pain intensity.

**Correlations between Change and Discharge Scores**

Change in acceptance had a significant negative association with discharge acceptance scores ($r = -.64, p < .01, N = 236$) and a significant positive association with discharge pain intensity ($r = .20, p < .01, N = 235$), self-rated disability ($r = .35, p < .01, N = 236$), and observed pain behaviors ($r = .19, p < .05, N = 171$). This demonstrates that patients who show greater improvements in acceptance rate themselves as more accepting of their pain, experience less severe pain, are less disabled, and display fewer pain behaviors while those who show only a little change in chronic pain acceptance rate themselves as less accepting of their pain, experience greater pain intensity, are more disabled, and display more pain behaviors. Change in pain intensity had significant negative correlations with discharge scores of pain intensity ($r = -.41, p < .01, N = 358$) and self-rated disability ($r = -.34, p < .01, N = 356$). This indicates that participants who demonstrate greater pain intensity decrease during treatment have lower ratings of pain.
intensity and self-reported disability at discharge than those whose pain intensity decreases less. Change in pain intensity was not correlated with discharge acceptance scores.

3.4 Hypothesis 4

The fourth hypothesis predicted acceptance would contribute more to disability and physical functioning than pain intensity. A series of hierarchical multiple linear regressions were conducted to examine the degree to which chronic pain acceptance and pain intensity contributed to subjective disability, the display of pain behaviors, and physical functioning. A sequential entry approach was used to examine the overlapping variance between acceptance and pain intensity. In the first set of regressions, pain intensity was entered in the first step and acceptance in the second step. In the second set of regressions, the order was reversed with acceptance entered in the first step and pain intensity in the second step. For both sets, regressions examining admission, discharge, and change scores were performed. Only one set for each dependant variable is presented. For the models in which pain contributed more to the dependant variable, only the first set is reported. For the models in which acceptance contributed more to the dependant variable, only the second set is reported.

Hierarchical Multiple Regression Analysis for Admission Scores

The hierarchical multiple regression summaries for predicting admission disability, pain behaviors, and physical functioning scores are presented in Table 4. While both acceptance and pain intensity significantly contributed to the predication of self-rated pain related disability, acceptance accounted for 8.8% of the variance
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<th>$df_1$</th>
<th>$df_2$</th>
<th>$\beta$</th>
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<td>.78</td>
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</table>

* $p \leq .05$

** $p \leq .01$
[\( F(1, 73) = 26.4, p < .01 \)] and pain intensity accounted for 3.4% \([F(1, 272) = 10.4, p < .01]\). While acceptance did not significantly contribute to the prediction of pain behaviors, pain intensity accounted for 3.3% of the variance \([F(1, 279) = 9.31, p < .01]\). Neither pain intensity nor acceptance significantly contributed to the variance of physical functioning.

**Hierarchical Multiple Regression Analysis for Discharge Scores**

The hierarchical multiple regression summaries for predicting discharge disability and physical functioning scores are presented in Table 5. Again both pain intensity and acceptance contributed significantly to the variance of self-rated disability; pain intensity accounted for 22.7% of the variance \([F(1, 298) = 87.32, p < .01]\) and acceptance 12.4% \([F(1, 277) = 56.87, p < .01]\). Pain intensity was the only significant predictor of discharge pain behaviors, accounting for 6.6% of the variance \([F(1, 217) = 15.23, p < .01]\). Neither pain intensity nor acceptance significantly contributed to the variance of physical functioning.

**Hierarchical Multiple Regression Analysis for Change Scores**

The hierarchical multiple regression summaries for predicting change in disability and physical functioning are presented in Table 6. Both change in acceptance and change in pain intensity contributed significantly to the prediction of self-rated disability; acceptance accounted for 18.9% of the variance \([F(1, 217) = 50.44, p < .01]\) and pain intensity accounted for 9.7% of the variance \([F(1, 216) = 29.16, p < .01]\). Change in acceptance was the only significant predictor of change in pain behaviors, accounting for 3.8% of the variance \([F(1, 169) = 6.63, p < .05]\). Neither acceptance nor pain intensity significantly contributed to the variance of physical functioning.
Table 5.
Linear Regression Analyses Predicting Discharge Disability, Pain Behaviors, and Physical Functioning

<table>
<thead>
<tr>
<th></th>
<th>R</th>
<th>R²</th>
<th>R²adj</th>
<th>ΔR²</th>
<th>Fchg</th>
<th>df₁</th>
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<td>.066</td>
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<td>226</td>
<td>-.029</td>
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</table>

* p ≤ .05
** p ≤ .01

Table 6.
Linear Regression Analyses Predicting Change in Disability, Pain Behaviors, and Physical Functioning

<table>
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<tr>
<th></th>
<th>R</th>
<th>R²</th>
<th>R²adj</th>
<th>ΔR²</th>
<th>Fchg</th>
<th>df₁</th>
<th>df₂</th>
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* p ≤ .05
** p ≤ .01
Hierarchical Multiple Regression Analysis predicting Discharge Scores from Change Scores

Table 7 illustrates results of the hierarchical multiple regression for predicting discharge scores of disability and physical functioning from changes in acceptance and pain intensity. Both changes in acceptance and changes in pain intensity contributed significantly to self-report disability discharge scores. Change in acceptance accounted for 12.4% of the variance \( F(1, 217) = 30.77, p < .01 \) while change in pain intensity accounted for 4.4% of the variance \( F(1, 216) = 11.31, p < .01 \). Change in acceptance was the only significant predictor of discharge pain behaviors, contributing 3.2% of the variance \( F(1, 158) = 5.30, p < .05 \). Neither change in acceptance nor change in pain intensity contributed significantly to discharge physical functioning.

3.5 Further Analyses

Since change in acceptance related most strongly to scores of disability, correlations and regressions were conducted for participants with the lowest admission acceptance scores. Of the patients who completed the CPRP, 50.9% scored less than or equal to 42 points out of a possible 120 points on their admission CPAQ. Analyses were rerun for these participants to control for ceiling effects of CPAQ. Mean admission, discharge, and change scores for this population are presented in Table 8. This subgroup showed no significant improvement in physical functioning and so this variable was excluded from analyses. Participants who scored low on admission acceptance showed significantly more improvement in change in acceptance, change in pain, and change in self-rated disability than participants who scored high on admission acceptance. At admissions, the means of the low scorers (30.17) and the high scorers (56.12)
Table 7.
*Linear Regression Analyses Predicting Discharge Disability, Pain Behaviors, and Physical Functioning from Change in Acceptance and Pain Severity*

<table>
<thead>
<tr>
<th></th>
<th>R</th>
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<th>ΔR²</th>
<th>Fchg</th>
<th>df₁</th>
<th>df₂</th>
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* p ≤ .05
** p ≤ .01
Table 8.
Change in Outcome Variables from Pre-Treatment to Post-Treatment in Low Acceptance Participants Compared to High Acceptance Participants

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<th></th>
<th>Mean Pre-Treatment (SD)</th>
<th>Mean Post-Treatment (SD)</th>
<th>Mean Change Score (SD)</th>
<th>With-in Low Scorers $t$</th>
<th>Mean (SD) Change Score for High Admission Acceptance</th>
<th>Mean Difference (SD) in Change Scores</th>
<th>Between Groups $t$</th>
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<td>-19.60 (17.63)</td>
<td>-21.64 (2.33)</td>
<td>-9.31**</td>
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<td>Pain Severity</td>
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<td>3.66 (3.36)</td>
<td>3.75 (3.76)</td>
<td>11.54**</td>
<td>2.93 (2.78)</td>
<td>.82 (.40)</td>
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<td>23.81 (15.14)</td>
<td>5.73 (1.82)</td>
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<td>1.58 (1.15)</td>
<td>3.66 (1.91)</td>
<td>20.28**</td>
<td>3.26 (1.61)</td>
<td>.40 (.25)</td>
<td>.16</td>
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<td>.21 (.98)</td>
<td>-.04 (.98)</td>
<td>-.46</td>
<td>-.11 (.16)</td>
<td>.17 (.15)</td>
<td>.04</td>
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*p ≤ .05
** $p ≤ .01$
significantly differed \[ t(259) = -19.01, p < .01 \] while at discharge the means (71.41 and 75.24, respectively) did not significantly differ \[ t(234) = -1.75, \text{ns} \].

Table 9 presents the correlation matrix for admission, discharge, and change scores for participants scoring low on admission acceptance. A stronger relationship between change in acceptance and discharge self-reported disability \[ r = .50, p < .01, N = 117 \] as well as change in self-reported disability \[ r = -.42, p < .01, N = 117 \] is apparent when compared to the correlation matrix presented in Table 3. This indicates that increasing chronic pain acceptance is related to lower self-reported disability.

Table 9. 
Correlation Matrices of Low Acceptance Participants

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<th>DIS</th>
<th>PB</th>
<th>ACC</th>
<th>PS</th>
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*p \leq .05  
**p \leq .01

The hierarchal multiple regression analyses are presented on Table 10 through Table 13. At admission pain intensity significantly contributed to 3.2% of the variance in self-reported disability. This was only significant finding for the admission data (Table 10). As shown in Table 11, discharge acceptance scores significantly account for 35.3% of the variance in discharge self-report disability while pain intensity significantly accounts for 4.8% of the variance. Table 12 summarizes the multiple regressions for the change scores. Change in acceptance significantly accounts for 17.6% of the variance in
change of self-reported disability, while change in pain intensity significantly accounts for 6.1% of the variance. Table 13 presents the multiple regressions predicting discharge scores from change scores. Change in acceptance significantly accounts for 27.4% of the variance in discharge scores of self-reported disability while change in pain intensity significantly accounts for 4.0% of the variance.
Table 10.
Linear Regression Analyses predicting Admission Disability and Pain Behaviors in Low Acceptance Participants

<table>
<thead>
<tr>
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<th>$R$</th>
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<td>.032</td>
<td>.039</td>
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<td>.015</td>
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<td>.015</td>
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<td>.011</td>
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<td>-1.22</td>
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* $p \leq .05$
** $p \leq .01$

Table 11.
Linear Regression Analyses predicting Discharge Disability and Pain Behaviors in Low Acceptance Participants

<table>
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<td>.093</td>
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* $p \leq .05$
** $p \leq .01$
### Table 12.
**Linear Regression Analyses Predicting Change in Disability and Pain Behaviors in Low Acceptance Participants**

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<td>.092</td>
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* $p \leq .05$
* * $p \leq .01$

### Table 13.
**Linear Regression Analyses Predicting Discharge Disability and Pain Behaviors from Change in Acceptance and Pain Severity in Low Acceptance Participants**

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<td>.274</td>
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* $p \leq .05$
* * $p \leq .01$
CHAPTER IV
DISCUSSION

The first part of this study examined the differences between patients who completed an interdisciplinary chronic pain rehabilitation program and those who dropped out early. The two groups did not differ by gender, work status, duration of pain, hours of rest, or admission levels of pain acceptance, pain intensity, subjective pain related disability, observed pain behaviors, or physical functioning. Patients who completed the program were more likely to be married and were on average 3.53 years older than non-completers. Although solicitious spouses reinforce pain behaviors, family and social support can play a pivotal role in encouraging chronic pain patients to maintain program participation.

To determine the effectiveness of an interdisciplinary chronic pain rehabilitation program in promoting chronic pain acceptance and physical functioning while decreasing disability, the admission scores of program completers were compared with discharge scores. Study participants significantly improved across all outcome variables. On average, study participants saw a 70.5% increase in pain acceptance, a 46.8% decrease in pain intensity, a 58.3% decrease in self-rated disability, a 68.8% in decrease in pain behaviors, and a 47.1% increase in physical functioning at discharge. These results are in
line with other studies demonstrating the improvement of chronic pain patients in interdisciplinary programs (Hooten et al., 2007; Gatchel & Okifuji, 2006; Scheman et al., 2006).

While research focusing on acceptance based therapies has shown changes in acceptance to be related to improvements in disability and physical functioning (McCracken, Vowles, & Eccleston, 2005; Cowles & McCracken, 2008; Wicksell et al., 2005), this study emphasizes a multidisciplinary treatment approach. The final goal of this study was to examine the relationship of acceptance and pain intensity with disability and physical functioning. The data support a relationship between acceptance and lower levels of disability at admission and discharge. A relationship between acceptance and fewer pain behaviors was only apparent after treatment. Increasing acceptance was related to decreasing both subjective disability and the number of observed pain behaviors. The data also supported that higher levels of pain intensity correlate with greater subjective disability and more observed pain behaviors. Decreased pain intensity was related to decreased subjective disability and fewer observed pain behaviors.

Interestingly, acceptance and pain intensity were not related to physical functioning. Physical functioning was weakly associated with subjective disability and pain behaviors. Although these findings are in line with other reports, some studies suggest a significant relationship between acceptance and physical functioning (Geisser et al., 200; Vlaeyen, Kole-Snijders, Boeren, & von Eek, 1995) as well as pain intensity and physical functioning (McCracken et al., 2002; Turk et al., 1996; Bryant et al., 2007).

Supporting McCracken (1998), these analyses indicate that acceptance is not merely a function of lower pain levels. Although acceptance was weakly related to lower
pain intensity at discharge, no relationship was apparent at admission. Also, change in acceptance was not related to change in pain intensity. Of most importance, the increase in acceptance that resulted from treatment related to lower discharge pain intensity scores whereas the decrease in pain intensity that resulted from treatment did not relate to discharge acceptance scores.

To further examine the relationship of acceptance and pain intensity with disability and physical function, regression analyses were performed. It was hypothesized that acceptance would account for greater variance in disability and physical functioning than pain intensity. At admission and discharge, pain acceptance accounted for significant unique variance in subjective disability but not the number of observed pain behaviors. Changes in acceptance during treatment accounted for significant unique variance in discharge subjective disability and discharge pain behaviors as well as changes in subjective disability and changes in pain behaviors during treatment. At admission and discharge, pain intensity accounted for significant unique variance in subjective disability as well as pain behaviors. Changes in pain intensity during treatment accounted for significant unique variance in discharge subjective disability and changes in subjective disability during treatment. Changes in pain intensity did not contribute to pain behaviors. Neither acceptance nor pain intensity significantly predicted physical functioning. That acceptance and pain intensity contribute more to self-report disability and pain behaviors at discharge than admission maybe a result of learning about pain acceptance. While both pain intensity and pain acceptance contributed to disability, acceptance generally contributed more than pain intensity except for discharge scores. These results support the importance of chronic pain
acceptance in the context of multidisciplinary pain rehabilitation programs and in improving subjective disability ratings.

Considering changes in acceptance during treatment contributed greatly to discharge and change scores of subjective disability and pain behaviors, concern about the ceiling effect of the Chronic Pain Acceptance Questionnaire became apparent. To control for the ceiling effect, additional analyses concentrating on the lowest CPAQ scoring participants were performed. Due to insignificant findings, physical functioning was excluded. Comparing the change scores of low admission CPAQ scores to high admission CPAQ scores, the groups significantly differed by change in acceptance, pain intensity, and subjective disability with lower CPAQ scorers showing greater improvements. There was no significant difference between the groups in change in pain behaviors or physical functioning. These results imply that patients entering an interdisciplinary chronic pain rehabilitation program, who are less accepting and more avoidant of their pain, improve more than those who are more accepting and less avoidant of their pain. This may be a function of the ceiling effect of the measures or a function of changing acceptance.

Examining the relationships between acceptance and pain intensity with subjective disability and pain behaviors, change in acceptance is more strongly related to discharge subjective disability and change in subjective disability than change in pain intensity. The more accepting a patient becomes during therapy, the less disabled they will rate themselves. In fact, change in acceptance accounts for 27.4% of the variance in discharge disability scores and 17.6% of the variance in change in disability scores while
pain intensity contributes 4.0% of the variance in discharge disability scores and 6.1% of the variance in change in disability scores.

Previous studies on chronic pain acceptance focused mainly on interdisciplinary contextual cognitive behavior therapies (Vowles & McCracken, 2008; Vowles, McCracken, & Eccleston, 2007) and came mainly from the same sources. Results indicate that although interdisciplinary pain rehabilitation programs do not concentrate solely on avoidance behaviors and acceptance, they do significantly improve the patients’ acceptance of chronic pain. Results indicate that learning to accept pain may decrease subjective disability more so than concentrating on lowering pain intensity. Of special interest, those entering an interdisciplinary pain rehabilitation program with lower acceptance had the most to gain from therapy.

There is a lack of previous research on the impact of changing acceptance. While most research examined the usefulness of different therapies in changing acceptance or pain intensity (Paez-Blarrina et al., 2008; Vowles & McCracken, 2008), only Vowles et al. (2007) examined the impact of changing acceptance on disability. Compared to Vowles et al., the current study was able to account for more variance in disability and physical functioning with acceptance and pain intensity.

There are several limitations to this study. One limitation is the use of retrospective correlation data analyses; significant correlations, no matter how strong, do not imply causation and unexamined confounding variables may exist. Correlation analyses only imply a relationship exists between the two variables. Furthermore, the intensive nature of the treatment lends this study to sampling bias and problems with the generalizability. The sample may be highly motivated to learn to accept their pain as
many participants have been through various treatments that did not assuage their pain. The tertiary care setting of this study may add to the sampling bias. Patients must be referred and if insurance does not cover care, must pay for all the expenses. Besides restrictions in demographic and socioeconomic status, generalizability is also limited as the use of change scores of the outcomes excludes patients who resisted treatment. Additionally, there are limitations due to the reliance on self report measures. Besides the occurrence of missing data, self report questionnaires lend themselves to errors in patient interpretation. Also, the short test-retest time and face validity of the measures may contribute to patients answering in a socially desirable way or malingering.
REFERENCES


APPENDIX
Cleveland State University

Institutional Review Board for Human Subjects in Research
Application for Project Review

I. Title Page
Date (mm/dd/yyyy): 09/30/2008  
Transaction Number (office use only): 38353-RAk-H5

Project Title: The role of chronic pain acceptance in disability

PRINCIPAL INVESTIGATOR OR ADVISOR
Name: (Last, First): Rakos, Richard  
Title: Professor
Department: Psychology  
Campus Address: CB156
Electronic Mail Address: R.RAKOS@csuohio.edu
Office Phone: (216) 687-5320  
Home Phone: (216) 991-6697
Has the investigator completed the CITI course in the protection of human subjects? Yes

CO-PRINCIPAL OR STUDENT INVESTIGATOR
Name: (Last, First): Ferguson, Lisa  
Title: Student
Department: Psychology
Electronic Mail Address: LMKL123@yahoo.com
Office Phone: ( )  
Home Phone: (216) 227-8992
Has the investigator completed the CITI course in the protection of human subjects? Yes

If this is a student investigator, please indicate status:
Undergraduate  
Master level student  
Doctoral level student

and level of involvement in the research:
Assisting Faculty Research  
Thesis  
Dissertation  
Classroom project: Class name/number

ADDITIONAL INVESTIGATORS?  Yes  No  (If yes, please complete the "Additional CSU Investigators" form.)

PROPOSED PROJECT DURATION (research may not begin prior to IRB approval):
From (mm/dd/yyyy): 10/01/2008  
To (mm/dd/yyyy): 10/01/2009 (date following anticipated approval; maximum one year later)

Please be aware that data collected prior to approval or outside of authorized dates may not be used. If your study (i.e. collection of data) will extend beyond the one year authorization, it is your responsibility to notify the IRB prior to expiration and request an extension.

***Type of funding or support: None

FOR IRB USE ONLY

Initial Evaluation

☐ Approve as is
☐ Requires Revision before evaluation or final action
☐ Full IRB review required

Final IRB Action

☐ Exempt Status: Project is exempt under 45 CFR 46.101
☐ Expedited Review: Approval Category
☐ Regular IRB approval
☐ Other:

Reviewer:  
Signature:  
Approval Date:  

Cleveland State University Office of Sponsored Programs and Research IRB
Form updated 11/30/2007
All other forms are obsolete
dpo
Institutional Review Board  
Human Subjects in Research  
Instructions and Checklist for Applicants

The Institutional Review Board (IRB) of Cleveland State University (CSU) is responsible for ensuring the protection and ethical treatment of human participants in research conducted under the auspices of the University. Accordingly, the IRB must evaluate all such research projects, in compliance with Federal Regulations. Your application to the IRB for permission to test human subjects should follow the guidelines provided below. Proposed Departures from the guidelines should be justified thoroughly.

Some protocols may be approved through one of the expedited or exempt categories in the Federal Regulations, and some require full Committee consideration. These determinations are made by the IRB, not by the researcher. If your protocol requires full Committee consideration, the University Office of Sponsored Programs and Research must receive it no later than two (2) full weeks prior to the IRB meeting; this meeting normally occurs during the first week of the month. Protocols should be submitted to the IRB, Office of Sponsored Programs and Research, 2258 Euclid Avenue, Hannifin Hall, Cleveland, OH 44115-2440 ATTN: IRB Coordinator.

Issues of Particular Concern to the IRB

- **Privacy:** In most research, subjects’ willingness to participate will depend on the researcher’s explanation of the project and its purpose, the subject’s understanding of risks and benefits, and the assurance that the specifics of their participation will not become known to other individuals. A mismatch between your assurance to the subjects and the procedures you explain in your Project Description will lead the IRB to request revisions before approval can be granted. Issues of anonymity and confidentiality are of special concern when subjects might divulge sensitive information, including situations in which their responses might place them in jeopardy (e.g., public embarrassment, threats to job security, self-incrimination). The care with which you address these issues in your procedures is very important to the IRB approval process.

- **Risk:** In much research, subjects’ participation involves little or no risk. If this is genuinely the case, say so; e.g., “minimal risk,” “no foreseeable risk,” “no risks beyond those of daily living.” If there is some risk, where physical, psychological, social, legal, or otherwise, the IRB will be particularly interested in the safeguards you implement to deal with these risks. The overall importance and soundness of the research project will be especially important if subjects are placed at some degree of risk by participating.

- **Special Populations:** Testing minors, pregnant women, prisoners, mentally retarded or disabled persons, or other special populations raises serious issues regarding risk and informed consent, which your protocol must address. On the other hand, recent federal guidelines mandate the inclusion of women and minorities in research. The nature of your subject population must be clear in your proposal, and you must provide your rationale for including/excluding identifiable subgroups based on gender and minority status.

- **IRB Procedures:** CSU’s IRB receives approximately 300 applications a year, each of which must be evaluated for adequate protection of the subjects against research risks. You will enhance the acceptability of your proposal, and the speed with which the IRB can evaluate it, if your protocol is concise, deals specifically with the issues discussed in these instructions, and shows your sensitivity to the overriding concerns of ethical treatment of human subjects. Please feel free to suggest any modifications or elaboration to these instructions that would be helpful to you as you write or revise your applications.
II. Participant Information

Total number of participants: **500**
Age range (lower limit – upper limit): **14-92**
Gender: **Both**
Ethnic Minority: **Multiracial**
Inclusionary criteria: *Any patient admitted into the Cleveland Clinic Chronic Pain Rehabilitation Program during 2006 and 2007*
Exclusionary criteria: **none**
Source of participants: **The Cleveland Clinic Chronic Pain Rehabilitation Program**

Is the data going to be extracted from records that already exist on these participants (e.g. school records, grade transcripts, medical records, etc.)?

☐ Yes ☐ No

If yes, will the data be recorded in a way that prevents subjects from being identified?

☐ Yes ☐ No

Length of participation (x time/session, y sessions, over z months): **Patients are typically in the program 3.5 weeks, 5 days a week, 8 hours a day**

Participants in Special Consideration Categories: (Check all that apply.)

☐ None ☐ Military personnel
☒ Children (age range: **14-18** ☐ Wards of the State
☐ Cognitively impaired persons ☐ Institutionalized individuals
☐ Prisoners ☐ Non-English speaking individuals
☐ Pregnant or lactating women ☐ Students
☐ Blind individuals ☐ Other subjects whose life circumstances may interfere with their ability to make free choice in consenting to take part in research (please specify): 

Site(s) of data collection: **Cleveland Clinic**
Letters of approval from project site officials: **are included in this submission.**

*You **MUST** include letters of approval from appropriate administrative officials at the facility where you will be collecting data.

III. Project Description

a. Give a concise statement of the area of research and briefly describe the purpose and objectives of your proposed research:

*The purpose of this study is to look at the effectiveness of a chronic pain rehabilitation program in changing pain acceptance and exploring the impact of change in acceptance on disability and physical functioning.*

b. Provide a detailed description of how participants will be recruited and used in the project. Please include a description of the tasks subjects will be performing, the circumstances of testing, and/or the nature of the subjects’ involvement.

*The data used for this study will be archival. All participants are patients at the Cleveland Clinic Chronic Pain Rehabilitation Program and all data was collected during the course of treatment. Data are obtained from patient evaluations, self-report measures, and follow-up phone interviews or mailed questionnaires.*

Cleveland State University Office of Sponsored Programs and Research IRB
Form updated 11/30/2007
All other forms are obsolete
dpo
c. Make an explicit statement concerning the possible risks and benefits associated with participating in the research. Describe the nature and likelihood of possible risks (e.g., physical, psychological, social) as a result of participation in the research. Risks include even mild discomforts or inconveniences, as well as potential for disclosure of sensitive information. If a risk exists, how does it compare to those of daily living? What are your safeguards for avoiding risks, for protecting subjects' privacy, etc.?

The research involves no more than minimal (if any) risk to the participant. All data were collected as part of the standard course of treatment.

d. Describe measures to be taken to protect subjects from possible risks or discomforts.

Patients are not identifiable from database. Any sub-investigator has to have permission from the CCF's principle investigator and must complete human subjects training unit on Research-Based Ethics.

e. Describe precautions to ensure the privacy of subjects and confidentiality of information. Be explicit if data are sensitive. Describe coding procedures for subject identification. Include the method, location and duration of data retention. (Federal regulations require data to be maintained for at least 3 years)

All data are part of a large database kept by the Cleveland Clinic Chronic Pain Rehabilitation Program since 1999. There are no patient identifiers in the database. The Cleveland Clinic IRB approved the maintenance of this database and any subsequent research from the database (see letter of continuation).

IV. Informed Consent Form

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Does the Informed Consent Statement?

1. Introduce you and your research (including names and phone numbers).
2. Provide the subject with a brief, understandable explanation of the research.
3. Explain the risks and benefits.
4. Explain the details of the time commitment for participation.
5. Explain how your protocol either protects confidentiality or is anonymous.*
6. Mention that participation is voluntary, and that the subject may withdraw at any time without penalty.
7. Include the exact statement about contacting the IRB.**
8. Provide a phone number where the subject may contact you for further information (students should include a phone number for themselves and also for their supervising faculty member).
9. Have a signature/date block for the subject to complete.***
Confidentiality and anonymity are not the same. Confidentiality means that the researcher will know the identity of specific subjects and their data. Anonymity means individuals' responses cannot be associated with the data they generate.

"I understand that if I have any questions about my rights as a research subject I can contact the CSU Institutional Review Board at (216) 687-3630," or if a minor, "I understand that if I have any questions about my child's rights as a research subject I can contact the CSU Institutional Review Board at (216) 687-3630."

If you wish to dispense with a signed consent form, for either procedural or substantive reasons, be sure to include a clear statement of your reasons and your alternate procedure for obtaining consent.

Data included in this study are part of a large database containing patient clinical data and records. All identifiable information is removed. All participants in this study signed an informed consent form as part of their inclusion in the Cleveland Clinic Chronic Pain Rehabilitation Program.

V. Copies of Instruments and Questionnaires

To complete this application, attach a copy of all questionnaires or other instruments. This application MUST include copies of instrumentation before approval can be granted.
VI. CERTIFICATION/SIGNATURE

I certify that the information contained in this protocol application and all attachments is true and correct. I certify that I have received approval to conduct this research from all persons named as collaborators and from officials of the project site(s). If this protocol is approved by the Cleveland State Institutional Review Board, I agree to conduct the research according to the approved protocol. I agree not to implement any changes in the protocol until such changes have been approved by The Cleveland State Institutional Review Board. If, during the course of the research, unanticipated risks or harm to subjects are discovered, I will cease collecting data and report them to IRB immediately.

[Signatures and Dates]

Forward this completed form to:
Cleveland State University
Institutional Review Board
Office of Sponsored Programs and Research
2258 Euclid Avenue
Hannifin Hall
Cleveland, OH 44115-2405
To Whom It May Concern:

This letter is to notify the Cleveland State University Institutional Review Board that Lisa L. Ferguson has our approval to use data collected at the Cleveland Clinic Chronic Pain Rehabilitation Program for her thesis.

Thank you,

Judith Scheman, Ph.D.
216/444-2875
Alteration and Waiver of Informed Consent:

This database is based entirely on clinically obtained data without additional patient contact and as such we expect that it is eligible for waiver of informed consent as the patients privacy interests are adequately protected since no patient's individual identification can be made from the database.

1. The research involves no more than minimal (if any) risk to the individual.
2. The waiver will not adversely effect the privacy rights and welfare of the individuals as no individual is identifiable in the database.
3. Although the research could be conducted without the waiver, the waiver would just inform patients that their information, once in the database, could not be individually identified or connected to them as an individual.
4. The research, as it is primarily involved in outcomes, could not be conducted without access to and use of protected health information.
5. There are no individual identifiers in the database.
6. Access to the raw data is available only to the CCF treatment personnel.
7. As the records used are part of the CCF Clinical Record, their destruction falls under the CCF purview.
8. As with all psychological records none of the records or data can be reused or disclosed to any person or entity without the approval of the psychologist.

Brief Description

The Chronic Pain Rehabilitation Program is a comprehensive, interdisciplinary CARF accredited program designed to treat patients with chronic non-malignant pain. It is dedicated to working in collaboration with people who have chronic pain, to help minimize their suffering and restore their ability to take joy from life while contributing to it. The program provides comprehensive specialized care to people experiencing chronic pain utilizing an interdisciplinary team approach. To these ends, the team works in a compassionate way to help people to exceed their perceived limitations, eliminate harmful behaviors and replace them with healthy living.

As part of its mission to treat patients in the most efficacious manner, and to be in compliance the CARF regulatory agency, the Chronic Pain Rehabilitation Program maintains a database that includes information on all patients evaluated and treated in the program, as well as its related clinics such as the Failed Back Clinic; Complex Patello-femoral Clinic and Chronic Pancreatitis Clinic.

Within the database, no patient is individually identifiable. The database includes basic demographic information as well as an assessment of mood, pain, medication, medical and developmental history. Data are gleaned from the initial patient evaluation and patient completed questionnaires, as well as phone follow-up interviews. Trained professionals who are part of the
Chronic Pain Rehabilitation Program team gather all information; the psychologist and post-doctoral fellow maintain the database itself.

In additional to treatment outcomes analysis done on a regular basis in compliance with CARF, the data base has been used to answer such questions as the role of chronic opioid maintenance in this population, the effectiveness of an interdisciplinary team evaluation of patients who have failed prior back surgeries, and mood as it relates to pain level among others things.

**Data Collection**

1. The database does not contain any patient identifiers.
2. The database, in one form or another, has been kept since the inception of the Chronic Pain Rehabilitation Program in 1979, and there are no plans to dismantle it. Only a limited number of people have access to the database, and they include the CCF Staff of the Chronic Pain Rehabilitation Program and the psychology fellows. All new fellows are trained in the maintenance of the database and it can be accessed only through the access secured server.
3. Data collection involves clinical interviews, chart review, questionnaires, and phone interviews. Once the data are entered into the database all identifiable information is excluded. All questionnaires and phone contacts are designed as to minimize the inconvenience on the part of the patient.
4. Data collection does not involve human biological materials such as blood or tissue.

**Data Use**

1. The objective of keeping this database is primarily to answer questions about outcome and how outcome is effected by a number of variables such as diagnoses, medication usage; personality variables, mood, employment status, etc.
2. Investigators include: Judith Scheman, Ph.D.; Edward Covington, M.D; Laura Burns, Ph.D.; Paul Minello, Ph.D. (post-doctoral fellows subject to change every 2 years)
3. There is no access granted to the database without contacting Dr. Scheman.
4. All sub-investigators will complete the human subjects training unit on Research-Based Ethics.
5. Since the database does not include individual identification, it does not need to be removed if data were to be transferred outside CCHS.
6. The psychologist and psychology fellows are trained in experimental design and analysis, the database is not used without consulting their expertise, and Biostatistics is consulted on an as needed basis.

**Informed Consent**

None of the data used in the database go beyond that which is collected in the course of what is considered to be clinically relevant and part of the standard course of treatment. Exempt status has been approved in the past (45CFR46.101) (4) as this research involves the collection and study of existing data, documents, records, pathological reports, or diagnostic studies that are
recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

**Patient Information**

1. All patients involved in the Chronic Pain Rehabilitation Program and its affiliated clinic are included in the database and none are excluded on the basis of race, economic class, age, pregnancy status, or mental ability.
2. The registry is composed entirely of Cleveland Clinic Foundation patients.

**Studies 2006-2007**


September 13, 2005

TO: Judith Scheman, Ph.D. / C21

RE: IRB 5645: REGISTRY: The Chronic Pain Rehabilitation Program Outcome

Dear Dr. Scheman:

Your renewal report dated August 26, 2005 is eligible for expedited review and was approved on September 9, 2005. This action will be reported on the Activity report to the full committee of the IRB.

The requested continuation involves no changes to the protocol or consent form. You are granted permission to continue your study as described effective for the period of September 27, 2005 to September 26, 2006.

The IRB has determined this research involves no more than minimal risk and the criteria for waiver of consent, as contained in the federal regulations, have been satisfied. This waiver of consent will not adversely affect the rights and welfare of the research subjects. This research could not practicably be conducted without the waiver of consent. The researchers are authorized to use identifiable subject information for review and analysis in accordance with procedures for maintaining subject privacy and confidentiality. This information shall not be removed from CCF premises nor disclosed to others outside CCF. Additional review and approval by the IRB is required if subject information is intended to be shared outside CCF.

The study is next subject to continuing review on or before September 26, 2006. You are required to submit a renewal or completion report before the expiration date.

As with the initial approval, changes to the study must be promptly reported and approved by the IRB. Any unanticipated problems or adverse events that are serious, unexpected, and associated with the research must be promptly reported to the IRB.

Sincerely,

Daniel Beyer, M.S., MHA, CIP
Executive Director
Institutional Review Board

EXPIRATION DATE: September 26, 2006
September 8, 2006

TO: Judith Scheman - Baumann, Ph.D. / C21

RE: IRB 5645: REGISTRY: The Chronic Pain Rehabilitation Program Outcome

Dear Dr. Scheman - Baumann:

Your renewal report received in the IRB office on August 24, 2006 for continuing review of the study listed above was reviewed under the expedited review process and approved on August 29, 2006. This action will be reported to the full committee of the IRB.

You are granted permission to conduct your study for the period of September 27, 2006 to September 26, 2007.

The IRB has determined this research involves no more than minimal risk and the criteria for waiver of consent, as contained in the federal regulations, have been satisfied. This waiver of consent will not adversely affect the rights and welfare of the research subjects. This research could not practicably be conducted without the waiver of consent. The researchers are authorized to use identifiable subject information for review and analysis in accordance with procedures for maintaining subject privacy and confidentiality. This information shall not be removed from CCF premises nor disclosed to others outside CCF. Additional review and approval by the IRB is required if subject information is intended to be shared outside CCF.

The approval period for this study will expire on September 26, 2007. You are required by federal regulations and IRB policy to submit a continuing renewal report or completion report 30 days prior to the expiration date and ensure that no research activities will continue beyond the expiration date.

Please note that any changes to the study as approved must be promptly reported and approved by the IRB prior to implementation. Any study deviations and unanticipated problems, including adverse events that are unexpected and related or possibly related to the research intervention must be promptly reported to the IRB. Please refer to IRB Policies #60 and #70 regarding specific reporting timeframes.

Sincerely,

Daniel Beyer, M.S., MHA, CHP
Executive Director
Institutional Review Board

DB: sr

EXPIRATION DATE: September 26, 2007
September 14, 2007

TO: Judith Scheman - Baumann, Ph.D. / C21

RE: IRB 5645: REGISTRY: The Chronic Pain Rehabilitation Program Outcome

Dear Dr. Scheman - Baumann:

Your renewal report received on September 5, 2007 for continuing review of the study listed above was reviewed under the expedited review process and approved on September 12, 2007. This action will be reported to the full committee of the IRB.

You are granted permission to conduct your study for the period of September 27, 2007 to September 26, 2008.

This research involves no more than minimal risk and the criteria for waiver of consent have been met. The rights and welfare of the research subjects will not be adversely affected and the research could not practicably be conducted without the waiver of consent. The protocol plan to protect private identifiable information from improper use and disclosure and to securely maintain the data in a confidential manner was acceptable. The release of data outside CCF must be de-identified or compliant with a limited data set application and data use agreement.

The approval period for this study will expire on September 26, 2008. You are reminded to submit a continuing renewal report up to 30 days prior to the expiration date. You must ensure that no research activities will continue beyond the expiration date. If you are not renewing, a completion report is required.

Please note that any changes to the study as approved must be promptly reported and approved by the IRB prior to implementation. Any study deviations and unanticipated problems, including adverse events that are unexpected and related or possibly related to the research intervention must be promptly reported to the IRB. Please refer to IRB Policies #60 and #70 regarding specific reporting timeframes.

Sincerely,

Daniel Beyer, M.S., MHA, CIP
Executive Director, Institutional Review Board

EXPIRATION DATE: September 26, 2008
CITI Collaborative Institutional Training Initiative

Human Research Curriculum Completion Report
Printed on Wednesday, September 10, 2008

**Learner:** Lisa Ferguson (username: Imk1123)
**Institution:** Cleveland Clinic Foundation
**Contact Information:** Department: Psychiatry and Psychology
Phone: 46179
Email: Imk1123@yahoo.com

**Group 1:** Required for all researchers registering with the Cleveland Clinic Foundation.

### Stage 1. Basic Course Passed on 03/06/06 (Ref # 929670)

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<th>Required Modules</th>
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<td>Introduction</td>
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<td>History and Ethical Principles</td>
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<td>Basic Institutional Review Board (IRB) Regulations and Review Process</td>
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<td>Social and Behavioral Research for Biomedical Researchers</td>
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<td>Records-Based Research</td>
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<td>Genetic Research in Human Populations</td>
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<td>Research With Protected Populations - Vulnerable Subjects: An Overview</td>
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<td>Vulnerable Subjects - Research Involving Minors</td>
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<td>Vulnerable Subjects - Research Involving Pregnant Women and Fetuses in Utero</td>
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<td>Group Harms: Research With Culturally or Medically Vulnerable Groups</td>
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<td>FDA-Regulated Research</td>
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<td>HIPAA and Human Subjects Research</td>
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<td>Workers as Research Subjects-A Vulnerable Population</td>
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<td>Conflicts of Interest in Research Involving Human Subjects</td>
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<td>Cleveland Clinic Foundation</td>
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For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
**CITI Collaborative Institutional Training Initiative**

**Human Research Curriculum Completion Report**
**Printed on Tuesday, September 30, 2008**

**Learner:** Lisa Ferguson (username: Imkl123)  
**Institution:** Cleveland Clinic Foundation  
**Contact Information:** Department: Psychiatry and Psychology  
**Information Phone:** 46179  
**Email:** Imkl123@yahoo.com

**Group 1:** Required for all researchers registering with the Cleveland Clinic Foundation.

**Stage 2. Refresher 2 Course Passed on 09/30/08 (Ref # 2162435)**

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<tr>
<td>How to Complete the CITI Refresher Course and Receive a Completion Report</td>
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For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator
The rating scales below measure the impact of chronic pain in your everyday life. We want to know how much your pain is preventing you from doing your normal activities. For each of the categories of life activity listed, circle the one number that best reflects the level of disability you typically experience. A score of 0 means no disability at all. A score of 10 means that all the activities which you would normally do have been disrupted or prevented by your pain. Your rating should reflect the overall impact of pain in your life, not just when the pain is at its worst. Make a rating for every category. If you think a category does not apply to you, circle 0.

**Family/home responsibilities:** This category refers to activities related to the home or family. It includes chores and duties performed around the house (e.g., yard work) and errands or favors for other family members (e.g., driving the children to school).

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**Recreation:** This category includes hobbies, sports, and other leisure-time activities.

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**Social activity:** This category includes parties, theater, concerts, dining out, and other social activities that are attended with family and friends.

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**Occupation:** This category refers to activities that are directly related to one’s job. This includes nonpaying jobs as well, such as that of a homemaker or volunteer worker.

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**Sexual behavior:** This category refers to the frequency and quality of one’s sex life.

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</tbody>
</table>

**Self-care:** This category includes personal maintenance and independent daily living activities (e.g., taking a shower, driving, getting dressed).

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>No disability</td>
<td>Mild</td>
<td>Moderate</td>
<td>Severe</td>
<td>Total Disability</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

**Life-support activity:** This category refers to basic life-supporting behaviors such as eating, sleeping, and breathing.

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
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<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
Patient: ____________________
Rater: ____________________

<table>
<thead>
<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Vocal Complaints: Non-Verbal (moans, groans, gasps, etc.)</td>
<td>None</td>
<td>Occasional</td>
<td>Frequent</td>
<td>Adm.</td>
<td>Disc.</td>
</tr>
<tr>
<td>3. Down-Time: (time spent lying down per day because of pain: 8 a.m.-8p.m.)</td>
<td>None</td>
<td>Occasional</td>
<td>Frequent</td>
<td>Adm.</td>
<td>Disc.</td>
</tr>
<tr>
<td>5. Standing Posture</td>
<td>None</td>
<td>Occasional</td>
<td>Frequent</td>
<td>Adm.</td>
<td>Disc.</td>
</tr>
<tr>
<td>6. Mobility</td>
<td>None</td>
<td>Occasional</td>
<td>Frequent</td>
<td>Adm.</td>
<td>Disc.</td>
</tr>
<tr>
<td>8. Use of visible supportive equipment: (braces, crutches, cane, leaning on furniture, TENS, etc.)</td>
<td>None</td>
<td>Occasional</td>
<td>Frequent</td>
<td>Adm.</td>
<td>Disc.</td>
</tr>
<tr>
<td>10. Medication</td>
<td>None</td>
<td>Occasional</td>
<td>Frequent</td>
<td>Adm.</td>
<td>Disc.</td>
</tr>
</tbody>
</table>

| The UAB Pain Behavior Scale (0-10) | | | | Adm. | Disc. |
|-----------------------------------|------|-----|------|

TOTAL


Directions: Below you will find a list of statements. Please rate the truth of each statement as it applies to you. Use the following rating scale to make your choices. For instance, if you believe a statement is “Always True” you would write a 6 in the black next to that statement.

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Never True</td>
</tr>
<tr>
<td>1</td>
<td>Very Rarely True</td>
</tr>
<tr>
<td>2</td>
<td>Seldom True</td>
</tr>
<tr>
<td>3</td>
<td>Sometimes True</td>
</tr>
<tr>
<td>4</td>
<td>Often True</td>
</tr>
<tr>
<td>5</td>
<td>Almost Always True</td>
</tr>
<tr>
<td>6</td>
<td>Always True</td>
</tr>
</tbody>
</table>

1. I am getting on with the business of living no matter what my level of pain is. _____
2. My life is going well, even though I have chronic pain. _____
3. It’s OK to experience pain. _____
4. I would gladly sacrifice important things in my life to control this pain better. _____
5. It’s not necessary for me to control my pain in order to handle my life well. _____
6. Although things have changes, I am living a normal life despite my chronic pain. _____
7. I need to concentrate on getting rid of my pain. _____
8. There are many activities I do when I feel pain. _____
9. I lead a full life even though I have chronic pain. _____
10. Controlling pain is less important than any other goals in my life. _____
11. My thoughts and feelings about pain must change before I can take important steps in my life. _____
12. Despite the pain, I am now sticking to a certain course in my life. _____
13. Keeping my pain level under control takes first priority whenever I’m doing something. _____
14. Before I can make any serious plans, I have to get some control over my pain. _____
15. When my pain increases, I can still take care of my responsibilities. _____
16. I will have better control over my life if I can control my negative thoughts about pain. _____
17. I avoid putting myself in situations where my pain might increase. _____
18. My worries and fears about what pain will do to me are true. _____
19. It’s a relief to realize that I don’t have to change my pain to get on with my life. _____
20. I have to struggle to do things when I have pain. _____