COMPARATIVE ABILITY OF THE PAIN DISABILITY QUESTIONNAIRE IN PREDICTING HEALTH OUTCOMES AND HEALTHCARE COSTS

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Given the tremendous personal and societal costs of chronic pain, efforts at improving pain conceptualization via the Biopsychosocial Model have become critical in addressing pain-related health outcomes and healthcare costs. The current study consisted of 254 (Average age= 49.72, SD= 14.55) adult chronic pain patients seeking treatment through an interdisciplinary chronic pain management clinic. Participants were administered a battery of assessments including the Pain Disability Questionnaire and other established measures of health and pain-related outcomes (e.g., SF-36, PROMIS pain-related measures) at baseline and post-treatment time points. Convergent validity was observed between the Pain Disability Questionnaire and other study measures. Hierarchical regression analyses demonstrated significant associations between pain-related disability as measured by the Pain Disability Questionnaire and a range of health and psychosocial outcomes. Pain Disability Questionnaire scores, as placed in categorical severity levels, demonstrated good discriminative abilities in terms of predicting health outcomes profiles. Further, logistic regression models established that the Pain Disability Questionnaire provided good predictive validity in terms of healthcare cost categorization at three month follow-up. These findings support the clinical use of the Pain Disability Questionnaire as an equivalent, and in some cases superior, empirically supported predictor of health-related outcomes as compared with other established measures of pain and health outcomes. Additionally, initial evaluation of the Pain Disability Questionnaire's predictive utility in terms of pain-related healthcare costs displayed significant predictive abilities. Overall, these findings suggest that the Pain Disability Questionnaire is a valuable tool in efforts to understand and manage chronic pain as well as predict associated healthcare costs for chronic pain patients.

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LIST OF ABBREVIATIONS

AHRQ – Agency for Healthcare Research and Quality

ARRA –American Recovery and Reinvestment Act

CAT – Computer Adaptive Test

CER – Comparative Effectiveness Research

FSC – Pain Disability Questionnaire: Functional Status Component

IRT – Item-Response Theory

MVAS- Million Visual Analog Scale

PSC- Pain Disability Questionnaire: Psychosocial Component

PDQ – Pain Disability Questionnaire

PROMIS – Patient Reported Outcome Measurement Information System

PROMIS-Anger – PROMIS Anger Item Bank Version 1.0

PROMIS-Anxiety – PROMIS Anxiety Item Bank Version 1.0

PROMIS-Depressive Sxs – PROMIS Depression Item Bank Version 1.0

PROMIS-Pain Behavior – PROMIS Pain Behavior Item Bank Version 1.0

PROMIS-Physical Functioning – PROMIS Physical Functioning Item Bank Version 1.0

PROMIS-Pain Interference – PROMIS Pain Interference Item Bank Version 1.0

PROMIS-Social Sat DSA – PROMIS Social Satisfaction with Discretionary Social Activities Item Bank Version 1.0

PROMIS-Social Sat Role – PROMIS Satisfaction with Social Role Activities Item Bank Version 1.0

SF-36 – Short Form (36) Health Survey

CHAPTER ONE

Introduction

Chronic pain is a significant problem at both a societal as well as individual level. Modern treatment interventions, based on the Biopsychosocial Model, have been developed in order to help meet the pressing demands of patients experiencing chronic pain conditions. Interdisciplinary Chronic Pain Management programs have been developed specifically to address this need, and ongoing empirical research has overwhelmingly supported the treatment- and cost-effectiveness of these programs (Gatchel & Okifuji, 2006). A critical element of this research is patient self-report measures. Patient self-report measures are recognized as important and often necessary elements in tracking patient health outcomes and guiding treatment decisions (Jensen, Turner, Romano, & Fisher, 1999). From these measures, clinicians benefit from relevant personal data to more appropriately inform healthcare decisions.

There exists a consensus that the patient's perceptions of health provides critical information central to monitoring health outcomes (Ware & Sherbourne, 1992). The use of empirically validated self-reported outcomes in chronic pain populations has emerged as a significant advancement in the provision of informed care for patients suffering from a wide range of chronic non-malignant pain conditions. The Pain Disability Questionnaire (PDQ) has been shown to be a valid and reliable self-report measure for use with patients suffering from a variety of musculoskeletal pain conditions (Anagnostis, Gatchel, & Mayer, 2004).

In fact, the PDQ has recently been included in the American Medical Association "Best Practice" guidelines (American Medical Association, 2008). The PDQ has also demonstrated good predictive validity in terms of health outcomes (Gatchel, Mayer, & Theodore, 2006). However, less is known about the comparative ability of the PDQ in predicting health outcomes against other commonly used health outcomes measures. Additionally, no attempts have been made to determine the PDQ's ability to predict healthcare costs. In order to gain a better understanding of the contextual backdrop of the growing interest in the PDQ, a review of the relevant literature in this area is warranted.

Overview

Recent literature consistently identifies the enormous societal costs associated with chronic pain conditions (e.g., Turk, 2002; Melhorn, 2000). A review by Verhaak (1998) and colleagues found that the adult chronic pain population ranges as high as 40 percent among adults. Similarly, Webb (2003) and colleagues indicate that approximately 30 percent of adults suffer from low back pain in any given month. Additionally, Elliott et al. (1999) suggest that up to 2.5 million individuals suffer from back pain every day of the year. Given the high prevalence of chronic pain, it is not surprising that related healthcare costs to treat these conditions are immense. The cost of medical expenses, lost work productivity, compensation, and lost earnings from back pain alone reaches $100 billion annually in the U.S. (Melhorn, 2000). Across pain-related conditions, a minority of patients account for the majority of healthcare costs (Engel, Von

Korff, & Katon, 1996). In fact, 80 percent of medical costs for back pain can be accounted for by the five to ten percent of acute back pain conditions that develop into chronic pain conditions (Gatchel & Mayer, 2000).

At an individual level, the costs of chronic pain are also an important consideration. Financially, a heavy burden is placed on chronic pain patients in order to maintain, for example, an opiate medication regimen. Given the ongoing nature of chronic pain conditions, the costs can become quite expensive over time. Additionally, these patients expend considerable personal time and other resources on healthcare utilization. Visits to physicians, psychotherapists, emergency rooms, physical therapists, and other healthcare providers are all but unaffordable for some. Quality of life may decline as a function of time and resources spent on significant health care utilization.

An additional concern expressed by sufferers of chronic pain involves functional disability. Chronic pain may affect basic movement processes involved in everyday tasks such as climbing stairs, carrying groceries, and walking. Missed work days, decreased work productivity, and declines in income are all examples of how chronic pain problems can interfere with occupational functioning (Gatchel, 2004). With both work life and home life negatively impacted, quality of life becomes sensitive to decline. Clearly, functional disability is an overarching problem that creates ongoing and debilitating difficulties for chronic pain sufferers.

As noted by Turk (2002), chronic pain affects not only the lives of patients, but also of friends and family as well. As patients experience pain-related functional losses, family members may need to invest effort and compensate for the losses. For example, transporting a patient to various healthcare appointments may become a regular necessity for family members of chronic pain patients. Daily tasks such as support in timing and administration of medications may also fall to family and friends. Psychosocial issues may arise for these patients, including feelings of guilt for the actual (or perceived) burden placed on family and caregivers. Therefore chronic pain is an issue that leaves few, if any, untouched by its challenges.

Comparative Effectiveness Research

Given such demands on chronic pain patients, there has been a recent impetus among U.S. federal programs to support research in the area of comparative effectiveness research (CER). CER made headlines in February of 2009 when the Obama administration signed into effect the American Recovery and Reinvestment Act (ARRA). Included in this act was 1.1 billion dollars for use in CER to help establish the most beneficial treatment available (DeMaria, 2009). Implicit in this notion is the need to identify the most cost-effective treatments available. Thus, a closer inspection of comparative effectiveness research is critical in understanding the link between valid and reliable assessment measures of health outcomes and the resulting evaluation of treatment- and cost-effectiveness.

The following quote by Golub and Fontanarosa (2012) speaks to the broad interests and implications of CER, as well as the purported benefits that CER may be capable of providing. The authors state:

> Comparative effectiveness research (CER) has captured the attention of the biomedical community, including physicians, other health care professionals, and clinical researchers; the public, including patients and their advocates; and policy makers, including funding agencies and health care insurers. This keen interest is based, at least in part, on the hope that the findings from CER will provide useful information to help clinicians make evidence-based decisions, will incorporate patient preferences and patient-centered perspectives, and, ultimately, will improve the quality of care and help control health care costs.

In order to better understand the impact of CER for chronic pain patients, a basic understanding of its historical backdrop is in order. CER is not a new concept. Modern efforts by the government to investigate and highlight successful health interventions can be traced to Health Technology Assessment in the 1970's (US Congress, 1996). Following this period, general health effectiveness research emerged in the 1980's. Outcomes research dominated the 1990's, and the 2000's and beyond introduced CER as described here. Clearly, the need to evaluate treatments has a longstanding basis in seeking to provide decision-makers with relevant information to make appropriate healthcare choices. Without critical data of this kind, clinical practice would be reduced to educated guesses and even potential harm to patients.

Of the 1.1 billion dollars allocated for CER, the National Institutes of Health received $400 million, the Agency for Healthcare Research and Quality (AHRQ) received $300 million, and the Office of the Secretary of the Department

of Health and Human Services received $400 million. Of note, AHRQ has agreed to manage the Office of the Secretary's $400 million (http://www.ahrq.gov/fund/recoveryawards/ accessed 5/14/12). In order to help organize and manage such an effort, the ARRA also established the Federal Coordinating Council for Comparative Effectiveness Research (The Council) (Federal Coordinating Council, 2009).

A first priority for The Council was to produce a definition of CER in an effort to provide clarity to the construct and a common language across interested parties. The Council defines CER as, "the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in 'real world' settings. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances (Federal Coordinating Council, 2009)." In other words, CER aims to provide useful information by comparing health and treatment outcomes across at least two interventions or strategies with as much specificity as possible in terms of patient population factors.

Translational researchers have long sought to identify the degree to which applied practice is successful in promoting patient improvement. Most often, the underlying research question is "Does this treatment work?" It is becoming

increasingly clear that research with such a narrow focus may not provide the type of data required by consumers and providers to make a fully informed treatment decision. The more comprehensive question that has often been missed in research is, "Does this treatment work better than others in the specific context of this individual?" CER makes strong headway in facilitating an answer to this question. For example, a cognitive behavioral treatment approach for elderly individuals suffering from chronic disabling occupational musculoskeletal disorders may be directly compared against a psychodynamic treatment approach. In doing so, the hope of CER is to identify the most successful and efficient method of treatment and then to pass along this information to healthcare decision-makers, including providers.

Another noteworthy factor that CER often attempts to evaluate is cost-effectiveness of the interventions. So, CER is not only intended to document benefits and harms of a given intervention, but also empirically evaluate it against other related interventions including a cost-effectiveness component. A related line of research is Cost Effectiveness Analysis (CEA). In their seminal work, Russell (1996) and colleagues defined CEA as "a method for evaluating the health outcomes and resource costs of health interventions (p. 1172)." This type of research serves as another guide for healthcare policy-makers, among others, to highlight differences in cost effectiveness between treatments (Bell, et al., 2006). Accordingly, CEA is quite relevant when discussing the healthcare cost outcomes dimension of CER as it helps objectively document the relationship between

healthcare utilization and price. As CER continues to come to the forefront of public attention, the role of CEA may become increasingly pronounced. Recent research has suggested the need for improved methods in cost utility analyses for particular conditions/populations (Dagenais, et al., 2009).

In 2010, the Patient Protection and Affordable Care Act created the Patient-Centered Outcomes Research Institute (PCORI) (Patient Protection, 2010). Consistent with PCORI's stated priority of accelerating patient-centered outcomes research, there is a current national impetus to employ research focused on helping patients make empirically informed healthcare decisions. As a component of the NIH-funded PROMIS initiative, the web-based resource "Assessment Center" was developed to provide storage, organization, and administration of patient-reported outcomes (Gershon, et al., 2010). This resource helps support PCORI's overall mission by featuring shareable and empirically validated patient-reported outcomes measures. Accurate instruments to evaluate health and cost-related outcomes are thus crucial tools in patient-centered outcomes research. With respect to pain-related patient centered outcomes, valid and reliable investigation of healthcare cost factors (e.g., cost-effectiveness, predictive utility of pain-focused instruments, etc.) is particularly salient.

Biopsychosocial Model of Chronic Pain

With such important financial considerations in mind, accurate conceptualization of the chronic pain experience is absolutely necessary in understanding and promoting cost- and treatment-effective chronic pain

management programs. Recent research has advanced the conceptualization of chronic pain and illuminated the multifaceted nature of the pain experience. In particular, the Biopsychosocial Model of chronic pain has become the gold-standard in conceptualizing the experience of chronic pain (Gatchel, et al., 2007). As first introduced by Engel (1977), the Biopsychosocial Model represents an advancement from previous models that did not incorporate a comprehensive system for explaining pain experiences. For example, biomedical reductionistic models were too narrowly focused on attributing pain to solely biophysiological mechanisms. As it turns out, a patient's pain experience cannot be fully explained by solely focusing on the amount of nociceptive damage. Rather, the Biopsychosocial model considers not only these biophysiological components, but also psychological and environmental aspects of the pain experience.

Loeser (1982) described four dimensions associated with the construct of pain: nociception, pain, suffering, and pain behaviors. Nociception may be described as the stimulation of nerves as to damage or potential damage to tissue. Pain is the subjective experience of the terminal result of the stimulus transmitted by these nerves to the brain. This pain perception may be mediated by the patient's genetic composition, psychological factors, and even sociocultural situation. Loeser goes on to describe suffering as a negative emotional response initiated by the nociceptive process. Finally, pain behaviors may be expressed both verbally and non-verbally to communicate pain and suffering.

As suggested by these models, accurate assessment of patients with chronic pain conditions must include consideration of psychological and sociocultural factors, not simply biophysiological damage. More specifically, accurate assessment must recognize the interconnected and dynamic nature of all of these aspects (Gatchel, et al., 2007). Psychological aspects to consider with regard to chronic pain patients are multiple and include pain-related cognitions, affective experience, pain behaviors, anxiety, depression, and substance abuse. The patient's initial psychological distress comes as a reaction to bodily harm or injury. This distress may take the form of anxiety, fear, worry, depression, or other related constructs. Following the initial distress, some patients experience the development or exacerbation of psychological problems. For example, a common issue in chronic pain expands upon Martin Seligman's general notion of "learned helplessness" (Dersh, Polatin, & Gatchel, 2002). In a chronic pain context, learned helplessness refers to a vicious cycle in which the patient's unsuccessful attempts at managing pain lead to the belief that they are unable to control their experience of pain. This, in turn, contributes to decreased efforts at even trying. Unfortunately, this can result in poor treatment adherence and slower healing.

Other examples of psychological factors influencing the patient's pain experience are pain behaviors. Pain behaviors include aspects of pain that are expressed through the actions of the patient. In other words, how is the pain influencing the person's behavioral pattern? Grimacing, whimpering, using a

walker, and requesting pain medications all fall under the broad category of pain behaviors. Pain behaviors can lead to social isolation and employment difficulties in patients who are unwilling to fully participate in work or social obligations due to pain. Landrine and Klonoff (1992) suggest that sociological and anthropological ideas may help shed light on differences observed with respect to pain behaviors across cultures. For example, they note that there are ethnic differences in chronic pain behavior, and add that these differences must be understood in order to effectively treat pain conditions.

Cognitions surrounding pain often reflect the patient's attempts to make meaning of their pain condition. Individuals vary in the degree to which their pain related cognitions reflect accurate assessments of meaning, and, as such, meaning is quite subjective. These cognitions may also impact the patient's treatment. The degree to which patients attribute their pain to internal/external, situational/global, and stable/unstable factors can mediate, for example, an active versus passive role in seeking or participating in treatment. Graham and colleagues (2008) found that meaning-making mediated depressed mood among a group of chronic pain patients. Thus, cognitive considerations such as meaning-making play an important role in managing chronic pain conditions.

The connection between psychological distress and healthcare outcomes has been well established (Sobel, 1995). Individuals with chronic pain often present with a number of emotional and psychiatric disorders (Dersh, Polatin, & Gatchel, 2002). Primary mood disorders, anxiety disorders, somatoform disorders

and substance abuse are just some of the co-morbid conditions often associated with chronic pain. Additionally, the literature suggests that histrionic, dependent, paranoid, and borderline personality disorders, respectively, constitute the most commonly identified personality disorders in chronic pain samples (Dersh, et al., 2002). Howard and Howard (2012) pinpoint hopelessness as a significant barrier to treatment seeking behavior in individuals with chronic upper extremity joint pain. Consistent with the biopsychosocial perspective, proper evaluation of psychological comorbidities is important in the current discussion as unrecognized psychopathology can significantly interfere with effective treatment for chronic pain (Gatchel, 1996).

The aforementioned psychiatric conditions may contribute to a vicious cycle in which treatment is adversely affected, the pain condition is maintained or worsened, and the result is maintenance or increase in psychological distress. Take for example a patient with chronic knee pain. As the patient's pain increases with movement of the knees, the patient may tend to avoid intentionally manipulating or exercising the knee. As a result, the knee becomes de-conditioned and would only hurt worse to attempt to move once it reaches this state. Accordingly, this would serve to reinforce the patient's avoidance of exercise and the cycle would continue. Clearly, this fear-avoidance pattern often seen in patients with pain conditions would contribute to both pain experience as well as emotional distress. Importantly, treatments that feature a biopsychosocial

approach to pain management may incorporate interventions aimed at addressing co-morbid psychiatric concerns as well.

Interdisciplinary Chronic Pain Management

Interdisciplinary (ID) treatment for chronic pain has emerged as a premium empirically validated approach to managing chronic pain conditions (Gatchel & Okifuji, 2006; Turk & Swanson, 2007). It has demonstrated utility in both treatment effectiveness as well as cost effectiveness. By utilizing a biopsychosocial conceptualization of patients, the ID approach offers treatment across biophysiological, psychological, and social factors that may affect the patient's pain experience. There are several essential components of ID programs that set the framework for understanding successful interdisciplinary chronic pain management. These components include a shared philosophy of rehabilitation among on-site providers, ongoing coordinated communication among providers, incorporation of services across providers, and active patient involvement in ID programs. Of primary importance is the integration and communication of healthcare professionals from sufficiently diverse disciplines to cover each domain of the Biopsychosocial Model of pain.

There has been some confusion in the literature regarding the distinction between "multidisciplinary" and "interdisciplinary" treatment for chronic pain management. Multidisciplinary approaches, similar to interdisciplinary approaches, feature the involvement of multiple health care providers. The distinction rests in the lack of emphasis on communication and collaboration

between providers within multidisciplinary treatment. These providers generally treat a specific focus of the patient's pain experience independently and are not typically in coordinated communication with each other. Also, the different providers involved in multidisciplinary care are rarely located in the same facility. Even when they are co-located, there remains a dearth of regular communication as well as a disconnected sense of patient goals and treatment considerations. By contrast, ID programs feature frequent communication between healthcare providers and highlights the importance of having them all work at the same location.

In general, all ID programs include at least two or more physicians (and/or psychiatrist), a clinical psychologist, and a physical therapist. Nurses, other healthcare providers, and other support personnel may be included as well, depending on the needs of the clinic. Examples of supportive personnel include vocational rehabilitation professionals, research and outcome database managers, nutritionists, chaplain services, and case managers (Noe & Williams, 2012). Collectively, this group of on-site healthcare providers, working collaboratively with a common philosophy of patient rehabilitation, provides the professional framework of ID programs.

ID programs vary in terms of recruitment of program participants, staff utilized, and amount and length of program. Still, an attempt will be made here to provide a general overview of a "typical" ID program. First, program patients must be screened for possible inclusion into the program. Usually, the patient's

first meeting is with one of the staff physicians, who may recommend additional evaluation by a psychologist and physical therapist to determine appropriateness for inclusion across Biopsychosocial aspects. Appropriate evaluation is critical for insuring the highest likelihood of patient success in treatment. Formal assessment measures (e.g., MMPI-2, PDQ, etc.) may be utilized at this point in order to provide informative data about the potential program participant. Following the initial evaluations, patients that are recommended for the ID program will be scheduled to begin on an established date.

As mentioned previously, some programs include various supportive personnel. For example, patients may interact with research coordinators prior to their initial visit in order to collect baseline data. Once the program begins, research (and other supportive initiatives such as nutritional intervention) may continue during and even after the program has completed. The demands of the particular clinic population heavily influence the inclusion or exclusion of these additive programs. A notable strength of ID programs is that treatment may be tailored to the patients based on their initial biopsychosocial evaluation, as well as their ongoing needs as they progress through the program. This flexibility enhances the ability of clinicians to respond adaptively to both initial as well as changing patient conditions over time.

In most ID programs, patients spend the majority of their program days participating in individual psychotherapy, group psychotherapy (including a psychoeducational component), and physical therapy. Interspersed throughout the

length of the program are visits with other healthcare providers including one of the staff physicians. ID program patients may be required to attend multiple days per week, in some cases every workday, depending on the program structure and established needs of the individual patient. Programs, including the program utilized in the current study, typically last approximately four weeks, but may be longer. According to recent evidence-based clinical practice guidelines, Sanders (2005) and colleagues suggest a time-limited model flexibly capped at 20 session-days. At program conclusion, patients may be provided with a certificate and formally discharged from the program given they have provided adequate attendance and participation.

There have been some challenges in the widespread implementation of ID programs. Robbins (2003) and colleagues explained that ID programs do not necessarily fit with managed care models of treatment. They note that some aspects of ID programs are "carved out" by managed care policies, and this depletion negatively impacts treatment outcomes. Other challenges include varying definitions and implementation of interdisciplinary care programs, poor media portrayal of excessive narcotic provision at pain clinics, and reluctance of third-party payers to fully compensate for such comprehensive care.

Measuring Health Outcomes

Despite the impressive collection of data concerning the cost- and treatment-effectiveness of ID programs, there remain certain areas of empirical inquiry that have yet to be fully illuminated. For example, evaluation of health

outcomes data following ID programs necessitates the use of empirically validated instruments to obtain this data. Health outcomes measures have been employed for decades in behavioral medicine and related fields to support, for example, health-related clinical decisions (Roach, 2006). In other words, is a given treatment associated with measurable changes in the patient's identified problem? Subjective opinions about improvement may be useful, but in order to establish a strong empirical basis for a given treatment or clinical decision, accurate and reliable instruments must be utilized.

With a more specific focus on pain and functional impairment, some commonly used measures include the Roland-Morris Disability Questionnaire (RDQ) and the Oswestry Disability Index (ODI) (Bombardier, 2000). They have demonstrated strong reliability and validity across multiple studies of pain and disability outcomes. However, these instruments have limitations as well. For example, the ODI does not account for psychosocial issues that may be related to pain and functional impairment. Similarly, the RDQ does not contain a mental health component. Thus, these measures neglect important elements of the Biopsychosocial Model and their applicability may therefore be limited. The aforementioned Pain Disability Questionnaire was designed with these types of limitations in mind, and in fact was developed with specific intention to address these shortcomings (Anagnostis, et al., 2004).

Particularly salient to the current study, the literature also supports the use of health outcome measures in predicting a range of clinically useful health

outcomes across various patient populations and time scales. For example, research has been conducted evaluating both short-term and long-term relationship between a health evaluation instrument score and health outcome variables (Angus, et al., 2000). Anagnostis (2003) and colleagues investigated the predictive utility of the Million Visual Analog Scale on tertiary rehabilitation outcomes. Other studies have also focused on health outcome prediction with pain populations (Mayer, et al., 2004; Webb, et al., 2003; Gatchel, et al., 2006).

Further, research has been conducted exploring the predictive relationships of health outcome measures and healthcare utilization. In an instrument validation study, Osbourne (2003) and colleagues compared the predictive validity of a new quality of life instrument against the SF-36 in a chronically ill population. Additionally, DeSalvo (2005) and colleagues identified a single item on the SF-36 as a potential unitary predictor of mortality and healthcare utilization. They also highlight the utility of self-reported health outcomes in predicting health outcomes. In a similar vein, it is important to note that the overall literature indicates that self-reported functional health status scales (including the SF-36) are useful in predicting future medical expenses (Fan, et al., 2002; Hornbrook, & Goodman, 1996). This literature was leaned upon in the current study to guide in established methods for healthcare cost prediction.

PROMIS Measures

As explained by the Biopsychosocial Model, psychosocial, psychiatric, and pain-related data are intrinsically connected. Given this fact, it was important

to include a spectrum of measures that cover multiple pain, impairment, and psychosocial variables in the current investigation. With this in mind, one source of measures for a range of unidimensional health-related constructs is the NIH-sponsored Patient Reported Outcome Measurement Information System (PROMIS) (Reeve, et al., 2007). As there exist multiple unidimensional PROMIS measures, a more in-depth examination of these measures is warranted.

Patient Reported Outcome Measurement Information System (PROMIS) measures were used to evaluate psychosocial and pain-related variables. The PROMIS item banks were established through an NIH-sponsored program of instrument development and validation (PROMIS, 2012). Each PROMIS scale utilizes a respective item bank from which selected items are administered using an item response theory (IRT) approach. PROMIS measure forms (excluding the Global Health measure) include self-report Computerized Adaptive Test (CAT) versions as well as short-forms. CATs offer test-takers the ability to have the item order and number adjusted based on the individual's test performance. Only the CAT versions were utilized in the current study. When administering PROMIS-based CATs, item number and order are guided by IRT-based algorithms. These algorithms serve to minimize the total number of items administered from each respective item bank, while preserving reliability and validity of the relevant construct (Cella, Gershon, Jin-Shei, & Seung, 2007).

Each PROMIS measure that was utilized in the current study used a Likert-type scale ranging from one (e.g., "Not at all") to five (e.g., "Very much).

One exception to this structure is the PROMIS Pain Behavior Item Bank 1.0, in which the range extends from one to six in order to include a “no pain” response option. The item response choices vary depending on the specific wording of the item. Respondents are instructed to utilize a seven day recall period. This time period was chosen because it was determined to be at the upper limits of ecological validity, yet still long enough that respondents may have accumulated enough significant event data (Cella, Yount, et al., 2007).

PROMIS measures were normed using a representative United States sample, including general and clinical populations across gender, age, race/ethnicity, and education. Each has a respective mean score of 50 and a standard deviation of 10 (Amtmann, et al., 2010). PROMIS measures have all demonstrated strong reliability and validity across extensive testing, have been found to be unidimensional, and initial concerns about differential item functioning have been adequately addressed (Reeve, et al., 2007; Cella, et al., 2007).

Pain Disability Questionnaire Overview

As mentioned previously, the Pain Disability Questionnaire (PDQ) was developed to help evaluate the patient’s pain experience with a specific focus on pain-related functional and psychosocial status. Its underpinnings are based on a biopsychosocial conceptualization of pain experiences. Of note, the PDQ has recently been included in the American Medical Association “Best Practice” guidelines (American Medical Association, 2008). As such, it is expected to

become increasingly utilized as both a research as well as clinical instrument. Unlike other measures of pain and functional disability (e.g., Oswestry Disability Index), the PDQ was created for use with the full range of chronic disabling musculoskeletal disorders rather than specific functional status/pain disorders. The 15-item assessment was constructed for a 6th grade reading level (Anagnostis, Gatchel, & Mayer, 2004). The relative brevity of the PDQ is noteworthy in that it places less of a burden on patients currently experiencing pain. The items are intended to measure the degree to which patient functioning is impacted by pain.

The PDQ was evaluated using a total sample of 446 individuals, divided into four groups in the initial validation study (Anagnostis, et al., 2004). These groups were: a Normative Population Group, an Acute Musculoskeletal Disorder Group, a Chronic Disabling Musculoskeletal Disorders (CDMD) Group, and a Heterogeneous Pain (HP) Group. Of note, the CDMD group did not differ from the HP group with respect to pretreatment PDQ scores. Inclusion of a heterogeneous pain group is particularly noteworthy as it allows for broader comparison of study results.

Test takers score PDQ items on a 10-point likert-type scale (0 = No problems, 10 = Total impairment). The scores may be collectively summed to yield a total functional disability score ranging from 0 (optimal function) to 150 (total disability). These total summed scores reflect the severity of patient-rated disability, and may be placed in one of three descriptive categories. The categories are: Mild/Moderate (1 – 70), Severe (71 – 100), and Extreme (101 –

150) severity. These categories were selected to reflect the categorization approach utilized by the similarly scaled Million Visual Analog Scale (MVAS) (Gatchel, et al., 2006). According to Anagnostis and colleagues (2003), these categories demonstrated an ability to predict both work- and health-related outcomes in the MVAS.

There does exist some criticism regarding the use of categorization approaches. For example, a common complaint is that there may be significant information loss when using this approach. However, the literature suggests that clinical utility and practical application may actually be enhanced when using this method. As Anagnostis et al. (2003) note, categorization of patients on an ordinally scaled level of severity is associated with greater clinical utility. Consequently, practical applications are bolstered by considering these classifications when evaluating health outcomes (Mayer, et al., 2004). For instance, patients placed in particular categories may be associated with lesser or greater risk for poor outcomes. Relevant to the current study then, categorization of PDQ scores were examined for clinical utility of predictive application in terms of health- and cost-outcomes.

Additionally, based on a factor analysis, researchers revealed a two-factor structure of the PDQ (Anagnostis, et al., 2004). The 9-item Functional Status Component (FSC) subscale primarily represents aspects of the respondent's physical functioning and related physical impairment. The FSC includes items meant to evaluate activities of daily living, work interference, and aspects of

physical movement. The 6-item Psychosocial Component (PC) subscale primarily represents mental health and social functioning. It includes items evaluating depression, anxiety, and interference with social relationships. Both of these factors, respectively, demonstrated strong correlations with established instruments of similar constructs (Anagnostis, et al., 2004).

There is strong empirical evidence that supports the reliability and validity of the PDQ (Anagnostis, et al., 2004; Gatchel, et al., 2006). In general, the PDQ has been shown to be valid across a variety of musculoskeletal pain conditions (e.g., Annaswamy, et al., 2012). Test-retest reliability coefficients for the CDMD group were found to be 0.94 ($P<.001$), indicating strong consistency across test administrations. Also, the researchers identified the internal consistency alpha coefficient at 0.96 ($p<.001$), suggesting that the scores of each respective PDQ item were clustered around the mean.

Upon initial evaluation of test validity, the PDQ was compared against other established measures of functional disability. The other measures included the MVAS, Oswestry, SF-36 MCS, and SF-36 PCS. The PDQ demonstrated the largest effect size among these instruments for the CDMD group (Effect size = 1.07) and HP group (Effect size = 0.85) between pre- and post-treatment (Anagnostis, et al., 2004). In other words, the PDQ displayed greater responsiveness to change as compared with other established measures. Thus, the PDQ accurately reflects clinical change in populations suffering from a range of pain conditions.

Construct validity may be considered another area of strength for the PDQ. Pearson's coefficients for pre-treatment PDQ scores from the combined CDMD and HP groups were shown to be significantly correlated (all p-values <.01) with other related measures (i.e., SF-36, the Oswestry Disability Questionnaire, the BDI, the HAM-D, the STAI, the Pain Intensity Drawing, and the Cumulative Physical Score). The 8 SF-36 subscales (e.g., Vitality, Bodily Pain scale, etc.) were significantly correlated with PDQ scores (e.g., Pain scale r = -0.53). In fact, PDQ correlations with the SF-36 scales overall were stronger than the respective correlations of the SF-36 scales and the MVAS and Oswestry. Post-treatment PDQ scores were also evaluated in terms of association between PDQ and other measures of a similar construct. Pearson's coefficients were again demonstrated to be more strongly correlated overall than the MVAS, SF-36, and Oswestry (Anagnostis, et al., 2004). Overall, the PDQ has exhibited excellent validity as summed by its test-retest reliability, Cronbach's alpha scores, responsiveness effect sizes, and concurrent validity when compared with other traditional measures of pain and functional disability.

Recent research utilizing the PDQ has skyrocketed across a variety of settings and with a variety of pain populations (e.g., Miciano, 2011; Annaswamy, et al., 2012). For example, Miciano (2011) explored the psychosocial distress experienced by individuals with poly-trauma and chronic pain using the PDQ as a primary measure. Similarly, Annaswamy et al. (2012) described the relationship between needle electromyography following lumbar epidural steroid injection and

pain-related functional outcomes (as assessed, in part, by the PDQ). Other research has implemented the PDQ to evaluate the psychological profiles of indigent populations suffering from severe osteoarthritis (Howard, et al., 2011). In a Russian study, Batysheva and colleagues (2009) used a modified version of the PDQ in a comparative study of patients suffering from subacute and chronic spondylogenic dorsalgia. Kenny and Faunce (2004) examined the impacts of group singing on mood, coping, and perceived chronic pain at six-month follow-up on patients participating in a multidisciplinary treatment program. The singing group was found to show improvements across pain-related variables as measured by the PDQ.

Additionally, attempts have been made to translate and adapt the PDQ into other languages. Giordano and associates (2012) developed a Brazilian Portuguese version of the PDQ and evaluated the new version's psychometric properties. They conclude that the translated version shares similarly strong psychometric properties as the original PDQ and therefore constitutes a valid linguistic and cultural adaptation. Brede and colleagues (2011) incorporated the PDQ in an exploration of the utility of the Pain Anxiety Symptoms Scale, and found that the PDQ displayed the largest correlation coefficient ($r = 0.561$) among measures of psychosocial distress.

Further, the PDQ has also been utilized to predict and track biopsychosocial outcomes in a functional restoration program for chronic pain patients. For example, Gatchel and colleagues (2006) evaluated the PDQ with

respect to functional and psychosocial rehabilitation outcomes at one year post-treatment. They found that the PDQ demonstrated strong predictive value in terms of various functional and psychosocial variables (e.g., depression, self-reported pain, etc.). Their findings support the utility of the PDQ in the prediction of performance outcomes. Still, there has not been any effort to compare the predictive value of the PDQ as compared with other instruments. This omission neglects the potential for the PDQ to demonstrate its predictive utility across other established measures of health-related functional outcomes. Additionally, research is needed to explore the utility of the PDQ in predicting healthcare costs.

SUMMARY

Chronic pain is a widespread and significant problem both individually and at a societal level. The most heuristic model for conceptualizing and treating chronic pain patients is the Biopsychosocial Model of chronic pain. This model has helped inform the Interdisciplinary Chronic Pain Management program treatment modality, which has demonstrated both treatment- and cost-effectiveness. Vitally important in measuring health outcomes are the instruments that are utilized towards this end. The PDQ has recently been included into the AMA's "Best Practice" guidelines for measurement of pain-related functional disability. The empirically validated PDQ has demonstrated excellent psychometric properties and shown good predictive validity in terms of health outcomes. Still, further research is required in evaluating the utility of the PDQ by comparing its predictive validity against other established health outcomes

measures. Additionally, in the modern climate of managed care and the emergence of CER, inspection of cost-effectiveness is currently of paramount importance alongside treatment effectiveness. No research has yet been conducted to evaluate the predictive utility of the PDQ with respect to healthcare costs, although the literature suggests that self-reported measures of functional health status are useful in predicting future medical expenses (Fan, et al., 2002). The present study compared the predictive ability of the PDQ against other established health outcomes measures in terms of a range of health-related outcomes. A secondary aim of the current study was to provide initial evaluation of the predictive utility of the PDQ with respect to healthcare cost. Results from this study will yield empirically established advancements in the understanding and utility of the PDQ, thus providing clinicians a greater ability to make evidence-based treatment decisions for patients with chronic pain.

CHAPTER TWO
Methodology

STUDY DESIGN

Setting

The current study population consisted of outpatients seeking treatment for chronic pain at the Eugene McDermott Center for Pain Management (EMCPM). The patients who participated in the study completed study measures at intake and at regular intervals over the course of the treatment. As part of a broader data collection effort, patients were asked to complete study measures at follow-up intervals spaced at every three months following the completion of treatment (terminating at 12 months post-treatment). The EMCPM, located in Dallas, Texas, is a part of The University of Texas Southwestern Medical Center. EMCPM offers both interdisciplinary chronic pain management programs as well as assorted general pain management interventions. The participants consisted of adult outpatients who were initiating care or receiving ongoing care at EMCPM. Patients were recruited for the study upon arrival to the waiting room area of EMCPM for their scheduled appointment with a EMCPM provider. Data collection and use was monitored by the Institutional Review Board of The University of Texas Southwestern Medical Center.

PARTICIPANTS

Inclusion Criteria

Patients were invited to participate in the study if they were initiating or receiving treatment intervention at EMCPM, were of adult age (18 and older),

were capable of providing informed consent, were able to read and speak English, were experiencing non-malignant pain-related problems, and were willing to allow access to their electronic medical records.

Exclusion Criteria

As the EMCPM does not typically provide care for children and adolescents (<18 years), children and adolescents were excluded from the present study. Empirically validated alternative language versions and norms are not available for every study measure involved in the current study. Thus, non-English speaking patients were excluded from the study. Also excluded were individuals with an identified source of pain solely stemming from cancer-related processes. Additionally, patients who were physically unable or unwilling to complete study questionnaires were excluded from the study. Patients were informed that declining to participate will not adversely affect the treatment received at EMCPM.

MEASURES

The data collected for the current study was composed of elements from a broader data collection effort at EMCPM. At the baseline time point, data was collected in the areas of demographic, personal history, psychosocial, psychiatric, and pain-related data. The pain-related data features evaluation of pain intensity, duration, associated opioid medication use, functional impairment, level of disability, and pain behaviors. Additionally, data was collected to identify healthcare utilization and allow for calculation of treatment costs.

Taken from this overall data collection were the specific measures utilized in the current study. These measures were the Pain Disability Questionnaire, the Short Form (36) Health Survey, PROMIS Bank v1.0- Physical Function, PROMIS Bank v1.0- Pain Interference, PROMIS Bank v1.0- Pain Behavior, and the Healthcare Utilization survey. The data collected from patients following treatment (i.e., post-treatment) consisted of the same baseline measures with the exception of demographic measures, the SF-36, and personal history measures. Again, data utilized for the current study reflected the same measures utilized at baseline with the exception of the SF-36. Thus, the current study implemented a pre- and post-treatment data collection structure.

The three PROMIS measures utilized in the current study were the PROMIS Bank v1.0- Physical Function, PROMIS Bank v1.0- Pain Interference, and the PROMIS Bank v1.0- Pain Behavior. As the precision level of PROMIS measures may be adjusted as desired by primary investigators, a brief description of this process is warranted with regard to the current study. According to Gershon and colleagues (2010), precision level using the PROMIS web-based resource Assessment Center (www.assessmentcenter.net) may be set at 90% or 95%. The level of precision with respect to confidence intervals was preset at 95% for all PROMIS CATs in the current study. According to Cella et al. (2010), CAT versions reach the preset level of precision in an average of five administered items.

PROMIS- Physical Functioning Scale

The PROMIS Physical Function Item Bank 1.0 (PROMIS-Physical Functioning) is a 124-item measure designed to assess physical functioning. Physical function refers to the individual's ability to conduct activities that require physical capability. The PROMIS-Physical Functioning employs a Likert-type scale ranging from one (e.g., "Unable to do") to five (e.g., "Without any difficulty"). These activities range from basic self-care behaviors to more dynamic activities requiring various degrees of mobility, endurance, and strength. The PROMIS-Physical Functioning includes four related sub-domains: mobility, dexterity, axial, and ability to carry out instrumental activities of daily living. Mobility refers to aspects of lower extremity function, whereas dexterity regards upper extremity function. The axial domain is intended to capture neck and back function.

PROMIS Sub-Domains of Pain

Regarding pain, this PROMIS domain is divided into two sub-domains which feature aspects of two conceptual dimensions. Together, these sub-domains comprise the construct of the patient's experience of pain. The total normative sample for both of the Pain sub-domains consisted of 967 chronic pain patients (Amtmann, et al., 2010).

PROMIS- Pain Interference

The PROMIS Pain Interference Item Bank 1.0 (PROMIS-Pain Interference) consists of 41 items that assess components of "pain quality." The

items in this first sub-domain assess the characteristics, intensity, frequency, and duration of pain. Accordingly, the items evaluate the impact of pain quality upon the individual's physical, mental and social activities (Amtmann, et al., 2010). Cronbach's Alpha internal consistency coefficients for both Pain category sub-domains ranged from 0.96 to 0.99 (Amtmann, et al., 2010). Although some items were found to show differential item functioning, Amtmann and colleagues (2010) noted that each of these items was included in the final PROMIS-Pain Interference item bank and adjustment for these items resulted in minimal impact on overall score estimates.

PROMIS- Pain Behavior

The second PROMIS sub-domain that comprises the construct of pain regards pain-related behaviors. The PROMIS Pain Behavior Item Bank 1.0 (PROMIS –Pain Behavior) consists of 39 items that evaluate behaviors used to reduce, avoid, and minimize pain (Cella, et al., 2007). Again, differential item functioning displayed negligible impact on overall score estimates for this measure (Cella, et al., 2010). Additionally, the PROMIS-Pain Behavior displayed high unidimensionality, high internal consistency, and good coverage of the pain behavior construct (Revicki, et al., 2009).

Short-Form Health Survey (SF-36)

The Short-Form Health Survey (SF-36) is a 36-item self-report measure designed to evaluate a range of health outcomes and aspects of health-related quality of life (Ware, et al., 2000). The SF-36 was initially created as a tool to

assess health status in the Medical Outcomes Study (Ware & Sherbourne, 1992). It was designed to evaluate multidimensional health concepts including: health-related limitations in physical activities, restrictions in social activities due to physical or emotional problems, health-related restrictions in usual role activities, bodily pain, general mental health, limitations in usual role activities because of emotional problems, vitality, and general health perceptions. There is also one item intended to assess transition, but this item is not used to score any of these eight subscales. Additionally, scores from the SF-36 may be broken into two primary factors deemed the Physical Component Summary (PCS) and Mental Component Summary (MCS) scales, respectively (Ware, Kosinski, & Keller, 1994). It has demonstrated excellent validity, including both psychometric and clinical validity across physical and mental health constructs (McHorney, Ware, & Raczek, 1993). Additionally, the SF-36 has displayed very strong reliability across diverse patient populations (McHorney, Ware, Lu, & Sherbourne, 1994). Further, subsequent research has established the SF-36 as one of the most robustly validated and highly utilized measures of health outcomes and quality of life available (Contopolous-Ioannidis, et al., 2009).

Pain Disability Questionnaire

The Pain Disability Questionnaire (PDQ) is a 15-item self-report measure of pain-related functional status. It has demonstrated excellent validity and reliability across multiple studies (e.g., Anagnostis, Gatchel, & Mayer, 2004; Gatchel, Mayer, & Theodore, 2006). Unlike other measures of pain and functional

disability (e.g., ODI), this instrument was created for use with the full range of chronic disability musculoskeletal disorders rather than specific pain disorders. The items are intended to measure the degree to which the patient's functioning is impacted by pain. Test takers score the items on a 10-point likert-type scale (0 = No problems, 10 = Total impairment). The scores may be collectively summed to yield a total functional disability score ranging from 0 (optimal function) to 150 (total disability). These total summed scores reflect the severity of patient-rated disability, and may be placed in one of three descriptive categories. The categories include Mild/Moderate (1 – 70), Severe (71 – 100), and Extreme (101 – 150) severity. Additionally, based on a factor analysis, a two-factor structure of the PDQ was revealed (Anagnostis, et al., 2004). The two identified factors are a Functional Status Component (FSC) and a Psychosocial Component (PSC).

Of note, in the current study, a wide array of pain conditions were included. As the population receiving care at the data collection site was heterogeneous in terms of pain concerns, it remains possible that participants were included in the sample that did not fall specifically within the CDMSD population. As a clinical sample, the expectation is that inclusion of a more fully representative sample of pain problems will result in a better understanding of the generalizability of the predictive value of the PDQ. As consideration was provided to a heterogeneous group of chronic pain patients included during initial validation of the PDQ, the confounding effect of not using a completely "pure" sample of CDMSD patients in the current study was minimal. In fact, as stated by

PDQ developers, “This measure appears to have comparable utility for use with a more heterogeneous chronic pain disability population (Anagnostis, et al., 2004).”

Three Month Follow-up Healthcare Utilization Survey

Additionally, data was collected regarding each patient’s utilization of healthcare services over a three month time period following the post-treatment time point. Items evaluated the number of healthcare provider visits, specific procedures performed, medication use, and ER/hospital visits. Additionally, this questionnaire distinguishes between pain-related healthcare utilization and non-pain-related healthcare utilization. This allows for a more detailed analysis of pain-specific healthcare utilization rather than healthcare use overall.

PROCEDURE

The current study consisted of a pre- and post-treatment structure. Participants (adult outpatients who were initiating care or receiving ongoing care at EMCPM) were greeted by study personnel prior to their appointment with EMCPM providers. At baseline data collection, participants were asked to complete a HIPPA release form and a UTSW IRB-approved Informed Consent form. Study personnel reviewed these forms with participants, answered any participant questions, and then proceeded to provide instructions for CAT administration of study measures with EMCPM computers.

The participants were asked to complete various measures centered on their perception of pain, healthcare utilization, pain medication use, and other

demographic and historical measures regarding the patient's pain experiences. These measures were accessed online by study personnel using the PROMIS-based web resource "Assessment Center." After reviewing instructions for completing study questionnaires, study personnel informed the participants that they may request help at the nearby nurse station, and study personnel were available to provide support. The instruments utilized for the current study were the Pain Disability Questionnaire, the Short-Form Health Survey (SF-36), PROMIS Bank v1.0- Physical Function, PROMIS Bank v1.0- Pain Interference, PROMIS Bank v1.0- Pain Behavior, and the Three Month Follow-up Healthcare Utilization survey. These assessment instruments were provided in an online survey format using EMCPM computers. Short-forms versions for each of the respective PROMIS measures (e.g., PROMIS Bank v1.0- Pain Behavior) were offered to those participants who lacked basic computer proficiency to participate in the online survey format.

At the post-treatment time point (approximately four weeks post-baseline), participants were greeted by study personnel at their final (not including follow-ups) scheduled appointment with EMCPM providers. Participants again had any questions answered, and then proceeded to complete the aforementioned study measures. Again, as part of the more extensive data collection effort at EMCPM, participants were reminded that they may be asked to participate in follow-up data collection at later time points.

STATISTICAL ANALYSIS PLAN

All analyses were conducted utilizing the SPSS software program. The PDQ sum score and severity categories, respectively, served as the independent variable in the following analyses. Osborne (2003) and colleagues identified the importance of establishing construct validity for scale evaluation. They hoped to benchmark a new instrument against the established SF-36 by evaluating the degree to which it measures up to SF-36 performance in their sample. The current study represents a similar attempt to evaluate the utility of the psychometrically sound PDQ against other comparable instruments. Accordingly, divergent and convergent validity were evaluated, and the relative strengths of correlations between instruments were expected to reflect the theorized direction of the pain-related functional disability construct featured in the PDQ. By comparing the PDQ severity categories to other established measures of pain and health-related outcomes using bivariate correlation models, construct validity was confirmed with the current sample, thus bolstering the robustness of the findings.

According to Shultz and Whitney (2005), one type of examination of criterion-related validity is through evaluation of predictive validity. Thus, a hierarchical linear regression model was utilized in order to evaluate the predictive criterion-related abilities of the PDQ, SF-36, and PROMIS measures, respectively, in terms of health outcomes prediction from pre- to post-treatment. Health outcome criterion variables to be considered included pain-related disability, psychosocial symptoms, and treatment related variables (e.g., quality of

life). Given the anticipated differences between total N for baseline versus post-treatment measures, multiple time-point analyses conducted utilized a paired-sample approach as appropriate. Univariate regression models were conducted to identify potential covariates (i.e., baseline patient demographic data, psychological factors, etc.). By using this form of analysis, covariates were identified and controlled for, thus bolstering validity.

There exists some controversy in the literature regarding the use of stepwise regression models. For example, Thompson (1995) identifies three areas of concern when utilizing these models. Inaccurate computer software models, problems with identifying the best variable set of a given size, and issues with replicability based on inappropriate consideration of sampling error are all considered areas of imperfection with stepwise regressions. The implication is that it offers biased regression coefficients in the direction of being too elevated. Inappropriate use of stepwise methods such as data mining primes the statistical complications, and therefore is discouraged. So, the current study did not utilize a stepwise approach, but rather featured hierarchical regression models as better supported in the literature (e.g., Petrocelli, 2003).

For some of the statistical analyses, PDQ scores were categorized into one of the three severity groups for this instrument. Again, those categories are Mild/Moderate (1 – 70), Severe (71 – 100), and Extreme (101 – 150). The literature suggests that this categorization approach supports practical application as well as clinical utility, including demonstrated efficacy in health outcome

prediction by the similarly scaled MVAS instrument (Anagnostis, et al., 2003). Each severity group was also assessed to identify any between or within group differences. Subgroup analyses for each of the PDQ severity categorization groups were performed to identify patient factors associated with improvements in patient outcomes and reductions in healthcare utilization.

Additionally, regression modeling was used to evaluate the secondary aim of the study. Namely, the analyses investigated the validity of the PDQ in predicting healthcare utilization cost at three-month follow-up time point. Healthcare utilization was assessed using the Three Month Follow-up Healthcare Utilization survey and included data on healthcare provider visits, procedures/treatments, medication use, and ER/hospital visits. One method described in the literature to evaluate cost-effectiveness is to consider the amount of healthcare utilization and resources that an individual consumes in treating their health problem (Turk, 2002). From this data, an estimate may be generated about the monetary costs of this healthcare consumption. Healthcare cost information for the current study was based on data collected from the AHRQ-supported Medical Expenditures Panel Survey (Medical Expenditures Panel Survey, 2013) as well as procedural charges from the McDermott Center for Pain Management. Using this data, healthcare cost estimates were created for each participant based upon reported healthcare utilization.

A categorical approach was utilized in order to support the practical application of a predictive model of healthcare consumption costs. Participants

were placed in either a “Low” or “High” healthcare cost group. A cutoff score was established in order to dichotomize this variable for statistical analysis. The low healthcare cost group was comprised of individuals reporting average or below average healthcare costs as compared to an estimate of the average healthcare costs for the overall chronic pain population. The high healthcare cost group consisted of individuals reporting above average healthcare costs as compared to an estimate of the average healthcare costs for the overall chronic pain population. Thus, for the present study, average healthcare costs of chronic pain patients was based on reported treatment and average cost data available in the literature (e.g., National Academy of Science, 2011). Bagley, White, and Golomb (2001) indicate that logistic regression modeling is the appropriate analysis when using dichotomous outcomes, as is the case in this analysis.

Additionally, linear regression modeling was employed to investigate the predictive validity of the PDQ in terms of summed total score. PDQ summed score at baseline was evaluated for associations with healthcare costs at three month follow-up. By using a continuous variable (healthcare cost in U.S. dollars), increased precision was afforded in the current study.

Baseline data was examined for any significant within-group demographic differences in order to statistically account for any observed differences for subsequent analyses. A priori power and sample size requirements were calculated by utilizing the GPower 3.1 power analysis software. This program was developed, in part, to provide a priori calculations of statistical power (Mayr,

et al., 2007). Power analyses of the primary statistical models indicated that a sample size of 89 participants would be required in order to satisfy statistical significance with 95% power and alpha error probability at .05. The primary models under this a priori calculation provided strong support for the statistical validity of the current study. Post-hoc power analyses were conducted for the realized sample size to describe that the study sample's achieved power level.

HYPOTHESES

Hypothesis One: At the pre-intervention time point, scores on the PDQ will demonstrate significant positive correlations with the SF-36, PROMIS – Physical Functioning, PROMIS- Pain Behavior, and PROMIS – Pain Interference, respectively. Thus, the PDQ (and associated PDQ severity categories) will have confirmed construct validity with the current sample. As detailed in the statistical plan, each study outcome variable will be examined for significance and will utilize a Bonferroni correction. Primary outcome variables include:

- Treatment variables (Health-related Quality of Life)
- Psychosocial symptom level (Anger, Anxiety, and Depression)
- Pain-related symptom level (Pain Behavior, Pain Disability, Physical Functioning)

Hypothesis Two: a) Scores on the PDQ, SF-36, PROMIS- Physical Functioning, PROMIS-Pain Behavior, and PROMIS- Pain Interference, respectively, will evidence significant differences among their respective abilities to predict primary

outcome variables. Specifically, the PDQ scores will demonstrate stronger correlation coefficients (i.e., greater predictive ability) than SF-36, PROMIS-Physical Functioning, PROMIS-Pain Behavior, and PROMIS- Pain Interference, respectively, with each of the outcome variables. As detailed in the statistical plan, each study outcome variable will be examined for significance using hierarchical regression modeling. Primary outcome variables parallel those listed in *Hypothesis One*.

b) Pre-treatment PDQ severity categories will evidence significant differences in their respective correlations with primary outcomes variables. Extreme severity type will be most strongly correlated with negative health outcomes and Mild/Moderate severity type will be least strongly correlated with negative health outcomes. Primary outcome variables parallel those listed in *Hypothesis One*.

Hypothesis Three: The PDQ categories will evidence significant differences in their respective ability to predict healthcare utilization. It is hypothesized that the PDQ scores in the Extreme category will be most predictive (i.e., most strongly and positively correlated) of the "High" category of healthcare costs, as calculated and dichotomized according to the aforementioned description in the statistical plan. Additionally, Mild/Moderate category will be most predictive of the "Low" category of healthcare costs. As detailed in the statistical plan, the healthcare cost variable will be examined for significance using logistic regression modeling. Primary outcome variables will include:

- Healthcare cost category (e.g., “low” versus “high” dichotomized variable) as estimated by data collected from Three Month Follow-up Healthcare Utilization. For added precision, cost as a continuous variable was also examined.

CHAPTER THREE

RESULTS

Sample Size

The sample size for the current study included 254 participants. Included in the sample cohort were all participants who completed the core baseline time-point measures. A total of 257 participants were consented; however, 3 of these were not included in the sample due to non-completion of assessments. As the current sample size was unbalanced across time points, the participant follow-up rate was reported for each statistical analysis conducted involving multiple time points. The actual number of participants who completed the post-treatment and 3-month follow-up time points reflects the follow-up rate for this cohort. Various factors contributed to variance in N across time points, including participant non-completion of treatment, adjustments in specific measures utilized for the assessment batteries in the aforementioned broader data collection effort, and lost to follow-up issues (e.g., outdated contact information, death, etc.). Again, the statistical analyses conducted for the present study considered and controls for the group size differences, as described in the Statistical Analysis. For clarity, the total number of participants who completed each respective primary outcome measure are described in Table 1.

Demographic Variables

Table 2 displays demographic information regarding gender, race, and ethnicity for this sample. Demographic data reported here represents information obtained at baseline. By gender, there were a total of 180 females and 74 males. The study sample consisted of Caucasian (73.2%), Black (16.9%), Asian (1.2%), American Indian or Alaska Native (0.8%), Native Hawaiian or Other Pacific Islander (0.4%), Other (3.5%), and 3.9% participants not providing information on race. In terms of ethnicity (N = 169), 78.7% were Not Hispanic or Latino, 5.3% were Hispanic and Latino, and 16.0% did not provide data on their ethnicity. The mean age of the participants in this sample was 49.72 (SD= 14.55), and the ages ranged from 18 to 81 (See Table 3). Analyses of differences between baseline and post-treatment sample cohorts revealed that participants at the post-treatment time point tended to have a greater relative percentage of males (32.5% versus 27.9% for baseline-only cohort) and were slightly younger on average (49.04 versus 49.75 for baseline-only cohort). Both cohorts included a similar distribution by race as well as ethnicity.

Of those participants for whom psychiatric history was reported (N = 69), 42% reported a history of anxiety spectrum disorders, and 30.4% reported a history of mood disorders. Reported (N = 145) pain conditions included back, spine, or neck problems (37.2%), generalized pain problems (15.9%), leg or foot pain problems (13.1%), thoracic or abdominal pain problems (11.7%), head or facial pain problems (8.3%), and 13.8% characterized pain as “Other”.

A total of 26.4% of study participants reported receiving current disability benefits, and 72.5% were unemployed (including part time and full time work). Mean score on the PDQ at baseline was 92.85 (95% CI: 88.89-96.80). The mean (95% CI) score on the PROMIS-Pain Behavior was 60.71 (60.11-61.32), PROMIS-Physical Functioning 35.84 (34.84-36.83), and PROMIS-Pain Interference 65.81 (64.92-66.71) are described in Table 1 along with other primary outcome variables. Given the standardized chronic pain population norms (Mean = 50, SD = 10), the current sample demonstrated relatively poor physical functioning, significant use of pain behaviors, and high pain-related interference.

Statistical Analyses

Pearson product-moment correlations were conducted to explore the relationships between outcome measures. Table 4 displays these data for each of the primary outcome variables (a post-hoc Holm-Bonferroni method was also employed in order to control for Familywise error rate). Correlation coefficients were all observed to be in the directions predicted between the primary outcome variables. In other words, conceptually-related measures and subscales were more strongly associated with related rather than unrelated scales. This finding provides support for convergent and divergent validity of the measures in the current sample.

One-tailed bivariate correlations were conducted in order to evaluate the relative relationships between the PDQ baseline summed score and the PDQ

severity category, respectively, against baseline SF-36 and pain-related PROMIS measures. Results indicated a large effect size (0.91) for the relationship between the PDQ baseline summed score and the PDQ severity category. Additionally, large effect sizes were observed between the PDQ baseline summed score and PROMIS-Pain Interference (r =0.70), PROMIS-Physical Functioning (r =-0.64) and PROMIS-Pain Behavior (r =0.56). The PDQ also demonstrated a strong relationship with the SF-36 PCS as theoretically anticipated. The SF-36 MCS did not demonstrate statistically significant correlations (following the Holm-Bonferroni adjustment) with the PROMIS-Physical Functioning measure or with the PDQ. The lack of significant correlations in this study was surprising, as previous research (e.g., Anagnostis, et al., 2004) found significant associations between the PDQ and SF-36 component summaries. As implied by the SF-36 MCS title, the constructs measured by the MCS differs intuitively from measures focusing on physical functioning and physical components of pain-related disability. So perhaps the lack of significant correlation here was reflective of the focus on different constructs, the use of a conservative statistical adjustment in the current analyses, or perhaps represented a unique artifact with the current study cohort.

The PDQ severity category scores demonstrated comparable performance in terms of strength and direction of correlation coefficients, as compared with the performance of the PDQ baseline summed score. Correlation coefficients with each of the other measures was slightly lower in strength as compared to PDQ

baseline summed score, but all were significant and in the direction theoretically expected. Importantly, the PDQ summed score, component scores (FSC & PSC), and PDQ severity category scores were very strongly and positively correlated, with all reflecting significant statistical correlations with each of the other primary outcome variables. For example, PROMIS-Pain Interference was positively correlated with the PDQ summed score ($r = .70$, $p < .001$), PDQ Psychosocial Component ($r = .67$, $p < .001$), PDQ Functional Status Component ($r = .65$, $p < .001$), and PDQ severity category ($r = .64$, $p < .001$). Subsequently, these outcomes provide support for the robustness of the current sample in being consistent with theorized and observed relationships found throughout the relevant literature.

As displayed in Table 4, results for the other study measures were all significantly correlated with the other primary study measures in the directions anticipated. Generally, the PDQ summed score provided the strongest overall associations across measures. Effect sizes for associations between PROMIS-Pain Behavior and PROMIS-Physical Functioning ($r = 0.29$, $p < .001$), as well as for PROMIS-Pain Behavior and SF-36 PCS ($r = 0.24$, $p < .01$) were found to be relatively small. This may have been due to inclusion of emotional content in the development of PROMIS-Pain Behavior items and, as such, were independent of the physical functioning construct.

Primary Analyses

Prior to conducting multiple regression analyses, it was necessary to assure that the obtained data did not violate the requisite statistical assumptions (e.g., multicollinearity issues). Thus, all primary study independent variables were evaluated for collinearity and demonstrated acceptable collinearity tolerance according to recommended guidelines by O'Brien (2007). Subsequently, they were included in the following models (exceptions to other statistical assumptions are described below by analysis).

Independent samples t-tests for gender and ethnicity categories were completed for the primary study outcome variables. Levene's test revealed no significant differences in population variance by gender for the outcome variables, except for the PROMIS-Physical Functioning and SF-36 PCS. However, no statistically significant difference was identified by gender with the SF-36 PCS, indicating that the difference between means is likely due to chance. Significant differences were observed by gender with respect to PROMIS-Physical Functioning [$t(206) = 3.07$, $p < .01$]. No other significant differences were observed between gender groups. There were also no significant differences found in analyses for the ethnicity categories of Hispanic or Other.

Also, an analysis of variance was utilized to evaluate age-related differences in the primary outcome measures. The results of the ANOVA indicated that age was a significant factor for PROMIS- Physical Functioning baseline mean [$F(57)=1.42$, $p<.05$]. No statistically significant demographic

between-group differences were found between the PDQ severity categories. Also, based on the results of a one-way MANOVA, there was no statistically significant difference in primary outcome scores by race (see Table 5).

The current study utilized hierarchical linear regression modeling for the primary study outcomes. Petrocelli (2003) provides recommendations for the order of entry in hierarchical regression models. Among his recommendations, Petrocelli suggests that predictor variable entry may be organized by the hierarchical relevance of each predictor to the criterion. An exploratory analysis was first utilized in order to guide predictor input in the hierarchical regression models. Certain PROMIS-based measures (e.g., PROMIS-Sleep Impairment, PROMIS-Fatigue) were excluded from the resulting models due to multicollinearity problems. Both of these measures were found to be strongly correlated with PROMIS-Depression, and likely reflected an element of vegetative symptoms often seen in mood disorders.

Using the results of the exploratory analysis along with Petrocelli's guidelines for predictor variable input order for each model, SF-36 summary scores were entered as the collective first block given their well-established, empirically-guided expectation of predictive utility across health-related outcomes. The PDQ baseline summed score was entered in order to detail the predictive ability of the PDQ above and beyond that already explained by SF-36 predictor variables. PROMIS-Pain Behavior, PROMIS-Pain Interference, and PROMIS-Physical Functioning were entered next as individual predictors.

Except for gender and age-related mean differences in PROMIS-Physical Functioning, preliminary analyses gave no statistically significant indication of mean differences among demographic variables, and thus demographic variables were not included as covariates in the regression models except for the PROMIS-Physical Functioning.

In order to examine the unique contribution of the PDQ in the prediction of health-related outcomes, hierarchical regression analyses were conducted. Primary study variables (including the PDQ) that explain health outcomes were entered as described above for evaluation of each primary outcome variable. The criterion variables included psychosocial factors (anger, anxiety, and depression), pain-related factors (pain behavior, pain interference, and physical functioning), and quality of life factors (social satisfaction-discretionary social activities, satisfaction with social roles). ANOVAs revealed that the models described below were each found to be statistically significant. The results of the regression model summaries and coefficients are displayed in Tables 6 through 13.

Regarding the psychosocial factor Anger, results of the regression models indicated that the variance accounted for in a model featuring SF-36 MCS and SF-36 PCS (one block), PROMIS-Pain Behavior, PROMIS-Physical Functioning, PROMIS-Pain Interference, and the PDQ baseline summed score equaled 38%. This finding was significantly different from zero [$F(6, 94) = 9.53$, $p<.001$]. However, neither PROMIS-Physical Functioning nor PROMIS-Pain Interference significantly contributed to change in variance. SF-36 MCS ($\beta = -.18$, $p = .05$) and

Pain Behavior (β = .53, p<.001) were statistically significant predictor variables in this model. The regression model summary and coefficients are presented in Table 6.

Regression analyses for Anxiety revealed statistically significant findings as well. The variance accounted for in a model featuring the SF-36 MCS and SF-36 PCS (one block), the PDQ baseline summed score, PROMIS-Pain Behavior, PROMIS-Pain Interference, and PROMIS-Physical Functioning equaled 46%. This finding was significantly different from the null [F(6, 93) = 13.10, p<.001]. Again, neither PROMIS-Physical Functioning nor PROMIS-Pain Interference significantly contributed to change in variance. The PDQ contributed to an increase of 14.7% in change in variability accounted for in this model, which was significantly different from zero [F(1, 96) =21.84, p<.001]. Significant predictors in this model were the SF-36 MCS (β= -.33, p<.001); SF-36 PCS (β= .28, p< .05); PDQ (β= .21, p= .09); and PROMIS-Pain Behavior (β=.34, p<.01). The regression model summary and coefficients are presented in Table 7.

Regression analyses for Depression also revealed statistically significant findings. The variance accounted for in a model featuring the SF-36 MCS and SF-36 PCS (one block), the PDQ baseline summed score, PROMIS-Pain Behavior, PROMIS-Pain Interference, and PROMIS-Physical Functioning equaled 53%. This finding was significantly different from zero [F(6, 95) = 17.78, p<.001]. The PDQ contributed to an increase of 12.6% in change in variability accounted for in this model, which was significantly different from zero [F(1, 98)

=19.16, p<.001]. However, the PDQ was not found to be a significant individual predictor in this model. Significant predictors in this model were the SF-36 MCS (β= -.33, p<.001), and PROMIS-Pain Behavior (β=.46, p<.001). The regression model summary and coefficients are presented in Table 8.

Another set of criterion variables centered on pain-related factors. For example, regression analyses for Pain Behavior revealed statistically significant findings. The variance accounted for in a model featuring the SF-36 MCS and SF-36 PCS (one block), the PDQ baseline summed score, PROMIS-Pain Interference, and PROMIS-Physical Functioning equaled 58%. This finding was significantly different from zero [F(5, 96) = 26.28, p<.001]. The PDQ contributed to an increase of 24.9% in change in variability accounted for in this model, which was significantly different from zero [F(1, 98) =38.69, p<.001]. In fact, only the PDQ (β=.27, p=.01) and Pain Interference (β=.59, p<.001) were found to be significant individual predictors in this model. The regression model summary and coefficients for Pain Behavior can be seen in Table 9.

Regression analyses for Pain Interference revealed statistically significant findings. The variance accounted for in a model featuring the SF-36 MCS and SF-36 PCS (one block), the PDQ baseline summed score, PROMIS-Pain Behavior, and PROMIS-Physical Functioning equaled 60%. This finding was significantly different from zero [F(5, 96) = 28.71, p<.001]. The PDQ contributed to an increase of 26.7% in change in variability accounted for in this model, which was significantly different from zero [F(1, 98) =43.52, p<.001]. Only the

PDQ (β=.26, p=.01) and Pain Behavior (β=.56, p<.01) were found to be significant individual predictors in this model. The regression model summary and coefficients are presented in Table 10.

As mentioned previously, significant mean differences were found between gender and age for the PROMIS-Physical Functioning. The results of step one indicated that the variance accounted for by age and gender (block) equaled .08, which was significantly different from zero [F(2, 99)=4.06, p<.001). Models incorporating the SF-36, PDQ, PROMIS-Pain Behavior, and PROMIS-Pain Interference contributed to a total of 65% variance accounted for [(F(1, 96)=20.32, p<.001]. Gender (β=-.15, p<.05), SF-36 PCS (β=.55, p<.001), and PDQ (β=.-34, p<.001) contributed significantly to the explanation of variance in Physical Functioning. The regression model summary and coefficients for PROMIS-Physical Functioning can be seen in Table 11.

Primary outcome variables also included quality of life factors. Regression analyses for Social Satisfaction-Discretionary Social Activities revealed statistically significant findings. The variance accounted for in a model featuring the SF-36 MCS and SF-36 PCS (one block), the PDQ baseline summed score, Pain Behavior, Pain Interference, and Physical Functioning equaled 46%. This finding was significantly different from zero [F(6, 95) = 13.24, p<.001]. The PDQ contributed to an increase of 11.8% in change in variability accounted for in this model, which was significantly different from zero [F(1, 98) =14.81, p<.001]. However, the PDQ was not found to be a significant individual predictor in this

model. Significant predictors in this model were the SF-36 MCS (β= -.17, p<.05), and PROMIS-Pain Interference (β=-.69, p<.001). The regression model summary and coefficients are presented in Table 12.

Regression analyses for Satisfaction with Social Roles revealed statistically significant findings. The variance accounted for in a model featuring the SF-36 MCS and SF-36 PCS (one block), the PDQ baseline summed score, Pain Behavior, Pain Interference, and Physical Functioning equaled 42%. This finding was significantly different from zero [F(6, 86) = 10.20, p<.001]. The PDQ contributed to an increase of 12.1% in change in variability accounted for in this model, which was significantly different from zero [F(1, 89) =16.16, p<.001]. In this model, the only significant individual predictor was Pain Interference (β=-.33, p<.05). The regression model summary and coefficients for Satisfaction with Social Roles can be seen in Table 13.

Furthermore, a multiple regression analysis was conducted to evaluate the degree to which PROMIS pain-related measures were able to predict pain disability as measured by the PDQ. The linear combination of PROMIS measures, as expected, were significantly associated with pain-related disability [F(3, 130) = 28.03, p<.01]. Accordingly, pain behavior, pain interference, and physical functioning accounted for 39% of the variance in pain disability. Individuals reporting higher amounts of pain interference, pain behavior, and relatively poor physical functioning tend to have higher levels of pain-related disability as measured by the PDQ.

Of note, as seen in Table 14, 93.9% of participants completing the PDQ measures at both baseline and post-treatment (N= 84) remained stable or improved in terms of categorization of severity from baseline to post-treatment. In total, 37.8% categorically improved from one severity category to another.

Analyses by PDQ Severity Category

A one-way multivariate analysis of variance was conducted to determine the association of the three PDQ severity categories on the primary outcome measures. Table 15 presents the results of this analysis. In order to account for multiple ANOVA tests being run and reduce Type One errors, a Bonferroni correction was utilized. The results of the MANOVA revealed significance for each respective primary outcome measure except for the SF-36 MCS. Similarly, significant between group differences were observed by category across primary outcome measures, but no significant between group differences were observed by category for the SF-36 MCS. Table 16 presents the results of the multiple comparisons.

A one-way multivariate analysis of variance was also conducted to determine the association of the three PDQ severity categories on the primary outcome variables. Bonferroni post hoc analyses for the univariate ANOVA's revealed that, at the .05 level, there were multiple statistically significant mean score differences. Significant differences were found among the three PDQ categories, Wilks' lambda = .47, $F(14, 360) = 11.71$, $p < .001$. Table 17 presents

the results of this analysis. The multivariate eta squared was found to be strong at .31.

In fact, mean scores for every one of the primary outcome variables were significantly different between severity categories, with only two exceptions. The exceptions were the means for Mild/Moderate and Severe categories for Pain Behavior as well as the means between the Severe and Extreme categories for Anger. The results of the multiple comparisons by severity category are displayed in Table 18. Figures 1 through 4 graphically display representative results of the ANOVAs. These findings suggest excellent discriminative abilities between the PDQ severity categories in biopsychosocial components of chronic pain.

Secondary Analyses

Because a secondary aim of the current study was to evaluate the predictive validity of the PDQ in terms of healthcare costs, regression analyses were conducted for both categorical "low" versus "high" healthcare cost users, as well as estimated healthcare cost in U.S. dollars. As described in the statistical plan, healthcare cost categories were based on estimated healthcare costs and compared against norms for chronic pain populations. Those participants with estimated healthcare costs that were below the national average were considered "low" healthcare cost users. Participants with estimated healthcare costs that were at or above the national average were considered "high" healthcare cost users.

Logistic regression analyses were utilized to investigate the ability of the PDQ to predict low versus high healthcare users. The PDQ severity categories did not demonstrate significant differences in their respective ability to differentiate between "low" and "high" healthcare cost categories at either baseline or post-treatment. Limited sample size likely contributed to this finding, as assumptions of variance between categories was violated between groups. To address this concern, a logistic regression analysis was also utilized with the PDQ summed score at baseline. Omnibus tests of model coefficients revealed a chi square of 7.61 (df=1, $p<.01$), supporting the overall significance of the model and that adding the PDQ baseline summed score to the model significantly increased the model's predictive ability. The overall success rate of prediction for this sample was 67.3% (up from 55.1% in the null model). The calculated odds ratio Exp(*B*) for this model was 1.11 ($p=.01$). Results of this logistic regression modeling are presented in Table 19.

As an additional component of the secondary analyses, analyses were conducted utilizing healthcare cost as a continuous variable based on estimated healthcare costs in U.S. dollars. Based on the exploratory analysis, a fairly broad range ($0.00 to >$16,000) was observed. One extreme outlier case contributed to significant skew and was thus excluded from further analyses in order to provide a more accurate representation of the overall sample. The summed total score of the PDQ at post-treatment time point demonstrated significant and positive coefficients ($r = 0.39$, $p=.02$), with estimated healthcare costs at 3-month follow

up time point. The summed total score of the PDQ at baseline demonstrated even stronger associations ($r = .42$, $p<.01$) with estimated healthcare costs at 3-month follow-up time point (see Table 20). A one-way ANOVA revealed no significant differences in healthcare cost correlation coefficients with respect to PDQ severity categories. Post-hoc results using a Bonferroni correction did not significantly differentiate between the PDQ severity categories in terms of associations with estimated healthcare costs at three month follow-up time point. Similarly, post-hoc tests revealed no significant mean differences between each of the respective categories.

Hypotheses

Hypothesis One*: At the pre-intervention time point, scores on the PDQ will demonstrate significant positive correlations with the SF-36, PROMIS – Physical Functioning, PROMIS- Pain Behavior, and PROMIS – Pain Interference, respectively.*

The results of a One-Way ANOVA and associated bivariate correlations revealed strong support for Hypothesis One. All hypothesized conditions were found to be statistically significant. PROMIS-Pain Interference was found to violate assumptions of homogeneity of variance, and thus the Games-Howell post-hoc test was reported for this item to describe the unequal variances. Importantly, all correlations were in the direction anticipated and effect sizes were

generally moderate to large according to Cohen's (1988) definitions. The respective measures are described in more detail below.

SF-36 Measure

As the SF-36 was scored according to its two primary summary indices, both the SF-36 Mental Component Summary scores and SF-36 Physical Component Summary scores were included. Results from the bivariate correlation model revealed a large effect size between the PDQ baseline scores and SF-36 PCS scores ($r=0.607$, $p<.001$). As theoretically indicated, there was a much weaker correlation ($r=-.199$, $p<.001$) between the PDQ baseline scores and the less-related constructs considered by the SF-36 MCS. These findings support Hypothesis One and demonstrate the close relationships between the theorized constructs.

PROMIS Measures

The results also demonstrated significant correlations between the PDQ and each of the respective primary PROMIS measures featured in the current investigation. Correlation coefficients between the PDQ and PROMIS-Pain Behavior ($r =.56$, $p<.001$), PROMIS-Physical Functioning ($r =-.64$, $p<.001$), and PROMIS-Pain Interference ($r =.70$, $p<.001$), respectively, are all considered strong. Again, these large effect sizes support Hypothesis One and demonstrate evidence for construct validity.

The convergent validity of these measures appears strong and collectively suggests suitability of these measures for inclusion in the current study's primary analyses.

***Hypothesis Two**: **a)** Scores on the PDQ, SF-36, PROMIS- Physical Functioning, PROMIS-Pain Behavior, and PROMIS- Pain Interference, respectively, will evidence significant differences among their respective abilities to predict primary outcome variables.*

Hypothesis Two for the present study was partially supported by the results of hierarchical regression models. Hierarchical linear regression models were employed to evaluate and compare predictive abilities of the primary study measures. The criterion variables included psychosocial factors (anger, anxiety, and depression), pain-related factors (pain behavior, pain interference, and physical functioning) and quality of life factors (social satisfaction-discretionary social activities, satisfaction with social roles). As seen in Tables 6 through 13, the PDQ demonstrated good predictive abilities across multiple biopsychosocial outcome variables as compared with other primary study measures. The PDQ contributed to several predictive models with significant r square changes. This finding suggests that the PDQ provides good predictive utility, as well as additive predictive precision, "above and beyond" that described by the other primary study measures.

b) *Pre-treatment PDQ severity categories will evidence significant differences in their respective correlations with primary outcomes variables.*

MANOVA results strongly supported this study hypothesis. Table 21 represents the frequencies of participants scoring in each category at both baseline and at post-treatment time points. Additionally, Figure 5 presents a graphical illustration of severity categories by time point. To evaluate mean differences by PDQ severity category, Bonferroni post-hoc tests were utilized. With a Bonferroni adjustment, mean scores for each primary outcome variable were significantly different between severity categories, with the exception of mean differences between categories for the SF-36 MCS and the means for Mild/Moderate and Severe categories for Pain Behavior. Table 15 and Table 16 present the findings of the one-way ANOVA, including post-hoc tests. These findings suggest strong abilities of PDQ severity categories in discriminating associations between a range of biopsychosocial components of chronic pain.

Hypothesis Three*: PDQ categories will evidence significant differences in their respective ability to predict healthcare utilization.*

Results from logistic regression analyses produced partial support for this hypothesis. The results did not reveal statistically significant differences between abilities of the PDQ categories at baseline or post-treatment to predict healthcare costs at the three month follow-up time point. Also, post-hoc analysis did not reveal statistical significance by severity category. Still, there appears to be a

trend in which participants scoring in the Extreme Category at baseline tended to have higher healthcare costs upon three-month follow-up as compared to Mild/Moderate or Severe Category participants. Figure 6 displays this trend across PDQ severity categories.

In order to potentially enhance precision, analyses were also conducted using continuous healthcare cost variables. A one-way ANOVA revealed no significant differences in healthcare cost correlation coefficients with respect to the PDQ severity categories. The results did not significantly differentiate between PDQ severity categories in terms of associations with estimated healthcare costs at three month follow-up time point.

However, the summed total score of the PDQ at baseline demonstrated significant and positive coefficients ($r = .42$, $p<.01$) with estimated healthcare costs at 3-month follow-up. Using linear regression modeling, the baseline PDQ summed total score was found to be a statistically significant contributor ($p = .007$) and correspondingly contributes to a regression model providing 67.3% prediction accuracy regarding healthcare costs at three month follow-up. Table 19 presents the results of this regression model. The summed total score at baseline was superior in performance as compared with summed total score of the PDQ at post-treatment (p-value not significant).

CHAPTER FOUR

DISCUSSION

Following increasing utilization of the PDQ (as evidenced by inclusion in the American Medical Association's "Best Practice" guidelines), advancement in research on the performance of the PDQ was clearly indicated. By adding to the developing literature on the PDQ's utility and comparison with other established measures of health outcomes, this study expands upon existing research and offers new clinically useful information in the evaluation and treatment of chronic pain.

The American Recovery and Reinvestment Act (ARRA), signed into effect by the Obama administration in 2009, has spurred an impetus to evaluate and improve treatment and cost-effectiveness in the U.S. healthcare system. An essential component of this line of research involves investigation into patient-reported outcomes and the measures utilized to obtain this information. Additionally, the ARRA contributes to a focus on comparative effectiveness research (CER) and its associated treatment and cost-effective comparison approach. Given the extremely high personal and societal costs associated with chronic pain, there is clearly a need for more research into treatment and cost-effectiveness to support advances in helping individuals with chronic pain conditions. According to the Biopsychosocial Model of chronic pain, a critical component of these research efforts rests in the validity and utility of the instruments used to evaluate chronic pain conditions across biopsychosocial outcomes.

With respect to chronic pain management, there have been a range of health outcomes measures that have traditionally been employed. Among the most utilized of these measures is the SF-36 health survey. Additionally, the NIH-funded PROMIS measures were developed to evaluate and compare a range of health-related outcomes. The Pain Disability Questionnaire is an important and increasingly utilized measure that has taken root as various aspects of its utility continue to be explored. No research has been conducted comparing the predictive utility of the PDQ with other established measures of health and pain-related outcomes. In light of the importance of self-report measures in the overall goals of CER, the current study attempts to contribute to the literature by comparing the PDQ with the SF-36 and PROMIS pain-related measures.

The current study attempted to examine several aspects of the psychometric performance of the PDQ as compared with other established measures of health and pain-related outcomes. More specifically, the study was designed to investigate and compare the predictive validity of the PDQ in terms of biopsychosocial outcomes and also healthcare costs in a chronic pain population. The results indicate that the PDQ demonstrated strong performance in multiple areas including construct validity, biopsychosocial outcome prediction, and healthcare cost prediction. When compared with other commonly used health outcomes instruments including the SF-36 and pain-related PROMIS measures, the PDQ appears to provide equivalent to superior performance across a range of biopsychosocial outcomes as described below.

The demographic characteristics for the current sample are presented in Table 2 and Table 3. Gender, age, race, ethnicity, level of employment/disability, and rate of psychiatric comorbidity were all generally consistent with the demographic data observed in previous studies of adults with chronic pain conditions (Gatchel, 1995). There were a disproportionate amount of females (71%) as compared to males (29%) in this sample. Also, the mean age for the current sample was 49.72 years old. Overall, the demographic makeup of the current sample provides support for the generalizability of results to the chronic pain population at large.

Study Findings and Implications

The PDQ demonstrated large effect sizes with respect to its association with the other primary outcomes measures. There were also strong correlations in the direction expected between the PDQ summed score at baseline, the PDQ summed score at post-treatment, PDQ Functional Status Component, PDQ Psychosocial Component, and by PDQ severity category. This suggests consistency in the PDQ's ability to evaluate pain-related disability across time and also to discriminate between factorial components.

After controlling for mean group differences, the current study demonstrated the ability of the PDQ to predict a range of biopsychosocial outcomes. For example, the PDQ demonstrated excellent performance in the prediction of pain-related factors. As an independent predictor, the PDQ was able to predict 49.4% of the variability in pain interference. Additionally, it

contributed to a model in which 60% model prediction was achieved (with 26.7% of the variability accounted beyond that contributed by SF-36). The PDQ also demonstrated strong performance in predicting pain behavior, with 31.7% accuracy as an individual predictor and 24.9% improvement over SF-36 and PROMIS-Physical Functioning. PROMIS-Pain Interference was also a significant contributor in predicting pain behavior.

The PDQ was not found to be a significant predictor of discretionary social activities or satisfaction with social roles, likely due to having limited items specifically addressing social activities and more items addressing functional impairment. As predictive efficacy was demonstrated in psychosocial factors, the PDQ still boasts an impressive evaluative range of biopsychosocial components. As explicated by the Biopsychosocial Model of chronic pain, the complex interconnections between biophysiological and psychosocial aspects of pain requires assessment from more than just a biomedical reductionistic viewpoint. Taken collectively, these are important findings as they potentially may "flag" patients that could benefit from additional/alternative follow-up treatment across multiple dimensions aside from simply the patient's subjective pain severity rating. For example, providers could use the PDQ as an evaluative tool to help shed light on patients with psychosocial barriers to treatment.

The fact that the PDQ outperformed other established measures of health outcomes in some areas offers consideration for using the PDQ as a key instrument in evaluating pain-related disability. There are clear implications here

for both research and clinical applications of the PDQ in Comparative Effectiveness Research and the advancement of treatment efficacy. With noteworthy responsiveness to treatment, the results of the current study imply that support for the use of the PDQ in tracking pain and health-related outcomes over time is well established.

The PDQ also demonstrated good capabilities in outcome prediction by severity category. Significant differences were found between the predictive abilities across Mild/Moderate, Severe, and Extreme categories. The results reveal good discriminative ability by severity category in terms of health outcomes profiles in chronic pain patients in the current sample. Implications of these findings include the clinical usefulness of using predictive models based on the patient's categorical severity level. Similar to other studies in the literature using categorical comparisons (e.g., Anagnostis, et al., 2003), the PDQ categorical approach was able to provide improved practical application of this instrument. Again, patients potentially benefit from the clinical usefulness of a categorical approach offering clear distinctions in outcomes profiles between category levels.

With regard to the two-factor structure of the PDQ, baseline comparisons across primary study measures for both the 9-item Functional Status Component (FSC) and the 6-item Psychosocial Component (PSC) were evaluated. Results suggested good correlational performance, such that all results were in the directions anticipated based on the factorial construct purported by each

respective summary scale. For example, FSC was strongly correlated with SF-36 PCS at 63.6% whereas PSC was, as theoretically anticipated, less correlated at only 46.9%. Overall, the components held true to their expected correlational abilities across study measures.

The majority of participants completing PDQ measures at baseline and post-treatment demonstrated improvement in PDQ score over time (i.e., lower total summed scores at post-treatment). By PDQ severity category, 93.9% of patients remained within the same severity category or improved in terms of severity category. In total, 37.8% of patients improved from one severity category to another, with some (3.7%) even improving two categories from Extreme to Mild/Moderate. This finding also supports the treatment efficacy of the interdisciplinary chronic pain management programs featured in the current sample.

Regarding healthcare costs, the results demonstrate the utility of the PDQ in predicting healthcare utilization outcomes following treatment for chronic pain. For example, a patient that has scored relatively high on the PDQ prior to treatment will be significantly more likely to have higher than average healthcare costs in the three months following treatment. Conversely, patients scoring low on the PDQ at baseline are more likely to have lower relative healthcare costs at three month follow up time point. Armed with this knowledge, providers may develop more informed treatment plans regarding predicted healthcare cost projections for their patients.

No statistically significant differences were found between the abilities of the three PDQ severity categories with regard to their respective abilities to predict healthcare costs by “low” versus “high” categories. This was likely due to the limited sample size providing healthcare cost information at the three month follow-up time point. Likewise, there were no statistically significant differences found between the abilities of the three PDQ severity categories with regard to their respective abilities to predict healthcare costs using estimated healthcare cost totals. Given the fairly broad range of scores within categories, inter-category comparisons may be confounded or not fully representative of trends in healthcare costs between categories. Additionally, group size differences between participants falling into each severity category contributed to analysis assumptions not being fully met. The presence of outliers likely contributed to skew, thus inhibiting statistical significance.

Still, there was a trend in which participants scoring in the Extreme severity category tended to have higher healthcare costs at the three month follow-up time point than participants scoring in the Mild/Moderate and Severe categories. Figure 6 depicts this trend in mean healthcare costs by category type. Even when potential outlier cases were controlled for, this trend persisted. This suggests that the trend is representative of more than just an artifact of skew in the sample’s respective healthcare utilization.

This study is the first in which the PDQ’s predictive abilities were compared with other established measures of health outcomes. As such, it

provides a unique opportunity to consider its relative performance alongside multiple other measures and subsequently deepen understanding of its potential role in predicting health outcomes. Additionally, this study was the first attempt to predict healthcare costs using the PDQ. Results from the current study were congruent with the literature in terms of initial explorations into predictive ability of health outcomes (Gatchel, et al., 2006). As such, the findings provide support for the reliability of this instrument in predicting health outcomes across study samples.

The emergence of the Biopsychosocial Model for conceptualizing chronic pain has allowed for a broader recognition of patient and environmental factors that influence a patient's experience of chronic pain. The results for the current study support the use of the Biopsychosocial Model as there exists a clear connection between psychosocial factors and health outcomes. The results found in the current study compliment previous studies on the PDQ's predictive utility. The findings are consistent with these previous studies in that the PDQ was found to have statistically significant predictive abilities across a range of biopyschosocial outcomes (Gatchel, et al., 2006). Further, results demonstrate the equivalent to superior performance of the PDQ in predictive accuracy as compared with SF-36 and PROMIS-based outcome measures.

Another implication of the results in the current study is that pain-related disability as a general construct is important in explaining variance in healthcare costs. It follows that as pain reduces a patient's ability to work or perform

essential movements or tasks, the patient is more likely to need and/or seek medical intervention. Thus, evaluation of the patient's level of pain-related disability is a critical element in conceptualizing the patient's overall pain experience. As healthcare utilization was another outcome featured in the current study, pain-related disability appears to have predictive power in predicting future healthcare costs. Thus, pain-related disability is a factor that should be included in initial evaluations of chronic pain sufferers.

Given the significant findings of patient pain-related disability reduction from pre-treatment to post-treatment, this study provides evidence that the PDQ is responsive to treatment. An auxiliary implication of the results is that they support the efficacy of interdisciplinary chronic pain management programs for the amelioration of pain-related disability. Although not a primary goal of the study, the results nonetheless provide evidence of patient improvement in a number of other biopsychosocial outcomes over time as well. For example, for each of the primary psychosocial outcomes including anger, anxiety, and depression, patients demonstrated mean improvements from baseline to post-treatment. Additionally, quality of life study variables including social satisfaction with discretionary social activities and role activities also demonstrated improvement across time.

The current study used a three-month follow up period following the completion of treatment, and thus the results represent a short-term model of cost evaluation. As such, clinician's may be afforded the opportunity to discuss

relatively acute issues regarding the post-treatment phase for patients with chronic pain via the PDQ. Addressing barriers to successful management of chronic pain (and subsequent healthcare costs) beyond initial treatment periods may now be discussed with increased evidence-based support for patients that have completed the PDQ.

Study Limitations

The current study featured baseline to three-month follow-up time points that covered a total period of approximately four months. Thus, there was a limited time window in which data was collected across time points. This length of time may limit generalizability of some of the findings, particularly when considering the longer-term predictive power of the PDQ. A larger sample size, particularly at the three month follow-up time point, would potentially add to the robustness of the findings. Still, adequate power was achieved in the current sample and results can be expected to generalize to the broader chronic pain population within the time frame described. Additionally, it represents a significant step in the initial exploration into the predictive ability of the PDQ with respect to estimated healthcare costs. One other caveat when interpreting results of the PDQ cost-prediction abilities was the statistical exclusion of one outlier that contributed to significant skew in the results. This was done in an effort be more representative of the current sample; however, this potentially could lead to results that do not accurately identify cases in the extreme ranges of healthcare utilization.

As explained in the review of the literature, chronic pain management programs may differ in terms of length, program structure and treatment focus (e.g., narcotic versus non-narcotic treatment options), and staff involved. For these reasons, demographic (e.g., urban versus rural) as well as treatment differences potentially limit how well the results may generalize to other pain clinics and geographic regions. Still, the current sample appeared to demographically match previous studies with adult chronic pain patients (e.g., Gatchel, 1995). The inclusion of chronic pain patients with longstanding, potentially treatment-resistant, chronic pain problems in the current study may respond differently than patients with more acute or treatment-reactive conditions. Still, the improvements made over time, particularly in the area of reductions in pain-related disability, support the notion that even longstanding chronic pain conditions can demonstrate improvements over time given appropriate treatment.

Also, the chronic pain sample utilized in the current study may have treatment-related features that potentially influenced the results. For example, the treatment provided in the current sample was non-narcotic in design and included interdisciplinary evaluation and treatment that not all chronic pain patients experience. Some caution should be provided in interpreting the results for chronic pain patients undergoing other types of treatment. The current study also provided data from only one urban pain clinic with an interdisciplinary chronic pain management program that may differ from others around the country. However, the interdisciplinary program utilized at the pain clinic for the current

study was comprised of core components associated with recommended interdisciplinary program structures in the literature (e.g., Noe, 2012). As such, differences between other true interdisciplinary chronic pain management programs around the country is expected to be minimal. Thus, the results of the current study should extrapolate to other interdisciplinary programs as well.

Some have argued that self-report measures may provide inaccurate or biased reports of outcomes (Hadjistavropoulos & Craig, 2002). Although this notion highlights the potential concerns for any self-report measure, the validity and clinical utility of patient self-report measures has been well established in the literature (e.g., Ware & Sherbourne, 1992). Additionally, the reliability and construct validity of the SF-36, PROMIS-based measures, and PDQ have been consistently demonstrated throughout the literature. As such, concerns that self-report measures may have biased results in the current study are minimal.

Another potential limitation of the current study regards the healthcare cost estimates. As operationalized, the averages and procedural costs are estimates of charges to patients based on data available in the literature. As they are the charges associated with respective healthcare treatments and procedures, they do not necessarily match out-of-pocket expenses as experienced by patients. Also, the data used to create the estimations in the current study includes non-regional data on costs and so may not be fully representative of local healthcare costs. Local and regional data were utilized, as available, in creating estimates of

healthcare costs in the current study. Thus, potential confounding elements of non-localized cost estimates were minimized.

Future Directions and Recommendations

As mentioned, there exist some limitations in the current study that provide room for advancements in future research. Primary among considerations for future research would be to incorporate a broader longitudinal framework. In other words, future studies may seek to utilize longer data collection and follow-up periods to evaluate the PDQ's predictive utility over greater lengths of time.

With respect to predicting healthcare utilization and costs, following participants over longer periods of time will provide a useful addition to the current study's initial attempts at healthcare cost prediction at three month follow-up time point. Given the significant findings in the current study regarding the PDQ's success at predicting future healthcare costs, additional research into the linear factors involved in pain-related disability and healthcare costs is warranted. Also, provided the significant effect sizes between the PDQ and PROMIS pain-related measures, an evaluation and comparison of the predictive utility of PROMIS measures in healthcare cost prediction appears warranted.

Other research may focus on localized cost estimates to evaluate potential differences between geographic regions. By including interdisciplinary chronic pain management programs from other geographic regions, inter-clinic and inter-region differences in biopsychosocial outcomes and healthcare cost prediction may be evaluated more thoroughly. Consideration of post-treatment factors may

provide further detail about the factors involved in healthcare utilization for chronic pain patients following interdisciplinary pain programs.

Also, a survival analysis could be conducted in order to detect possible differences between completers and non-completers of chronic pain management programs. Using the PDQ in such an investigation could lead to potential gains in understanding disability-related factors associated with interdisciplinary program non-completion.

Additionally, future research can evaluate the predictive validity of the PDQ in other types of treatment settings (e.g., primary care, inpatient settings, etc.). As the current study cohort was comprised exclusively of patients reporting non-malignant pain, additional consideration should be provided to evaluating the utility of the PDQ in a patient population with cancer-related chronic pain conditions. Comparisons with other established measures of health outcomes in these specific settings could, in conjunction with the current study, also add to the existing literature on the utility of the PDQ.

Conclusions

In conclusion, the current study has provided empirical support for the use of the PDQ as a valuable instrument in evaluating pain-related disability amongst a representative sample of adult chronic pain patients participating in interdisciplinary chronic pain management programs. Direct comparisons with established measures of health outcomes including the SF-36 and PROMIS-based outcomes measures revealed comparable and, in some cases, superior

performance of the PDQ in accurately predicting health outcomes. Strong correlations were observed between the PDQ and the other measures of health outcomes, providing support for good construct validity that converges as hypothesized with similar measures.

The PDQ also performed well in predicting a range of biopsychosocial outcomes above and beyond the predictive ability of other instruments in the current study. It demonstrated particularly strong performance in predicting pain behavior, pain interference, and physical functioning outcomes. Also, PDQ severity categories demonstrated strong abilities to discriminate between health outcomes profiles, as almost all inter-category comparisons produced significant results.

Moreover, the findings add to the established utility of the PDQ as a predictive tool with regard to healthcare cost prediction. Results of this study support the use of the PDQ summed score in predicting estimated healthcare costs. Although there were no statistically significant findings in the discriminative abilities of the PDQ severity categories, there nonetheless was a trend observed in which scorers in the Extreme category appeared more likely to have higher healthcare costs at three month follow up time point than scorers in the Mild/Moderate or Severe categories.

Overall, the current study achieved its stated goals of evaluating the predictive utility of the PDQ in comparison with other established health outcomes measures. It contributed to the understanding and expanded upon the

clinical utility of the PDQ by also demonstrating efficacy in healthcare cost prediction. Exploration into the PDQ by severity category produced more limited results, but still allows for useful comparisons as well as potentially helpful clinical information. The current study offers an important contribution to understanding and evaluating chronic pain and the multifaceted nature of biopsychosocial outcomes and healthcare costs. It is anticipated that future clinical research will continue to expand upon the implications from this study and contribute to more effective evaluation and treatment for individuals suffering from chronic pain.

APPENDIX A

STUDY MEASURES

Pain Disability Questionnaire (PDQ)

Patient Name: _____Date: _____

Instructions: These questions ask for your views about how your pain now affects how you function in everyday activities.

Please answer every question and mark the ONE number on EACH scale that best describes how you feel.

1. Does your pain interfere with your normal work inside and outside the home?

Work normally Unable to work at all

0 -------- 1 -------- 2 -------- 3 -------- 4 -------- 5 -------- 6 -------- 7 -------- 8 -------- 9 -------- 10

2. Does your pain interfere with personal care (such as washing, dressing, etc.)?

Take care of myself completely Need help with all my personal care

0 -------- 1 -------- 2 -------- 3 -------- 4 -------- 5 -------- 6 -------- 7 -------- 8 -------- 9 -------- 10

3. Does your pain interfere with your traveling?

Travel anywhere I like Only travel to see doctors

0 -------- 1 -------- 2 -------- 3 -------- 4 -------- 5 -------- 6 -------- 7 -------- 8 -------- 9 -------- 10

4. Does your pain affect your ability to sit or stand?

No problems Cannot sit / stand at all

0 -------- 1 -------- 2 -------- 3 -------- 4 -------- 5 -------- 6 -------- 7 -------- 8 -------- 9 -------- 10

5. Does your pain affect your ability to lift overhead, grasp objects, or reach for things?

No problems Cannot do at all

0 -------- 1 -------- 2 -------- 3 -------- 4 -------- 5 -------- 6 -------- 7 -------- 8 -------- 9 -------- 10

6. Does your pain affect your ability to lift objects off the floor, bend, stoop, or squat?

No problems Cannot do at all

0 -------- 1 -------- 2 -------- 3 -------- 4 -------- 5 -------- 6 -------- 7 -------- 8 -------- 9 -------- 10

7. Does your pain affect your ability to walk or run?

No problems Cannot walk / run at all

0 -------- 1 -------- 2 -------- 3 -------- 4 -------- 5 -------- 6 -------- 7 -------- 8 -------- 9 -------- 10

8. Has your income declined since your pain began?

No decline Lost all income

0 -------- 1 -------- 2 -------- 3 -------- 4 -------- 5 -------- 6 -------- 7 -------- 8 -------- 9 -------- 10

9. Do you have to take pain medication every day to control your pain?

No medication needed On pain medication throughout the day

0 -------- 1 -------- 2 -------- 3 -------- 4 -------- 5 -------- 6 -------- 7 -------- 8 -------- 9 -------- 10

10. Does your pain force you to see doctors much more often than before your pain began?

Never see doctors See doctors weekly

0 -------- 1 -------- 2 -------- 3 -------- 4 -------- 5 -------- 6 -------- 7 -------- 8 -------- 9 -------- 10

11. Does your pain interfere with your ability to see the people who are important to you as much as you would like?

No problem Never see them

0 -------- 1 -------- 2 -------- 3 -------- 4 -------- 5 -------- 6 -------- 7 -------- 8 -------- 9 -------- 10

12. Does your pain interfere with recreational activities and hobbies that are important to you?

No interference Total interference

0 -------- 1 -------- 2 -------- 3 -------- 4 -------- 5 -------- 6 -------- 7 -------- 8 -------- 9 -------- 10

13. Do you need the help of your family and friends to complete everyday tasks (including both work outside the home and housework) because of your pain?

Never need help Need help all the time

0 -------- 1 -------- 2 -------- 3 -------- 4 -------- 5 -------- 6 -------- 7 -------- 8 -------- 9 -------- 10

14. Do you now feel more depressed, tense, or anxious than before your pain began?

No depression / tension Severe depression /tension

0 -------- 1 -------- 2 -------- 3 -------- 4 -------- 5 -------- 6 -------- 7 -------- 8 -------- 9 -------- 10

15. Are there emotional problems caused by your pain that interfere with your family, social, and / or work activities?

No problems Severe problems

0 -------- 1 -------- 2 -------- 3 -------- 4 -------- 5 -------- 6 -------- 7 -------- 8 -------- 9 -------- 10

Anagnostis C, Gatchel RJ, Mayer TG. The Pain Disability Questionnaire: A New Psychometrically Sound Measure for Chronic Musculoskeletal Disorders. Spine 2004; 29 (20): 2290-2302

Three Month Follow-up Healthcare Utilization

Pt Name:

Pt PID:

Date:

Pt Contact #:

Introduction: I'm calling for Dr. Noe at the McDermott Center for Pain Management. We're doing a follow-up with you to increase our quality of care and we value your opinion. Do you have a moment to discuss some questions regarding your treatment? ___ **Yes** (continue) ___**No** (request another date/time _____)

Thank you. Do you keep a calendar of your appointments? For the following questions, it may be helpful to have that calendar or record of your pain-related healthcare appointments covering the three months after your ID program ended. I will be asking questions related to the *original* pain problem that you sought treatment for here. In other words, these questions refer to _____, which you initially came to treatment for at our clinic on _____(date).

1. **In the 3 months following the end of your ID program**, how many times did you visit a physician for _____ (Pain problem)?
   _____visits
   How many times did you visit another type of treatment provider for _____(Pain problem)? (e.g., psychologist, physical therapist, etc.)
   _____ visits
   a) **Who did you see?**
   b) **On what dates?**
   c) **What specific procedure(s) were performed during the visit?** (e.g. injections, surgeries, etc.)

d) **Were there any diagnostic tests conducted?**

e) **Were any medications prescribed? _____Yes _____No**

(Did you have this prescription filled and take this medication? ____Yes ____No)

a. **Name:** **Dosage:**

2. **In the 3 months following the end of your ID program**, how many times did you go to a **hospital** emergency room for _____(Pain problem)?

_____ times

3. How many different times did you stay in a hospital **overnight** or longer **in the 3 months following the end of your ID program**?

_____ times

4. How many **total** NIGHTS did you spend in the hospital **in the 3 months following the end of your ID program**?

_____ nights

Thank you for taking the time to answer these follow-up questions. Do you have any questions before we end today's follow-up?

APPENDIX B
FIGURES

Figures 1 – 4

Sample Primary Outcome Variables by PDQ Severity Category

Figure 1

Anger

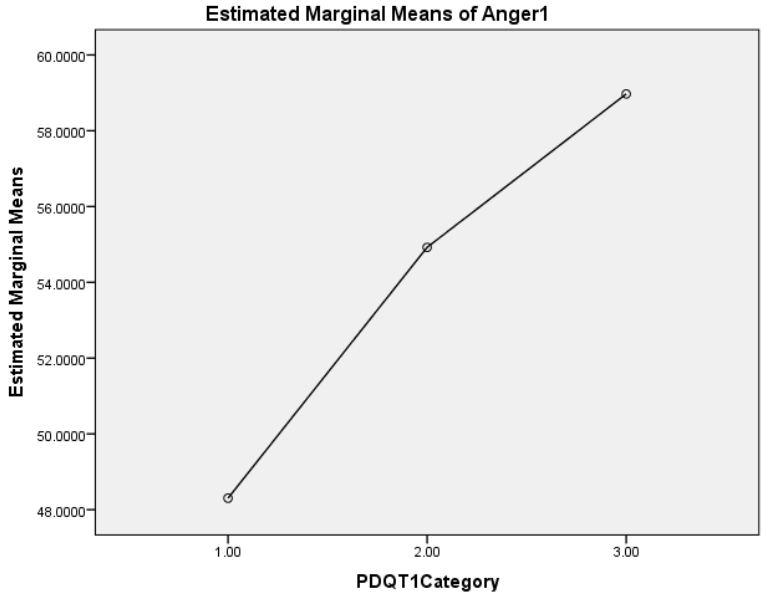


Figure 2

Anxiety

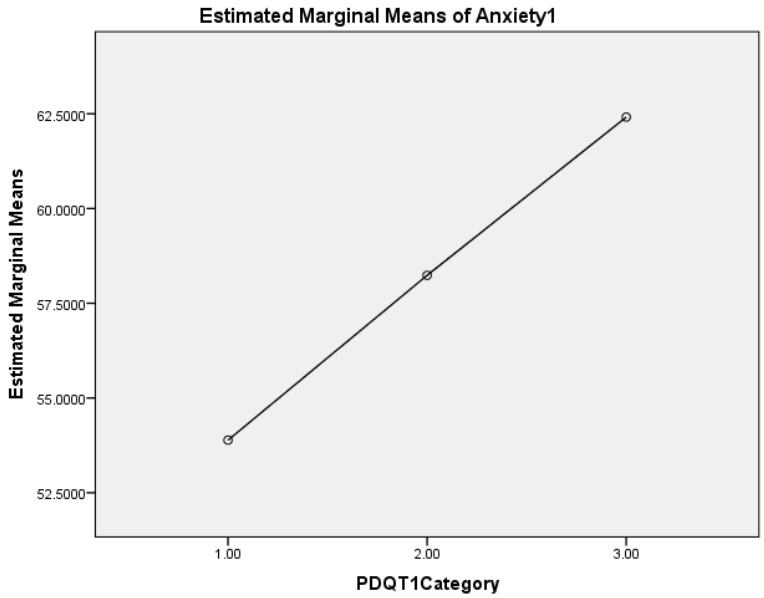


Figure 3
Pain Interference

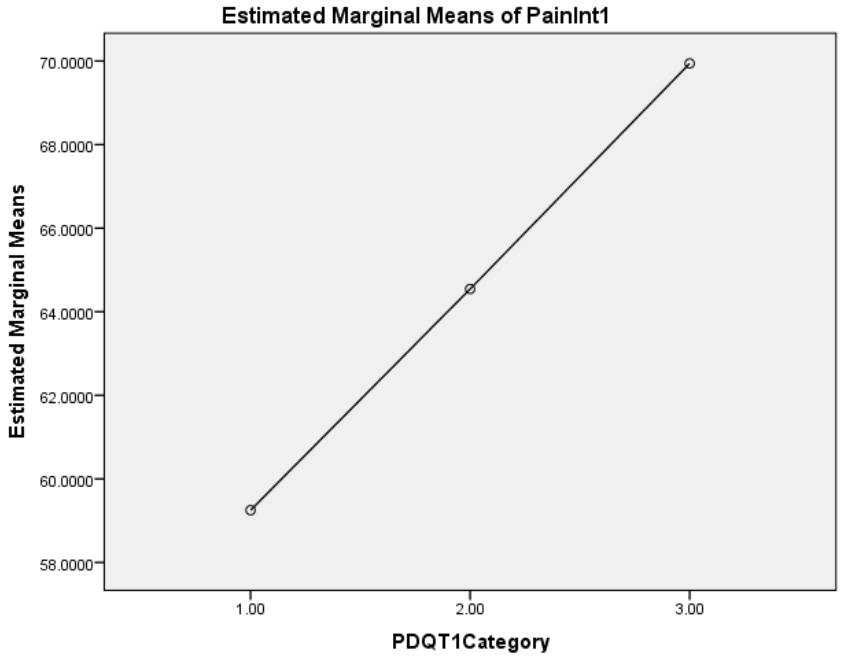


Figure 4
Pain Behavior

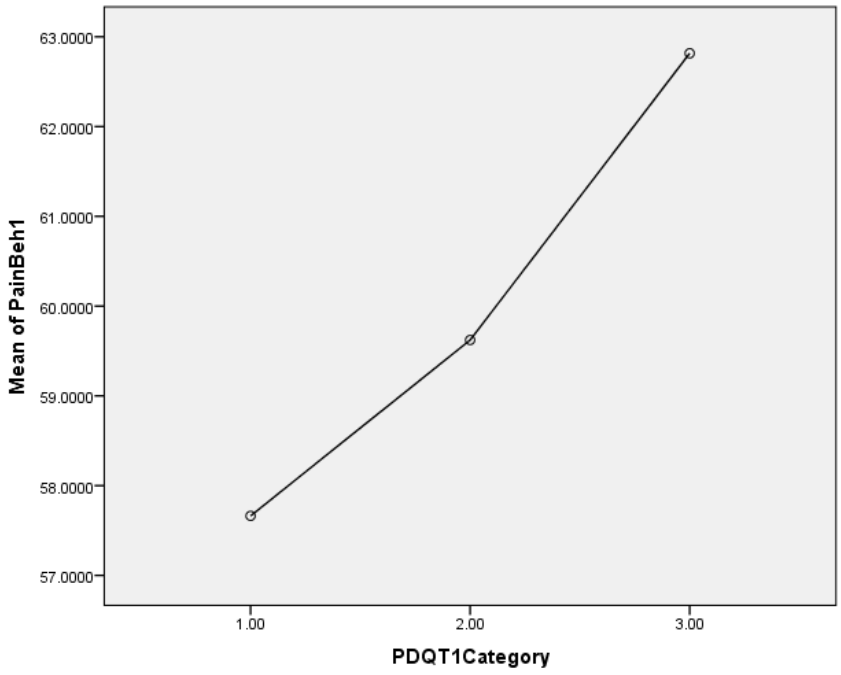
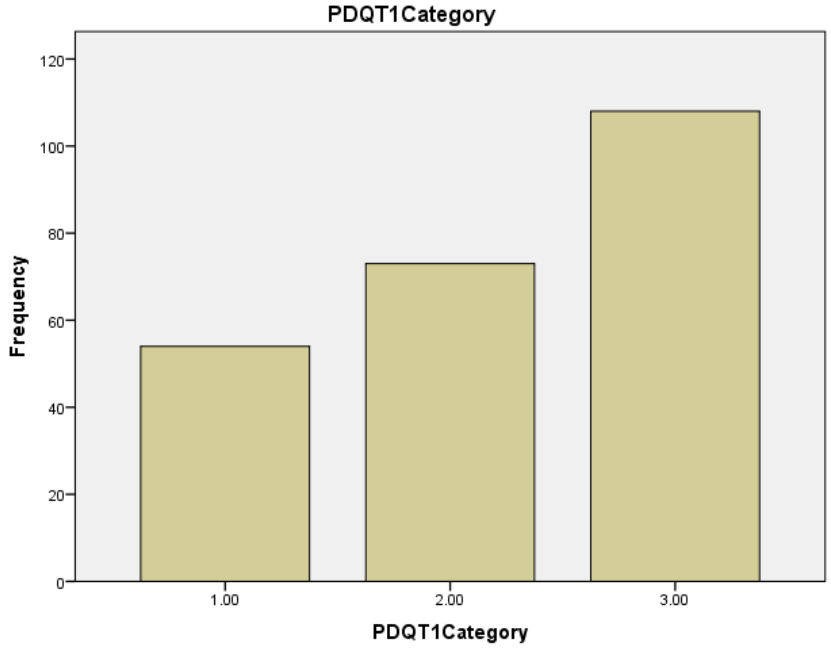


Figure 5

PDQ Severity Categories by Time Point



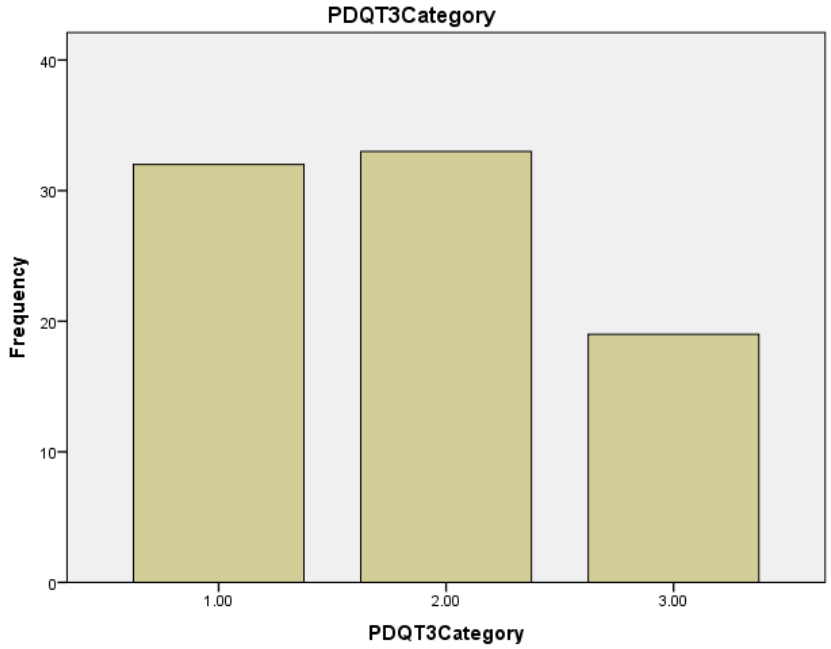
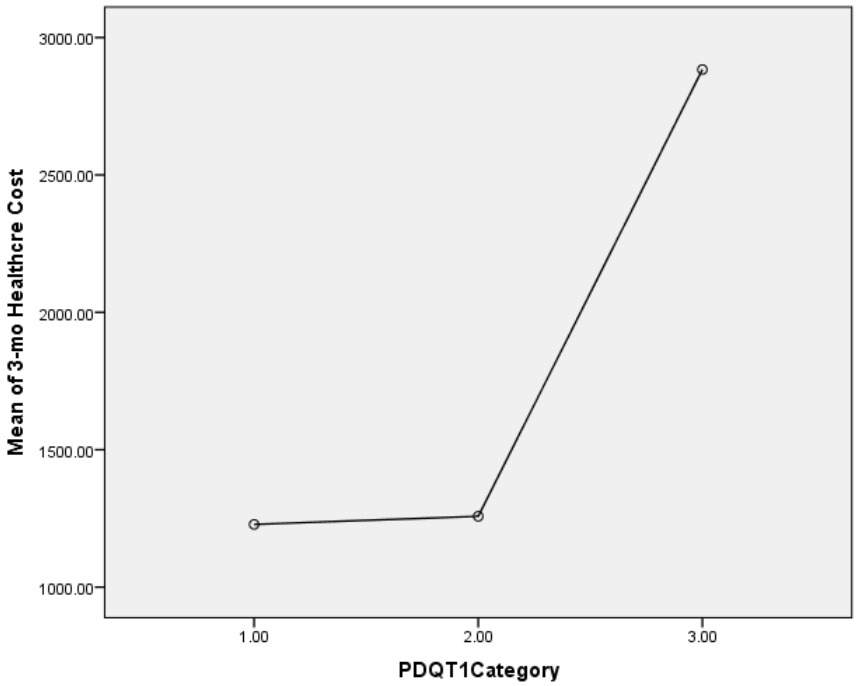


Figure 6

Healthcare Cost Trend Across PDQ Severity Categories



***In (2011) U.S. dollars**

APPENDIX C
TABLES

Table 1

Descriptive Statistics for Primary Outcome Variables

	N	Range	Minimum	Maximum	Mean	Std. Deviation
Baseline PDQ	235	143	7	150	92.85	30.756
Post-Treatment PDQ	84	128	4	132	75.24	30.729
Anger1	205	56.4000	28.6000	85.0000	55.465548	9.8767043
Anger2	84	44.0000	28.6000	72.6000	50.263054	7.4129818
Anxiety1	204	52.0000	33.0000	85.0000	59.282876	9.1825523
Anxiety2	84	37.0000	33.0000	70.0000	54.960981	6.6849096
DepressiveSxs1	206	50.0000	34.0000	84.0000	55.987156	9.6971105
DepressiveSxs2	84	43.0000	34.0000	77.0000	52.357882	8.1839359
PainBeh1	207	43.0000	35.0000	78.0000	60.713352	4.4339851
PainBeh2	84	21.0000	45.0000	66.0000	58.586423	3.7008713
PhysFx1	208	52.6000	15.0000	67.6000	35.839375	7.2794405
PhysFx2	84	29.3000	26.8000	56.1000	39.110612	5.8714338
SocSatDSA1	206	42.2000	26.8000	69.0000	40.555103	8.2278123
SocSatDSA2	84	33.6000	26.8000	60.4000	44.942308	7.2792648
PainInt1	208	45.0000	39.0000	84.0000	65.815816	6.5537561
PainInt2	85	35.5000	38.6000	74.1000	61.378427	6.1621107
MCS SF-36	129	47.18	18.07	65.25	50.0000	10.00000
PCS SF-36	129	44.39	31.74	76.13	50.0000	10.00000

Table 2

Demographic Data: Gender, Race, & Ethnicity

		Frequency	Percent	Valid Percent	Cumulative Percent
Gender	Male	74	28.8	29.1	29.1
	Female	180	70.0	70.9	100.0
	Total	254	98.8	100.0	
Race	White	186	72.4	73.2	73.2
	Black or African American	43	16.7	16.9	90.2
	Asian	3	1.2	1.2	91.3
	American Indian or Alaska Native	2	.8	.8	92.1
	Native Hawaiian or Other Pacific Islanders	1	.4	.4	92.5
	Other	9	3.5	3.5	96.1
	Not Provided	10	3.9	3.9	100.0
	Total	254	98.8	100.0	
Ethnicity	Not Provided	27	10.5	16.0	16.0
	Not Hispanic or Latino	133	51.8	78.7	94.7
	Hispanic or Latino	9	3.5	5.3	100.0
	Total	169	65.8	100.0	

Table 3

Demographic Data: Age

	N	Range	Minimum	Maximum	Mean	Std. Deviation
Age	254	63	18	81	49.72	14.549

Table 4

Correlations Between Primary Outcomes at Baseline

		Baseline PDQ	Baseline PDQ Categories	SF-36 MCS	SF-36 PCS	Pain Behavior	Physical Functioning	Pain Interference
Baseline PDQ Total Score	Pearson Correlation	1	.914**	-.199*	-.607**	.563**	-.637**	.703**
	Sig. (1-tailed)		0.00	0.012	0.00	0.00	0.00	0.00
	N	235	235	129	129	195	196	196
Baseline PDQ Categories	Pearson Correlation	.914**	1	-.192*	-.573**	.466**	-.580**	.636**
	Sig. (1-tailed)	0.00		0.015	0.00	0.00	0.00	0.00
	N	235	235	129	129	195	196	196
SF-36 MCS	Pearson Correlation	-.199*	-.192*	1	.205*	-.311**	.201*	-.267**
	Sig. (1-tailed)	0.012	0.015		0.01	0.001	0.021	0.003
	N	129	129	129	129	102	103	103
SF-36 PCS	Pearson Correlation	-.607**	-.573**	.205*	1	-.242**	.746**	-.310**
	Sig. (1-tailed)	0.00	0.00	0.01		0.007	0.00	0.001
	N	129	129	129	129	102	103	103
PROMIS Pain Behavior	Pearson Correlation	.563**	.466**	-.311**	-.242**	1	-.293**	.671**
	Sig. (1-tailed)	0.00	0.00	0.001	0.007		0.00	0.00
	N	195	195	102	102	207	207	207
PROMIS Physical Functioning	Pearson Correlation	-.637**	-.580**	.201*	.746**	-.293**	1	-.526**
	Sig. (1-tailed)	0.00	0.00	0.021	0.00	0.00		0.00
	N	196	196	103	103	207	208	208
PROMIS Pain Interference	Pearson Correlation	.703**	.636**	-.267**	-.310**	.671**	-.526**	1
	Sig. (1-tailed)	0.00	0.00	0.003	0.001	0.00	0.00	
	N	196	196	103	103	207	208	208

**. Correlation is significant at the 0.01 level (1-tailed).

*. Correlation is significant at the 0.05 level (1-tailed).

Table 5

MANOVA: Race at Baseline Time Point

Multivariate Tests[a]

Effect		Value	F	Hypothesis df	Error df	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[d]
Intercept	Pillai's Trace	0.977	630.826[b]	6	91	0	0.977	3784.953	1
	Wilks' Lambda	0.023	630.826[b]	6	91	0	0.977	3784.953	1
	Hotelling's Trace	41.593	630.826[b]	6	91	0	0.977	3784.953	1
	Roy's Largest Root	41.593	630.826[b]	6	91	0	0.977	3784.953	1
Race	Pillai's Trace	0.302	1.018	30	475	0.443	0.06	30.526	0.884
	Wilks' Lambda	0.724	1.025	30	366	0.433	0.063	24.409	0.765
	Hotelling's Trace	0.346	1.032	30	447	0.422	0.065	30.961	0.888
	Roy's Largest Root	0.217	3.434[c]	6	95	0.004	0.178	20.602	0.931

a. Design: Intercept + Race

b. Exact statistic

c. The statistic is an upper bound on F that yields a lower bound on the significance level.

d. Computed using alpha = .05

Table 6 – 13
Results of Linear Regression Modeling

Table 6
Anger

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.330[a]	.109	.091	9.4839909	.109	6.007	2	98	.003
2	.448[b]	.201	.176	9.0288109	.092	11.130	1	97	.001
3	.611[c]	.373	.347	8.0385519	.172	26.371	1	96	.000
4	.611[d]	.373	.340	8.0793598	.000	.033	1	95	.857
5	.615[e]	.378	.339	8.0896421	.005	.759	1	94	.386

a. Predictors: (Constant), PCS SF-36, MCS SF-36

b. Predictors: (Constant), PCS SF-36, MCS SF-36, PDQ Summed

c. Predictors: (Constant), PCS SF-36, MCS SF-36, PDQ Summed , PainBeh1

d. Predictors: (Constant), PCS SF-36, MCS SF-36, PDQ Summed , PainBeh1, PainInt1

e. Predictors: (Constant), PCS SF-36, MCS SF-36, PDQ Summed , PainBeh1, PainInt1, PhysFx1

Table 6 (Continued)
Anger

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	72.133	6.005		12.011	.000
	MCS SF-36	-.336	.102	-.329	-3.298	.001
	PCS SF-36	-.004	.098	-.004	-.042	.967
2	(Constant)	40.135	11.166		3.594	.001
	MCS SF-36	-.271	.099	-.266	-2.741	.007
	PCS SF-36	.178	.108	.181	1.642	.104
	PDQ Summed	.392	.117	.370	3.336	.001
3	(Constant)	-6.543	13.470		-.486	.628
	MCS SF-36	-.184	.090	-.180	-2.050	.043
	PCS SF-36	.107	.097	.109	1.097	.275
	PDQ Summed	.055	.123	.052	.442	.659
	PainBeh1	1.044	.203	.524	5.135	.000
4	(Constant)	-6.150	13.712		-.449	.655
	MCS SF-36	-.185	.090	-.181	-2.044	.044
	PCS SF-36	.107	.098	.109	1.095	.276
	PDQ Summed	.062	.130	.058	.474	.637
	PainBeh1	1.071	.252	.537	4.257	.000
	PainInt1	-.036	.198	-.023	-.181	.857
5	(Constant)	-10.726	14.700		-.730	.467
	MCS SF-36	-.179	.091	-.175	-1.977	.051
	PCS SF-36	.041	.124	.042	.330	.742
	PDQ Summed	.100	.138	.095	.729	.468
	PainBeh1	1.049	.253	.527	4.147	.000
	PainInt1	-.017	.199	-.011	-.086	.932
	PhysFx1	.161	.184	.117	.871	.386

a. Dependent Variable: Anger1

Table 7
Anxiety

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.455[a]	.207	.190	8.4352293	.207	12.629	2	97	.000
2	.595[b]	.354	.333	7.6531389	.147	21.838	1	96	.000
3	.673[c]	.453	.430	7.0777053	.099	17.245	1	95	.000
4	.676[d]	.457	.428	7.0868708	.004	.754	1	94	.387
5	.677[e]	.458	.423	7.1207104	.001	.109	1	93	.742

a. Predictors: (Constant), PCS SF-36, MCS SF-36

b. Predictors: (Constant), PCS SF-36, MCS SF-36, PDQ Summed

c. Predictors: (Constant), PCS SF-36, MCS SF-36, PDQ Summed , PainBeh1

d. Predictors: (Constant), PCS SF-36, MCS SF-36, PDQ Summed , PainBeh1, PainInt1

e. Predictors: (Constant), PCS SF-36, MCS SF-36, PDQ Summed , PainBeh1, PainInt1, PhysFx1

Table 7 (Continued)
Anxiety

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	75.125	5.332		14.091	.000
	MCS SF-36	-.454	.090	-.476	-5.022	.000
	PCS SF-36	.114	.088	.123	1.300	.197
2	(Constant)	36.482	9.580		3.808	.000
	MCS SF-36	-.377	.084	-.395	-4.504	.000
	PCS SF-36	.335	.092	.362	3.622	.000
	PDQ Summed	.472	.101	.471	4.673	.000
3	(Constant)	3.717	11.864		.313	.755
	MCS SF-36	-.317	.079	-.332	-4.030	.000
	PCS SF-36	.282	.086	.305	3.263	.002
	PDQ Summed	.229	.110	.229	2.075	.041
	PainBeh1	.742	.179	.397	4.153	.000
4	(Constant)	2.023	12.038		.168	.867
	MCS SF-36	-.314	.079	-.329	-3.985	.000
	PCS SF-36	.280	.087	.303	3.232	.002
	PDQ Summed	.197	.116	.197	1.698	.093
	PainBeh1	.633	.219	.338	2.887	.005
	PainInt1	.151	.173	.105	.869	.387
5	(Constant)	.396	13.064		.030	.976
	MCS SF-36	-.312	.080	-.327	-3.921	.000
	PCS SF-36	.258	.109	.279	2.367	.020
	PDQ Summed	.212	.125	.211	1.699	.093
	PainBeh1	.628	.221	.336	2.849	.005
	PainInt1	.154	.174	.107	.880	.381
	PhysFx1	.054	.165	.041	.330	.742

a. Dependent Variable: Anxiety1

Table 8
Depression

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.478[a]	.229	.213	8.8521235	.229	14.663	2	99	.000
2	.596[b]	.355	.335	8.1371198	.126	19.163	1	98	.000
3	.723[c]	.523	.503	7.0341882	.168	34.141	1	97	.000
4	.727[d]	.528	.504	7.0307413	.005	1.095	1	96	.298
5	.727[e]	.529	.499	7.0609620	.001	.180	1	95	.672

a. Predictors: (Constant), PCS SF-36, MCS SF-36

b. Predictors: (Constant), PCS SF-36, MCS SF-36, PDQ Summed

c. Predictors: (Constant), PCS SF-36, MCS SF-36, PDQ Summed , PainBeh1

d. Predictors: (Constant), PCS SF-36, MCS SF-36, PDQ Summed , PainBeh1, PainInt1

e. Predictors: (Constant), PCS SF-36, MCS SF-36, PDQ Summed , PainBeh1, PainInt1, PhysFx1

Table 8 (Continued)
Depression

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	77.668	5.585		13.906	.000
	MCS SF-36	-.501	.095	-.489	-5.281	.000
	PCS SF-36	.041	.092	.041	.442	.659
2	(Constant)	39.890	10.042		3.972	.000
	MCS SF-36	-.425	.089	-.415	-4.781	.000
	PCS SF-36	.255	.097	.258	2.618	.010
	PDQ Summed	.463	.106	.434	4.378	.000
3	(Constant)	-6.190	11.728		-.528	.599
	MCS SF-36	-.341	.078	-.333	-4.368	.000
	PCS SF-36	.183	.085	.185	2.152	.034
	PDQ Summed	.127	.108	.119	1.179	.241
	PainBeh1	1.037	.177	.516	5.843	.000
4	(Constant)	-8.352	11.903		-.702	.485
	MCS SF-36	-.337	.078	-.329	-4.315	.000
	PCS SF-36	.182	.085	.184	2.140	.035
	PDQ Summed	.091	.113	.086	.808	.421
	PainBeh1	.908	.216	.452	4.202	.000
	PainInt1	.177	.169	.115	1.046	.298
5	(Constant)	-6.377	12.828		-.497	.620
	MCS SF-36	-.340	.079	-.332	-4.316	.000
	PCS SF-36	.210	.108	.212	1.949	.054
	PDQ Summed	.075	.120	.070	.623	.535
	PainBeh1	.915	.218	.456	4.205	.000
	PainInt1	.171	.171	.111	1.001	.319
	PhysFx1	-.068	.160	-.049	-.424	.672

a. Dependent Variable: DepressiveSxs1

Table 9
Pain Behavior

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.348[a]	.121	.103	4.7059829	.121	6.825	2	99	.002
2	.608[b]	.370	.351	4.0050230	.249	38.687	1	98	.000
3	.758[c]	.575	.558	3.3051639	.205	46.896	1	97	.000
4	.760[d]	.578	.556	3.3121053	.003	.594	1	96	.443

a. Predictors: (Constant), PCS SF-36, MCS SF-36

b. Predictors: (Constant), PCS SF-36, MCS SF-36, PDQ Summed

c. Predictors: (Constant), PCS SF-36, MCS SF-36, PDQ Summed , PainInt1

d. Predictors: (Constant), PCS SF-36, MCS SF-36, PDQ Summed , PainInt1, PhysFx1

Table 9 (Continued)
Pain Behavior

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	70.870	2.969		23.868	.000
	MCS SF-36	-.134	.050	-.262	-2.652	.009
	PCS SF-36	-.081	.049	-.164	-1.657	.101
2	(Constant)	50.864	4.090		12.435	.000
	MCS SF-36	-.081	.044	-.158	-1.843	.068
	PCS SF-36	.069	.048	.141	1.445	.152
	PDQ Summed	.105	.017	.609	6.220	.000
3	(Constant)	27.033	4.848		5.576	.000
	MCS SF-36	-.044	.036	-.087	-1.218	.226
	PCS SF-36	.044	.040	.089	1.104	.272
	PDQ Summed	.042	.017	.240	2.474	.015
	PainInt1	.448	.065	.585	6.848	.000
4	(Constant)	25.469	5.265		4.837	.000
	MCS SF-36	-.042	.037	-.082	-1.142	.256
	PCS SF-36	.020	.050	.041	.396	.693
	PDQ Summed	.046	.018	.265	2.586	.011
	PainInt1	.450	.066	.589	6.865	.000
	PhysFx1	.058	.075	.083	.771	.443

a. Dependent Variable: PainBeh1

Table 10
Pain Interference

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.367[a]	.135	.117	6.1061550	.135	7.708	2	99	.001
2	.633[b]	.401	.382	5.1071479	.266	43.519	1	98	.000
3	.772[c]	.596	.579	4.2146976	.195	46.896	1	97	.000
4	.774[d]	.599	.578	4.2202396	.003	.745	1	96	.390

a. Predictors: (Constant), PCS SF-36, MCS SF-36

b. Predictors: (Constant), PCS SF-36, MCS SF-36, PDQ Summed

c. Predictors: (Constant), PCS SF-36, MCS SF-36, PDQ Summed , PainBeh1

d. Predictors: (Constant), PCS SF-36, MCS SF-36, PDQ Summed , PainBeh1, PhysFx1

Table 10 (Continued)
Pain Interference

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	80.287	3.853		20.840	.000
	MCS SF-36	-.153	.065	-.229	-2.333	.022
	PCS SF-36	-.146	.063	-.227	-2.312	.023
2	(Constant)	44.555	6.303		7.069	.000
	MCS SF-36	-.081	.056	-.121	-1.449	.150
	PCS SF-36	.057	.061	.088	.929	.355
	PDQ Summed	.438	.066	.630	6.597	.000
3	(Constant)	12.197	7.027		1.736	.086
	MCS SF-36	-.022	.047	-.033	-.473	.637
	PCS SF-36	.006	.051	.010	.125	.901
	PDQ Summed	.202	.065	.291	3.125	.002
	PainBeh1	.728	.106	.557	6.848	.000
4	(Constant)	14.495	7.523		1.927	.057
	MCS SF-36	-.025	.047	-.038	-.536	.593
	PCS SF-36	.040	.064	.062	.623	.535
	PDQ Summed	.181	.069	.260	2.600	.011
	PainBeh1	.731	.107	.559	6.865	.000
	PhysFx1	-.082	.095	-.091	-.863	.390

a. Dependent Variable: PainInt1

Table 11
Physical Functioning

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.275[a]	.076	.057	6.9747647	.076	4.059	2	99	.020
2	.760[b]	.577	.560	4.7667616	.501	57.478	2	97	.000
3	.807[c]	.651	.633	4.3529258	.074	20.320	1	96	.000
4	.808[d]	.652	.630	4.3682872	.001	.326	1	95	.569
5	.809[e]	.655	.629	4.3740651	.003	.749	1	94	.389

a. Predictors: (Constant), Age.1, Gender

b. Predictors: (Constant), Age.1, Gender, PCS SF-36, MCS SF-36

c. Predictors: (Constant), Age.1, Gender, PCS SF-36, MCS SF-36, PDQ Summed

d. Predictors: (Constant), Age.1, Gender, PCS SF-36, MCS SF-36, PDQ Summed , PainBeh1

e. Predictors: (Constant), Age.1, Gender, PCS SF-36, MCS SF-36, PDQ Summed , PainBeh1, PainInt1

Table 11 (Continued)
Physical Functioning

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	45.794	3.723		12.301	.000
	Gender	-2.917	1.654	-.171	-1.764	.081
	Age.1	-.103	.047	-.210	-2.170	.032
2	(Constant)	16.994	4.390		3.871	.000
	Gender	-2.381	1.143	-.139	-2.084	.040
	Age.1	-.042	.033	-.085	-1.271	.207
	MCS SF-36	-.019	.052	-.025	-.361	.719
	PCS SF-36	.518	.050	.727	10.381	.000
3	(Constant)	33.254	5.393		6.166	.000
	Gender	-2.324	1.044	-.136	-2.227	.028
	Age.1	-.051	.030	-.104	-1.688	.095
	MCS SF-36	-.061	.048	-.083	-1.269	.207
	PCS SF-36	.398	.053	.558	7.525	.000
	PDQ Summed	-.083	.018	-.333	-4.508	.000
4	(Constant)	30.078	7.762		3.875	.000
	Gender	-2.429	1.063	-.142	-2.284	.025
	Age.1	-.049	.030	-.100	-1.614	.110
	MCS SF-36	-.056	.049	-.076	-1.150	.253
	PCS SF-36	.394	.053	.552	7.361	.000
	PDQ Summed	-.090	.022	-.359	-4.104	.000
	PainBeh1	.064	.112	.044	.571	.569
5	(Constant)	31.391	7.919		3.964	.000
	Gender	-2.483	1.067	-.145	-2.328	.022
	Age.1	-.047	.031	-.095	-1.519	.132
	MCS SF-36	-.058	.049	-.079	-1.186	.238
	PCS SF-36	.395	.054	.554	7.371	.000
	PDQ Summed	-.084	.023	-.336	-3.651	.000
	PainBeh1	.133	.138	.092	.965	.337
	PainInt1	-.092	.106	-.083	-.866	.389

a. Dependent Variable: PhysFx1

Table 12

Social Satisfaction- Discretionary Social Activities

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.317[a]	.101	.083	7.4167891	.101	5.542	2	99	.005
2	.468[b]	.219	.195	6.9479541	.118	14.811	1	98	.000
3	.512[c]	.262	.232	6.7855058	.044	5.749	1	97	.018
4	.673[d]	.453	.424	5.8749560	.190	33.398	1	96	.000
5	.675[e]	.455	.421	5.8914621	.003	.463	1	95	.498

a. Predictors: (Constant), PCS SF-36, MCS SF-36

b. Predictors: (Constant), PCS SF-36, MCS SF-36, PDQ Summed

c. Predictors: (Constant), PCS SF-36, MCS SF-36, PDQ Summed , PainBeh1

d. Predictors: (Constant), PCS SF-36, MCS SF-36, PDQ Summed , PainBeh1, PainInt1

e. Predictors: (Constant), PCS SF-36, MCS SF-36, PDQ Summed , PainBeh1, PainInt1, PhysFx1

Table 12 (Continued)
Social Satisfaction- Discretionary Social Activities

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	28.778	4.68		6.15	0
	MCS SF-36	-0.026	0.079	-0.033	-0.329	0.743
	PCS SF-36	0.25	0.077	0.326	3.259	0.002
2	(Constant)	57.138	8.574		6.664	0
	MCS SF-36	-0.083	0.076	-0.105	-1.095	0.276
	PCS SF-36	0.089	0.083	0.116	1.071	0.287
	PDQ Summed	-0.347	0.09	-0.42	-3.849	0
3	(Constant)	75.377	11.313		6.663	0
	MCS SF-36	-0.116	0.075	-0.146	-1.541	0.126
	PCS SF-36	0.118	0.082	0.153	1.431	0.156
	PDQ Summed	-0.215	0.104	-0.259	-2.061	0.042
	PainBeh1	-0.41	0.171	-0.263	-2.398	0.018
4	(Constant)	85.353	9.946		8.582	0
	MCS SF-36	-0.134	0.065	-0.169	-2.056	0.043
	PCS SF-36	0.123	0.071	0.16	1.726	0.087
	PDQ Summed	-0.049	0.095	-0.06	-0.521	0.603
	PainBeh1	0.185	0.18	0.119	1.026	0.308
	PainInt1	-0.818	0.142	-0.687	-5.779	0
5	(Constant)	87.995	10.703		8.221	0
	MCS SF-36	-0.138	0.066	-0.173	-2.097	0.039
	PCS SF-36	0.16	0.09	0.208	1.78	0.078
	PDQ Summed	-0.071	0.1	-0.086	-0.712	0.478
	PainBeh1	0.195	0.182	0.125	1.073	0.286
	PainInt1	-0.826	0.142	-0.694	-5.8	0
	PhysFx1	-0.091	0.133	-0.084	-0.68	0.498

a. Dependent Variable: SocSatDSA1

Table 13
Satisfaction with Social Roles

Model Summary[f]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.461[a]	.212	.195	8.9189745	.212	12.119	2	90	.000
2	.577[b]	.333	.311	8.2509785	.121	16.163	1	89	.000
3	.609[c]	.371	.342	8.0603287	.038	5.260	1	88	.024
4	.642[d]	.413	.379	7.8335141	.042	6.170	1	87	.015
5	.645[e]	.416	.375	7.8567587	.003	.486	1	86	.488

a. Predictors: (Constant), PCS SF-36, MCS SF-36

b. Predictors: (Constant), PCS SF-36, MCS SF-36, PDQ Summed

c. Predictors: (Constant), PCS SF-36, MCS SF-36, PDQ Summed , PainBeh1

d. Predictors: (Constant), PCS SF-36, MCS SF-36, PDQ Summed , PainBeh1, PainInt1

e. Predictors: (Constant), PCS SF-36, MCS SF-36, PDQ Summed , PainBeh1, PainInt1, PhysFx1

f. Dependent Variable: SocSatRol1

Table 13 (Continued)
Satisfaction with Social Roles

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	7.893	5.872		1.344	.182
	MCS SF-36	.186	.100	.183	1.865	.065
	PCS SF-36	.365	.097	.370	3.766	.000
2	(Constant)	35.487	8.753		4.054	.000
	MCS SF-36	.106	.094	.105	1.127	.263
	PCS SF-36	.159	.103	.161	1.539	.127
	PDQ Summed	-.144	.036	-.425	-4.020	.000
3	(Constant)	60.334	13.802		4.371	.000
	MCS SF-36	.066	.094	.065	.700	.486
	PCS SF-36	.194	.102	.197	1.902	.060
	PDQ Summed	-.094	.041	-.277	-2.275	.025
	PainBeh1	-.487	.212	-.244	-2.293	.024
4	(Constant)	65.560	13.577		4.829	.000
	MCS SF-36	.059	.091	.058	.647	.519
	PCS SF-36	.206	.099	.209	2.076	.041
	PDQ Summed	-.061	.042	-.179	-1.436	.155
	PainBeh1	-.084	.262	-.042	-.320	.750
	PainInt1	-.502	.202	-.338	-2.484	.015
5	(Constant)	62.409	14.348		4.350	.000
	MCS SF-36	.063	.092	.062	.686	.494
	PCS SF-36	.156	.123	.158	1.273	.206
	PDQ Summed	-.050	.045	-.148	-1.107	.271
	PainBeh1	-.098	.264	-.049	-.370	.713
	PainInt1	-.491	.203	-.331	-2.420	.018
	PhysFx1	.128	.184	.092	.697	.488

a. Dependent Variable: SocSatRol1

Table 14
PDQ Severity Category Change Across Time Points

PDQ Category Changed from Pre to Post

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	-1.00	5	1.9	6.1	6.1
	.00	46	17.9	56.1	62.2
	1.00	28	10.9	34.1	96.3
	2.00	3	1.2	3.7	100.0
	Total	82	31.9	100.0	
Missing	System	175	68.1		
Total		257	100.0		

Table 15
ANOVA for PDQ Severity Categories by Primary Outcome Measures

ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
MCS SF-36	Between Groups	522.489	2	261.245	2.681	.072
	Within Groups	12277.511	126	97.441		
	Total	12800.000	128			
PCS SF-36	Between Groups	4217.368	2	2108.684	30.957	.000
	Within Groups	8582.632	126	68.116		
	Total	12800.000	128			
PROMIS PainInt1	Between Groups	3516.539	2	1758.270	65.794	.000
	Within Groups	5157.706	193	26.724		
	Total	8674.245	195			
PROMIS PhysFx1	Between Groups	3597.388	2	1798.694	49.391	.000
	Within Groups	7028.607	193	36.418		
	Total	10625.995	195			
PROMIS PainBeh1	Between Groups	884.826	2	442.413	27.209	.000
	Within Groups	3121.918	192	16.260		
	Total	4006.744	194			

Table 16

Multiple Comparisons of Primary Outcome Measures by PDQ Category

Multiple Comparisons

Bonferroni

Dependent Variable	(I) PDQT1Cat	(J) PDQT1Cat	Mean Diff (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
MCS SF-36	1	2	0.82447	2.39718	1	-4.992	6.6409
		3	4.45615	2.20727	0.13	-0.8995	9.8118
	2	1	-0.82447	2.39718	1	-6.6409	4.992
		3	3.63169	2.03039	0.228	-1.2948	8.5582
	3	1	-4.45615	2.20727	0.13	-9.8118	0.8995
		2	-3.63169	2.03039	0.228	-8.5582	1.2948
PCS SF-36	1	2	6.33968*	2.00427	0.006	1.4766	11.2028
		3	14.07974	1.84548	0	9.6019	18.5576
	2	1	-6.3396*	2.00427	0.006	-11.2028	-1.4766
		3	7.74006*	1.6976	0	3.6211	11.8591
	3	1	-14.0797*	1.84548	0	-18.5576	-9.6019
		2	-7.74006*	1.6976	0	-11.8591	-3.6211
PROMIS Pain Interference	1	2	-4.90804*	1.03654	0	-7.41175	-2.4068
		3	-10.5688*	0.95172	0	-12.8607	-8.2631
	2	1	4.90804*	1.03654	0	2.40516	7.4117
		3	-5.65384*	0.85862	0	-7.72678	-3.5795
	3	1	10.5628*	0.951725	0	8.26318	12.8600
		2	5.65684*	0.858628	0	3.57955	7.72678
PROMIS Physical Functioning	1	2	6.16870*	1.210029	0	3.24650	9.091013
		3	10.92967*	1.111010	0	8.24648	13.61272
	2	1	-6.16875*	1.210029	0	-9.09101	-3.24650
		3	4.760847*	1.002332	0	2.34018	7.181508
	3	1	-10.9260*	1.111010	0	-13.6127	-8.24648
		2	-4.76087*	1.002332	0	-7.18150	-2.34018

Table 16 (Continued)
Multiple Comparisons of Primary Outcome Measures by PDQ Category

Dependent Variable	(I) PDQT1Cat	(J) PDQT1Cat	Mean Diff (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
PROMIS Pain Behavior	1.00	2.00	-1.95917	.8114702	.050	-3.918991	.000634
		3.00	5.15334*	.7423731	.000	-6.946276	-3.360408
	2.00	1.00	1.95917	.8114702	.050	-.000634	3.918991
		3.00	3.19416*	.6732928	.000	-4.820259	-1.568069
	3.00	1.00	5.15334*	.7423731	.000	3.360408	6.946276
		2.00	3.19416*	.6732928	.000	1.568069	4.820259

*. The mean difference is significant at the 0.05 level.

Table 17
Predictive Ability by PDQ Category Severity

Multivariate Tests[a]

Effect		Value	F	Hypo df	Error df	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[d]
Intercept	Pillai's Trace	0.998	11752.801[b]	7	180	0	0.998	82269.604	1
	Wilks' Lambda	0.002	11752.801[b]	7	180	0	0.998	82269.604	1
	Hotelling's Trace	457.053	11752.801[b]	7	180	0	0.998	82269.604	1
	Roy's Largest Root	457.053	11752.801[b]	7	180	0	0.998	82269.604	1
PDQ Category	Pillai's Trace	0.544	9.669	14	362	0	0.272	135.364	1
	Wilks' Lambda	0.472	11.705[b]	14	360	0	0.313	163.873	1
	Hotelling's Trace	1.083	13.841	14	358	0	0.351	193.778	1
	Roy's Largest Root	1.049	27.128[c]	7	181	0	0.512	189.896	1

a. Design: Intercept + PDQT1Category

b. Exact statistic

c. The statistic is an upper bound on F that yields a lower bound on the significance level.

d. Computed using alpha = .05

Table 18

PDQ Severity Category Comparisons with Primary Outcome Variables

Multiple Comparisons

Bonferroni

Dependent Variable	(I) PDQT1Category	(J) PDQT1Category	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Anger	1	2	-7.18722*	1.96373	0.001	-11.9243	-2.436991
		3	-10.8752*	1.79231	0	-15.2308	-6.538396
	2	1	7.182722*	1.96873	0.001	2.43691	11.92453
		3	-3.69313	1.66325	0.083	-7.71191	0.325531
	3	1	10.87852*	1.79401	0	6.53396	15.21308
		2	3.69313	1.66325	0.083	-0.32531	7.711791
Anxiety	1	2	-4.79187*	1.85493	0.032	-9.27178	-0.312196
		3	-8.93422*	1.69575	0	-13.0286	-4.840858
	2	1	4.791187*	1.85493	0.032	0.31196	9.270178
		3	-4.14335*	1.56989	0.027	-7.93122	-0.350548
	3	1	8.934522*	1.69575	0	4.84058	13.02886
		2	4.143335*	1.56989	0.027	0.30548	7.936122
DepressiveSxs	1	2	-4.85171*	1.94274	0.041	-9.56946	-0.143397
		3	-10.0751*	1.78972	0	-14.3958	-5.728244
	2	1	4.854171*	1.94274	0.041	0.14397	9.564946
		3	-5.17580*	1.65088	0.006	-9.16864	-1.190519
	3	1	10.03751*	1.78872	0	5.72244	14.33258
		2	5.179580*	1.65088	0.006	1.19019	9.16864
Pain Behavior	1	2	-1.881034	0.84075	0.083	-3.92484	0.164417
		3	-5.44202*	0.77317	0	-7.31383	-3.573421
	2	1	1.881034	0.84675	0.083	-0.16417	3.926484
		3	-3.561869*	0.71796	0	-5.29946	-1.829791
	3	1	5.442902*	0.773317	0	3.573421	7.312383
		2	3.561869*	0.74796	0	1.82991	5.293946

Table 18 (Continued)
PDQ Severity Category Comparisons with Primary Outcome Variables

Dependent Variable	(I) PDQT1Category	(J) PDQT1Category	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Pain Interference	1	2	-5.365830*	1.0958602	0	-8.01054	-2.716606
		3	-10.94601*	1.0015834	0	-13.3613	-8.51929
	2	1	5.365830*	1.0958602	0	2.716606	8.015054
		3	-5.574771*	0.9279689	0	-7.81821	-3.331422
	3	1	10.940601*	1.0015834	0	8.51929	13.361913
		2	5.574771*	0.9279689	0	3.331422	7.818121
Physical Functioning	1	2	6.476392*	1.2566094	0	3.438559	9.514224
		3	11.093512*	1.1485034	0	8.317024	13.87
	2	1	-6.476392*	1.2566094	0	-9.51424	-3.438559
		3	4.617120*	1.0640906	0	2.044698	7.189541
	3	1	-11.09512*	1.1485034	0	-13.87	-8.317024
		2	-4.617120*	1.0640906	0	-7.18541	-2.044698
Social Satisfaction DSA	1	2	6.712235*	1.5307255	0	3.011731	10.412739
		3	10.481969*	1.3990374	0	7.099819	13.864119
	2	1	-6.712235*	1.5307255	0	-10.4139	-3.011731
		3	3.769734*	1.2962107	0.012	0.636166	6.903302
	3	1	-10.48169*	1.3990374	0	-13.8619	-7.099819
		2	-3.769734*	1.2962107	0.012	-6.90302	-0.636166
Satisfaction-Social Role	1	2	6.853736*	1.9911191	0.002	2.040238	11.667233
		3	13.103346*	1.8198234	0	8.703953	17.502739
	2	1	-6.853736*	1.9911191	0.002	-11.6623	-2.040238
		3	6.249610*	1.6860698	0.001	2.173564	10.325656
	3	1	-13.10346*	1.8198234	0	-17.5029	-8.703953
		2	-6.249610*	1.6860698	0.001	-10.3256	-2.173564

Based on observed means.

The error term is Mean Square(Error) = 90.886.

*. The mean difference is significant at the .05 level.

Table 19

Logistic Regression: PDQ Baseline Total Score and Low/High Healthcare Cost

Classification Table[a]

Observed			Predicted		
			Low/High Healthcare Cost		
			Low Cost	High Cost	Percentage Correct
Step 1	Low/High Healthcare Cost	Low Cost	13	9	59.1
		High Cost	7	20	74.1
	Overall Percentage				67.3

a. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1[a]	PDQ_Pre	.100	.039	6.615	1	.010	1.105
	Constant	-4.963	2.020	6.038	1	.014	.007

a. Variable(s) entered on step 1: PDQ_Pre.

PDQ_Category * Low/High Healthcare Cost Crosstabulation

			Low/High Healthcare Cost		
			Low Cost	High Cost	Total
PDQ Severity Category	Mild/Moderate	Count	7	3	10
		% within Category	70.0%	30.0%	100.0%
	Severe	Count	6	8	14
		% within Category	42.9%	57.1%	100.0%
	Extreme	Count	9	16	25
		% within Category	36.0%	64.0%	100.0%
Total		Count	22	27	49
		% within Category	44.9%	55.1%	100.0%

Table 20

PDQ Summed Score and Healthcare Cost by Time Point

Correlations

		PDQ_Pre	PDQ_Post	3-month Healthcare Cost
PDQ_Pre	Pearson Correlation	1	.777**	.423**
	Sig. (1-tailed)		.000	.001
	N	48	26	48
PDQ_Post	Pearson Correlation	.777**	1	.391*
	Sig. (1-tailed)	.000		.022
	N	26	27	27
3-month Healthcare Cost	Pearson Correlation	.423**	.391*	1
	Sig. (1-tailed)	.001	.022	
	N	48	27	50

**. Correlation is significant at the 0.01 level (1-tailed).

*. Correlation is significant at the 0.05 level (1-tailed).

Table 21

PDQ Severity Category Frequencies by Time Point

PDQ_Pre-Treatment Category

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1.00	54	21.0	23.0	23.0
	2.00	73	28.4	31.1	54.0
	3.00	108	42.0	46.0	100.0
	Total	235	91.4	100.0	
Missing	System	22	8.6		
Total		257	100.0		

PDQ_Post-Treatment Category

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1.00	32	12.5	38.1	38.1
	2.00	33	12.8	39.3	77.4
	3.00	19	7.4	22.6	100.0
	Total	84	32.7	100.0	
Missing	System	173	67.3		
Total		257	100.0		

APPENDIX D
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