COMPUTER-ADMINISTERED PATIENT-REPORTED OUTCOMES (PRO) AND PSYCHIATRIC SCREENING IN OUTPATIENT PAIN PATIENTS: EFFECT OF A POINT-OF-CARE BIOPSYCHOSOCIAL PATIENT HEALTH REPORT ON TREATMENT OUTCOMES

APPROVED BY SUPERVISORY COMMITTEE

Robert J. Gatchel, PhD, ABPP – Chairperson

Carl Noe, MD

Betsy Kennard, PsyD

Martin Deschner, PhD

Monty Evans, PhD

DEDICATION

For my family, whose support and encouragement have made these achievements possible for me.

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Eric Swanholm, 2011

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BY

ERIC NEAL SWANHOLM

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ERIC NEAL SWANHOLM, B.A.

The University of Texas Southwestern Medical Center at Dallas

ROBERT J. GATCHEL, PhD

Chronic pain is a widespread health problem that carries steep costs for both individuals and society. Pain-related complaints represent one of the most common presenting symptoms across ambulatory care settings. Individuals with chronic pain often have comorbid psychiatric symptoms and/or psychosocial dysfunction. Given the related impact on treatment and health-care costs, tracking psychiatric and psychosocial outcomes is beneficial for chronic pain patients, their health care providers, and service providers. Outcome-tracking interventions that could positively affect treatment outcomes hold potential benefits for patient care.

The purpose of the present study was to examine the effects of the regular collection and results feedback prior to the point-of-care on multiple patient-reported outcome (PRO) domains in outpatient pain patients. Maximizing ecological validity and non-disruption of clinic flow were given significant focus in the study design and process.

This study used repeated measures and was conducted in an outpatient pain management and interdisciplinary treatment clinic (2 anesthesiologists, 1 psychiatrist, 1 psychologist, 1 counselor, 1 physical therapist). A total of 69 pain patients were randomly assigned to one of two protocol-based PRO feedback intervention groups (separate feedback to both patients and providers [Dual Feedback]; Provider-Only Feedback) or a non-intervention group (Chart-Review Only). Assessments were completed prior to the point-of-care; feedback for intervention groups was based upon a real-time, automated report generated from their PRO data. Data were gathered on touch-screen tablet-pc's using multiple computer-adaptive-tests from the NIH-sponsored Patient Reported Outcomes Measurement Information Systems (PROMIS) Assessment Center platform; outcome domains included pain-related functioning (Pain Disability Questionnaire [PDQ]; VAS pain rating; PROMIS Physical Functioning, Pain Behavior, and Pain Interference), psychological symptoms and psychosocial variables (PROMIS Depression, Anxiety, Sleep-Related Impairment, Fatigue, Social Functioning; hypomania history screen; Pain Medication Questionnaire [PMQ; opioid misuse risk]), global HRQoL (PROMIS Mental and Physical Health domains), treatment alliance (Working Alliance Inventory [WAI]; ratings from both patients and providers]), and illness perception and optimism (Brief Illness Perception Questionnaire [BIPQ]; Life Orientation Test- Revised). Performance-based data (walking time, grip strength, range-of-motion/flexibility) were collected by the physical therapist for study patients whose treatment included a PT component (e.g. interdisciplinary pain program, individual

services). Significant covariates were identified and incorporated into the primary analyses. Primary outcomes were the individual measures within each outcome domain. Analyses utilized mixed-effects modeling with random coefficients and multiple regression in comparisons of all three study groups. Secondary analysis included tabulation of completion time and comparisons between a Combined Feedback group (both intervention groups) and Chart-Review Only.

Significant covariates included treatment type, history of psychiatric diagnosis, and a biological family history of psychiatric diagnosis. Comparing Dual Feedback vs. Chart Review Only, patients in the Dual Feedback intervention had significantly better outcomes over time for a number of domain outcomes; specifically, in pain-related functioning/symptoms (PDQ [$P = .003$]; PROMIS Pain Interference [$P = .023$]; VAS pain [$P = .03$]), psychological and psychosocial variables (PROMIS Anger [$P = .001$]; PROMIS Anxiety [$P = .012$]; PROMIS Depression [$P = .029$]; PROMIS Sleep-Related Impairment [$P = .001$]; PROMIS Social Functioning – Satisfaction with Discretionary Social Activities [$P = .047$]), PROMIS Global HrQOL (Mental Health [$P = .021$]; Physical Health [$P = .032$]), treatment alliance (WAI – Bond [patient-rated][$P = .046$]), illness perceptions (BIPQ – Consequence [$P = .017$]; BIPQ – Timeline [$P = .011$]; BIPQ – Treatment Control [$P = .029$]), and one performance-based measure (Walk Time [$P = .007$]). Similarly, patients in the Provider-Only group had better outcomes over time for multiple outcome domains; including, pain-related functioning/symptoms (PDQ [$P = .033$]; PROMIS Pain Interference [$P = .031$]; PROMIS Fatigue [$P = .036$]; PROMIS Physical Functioning [$P = .049$]), psychological and psychosocial

variables (PMQ [opioid misuse risk][*P* = .041]), treatment alliance (WAI – Bond [patient-rated][*P* = .076]; WAI – Bond [provider-rated][*P* = .008]), illness perceptions (BIPQ – Timeline [*P* = .048]; BIPQ – Personal Control [*P* = .027]), and one performance-based measure (Walk Time [*P* = .035]). Comparisons between patients in the Dual Feedback and Provider-Only Feedback groups were significant for a few domain outcomes. Compared to Provider-Only Feedback, Dual Feedback had better outcomes over time for multiple domain measures; including, the PDQ (*P* = .085), PROMIS Anger (*P* = .000), PROMIS Anxiety (*P* = .018), and BIPQ – Treatment Control (*P* = .015). Conversely, the Provider-Only group had better outcome scores over time for PROMIS Global HrQOL (Mental Health (*P* = .032); Physical Health (*P* = .074). Analyses of process variables showed a mean completion time of 15.8 minutes for the entire assessment; completion-time statistics were also calculated for the 11 PROMIS computer-adaptive-tests (*M* = 7.57 minutes [all PROMIS CAT's]; *M* = 41.3 second per measure, *SD* = 9.3 seconds) and other primary outcomes (PDQ, PMQ, BIPQ) (*M* = 8.23 minutes total; *M* = 2.74 minutes per measure, *SD* = .99 minutes).

The provision of dual feedback (patient and providers) from PRO data collected prior to the point-of-care had an impact on several outcomes from multiple domains (pain-related functioning, psychological symptoms, psychosocial variables, illness perception, walking performance) over time, compared to patients who received no point-of-care feedback. To a lesser extent, group by time effects were also observed in comparisons between patients

receiving provider-only feedback and those with no feedback. Brought together, high ecological validity was maintained with minimal disruption of clinic flow; likely contributing factors include the use of a set framework for outcome-tracking, protocol-based delivery of feedback, and efficiency of administration. This is the first study to show the potential benefits of providing PRO data feedback to both patients and providers prior to the point-of-care.

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LIST OF ABBREVIATIONS

BIPQ – Brief Illness Perception Questionnaire

CAT – Computer Adaptive Test

DIF – Differential Item Functioning

DSM – Diagnostic and Statistical Manual of Mental Disorders

Dx – Diagnosis

ePRO – Electronic Patient Reported Outcome

IRT – Item-Response Theory

HCL-32 – Hypomania Checklist

Hx - History

LOT-R – Life Orientation Test - Revised

PDQ – Pain Disability Questionnaire

PMQ – Pain Medication Questionnaire

PROMIS – Patient Reported Outcome Measurement Information System

PROMIS-Ag – PROMIS ANGER Item Bank Version 1.0

PROMIS-Ax – PROMIS Anxiety Item Bank Version 1.0

PROMIS-D – PROMIS Depression Item Bank Version 1.0

PROMIS-F – PROMIS Fatigue Item Bank Version 1.0

PROMIS-GH-SF – PROMIS Global Health Short-Form

PROMIS-PB – PROMIS Pain Behavior Item Bank Version 1.0

PROMIS-PF – PROMIS Physical Functioning Item Bank Version 1.0

PROMIS-PI – PROMIS Pain Interference Item Bank Version 1.0

PROMIS-SD – PROMIS Sleep Disturbance Item Bank Version 1.0

PROMIS-SRI – PROMIS Sleep-related Impairment Item Bank Version 1.0

PRO – Patient Reported Outcome

Sxs - Symptoms

WAI – Working Alliance Index

CHAPTER ONE
INTRODUCTION

Scope and significance

Overview

Chronic pain is a multidimensional problem that affects nearly one-third of the Unites States population (Johannes, Le, Zhou, Johnston, & Dworkin, In Press) and ranks among the world's top health problems (Latham, 1994). In addition to substantial impact on the quality of life of patients and their families, chronic pain carries a steep social cost (Gatchel, 2004). A number of factors related to chronic pain (e.g., loss of income, decreased work productivity, additional medical costs from increased health care utilization, greater use of social security disability insurance) contribute to approximately $90 billion in annual economic cost in the US (Gatchel, 2004; Nuovo, 2007). Pain-related complaints account for approximately 80% of all physician visits, representing one of the most common presenting symptoms across ambulatory care settings (Amtmann, et al., 2010; Nuovo, 2007). Thus, chronic pain represents a widespread health problem with high societal costs.

Pain disorders are often a confluence of medical pathology, psychiatric symptoms, and psychosocial issues. In addition to their chronic pain, these patients often have one or more comorbid medical conditions (Rothrock, et al., 2010). The presence of multiple medical conditions has been found to significantly affect treatment outcomes and general functionality (Rothrock, et al., 2010). A wealth of studies report high percentages of psychiatric comorbidity [e.g. depressive disorder, anxiety-related disorders (generalized, panic), substance use, personality pathology] in chronic pain patients (Gatchel, 2004; Workman, 2002). Rather than just a post-injury phenomenon, a well-regarded study found psychiatric disorders were often present prior to the development of chronic pain for a significant number of patients (Polatin, et al., 1993). Intuitively,

chronic pain can have significant impact on the social, interpersonal, and occupational functioning of patients. It is well established that these general indicators and other psychosocial factors often play an integral role in the onset, maintenance, and/or exacerbation of chronic pain (Gatchel, Polatin, & Mayer, 1995). Coherent synthesis of this research requires an inclusive theoretical approach that incorporates the biological, psychological, and social aspects of patients.

The Biopsychosocial Perspective (BPS) provides a model that successfully accounts for these factors. Gatchel (2004) describes the BPS model as, "view[ing] physical disorders such as pain as the result of a dynamic interaction among physiologic, psychologic and social factors, which perpetuates and may worsen the clinical presentation" (p#?). The BPS approach has led to the development of evidence-based treatments for individuals with different types of chronic pain and other conditions with mental-health/physical components (Gatchel & Oordt, 2003). In addition to particular condition-specific interventions, the BPS model has influenced the development and proliferation of inter- and multi-disciplinary treatment approaches (Gatchel, 2004).

The gains from clinical research have been of clear benefit to clinical practitioners working with patients with pain-related difficulties. In clinical practice, providers are better able to identify specific factors (e.g., psychiatric, psychosocial, demographic) that may impact the onset, chronicity, exacerbation, and treatment of individuals with chronic pain. Naturally, increased understanding of treatment-related factors allows for greater measurement precision of relevant treatment outcomes and related variables. As part of a larger trend, assessment of health-related outcomes has become increasingly "patient-centered," with a focus on "health-related

quality of life" in recent years (Cella, Gershon, Jin-Shei, & Seung, 2007; Deutscher, D. Hart, R. Dickstein, S. Horn, & M. Gutvirtz, 2008; Rothrock, et al., 2010).

A "patient-reported outcome" (PRO) refers to self-report measures of health status (Gwaltney, Shields, & Shiffman, 2008). PRO measures have been well-accepted in the realm of clinical research, and have important implications in clinical practice (Deutscher, Hart, Dickstein, Horn, & Gutvirtz, 2008; Reise & Waller, 2009). Recent publications have highlighted several potential benefits of integrating PRO data into health-related clinical practice (e.g., promotion of patient-centered care, use as point-of-care screening and monitoring tools, aid for clinical decision-making, means for facilitating communication within multidisciplinary teams, monitoring quality assurance of patient care) (Feldman-Stewart & Brundage, 2009; Greenhalgh, 2009; Gwaltney, et al., 2008; Rose & Bezjak, 2009). To some degree, this promise has not been attained because of inconsistent and non-significant findings from a number of previous studies (Greenhalgh, 2009). However, several authors have argued that results of previous studies were impacted by a lack of both methodological and theoretical clarity (Feldman-Stewart & Brundage, 2009; Greenhalgh, 2009; Rose & Bezjak, 2009). Recommendations for the methodology of future studies included the use of well-defined outcome measures, selecting condition- and population-specific PROs, and the incorporation of time-efficient modes of administration (e.g., interactive voice recognition, computer-based) and testing (i.e., computer-adaptive-testing) (Greenhalgh, 2009; Rose & Bezjak, 2009). Greenhalgh (2009) argued that future research in this area would benefit from the establishment of "taxonomy of applications" for PROs in clinical practice. He and his colleagues posited a framework through which study parameters and related

research questions could be clearer and more grounded. Feldman-Stewart and Brundage (2009) proposed a conceptual framework of provider-patient communication that accounted for some inconsistencies in previous studies. They argued that the incorporation of a communications-based model into future research could improve the study of PROs by allowing for more precise and testable hypotheses (Feldman-Stewart & Brundage, 2009).

The array of potential treatment-related concerns of chronic pain patients (e.g., multiple medical conditions, high psychiatric comorbidity, psychosocial concerns) highlights the need and potential benefit of studying PRO data in clinical practice settings. There is a dearth of research that has incorporated this focused methodology with newer administration modes to examine the effect PRO data feedback in chronic pain clinical practice. The present study seeks to incorporate these methodological and theoretical recommendations into a study of the effect of PRO data feedback at the point-of-care in a chronic pain clinical practice.

CHAPTER TWO
REVIEW OF THE LITERATURE

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Overview

The International Association for the Study of Pain defines pain as, " an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" (Merskey & Bogduk, 1994). Chronic pain is defined as non-cancer-related pain that persists beyond three months (Gatchel & Okifuji, 2006; Nuovo, 2007). Over the last few decades, the understanding and treatment of pain have undergone a shift from a strict biomedical conception (i.e., pain as having a one-to-one correspondence to tissue damage) to a biospychosocial perspective (i.e., an inclusive approach that views pain in terms of the mind-body connection, as influenced by the environment (Gatchel, 2004). The corresponding biological processes that have influenced this shift are well-detailed (Gatchel, 2004). The exact workings of biologically-related pain processes are not the focus of the proposed study. Rather, assessment of the presence and impact of distress, in its various forms, in relation to underlying pain processes is a primary focus. Specifically, the proposed study will examine the means of identifying and facilitating treatment for those psychosocial factors that impact the experience of chronic pain patients. The corresponding patient-provider communication that occurs in treatment settings is inherent to the focus of this research. To provide context for this proposed study, relevant literature associated with these specific topics will be reviewed.

Psychiatric Comorbidity

The overall prevalence rate of psychiatric disorders in chronic pain patients is significantly higher than the general population (Dersh, Gatchel, Polatin, & Mayer, 2002; Gatchel, 2004). These particular studies evaluated large samples of chronic pain patients, and found that a range of 64% to 77% of sampled patients had at least one current psychiatric disorder. Similarly, multiple studies have reported that chronic pain patients have significantly higher rates of psychiatric disorders than the general population (Bair, Robinson, Katon, & Kroenke, 2003; Demyttenaere, et al., 2007; Lachlan, Brian, & Murray, 2003; Nicolson, Caplan, Williams, & Stern, 2009; Stein, 2009). To highlight the clear overlap between these pathologies, a common finding is that a majority of patients with mental health symptoms often present with somatic or pain-related symptoms (Miller, 2006). As defining symptoms in chronic pain conditions, pain and fatigue are some of the most common patient-reported symptoms across a broad range of other chronic diseases and conditions (Yorkston, Johnson, Boesflug, Skala, & Amtmann, 2010). Psychosocial factors and diagnosable psychiatric disorders often play a role in the development (i.e., are present prior to the development of a chronic pain condition) course, and/or chronicity of pain-related conditions (Bair, et al., 2003; Nicolson, et al., 2009; Peng, Fuchs, & Gatchel, 2006; Polatin, 1993).

Both depressive disorders and anxiety disorders are common in chronic pain patients (Gatchel, 2004). These disorder groups are some of the most common diagnoses within the general population (e.g., Depressive Disorders 2-14%; Anxiety-related Disorders 18%); however, their prevalence within the

chronic pain population has been found to be significantly higher. Even with increased awareness, both disorder groups have high under-diagnosis rates across the spectrum of ambulatory care settings (Falagas, Vardakas, &Vergidis, 2007; Lepine, Gastpar, Mendlewicz, et al., 1997; Lecrubier, 2001). As would be expected, a recent study reported that depression, if unrecognized and left untreated, often leads to substantial morbidity and complicates the course of a spectrum of chronic medical conditions (Weissman, et al., 2010).

Substance-use disorders are highly prevalent in chronic pain patients with estimates between 11% - 44% (Manchikanti, 2006). Further, it is estimated that up 41% of individuals seeking care at chronic pain clinics misuse their opioid medication. Manchikanti (2006) reported that approximately 40% of patients in a large (N=500) study used illicit substances. Another study found that these disorders were present before patients' onset of pain 94% of the time (Gatchel, 2004). An inherent complication for pain patients is that opioid medication is frequently prescribed and often indicated for treatment. Intuitively, the significant treatment cost associated with opioid misuse and addiction adds further weight to the societal costs of chronic pain. As highly prevalent disorders, assessing for and monitoring substance use disorders are of clear importance in the treatment of chronic pain.

The prevalence of Bipolar Spectrum Disorders (BSD) is elevated in the chronic pain population as well (Dersh et al., 2002). Beyond its identification in research, BSD is often unrecognized and under-diagnosed across ambulatory care settings. The overall prevalence rate for BSD is estimated to be between 0.5-4%

with an estimated under-diagnosis rate of 60-80% (Falagas et al., 2007, Das, Olfson, & Gameroff, 2005; Mitchell, Slade, & Andrews, 2004). To highlight the potential rate of misdiagnosis, a recent study with primary care patients reported that only 19.8% of BPD patients were accurately identified, 31.2% received an inaccurate diagnosis of depression, and 49% were completely overlooked (Hirschfeld, Holzer, & Calabrese, 2003). An earlier meta-analysis reported a similar misdiagnosis rate of 26-28% of patients diagnosed with major depressive disorder (MDD) screened positive for Bipolar Disorder (BPD) in primary care settings (Manning et al. 1997; Hantouhche et al., 1998). While these studies were conducted with primary care patients, the potential for misdiagnosis amongst the chronic pain population is equally plausible. Due to pharmacological differences in the treatment of depressive disorder and bipolar spectrum disorders, screening to differentiate between Bipolar Spectrum disorders and depressive disorders is important (Weissman, et al., 2010).

Unrecognized and untreated psychiatric comorbidities are associated with poor treatment outcomes, and lead to greater treatment costs for both providers and patients in chronic pain and other medical care settings (Falagas, Vardakas, & Vergidis, 2007; Gatchel, 2004; Nuovo, 2007).

Psychosocial Factors

The term psychosocial refers to the general interaction between social environment and an individual's psychological aspects or development. Broadly, psychosocial factors can be placed in a number of categories (e.g., financial,

social, interpersonal, educational, familial) (Gatchel et al., 1995). Factors of particular concern to chronic pain patients includes basic demographic variables, disability status, work status, financial status, relationship status, and

Psychosocial factors impact treatment response, accrual of treatment cost, and amount of health care utilization by chronic pain patients and across other ambulatory medical care settings (Gatchel, et al., 1995; Nuovo, 2007). The far-reaching impact of these factors highlights the need to identify, track, and facilitate care with regard to identifiable psychiatric and psychosocial difficulties.

ASSESSMENT OF CHRONIC PAIN PATIENTS

Overview

Traditional methods of assessment in pain management practice and other ambulatory care settings include face-to-face interviews and paper-and-pencil questionnaires. In recent years, computerized methodologies have been increasingly used for their ability "to make assessment results immediately available for the clinical encounter" (Rose & Bezjak, 2009). This automated function is made possible by the "real-time" efficiency with which data is entered, administered, analyzed, and summarized in printout (Rose & Bezjak, 2009).

Measurement Equivalence

Measurement equivalence (i.e., equivalent reliability and validity) between paper-and-pencil and different modes of administration is an important consideration. The shift to electronically-administered measures requires the

establishment of equivalence between computer-based and the original versions (Gwaltney, et al., 2008; Gwaltney, 2009). Lack of measurement equivalence can stem from changes to the presentation or content of measures (e.g., change to item stems, instructions, or general wording; number of questions per screen, size of screen displaying items). Lack of measurement equivalence can also stem from lack of computer-proficiency or anxiety related to using computers (Gwaltney, et al., 2008). Gwaltney (2009) reported that, when previous studies accounted for these two factors, equivalence was consistently demonstrated. This meta-analytic review of measurement equivalence studies concluded that, provided content and presentation changes are minimal, "extensive evidence indicates that paper- and computer-administered [measures] are equivalent" (Gwaltney, 2009).

Computerized Assessment

Gwaltney and colleagues (2008) argued that computerized assessments have several advantages over paper-and-pencil assessments including: reduction of missing data and patient selection of multiple answers to an item; ability to simplify more complex skip functions; and the reduction of data-entry burden (Gwaltney, et al., 2008).

Multiple studies have evaluated the measurement equivalence (i.e., comparability of the psychometric properties of data) between measures by administration mode (Coons, et al., 2009; Gwaltney, et al., 2008). Specifically, these studies have examined measurement equivalence for a variety of patient-reported outcome (PRO) measures and administration-mode comparisons [e.g.

computer-based (via the internet at home, within the provider's office), PDA, tablet-based, telephone-based or interactive voice recognition (IVR), and paper-based]. In total, the majority of studies have found measurement equivalence by mode-of-administration (Coons, et al., 2009; Gwaltney, et al., 2008).

Computerized administration carries concerns about the nature of the patient population being studied; in particular, literacy, reading level, visual ability, familiarity with touch-screen computers, and manual dexterity (Rose & Bezjak, 2009).

The development of computer adaptive tests based upon Item-Response Theory may provide a means of addressing the limitations of current questionnaires. Through their design, CAT's are able to decrease respondent burden while increasing measurement precision (Rose & Bezjak, 2009).

Item Response Theory (IRT)

Item-response theory is a statistical approach that measures underlying traits through an analysis of response scores. Rather than producing summary scores, as do measures that use Classical Test Theory, IRT-based measures yield trait scores or trait estimates. There are a number of IRT-based statistical models with applications in a variety of fields. IRT-related statistical methods are widely accepted within the academic community, and are often used to enhance measurement precision (e.g., reliability, validity) and/or test-length/efficiency through the development of short-forms (Cella, et al., 2007).

IRT-based methods have also been increasingly used to conduct differential item functioning (DIF) analysis for existing measures: DIF analysis refers the process of testing whether an instrument's scores measure the same underlying traits across examinee groups (Reise & Waller, 2009). DIF analysis is an integral part of establishing equivalence (i.e., a form of reliability for IRT). There are also a variety of IRT models upon which computer-adaptive-tests can be based. These models differ by what kinds of data characteristics they are able to analytically manage (e.g., dichotomous vs. polytomous response data, ordered vs. unordered data, unidimensional and multidimensional data;Reeve, 2006). An author associated with the Patient-Reported Outcomes Measurement Information System (PROMIS) initiative argued that, due to its related item properties (e.g., varying "difficulty" and "discrimination" among responses), the two-parameter IRT model is the most appropriate model for application to health-related CATs (Reeve, 2006).

The item property of "difficulty" refers to "the trait level necessary to endorse an item's response category" (Reeve, 2006). As an example, a question related to suicidal ideation gauges higher order or more severe depressive symptoms (higher difficulty) than the question, "Do you feel sad sometimes?" (lower difficulty; Reeve, 2006). The item property of "discrimination" reflects the strength of association between item response and the latent trait being measured. In conjunction with item difficulty, greater item discrimination indicates that it can better distinguish between individuals with "higher or lower trait levels" (Reeve, 2006).

A recent review of the clinical use of IRT indicated that health outcomes researchers have increasingly adopted IRT, and that clinical researchers are beginning to use IRT with greater frequency as well (Reise & Waller, 2009). Evaluation of the statistical comparability of IRT trait estimates and traditional summary scores on measures of similar constructs have found that they are highly correlated (i.e., often .90 or higher) (;Reise & Waller, 2009). This finding suggests that IRT trait estimates are clinically interpretable. In the place of reliability, IRT offers the test information function which shows the degree of precision at different values of theta (Reise & Waller, 2009).

Computer-Adaptive-Testing (CAT)

Reeve (2006) argues that "we are on the brink of a new era for health outcomes measurement with the availability of CAT-based tools". Until recently, the primary application of IRT-based CATs was in the realm of educational assessment. Several recent articles note that IRT has been increasingly applied to develop short-forms of existing measures and to create computer adaptive tests (CAT; Ader, 2004; Cella, et al., 2007; Cella, et al., 2007; Deutscher, Hart, Dickstein, Horn, & Gutvirtz, 2008).

As an overview of the process of IRT-based CATs, the test begins with an "anchor" or starting item of average "difficulty." Based upon response, the CAT's predetermined algorithm will adjust the estimated level of the latent trait for the respondent. The algorithm selects subsequent questions based upon what will best discriminate theta (i.e., term for latent trait being measured). This is repeated

until a predetermined level of precision is achieved [i.e., a termination criterion is reached (90 – 95% CI); Aletaha, 2010).

Several other clinical research studies have utilized IRT-based methods to create CATs. Two related studies were able to successfully use item banking to create CATs based upon several existing headache impact scales (Ware et al., 2000; Bjorner et al., 2003). A more recent study sought to create a CAT for depression using similar methodology (Fliege, 2005). However, concerns with scale design hampered its widespread use and acceptance as a clinical measure (Reise & Waller, 2009). Reise and Waller (2009) note that these studies utilized real-data simulations (i.e. CAT simulation using existing data sets) and that "few clinical studies have implemented CAT in real time". As an exception, a recent study developed and examined the use a set of CATs for screening/monitoring health-risk and psychiatric symptoms in adolescents and young adults (Diamond, et al., 2010).

Greater application of computer-adaptive-testing with health outcomes research has an array potential benefit for patients, healthcare providers, and researchers, as delineated below: greater access through multiple platforms/delivery for disabled individuals; rapid collection of PRO data with elimination of human entry or processing error; instant health status reports tailored for the patient, their healthcare provider, or researcher; the ability to adaptively administer ePRO's with reduced response burden, decreased floor and ceiling effects, and improved measurement precision over static forms (Reeve, et

al., 2004). Reeve (2006)stated that, in the future, "a CAT-based system will be a powerful tool to assess, collect, and report PRO data".

PATIENT-REPORTED OUTCOMES

Overview

Patient-reported outcome (PRO) data are measures used in clinical practice "to characterize a patient's experiences of a health situation so that the information can then be shared with clinicians and/or other patients" (Feldman-Stewart & Brundage, 2009). Patient-reported outcomes can take multiple forms in clinical practice: measures of health-related quality of life (HRQL), health status reports, symptom assessment, patient-reported function or disability, and patient satisfaction (Rose & Bezjak, 2009).

Systematic outcome-tracking of health outcomes has gained increasing traction and attention in both clinical practice and related research within a variety of medical settings (Ader, 2004; Cella, et al., 2007; Fries, 2005; Garcia, et al., 2007; Hays, Bjorner, Revicki, Spritzer, & Cella, 2009). Patient-reported outcomes "supply valuable information on health status and treatment effects that could not be collected in any other way" (Gwaltney, et al., 2008). First, they measure constructs that are summarily unobservable (e.g., levels of pain, fatigue, depressive symptoms) without patient-report. Second, in studies that examined the same underlying constructs (e.g., pain, emotional distress), PRO measures often had better reliability than many clinician-administered interviews (Gwaltney, et al., 2008). PRO data can also potentially assist treatment providers in their clinical decision-making at the point-of-care (Deutscher, et al., 2008; Gershon, et al., 2010). Comprehensive

tracking of PRO data collected prior to the point of care and during subsequent appointments could provide information that is useful for individual patients and/or an overall practice. Along with tracking PRO's, ongoing evaluation of psychosocial factors is essential for assessing overall treatment quality for care centers and course of treatment for individual patients (Deutscher et al., 2010).

It is difficult to define the various applications of PRO's in clinical practice. The difficulty with precisely defining its application stems from a "lack of clarity" of how the intervention should be applied (Greenhalgh, 2009). Interventions using PRO data and feedback in clinical settings have not been uniform, varying along a number of dimensions; specifically, variation has been in the type of PRO used, who gets feedback, how often clinicians get feedback, whether training for PRO interpretation was conducted, and the nature of the information being fed back (Valderas, 2005). Greenhalgh writes that, "the heterogeneity [of PRO interventions in clinical practice] suggests a lack of consensus amongst researchers regarding what the intervention is and how it is supposed to work" (2009). This difficulty can be attributed to the complexity of the intervention and variety between studies in terms of "the type of PRO used, how the PRO is fed back, and to whom it is fed back" (Greenhalgh, 2009).

Review of PRO's in clinical practice

Several authors have extensively reviewed the use of PRO's in clinical practice. Evidence from randomized clinical trials of PRO's in clinical practice found that their use increased communication and detection of health-related

quality of life concerns; however, these studies found that PRO's had little impact on clinician's management of patient care and on patient outcomes (Greenhalgh, 2009).

A summary review of the evidence-based impact of PRO's on the "process and outcomes of care in clinical practice" identified significant methodological problems across the majority of studies. Most prominent were problems with randomization approach (i.e. not accounting for a variety of provider-related issues) and conceptualizing the impact of PRO data/feedback in clinical practice (Greenhalgh, 2009). Regarding impact, the "effectiveness" of well-defined PRO interventions has not been evaluated in a consistent way.

Greenhalgh argued that this general lack of impact is due to the ability of PRO's to "fit" or "not fit" into the routine ways that clinicians/patients communicate, how clinicians make decisions, and how health care is organized overall (Greenhalgh, 2009). In short, the impact of PRO data and intervention may be linked to the degree to which these interventions can be successfully blended into the routine flow of clinical practice.

Separately, Rose and Bezjak observed that there have been no large-scale randomized trials that have shown PRO assessments in clinical practice to have any significant impact on medical decision-making or treatment outcome (2009). They argue that the choice of instruments in previous PRO studies have had psychometric "shortcomings;" specifically, assessment of individuals, rather than groups, requires much greater measurement precision (i.e. ability of an instrument to separate true chance from random error). They argue that lack of commercially

available software for ePRO's has been a limiting factor as well (Rose & Bezjak, 2009).

Achieving greater measurement precision is possible if lengthier and more complex instruments are used; however, this fix is impractical in clinical settings due to increased patient burden. As a balance, brief composite measures (e.g. Patient Health Questionnaire, SF-36) are the most widely used PRO's; however, "they represent a compromise in measurement precision and range in favor of practicality" (Rose & Bezjak, 2009).

Another recent review argued that there has been a general lack of "theoretical guidance in how to use and assess the impact of PRO's in clinical practice (Feldman-Stewart & Brundage, 2009). At present, no trials have examined the impact of PRO feedback on clinician/patient treatment alliance or level of patient self-efficacy. Recent reviews have provided theoretical basis for and argued the practical significance of using these two constructs as distal outcome measures in PRO studies in clinical practice (Feldman-Stewart & Brundage, 2009; Greenhalgh, 2009).

A well-designed randomized controlled trial from 2004 examined the effect of an ePRO-based intervention in a large sample (N=286) of cancer patients (Velikova, et al., 2004). The intervention involved study patients completing a health-related quality of life (HRQL) measure and other outcomes (e.g. measures of psychiatric symptoms and quality of life [specific to cancer populations]) on touch-screen computers prior to each appointment at their regular oncology clinic. Further, summary scores were fed back to the physicians of intervention group

patients each time they completed HRQL and outcome measures. The intervention group was compared to an "Attention-Control" group (completed all study measures with no physician feedback) and control group (no completion of study measures prior to appointments; completed at different time-point). Study patients were randomized to one of the three groups with participation lasting for approximately 6 months. Results indicated that the ePRO intervention positively impacted both overall symptom control and health-related communication between physicians and patients (Velikova, et al., 2004). A significant finding was that intervention patients communicated with physicians about questionnaire-related symptoms and pain symptoms with no increase in overall appointment time compared to other study groups. Further, results reflected significant improvement in HRQL and emotional functioning for a number of intervention patients. Authors concluded that "routine repeated HRQL assessments in individual patients is a feasible and effective approach for improving medical practice" (Velikova, et al., 2004). Altogether, this study demonstrated that a repeated ePRO-based intervention with HCP feedback improved symptom control and emotional functioning with a population of chronic-illness outpatients (Velikova, et al., 2004).

A recent study found that screening for pain, fatigue, and emotional distress in cancer patients was important for "optimizing management [of care] and reducing the risk of morbidity" (Butt, et al., 2008). In addition, a study of adolescents and young adults in primary care created a computer-administered "Behavioral Health Screen" that was integrated into an EHR (Diamond, et al.,

2010). This study used an internet-based platform to administer health-risk and psychiatric measures across 13 domains. The investigators utilized this assessment over multiple time points as a means screening and tracking progress. Results indicated that the BHS was valid and able to be practically integrated into its study practice (Diamond, et al., 2010). In particular, the study found that this screening/tracking method was effective for triaging patients with severe psychiatric difficulties (Diamond, et al., 2010). These authors concluded that the features of the BHS (e.g., rapid distribution, administration, scoring, and interpretation as compared to single domain paper-and-pencil depression screens), a computer-administered set of CATs, reduced barriers that "contribute to low rates of use of existing screening tools."

Directions for Future Research and Current Initiatives

Recommendations for future research

This review and other recent publications have offered several suggestions for how future research could better demonstrate broad impacts of using PRO data/feedback systems in clinical practice. Greenhalgh argued that the outcome indicators of the process of PRO-based interventions should be viewed on a continuum from the most "proximal" to the clinician/patient encounter (2005; 2009). Base points for outcomes in this continuum include the "proximal" (i.e. communication between clinician/patient during encounter), "intermediate" (i.e. related to the clinician/patient decision-making process), and "distal" (e.g. clinician/patient management of health problems, patient satisfaction with care, health outcomes) (Greenhalgh, 2009). Further suggestions included the use of a

condition-specific set of measures that targets well-known areas of potential concern for the given patient population. For example, this suggestion would argue that the well-established link between pain-related outcomes and psychosocial problems in chronic pain patients would indicate the inclusion of psychosocial measures in PRO's administered within that population. Authors argued that psychosocial interventions would be appropriate for those individuals identified to have such difficulties. Authors suggested that PRO feedback should be provided to the clinician/patient on multiple occasions correspondent to appointment visits; this practice would create consistency with the intervention and yield more robust outcomes from multiple time-points. Additional recommendations included conducting training with HCP's for interpretation of PRO data and assessing/adapting the "fit" of PRO's for use within a given clinical practice (D. Deutscher, et al., 2008; Greenhalgh, 2009; Rose & Bezjak, 2009).

Future studies would benefit from conceptualizing PRO interventions in terms of their "impact on the process and outcomes of patient care" within clinical settings (Greenhalgh, 2009). An overarching recommendation from this review was for future studies to adopt framework-driven trial designs (Greenhalgh, 2009).

A recent review of the application of PRO's in clinical practice delineated taxonomy from which future research can draw to frame study interventions. (Greenhalgh, 2009). In order to facilitate growth in PRO research, Greenhalgh argued for use of taxonomy in designing the interventions and articulating the outcomes. Authors identified two dimensions through which to categorize PRO

data interventions in research studies: level of aggregation of PRO data (e.g. individual, group) and whether PRO data feedback is used at the interface between clinician/patient (Greenhalgh, 2009). This creates four possible quadrants within Greenhalgh's proposed taxonomy: individual level of data aggregation using PRO data at clinician/patient interface, group level of data aggregation using PRO data at clinician/patient interface, individual data aggregation not using PRO data at interface, group data aggregation not using PRO data at interface (Greenhalgh, 2009).

The first quadrant (individual data using clinician/patient interface) includes three categories of interventions: screening, monitoring, and promotion of patient-centered care (Greenhalgh, 2009). PRO data/feedback has often been studied as a monitoring tool within the domain of psychotherapy. The underlying theory for monitoring PRO's in psychotherapy follows that ongoing PRO feedback enables clinicians/patients to evaluate treatment efficacy and change treatment if necessary (Asay et al., 2002). The initiative toward "patient-centered" care is relevant in considering applications of PRO data on the individual level using the clinician/patient interface (Greenhalgh, 2009). The 2004 US policy initiative emphasized the importance of patient self-management and involvement in care, as well as shared decision-making with healthcare providers.

The second quadrant includes a group level of PRO data aggregation that uses feedback at the clinician/patient interface. This avenue of research uses existing studies to augment clinical decision-making during clinical contact with

patients (Greenhalgh, 2009). Using a group level of data aggregation as a research intervention has produced a spectrum of results; specifically, some studies report such an intervention (i.e. clinician using computer-based tools to assist with differential diagnosis, checking drug interactions) leads to better patient outcomes and process variables (e.g. better response to treatment, improvement in adherence, greater level of health engagement by patients). However, drawbacks have been thoroughly discussed;digital tools can be distracting to patients; patients may feel less connected with their HCP as well.

The third quadrant refers to PRO data/feedback on the individual level of data aggregation that is not used during the clinician/patient interface. The primary use of this PRO application is for providing feedback to members of multidisciplinary teams as a means of facilitating communication amongst them. A benefit of this application of PRO data/feedback is that it establishes a common language with which HCP's can discuss patient outcomes, concerns with treatment process, and general goals for care of the patient (Greenhalgh, 2009). The potential for communication concerns is inherent whenever a larger number of care providers collaborate across treatment settings. Thus, the use of such PRO feedback is particularly important in rehabilitation and other MDT settings (Greenhalgh, 2009).

The implementation of PRO screening/monitoring in clinical practice may facilitate patient-centered care in a number of ways. The process of completing a PRO may tap into an existent health-related concern of a patient and lead that individual to clarify their care priorities with their HCP. Resultant discussions in

this scenario would facilitate greater clinical focus on the desired outcome of the patient (Greenhalgh, 2009).

The fourth quadrant refers to a group level of data aggregation that is not integrated into the interface between clinicians/patients. The primary applications in this frame are "quality of care" and "effectiveness" studies for individual practices, health-care consortiums, hospital care, and/or specific treatments. A promising direction within this frame is for the promotion and establishment of a set of common PRO measures amongst researchers. Such an initiative would allow for comparison of study findings across randomized clinical trials of the same interventions (Greenhalgh, 2009). A large research initiative, the Patient-Reported Outcomes Measurement Information System (PROMIS), has sought to establish this commonality of health-outcomes measurement. Specifically, PROMIS has developed a set of PRO's for use as computer-adaptive-tests; these PRO's were designed for use with all capable patient populations for which their specific measures apply (Cella, et al., 2010).

Patient-Reported Outcome Measurement Information System

An NIH-sponsored clinical research initiative, the Patient Reported Outcome Measurement Information System (PROMIS), is a national multi-site project that has sought to develop both item banks and computerized adaptive tests across multiple domains for patients with a range of chronic diseases (Cella, et al., 2010; Gershon, et al., 2010). An overall aim of PROMIS is to provide item banks that "offer the potential for efficient (minimizes item number without compromising reliability), flexible (enables optional use of interchangeable items), and precise (has minimal

error in estimate) measurement of commonly studied PROs" (Cella, et al., 2010). As a product of the study development process (e.g., identify relevant domains, qualitative item review, patient/non-patient focus groups, cognitive interviews with patients for item clarity, initial testing with normal/clinical samples), the project has produced five domains (i.e., physical functioning, pain, fatigue, emotional distress, social functioning) with several sub-domains and corresponding item banks. As a primary goal, PROMIS "sought to build item banks that measured key health outcome domains that were relevant and manifested in a wide range of chronic diseases (Cella, et al., 2007; Cella, et al., 2010; Gershon, et al., 2010). For a majority of the domains/sub-domains, relevant clinical samples were used to establish the validity and calibration of CAT item banks (Cella, et al., 2010).

As a component of the PROMIS initiative, web-based software was created "to enable researchers to create study-specific websites that could administer PROMIS CATs and other instruments to research participants or clinical samples" (Gershon, et al., 2010). The PROMIS web-based resource (the "Assessment Center") was developed for "storage, retrieval, organization, sharing, and administration of patient-reported outcomes (PRO) instruments" (Gershon, et al., 2010).

As an additional tool for researchers, the Assessment Center has the functional capability to automatically generate a summary of results from any given study participant. The "Patient Report" includes both a graphical summary and displays PROMIS CAT scores based upon their age- and gender-specific normative samples (Cella, et al., 2010; Gershon, et al., 2010). Given the efficient and accessible nature of the PROMIS Patient Health Report (e.g., graphical display of scores, use of clear interpretive language, generated automatically following completion of

measures), it has clear potential as means of PRO feedback for patients, providers, and/or treatment teams in clinical research studies.

Mental Health Screening

High prevalence and under-diagnosis rates of mental disorders in chronic pain patients and other outpatient populations highlight the need to efficiently identify patients suffering from mental illness.

Studies of PRO's in clinical practice have primarily examined their use as screening tools for mental health (e.g. depression, anxiety) with a selection of studies examining functional disability in various domains (e.g. physical, social, emotional) (Greenhalgh, 2009). Screening for the purpose of facilitating care has been most widely applied to mental health-related concerns across a number of patient populations. In addition to gauging the effect on treatment outcomes, these studies have also examined the psychometric properties of particular measures and/or the prevalence of psychiatric disorders in a given medical setting.

With regard to efficacy, research into the utility and basic patient outcomes (e.g., increased treatment utilization, symptom reduction) of psychiatric screening in ambulatory care settings has been mixed. Studies in different patient populations found that mental health screening was costly for clinics, and led to no significant changes in patients' utilization of mental health care or level of symptoms (Akiskal, et al., 1998; Ballenger, et al., 2001; Das, et al., 2005; Dudek, et al., 2010; Sharma, et al., 2004; Valenstein, Vijan, Zeber, Boehm, & Buttar, 2001; Weissman, et al., 2010). A major drawback of these studies was that they

did not include structured follow-up care for those individuals who screened positive for a mental health disorder.

A notable study by Weissman et al. (2010) reported that patients who screened positive for mental health difficulties had significant symptomatic impairment and were more likely to have utilized psychiatric emergency services after a four-year follow-up. These results excluded individuals who were already receiving psychology-related services at baseline. Results of this study highlight a major point underlying the purpose of mental health screening, namelywill individuals have or develop significant psychiatric difficulties whether screening occurs or not. Together, these studies suggest that psychiatric screening is related to positive outcomes, as long as structured follow-up care is incorporated and made available. Arguably, the issue is not whether psychiatric screening in outpatient settings is unjustifiable due to lack of positive outcome studies. Rather, a logical conclusion is that the process of mental health screening and facilitation of follow-up have yet to be effectively coordinated in these settings. However, multiple studies have found that intervention that included both screening and evidence-based follow-up treatment found psychiatric screening (e.g., depressive symptoms, select substance-abuse problems, composite psychiatric screening measures) to be significantly related to improved outcomes for patients who had positive screens (Dudek, et al., 2010; Sharma, et al., 2004; Valenstein, et al., 1997; Weissman, et al., 2010). Weissman et al. (2010) argues that "screening-related improvement in long-term outcomes will require that detection be followed by effective treatment [and] screening should be considered only as part of a package

of enhanced care." Findings from a recent study also support screening in ambulatory care settings where prevalence of mental disorder is generally high (Weissman, et al., 2010).

Patient-Provider Communication in Clinical Practice

For individuals with chronic pain or disability, research has found that effective communication is critical for the management of pain and fatigue. A recent study qualitatively examined issues related to the manner in which patients and providers communicate about pain and fatigue (Yorkston, et al., 2010). In particular, this study reported that the inclusion of psychosocial variables in discussion of biomedical complaints with providers was "strongly valued" by participants. Further, the authors also reported that the majority of study participants felt it would be beneficial for providers to ask about how pain and fatigue disrupted their lives (Yorkston, et al., 2010).

Greenhalgh hypothesizes that the occurrence of PRO-related clinician/patient discussion could lead to increased patient involvement in care decisions and, thereby, patients may experience an increased sense of self-efficacy in their ability to manage their own health (Greenhalgh, 2009). As an operational variable, self-efficacy can be viewed as greater feelings of optimism and beliefs related to perceived ability to control or master an illness threat.

Barriers

While there are clear benefits to the use of PRO data, significant barriers exist with its integration into busy clinical practice settings. These barriers involve multiple

"logistical complexities" inherent to medical care settings (e.g., staff burden; need for immediate scoring, interpretation, and response summarization; patient burden when completing a set of measures; overall time required for administration through results delivery; Gershon, et al., 2010; Gwaltney, et al., 2008). At the same time, there are significant barriers to the implementation of comprehensive outcome-tracking and/or screening in outpatient medical care settings, namely time-related concerns (e.g., general length of administration, patient burden, interruption/delays in flow of normal care), lack of staff support for scoring, lack of availability of trained professional for interpretation, and the procedures for feedback to patients and providers in regard to results of psychiatric screening (Cella, et al., 2007; D. Deutscher, et al., 2008; Martin, et al., 2004; Sharma, et al., 2004). However, developments in both computer technology and statistical methods have made it possible to overcome these barriers (Reise & Waller, 2009; Rose & Bezjak, 2009). Several studies have demonstrated the feasibility of using of computer-based administration for screening and/or outcome tracking research (ADD CITES). Several studies have examined methods (e.g., differing modes of administration, variations of statistical methods and results delivery) that were able to address several identified barriers (Gwaltney, et al., 2008; Sharma, et al., 2004).

Altogether, a review of this literature suggests that comprehensive assessments of current health status within routine care (in medical or other ambulatory care populations) are much less feasible without the use of efficient systems of administration, collection, and feedback.

Outcome-tracking of PROs in Clinical Practice

Health-Care Utilization and Treatment Cost

Amount of health-care utilization and overall treatment cost have both been widely used to gauge the relative impact of a given variable or intervention in health-related studies. As suggested by Greenhalgh (2009), these two variables are well-suited for use as study outcomes in research examining the potential impact of PRO feedback in clinical practice.

Illness Perception

In their recommendations for global outcome measures for future PRO studies in clinical practice, Feldman and colleagues (2009) argued that patient perceptions of illness or condition be included (e.g., control, emotional representations). As a potentially helpful framework, Levanthal's Common Sense Model of self-regulation provides a well-researched a model through which illness perception can be conceptualized (Hale, Treharne, & Kitas, 2007; Leventhal, Diefenbach, & Leventhal, 1992; Leventhal, Meyer, & Nerenz, 1980). An individual's illness perception is conceptualized dimensionally in terms of both cognitive and emotional representations. As a response to a perceived health threat, these representations are processed in parallel throughout three stages in a continual feedback loop (e.g., formation of illness representations from threat, adoption of coping behaviors, evaluation of efficacy of coping behaviors; H. Leventhal, et al., 1992; Leventhal, Meyer & Nerenz, 1980). Within this model, there are dimensions to both the cognitive and emotional representations. The cognitive dimensions include identity (i.e., person's label of their illness and associated symptoms), consequences (i.e., expectation of outcome of the illness),

cause, timeline, and cure/control (i.e., degree to which patient believes they can recover from or control the illness), whereas the emotional dimensions include negative reactions (e.g., anger, fear, distress; Broadbent, Petrie, Main, & Weinman, 2006).

Appraisal of potential outcomes of illness is the primary concept with the cognitive dimension of consequences. Researchers have explored this dimension in terms of positive or negative expectancies. This has been operationalized in terms of measuring optimism and pessimism within studies (Scheier & Carver, 1987; Schou, Ekeberg, Ruland, Sandvik, & Kåresen, 2004). This variable has been utilized as a predictor or complementary variable in multiple health-outcomes studies (Scheier & Carver, 1987). Researchers developed multiple instruments through which these dimensions could be quantified, specifically, the Illness Perception Questionnaire (IPQ), the IPQ-R, and the Brief Illness Perception Questiononaire (B-IPQ; Broadbent, et al., 2006). The latter two forms of the Illness Perception Questionnaire (IPQ-R, BIPQ) have demonstrated validity as an outcome capable of assessing change in these dimensions within several condition-specific populations (Fischer, et al., 2010; French, 2006; Petrie, Jago, & Devcich, 2007).

Therapeutic Alliance and Clinician/Patient Communication

It is reasonable to appraise the use of PRO's in clinical practice as "communication events" (Feldman-Stewart & Brundage, 2009). Feldman-Stewart and Brundage identified, "communication as a multidimensional process,

including both a relationship and content that occurs within a complex environment that can have subtle but important impact on many aspects of the communication" (2009).

As a blended theory, Feldman-Stewart and Brundage wrote that this conceptual framework included components that made it unique for use with the application of PRO data/feedback in clinical practice (2009). A first tenet of this framework is that each participant communicates to address their individual goal(s) and that each participant has individual goals. Couched within the first component, the second component refers to "kernel attributes" of each participant that are important to how each communicates. These attributes include needs, beliefs, values, skills, and emotions. The "skills" attribute refers to "the elements that underlie the person's ability to communicate;" delivering and receiving messages are differentiated within this attribute. The other four attributes can be seen as face-valid. The third component involves three types of messages (e.g. verbal, non-verbal, silent) conveyed by either the clinician/patient. The fourth component represents the environment within which the communication takes place.

The use of this framework allowed authors to develop testable hypotheses within the context of previous studies in this area. The authors hypothesized that "filling out the forms improves patients' skills at describing their symptoms, such as the skills related to identifying and classifying their symptoms" (Feldman-Stewart & Brundage, 2009). Further, authors hypothesized that, in consideration of the HCP's beliefs, the "use of PRO's overcomes the belief that if the patient

doesn't say anything about a symptom, the patient does not think it is a problem" (Feldman-Stewart & Brundage, 2009). Authors further hypothesized that, in consideration of individual values, using PRO's might aid in overcoming values that may make it difficult for men to report their symptoms. The completion of PRO measures "might validate the appropriateness of reporting the symptoms to a physician. For those sub-groups that tend to under-report psychiatric symptoms, completion of an emotional distress-related PRO may, in some regard, fulfill unmet fundamental needs (e.g. to have "a sense of control over their situations," to feel cared for) (Feldman-Stewart & Brundage, 2009). Authors proposed that testing these hypotheses will lead to a greater understanding of using PRO's in clinical practice.

Feldman-Stewart and Brundage argued that an integration between their "communication framework's psychological constructs and Greenhalgh's PRO-specific actions and outcomes would further improve the potential for PRO explanation [of a more inclusive and testable theoretical framework]" Greenhalgh 2005 (Feldman-Stewart & Brundage, 2009).

Feldman-Stewart and Brundage incorporated Velikova's finding of improved emotional functioning into their theoretical framework. They argued that this improved emotional functioning may have reflected a greater sense of control over their care for patients (2009). These findings led the authors to conclude that emotional functioning is an important outcome for PRO studies in clinical practice and that this dimension should be included as a standard outcome in future research with clinical PRO's (Feldman-Stewart & Brundage, 2009).

This is a significant association because improvement in patients' sense of control over care has been associated with decreased levels of health-care utilization. Kennedy 2004(Feldman-Stewart & Brundage, 2009).

SUMMARY

The present study examines a computer-based administration of PROMIS measures and selected psychosocial measures using the PROMIS Assessment Center platform. Based upon research recommendations, the current study uses defined modes of point-of-care feedback (e.g., providers, patients and providers, chart-review only) of PRO data to examine their effects on treatment-related and patient-centered variables. The present study incorporates recommendations from several recent review articles regarding different dimensions of PRO research in clinical practice. These recommendations discuss the use of a theoretical framework, PRO research taxonomy, and specific outcomes that may provide a better grounding for research in this area. Building on these recommendations, the current study will examines the provider/patient working alliance, perceptions of illness, healthcare utilization, and treatment cost in the context several additional study variables (e.g., psychiatric symptoms, pain-related symptoms/variables, psychosocial variables, functional measures). Results from this study yield theoretically grounded data regarding the effect of PRO data/feedback in a population of chronic pain patients.

Hypotheses

Hypothesis One: Study participants in the Joint Feedback Group (i.e. both clinicians and patients receive feedback prior to the point-of-care), as compared to the Control Group (i.e. no feedback at point-of-care, MDT review only), will evidence significant differences across outcome scores over time (i.e. maximum of 5 follow-ups per patient). As detailed in the statistical plan, each study outcome variable will be examined for significance using mixed-effect modeling. Primary outcome variables include:

- Health-care utilization prior to and between time-points

- Treatment cost as calculated from health care utilization
- Psychosocial variables (Satisfaction with Social Roles and Discretionary Activities, index of disability)
- Symptom level: Psychiatric
- Symptom level: Pain-related (Pain Impact, Pain Behavior, Fatigue, Sleep-related Impairment)
- Clinician/patient working alliance (completed by both clinicians and patients; separate and summary scores will be used)
- Illness perceptions (Partially interpreted as a self-efficacy related to care/treatment)

Hypothesis Two: Study participants in the Joint Feedback Group (i.e. both clinicians and patients receive feedback prior to the point-of-care; MDT weekly review), as compared to the Clinician Only Group (i.e. only the clinician receives feedback at point-of-care, MDT weekly review), will evidence significant differences across outcome scores over time (i.e. maximum of 5 follow-ups per patient). As detailed in the statistical plan, each study outcome variable will be examined for significance using mixed-effect modeling. Primary outcome variables parallel those listed in *Hypothesis One.*

Hypothesis Three: Study participants in the Clinician Only Group (i.e. only the clinician receives feedback at point-of-care, MDT weekly review), as compared to the Control Group (i.e. no feedback at point-of-care, MDT review only), will evidence significant differences across outcome scores over time (i.e. maximum of 5 follow-ups per patient). As detailed in the statistical plan, each study

outcome variable will be examined for significance using mixed-effect modeling. Primary outcome variables parallel those listed in *Hypothesis One.*

CHAPTER THREE
METHODOLOGY

study design

Setting

This prospective, randomized controlled trial will examine how point-of-care summaries of patient data for multiple treatment-related domains (e.g., psychiatric symptoms, psychosocial functioning, and pain-related measures) may affect a variety of treatment outcomes over time. This study will be conducted with a population of outpatients seeking care for chronic pain at the Eugene McDermott Center for Pain Management. Patients who participate in the study will complete study measures at intake and at regular intervals during the following 12 months. Located in Dallas, Texas, the Eugene McDermott Center for Pain Management (the Center) is a part of The University of Texas Southwestern Medical Center. This Center includes interdisciplinary care, as well as general pain management. Both groups will consist of adult outpatients who are initiating care or receiving ongoing care at the Center.

PARTICIPANTS

Inclusionary Criteria

Patients will be recruited for the study in the waiting area of the Center during the 12-month recruitment period. Patients will be invited to participate in the study if they are of adult age (18 and older), are initiating or receiving ongoing care at the Center, capable of providing informed consent, able to read and speak English, and willing to allow access to their existing medical records.

Exclusionary Criteria

The Center provides care to an exclusively adult population (age 18 <). Thus, there will not be a population of minors from which to draw for inclusion in

the study. As such, minors (age <18 yrs) will be excluded from the study. Patients who are not English-speaking will be excluded from the study due to the fact that validated Spanish versions are not available for all study measures. Given that translating measures between languages can disrupt measurement equivalence (Gwaltney, et al., 2008), translating (i.e., English to Spanish) and using measures without previous validation with Spanish-speaking populations is not appropriate at this point in time.

MEASURES

With the exception of demographic and history-related data, study variables can be categorized into three groups [e.g., psychosocial, pain-related measures (level of disability, risk for opioid abuse, functional impairment), psychiatric]. Data used to calculate treatment cost and health care utilization will be gathered at each time point. Given their interrelated nature, there is some degree of overlap between psychosocial and pain-related variables. The present study incorporates several measures from the NIH-sponsored Patient Reported Outcome Measurement Information System (PROMIS) study. The use of multiple forms of these measures (e.g., short-form versions, computer adaptive tests) and the unique nature of that project warrant additional focus. In this regard, a brief review of relevant information will be included just prior to description of the individual PROMIS measures.

Pain Disability Questionnaire

The Pain Disability Questionnaire (PDQ) is a 15-item self-report measure of functional status that incorporates psychosocial variables. It was designed as a clinical outcome measure for use with the entire spectrum of chronic disabling musculoskeletal disorders. The PDQ utilizes a 10-point likert-type scale. It yields a total functional disability score that ranges from 0 (optimal function) to 150 (total disability). Scores are interpreted to be in categories of severity of disability; specifically, the severity categories include mild/moderate (1 – 70), severe (71 – 100), and Extreme (101 – 150). It has shown excellent reliability in multiple studies (Anagnostis, Gatchel, & Mayer, 2004; Gatchel, Mayer, & Theodore, 2006). Individual patient scores from this measure will be graphically represented with the severity-score ranges. Along with other measures from this study, this graphic will be incorporated into the composite "Biopsychosocial Health Report" to be used with intervention group patients.

Pain Medication Questionnaire

The Pain Medication Questionnaire (PMQ) is a 26-item self-report screening tool to assess potential misuse of opioid medication within a chronic pain population. The questions use a 5-point likert scale with assigned numerical values of 0 to 4 assigned for scoring purposes. Its scores are interpreted in terms of the lowest (L-PMQ), middle (M-PMQ), and highest (H-PMQ) one-third of the total PMQ score. Higher PMQ scores have associated with greater potential for opioid misuse. Further, higher PMQ scores have been associated with concurrent measures of substance use, psychopathology, and physical/life-functioning. This

measure has demonstrated good reliability and validity in multiple studies of chronic pain patients (Adams, et al., 2004; Dowling, Gatchel, Adams, Stowell, & Bernstein, 2007; Holmes, et al., 2006). This measure will also be graphically represented with its interpretive categories and incorporated into the "Biopsychosocial Health Report" for use with intervention group patients.

The Pain Assessment Questionnaire

The Pain Assessment Questionnaire is an intake questionnaire that gathers basic information about subjects' pain symptoms, related medical history, and general functioning. This instrument is a history-taking measure and has not been published. These questions do not yield any composite scores and will be used as covariates or grouping variables.

Life-Orientation Test – Revised

The Life-Orientation Test - Revised (LOT-R) is a 10-item self-report measure that yields scores for both optimism and pessimism (Scheier, Carver & Bridges, 1994). In broad interpretation, these dimensions can be translated as positive and negative expectancies, respectively. These constructs, as assessed with a previous form of the measure (Life Orientation Test), have been utilized in a variety of studies that involve a health-related and/or psychosocial component (Scheier & Carver, 1987). In multiple studies, both of the LOT-R's dimensions of optimism and pessimism have been strongly related to health outcomes (e.g., measures of coping, appraisal, quality of life) in patients with chronic conditions (Carver, et al., 2005; Schou, et al., 2004). Given the role of positive and negative

expectancies in Cognitive Dimension of Control in Levanthal's Common Sense Model, this variable will be incorporated as a potential mediating/moderating variable in data analyses.

Hypomania Checklist

The Hypomania Checklist (HCL-32) is a 32-item self-report screening instrument for mania and hypomania. Studies indicate that the HCL-32 has high sensitivity/specificity for detecting a history of mania/hypomania in both clinically-based and community-based adult samples (Jules Angst, et al., 2005; Angst, Gamma, & Meyer, 2009; Angst & Gamma, 2010). Designated cutoffs scores indicate the likelihood of a history of hypomania and/or mania. Given a review of the literature [e.g., FDA-mandated guidelines, high rates of non-recognition and misdiagnosis, and potential medication contraindications (i.e., activating properties of antidepressants in BSDs)], the inclusion of this hypomania/mania screen is indicated. Summary scores with the designated cutoff values will be graphically represented for each patient and included in the "Biopsychosocial Health Report" for use with the intervention groups.

Brief Illness Perception Questionnaire

The Brief Illness Perception Questionnaire (BIPQ) is a nine-item self-report measure that assesses medication adherence within the context of the respondent's particular health concern. In part, this variable will be used in separate analyses as both a control variable for treatment response and as an

overall outcome. Its illness designation is filled in by the patient and it demonstrated good reliability and predictive validity in its normative sample (Moriskey, Ang, & Krousel-Wood et al., 2009). The BIPQ's content and design is based upon Levanthal's Common Sense Model. It includes items that assess each of the dimensions that compose the cognitive and emotional representations within the model. Per the recommendations of Feldman-Stewart and Brundage (2009) discussed previously, the BIPQ will be included as one of the overall outcomes for the PRO feedback intervention groups. This measure assesses a range of constructs associated with respondents' cognitive and emotional appraisals of their specific health concern. Adapted from the Illness Perception Questionnaire, this measure includes 10 questions with an 11-point likert-type response format. As the effective short-form of its previous version, each question represents a different dimension of health perception with no calculable overall sum score (Moriskey, Ang, & Krousel-Wood et al., 2009).

Working Alliance Inventory

The Working Alliance Inventory (WAI) is a twelve-item instrument with forms completed by both providers and patients following a clinical encounter (Horvath & Greenberg, 1989). Items for each form are identical save for the person referenced in the questions. Both forms are scored and combined to yield a general Working Alliance Factor. Three sub-factors are also derived from the combined score: Goal (agreement about goals), Task (agreement about task of encounter), Bond (bond between provider and patient) (Andrusnya, et al., 2001;

Bordin, 1979). The WAI has been primarily utilized in the context of psychotherapy; however, it has been increasingly used in a broader array of patient populations. It has shown excellent reliability with both medical and psychotherapy patient populations (Hanson, Curry, & Bandalos, 2002; Fuertes, Boylan, & Fontanella, 2009).

Measures from the Patient Reported Outcome Measurement Information System (PROMIS)

Multiple measures from the PROMIS study will be used to evaluate psychiatric symptoms/risk (e.g., level of depressive symptoms, level of anxiety-related symptoms, level of maladaptive anger) and to assess psychosocial and pain-/health-related variables. PROMIS -derived measures have all been shown to be unidimensional, to have high reliability and validity from large-scale testing (Cella, et al., 2007). All PROMIS-derived CATs are self-report and have individual item-banks of varied size. These item banks are the source from which the IRT-based algorithms select items for each CAT. Descriptions of PROMIS-derived measures are based upon information gathered from the study's NIH-sponsored website (www.nihpromis.org). The PROMIS domains and measures utilized in the study are described separately below. During the study set-up in the Assessment Center, level of precision (i.e., relative to confidence intervals) can be preset (e.g., either 90% or 95%) for all PROMIS computer-adaptive-tests (Gershon, et al., 2010). For the current study, all CATs will be set for at a precision level of 95%. Per design of the PROMIS study, all scores on PROMIS

measures (e.g., CATs, short-forms) were anchored to a representative US population and have a mean score of 50 with a standard deviation of 10 (Amtmann, et al., 2010). As a result, all PROMIS measures are based upon a common metric. Thus, scores from PROMIS short-forms and CATs can be comparably analyzed (Cella, et al., 2010; Thissen & Mislevy, 2000). A component of the Assessment Center, an individualized "Patient Health Report," can be automatically generated for a respondent's scores on all PROMIS-derived CATs (Gershon, et al., 2010). The report graphically displays scores based upon the overall normative sample (e.g., combination of general and clinical populations) and age/gender specific norms (Cella, et al., 2010; Gershon, et al., 2010). Except for the Global Health measure, all PROMIS measures used in this proposed study have CAT versions (PROMIS Version 1.0 Item Banks) and short-forms. For the purpose of this study, the CAT versions of PROMIS domains and sub-domains will be primarily used. Short-forms for all PROMIS measures will be kept available as a means of participation for those who lack basic computer proficiency and do not benefit from the tutorial/demonstration provided by study personnel during consent. All PROMIS item banks use a "past 7 days" reporting period, and the majority of items employ five response options (i.e., 1=Not at all, 2=A little bit, 3=Somewhat, 4=Quite a bit, 5=Very much). As one exception, the pain intensity item on the PROMIS Global Health Short-Form utilizes an 11-point response scale. Further, items on the Global Health SF are worded to measure current status. As the other exception, the PROMIS Pain Behavior Item Bank 1.0 utilizes six response options, which allows for the response-option of "no pain."

CAT versions of the measures require an average of five questions to achieve the preset level of precision (NIH; Cella, 2010). As part of data analyses, the 5 most frequently administered items from each PROMIS CAT were determined; these are presented by item and frequency statistics. These items are included with full-length copies of all other study measures as Appendix A. Frequency statistics for each PROMIS CAT are included in Table 1.

PROMIS Emotional Distress - Depression

The PROMIS Depression Item Bank 1.0 (PROMIS-D) contains 28 items that focus on negative mood (e.g., sadness, guilt), decrease in positive affect (e.g., loss of interest), information-processing deficits (e.g., problems in decision-making), negative views of the self (e.g., self-criticism, worthlessness), and negative social cognition (e.g., loneliness, interpersonal alienation). This measure is included within the Emotional Distress domain of the overall PROMIS Domain Framework. A recent study evaluated the psychometric properties for both the PROMIS-D and the PROMIS Depression Short-Form; results indicated that these forms were unidimensional and displayed local independence (Choi, Reise, Pilkonis, Hays, & Cella, 2010). \

PROMIS Emotional Distress – Anxiety

The PROMIS Anxiety Item Bank 1.0 (PROMIS-Ax) contains 29 items that focus on fear (e.g., fearfulness, feelings of panic), anxious misery (e.g., worry, dread), hyperarousal (e.g., tension, nervousness, restlessness), and somatic symptoms

related to arousal (e.g., cardiovascular symptoms, dizziness). This item bank demonstrated good reliability and excellent construct validity per strong correlations with "legacy" measures of anxiety symptoms (Cella, et al., 2010).

PROMIS Emotional Distress – Anger

The PROMIS Anger Item Bank 1.0 (PROMIS-Ag) contains 29 items that assess angry mood (e.g., irritability, frustration), negative social cognitions (e.g., interpersonal sensitivity, envy, disagreeableness), verbal aggression, and efforts to control anger. Anger has been identified as a significant construct for both general health and pain-related conditions; CITE. This item bank demonstrated good reliability and excellent construct validity per strong correlations with "legacy" measures of anger symptoms (Cella, et al., 2010).

PROMIS Fatigue

The PROMIS Fatigue Item Bank 1.0 (PROMIS-Fg) contains 95 items that assess both the experience of fatigue (e.g., intensity, frequency and duration) and the impact of fatigue upon physical, mental and social activities. Descriptively, the PROMIS-Fg assesses a range of subjective fatigue, from mild feelings of tiredness to an overwhelming, debilitating, and sustained sense of exhaustion. Degree of impairment related to fatigue (e.g., decreased ability to work, lower participation in IADL's, impaired social functioning within family and social roles; D. Cella, et al., 2007; NIH; Cella, 2010).

PROMIS Physical Functioning Scale

The PROMIS Physical Functioning Item Bank 1.0 (PROMIS-PF) is a 124-item measure that was developed to be conceptually multidimensional. It includes four related sub-domains: mobility (lower extremity function); dexterity (upper extremity function); axial (neck and back function); and ability to carry out instrumental activities of daily living (IADL). Physical function is defined as one's ability to carry out various activities that require physical capability, ranging from self-care (activities of daily living) to more vigorous activities that require increasing degrees of mobility, strength, or endurance.

PROMIS Sleep Functioning

The PROMIS Sleep Functioning Domain includes two sub-domains that were developed from two separate calibration studies. The initial sample was composed of 150 sleep-disordered patients and 150 individuals with no sleep-related diagnosis. The second sample was much larger (N = 2, 252) and was split between non-clinical participants and patients who had a sleep disorder or self-identified as having “sleep problems” (Buysse, 2010). Both subdomains demonstrated unidimensionality and local independence, indicating that they adequately represent the constructs they intend to measure. Buysse reported that both subdomains demonstrated good face validity and construct validity. Thus, each subdomain can be viewed as being clinically representative. Buysse (2010) further reported that study results indicate both Sleep Functioning sub-domains

are responsive measures of change for individuals who undergo sleep-related treatment.

Sleep Disturbance

The Sleep Disturbances Item Bank 1.0 includes 27 items that focus on: perceptions of sleep quality; sleep depth; and restoration associated with sleep; perceived difficulties with getting to sleep or staying asleep; and perceptions of the adequacy of and satisfaction with sleep.

Sleep-Related Impairment (Sleep/Wake Disturbance)

The PROMIS Sleep-Related Impairment Item Bank 1.0 includes 17 items that assess perception of alertness, sleepiness, and tiredness during usual waking hours. This item bank also assesses perceived functional impairments during wakefulness associated with sleep problems or impaired alertness.

PROMIS Pain Domain

The domain of pain is conceptually divided into components that are grouped into two sub-domains.

Pain Interference

The first sub-domain is the PROMIS Pain Interference Item Bank 1.0 (PROMIS-PI). It is composed of 41 items that assess components of "pain quality" (e.g., items assess the nature, characteristics, intensity, frequency, and duration of pain) and the impact of pain upon physical, mental and social activities (Amtmann, et al., 2010). A recent study with multiple pain-related

populations (e.g., chronic pain, patients with cancer-related pain) found that the PROMIS-PI scores significantly discriminated among persons along several key variables (e.g., different numbers of chronic conditions, disabling conditions, levels of self-reported health, and pain intensity; Amtmann, et al., 2010). The normative sample for both of the Pain sub-domains was composed of 967 chronic pain patients. For internal consistency, Cronbach's Alpha ranged from .96 - .99. Multiple items were found to have DIF. However, adjustment for DIF resulted in little practical impact on overall score estimates, and all of those items were retained for the final item bank (Amtmann, et al., 2010).

Pain Behaviors

The second sub-domain is the PROMIS Pain Behavior Item Bank 1.0 (PROMIS –PB). It is composed of 39 items that assess behaviors one engages in to avoid, minimize or reduce pain (Cella, et al., 2007). The PROMIS-PB demonstrated high internal reliability, unidimensionality, and evidenced no significant impact of DIF (Cella, et al., 2010).

PROMIS Social Health Domain

Similar to the domain of pain, social health is conceptually divided into sub-domains. At present, two sub-domains within social health have been developed and validated for use as Item Banks for CAT. These two item banks were developed from an analytic sample of 956 adults gathered to be demographically representative of the 2000 Census (Hahn, et al., 2010). Both

sub-domains have demonstrated high reliability, unidimensionality, and no significant DIF-related impact (Cella, et al., 2007).

Satisfaction with Participation in Social Roles

The first validated Social Health sub-domain is the PROMIS Satisfaction with Participation in Social Roles Item Bank 1.0 (PROMIS-SPSR). It is composed of 14 items that assess satisfaction with usual social roles in life's situations and activities.

Satisfaction with Participation in Discretionary Social Activities

The second Social Health sub-domain is the PROMIS Satisfaction with Participation in Discretionary Social Activities Item Bank 1.0 (PROMIS-SDSA). It is composed of 12 items that assess satisfaction with level of involvement in usual social roles in life's situations and activities.

PROMIS Global Health Short-Form

The PROMIS Global Health Short-Form is composed of 10 items that tap global ratings of the 5 primary PROMIS domains (physical function, fatigue, pain, emotional distress, social health) and general health perceptions that cut across domains. Global items allow respondents to weigh together different aspects of health to arrive at a 'bottom-line" indicator of their health status.

Performance-based Physical Functioning

A subset of patients that receive care from the Center will participate in the Interdisciplinary Pain Program. This program is offered at the Center, and

includes multiple treatment-types (e.g., anesthesiology, psychiatry, psychology, physical therapy). For the patients in this program, basic measures of physical functioning (e.g., quantitative measures of flexibility, cardiovascular performance (walking time over set distance), and strength (e.g., grip strength) will be recorded by the physical therapist. The inclusion of objective/performance-based measures of basic physical functioning will serve to balance the study's self-report measures. The scores of the performance-based measures will be combined to form an overall score. However, the individual physical functioning measures will be analyzed separately as well. The specific measures of physical functioning are based upon methods utilized in previous studies of pain-related populations (Gatchel, 2006).

PROMIS Patient Health Reports: As based upon age/gender specific norms of its standardization sample (n= 21,133) of general and clinical populations, the Assessment Center is capable of scoring and producing an individualized Patient Health Report for a respondent's performance on each of the PROMIS computer adaptive tests. Scores relative to the general population and age/gender specific norms are individually presented. As a component of this report, a graphic profile of the individual domain scores is included. This graphic provides a straightforward means of rapidly interpreting a respondent's scores. These reports were designed for use by patients, treatment providers, and researchers (Gershon, et al., 2010). Intuitively, the graphic representation of scores may be an accessible method of patient results for treatment providers in busy clinical

settings. The patient usability is evident in the relatively straightforward language used to explain scores. For reference, sample patient reports for both single and multiple time points are included in Appendix B.

PROCEDURES

The study consisted of multiple time-points. Consented participants completed a baseline set of questionnaires, and up to four follow-ups, as based upon their individual course of treatment. Due to the practice-based nature of the study, and the variation in patients' type of treatment (e.g., medication management follow up, interdisciplinary care, procedure follow up), follow-up time points were determined by patients' future appointment schedules within the clinic. This approach yielded greater ecological validity, as well as decreased patient burden by not adding separate research appointments.

Regarding initial participant contact, study procedures lasted for approximately 25 to 40 minutes. Study procedures for initial participant contact included study notification (< 1 minute), consent (~ 5 – 10 minutes), and the completion of study questionnaires (~ 20 – 30 minutes). Patients were notified of the study by administrative personnel at the front desk at the time of their arrival to the Center. Patients that expressed interest were directed to study personnel for completion of consent. Study personnel consisted of those individuals designated as part of the study team on the approved IRB of UTSWMC. In a designated portion of the waiting room or

exam room, study personnel read through the consent with potential participants, answering questions as needed. Study personnel discussed the randomized component of the study, and communicated that their group assignment will be disclosed upon completion of the intake questionnaires following their Time Point 2 assessment. Upon consent to participate, study participants signed copies of the IRB-approved consent form and HIPAA form. Separate copies of each were provided to the patient, while the signed copies were retained by the study team. As discussed during consent, study personnel created an initial timeline for the follow-up assessments, attempting to coordinate with any future appointments participants may have. Consented participants were assigned a unique participant identification number (PID) following their signatures were obtained. This data was stored in a locked office within the clinic.

Study personnel gathered the appropriate research materials (e.g., touch-screen tablet-pc, Working Alliance Index – C form), and rejoined the patient in the exam room. Study personnel will demonstrate the basic functions of the equipment (e.g., conversion to and from tablet configuration, touch-screen capability. Study personnel then opened the tablet-pc's web-link to the Assessment Center's secure site and placed the tablet-pc in front of the participant. Study personnel mentioned to participants that they can approach the nurse-desk area and ask for study personnel should they have any questions or difficulties with any aspect of the study. The Assessment Center software automatically generates a new subject-PID and password each time a

new survey is started. This information was automatically recorded in the project database in the Assessment Center and was used for tracking participants as they progress through the study. Subject identification number generated by the Assessment Center was linked with the McDermott PID and group-type in a separate study database. Participants were instructed to return the tablet-pc to the nurse's station or directly to study personnel upon completion of the study questionnaires.

During the administration of study measures at Time Point 1 (or Time Point 2 if no T1 data were available), study personnel accessed the designated webpage for the study's randomization generator (Gallagher, Marbach, Raphael, Dohrenwend, & Coitre, 1991). An Urn Randomization method using factors of age and gender was utilized. Related literature described this general randomization method as an effective means of approximating complete randomization with parallel-groups in randomized controlled trials (Wei 1988; Wei 1978). Study personnel entered the age and gender of the participants into the Randomization Trial program to generate their group type (e.g., Provider Only, Provider and Patient, Control). For the "Provider Only" and "Provider and Patient" groups, study personnel accessed the secure project page on the Assessment Center site and completed the necessary steps to generate the PROMIS Patient Report. As discussed previously, this report is automatically generated from participant responses to the PROMIS CAT instruments. Study personnel then accessed the data for the individual participant and downloaded it into an Excel file. A reference Excel was also

opened and the automated process for generating the patient report was initiated. The functions for this process were designed by specifically for use with this study. Data was then automatically scored and summary graphic of the study measures scores was generated. In the "Provider Only" group, study personnel printed the Biopsychosocial Health Report (i.e., combination of PROMIS Patient Report and summary sheet of psychosocial/pain-related measures) and sought out providers to offer feedback prior to the point-of-care. For the "Provider and Patient" group, the Biopsychosocial Health Report was printed and provided to both. A protocol for the procedures and provision of feedback to patients for this process. A copy of the protocol is included as Appendix D. For the control group, patient data was accessed through the Assessment Center and transferred into study databases. A subset of the study sample received receiving interdisciplinary care; summary data for those patients in either feedback condition were verbally reviewed with the treatment team during weekly case conference.

A pared-down version of the baseline measures were administered at each of the follow-up time points. Per design, participants remained in the same study group (e.g., provider only, provider and patient, control) for all follow up time-points. As part of tracking participant data, study personnel tracked participant group-type to ensure that appropriate group conditions were met during follow up time points.

statistical analysis plan
Study Analyses

Baseline data within and between groups were examined for any significant demographic imbalances. Although study participants were randomized to their groups by age and gender (using the Urn randomization method), t-tests for both within and between groups differences amongst demographic variables were conducted. Any potential differences will be incorporated into and accounted for in subsequent analyses.

Mixed-effects modeling were used for all primary analyses. Initial exploratory analyses were conducted to identify covariates for inclusion in primary analyses. Univariate regression models using outcome change-scores were conducted to identify potential covariates amongst time-related variables (e.g. number of follow ups, length of time between appointments, total length of participation), demographic data and other patient factors (e.g. medical, psychiatric, and treatment-related variables). Significant predictors were retained for use in the primary multivariate models.

A random coefficients model was be utilized due to expected variation in the timing of assessments across patients and groups. Separate models were used for each of the identified outcome variables (e.g. illness perceptions, physician/patient working alliance, symptom level [pain-related, psychiatric], psychosocial impairment). Per recent literature of their theoretical and empirical relationship, illness perception was analyzed apart from and in conjunction with level of positive/negative expectancy. For study participants that received interdisciplinary care, the summary physical functioning scores (i.e. composed of

grip strength, measure of cardiovascular performance, range of motion) were incorporated as an outcome. For each model, scores over time (T1 – T5) and change scores (T2 – T5) for each outcome variable were treated as primary outcomes. Within each model, covariates included baseline scores of the designated outcome variable as well as those the possible predictors identified from the initial exploratory analyses. Using this model, comparisons between each of the study groups were made.

Separate subgroup analyses for each of the intervention groups as well as the control group (i.e. MDT review only) were performed to identify potential patient factors that may be associated with improvements in patient outcomes. Multiple regression analyses (linear and hierarchical) were performed, using outcome change-scores and identified covariates as analytically applicable.

Sample Size/Power Analysis

A total of 69 participants were included in the study sample; participants who completed at least one follow up were included in analyses. The number of participants in each study group were as follows; Joint Feedback (n=16), Provider-Only Feedback (n=18), and Chart-Review (n=35). A diagram that summarizes participant flow through the study across 5 time points is included as Figure 1. This figure represents the number of consented participants, study withdrawals, incomplete assessment, and completed assessments by time point and group. A post-hoc power analysis using the current sample size and an adjusted number of follow ups was conducted. The analysis indicated that the

current sample achieves 80% power [*f*(.40)] at a 5% significance level. Power and effect size were calculated using a recently developed software program for power analysis (Velikova et al., 2004; Faul, Erdfelder, Lang, & Buchner, 2007; Faul, Erdfelder, Buchner, & Lang, 2009). Random assignment was carried out using the Urn Randomization method with age, gender, and ethnicity as set parameters.

CHAPTER FOUR

Results

Descriptive Statistics

Sample Size and Group Assignment

The valid sample size for the current study included 69 total participants. Completion of multiple time points was required for participants to be included in the study sample and subsequent analyses. A total of 92 participants were consented; however, 23 of these were not included in the valid sample due non-completion of assessments and/or lack of assessments across multiple time points. Figure 1 presents the number of completed assessments by time point in the context of study group type. As anticipated, the sample was unbalanced for the number of assessments completed both within and between time points. For each valid assessment and time point, core outcome measures were completed by all study participants. However, the sample size is decreased for those analyses that include performance-based and therapeutic alliance data. Given that treatment type differed within the sample (i.e., some participants were not recommended for any physical therapy-based treatment), performance-based data for multiple time points was not available for all study participants. The statistical model used for the primary analyses accounts for this imbalance, as discussed in the statistical analyses plan. Group size was imbalanced across the three study groups; Patient/Provider Feedback (n=16), Provider Only Feedback (n=18), and Chart Review Only (n=35). As will be discussed in the following chapter, patient and environmental factors affected randomization of patients to the intervention

groups (e.g., patients not arriving on time for appointments). Those factors made it necessary to "default" patients from an intervention group to Chart Review Only.

Demographic Variables

Study participants were primarily female (67%) with an average age of 48.35 years (*SD*=14.51, range=18-81 years). Regarding race/ethnicity, the sample was primarily Caucasian (71%), followed by African American (17.4%), Hispanic (8.7%), and other (2.9%). Study subjects tended to be married (59.6%) and to have children (76.2%). The sample had an average of 13.34 (*recheck*) years of education and 1.62 children. At baseline, a percentage of study participants reported receiving current disability benefits (26.4%). A majority of patients were not employed (27.5% employed full/part-time). A majority of participants endorsed some form of pending litigation (worker's compensation [30.4%]; personal injury [37.7%]). Full study demographics are presented in Table 2.

Treatment and Pain-Related Variables

For each study participant, treatment type following the interdisciplinary evaluation (i.e., Time Point 2) was recorded and tracked. The majority of the sample engaged in either Pain Management Only (46.4%) or the Interdisciplinary Pain Treatment Program (29%). The remainder of the sample engaged in

Physical Therapy Only (5.8%), Cognitive-Behavioral Therapy and PT (5.8%), CBT Only (4.3%) and Psychiatry Only (4.3%). It should be noted that approximately 50% of participants in "Pain Management Only" were either not compliant with or were unable to engage recommendations for some form of interdisciplinary treatment. At baseline, about half of participants reported a history of chronic pain for 2+ years (47.8%), one or more pain-related surgeries (52%) and a positive family history of pain-related health problems (47.2%). The majority reported having only one active pain-related complaint at baseline (65.2%). A majority of patients reported regular use of pain medication (73.9%) as well ongoing treatment for their pain complaint (92.5%). Participants provided ratings for both their current pain level (0=no pain, 10=worst pain possible; *mean*=6.54, *SD*=1.41) and perceived helpfulness of their current pain treatment (*mean*=5.31, *SD*=1.33, *range* 0-10). In the overall sample, 24.6% of study participants reported engaging in regular exercise 1 or more times weekly. Treatment and pain-related variables by group are presented in Table 3.

Clinical Characteristics

The majority of the sample reported a history of one or more psychiatric diagnoses (66.7%); anxiety-related disorders (42%) and mood disorders (30.4%) were the most commonly reported diagnoses. A majority of those with existing psychiatric diagnoses reported a history of psychiatric medications and of receiving psychiatric treatment from a mental health professional or other treatment provider in the past. The majority of study participants also reported a

family history of psychiatric diagnoses (56.5%); of those, 31.5% reported a known biological family history of psychiatric diagnoses with 24.6% reporting a positive, but unknown family psychiatric history. As a separate variable, a percentage of study participants reported existing pain-related diagnoses (37.7%). Clinical characteristics for the sample are presented in Table 4.

Group comparisons by demographic, pain-related, and clinical characteristics

Analyses to assess for group differences were conducted. Significant group differences were found by Treatment Type, $\varkappa^2$ (10, n=69) = 28.14, p<.01, Family History of Pain $\varkappa^2$ (2, n=69) = 5.98, p=.05, History of Psychiatric Diagnosis $\varkappa^2$ (4, n=69) = 26.38, p<.001, and Biological Family Psychiatric History $\varkappa^2$ (10, n=69) = 16.99, p<.08. Individual analyses were conducted to identify specific group differences for each of these variables. Treatment Type was recoded by individual category and separately analyzed between each group pair. For Treatment Type, group differences for Pain Management were found between the Patient/Provider and Chart Review group (t (50)=5.09, p<.001), as well as the Chart Review and Provider Only groups (t (52)=2.68, p < .05). A similar pattern of group differences was found for the ID Program treatment category; Patient/Provider by Chart Review (t (50)=-2.29, p<.01) and Provider Only by Chart Review (t (52)=-2.45, p<.05. Group differences between the Patient/Provider and Chart Review group were found for the other identified variables; Family Hx of Pain (t (37)=2.49, p<.05), Hx of Psych Dx (t (37)=-3.05, p<.01), and Family Hx of Pain (t (16)=-3.30.09, p<.01). No group differences

were found between the Provider Only and Chart Review groups for these variables. Comparisons between the Patient/Provider and Provider Only group yielded significant differences for two of these variables; Hx of Psych Dx ($t(52)=-2.53$, $p < .05$) and Biological Family Psych Hx ($t(52)=-3.10$, $p < .05$). Given these significant group differences, Treatment Type, Family Hx of Pain, Hx of Psych Dx, and Biological Family Psych Hx were included as factors in the primary study analyses.

Univariate Analyses

Scores for all outcome measures within groups by time point were examined for equality of variance prior to conducting statistical analyses. The majority of group scores by time point did not violate the assumption of equal variances. These data are presented with the descriptive statistics for all outcomes in Table 6. Each outcome measure includes multiple representations; including the baseline mean, post-intervention mean, and mean change score. The baseline mean was derived from completed assessments at Time Point 1 and Time Point 2. The post-intervention mean change was derived from the mean of average change scores from Time Point 3 through Time Point 5.

Pearson product-moment correlations were conducted to explore the relationships between outcome measures and demographic, treatment/pain-related, and psychological variables. Correlations were conducted using both the baseline mean scores and the post-intervention mean change scores for all 37 outcomes included in the study. There were numerous significant correlations for

both sets of analyses; these were incorporated into multiple regressions performed as part of the secondary exploratory analyses. These analyses are included in Table 7.

Independent samples t-tests for gender and each race/ethnicity category were conducted with each outcome variable type. Gender was significant for the baseline mean of multiple outcomes; including PROMIS Sleep Disturbance (baseline mean [t (49)=-2.65, $p < .05$]), Illness Perception – Identity (baseline mean [t (45)=2.36, $p < .05$]), and the Medication Adherence Scale (baseline mean [t (44)=2.38, $p < .05$]). Gender was significant for the post-intervention mean of two outcomes; including, Illness Perception – Personal Control (post mean [t (54)=-2.29, $p < .05$]) and Illness Perception – Comprehension (post mean [t (54)=-2.48, $p < .05$). Gender was significant for both the baseline mean and post-intervention mean for two outcomes; including, PROMIS Pain Behavior (baseline mean [t (58)=-2.07, $p < .05$]; post mean [t (54)=-1.94, $p < .05$]), and PROMIS Physical Functioning (baseline mean [t (58)=2.01, $p < .05$]; post mean [t (54)=-2.69, $p < .01$]). Gender was significant for only one of the post mean change outcome scores; specifically, PROMIS Sleep Disturbance (post mean change [t (32)=2.51, $p < .05$]).

Similar analyses were conducted for each race/ethnicity category. For Caucasians in the sample, significant differences were found in multiple outcomes; including, Illness Perception – Emotions baseline mean [t (45)=-2.51, $p < .05$] and the PROMIS Fatigue mean change [t (59)=2.64, $p < .05$]. For African Americans, significant differences were found in multiple outcomes; including,

Illness Perception – Emotional Concern post mean [t (54)=-2.06, p < .05], the Illness Perception – Comprehension post mean [t (54)=-2.06, p < .05], and the PROMIS Pain Behavior post mean [t (58)=-2.06, p < .05]. There were no significant differences found in analyses for the race/ethnicity categories of Hispanic or Other. All patient characteristics by group type are presented in Table 5.

An analysis of variance (ANOVA) was conducted to assess for age-related differences in the outcome measures. Age was a significant factor for multiple outcomes; including, PROMIS Sleep Disturbance post mean [$F(46)=4.87$, $p<.01$], Global Health-Related Quality of Life – Physical Health post mean [$F(47)=4.22$, $p<.01$], and Global Health-Related Quality of Life – Mental Health post mean [$F(47)=5.02$, $p<.01$]. Significant factors from each of the preliminary analyses were incorporated into the corresponding outcome model for the primary analyses.

Primary Analyses

Mixed effects models for all study outcomes are presented as Tables 18 - 37. Significant fixed effects on the PROMIS Anger change score were observed for Group Type ($P <.004$) and Group Type by Time Point ($P = .006$); a reduction in PROMIS Anger change score was detected for Patient/Provider versus Chart Review (Study Group, $P < 0.002$; Study Group by Time Point, $P < .001$) and in the Patient/Provider versus Provider Only (Study Group, $P < 0.001$; Study Group

by Time Point, $P < .001$). Family History of Pain was a significant covariate in the overall model ($P = .028$).

A significant overall effect on PROMIS Anxiety change score was observed for Study Group ($P = .094$); a reduction in the PROMIS Sleep Related Impairment change score for the Patient/Provider versus Chart Review groups was detected ($P = .031$). However, no significant effect was detected between the Patient/Provider and Provider Only groups ($P = .268$).

A significant overall effect on PROMIS Depressive Symptoms change score was observed for Study Group by Time Point ($P = .088$); a reduction in PROMIS Depressive Sxs change score for the Patient/Provider versus Chart Review groups was detected ($P = .029$). However, no significant effect was detected between the Patient/Provider and Provider Only groups ($P = .252$) throughout the model.

A significant overall effect on PROMIS Pain Interference change score was observed for Study Group by Time Point ($P = .051$); a reduction in PROMIS Pain Interference change score for the Patient/Provider versus Chart Review groups was detected ($P = .023$). However, no significant effect was detected between the Patient/Provider and Provider Only groups ($P = .635$) in the overall model. Pairwise comparisons of the estimated means for each Study Group showed a significant difference between the adjusted means for the Patient/Provider and Chart Review groups ($P = .056$) and the Provider Only and Chart Review groups ($P = .078$).

A significant overall effect on PROMIS Sleep Related Impairment change score was observed for Study Group ($P = .012$) and for Study Group by Time Point ($P = .006$); reductions were observed in the PROMIS Sleep Related Impairment change score for Patient/Provider versus Chart Review (Study Group, $P = 0.003$; Study Group by Time Point, $P = .001$) and Patient/Provider vs. Provider Only (Study Group, $P = .090$; Study Group by Time Point, $P = .055$).

A significant overall effect on the Pain Disability Questionnaire (PDQ) change score was observed for Study Group ($P = .004$) and Study Group by Time Point ($P = .002$); a significant reduction in PDQ change score was detected for the Patient/Provider versus Chart Review (Study Group, $P = 0.002$; Study Group by Time Point, $P = .001$). However, no significant effect was detected between the Patient/Provider and Provider Only groups in the overall model. Pairwise comparisons of the adjusted estimated means between each Study Group were not significant.

Significant overall effects for Study Group on change scores for two subscales of the Working Alliance Inventory (patient-rated) were observed. Specifically, significant effects for Study Group were observed for the WAIc-Task change score (Study Group, $P = 0.002$; Study Group by Time Point, $P = .001$) and the WAIc-Bond change score ($P = .010$). Significant increases in Working Alliance for each subscale for the Patient/Provider versus Chart Review groups was observed (WAIc-Task, $P = .097$; WAIc-Bond, $P = .085$). Significant Study Group effects were not observed between the Patient/Provider and Provider Only groups in either model (WAIc-Task, $P = .633$; WAIc-Bond, $P = .288$). Pairwise

comparisons of the adjusted estimated means between each Study Group were not significant for either model.

Significant overall effects for Study Group and Study Group by Time Point on change scores WAIt-Bond (provider completed) were observed (Study Group, $P = .055$; Study Group by Time Point, $P = .033$).

Significant overall effects for Study Group and Study Group by Time Point were observed for multiple subscales of the Brief Illness Perception Questionnaire. Specifically, a significant Study Group effect was observed for Illness Perception Consequences score over time ($P = .048$) and Illness Perception Timeline score over time ($P = .009$).

Adaptive increases for both the Illness Perception Consequences score over time ($P = .033$) and the Illness Perception Timeline score over time ($P = .002$) for the Patient/Provider and Chart Review groups. For the Illness Perception Identity change score, both Study Group effects ($P = .018$) and Study Group by Time Point effects were observed ($P = .018$). Adaptive score increases were detected between the Patient/Provider and Chart Review groups (Study Group, $P = 0.006$; Study Group by Time Point, $P = .005$) and Patient/Provider vs. Provider Only (Study Group, $P = .030$; Study Group by Time Point, $P = .040$). Pairwise comparisons of the adjusted estimated means between each Study Group were not significant.

Study Group by Time Point effects were observed for Illness Perception Timeline change score ($P = .011$) with an adaptive score increase detected between the Patient/Provider and Chart Review groups for Study Group by Time

Point (*P* = .010). Pairwise comparisons of the estimated means for each Study Group showed a significant difference between the adjusted means for the Patient/Provider and Chart Review groups (*P* = .013) but not the Patient/Provider and Provider Only (*P* = .413).

A significant overall effect on PROMIS Global Health-Related Quality of Life – Physical Health change score was observed for Study Group (*P* = .031) and for Study Group by Time Point (*P* = .094); reductions were observed in the PROMIS Global Physical Health change score for Patient/Provider versus Chart Review (Study Group, *P* = 0.009; Study Group by Time Point, *P* = .031) and Patient/Provider vs. Provider Only (Study Group, *P* = .095).

Graphical representations of the estimated marginal means for all outcome change scores are presented as Figures 4 – 18. Completion-time for all PROMIS computer-adaptive-tests are presented in Tables 38-40.

Some outcome models showed significant fixed effects for Group and Group by Time without significant group differences in comparisons of the fixed effects estimates. For those models, the two feedback groups were combined and the primary analyses were conducted again. Summaries of these analyses are presented in Table 41. Significant Group*Time effects between the Combined Feedback and Chart Review groups were found for the change score of the Personal Control dimension of the BIPQ (*P*=.034), PROMIS Fatigue change score (*P*=.042), and PROMIS Physical Functioning (*P*=.05).

Hypotheses

Hypothesis One*: Study participants in the Joint Feedback Group, as compared to the Control Group (i.e. Chart Review only), will evidence significant differences across outcome scores over time.*

Partial support was confirmed for this study hypothesis. As discussed, significant group effects for Study Group and Study Group by Time Point were observed between the Joint Feedback Group and the Control Group. However, the predicted group effects were not detected for many outcome variables. Each is listed in the outcome categories below.

Psychosocial variables

Results from the mixed effects model for the Pain Disability Questionnaire support the study hypothesis. Change scores were significant for Study Group (P = .004) and Study Group by Time Point (P = .002); a significant reduction in PDQ change score was detected for the Patient/Provider versus Chart Review groups (Study Group, P = .002; Patient/Provider vs. Chart, P = .001). Results from the mixed effects models for the Pain Medication Questionnaire (PMQ; Opioid Misuse Risk) did not evidence significant group effects. Results from the mixed effects models for PROMIS Satisfaction with Discretionary Social Activities showed … Further, the models for PROMIS Satisfaction with Social Roles and the Life Orientation Test – Revised (LOTR; Optimism) did not evidence significant group effects.

Symptom level

Results from the mixed effects models for PROMIS Anger, PROMIS Anxiety, PROMIS Depressive Sxs, PROMIS Pain Interference, and the PROMIS Sleep Related Impairment support the study hypothesis. Change scores were significant for Study Group (PROMIS Anger, *P* = .001; PROMIS Anxiety, (*P* = .094); PROMIS Sleep Related Impairment, *P* = .088) and Study Group by Time Point (PROMIS Depressive Sxs (*P* = .088); PROMIS Pain Interference, *P* = .051); in each model, significant reduction change scores were detected for the Patient/Provider versus Chart Review groups (PROMIS Anger, *P* = .001; PROMIS Depressive Sxs (*P* = .029); PROMIS Anxiety (*P* = .031), PROMIS Pain Interference, *P* = .027; PROMIS Sleep Related Impairment, *P* = .027). Results from the mixed effects models for the PROMIS Fatigue did not evidence significant group effects; however, results from the change scores model suggest a trend toward a Study Group effect (*P* = .113). Results from the mixed effects models for PROMIS Pain Behavior, and PROMIS Physical Functioning did not evidence significant group effects.

Clinician/patient working alliance

Results from mixed effects models for this category partially support the study hypothesis. The two significant models came from the patient-reported form, while none of the three models for provider-reported working alliance were significant. Significant effects for Study Group were observed for the WAIc-Task change score (*P* = .056) and the WAIc-

Bond change score (*P* = .010). Significant increases in Working Alliance for each subscale for the Patient/Provider versus Chart Review groups was observed (WAIc-Task, *P* = .097; WAIc-Bond, *P* = .085). Results from the mixed effects models for the provider –completed forms (WAIt – Bond, WAIt – Task, WAIt – Goal) and one of the patient-completed forms (WAIc – Goal) did not evidence significant group effects.

Illness perceptions

Results from the mixed effects modeling for this outcome category partially support the study hypothesis. Multiple subscales of the Brief Illness Perception Questionnaire evidenced significant group effects supportive of the study hypothesis; including, Illness Perception – Consequences scores over time (Study Group, *P* = .090; Patient/Provider vs. Chart, *P* = .033), Illness Perception – Timeline scores over time (Study Group, *P* = .007; Patient/Provider vs. Chart, *P* = .002), Illness Perception – Timeline change scores (Study Group by Time, *P* = .001; Patient/Provider vs. Chart, *P* = .077), and Illness Perception – Identity (Study Group, *P* = .082; Study Group by Time, *P* = .020; Patient/Provider vs. Chart, *P* = .034).

Health-care utilization and Treatment Cost

As discussed, data for this outcome were unanalyzable. Sufficient data to conduct the mixed effects model for this outcome were not available. At present, the study hypothesis is neither affirmed nor rejected for this outcome.

***Hypothesis Two**:* Study participants in the Joint Feedback Group, as compared to the Provider-Only Group, will evidence significant differences across outcome scores over time.

This study hypothesis is partially supported by the results of mixed effects models. Results from the mixed effects model for PROMIS Anger change scores evidenced a significant group effect between the Patient/Provider and Provider Only groups (Study Group, $P < .001$; Study Group by Time Point, $P < .001$). Results from the PROMIS Pain Interference change scores mixed effects model evidenced a significant group effect as well ($P = .027$). Results for the PROMIS Sleep Related Impairment change scores model evidenced significance between the Patient/Provider and Provider Only groups (Study Group, $P = .090$; Study Group by Time Point, $P = .055$). Significant Study Group effects were not observed between the Patient/Provider and Provider Only groups in models for the PDQ, PMQ, PROMIS Depressive Symptoms, PROMIS Anxiety, PROMIS Fatigue,

PROMIS Physical Functioning, the provider-completed subscales of the Working Alliance Inventory, or the patient completed WAI Goal subscale.

Hypothesis Three*:* Study participants in the Clinician Only Group, as compared to the Control Group, will evidence significant differences across outcome scores over time.

Results from mixed effects models yielded partial support for this hypothesis. Adjusted pairwise comparisons of estimated means found significant or trending differences for multiple outcomes for the Provider Only and Chart Review groups (PROMIS Pain Interference, $P = .078$; Illness Perception – Time change score, $P = .072$, WAIt – Bond, $P = .050$; Depressive Sxs, $P = .183$).

CHAPTER FIVE

Discussion and Conclusions

This study sought to test the effects of two levels of a PRO-based intervention administered prior to the point-of-care at multiple time points in an outpatient chronic pain population. Recommendations from recent theory/research were incorporated into the study design; including, computer-based test administration (i.e., touch-screen tablet-PC's), use of efficient, precise assessment methods (i.e., IRT-based computer-adaptive-testing, population-specific assessments), use of a structured framework for PRO feedback (e.g., two PRO feedback conditions with a chart-review only comparison group, protocol-based feedback, standardized report format), and the collections of outcomes from multiple domains (e.g., psychosocial factors, population-specific outcomes, measures of treatment alliance, performance-based outcomes). By including these recommendations, the study design extends existing research in the area of PRO-based feedback and tests the utility of innovative methods of treatment outcome tracking in outpatient clinical settings.

Study Generalizability

Demographic characteristics for both the overall sample and amongst the study groups are consistent with previous studies of adult outpatients with chronic pain (Gatchel, 1995); including, gender, race/ethnicity, annual income, level of unemployment, and rate of psychiatric comorbidity. However, the current study sample tended to be younger on average (M=48.35) than other studies of adults

with chronic pain. Characteristics of the overall study sample and groups suggest results are generalizable to the larger chronic pain population.

In terms of process, the study procedures for feedback, report-creation, and structure/timing of assessments were protocol-based; thus, these components are generalizable/applicable as a framework for future clinical outcome-tracking research/intervention.

Study Findings

Using a representative sample with groups matched by age, gender, and ethnicity, the current study demonstrated a causal relationship between the provision of joint feedback and adaptive changes in multiple outcome domains over time in outpatients with chronic pain. This study represents the first instance in which such a joint feedback effects has been observed. Compared to a chart review only condition, the provision of joint feedback prior to the point-of-care showed significant group effects for multiple treatment outcomes. Significant outcomes included measures of emotional distress and psychological symptoms (PROMIS: Anger, Depressive Symptoms, Anxiety symptoms), pain-related measures of functioning and psychosocial status (Pain Disability Questionnaire, PROMIS: Pain Interference, Pain Behavior, Sleep Related Impairment), dimensions of health/illness perception, and treatment alliance separately reported by patients and providers. In the context of these outcomes, study findings support the presence of an ameliorative feedback effect.

Significant fixed effects for Study Group and/or Study Group by Time Point were observed in separate mixed effects models for these outcomes.

Significant pairwise comparisons between the covariate adjusted estimated means were observed for a number of those outcomes models. For each outcome model, findings indicate significant outcome-score changes can be attributed to the provision feedback (e.g., patients and providers, provider-only) prior to the point-of-care.

Relative to previous research, findings from models within the PROMIS Emotional Distress domain (Anger, Anxiety, Depressive Symptoms) parallel significant findings from a previous study of PRO feedback within an outpatient clinic setting. A 2004 study found a significant increase in emotional well-being for study patients whose providers received feedback from assessments completed by patients prior to the point-of-care (Velikova et al., 2004). The current study yielded similar findings; the provision of feedback prior to the point-of-care led to a measured decrease in emotional distress. Velikova tested a provider-only feedback condition and significant group effects were only found for outcome measures associated with emotional well-being (2004). As an extension of these findings, the current study found significant group effects for a joint feedback condition across multiple outcome domains (e.g. emotional distress, pain-related functioning, illness perception, alliance with treatment providers, performance-based walking time) over multiple time points.

Based upon their sensitivity and responsiveness to feedback intervention and/or treatment, the majority of study measures demonstrated utility as treatment outcomes for an adult population of outpatients with chronic pain. For the

overall sample and identified group comparisons, the detection of treatment and intervention effects supports the sensitivity and responsiveness of study outcomes.

While the strength and group expanse of intervention effects differed between and within domains, results from these models collectively support the responsiveness and sensitivity to change of these outcomes and their targeted symptoms. The majority of outcome measures demonstrated responsiveness to the feedback intervention and/or treatment type. In terms of feedback effects, pain-related functional disability (PDQ) and the PROMIS Emotional Distress domain (Anger, Anxiety, Depressive Symptoms) represent the most responsive and significant set of outcomes.

The PDQ assesses respondents' degree of pain-related disability in terms of the concrete limits and impact chronic pain may have on areas of functioning (e.g., physical activity, social engagement, emotional functioning, financial impact). Previous studies have demonstrated the broad utility of the PDQ in terms of disability, level of psychiatric comorbidity, and psychosocial dysfunction (Gatchel et al., 2006). This sensitivity to an array of constructs was reflected in the results of the current study; the PDQ had the highest frequency of significant correlation in analyses of all outcome means across time points. In terms of utility for treatment outcome tracking, this measure detected significant intervention effects and was sensitive to change in other study outcomes. Beyond the PDQ, PROMIS Anger was the most responsive and sensitive individual outcome. This measure taps into respondents' anger-based symptoms (e.g. irritability, frustration), negative social cognitions (e.g., interpersonal sensitivity,

envy, disagreeableness), verbal aggression, and efforts to control anger (Cella, et al., 2010). To a lesser degree, PROMIS Anxiety and Depression demonstrated sensitivity to treatment and feedback effects.

The PROMIS Sleep Related Impairment demonstrated similar sensitivity and responsiveness to both treatment and feedback interventions. In addition to assessing respondents' perception of alertness, sleepiness, and waking tiredness, it measures perceived functional impairments during wakefulness associated with sleep problems or impaired alertness (Buysse, 2010). While this construct taps symptoms associated with a sleep-related disorder, it was developed to be responsive to those wakeful symptoms of less chronic sleep problems. Its sensitivity to changes in basic alertness and sleepiness suggest it may tap into poor sleep quality related to the effect of intermittent waking from increased pain.

Results from the health perception model indicate that, compared the Chart Review condition, the Joint Feedback intervention affected group members' appraisal of current pain impact, symptom burden, and projected impact of their pain-related difficulties. Positive expectancy was included as a fixed factor in all illness perception models; however, it showed no significant effects in those analyses or individual mixed effects models. The cause for this lack of significance is currently unclear; further analyses are needed to determine if this instrument suitably taps into optimistic appraisal of health perceptions.

Measures of treatment alliance also demonstrated responsiveness and sensitivity to both feedback and treatment effects. In terms of patients' sense of

alignment and alliance with providers, significant group effects were observed. Together, these results indicate that the Joint Feedback intervention led to a measurable increase in the patients' adaptive identification with the treatment provider. To some degree, this is reflected by significant group effects between the Patient/Provider and Chart Review groups for the provider-rated version of the treatment alliance subscale (WAI-T Bond).

Adaptive changes for the majority outcome measures were observed across the entire sample. However, significant group effects were not observed for many study outcomes. These include a number of PROMIS measures (Fatigue, Physical Functioning, Sleep Disturbance, Satisfaction with Discretionary Social Activities, composite Global Health-Related Quality of Life), Opioid Misuse Risk, positive expectancy, and some performance-based measures of physical functioning (e.g. flexibility, grip strength). Even as group effects were not observed between the Patient/Provider and Provider-Only/Chart Review conditions, there were only a limited number of models that evidenced significant group effects between the Provider-Only and Chart Review conditions (Hypothesis Three). Although group effects were present for the identified models, this lack of significance questions the assumption that Provider-Only Feedback represents a lesser form of the underlying Feedback intervention mechanism.

While adherence to the feedback protocol and personnel providing feedback were consistent throughout the study, a number of factors may have caused the limited group effects between the Provider-Only and Chart Review

conditions. Possibilities include the methodology of the feedback protocol, the physical location where feedback was provided in the clinic, potential variation in length of time spent providing feedback, and the effectiveness of the initial training conducted with providers.

Review of the study process supports the utility of computer-based administration (touch-screen table PC's) and the use of computer-adaptive-testing with patient reported outcomes in an outpatient clinic setting. The completion of study outcomes yielded meaningful patient outcomes with a relatively low average completion time. Data collection and aggregation of results was efficiently carried out with the use of the PROMIS Assessment Center. As a hub for data collection and study management, the data and patient reports were available in real time as participants completed assessments. This efficient management of data allowed for the BPS reports to be generated within 3-4 minutes of participants' completion of assessments. The functionality of the Assessment Center in the current study supports the feasibility of PRO data collection/feedback within similar clinic settings.

Altogether, study findings support an ameliorative effect from a joint feedback intervention in adult outpatients with chronic pain. Observance of the study process through a review of completion-time statistics supports the efficiency of this approach to treatment outcome tracking. Given their sensitivity and responsiveness to intervention and/or treatment effects, the majority of study measures demonstrated utility as outcomes for adult outpatients with chronic pain.

Study findings provide support for additional research of the integration of PRO assessment and timely feedback within similar outpatient treatment settings.

Study Implications

The current study represents the first instance in which a joint feedback intervention with patients and providers has yielded significant group effects across multiple outcome domains. Further, this study is the first to implement an outcome tracking system and feedback intervention utilizing innovative testing methodology, efficient technology, and a theoretical-based framework in a population of outpatient chronic pain patients. In light of these findings, the potential benefit of the feedback intervention and system of outcome tracking warrant further research to clarify and refine these processes.

Given their responsiveness and sensitivity to intervention and/or treatment effects, these measures could be expected to perform similarly in other outpatient clinic settings and with an adult chronic pain population. The assessment structure by time point and treatment type utilized in the current study may be a helpful framework that could be adapted for PRO data collection/feedback in other clinic settings. The graphical representation of this structure is too large to be displayed outside of electronic format. This file will be included in documents sent to committee members.

Study results highlight the potential patient care benefits that may be associated with this form of treatment outcome tracking and joint feedback intervention. The efficiency of implementing this system and the nature of results

warrant follow-up research. While study findings are preliminary, there are multiple implications that could prove fruitful for future clinical research in this area.

Study Limitations

Data included in the study analyses were collected over a period of approximately 9 ½ months; this length of time limited the number of potential participants. Although adequate power was achieved, larger sample and group sizes would make findings more robust. The mixed findings for comparisons between the Provider-Only group and Chart review group call into question the graded model of feedback effects upon which the intervention group were formed. Thus, as compared to the Joint Feedback condition, the Provider-Only condition does not represent a "step-down" feedback effect.

Inconsistent opportunity to perform either feedback intervention represents a significant study limitation. The process for inclusion in either intervention condition was predicated upon potential study participants arriving 30 minutes early for the Time Point 2 assessment (Interdisciplinary Evaluation). Despite prompts ahead of time, many participants did not arrive early enough to be randomized into one of the intervention conditions. Even when arriving early, a minority of participants took longer than average time to complete their assessment. In both instances, there was not sufficient time to provide feedback for either group condition; as such, it was necessary to "default" those participants

into the Chart Review only group. As a result, group size was imbalanced, yielding additional study limitation.

Future Directions and Recommendations

As discussed, the significant group and group by time effects for the primary feedback condition on multiple treatment outcomes warrant additional research into the nature and degree of effect for PRO data feedback prior to the point-of-care. Future studies that utilize larger sample/group sizes will likely yield more precise and robust findings. In light of the mixed findings for the secondary feedback condition, this overall area of research could be furthered by the review and refinement of the feedback-provision process. Given the factors that limited size of the intervention groups, future studies would benefit from an increased emphasis and structure related to securing pre-appointment time for assessment. The current study benefitted from a helpful and accommodating clinic staff and set of treatment providers. With such an environment in place, consistency of pre-appointment assessment time could be improved through a structured coordination of scheduling and patient flow.

Conclusions

Using a representative sample and demographically balanced groups, results showed the provision of joint feedback prior to the point-of-care had a significant, ameliorative effect on treatment outcomes from multiple domains. In addition to patient-reported outcomes, significant group effects were observed for one of the performance-based measures (Walking Time Change) over time.

Observance of the study process and completion time data suggest that the computer-based mode of assessment, type of assessment, scoring, creation of patient reports, and aggregation of data were all carried out efficiently within a busy clinic environment. This study reached its overall established goal of implementing a treatment outcome-tracking system and evaluating the potential effects of PRO data feedback across multiple time points. To some degree, the study's aim for ecological validity (i.e. incorporation of outcome-tracking with minimal disruption of clinic flow) played a role in conflating the discussed limitations. Altogether, the current study makes a unique contribution in the area of patient-centered care and treatment outcomes tracking with adult outpatients with chronic pain. A review of the study process and results yield a number of potential implications for future clinical research and patient care with this population.

APPENDIX A
FIGURES

Figure 1
Flow Diagram of Study Sample by Progress through the Study and Group Type

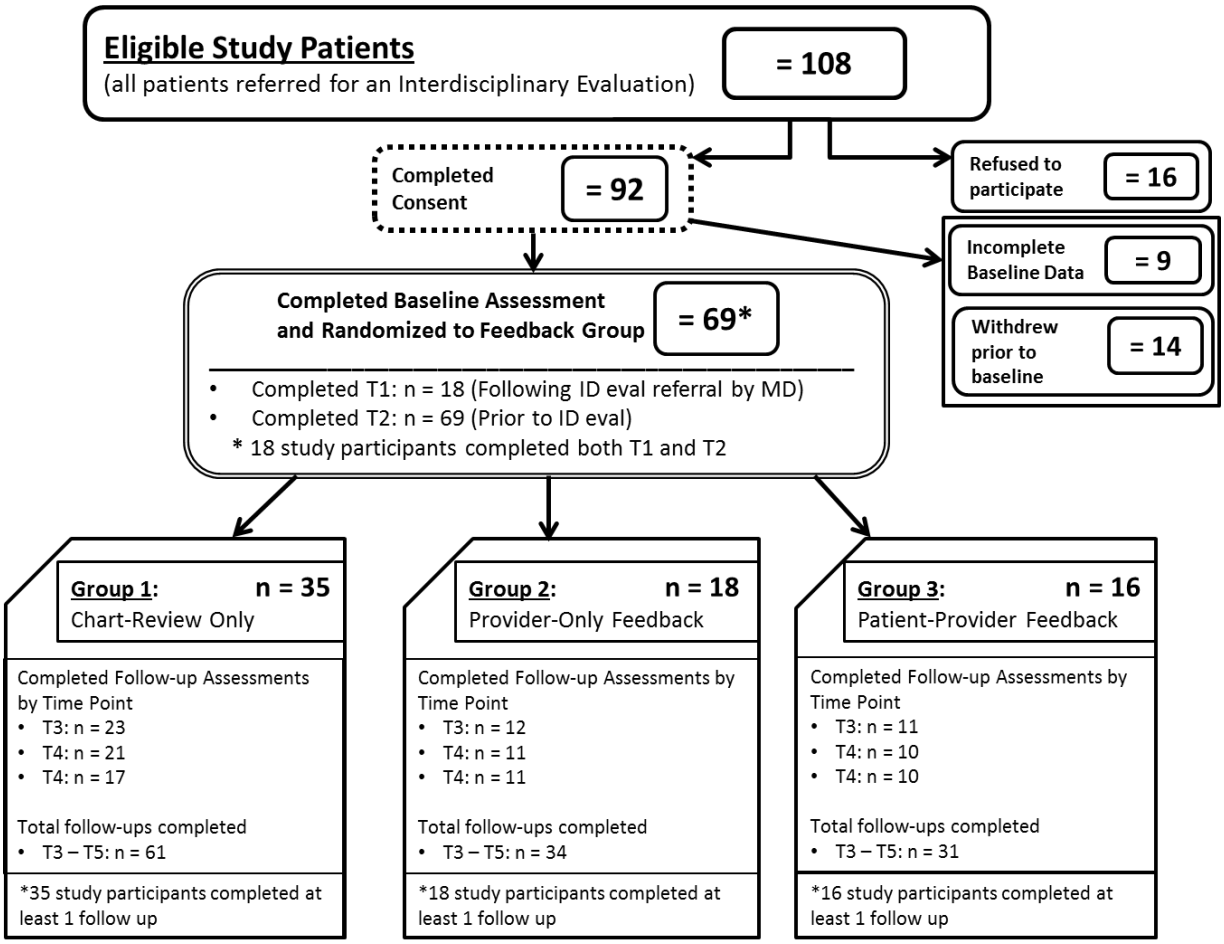
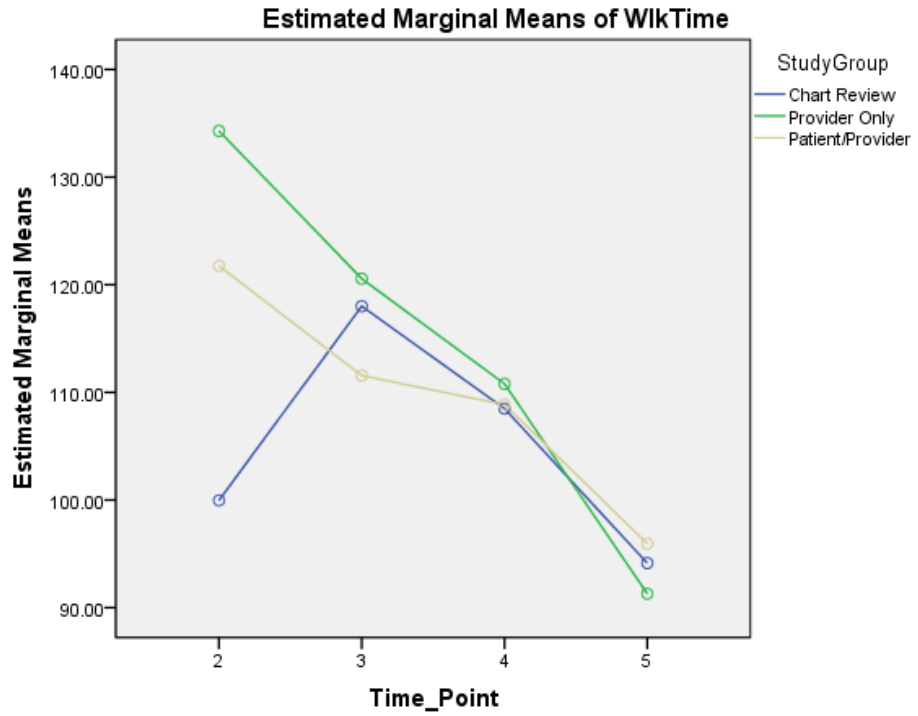
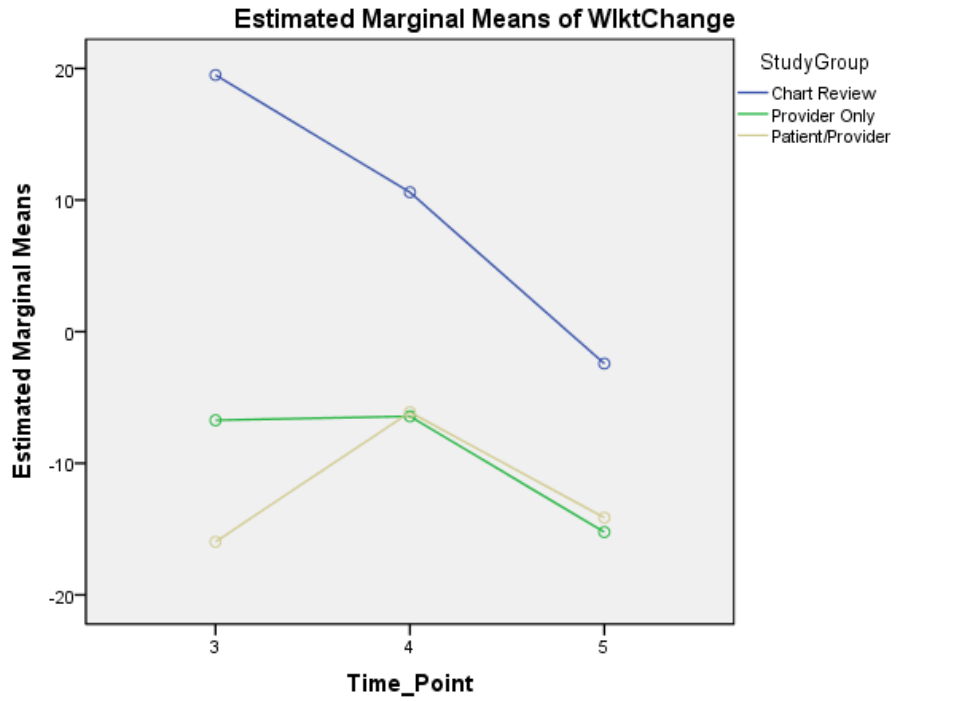


Figure 2
Walking Time Scores (4 Time Points) by Group and Time Point



Covariates appearing in the model are evaluated at the following values: Family Hx of Pain = 1.25, Hx Psyc Dx = .18, Biological Family Hx_Psych Dx = 4.4948

Figure 3
Walking Time Change Scores (3 Time Points) by Group and Time Point



Covariates appearing in the model are evaluated at the following values: Family Hx of Pain = 1.16, Hx Psyc Dx = .18, Biological Family Hx_Psych Dx = 4.7097, IDProg_Tx = .5000

Figure 4
PROMIS Physical Functioning – Change Score

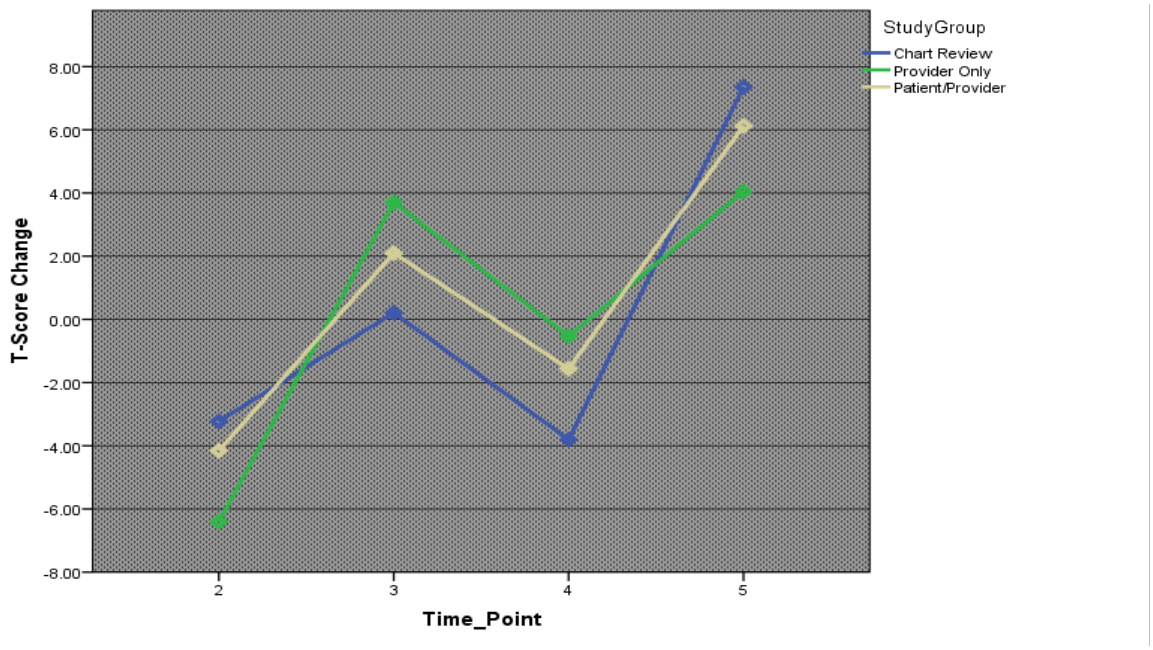


Figure 5
PROMIS Satisfaction with Discretionary Social Activities – Change Score

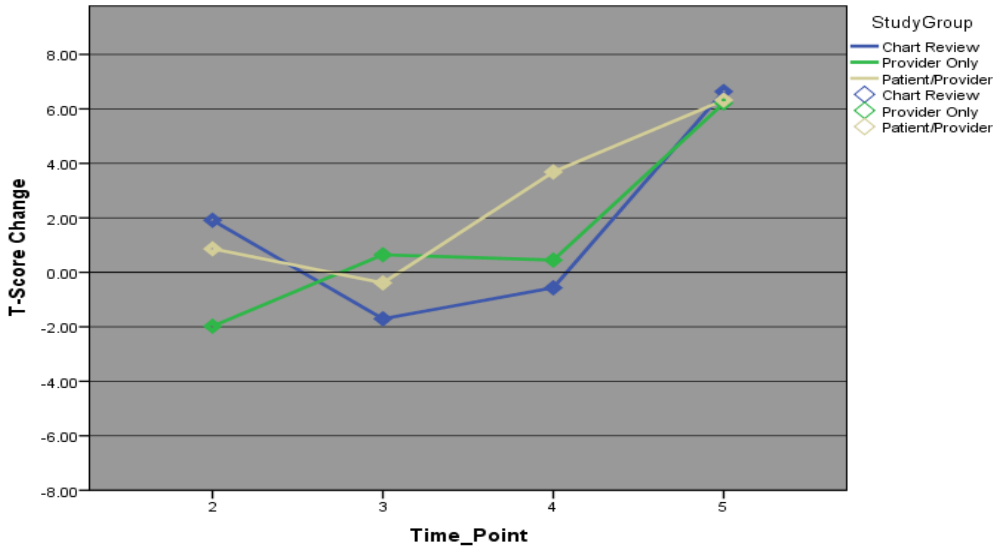


Figure 6
PROMIS Sleep Related Impairment – Change Score

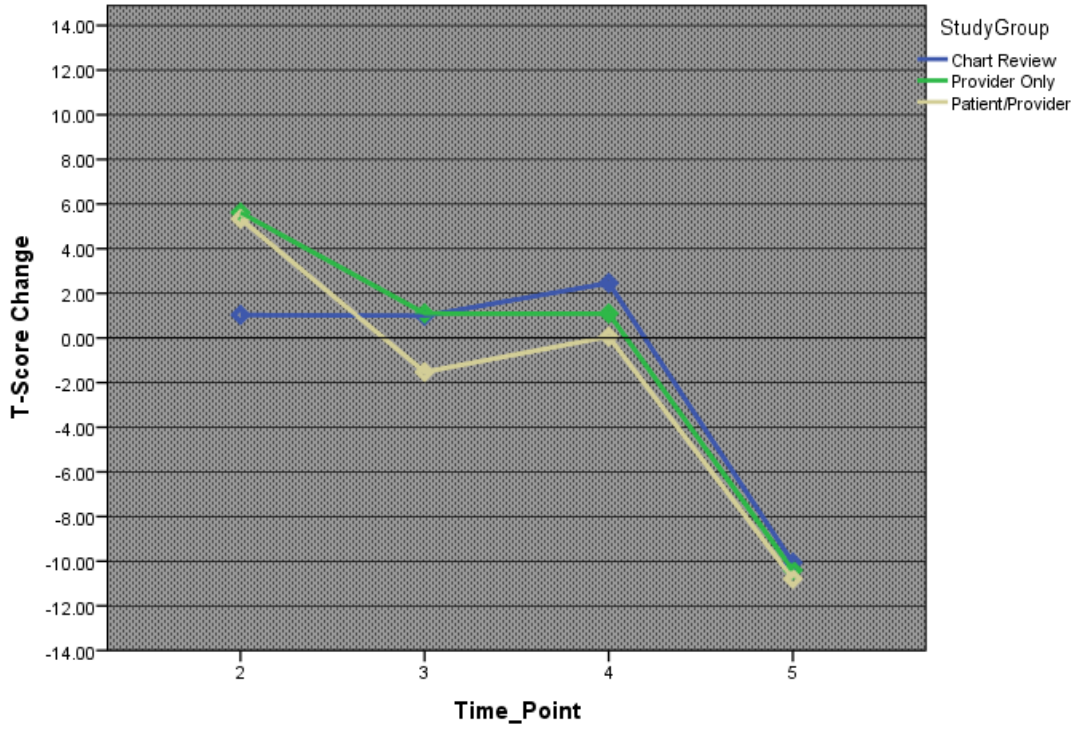


Figure 7

PROMIS Pain Interference – Change Score

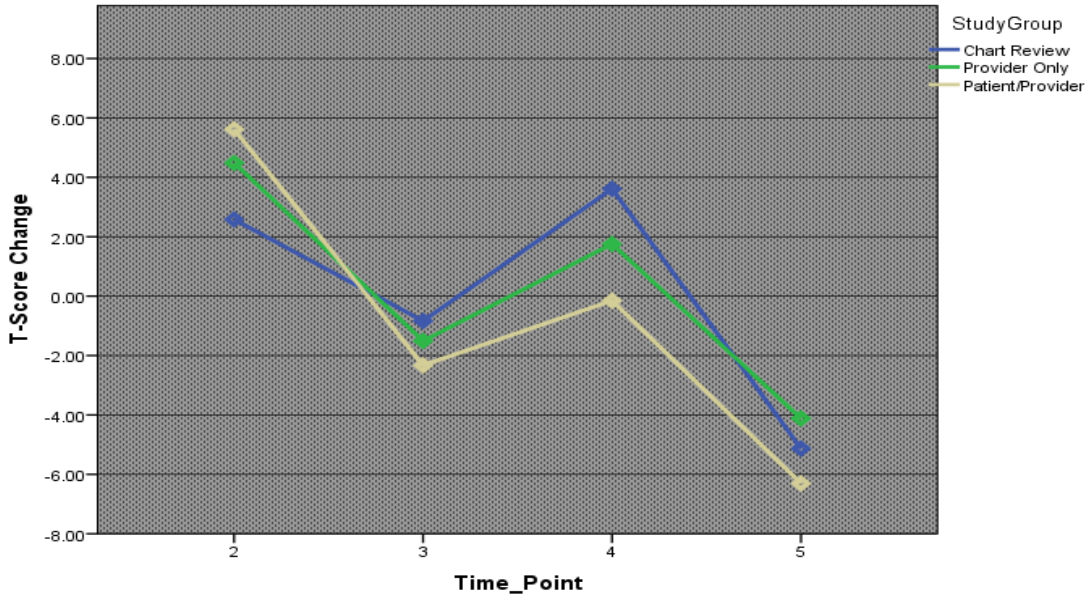


Figure 8

PROMIS Pain Behavior – Change Score: Study Group by Time Point

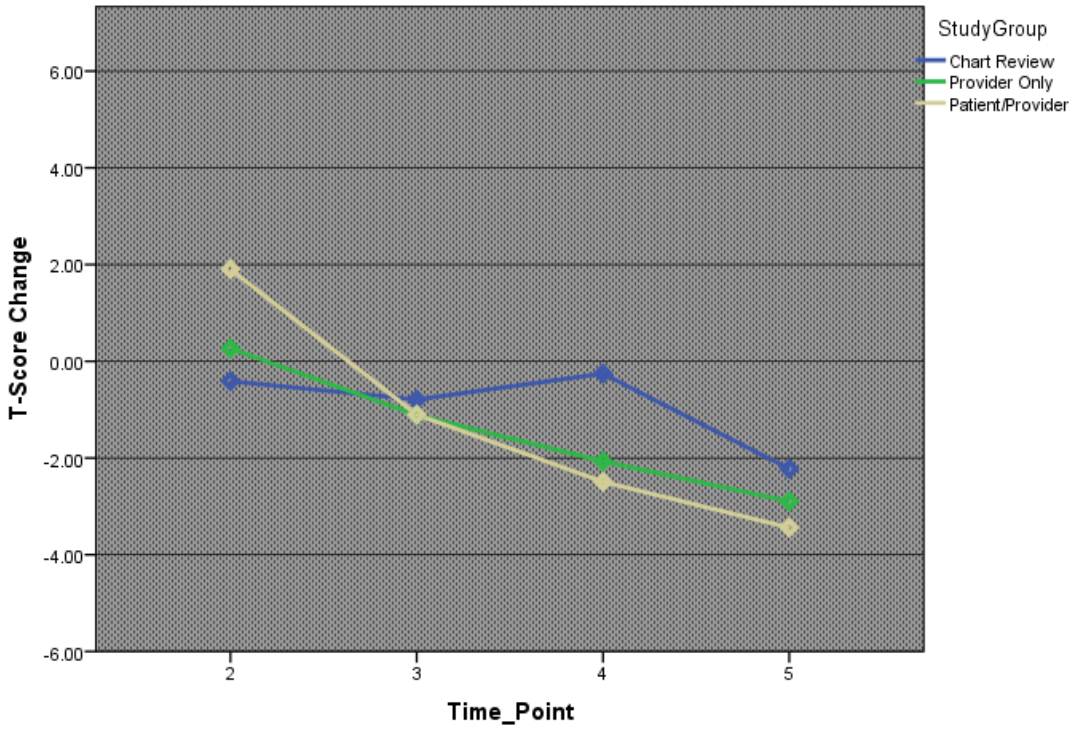


Figure 9

PROMIS Depressive Sxs – Change Score

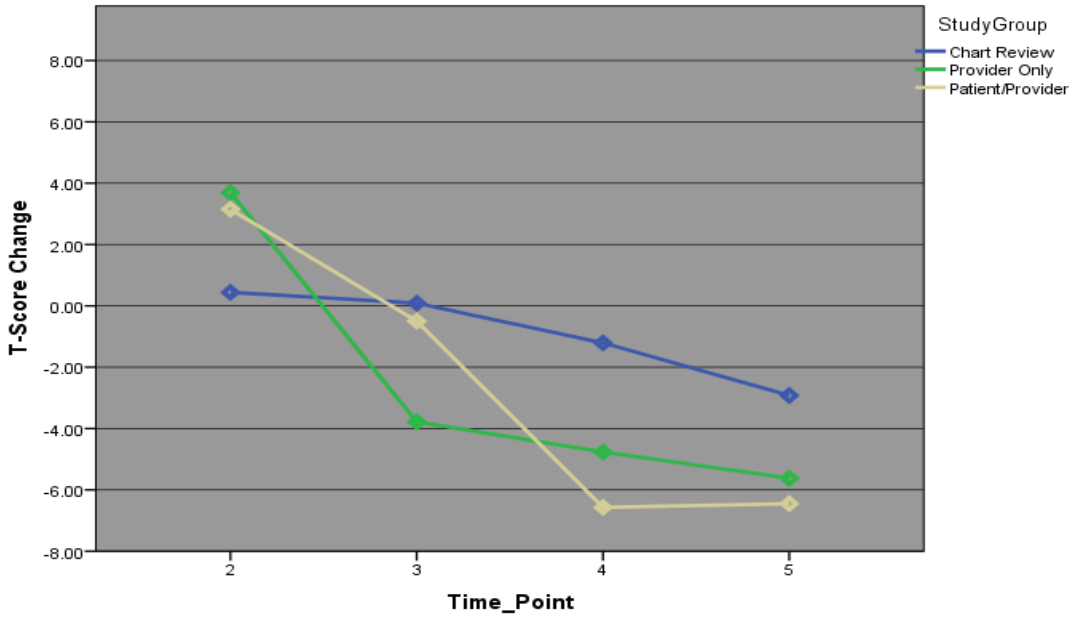


Figure 10

PROMIS Anxiety – Change Score

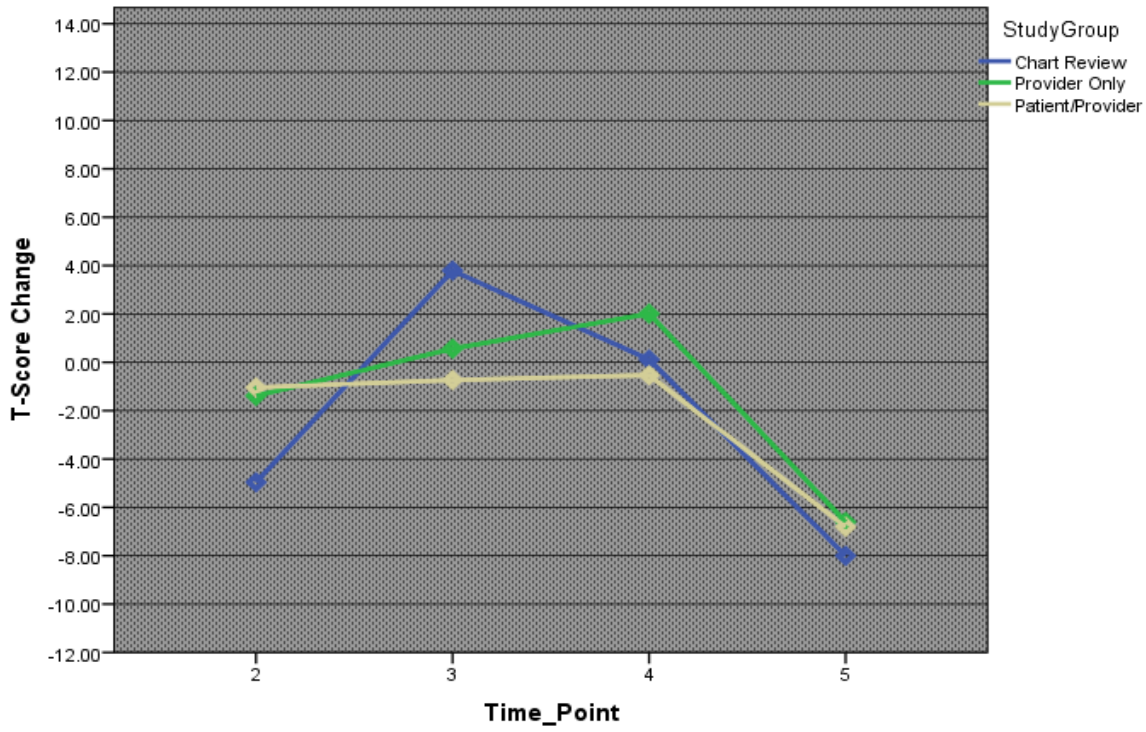


Figure 11

PROMIS Fatigue– Change Score

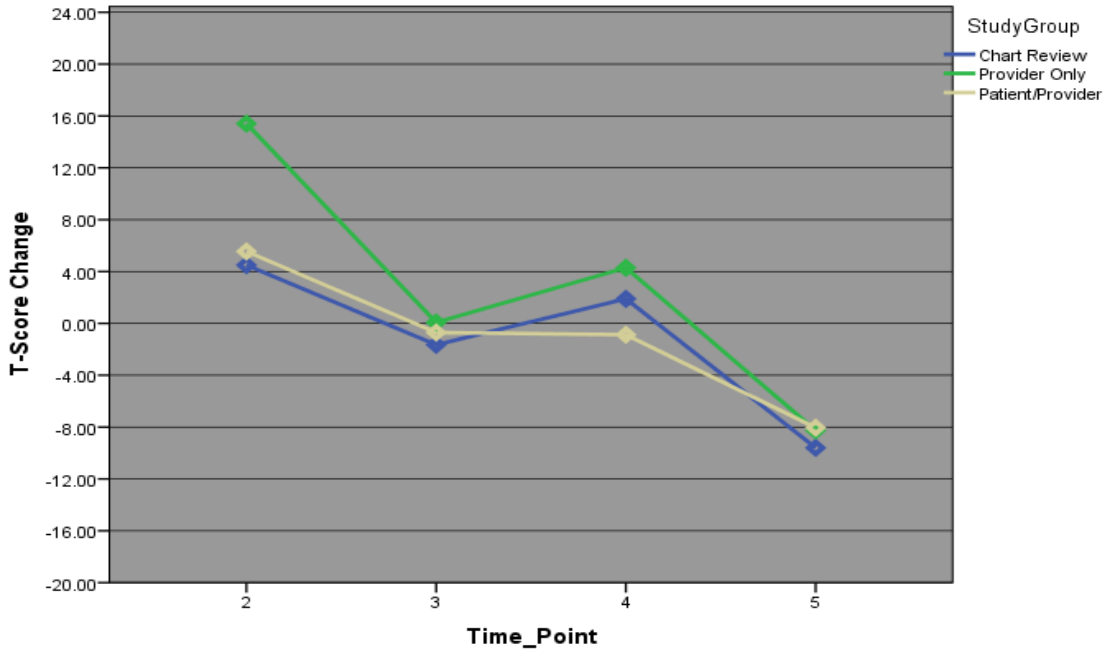


Figure 12

PROMIS Anger – Change Score

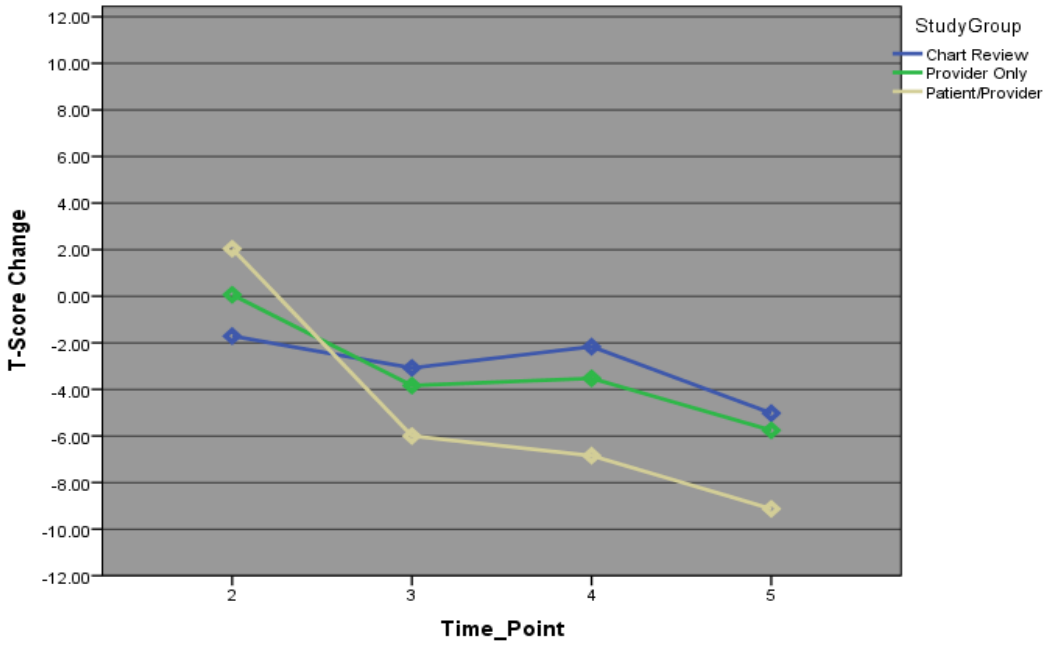


Figure 13

PDQ Change Score: Study Group by Time Point

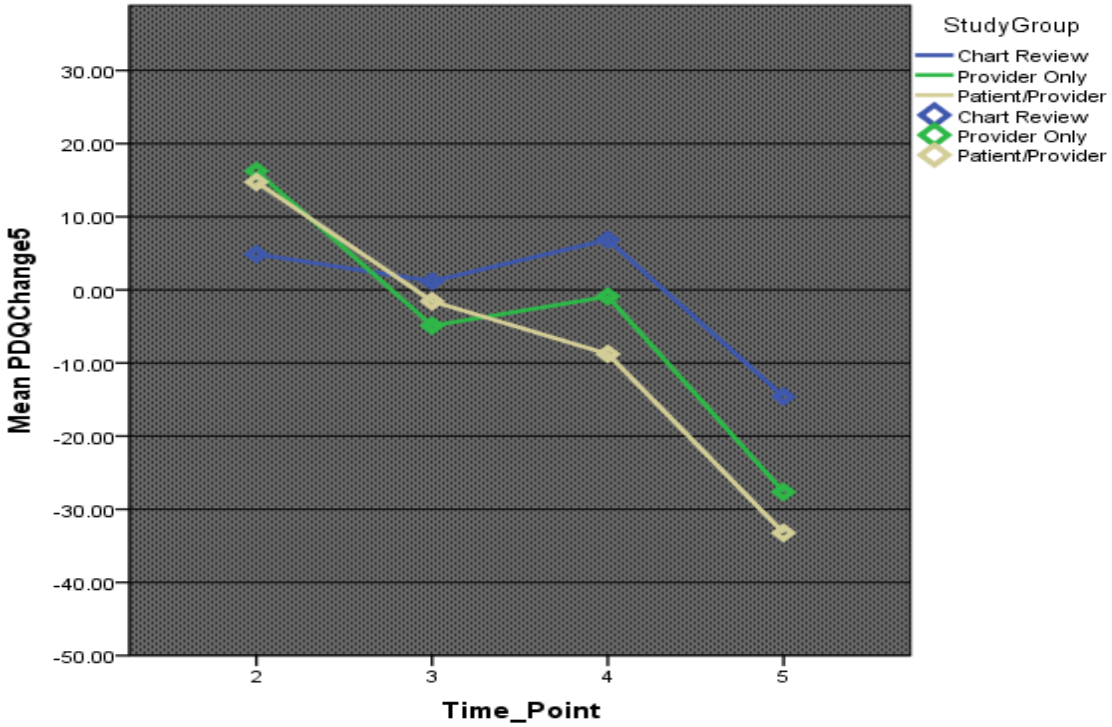


Figure 14

PMQ Score Change Group by Time Point

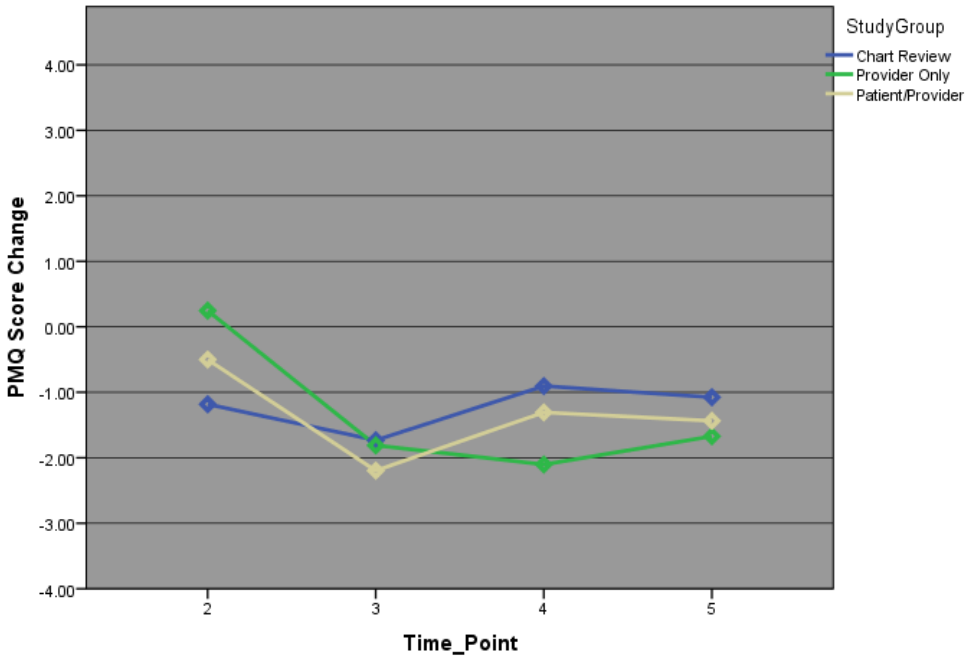


Figure 15
Optimism (LOT-R) Change Score: Study Group by Time Point

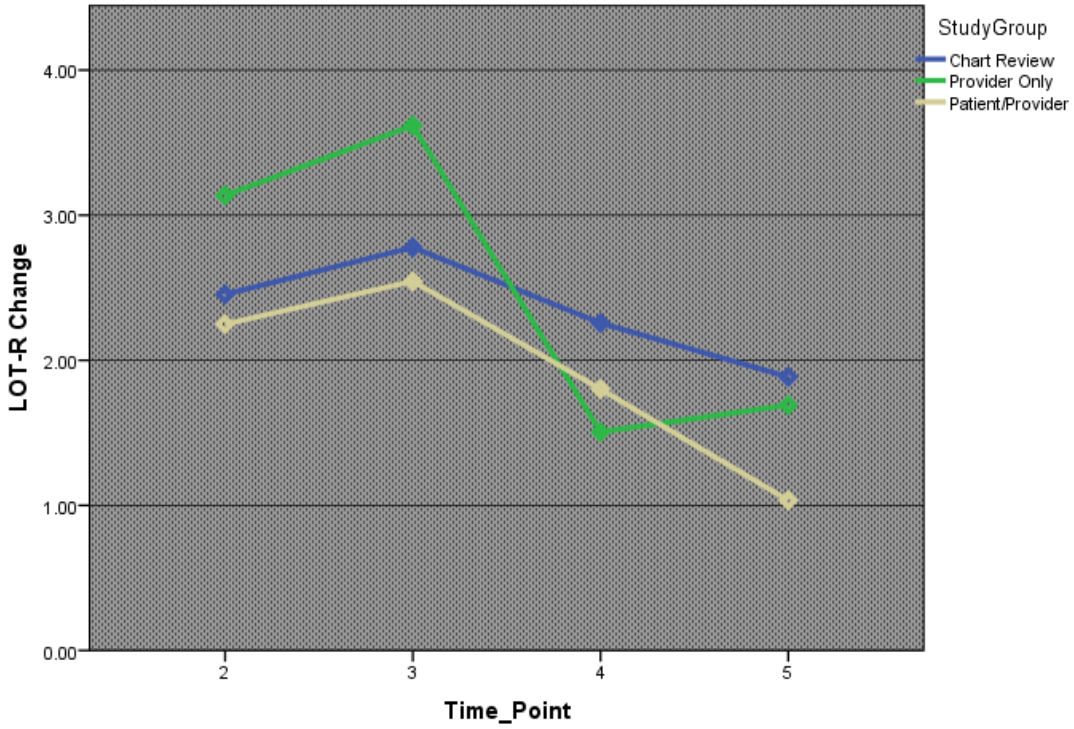


Figure 16
Illness Perception_Timeline Change Score by Study Group

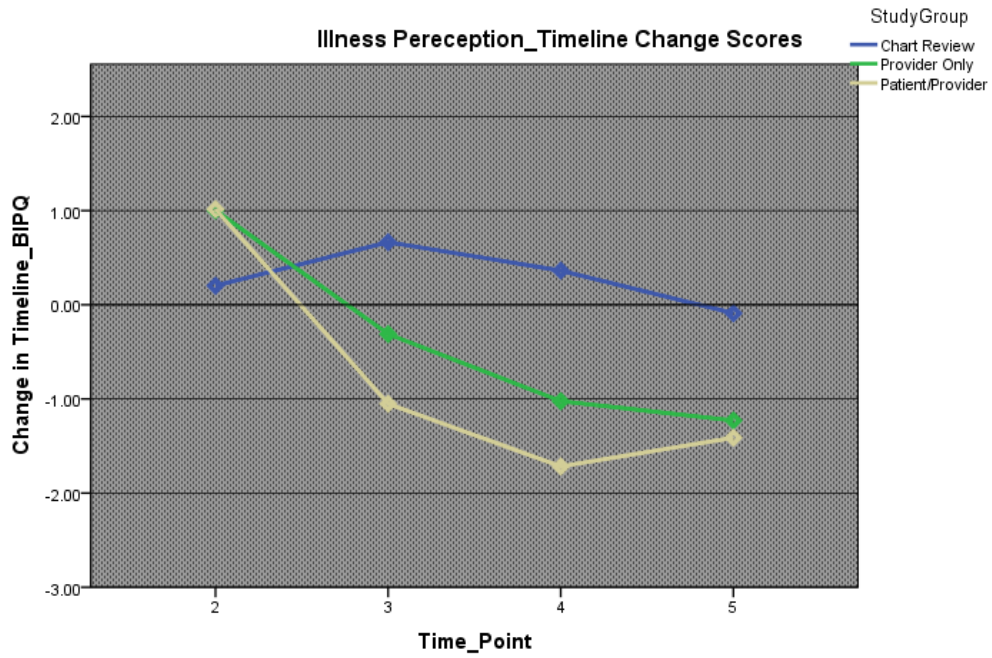


Figure 17
Illness Perception_Identity Change Score by Study Group

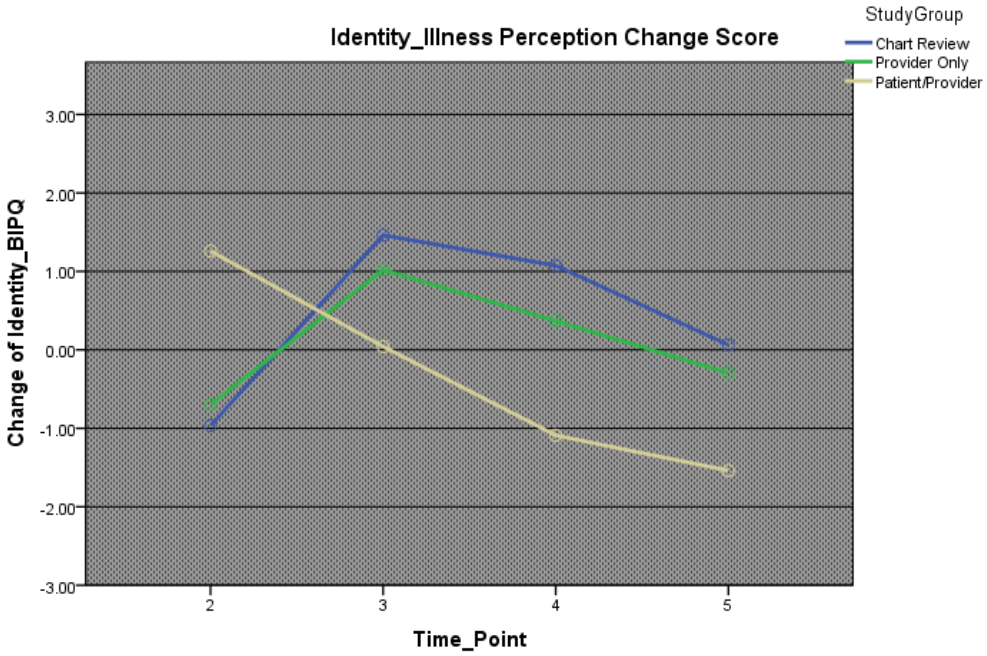
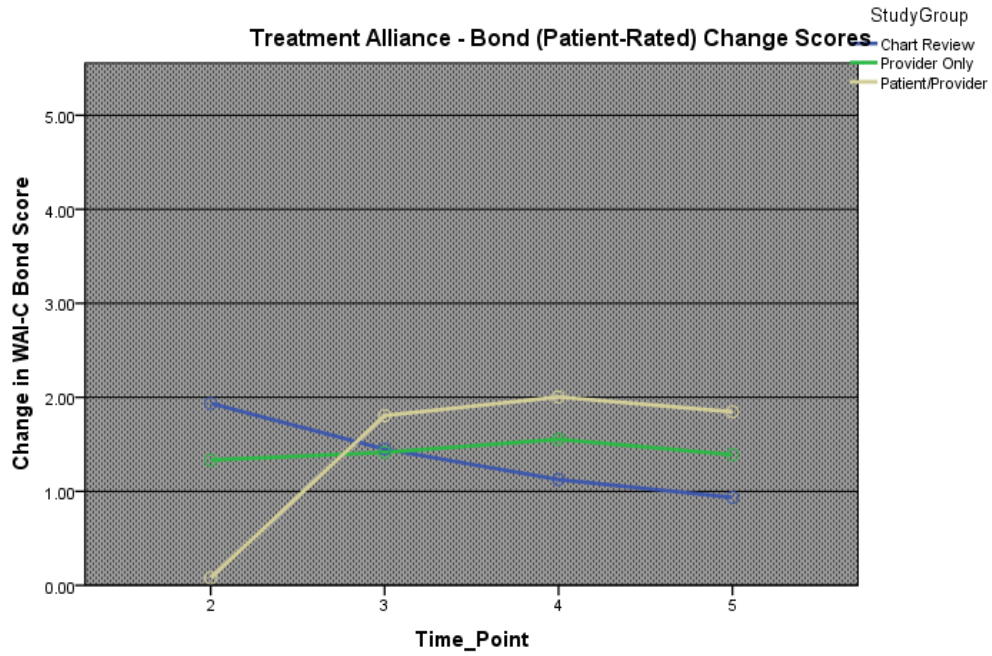


Figure 18

Working Alliance Inventory – Bond subscale (Patient-rated form) Change Score by Study Group



APPENDIX B
TABLES

Table 1
Item Frequency for PROMIS Computer-Adaptive-Tests

PROMIS Computer Adaptive Tests: 5 Most Frequently Administered Items		
PROMIS CAT	Item ID	% Participants Administered Item
Anxiety	Anxiety27	100.00%
	Anxiety19	65.12%
	Anxiety20	58.91%
	Anxiety5	58.14%
	Anxiety28	28.68%
Depression	Depression	100.00%
	Depression15	92.79%
	Depression21	69.37%
	Depression3	65.77%
	Depression1	55.86%
Fatigue	Fatigue86	100.00%
	Fatigue2	93.33%
	Fatigue93	91.11%
	Fatigue65	82.22%
	Fatigue69	76.67%
Anger	Anger26	100.00%
	Anger19	85.87%
	Anger18	74.72%
	Anger16	71.75%
	Anger10	63.20%

Table 1 (*continued*)
Item Frequency for PROMIS Computer-Adaptive-Tests

PROMIS Computer Adaptive Tests: 5 Most Frequently Administered Items		
PROMIS CAT	Item ID	% Participants Administered Item
Sleep Disturbance	Sleep Disturbance11	100.00%
	Sleep Disturbance5	100.00%
	Sleep Disturbance16	88.89%
	Sleep Disturbance3	64.44%
	Sleep Disturbance24	44.44%
Sleep-Related Impairment	Sleep-Related Impairment9	100.00%
	Sleep-Related Impairment2	79.37%
	Sleep-Related Impairment8	77.78%
	Sleep-Related Impairment5	69.05%
	Sleep-Related Impairment6	19.05%
Social Satisfaction with Discretionary Social Activities	Social Sat DSA5	100.00%
	Social Sat DSA7	96.08%
	Social Sat DSA1	90.20%
	Social Sat DSA12	81.37%
	Social Sat DSA11	52.94%
Pain Behavior	Pain Behavior4	100.00%
	Pain Behavior16	94.12%
	Pain Behavior17	92.16%
	Pain Behavior22	88.24%
	Pain Behavior8	80.39%
Pain Interference	Pain Interference21	100.00%
	Pain Interference6	85.95%
	Pain Interference41	76.03%
	Pain Interference17	69.42%
	Pain Interference25	66.94%
Physical Functioning	Physical Function100	100.00%
	Physical Function124	100.00%
	Physical Function10	87.50%
	Physical Function6	55.77%
	Physical Function110	35.58%

Table 2

Demographic Sample Characteristics

Sample Characteristics

		Count	%
Gender	Male	22	31.88%
	Female	47	68.12%
Race	Caucasian	49	71.01%
	AfrAmerican	12	17.39%
	Native American	2	2.90%
	Hispanic	6	8.70%
	Not Provided	0	0.00%
Marital status	single	7	14.89%
	married	28	59.57%
	widowed	0	0.00%
	divorced/separated	8	17.02%
	engaged	4	8.51%
Have children	no	10	23.81%
	yes	32	76.19%
Annual income	<10K	5	10.64%
	10-19.9K	3	6.38%
	20-29.9K	4	8.51%
	30-39.9K	4	8.51%
	40-49.9K	7	14.89%
	50-59.9K	3	6.38%
	60-79.9K	1	2.13%
	80-99.9K	7	14.89%
	100K+	13	27.66%

Table 2 (*continued*)
Basic Sample Characteristics

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Age.1	69	18	81	48.35	14.505
Avg Hrs Sleep	69	2	9	5.50	1.316
Baseline Pain Rating	69	1	10	6.54	1.418
Tx Helpfulness	69	1	10	5.31	1.327
Valid N (listwise)	69				

Table 3
Full Sample Treatment/Pain-Related Variables

Table 4
Psychological Variables

Sample Characteristics: Psychological

		Count	Sample %
Past Pain Dx	Yes	26	40.00%
	No	39	60.00%
Hx Psyc Dx	no	22	32.35%
	yes	46	67.65%
Psyc Dx	No Psych Dx Reported	19	27.94%
	MDD	21	30.88%
	Anxiety-related d/x	29	42.65%
	Bipolar d/x	0	#DIV/0!
	Substance-use d/x	0	#DIV/0!
	other dx	0	#DIV/0!
Family Psyc Hx	no	5	7.46%
	yes	39	58.21%
	Not provided	22	32.84%
Biological Family Hx_Psych Dx	No biological family Psych Dx reported	31	44.93%
	Depressive Disorder	7	10.14%
	Bipolar Spectrum Disorder	4	5.80%
	Anxiety-related Disorder	0	0.00%
	Multiple Dx - No Psychotic/Bipolar Spectrum	2	2.90%
	Substance Use	2	2.90%
	Schizophrenia - Primary Psychotic DO	1	1.45%
	Multiple Dx - Psychotic/Bipolar Spectrum DO present	5	7.25%
	Unspecified Family Psych Hx	17	24.64%

Table 5
Sample Characteristics by Group Type

		Group Type					
		Chart Review		Provider Only		Patient/Provider	
		Count	Group %	Count	Group %	Count	Group %
Gender	Male	13	59.10%	4	18.20%	5	22.70%
	Female	27	57.40%	13	27.70%	7	14.90%
Race	Caucasian	28	57.10%	13	26.50%	8	16.30%
	Afr American	6	50.00%	3	25.00%	3	25.00%
	Native American	1	50.00%	1	50.00%	0	0.00%
	Hispanic	5	83.30%	0	0.00%	1	16.70%
	Not Provided	0	0.00%	0	0.00%	0	0.00%
Employed	No	16	66.70%	5	20.80%	3	12.50%
	Yes	10	52.60%	5	26.30%	4	21.10%
Annual income	<10K	2	40.00%	1	20.00%	2	40.00%
	10-19.9K	2	66.70%	1	33.30%	0	0.00%
	20-29.9K	1	25.00%	2	50.00%	1	25.00%
	30-39.9K	2	50.00%	1	25.00%	1	25.00%
	40-49.9K	5	71.40%	1	14.30%	1	14.30%
	50-59.9K	2	66.70%	1	33.30%	0	0.00%
	60-79.9K	1	100.00%	0	0.00%	0	0.00%
	80-99.9K	7	100.00%	0	0.00%	0	0.00%
	100K+	7	53.80%	3	23.10%	3	23.10%
Marital status	single	2	28.60%	2	28.60%	3	42.90%
	married	17	60.70%	6	21.40%	5	17.90%
	widowed	0	0.00%	0	0.00%	0	0.00%
	divorced/separated	6	75.00%	2	25.00%	0	0.00%
	engaged	4	100.00%	0	0.00%	0	0.00%
Have children	no	6	60.00%	1	10.00%	3	30.00%
	yes	20	62.50%	8	25.00%	4	12.50%

Table 5 (*continued*)
Sample Characteristics by Group Type

		Group Type					
		Chart Review		Provider Only		Patient/Provider	
		Count	Group %	Count	Group %	Count	Group %
TxType	Pain Management Only	31	88.60%	3	8.60%	1	2.90%
	Psychiatry	1	33.30%	1	33.30%	1	33.30%
	PT	2	50.00%	2	50.00%	0	0.00%
	CBT	1	33.30%	0	0.00%	2	66.70%
	CBT_PT	1	25.00%	0	0.00%	3	75.00%
	ID Program	4	20.00%	11	55.00%	5	25.00%
Pain Duration at Baseline	Chronic Pain 3+ months	13	50.00%	7	26.90%	6	23.10%
	Chronic Pain 6 months - 2 yrs	7	70.00%	2	20.00%	1	10.00%
	Chronic Pain 2+ yrs	20	60.60%	8	24.20%	5	15.20%
Total Active Pain-Related Medical Problems (Baseline)	1 Active Pain-Related Problem Reported	23	51.10%	14	31.10%	8	17.80%
	2+ Active Pain Complaints Reported	17	70.80%	3	12.50%	4	16.70%
Total Pain-Related Surgeries	0	17	73.90%	2	8.70%	4	17.40%
	1	3	37.50%	2	25.00%	3	37.50%
	2	5	62.50%	3	37.50%	0	0.00%
	3	1	33.30%	1	33.30%	1	33.30%
	5	3	60.00%	2	40.00%	0	0.00%
Receiving Pain Tx	Yes	28	57.10%	13	26.50%	8	16.30%
	No	4	100.00%	0	0.00%	0	0.00%
Take Pain Meds	Yes	28	54.90%	13	25.50%	10	19.60%
	No	12	66.70%	4	22.20%	2	11.10%
Pending legal	None	0	0.00%	0	0.00%	0	0.00%
	Worker's Compensation	12	57.10%	3	14.30%	6	28.60%
	Personal Injury	17	65.40%	7	26.90%	2	7.70%
	Other	0	0.00%	0	0.00%	0	0.00%
Disability	No Response	13	50.00%	7	26.90%	6	23.10%
	Yes	7	70.00%	2	20.00%	1	10.00%
	No	20	60.60%	8	24.20%	5	15.20%
Exercise	no	15	60.00%	5	20.00%	5	20.00%
	yes	11	64.70%	4	23.50%	2	11.80%

Table 6

A. Descriptive Statistics for Outcome Variables (Time Points Combined)

Descriptive Statistics

	N	Range	Minimum	Maximum	Mean	Std. Deviation
AngerSf	69	47.43	28.25	75.69	54.5857	8.58821
AnxietySf	69	35.80	39.00	74.80	60.1785	4.73502
DepressiveSxsSf	69	44.00	34.20	78.20	56.9934	5.98678
FatigueSf	69	41.60	34.40	76.00	60.4965	5.68419
PainBhSf	69	20.30	51.20	71.50	60.9459	2.59290
PainSkSf	69	34.10	49.70	83.80	64.9145	4.15506
PhysFxSf	69	44.10	23.50	67.60	37.2552	4.47925
SleepDistSf	69	46.60	28.50	75.10	56.1752	8.09478
SleepRelImp	69	54.10	26.20	80.30	60.0778	6.14588
SocSatDiffSf	69	42.10	26.80	68.90	40.0330	5.12724
SocSatRelSf	69	50.58	22.82	73.41	44.0541	9.28378
HrQOL_Phys	69	24.1000	26.7000	50.8000	36.091130	2.60533916
HrQOL_MH	69	30.9000	25.1000	56.0000	38.609430	4.05696693
HealthPerc_Consequences_1	69	10.00	.00	10.00	7.8595	1.64058
HealthPerc_Timeline_1	69	8.00	2.00	10.00	8.3723	1.43794
HealthPerc_PersControl_1	69	10.00	.00	10.00	4.3285	2.06525
HealthPerc_IxControl_1	69	8.00	2.00	10.00	6.5675	1.65589
HealthPerc_Identity_1	69	8.00	2.00	10.00	7.8814	1.59667
HealthPerc_EmotConc_1	69	9.00	1.00	10.00	8.8321	1.52747
HealthPerc_Coherh_1	69	10	0	10	6.51	2.384
HealthPerc_Emotions_1	69	10	0	10	7.77	1.839
PainDisability_Sum_1	69	122	14	136	85.49	21.348
PMQ_Sum_1	69	43	9	52	21.89	4.752
WAITask	27	14.00	14.00	28.00	20.2294	2.84401
WAITBond	27	14.00	14.00	28.00	22.3563	3.08344
WAITGoal	10	15.00	13.00	28.00	21.5648	3.80857
WAITTask	28	18.00	10.00	28.00	22.8184	3.51462
WAITBond	28	24.00	4.00	28.00	23.1903	3.67550
WAITGoal	10	12.00	16.00	28.00	23.8417	3.77832
FlexComp	20	58.00	-3.00	55.00	33.0921	11.79468
RxMR	17	55.00	25.00	80.00	54.3873	13.40802
RxML	17	57	28	85	56.36	15.028
WTKTime	19	92.00	78.00	170.00	108.2608	19.00513
GripR	20	95.00	25.00	120.00	64.0137	19.87467
GripL	9	92.00	14.00	106.00	56.6809	23.95476

Table 6 (*continued*)

B. Descriptive Statistics for Study Outcomes (Change Scores – 4 time points)

Descriptive Statistics

	N	Range	Minimum	Maximum	Mean	Std. Deviation
Anger_Change_1	69	54.3615	-23.2615	31.1000	-3.533996	7.3266996
Anxiety_Change_1	69	47.7867	-24.2667	23.5200	-.567254	7.9110363
Depressive Sxs_Change_1	69	45.5867	-25.3667	20.2200	-1.618080	7.4203203
Fatigue_Change1	66	69.49	-23.43	46.06	-.2486	11.33318
PainBoh_Change_1	69	24.5026	-15.2692	9.2333	-1.157288	3.9342298
PainInterf_Change_1	69	36.2288	-20.4538	15.7750	-1.017980	6.4563644
PhysFx_Change_1	69	42.1143	-25.9688	16.1462	.426283	7.1030311
SleepDist_Change_1	69	55.8107	-31.7857	24.0250	-.635422	7.6065219
SleepRstSh_Change_1	69	48.8457	-27.4769	21.3688	-.987121	9.1738410
SocSatDSM_Change_1	69	40.6024	-21.2667	19.3357	.242759	7.3688992
PainDisability_Change_1	69	173.6964	-89.5714	84.1250	-9.461667	26.2196154
PMCsum_Change_1	69	35.1111	-17.2778	17.8333	-1.288194	4.1576787
Optimism_Change_1	69	17.0000	-6.0000	11.0000	2.275770	2.3358398
SocSatRole_Change_1	69	110.6000	-44.4000	66.2000	-2.657021	14.3251016
PhysHRQOL_Change_1	69	20.0429	-9.0000	11.0429	.628634	3.0433524
PsychHRQOL_Change_1	69	43.8143	-25.7000	18.1143	-2.044074	8.3820365
EMPCon_Change_1	69	15.5179	-8.3750	7.1429	-.559538	2.1207983
EMPTime_Change_1	69	12.2000	-6.2000	6.0000	-.166086	1.9907614
EMPSpc_Change_1	69	16.2500	-8.2500	8.0000	.373498	2.7764967
EMPExcont_Change_1	69	14.5714	-7.0000	7.5714	.613222	2.6141111
EMPCden_Change_1	69	14.2589	-6.5714	7.6875	.140771	2.6617246
EMPCmcon_Change_1	69	16.4286	-7.4286	9.0000	.120667	2.2501262
EMPCmcts_Change_1	69	17.3846	-7.3846	10.0000	.171699	2.6837106
WAITBend_Change_1	60	15.7273	-9.0000	6.7273	-.328217	2.6174263
WAITTask_Change_1	60	18.1273	-6.7273	11.4000	2.098960	3.1587730
WAITGoal_Change_1	60	14.4545	-6.0909	8.3636	.931711	2.3203943
WAKEBend_Change_1	62	24.1429	-6.0000	18.1429	1.398066	3.0385019
WAKETask_Change_1	62	20.5556	-8.6667	11.8889	1.664720	2.9561038
WAKEGoal_Change_1	62	18.4571	-7.1000	11.3571	1.148925	2.8324619
WktChange	16	88	-55	33	-4.05	18.282
GripRxChange	16	101.76	-32.33	69.43	7.7484	22.32773
GripLxChange	16	59	-13	46	10.30	13.630

Tables 8 – 13

Results Summary for Linear Mixed Models with Random Coefficients _ Pain-Related Functioning and Symptoms Outcomes Domain

Table 8

Pain Disability Questionnaire

Outcome Measure	Score Type	Model	Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
							95% Confidence Interval		
		Parameter	F	*p* value	Estimate	Sig.	Lower Bound	Upper Bound	-2 Restricted Log Likelihood
Pain Disability Questionnaire (PDQ)	Over Time (5 time points)	Intercept	789.74	0.000		0.491	-5.18	7.96	
		Time Point	33.61	0.000		0.015	-3.84	-0.42	
		Study Group	0.92	0.402					
		Joint Feedback v Chart Review			-7.14	0.075	-15.00	0.72	3024.87
		Joint Feedback v Provider Only			-5.41	0.198	-14.17	2.95	
		Study Group * Time Point	0.72	0.49					
		Joint Feedback v Chart Review			2.13	0.048	0.02	4.23	
		Joint Feedback v Provider Only			2.07	0.085	-0.29	4.42	
	Change Score (4 Time Points)	Intercept	24.08	0.000	45.54	0.000	27.39	63.68	
		Time Point	38.69	0.000	-14.48	0.000	-20.34	-8.63	
		Study Group	5.58	0.004					
		Joint Feedback v Chart Review			-34.77	0.001	-54.50	-13.04	2529.9
		Joint Feedback v Provider Only			-11.25	0.337	-34.29	11.78	
		Study Group * Time Point	5.22	0.006					
		Joint Feedback v Chart Review			11.10	0.003	3.89	18.31	
		Joint Feedback v Provider Only			3.54	0.389	-4.52	11.60	

Table 9

PROMIS Pain Behavior

Outcome Measure	Score Type	Model	Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
							95% Confidence Interval		
		Parameter	F	*p* value	Estimate	Sig.	Lower Bound	Upper Bound	-2 Restricted Log Likelihood
PROMIS Pain Behavior	Over Time (5 time points)	Intercept	34.24	0.000	42.43	0.000	41.09	43.77	
		Time Point	8.04	0.005	-0.21	0.270	-0.58	0.16	
		Study Group	1.04	0.356					
		Joint Feedback v Chart Review			-0.57	0.485	-2.20	1.05	1620.15
		Joint Feedback v Provider Only			-1.27	0.155	-3.02	0.48	
		Study Group * Time Point	0.22	0.804					
		Joint Feedback v Chart Review			-0.15	0.528	-0.61	0.31	
		Joint Feedback v Provider Only			-0.04	0.821	-0.57	0.44	
	Change Score (4 Time Points)	Intercept	6.62	0.012	5.07	0.010	1.25	8.88	
		Time Point	13.20	0.001	-1.74	0.004	-2.90	-0.58	
		Study Group	1.66	0.197					
		Joint Feedback v Chart Review			-4.27	0.073	-8.94	0.40	1453.66
		Joint Feedback v Provider Only			-2.84	0.175	-8.04	2.32	
		Study Group * Time Point	1.55	0.220					
		Joint Feedback v Chart Review			1.25	0.085	-0.18	2.68	
		Joint Feedback v Provider Only			0.70	0.387	-0.90	2.29	

Table 10
PROMIS Pain Interference

Outcome Measure	Score Type	Model		Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
								95% Confidence Interval		
		Parameter		F	p value	Estimate	Sig.	Lower Bound	Upper Bound	-2 Restricted Log Likelihood
PROMIS Pain Interference	Over Time (5 time points)	Intercept		5331.54	0.000	67.70	0.000	64.77	70.64	2145.74
		Time Point		6.44	0.011	-0.57	0.180	-1.40	0.26	
		Study Group		1.05	0.352					
			Joint Feedback v Chart Review			-2.30	0.204	-5.85	1.24	
			Joint Feedback v Provider Only			-0.39	0.842	-4.23	3.45	
		Study Group * Time Point		0.55	0.58					
			Joint Feedback v Chart Review			0.27	0.408	-0.76	1.29	
			Joint Feedback v Provider Only			-0.25	0.664	-1.40	0.89	
	Change Score (4 Time Points)	Intercept		23.14	0.000	9.04	0.002	3.93	14.19	1760.63
		Time Point		45.93	0.000	-3.04	0.000	-4.43	-1.65	
		Study Group		0.71	0.507					
			Joint Feedback v Chart Review			-3.44	0.259	-9.63	2.75	
			Joint Feedback v Provider Only			-1.60	0.421	-8.28	5.08	
		Study Group * Time Point		2.00	0.041					
			Joint Feedback v Chart Review			1.55	0.023	-0.16	3.26	
			Joint Feedback v Provider Only			0.53	0.568	-1.38	2.45	

Table 11
PROMIS Fatigue

Outcome Measure	Score Type	Model		Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
								95% Confidence Interval		
		Parameter		F	p value	Estimate	Sig.	Lower Bound	Upper Bound	-2 Restricted Log Likelihood
PROMIS Fatigue	Over Time (5 time points)	Intercept		2068.93	0.000	65.44	0.000	61.48	69.84	2341.88
		Time Point		14.43	0.000	-1.27	0.029	-2.41	-0.13	
		Study Group		1.14	0.315					
			Joint Feedback v Chart Review			-2.77	0.264	-7.44	2.11	
			Joint Feedback v Provider Only			0.44	0.849	-4.82	5.70	
		Study Group * Time Point		0.99	0.37					
			Joint Feedback v Chart Review			0.55	0.440	-0.85	1.94	
			Joint Feedback v Provider Only			-0.39	0.623	-1.94	1.18	
	Change Score (4 Time Points)	Intercept		23.14	0.000	14.89	0.001	6.98	24.81	1930.56
		Time Point		47.47	0.000	-5.07	0.000	-7.29	-2.85	
		Study Group		1.80	0.021					
			Joint Feedback v Chart Review			-8.55	0.157	-20.39	3.30	
			Joint Feedback v Provider Only			4.87	0.449	-8.34	18.10	
		Study Group * Time Point		1.37	0.254					
			Joint Feedback v Chart Review			1.72	0.218	-1.02	4.46	
			Joint Feedback v Provider Only			-1.22	0.444	-4.35	1.91	

Table 12
PROMIS Physical Functioning

Outcome Measure	Score Type	Model		Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
		Parameter		F	p value	Estimate	Sig.	95% Confidence Interval		-2 Restricted Log Likelihood
								Lower Bound	Upper Bound	
PROMIS Physical Functioning	Over Time (5 time points)	Intercept		1298.78	0.000	35.97	0.000	33.14	38.80	1977.35
		Time Point		12.22	0.001	0.47	0.159	-0.19	1.13	
		Study Group		0.38	0.684					
			Joint Feedback v Chart Review			0.10	0.952	-3.16	3.36	
			Joint Feedback v Provider Only			-1.17	0.509	-4.47	2.33	
		Study Group * Time Point		0.14	0.851					
			Joint Feedback v Chart Review			0.23	0.572	-0.58	1.05	
			Joint Feedback v Provider Only			0.17	0.719	-0.74	1.08	
	Change Score (4 Time Points)	Intercept		12.47	0.001	-6.38	0.029	-12.08	-0.68	1789.94
		Time Point		30.60	0.000	2.22	0.003	0.77	3.66	
		Study Group		1.22	0.301					
			Joint Feedback v Chart Review			1.68	0.617	-5.00	8.36	
			Joint Feedback v Provider Only			-3.14	0.374	-10.47	3.98	
		Study Group * Time Point		2.16	0.124					
			Joint Feedback v Chart Review			-1.08	0.231	-2.86	0.70	
			Joint Feedback v Provider Only			0.65	0.518	-1.34	2.64	

Table 13
Pain Rating (Visual Analog Scale – Pain)

Outcome Measure	Score Type	Model		Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
		Parameter		F	p value	Estimate	Sig.	95% Confidence Interval		-2 Restricted Log Likelihood
								Lower Bound	Upper Bound	
Pain Rating (Visual Analog Scale - Pain)	Over Time (5 time points)	Intercept		253.21	0.000	6.04	0.000	5.13	7.00	1399.91
		Time Point		0.59	0.443	0.02	0.880	-0.27	0.32	
		Study Group		1.73	0.178					
			Joint Feedback v Chart Review			0.94	0.044	-0.04	1.94	
			Joint Feedback v Provider Only			0.44	0.364	-0.54	1.44	
		Study Group * Time Point		0.77	0.44					
			Joint Feedback v Chart Review			-0.21	0.149	-0.57	0.14	
			Joint Feedback v Provider Only			-0.04	0.838	-0.45	0.37	
	Change Score (4 Time Points)	Intercept		0.44	0.498	-0.91	0.089	-1.94	0.14	1030.65
		Time Point		0.00	0.971	0.14	0.290	-0.14	0.47	
		Study Group		2.54	0.084					
			Joint Feedback v Chart Review			1.35	0.030	0.14	2.56	
			Joint Feedback v Provider Only			0.47	0.317	-0.44	1.00	
		Study Group * Time Point		1.33	0.253					
			Joint Feedback v Chart Review			-0.31	0.104	-0.68	0.07	
			Joint Feedback v Provider Only			-0.18	0.400	-0.59	0.24	

Tables 14 – 21

Psychosocial Variables and Psychological Symptoms Outcomes Domain: Results Summary for Linear Mixed Models with Random Coefficients

Table 14

PROMIS Anger

Outcome Measure	Score Type	Model	Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
							95% Confidence Interval		
		Parameters	F	*p* value	Estimate	Sig.	Lower Bound	Upper Bound	-2 Restricted Log Likelihood
PROMIS: Anger	Over Time (5 time points)	Intercept	1319.34	0.000	44.15	0.000	58.93	49.30	23685.32
		Time Point	23.54	0.000	-1.87	0.004	-3.12	-0.62	
		Study Group	1.45	0.199					
		Joint Feedback v Chart Review			-5.40	0.087	-11.60	0.81	
		Joint Feedback v Provider Only			-4.88	0.147	-11.53	1.77	
		Study Group * Time Point	0.22	0.807					
		Joint Feedback v Chart Review			0.50	0.520	-1.04	2.04	
		Joint Feedback v Provider Only			0.40	0.641	-1.32	2.12	
	Change Score (4 Time Points)	Intercept	5.02	0.045	10.39	0.000	5.42	14.54	1819.64
		Time Point	33.91	0.000	-4.63	0.000	-6.14	-3.12	
		Study Group	5.30	0.004					
		Joint Feedback v Chart Review			-10.18	0.003	-16.84	-3.51	
		Joint Feedback v Provider Only			-10.82	0.003	-17.32	-3.81	
		Study Group * Time Point	7.71	0.001					
		Joint Feedback v Chart Review			3.24	0.001	1.38	5.09	
		Joint Feedback v Provider Only			3.75	0.000	1.47	5.82	

Table 15

PROMIS Anxiety

Score Type	Model		Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
	Parameters		F	p value	Estimate	Sig.	95% Confidence Interval		-2 Restricted Log Likelihood
							Lower Bound	Upper Bound	
Over Time (5 time points)	Intercept		4389.35	0.000	64.15	0.000	61.43	66.87	20392.92
	Time Point		2.14	0.145	-0.77	0.044	-1.52	-0.02	
	Study Group		3.05	0.051					
		Joint Feedback v Chart Review			-1.48	0.359	-4.65	1.70	
		Joint Feedback v Provider Only			-4.13	0.018	-7.54	-0.71	
	Study Group * Time Point		1.89	0.153					
		Joint Feedback v Chart Review			0.35	0.414	-0.50	1.21	
		Joint Feedback v Provider Only			0.92	0.058	-0.03	1.88	
Change Score (4 Time Points)	Intercept		0.07	0.792	3.92	0.194	-2.00	9.85	19404.46
	Time Point		1.45	0.229	-2.22	0.022	-4.11	-0.32	
	Study Group		3.12	0.045					
		Joint Feedback v Chart Review			-8.63	0.013	-15.43	-1.82	
		Joint Feedback v Provider Only			-4.87	0.186	-12.10	2.36	
	Study Group * Time Point		3.18	0.042					
		Joint Feedback v Chart Review			2.70	0.012	0.60	4.80	
		Joint Feedback v Provider Only			1.70	0.156	-0.65	4.05	

Table 16
PROMIS Depressive Symptoms

Outcome Measure	Score Type	Model		Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
		Parameters		F	p value	Estimate	Sig.	95% Confidence Interval		-2 Restricted Log Likelihood
								Lower Bound	Upper Bound	
PROMIS Depression	Over Time (5 time points)	Intercept		1425.38	0.000	60.23	0.000	55.98	64.48	22455.05
		Time Point		6.31	0.014	-0.66	0.174	-1.62	0.30	
		Study Group		2.00	0.143					
			Joint Feedback v Chart Review			-4.53	0.069	-9.42	0.36	
			Joint Feedback v Provider Only			-1.26	0.632	-6.47	3.96	
		Study Group * Time Point		1.59	0.211					
			Joint Feedback v Chart Review			0.55	0.353	-0.63	1.73	
			Joint Feedback v Provider Only			-0.45	0.502	-1.76	0.87	
	Change Score (4 Time Points)	Intercept		2.73	0.101	7.62	0.015	1.55	13.70	1819.53
		Time Point		24.63	0.000	-3.45	0.000	-5.12	-1.78	
		Study Group		2.24	0.112					
			Joint Feedback v Chart Review			-7.28	0.038	-14.33	-0.43	
			Joint Feedback v Provider Only			-5.73	0.154	-13.67	2.21	
		Study Group * Time Point		2.52	0.088					
			Joint Feedback v Chart Review			2.30	0.029	0.25	4.34	
			Joint Feedback v Provider Only			1.33	0.251	-0.97	3.63	

Table 17
PROMIS Sleep Disturbance

Outcome Measure	Score Type	Model		Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
		Parameters		F	*p* value	Estimate	Sig.	95% Confidence Interval		-2 Restricted Log Likelihood
								Lower Bound	Upper Bound	
PROMIS Sleep Disturbance	Over Time (5 time points)	Intercept		2519.75	0.000	60.58	0.000	57.11	64.05	22421.63
		Time Point		10.93	0.001	-0.87	0.091	-1.89	0.14	
		Study Group		0.31	0.733					
			Joint Feedback v Chart Review			-0.98	0.435	-5.04	3.08	
			Joint Feedback v Provider Only			-1.75	0.431	-6.14	2.63	
		Study Group * Time Point		0.31	0.735					
			Joint Feedback v Chart Review			-0.40	0.497	-1.57	0.77	
			Joint Feedback v Provider Only			-0.04	0.933	-1.36	1.25	
	Change Score (4 Time Points)	Intercept		14.52	0.000	13.51	0.000	6.61	20.40	20764.10
		Time Point		13.63	0.000	-4.12	0.001	-6.55	-1.69	
		Study Group		0.69	0.501					
			Joint Feedback v Chart Review			-3.34	0.402	-11.15	4.48	
			Joint Feedback v Provider Only			-4.85	0.244	-13.05	3.35	
		Study Group * Time Point		0.81	0.443					
			Joint Feedback v Chart Review			1.40	0.298	-1.24	4.04	
			Joint Feedback v Provider Only			1.82	0.224	-1.13	4.77	

Table 18
PROMIS Sleep-Related Impairment

Outcome Measure	Score Type	Model		Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
		Parameters		F	*p* value	Estimate	Sig.	95% Confidence Interval		-2 Restricted Log Likelihood
								Lower Bound	Upper Bound	
PROMIS Sleep-Related Impairment	Over Time (5 time points)	Intercept		1202.21	0.000	64.79	0.000	62.58	71.00	24830.84
		Time Point		1.13	0.290	-1.08	0.149	-2.55	0.39	
		Study Group		3.00	0.051					
			Joint Feedback v Chart Review			-5.27	0.021	-9.72	-0.81	
			Joint Feedback v Provider Only			-1.77	0.428	-6.16	2.62	
		Study Group * Time Point		1.89	0.151					
			Joint Feedback v Chart Review			1.24	0.088	-0.19	2.70	
			Joint Feedback v Provider Only			0.21	0.798	-1.40	1.83	
	Change Score (4 Time Points)	Intercept		10.97	0.001	13.35	0.000	7.39	19.30	19860.05
		Time Point		19.18	0.000	-5.11	0.000	-7.17	-3.05	
		Study Group		4.84	0.008					
			Joint Feedback v Chart Review			-10.70	0.002	-17.45	-3.96	
			Joint Feedback v Provider Only			-4.57	0.049	-13.44	0.51	
		Study Group * Time Point		5.19	0.006					
			Joint Feedback v Chart Review			3.47	0.001	1.44	5.51	
			Joint Feedback v Provider Only			2.45	0.054	-0.05	4.95	

Table 19

PROMIS Social Functioning – Satisfaction with Discretionary Social Activities

Outcome Measure	Score Type	Model Parameters	Fixed Effects F	Fixed Effects p value	Estimates of Fixed Effects Estimate	Sig.	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound	Information Criteria Curve (ICC) -2 Restricted Log Likelihood
PROMIS Social Functioning - Satisfaction with Discretionary Social Activities	Over Time (5 time points)	Intercept	1111.91	0.000	37.05	0.000	33.94	40.16	21187.95
		Time Point	7.96	0.005	0.80	0.090	-0.13	1.73	
		Study Group	2.83	0.060					
		Joint Feedback v Chart Review			4.17	0.023	0.57	7.77	
		Joint Feedback v Provider Only			1.54	0.425	-2.29	5.41	
		Study Group * Time Point	0.74	0.470					
		Joint Feedback v Chart Review			-0.25	0.640	-1.29	0.79	
		Joint Feedback v Provider Only			0.38	0.521	-0.78	1.54	
	Change Score (4 Time Points)	Intercept	3.52	0.041	-5.40	0.021	-10.34	-0.84	18964.65
		Time Point	4.51	0.034	1.79	0.051	-0.01	3.60	
		Study Group	2.59	0.074					
		Joint Feedback v Chart Review			5.41	0.047	0.07	10.75	
		Joint Feedback v Provider Only			0.84	0.744	-4.72	6.41	
		Study Group * Time Point	2.22	0.103					
		Joint Feedback v Chart Review			-1.58	0.110	-3.51	0.35	
		Joint Feedback v Provider Only			0.18	0.871	-1.98	2.34	

Table 20

PROMIS Social Functioning – Satisfaction with Social Roles

Outcome Measure	Score Type	Model Parameters	Fixed Effects F	Fixed Effects p value	Estimates of Fixed Effects Estimate	Sig.	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound	Information Criteria Curve (ICC) -2 Restricted Log Likelihood
PROMIS Social Functioning - Satisfaction with Social Roles	Over Time (5 time points)	Intercept	448.01	0.000	33.03	0.000	28.12	37.94	21429.71
		Time Point	34.93	0.000	2.89	0.000	1.50	4.27	
		Study Group	3.20	0.047					
		Joint Feedback v Chart Review			7.05	0.017	1.31	12.79	
		Joint Feedback v Provider Only			2.31	0.352	-3.23	9.10	
		Study Group * Time Point	1.14	0.327					
		Joint Feedback v Chart Review			-0.98	0.219	-2.56	0.60	
		Joint Feedback v Provider Only			-0.04	0.965	-1.81	1.73	
	Change Score (4 Time Points)	Intercept	4.65	0.032	-11.34	0.031	-21.66	-1.05	21757.34
		Time Point	1.45	0.229	2.78	0.154	-1.04	6.60	
		Study Group	1.81	0.169					
		Joint Feedback v Chart Review			10.24	0.038	-1.89	22.41	
		Joint Feedback v Provider Only			1.58	0.814	-11.60	14.75	
		Study Group * Time Point	1.01	0.334					
		Joint Feedback v Chart Review			-3.79	0.091	-8.19	0.62	
		Joint Feedback v Provider Only			-0.30	0.906	-5.22	4.63	

Table 21

Pain Medication Questionnaire (PMQ: Opioid Misuse Risk)

Outcome Measure	Score Type	Model		Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
		Parameters		F	p value	Estimate	Sig.	Interval Bound	Interval Bound	-2 Restricted Log Likelihood
Pain Medication Questionnaire (PMQ: Opioid Misuse Risk)	Over Time (5 time points)	Intercept		427.83	0.000	24.34	0.000	22.08	30.63	2184.25
		Time Point		44.81	0.000	-2.02	0.000	-3.12	-0.93	
		Study Group		1.43	0.248					
			Joint Feedback v Chart Review			1.71	0.503	-3.34	4.78	
			Joint Feedback v Provider Only			4.57	0.103	-0.95	10.10	
		Study Group * Time Point		1.64	0.203					
			Joint Feedback v Chart Review			-0.62	0.334	-1.89	0.64	
			Joint Feedback v Provider Only			-1.25	0.074	-2.71	0.14	
	Change Score (4 Time Points)	Intercept		1.41	0.238	-3.08	0.429	-10.78	4.63	1884.29
		Time Point		0.11	0.737	0.63	0.679	-1.65	2.92	
		Study Group		1.05	0.355					
			Joint Feedback v Chart Review			-2.70	0.564	-11.99	6.60	
			Joint Feedback v Provider Only			3.75	0.448	-6.50	14.01	
		Study Group * Time Point		2.26	0.110					
			Joint Feedback v Chart Review			0.37	0.777	-2.20	2.93	
			Joint Feedback v Provider Only			-2.21	0.128	-5.08	0.65	

Tables 22 – 23

Global Health-Related Quality of Life Outcomes Domain: Results Summary for Linear Mixed Models with Random Coefficients

Table 22

PROMIS Global Health-Related Quality of Life – Mental Health Domain

Outcome Measure	Score Type	Model		Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
		Parameter		F	p value	Estimate	Sig.	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound	-2 Restricted Log Likelihood
PROMIS: Global Health-Related Quality of Life - Mental Health	Over Time (5 time points)	Intercept		1130.04	0.000	43.21	0.000	39.89	46.52	2166.83
		Time Point		4.34	0.054	-1.13	0.014	-2.09	-0.16	
		Study Group		0.45	0.639					
			Joint Feedback v Chart Review			-1.35	0.473	-5.09	2.39	
			Joint Feedback v Provider Only			-1.83	0.357	-5.75	2.10	
		Study Group * Time Point		1.43	0.24					
			Joint Feedback v Chart Review			0.89	0.134	-0.30	2.08	
			Joint Feedback v Provider Only			0.96	0.149	-0.34	2.19	
	Change Score (4 Time Points)	Intercept		22.10	0.000	14.35	0.000	10.19	22.52	1906.72
		Time Point		47.51	0.000	-5.18	0.000	-7.08	-3.28	
		Study Group		3.49	0.032					
			Joint Feedback v Chart Review			-9.05	0.013	-14.15	-1.96	
			Joint Feedback v Provider Only			-8.27	0.032	-15.83	-0.72	
		Study Group * Time Point		2.83	0.060					
			Joint Feedback v Chart Review			2.76	0.021	0.42	5.10	
			Joint Feedback v Provider Only			2.41	0.071	-0.21	5.03	

Table 23

PROMIS Global Health-Related Quality of Life – Physical Health Domain

Outcome Measure	Score Type	Model	Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
							95% Confidence Interval		
		Parameter	F	*p* value	Estimate	Sig.	Lower Bound	Upper Bound	-2 Restricted Log Likelihood
PROMIS: Global Health-Related Quality of Life - Physical Health	Over Time (5 time points)	Intercept	3056.42	0.000	35.45	0.000	33.68	37.41	
		Time Point	1.23	0.278	0.27	0.218	-0.16	0.70	
		Study Group	0.91	0.414					
		Joint Feedback v Chart Review			1.43	0.196	-0.78	3.64	1648.06
		Joint Feedback v Provider Only			1.11	0.340	-1.21	3.43	
		Study Group * Time Point	0.44	0.45					
		Joint Feedback v Chart Review			-0.23	0.355	-0.71	0.25	
		Joint Feedback v Provider Only			-0.12	0.454	-0.66	0.41	
	Change Score (4 Time Points)	Intercept	20.62	0.000	5.96	0.000	3.46	8.47	
		Time Point	15.23	0.000	-1.24	0.001	-1.93	-0.55	
		Study Group	3.95	0.024					
		Joint Feedback v Chart Review			-4.21	0.007	-7.20	-1.21	1354.04
		Joint Feedback v Provider Only			-2.93	0.074	-6.24	0.23	
		Study Group * Time Point	2.41	0.098					
		Joint Feedback v Chart Review			0.91	0.032	0.08	1.74	
		Joint Feedback v Provider Only			0.55	0.238	-0.37	1.48	

Tables 24-27

Treatment Alliance Outcomes Domain: Results Summary for Linear Mixed Models with Random Coefficients

Table 24

Working Alliance Inventory (Patient-Rated) - Bond

Outcome Measure	Score Type	Model		Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
		Parameter		F	*p* value	Estimate	Sig.	95% Confidence Interval		-2 Restricted Log Likelihood
								Lower Bound	Upper Bound	
Working Alliance Inventory (Patient-rated): Bond	Over Time (5 time points)	Intercept		206.75	0.000	20.55	0.000	16.66	24.44	740.09
		Time Point		7.12	0.008	0.97	0.047	-0.07	2.00	
		Study Group		0.23	0.796					
			Joint Feedback v Chart Review			0.21	0.928	-4.41	4.83	
			Joint Feedback v Provider Only			-1.24	0.429	-4.23	3.81	
		Study Group * Time Point		0.14	0.87					
			Joint Feedback v Chart Review			-0.30	0.827	-1.49	0.90	
			Joint Feedback v Provider Only			-0.08	0.900	-1.40	1.24	
	Change Score (4 Time Points)	Intercept		0.96	0.332	-0.67	0.667	-3.78	2.43	1227.09
		Time Point		0.01	0.934	0.45	0.216	-0.27	1.17	
		Study Group		1.23	0.299					
			Joint Feedback v Chart Review			3.03	0.122	-0.83	6.89	
			Joint Feedback v Provider Only			1.90	0.371	-2.30	6.10	
		Study Group * Time Point		2.07	0.135					
			Joint Feedback v Chart Review			-0.88	0.046	-1.74	-0.01	
			Joint Feedback v Provider Only			-0.52	0.281	-1.49	0.44	

Table 25

Working Alliance Inventory (Patient-Rated) - Task

Outcome Measure	Score Type	Model	Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
							95% Confidence Interval		
		Parameter	F	*p* value	Estimate	Sig.	Lower Bound	Upper Bound	-2 Restricted Log Likelihood
Working Alliance Inventory (Patient-rated): Task	Over Time (5 time points)	Intercept	*193.37*	*0.000*	*19.59*	*0.000*	*15.78*	*23.39*	
		Time Point	*14.87*	*0.005*	*1.20*	*0.022*	*0.20*	*2.20*	
		Study Group	*0.25*	*0.780*					
		Joint Feedback v Chart Review			*-1.54*	*0.484*	*-6.02*	*2.93*	718.1
		Joint Feedback v Provider Only			*-1.13*	*0.640*	*-6.02*	*3.74*	
		Study Group * Time Point	*0.04*	*0.96*					
		Joint Feedback v Chart Review			*-0.14*	*0.804*	*-1.24*	*0.99*	
		Joint Feedback v Provider Only			*-0.14*	*0.820*	*-1.38*	*1.11*	
	Change Score (4 Time Points)	Intercept	*3.52*	*0.063*	*3.84*	*0.178*	*-1.84*	*9.53*	
		Time Point	*5.60*	*0.024*	*-0.84*	*0.279*	*-2.41*	*0.72*	
		Study Group	*0.47*	*0.628*					
		Joint Feedback v Chart Review			*-1.73*	*0.605*	*-8.55*	*5.08*	588.23
		Joint Feedback v Provider Only			*1.24*	*0.731*	*-4.20*	*8.71*	
		Study Group * Time Point	*0.97*	*0.394*					
		Joint Feedback v Chart Review			*0.49*	*0.605*	*-1.45*	*2.44*	
		Joint Feedback v Provider Only			*-0.74*	*0.470*	*-2.91*	*1.38*	

Table 26

Working Alliance Inventory (Provider-Rated) - Bond

Outcome Measure	Score Type	Model	Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
							95% Confidence Interval		
		Parameter	F	*p* value	Estimate	Sig.	Lower Bound	Upper Bound	-2 Restricted Log Likelihood
Working Alliance Inventory (Provider-rated): Bond	Over Time (5 time points)	Intercept	*554.83*	*0.000*	*19.05*	*0.000*	*16.70*	*21.40*	
		Time Point	*47.59*	*0.000*	*1.10*	*0.001*	*0.49*	*1.71*	
		Study Group	*1.43*	*0.246*					
		Joint Feedback v Chart Review			*-1.51*	*0.244*	*-4.08*	*1.06*	594.28
		Joint Feedback v Provider Only			*0.31*	*0.825*	*-2.49*	*3.11*	
		Study Group * Time Point	*0.46*	*0.63*					
		Joint Feedback v Chart Review			*0.31*	*0.357*	*-0.36*	*0.98*	
		Joint Feedback v Provider Only			*0.14*	*0.721*	*-0.62*	*0.90*	
	Change Score (4 Time Points)	Intercept	*0.08*	*0.778*	*-0.64*	*0.752*	*-4.75*	*3.47*	
		Time Point	*4.57*	*0.044*	*0.73*	*0.227*	*-0.48*	*1.95*	
		Study Group	*3.75*	*0.034*					
		Joint Feedback v Chart Review			*-2.44*	*0.287*	*-7.05*	*2.16*	518.83
		Joint Feedback v Provider Only			*3.24*	*0.203*	*-1.84*	*8.34*	
		Study Group * Time Point	*4.03*	*0.030*					
		Joint Feedback v Chart Review			*0.84*	*0.204*	*-0.50*	*2.23*	
		Joint Feedback v Provider Only			*-0.90*	*0.246*	*-2.45*	*0.66*	

Table 27

Working Alliance Inventory (Provider-Rated) - Task

Outcome Measure	Score Type	Model		Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
								95% Confidence Interval		
		Parameter		F	*p* value	Estimate	Sig.	Lower Bound	Upper Bound	-2 Restricted Log Likelihood
Working Alliance Inventory (Provider-rated): Task	Over Time (5 time points)	Intercept		309.73	0.000	19.04	0.000	15.88	22.21	654.64
		Time Point		0.09	0.772	-0.05	0.908	-0.82	0.73	
		Study Group		0.54	0.584					
			Joint Feedback v Chart Review			-0.55	0.743	-3.94	2.83	
			Joint Feedback v Provider Only			1.03	0.573	-2.41	5.48	
		Study Group * Time Point		0.22	0.80					
			Joint Feedback v Chart Review			0.24	0.541	-0.57	1.08	
			Joint Feedback v Provider Only			0.09	0.658	-0.84	1.03	
	Change Score (4 Time Points)	Intercept		0.03	0.864	-1.44	0.502	-6.44	3.18	578.83
		Time Point		0.25	0.620	0.40	0.381	-0.75	1.56	
		Study Group		1.39	0.254					
			Joint Feedback v Chart Review			0.12	0.944	-5.22	5.46	
			Joint Feedback v Provider Only			3.95	0.185	-1.91	9.82	
		Study Group * Time Point		1.55	0.214					
			Joint Feedback v Chart Review			-0.01	0.988	-1.50	1.47	
			Joint Feedback v Provider Only			-1.20	0.145	-2.89	0.50	

Illness Perception and Positive Expectancy Outcomes Domain: Results Summary for Linear Mixed Models with Random Coefficients

Table 28

Illness Perception - Consequences

Outcome Measure	Score Type	Model	Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
							95% Confidence Interval		
		Parameter	F	*p* value	Estimate	Sig.	Lower Bound	Upper Bound	-2 Restricted Log Likelihood
Brief Illness Perception Questionnaire: Consequences	Over Time (5 time points)	Intercept	804.63	0.000	9.39	0.000	8.53	10.25	
		Time Point	19.52	0.000	-0.50	0.001	-0.77	-0.22	
		Study Group	1.93	0.136					
		Joint Feedback v Chart Review			-1.00	0.048	-1.99	-0.01	963.18
		Joint Feedback v Provider Only			-0.52	0.334	-1.57	0.54	
		Study Group * Time Point	1.04	0.35					
		Joint Feedback v Chart Review			0.21	0.179	-0.10	0.52	
		Joint Feedback v Provider Only			0.07	0.769	-0.28	0.41	
		Positive Expectancy Baseline Mean (LOT-R: Optimism)	1.25	0.283	-0.03	0.283	-0.08	0.03	
	Change Score (4 Time Points)	Intercept	0.04	0.844	-1.41	0.359	-8.77	3.55	
		Time Point	0.17	0.680	0.70	0.205	-0.39	1.79	
		Study Group	2.84	0.072					
		Joint Feedback v Chart Review			2.01	0.318	-2.04	6.09	770.29
		Joint Feedback v Provider Only			4.41	0.034	0.33	8.89	
		Study Group * Time Point	2.94	0.055					
		Joint Feedback v Chart Review			-0.89	0.135	-2.07	0.28	
		Joint Feedback v Provider Only			-1.57	0.017	-2.84	-0.28	
		Positive Expectancy Baseline Mean (LOT-R: Optimism)	0.04	0.82	-0.02	0.821	-0.22	0.18	

Table 29

Illness Perception - Timeline

Outcome Measure	Score Type	Model	Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
							95% Confidence Interval		
		Parameter	F	*p* value	Estimate	Sig.	Lower Bound	Upper Bound	-2 Restricted Log Likelihood
Brief Illness Perception Questionnaire: Timeline	Over Time (5 time points)	Intercept	799.84	0.000	9.10	0.000	8.18	9.92	
		Time Point	3.93	0.118	-0.24	0.031	-0.46	-0.02	
		Study Group	3.84	0.015					
		Joint Feedback v Chart Review			-1.25	0.009	-2.19	-0.31	963.18
		Joint Feedback v Provider Only			-0.45	0.371	-1.45	0.55	
		Study Group * Time Point	3.08	0.05					
		Joint Feedback v Chart Review			0.29	0.025	0.04	0.54	
		Joint Feedback v Provider Only			0.07	0.424	-0.21	0.35	
		Positive Expectancy Baseline Mean (LOT-R: Optimism)	0.14	0.709	0.01	0.709	-0.05	0.07	
	Change Score (4 Time Points)	Intercept	12.91	0.001	2.24	0.003	0.80	3.68	
		Time Point	12.24	0.001	-0.73	0.002	-1.18	-0.28	
		Study Group	2.76	0.049					
		Joint Feedback v Chart Review			-1.59	0.044	-3.18	0.11	770.29
		Joint Feedback v Provider Only			0.05	0.360	-1.79	1.88	
		Study Group * Time Point	4.85	0.011					
		Joint Feedback v Chart Review			0.68	0.011	0.16	1.20	
		Joint Feedback v Provider Only			0.04	0.845	-0.52	0.64	
		Positive Expectancy Baseline Mean (LOT-R: Optimism)	0.01	0.92	0.00	0.921	-0.03	0.03	

Table 30

Illness Perception – Personal Control

Outcome Measure	Score Type	Model	Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
							95% Confidence Interval		
		Parameter	F	*p* value	Estimate	Sig.	Lower Bound	Upper Bound	-2 Restricted Log Likelihood
Brief Illness Perception Questionnaire: Personal Control	Over Time (5 time points)	Intercept	10.11	0.003	3.45	0.025	0.44	6.84	
		Time Point	0.05	0.824	-0.21	0.529	-0.87	0.45	
		Study Group	1.34	0.268					
		Joint Feedback v Chart Review			0.48	0.722	-2.18	3.14	1117.38
		Joint Feedback v Provider Only			-1.18	0.413	-4.05	1.68	
		Study Group * Time Point	0.58	0.56					
		Joint Feedback v Chart Review			0.13	0.719	-0.58	0.83	
		Joint Feedback v Provider Only			0.38	0.335	-0.40	1.16	
		Positive Expectancy Baseline Mean (LOT-R: Optimism)	1.60	0.218	0.05	0.218	-0.03	0.14	
	Change Score (4 Time Points)	Intercept	0.00	0.951	0.75	0.794	-4.98	6.48	
		Time Point	0.04	0.849	-0.37	0.632	-1.92	1.18	
		Study Group	2.51	0.093					
		Joint Feedback v Chart Review			1.24	0.666	-4.55	7.04	974.81
		Joint Feedback v Provider Only			-3.81	0.234	-10.17	2.55	
		Study Group * Time Point	3.22	0.050					
		Joint Feedback v Chart Review			-0.41	0.633	-2.13	1.31	
		Joint Feedback v Provider Only			1.31	0.169	-0.58	3.21	
		Positive Expectancy Baseline Mean (LOT-R: Optimism)	0.34	0.55	0.03	0.553	-0.07	0.13	

Table 31

Illness Perception – Treatment Control

Outcome Measure	Score Type	Model	Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
							95% Confidence Interval		
		Parameter	F	*p* value	Estimate	Sig.	Lower Bound	Upper Bound	-2 Restricted Log Likelihood
Brief Illness Perception Questionnaire: Treatment Control	Over Time (5 time points)	Intercept	75.89	0.012	7.58	0.005	3.98	11.18	
		Time Point	0.04	0.838	-0.14	0.592	-0.64	0.37	
		Study Group	0.16	0.854					
		Joint Feedback v Chart Review			-0.53	0.628	-2.83	1.76	989.18
		Joint Feedback v Provider Only			-0.21	0.858	-2.65	2.23	
		Study Group * Time Point	1.30	0.28					
		Joint Feedback v Chart Review			0.38	0.173	-0.17	0.92	
		Joint Feedback v Provider Only			0.11	0.703	-0.48	0.71	
		Positive Expectancy Baseline Mean (LOT-R: Optimism)	1.40	0.404	-0.04	0.404	-0.16	0.18	
	Change Score (4 Time Points)	Intercept	0.63	0.429	2.06	0.282	-1.71	5.83	
		Time Point	7.58	0.006	-0.16	0.749	-1.17	0.84	
		Study Group	3.24	0.041					
		Joint Feedback v Chart Review			-4.07	0.026	-7.65	-0.50	852.03
		Joint Feedback v Provider Only			-4.87	0.015	-8.77	-0.97	
		Study Group * Time Point	2.82	0.061					
		Joint Feedback v Chart Review			1.24	0.029	0.13	2.35	
		Joint Feedback v Provider Only			1.37	0.028	0.15	2.59	
		Positive Expectancy Baseline Mean (LOT-R: Optimism)	0.01	0.91	0.00	0.912	-0.08	0.07	

Table 32
Illness Perception – Identity

Outcome Measure	Score Type	Model	Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
							95% Confidence Interval		
		Parameter	F	*p* value	Estimate	Sig.	Lower Bound	Upper Bound	-2 Restricted Log Likelihood
Brief Illness Perception Questionnaire: Identity	Over Time (5 time points)	Intercept	177.47	0.000	8.30	0.000	6.32	10.28	
		Time Point	5.82	0.017	0.46	0.064	0.01	0.91	
		Study Group	0.47	0.625					
		Joint Feedback v Chart Review			0.55	0.530	-1.17	2.26	953.72
		Joint Feedback v Provider Only			0.91	0.334	-0.95	2.74	
		Study Group * Time Point	0.99	0.37					
		Joint Feedback v Chart Review			-0.15	0.546	-0.64	0.34	
		Joint Feedback v Provider Only			-0.36	0.188	-0.90	0.18	
		Positive Expectancy Baseline Mean (LOT-R: Optimism)	3.41	0.067	-0.05	0.067	-0.09	0.00	
	Change Score (4 Time Points)	Intercept	0.10	0.749	1.43	0.478	-2.52	5.38	
		Time Point	0.22	0.634	-0.19	0.737	-1.32	0.94	
		Study Group	1.25	0.289					
		Joint Feedback v Chart Review			-2.48	0.198	-6.27	1.31	858.83
		Joint Feedback v Provider Only			-0.64	0.740	-4.77	3.49	
		Study Group * Time Point	1.73	0.179					
		Joint Feedback v Chart Review			0.89	0.163	-0.36	2.13	
		Joint Feedback v Provider Only			0.10	0.887	-1.27	1.47	
		Positive Expectancy Baseline Mean (LOT-R: Optimism)	0.08	0.78	0.01	0.782	-0.07	0.09	

Table 33
Illness Perception – Emotional Concern

Outcome Measure	Score Type	Model	Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
		Parameter	F	*p* value	Estimate	Sig.	95% Confidence Interval		-2 Restricted Log Likelihood
							Lower Bound	Upper Bound	
Brief Illness Perception Questionnaire: Emotional Concern	Over Time (5 time points)	Intercept	307.54	0.000	9.54	0.000	7.77	11.34	840.01
		Time Point	2.47	0.113	-0.19	0.194	-0.55	0.17	
		Study Group	0.74	0.470					
		Joint Feedback v Chart Review			-0.73	0.199	-2.13	0.47	
		Joint Feedback v Provider Only			-0.24	0.749	-1.74	1.24	
		Study Group * Time Point	0.97	0.38					
		Joint Feedback v Chart Review			0.17	0.404	-0.23	0.56	
		Joint Feedback v Provider Only			-0.04	0.857	-0.47	0.39	
		Positive Expectancy Baseline Mean (LOT-R: Optimism)	1.55	0.303	0.02	0.303	-0.04	0.09	
	Change Score (4 Time Points)	Intercept	4.25	0.040	-1.82	0.325	-5.44	1.81	847.58
		Time Point	1.39	0.238	0.10	0.852	-0.94	1.13	
		Study Group	0.71	0.493					
		Joint Feedback v Chart Review			-1.55	0.345	-4.78	1.68	
		Joint Feedback v Provider Only			-0.34	0.847	-3.84	3.15	
		Study Group * Time Point	0.45	0.637					
		Joint Feedback v Chart Review			0.47	0.398	-0.64	1.61	
		Joint Feedback v Provider Only			0.19	0.761	-1.05	1.43	
		Positive Expectancy Baseline Mean (LOT-R: Optimism)	1.31	0.25	0.05	0.254	-0.04	0.13	

Table 34
Illness Perception – Comprehension

Outcome Measure	Score Type	Model	Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
		Parameter	F	*p* value	Estimate	Sig.	95% Confidence Interval		-2 Restricted Log Likelihood
							Lower Bound	Upper Bound	
Brief Illness Perception Questionnaire: Comprehension	Over Time (5 time points)	Intercept	24.97	0.000	6.42	0.002	2.54	10.31	1188.35
		Time Point	0.35	0.558	0.09	0.845	-0.83	1.01	
		Study Group	0.10	0.904					
		Joint Feedback v Chart Review			-0.76	0.474	-4.38	2.86	
		Joint Feedback v Provider Only			-0.42	0.831	-4.34	3.52	
		Study Group * Time Point	0.39	0.68					
		Joint Feedback v Chart Review			-0.22	0.471	-1.23	0.80	
		Joint Feedback v Provider Only			-0.47	0.404	-1.58	0.65	
		Positive Expectancy Baseline Mean (LOT-R: Optimism)	0.00	0.955	0.00	0.955	-0.09	0.09	
	Change Score (4 Time Points)	Intercept							
		Time Point							
		Study Group							
		Joint Feedback v Chart Review							
		Joint Feedback v Provider Only							
		Study Group * Time Point							
		Joint Feedback v Chart Review							
		Joint Feedback v Provider Only							
		Positive Expectancy Baseline Mean (LOT-R: Optimism)							

Unspecified computational error occurred when conducting this analysis

Table 35
Illness Perception – Emotions

Outcome Measure	Score Type	Model	Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
		Parameter	F	*p* value	Estimate	Sig.	95% Confidence Interval		-2 Restricted Log Likelihood
							Lower Bound	Upper Bound	
Brief Illness Perception Questionnaire: Emotions	Over Time (5 time points)	Intercept	147.41	0.000	9.73	0.000	7.73	11.74	
		Time Point	1.88	0.171	-0.25	0.296	-0.73	0.22	
		Study Group	1.41	0.247					
		Joint Feedback v Chart Review			-1.40	0.038	-3.07	0.26	964.2
		Joint Feedback v Provider Only			-0.96	0.292	-2.75	0.83	
		Study Group * Time Point	0.70	0.50					
		Joint Feedback v Chart Review			0.22	0.606	-0.30	0.73	
		Joint Feedback v Provider Only			0.00	0.997	-0.56	0.56	
		Positive Expectancy Baseline Mean (LOT-R: Optimism)	0.12	0.734	-0.01	0.734	-0.06	0.04	
	Change Score (4 Time Points)	Intercept	2.67	0.109	2.48	0.280	-2.07	7.03	
		Time Point	1.62	0.209	-0.61	0.361	-1.93	0.72	
		Study Group	0.14	0.874					
		Joint Feedback v Chart Review			-1.10	0.646	-5.88	3.68	845.72
		Joint Feedback v Provider Only			-0.44	0.847	-5.48	4.80	
		Study Group * Time Point	0.33	0.719					
		Joint Feedback v Chart Review			0.50	0.699	-0.98	1.98	
		Joint Feedback v Provider Only			0.14	0.861	-1.49	1.77	
		Positive Expectancy Baseline Mean (LOT-R: Optimism)	0.03	0.88	-0.01	0.874	-0.08	0.07	

Table 36

Positive Expectancy (Optimism)

Outcome Measure	Score Type	Model	Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
		Parameter	F	*p* value	Estimate	Sig.	95% Confidence Interval		-2 Restricted Log Likelihood
							Lower Bound	Upper Bound	
Life Orientation Test - Revised (Optimism)	Over Time (5 time points)	Intercept	890.93	0.000	20.88	0.000	18.81	22.95	
		Time Point	31.68	0.000	0.93	0.002	0.37	1.50	
		Study Group	0.57	0.570					
		Joint Feedback v Chart Review			0.83	0.494	-1.59	3.25	1818.28
		Joint Feedback v Provider Only			-0.32	0.805	-2.94	2.29	
		Study Group * Time Point	0.16	0.86					
		Joint Feedback v Chart Review			0.00	0.998	-0.65	0.65	
		Joint Feedback v Provider Only			0.16	0.655	-0.56	0.89	
	Change Score (4 Time Points)	Intercept	0.44	0.507	-1.96	0.254	-5.32	1.41	
		Time Point	9.39	0.002	1.47	0.013	0.31	2.63	
		Study Group	0.67	0.515					
		Joint Feedback v Chart Review			0.99	0.610	-2.82	4.81	1684.07
		Joint Feedback v Provider Only			2.32	0.257	-1.70	6.34	
		Study Group * Time Point	0.29	0.751					
		Joint Feedback v Chart Review			-0.27	0.673	-1.54	0.99	
		Joint Feedback v Provider Only			-0.55	0.450	-1.96	0.87	

Table 37

Walking Time _ Performance-Based Outcomes Domain: Results Summary for Linear Mixed Models with Random Coefficients

Outcome Measure	Score Type and Sample Size	Model		Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
		Parameter		F	*p* value	Estimate	Sig.	95% Confidence Interval		-2 Restricted Log Likelihood
								Lower Bound	Upper Bound	
Walk Time: Seconds to complete 500 ft	**Score (4 time points)**	Intercept		243.10	0.000	132.10	0.000	108.24	155.55	
		Time Point		8.07	0.007	-5.72	0.058	-11.65	0.21	
	Joint FeedBack (n=9)	Study Group		2.77	0.081					
			Joint Feedback v Chart Review			-21.27	0.220	-54.01	13.47	767.99
	Provider Only (n=6)		Joint Feedback v Provider Only			24.78	0.189	-14.00	67.55	
		Study Group * Time Point		2.28	0.12					
	Chart Review (n=8)		Joint Feedback v Chart Review			4.67	0.264	-3.75	13.08	
			Joint Feedback v Provider Only			-5.93	0.227	-15.78	3.92	
	Change Score (3 Time Points)	Intercept		20.62	0.000	3.70	0.813	-28.27	35.66	
		Time Point		15.23	0.000	-2.67	0.439	-10.00	4.66	
	Joint FeedBack (n=9)	Study Group		3.95	0.024					
			Joint Feedback v Chart Review			66.87	0.007	20.68	113.06	447.12
	Provider Only (n=6)		Joint Feedback v Provider Only			15.23	0.550	-37.03	67.49	
		Study Group * Time Point		2.41	0.098					
	Chart Review (n=8)		Joint Feedback v Chart Review			-10.74	0.028	-20.14	-1.31	
			Joint Feedback v Provider Only			-2.88	0.580	-13.57	7.82	

Tables 38 – 40
Completion Time Statistics

Table38
PROMIS Computer Adaptive Tests Completion Time Summary

PROMIS Computer Adaptive Tests		Average Seconds	Average Minutes
Measure/Group	Anger	43.75	.73
	Anxiety	39.23	.65
	Depression	26.94	.45
	Fatigue	33.66	.56
	Pain Behavior	44.77	.75
	Pain Interference	37.46	.62
	Physical Function	61.46	1.02
	Sleep-Related Impairment	33.30	.56
	SleepDisturbance	49.10	.82
	Social Sat DSA	46.15	.77
	SocialSatisfactionRole	38.38	.64
Summary Statistics	Mean per measure_PROMIS	41.30	.69
	Mean Total Assessment_PROMIS	454.28	7.57

Table 39
Non-PROMIS Study Measures _ Completion Time Summary

Study Measures (Non-PROMIS)		Average Seconds	Average Minutes
Measure/Group	Brief Illness Perception Questionnaire	160.16	2.67
	Global Health_PROMIS (Non-CAT)	143.28	2.39
	Hypomania/Mania Hx Screen (HCL32)*	306.16	5.10
	Life Orientation Test - Rev (LOT-R: Optimism)	100.18	1.67
	Pain Disability Questionnaire (PDQ)	175.86	2.93
	Pain Medication Questionnaire (PMQ)	217.55	3.63
Summary Statistics	Mean per measure_Non-PROMIS	183.87	3.06
	Total Time Mean_Non-PROMIS	1103.21	18.39

a. MeasType = Non-PROMIS Measures

* The HCL32 was administered at Time Points 1 or 2 (n=60)

Table 40

Overall Completion Time Summary

Completion Time Summary[1]		
Summary Statistics	Seconds (Mean)	Minutes (Mean)
Mean per measure_PROMIS	41.30	0.69
Mean per measure_Non-PROMIS	183.87	3.06
Total Time Mean_PROMIS	454.28	7.57
Total Time Mean_Non-PROMIS	1103.21	18.39
Mean Assessment Time (Core)[2]	1251.33	20.86
Mean Assessment Time (Full)[3]	1557.49	25.96

[1] Sample (n=207)

[2] Represents all measures minus the HCL32

[3] Includes all study measures

Table 41

Linear Mixed Models for Combined Feedback Group Outcome Analyses

Outcome Measure	Score Type	Model	Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
							95% Confidence Interval		
		Parameter	F	*p* value	Estimate	Sig.	Lower Bound	Upper Bound	-2 Restricted Log Likelihood
Personal Control_Illness Perception (BIPQ)	Change Score (4 Time Points)	Intercept	*1.01*	*0.317*	*-0.44*	*0.474*	*-1.44*	*1.73*	
		Time Point	*0.01*	*0.934*	*0.50*	*0.110*	*-0.11*	*1.11*	
		Feedback Group	*3.59*	*0.062*					
		Combined Feedback v Chart Review			*2.74*	*0.062*	*-0.14*	*5.44*	1448.92
		Feedback Group * Time Point	*4.44*	*0.034*					
		Combined Feedback v Chart Review			*-0.94*	*0.034*	*-1.84*	*-0.07*	
WAI-t Bond Change	Change Score (4 Time Points)	Intercept	*2.24*	*0.685*	*1.04*	*0.542*	*-3.08*	*5.14*	
		Time Point	*211.48*	*18.113*	*0.51*	*0.203*	*-0.28*	*1.31*	
		Feedback Group	*50.64*	*5.413*					
		Combined Feedback v Chart Review			*-4.25*	*0.024*	*-7.93*	*-0.58*	517.72
		Feedback Group * Time Point	*5.84*	*0.014*					
		Combined Feedback v Chart Review			*1.35*	*0.014*	*0.25*	*2.45*	

Table 41 (*continued*)
Linear Mixed Models for Combined Feedback Group Outcome Analyses

Outcome Measure	Score Type	Model		Fixed Effects		Estimates of Fixed Effects				Information Criteria Curve (ICC)
								Interval		
		Parameter		F	p value	Estimate	Sig.	Lower Bound	Upper Bound	-2 Restricted Log Likelihood
PROMIS Physical Functioning	Change Score (4 Time Points)	Intercept		10.24	0.002	-7.97	0.000	-12.31	-3.63	1795.48
		Time Point		24.42	0.000	2.54	0.000	1.57	3.55	
		Feedback Group		1.71	0.195					
			Combined Feedback v Chart Review			3.52	0.195	-1.85	8.89	
		Feedback Group * Time Point		3.92	0.052					
			Combined Feedback v Chart Review			1.42	0.052	-2.85	0.01	
PROMIS Fatigue	Change Score (4 Time Points)	Intercept		18.40	0.000	19.29	0.000	11.81	24.78	1937.61
		Time Point		63.00	0.000	-5.48	0.000	-7.24	-4.11	
		Feedback Group		5.09	0.025					
			Combined Feedback v Chart Review			-11.01	0.025	-20.41	-1.41	
		Feedback Group * Time Point		4.18	0.042					
			Combined Feedback v Chart Review			2.33	0.042	0.08	4.57	

Table 42
Summary of Significant Group Comparisons for All Study Groups

Outcome Domain	Measure	Score Type[1,2]	Significant Group Comparisons (*p* [.05]=**X**,*p* [.10]=x)							
			Joint Feedback vs Chart Review		Joint Feedback vs Provider-Only Feedback		Provider-Only Feedback vs Chart Review		Composite Feedback Group vs Chart Review	
			Study Group	Study Group * Time	Study Group	Study Group * Time	Study Group	Study Group * Time	Study Group	Study Group * Time
Pain-Related Functioning and Symptoms	Pain Disability Questionnaire	Over Time	x	**X**		x	**X**			
		Change Scores	**X**	**X**			**X**	**X**		
	PROMIS Pain Behavior[3]	Over Time								
		Change Scores	x	x						
	PROMIS Pain Interference	Over Time					**X**			
		Change Scores		**X**						
	PROMIS Fatigue	Over Time								
		Change Scores					**X**	**X**	**X**	**X**
	PROMIS Physical Functioning	Over Time								
		Change Scores						**X**		x
	VAS Pain Rating	Over Time	x							
		Change Scores	**X**							
Psychosocial and Psychological Variables	PROMIS Anger	Over Time	x							
		Change Scores	**X**	**X**	**X**	**X**				
	PROMIS Anxiety	Over Time			**X**	x				
		Change Scores	**X**	**X**						
	PROMIS Depression Sxs	Over Time	x					x		
		Change Scores	**X**	**X**						
	PROMIS Sleep Disturbance[3]	Over Time								
		Change Scores								
	PROMIS Sleep-Related Impairment	Over Time	**X**	x						
		Change Scores	**X**	**X**	x	x				
	PROMIS Social Functioning - Satisfaction with Discretionary	Over Time	**X**				x	x		
		Change Scores	**X**							
	PROMIS Social Functioning - Satisfaction with Social Roles	Over Time	**X**							
		Change Scores	x	x						
	Pain Medication Questionnaire (Opioid Misuse Risk)	Over Time				x	**X**	**X**		
		Change Scores						**X**		

[1]*Over Time* Score Type refers to analyses using all 5 time points

[2]*Change Scores* Score Type refers to analyses using change scores for 4 time points

[3]Analyses using the Combined Feedback vs Chart Review group comparison were conducted for these outcome measures; findings were nonsignificant

Table 42 (*continued*)
Summary of Significant Group Comparisons for All Study Groups

Outcome Domain	Measure	Score Type[1,2]	Significant Group Comparisons (p [.05]=**X**, p [.10]=x)							
			Joint Feedback vs Chart Review		Joint Feedback vs Provider-Only Feedback		Provider-Only Feedback vs Chart Review		Composite Feedback Group vs Chart Review	
			Study Group	Study Group * Time	Study Group	Study Group * Time	Study Group	Study Group * Time	Study Group	Study Group * Time
Global Health-Related Quality of Life	Global HrQOL: Mental Health Domain[3]	Over Time								
		Change Scores	x	x	x	x				
	Global HrQOL: Physical Health Domain	Over Time								
		Change Scores	x	x	x					
Treatment Alliance (Provider and Patient-rated Forms)	WAI - Bond (Patient-rated)	Over Time								
		Change Scores		**X**			x	x		
	WAI - Task (Patient-rated)[3]	Over Time								
		Change Scores								
	WAI - Bond (Provider-rated)	Over Time								
		Change Scores					**X**	**X**	**X**	**X**
	WAI - Task (Provider-rated)[3]	Over Time								
		Change Scores								
Illness Perception and Positive Expectancy (Optimism)	BIPQ - Consequences	Over Time	**X**				x			
		Change Scores	**X**	**X**						
	BIPQ - Timeline	Over Time	**X**	**X**			x	x		
		Change Scores	x	**X**			**X**	**X**		
	BIPQ - Personal Control	Over Time					**X**	x		
		Change Scores							x	**X**
	BIPQ Treatment Control	Over Time								
		Change Scores	**X**	**X**	**X**	**X**				
	BIPQ - Identity[3]	Over Time								
		Change Scores	x	x						
	BIPQ - Emotional Concern[3]	Over Time								
		Change Scores								
	BIPQ - Comprehension[3]	Over Time								
		Change Scores								
	BIPQ - Emotions	Over Time	x							
		Change Scores								
	Optimism (LOT-R)[3]	Over Time								
		Change Scores								
Performance-Based Measures	Walk Time (500 ft)	Over Time					**X**	**X**		
		Change Scores	**X**	**X**			x			

[1] *Over Time* Score Type refers to analyses using all 5 time points

[2] *Change Scores* Score Type refers to analyses using change scores for 4 time points

[3] Analyses using the Combined Feedback vs Chart Review group comparison were conducted for these outcome measures; findings were nonsignificant

APPENDIX C
FEEDBACK PROTOCOLS

FEEDBACK PROTOCOL

- **General Concerns**
  - This is a crucial part of the study process; it involves the delivery of the Patient BPS Health Report (composed of both the PROMIS and Non-PROMIS reports), as well as brief verbal feedback to the patient and/or provider.
  - As described in the "Study Procedures" training document, feedback will be provided prior to the point-of-care for Groups 2 and 3 from Time-point 2 through Time-point 5. There will be some variation to this based upon the type of treatment they're receiving in the clinic (i.e. Interdisciplinary Program vs. individual services).
  - Time constraints differ between time-points as well as by what type of treatment they're receiving in the clinic. Guidelines for this are provided below:
- Overview of Time-Points with Potential for Feedback
  - Time-point 2 (T2): All study participants will be scheduled to arrive 30 – 45 minutes prior to their Interdisciplinary Evaluation. A participant's feedback group will already be determined at this point in the study and this will be noted in the weekly schedule spreadsheet.
  - Time-points 3 and 4 (T3/T4):
    - Interdisciplinary Program Patients: Two 1 ½ hour windows have been secured for us to administer the T3 Assessment to the four program patients on their 1st day of the program and at the beginning of their last week in the ID treatment program (Tuesday of the program patients' 4th week).
      - Given the nature of an Interdisciplinary Treatment program, feedback to providers and/or patients will be conducted in between their appointments that day
      - The approximate time that this will occur will be reflected in the week's patient schedule spreadsheet. The assessment times set by the clinic during the 1st day of the interdisciplinary program are listed below:
        - 2 at 10:30 AM
        - 2 at 12:00 PM

- Individual Treatment Patients (CBT or Physical Therapy Only (PT), CBT or PT / Psychiatry Follow-Up, Psychiatry Follow-Up only):
    - Feedback Group type will be reflected in the Weekly Schedule and if the study patient is in Group 2 or Group 3, they will be scheduled to arrive 30 – 45 minutes early for their given appointment
    - T3 – T5 (for study participants receiving CBT or PT with/without psychiatry follow-up)
        - As based upon Feedback Group, study patients will be individually scheduled to arrive early for a "Treatment Baseline," "Treatment Midpoint," and a "Treatment Endpoint."
    - T3 – T5 for Psychiatry Follow-Up Only
        - The appointment time-frame for these patients will not be uniform and the duration between time-points could range from 2 weeks to 1-2 months or more.
        - Feedback protocol will be the same as that for individual services except that there will be no treatment baseline, midpoint, or endpoint

- Efficiency/Brevity of feedback prior to the point-of-care
    - **Do not exceed the 45 minute window; we will not delay the provider's scheduled appt time**
        - **The only exceptional circumstance is if the provider directly communicates that they will allow additional time**
        - **This has to be initiated by the provider; we will never ask for additional time**
    - What to do if the feedback portion with the patient is cut short due to their appointment time…
        - Let them know that you can briefly meet with them after their appt if they have additional questions
        - OR direct them to the contact information at the bottom of the Non-PROMIS BPS Report component to set up a future time to discuss results further (this has my UTSW voicemail)

        - Follow the verbal feedback guidelines below as closely as possible; however, they do not have to be given verbatim.
    - Results interpretation
        - All assessments included in the Patient BPS Report are face valid; meaning, the construct measured by each item bank or instrument can generally be equated to its name or sub-heading (e.g. the Depression Item Bank measures level of depressive symptoms and the Pain Medication Questionnaire measures risk of opioid misuse, etc)
        - Per the design of each report, the significance of results are clearly interpretable; however, identifying and communicating the most significant results to patients/providers must be succinct
            - A brief guide for identifying highly significant results is included
        - Non-PROMIS BPS Report Component
            - Cutoff scores, risk categories, and measure explanations are included on the report itself
            - These measure should require little to no separate interpretation (on the part of research personnel) prior to the provision of feedback

        - PROMIS BPS Report Component
            - This report is automatically generated from the PROMIS Assessment Center
            - Statistical considerations
                - Each measure generates a uniform T-Score for each construct (mean=50, SD=10)
                - Based upon the PROMIS normative data, three percentile scores are generated from that T-Score, including:
                    - General population
                    - Specific age range of the patient (25-34, 35-44, etc.)
                    - Gender-based
                - Multiple percentiles are generated to account for the varied degree of measurement inequivalence introduced by age/gender
                - Given **these are not diagnostic instruments**, we will **never** communicate to a patient/provider that the patient **has** a particular psychiatric disorder

- Instead, we will communicate that a given patient is endorsing significantly higher/lower levels of a given construct
  - A script for communicating this will be provided in the verbal feedback to patients section of this document

- PROMIS Interpretation Reference Document: A pre-feedback interpretation process and a list of the specific PROMIS measures and what they assess is included as a separate document for the use of researchers
-

- **Verbal Feedback to Providers (Group 2 and Group 3)**

  Things to keep in mind
  - Make sure to have completed the short pre-feedback interpretive process described in this document
  - The purpose of the Provider Feedback is to direct their attention to any of the assessment's significant results
  - The provider is to hold onto this copy.
  - If the patient will receive feedback also, make sure to let the provider know that so they will be prepared.

  Basic script for communicating/delivering assessment results to providers:

  - Take the interpreted report materials to the provider associated with the study patient, and use the following script:

    - *Hi Dr. Van Wright or Dr. Whitfill or Judy, I have the assessment results for the patient you're about to see, (insert study patient's name)*-------- Hand them the results--------- *Thanks.*

- **Verbal Feedback to Patients (Group 3)**

  Basic script for communicating assessment results to patients:

  - **PROMIS (*significant results for feedback should already be selected*):**

    - Your score on the (*depression measure*) indicates that your reported level of (*depressive*) symptoms is higher than 85%

of the general population, 83% of female respondents, and 88% of respondents ages (*ages 25 – 34, 45 – 54, etc*).

- ***Repeat for each significant PROMIS measure***

- **BPS Health Report:**

  - **PMQ:** Your score of ___ was in the (low/moderate/high) risk category for current risk of opioid misuse. (*provide this basic feedback only when they border moderate risk or are in the moderate to high risk range*)

  - **PDQ:** Your score of ____ was in the (extreme/severe/moderate) range for current pain-related functional disability. This measure helps us understand how your pain affects you during your day-to-day activities.

- **In summary…**

  - An elevated score (or scores) or increased risk indicates this symptom area may be an area of particular concern for you and that **it would be appropriate/helpful to discuss it with your provider during appointment**

  - ***it is essential that we communicate the underlined portion during any patient feedback***

- **Do you have any questions for me?**

- **Thank you for your participation and you'll see me or another member of the research team _____** (per their next time-point)

- The names of any PROMIS measures can be substituted into this script for patient feedback.
- If the patient inquires further about the meaning of given measure, use the interpretive PROMIS reference sheet at the end of this document

Problem-Solving

- REMINDER: During feedback with patients, always be aware of the time and how much of the 45 minute window is left until their scheduled provider appointment.

- WHAT TO DO IF…

    - If you have already initiated feedback with the patient and the 45 minute pre-appointment window is almost up, take the steps listed below:

        1. Communicate to the patient that he/she can receive additional feedback after their appointment OR the patient can leave a voicemail message for me and I will coordinate additional feedback before/after his/or her next appt. (my UTSW voicemail is listed at the bottom of "Biopsychosocial" report that we produce

APPENDIX d

FULL-LENGTH COPIES OF STUDY MEASURES

APPENDIX e

Patient health reports

SAMPLE PROMIS PATIENT HEALTH REPORT (SINGLE TIME POINT)
BIOPSYCHOSOCIAL PATIENT HEALTH REPORT (SINGLE TIME POINT)
SAMPLE PATIENT HEALTH REPORT (MULTIPLE TIME POINTS)
BIOPSYCHOSOCIAL PATIENT HEALTH REPORT (MULTIPLE TIME POINTS)

Sample copies of the Patient Health Reports (single and multiple time point) are attached as separate PDF's. These could not be pasted here due to formatting conflicts.

APPENDIX F

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[**BIPQ.001**]

For the following questions, please select the number that best corresponds to your views.

How much does your illness affect your life?

- 0 - no affect at all
- 1 -
- 2 -
- 3 -
- 4 -
- 5 -
- 6 -
- 7 -
- 8 -
- 9 -
- 10 - severely affects my life

[**BIPQ.002**]

How long do you think your illness will continue?

- 0 - a very short time
- 1 -
- 2 -
- 3 -
- 4 -
- 5 -
- 6 -
- 7 -
- 8 -
- 9 -
- 10 - forever

[**BIPQ.003**]

How much control do you feel you have over your illness?

- 0 - absolutely
- 1 -
- 2 -
- 3 -
- 4 -
- 5 -
- 6 -
- 7 -
- 8 -
- 9 -
- 10 - extreme amount of control

[**BIPQ.004**]

How much do you think treatment can help your illness?

- 0 - not at all
- 1 -
- 2 -
- 3 -
- 4 -
- 5 -
- 6 -
- 7 -
- 8 -
- 9 -
- 10 - extremely helpful

[**BIPQ.005**]

How much do you experience symptoms from your illness?

- 0 - no symptoms at all
- 1 -

- 2 -
- 3 -
- 4 -
- 5 -
- 6 -
- 7 -
- 8 -
- 9 -
- 10 - many severe symptoms

[**BIPQ.006**]

How concerned are you about your illness?

- 0 - not at all concerned
- 1 -
- 2 -
- 3 -
- 4 -
- 5 -
- 6 -
- 7 -
- 8 -
- 9 -
- 10 - extremely concerned

[**BIPQ.007**]

How well do you feel you understand your illness?

- 0 - don't understand at all
- 1 -
- 2 -
- 3 -
- 4 -
- 5 -

- 6 -
- 7 -
- 8 -
- 9 -
- 10 - understand very clearly

[**BIPQ.008**]

How much does your illness affect you emotionally? (e.g. does it make you angry, scared, upset, or depressed?)

- 0 - not at all affected emotionally
- 1 -
- 2 -
- 3 -
- 4 -
- 5 -
- 6 -
- 7 -
- 8 -
- 9 -
- 10 - extremely affected emotionally

[**BIPQ.009**]

To help understand what led to your illness, please list in rank-order the three most factors that caused your illness.

The most important causes for me:

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[**HCL32.001**]

At different times in life, everyone experiences changes or swings in energy, activity, and mood ("highs and lows" or "ups and downs"). The aim of the following questions is to assess the characteristics of the "high"periods. Please select "next" to continue.

- Next

[**HCL32002**]

First of all, how are you feeling TODAY compared to your usual state?

- Much worse than usual
- Worse than usual
- A little worse than usual
- Neither better nor worse than usual
- A little better than usual
- Better than usual
- Much better than usual

[**HCL32003**]

Independently of how you feel today, please tell us how you are normally in comparison to other people by selecting which of the following statements describes you best ... COMPARED TO OTHER PEOPLE my level of activity, energy, and mood...

- ... is always stable and even
- ... is generally higher
- ... is generally lower
- ... repeatedly shows periods of ups and downs

[**HCL32004**]

The next set of questions refer to a period of your life when you were in a "high" state. How did you feel then? Please answer all of these questions independently of your present condition. Please select "next" to continue

- Next

[**HCL32005**]

In a "high" state ...

I need less sleep

- Yes
- No

[**HCL32006**]

In a "high" state ...

I feel more energetic and more active

- Yes
- No

[**HCL32007**]

In a "high" state ...

I am more self-confident

- Yes
- No

[**HCL32008**]

In a "high" state ...

I enjoy my work more

- Yes
- No

[**HCL32009**]

In a "high" state ...

I am more sociable (e.g., I make more phone calls, go out more)

- Yes
- No

[**HCL32010**]

In a "high" state

I want to travel more than I usually do

- Yes
- No

[**HCL32011**]

In a "high" state ...

I tend to drive faster or take more risks when driving

- Yes
- No

[**HCL32012**]

In a "high" state ...

I spend too much money or I spend much more money than usual

- Yes
- No

[**HCL32013**]

In a "high" state ...

I take more risks in my daily life (e.g., in my work or other activities)

- Yes
- No

[**HCL32014**]

In a "high" state ...

I am physically more active (e.g., exercise more, play sports more often, etc.)

- Yes
- No

[**HCL32015**]

In a "high" state ...

I plan more activities or projects

I plan more activities or projects

- Yes
- No

[**HCL32016**]

In a "high" state ...

I have more idea and I am more creative

- Yes
- No

[**HCL32017**]

In a "high" state ...

I am less shy or inhibited

- Yes
- No

[**HCL32018**]

In a "high" state ...

I wear more colorful and extravagant clothes or makeup

- Yes
- No

[**HCL32019**]

In a "high" state ...

I meet more people or feel like I want to meet more

- Yes
- No

[**HCL32020**]

In a "high" state ...

I am more interested in sex or have an increased sexual desire

- Yes
- No

No

[**HCL32021**]

In a "high" state ...

I am more flirtatious and/or more sexually active

- Yes
- No

[**HCL32022**]

In a "high" state ...

I talk more

- Yes
- No

[**HCL32023**]

In a "high" state ...

I think faster

- Yes
- No

[**HCL32024**]

In a "high" state ...

I make more jokes or puns when I am talking

- Yes
- No

[**HCL32025**]

In a "high" state ...

I am more easily distracted

- Yes
- No

[**HCL32026**]

In a "high" state ...

I engage in a lot of new things

- Yes
- No

[**HCL32027**]

In a "high" state ...

My thoughts jump from topic to topic

- Yes
- No

[**HCL32028**]

In a "high" state ...

I do things more quickly and/or more easily

- Yes
- No

[**HCL32029**]

In a "high" state ...

I am more impatient and/or get irritable more easily

- Yes
- No

[**HCL32030**]

In a "high" state ...

I can be exhausting or irritating for others

- Yes
- No

[**HCL32031**]

In a "high" state ...

I get into more arguments

- Yes

- Yes
- No

[**HCL32032**]

In a "high" state ...

My mood is higher and more optimistic

- Yes
- No

[**HCL32033**]

In a "high" state ...

I drink more coffee and/or other caffeinated drinks

- Yes
- No

[**HCL32034**]

In a "high" state ...

I smoke more cigarettes

- Yes
- No

[**HCL32035**]

In a "high" state ...

I drink more alcohol

- Yes
- No

[**HCL32036**]

In a "high" state ...

I take more drugs (e.g., sedatives, anxiolytics, stimulants, pain medication, etc.)

- Yes
- No

[**HCL32037**]

The last several questions asked about thoughts/feelings/behaviors that you might feel during a "high" state. This question relates to how often you may have these thoughts/feelings/behaviors. Please select "next" to continue.

- Next

[**HCL32038**]

Did the previous question describe how you are SOMETIMES?

- Yes
- No

[**HCL32039**]

Did the previous questions describe how you are MOST OF THE TIME?

- Yes
- No

[**HCL32040**]

The previous questions (e.g. In such a "high" state...) are not applicable to me.

- I have NEVER experienced such a "high"
- Not sure

[**HCL32041**]

The next few questions ask about the impact of your "highs" on various aspects of your life. What kind of impact have your "highs" had on your family life?

- No impact
- Negative
- Positive
- Both positive and negative

[**HCL032050**]

What kind of impact have your "highs" had on your social life?

- No impact
- Negative
- Positive
- Both positive and negative

[**HCL32042**]

What kind of impact have your "highs" had on your work?

- No impact
- Negative
- Positive
- Both positive and negative

[**HCL32043**]

What kind of impact have your "highs" had on your leisure?

- No impact
- Negative
- Positive
- Both positive and negative

[**HCL32044**]

How did other people close to you react to or comment on your "highs"?

- Positively (encouragingly or supportively)
- Neutral
- Negatively (concerned, annoyed, irritated, critical)
- Positively and negatively
- No reactions

[**HCL32045**]

On average, what is the length of your "highs"?

- 1 day
- 2-3 days

- 4-7 days
- Longer than one week
- Longer than one month

[**HCL32046**]

Have you experienced such "highs" in the last twelve months?

- Yes
- No

[**HCL32047**]

Please estimate the total number of days you spent in "highs" during the last twelve months:

[**HCL32048**]

Please select "next" to continue

- Next

[**HCL32049**]

The next few questions ask about the impact of your "highs" on various aspects of your life. What kind of impact have your "highs" had on your family life?

- No impact
- Negative
- Positive
- Both positive and negative

[**HCL3241a**]

What kind of impact have your "highs" had on your social life?

- No impact
- Negative
- Positive
- Both positive and negative

[**HCL32051**]

[**HCL32051**]

What kind of impact have your "highs" had on your work?

- No impact
- Negative
- Positive
- Both positive and negative

[**HCL32053**]

What kind of impact have your "highs" had on your leisure?

- No impact
- Negative
- Positive
- Both positive and negative

[**HCL32052**]

How did other people close to you react to or comment on your "highs"?

- Positively (encouragingly or supportively)
- Neutral
- Negatively (concerned, annoyed, irritated, critical)
- Positively and negatively
- No reactions

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[**LOT-R.01**]

Please be as honest and accurate as you can throughout. Try not to let your response to one statement influence your responses to other statements. There are no 'correct' or 'incorrect' answers. Answer according to your own feelings, rather than how you think 'most people' would answer. Each question will ask you to rate your level of agreement with a given statement. Please select "next" to continue.

[**LOT-R.02**]

Questions will ask you to rate your level of agreement with a given statement.

- 0 - strongly disagree
- 1 - disagree
- 2 - neutral
- 3 - agree
- 4 - strongly agree

[**LOT-R.03**]

In uncertain times, I usually expect the best.

- 0 - strongly disagree
- 1 - disagree
- 2 - neutral
- 3 - agree
- 4 - strongly agree

[**LOT-R.04**]

It's easy for me to relax.

- 0 - strongly disagree
- 1 - disagree
- 2 - neutral
- 3 - agree
- strongly agree

[**LOT-R.05**]

If something can go wrong for me it will.

- 0 - strongly disagree
- 1 - disagree
- 2 - neutral
- 3 - agree
- 4 - strongly agree

[**LOT-R.06**]

I'm always optimistic about my future.

- 0 - strongly disagree
- 1 - disagree
- 2 - neutral
- 3 - agree
- 4 - strongly agree

[**LOT-R.07**]

I enjoy my friends a lot.

- 0 - strongly disagree
- 1 - disagree
- 2 - neutral
- 3 - agree
- 4 - strongly agree

[**LOT-R.08**]

It's important for me to keep busy.

- 0 - strongly disagree
- 1 - disagree
- 2 - neutral
- 3 - agree
- 4 - strongly agree

[**LOT-R.09**]

I hardly expect things to go my way.

- 0 - strongly disagree
- 1 - disagree
- 2 - neutral
- 3 - agree
- 4 - strongly agree

[**LOT-R.10**]

I don't get upset too easily.

- 0 - strongly disagree
- 1 - disagree
- 2 - neutral
- 3 - agree
- 4 - strongly agree

[**LOT-R.11**]

I rarely count on good things happening to me.

- 0 - strongly disagree
- 1 - disagree
- 2 - neutral
- 3 - agree
- 4 - strongly agree

[**LOT-R.12**]

Overall, I expect more good things to happen to me than bad.

- 0 - strongly disagree
- 1 - disagree
- 2 - neutral
- 3 - agree
- 4 - strongly agree

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[**MAS.01**]

Are you currently taking medication for your pain?

- Yes
- No

[**MAS.02**]

You indicated that you are taking medication for your pain-related health concern. Individuals have identified several issues regarding their medication-taking behavior and we are interested in your experiences. There is no right or wrong answer. Please answer each question based on your personal experience with your pain medication. The first several questions will ask you to provide a yes/no answer about your personal experience. Please select "next" to continue.

[**MAS.03**]

Do you sometimes forget to take your pain medication for your health concern?

- Yes
- No

[**MAS.04**]

People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your pain medicine?

- Yes
- No

[**MAS.05**]

Have you ever cut back or stopped taking your medication without telling your doctor, because you felt worse when you took it?

- Yes
- No

[**MAS.06**]

When you travel or leave home, do you sometimes forget to bring along your pain medication?

- Yes
- No

[**MAS.07**]

Did you take your pain medicine yesterday?

- Yes
- No

[**MAS.08**]

When you feel like your pain is under control, do you sometimes stop taking your medicine?

- Yes
- No

[**MAS.09**]

Taking medication everyday is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan for your pain-related health concern?

- Yes
- No

[**MAS.10**]

How often do you have difficulty remembering to take all your medications?

- 0 - Never/Rarely
- 1 - Once in a while
- 2 - Sometimes
- 3 - Usually
- All the time

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[PDQ.001]

This survey asks for your views about how your pain now affects how you function in everyday activities. This information will help you and your care provider know how you feel and how well you are able to do your daily tasks at this time. Please answer every question by selecting a rating to show how much your pain problem has affected you (from having no problems at all (0 rating) to having the most severe problems (10 rating) you can imagine). Please click NEXT to begin this survey.

[PDQ.002]

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

- 0 - (0=Able to work normally)
- 1 -
- 2 -
- 3 -
- 4 -
- 5 -
- 6 -
- 7 -
- 8 -
- 9 -
- 10 - (10=Unable to work at all)

[PDQ.003]

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

- 0 - (0=Take care of myself completely)
- 1 -
- 2 -
- 3 -
- 4 -

- 5 -
- 6 -
- 7 -
- 8 -
- 9 -
- 10 - (10=Need help with all my personal care)

[PDQ.004]

Does your pain interfere with your traveling?

- 0 - (0=Travel anywhere I like)
- 1 -
- 2 -
- 3 -
- 4 -
- 5 -
- 6 -
- 7 -
- 8 -
- 9 -
- 10 - (10=Only travel to see doctors)

[PDQ.005]

Does your pain interfere with your ability to sit or stand?

- 0 - (0=No problems)
- 1 -
- 2 -
- 3 -
- 4 -
- 5 -
- 6 -
- 7 -
- 8 -

- 9 -
- 10 - (10=Cannot sit or stand at all)

[PDQ.006]

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

- 0 - (0=No problems)
- 1 -
- 2 -
- 3 -
- 4 -
- 5 -
- 6 -
- 7 -
- 8 -
- 9 -
- 10 - (10=Cannot do at all)

[PDQ.007]

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

- 0 - (0=No problems)
- 1 -
- 2 -
- 3 -
- 4 -
- 5 -
- 6 -
- 7 -
- 8 -
- 9 -
- 10 - (10=Cannot do at all)

[**PDQ.008**]

Does your pain affect your ability to walk or run?

- 0 - (0=No problems)
- 1 -
- 2 -
- 3 -
- 4 -
- 5 -
- 6 -
- 7 -
- 8 -
- 9 -
- 10 - (10=Cannot walk/run at all)

[**PDQ.009**]

Has your income declined since your pain began?

- 0 - (0=No decline)
- 1 -
- 2 -
- 3 -
- 4 -
- 5 -
- 6 -
- 7 -
- 8 -
- 9 -
- 10 - (10=Lost all income)

[**PDQ.010**]

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

- 0 - (0=No medication needed)

- 1 -
- 2 -
- 3 -
- 4 -
- 5 -
- 6 -
- 7 -
- 8 -
- 9 -
- 10 - (10=On pain medication throughout the day)

[**PDQ.011**]

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

- 0 - (0=Never see doctors)
- 1 -
- 2 -
- 3 -
- 4 -
- 5 -
- 6 -
- 7 -
- 8 -
- 9 -
- 10 - (10=See doctors weekly)

[**PDQ.012**]

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

- 0 - (0=No problems)
- 1 -
- 2 -

- 3 -
- 4 -
- 5 -
- 6 -
- 7 -
- 8 -
- 9 -
- 10 - (10=Never see them)

[**PDQ.013**]

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

- 0 - (0=No interference)
- 1 -
- 2 -
- 3 -
- 4 -
- 5 -
- 6 -
- 7 -
- 8 -
- 9 -
- 10 - (10=Total interference)

[**PDQ.014**]

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

- 0 - (0=Never need help)
- 1 -
- 2 -
- 3 -
- 4 -

- 5 -
- 6 -
- 7 -
- 8 -
- 9 -
- 10 - (10=Need help all the time)

[PDQ.015]

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

- 0 - (0=No depression/tension)
- 1 -
- 2 -
- 3 -
- 4 -
- 5 -
- 6 -
- 7 -
- 8 -
- 9 -
- 10 - (10=Severe depression/tension)

[PDQ.016]

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

- 0 - (0=No problems)
- 1 -
- 2 -
- 3 -
- 4 -
- 5 -
- 6 -

- 7 -
- 8 -
- 9 -
- 10 - (10=Severe problems)

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[**PMQ.001**]

Are you currently taking any pain medication(s)?

- Yes
- No

[**PMQ.002**]

In order to develop the best treatment plan, we want to understand your thoughts, needs and experiences related to your pain medications. Please read each statement and indicate how much it applies to you by selecting one of the response options. Please select "next" to continue.

[**PMQ.003**]

I believe I am receiving enough medication to relieve my pain.

- Disagree
- Somewhat Disagree
- Neutral
- Somewhat Agree
- Agree

[**PMQ.004**]

My doctor spends enough time talking to me about my pain medication during appointments.

- Disagree
- Somewhat Disagree
- Neutral
- Somewhat Agree
- Agree

[**PMQ.005**]

I believe I would feel better with a higher dose of my pain medication.

- Disagree
- Somewhat Disagree

- Somewhat Disagree
- Neutral
- Somewhat Agree
- Agree

[**PMQ.006**]

In the past, I have had some difficulty getting the medication I need from my doctor(s).

- Disagree
- Somewhat Disagree
- Neutral
- Somewhat Agree
- Agree

[**PMQ.007**]

I wouldn't mind quitting my current pain medication and trying a new one, if my doctor recommends it.

- Disagree
- Somewhat Disagree
- Neutral
- Somewhat Agree
- Agree

[**PMQ.008**]

I have clear preferences about the type of pain medication I need.

- Disagree
- Somewhat Disagree
- Neutral
- Somewhat Agree
- Agree

[**PMQ.009**]

Family members seem to think that I may be too dependent on my pain

medication.

- Disagree
- Somewhat Disagree
- Neutral
- Somewhat Agree
- Agree

[**PMQ.010**]

It is important to me to try ways of managing my pain in addition to the medication (such as relaxation, biofeedback, physical therapy, TENS unit, etc.).

- Disagree
- Somewhat Disagree
- Neutral
- Somewhat Agree
- Agree

[**PMQ.011**]

At times, I take pain medication when I feel anxious and sad, or when I need help sleeping.

- Never
- Occasionally
- Sometimes
- Often
- Always

[**PMQ.012**]

At times, I drink alcohol to control my pain.

- Never
- Occasionally
- Sometimes
- Often
- Always

[**PMQ.013**]

My pain medications make it hard for me to think clearly sometimes.

- Never
- Occasionally
- Sometimes
- Often
- Always

[**PMQ.015**]

I find it necessary to go to the emergency room to get treatment for my pain.

- Never
- Occasionally
- Sometimes
- Often
- Always

[**PMQ.015.1**]

My pain medication makes me nauseated and constipated sometimes.

- Never
- Occasionally
- Sometimes
- Often
- Always

[**PMQ.016**]

At times, I need to borrow pain medication from friends and family to get relief.

- Never
- Occasionally
- Sometimes

- Often
- Always

[**PMQ.017**]

I get pain medication from more than one doctor in order to have enough medication for my pain.

- Never
- Occasionally
- Sometimes
- Often
- Always

[**PMQ.018**]

At times, I think I may be too dependent on my pain medication.

- Never
- Occasionally
- Sometimes
- Often
- Always

[**PMQ.019**]

To help me out, family members have obtained pain medications for me from their own doctors.

- Never
- Occasionally
- Sometimes
- Often
- Always

[**PMQ.020**]

At times, I need to take pain medication more often than it is prescribed in order to relieve my pain.

- Never

- Occasionally
- Sometimes
- Often
- Always

[**PMQ.021**]

I save any unused pain medication I have in case I need it later.

- Never
- Occasionally
- Sometimes
- Often
- Always

[**PMQ.022**]

At times, I run out of pain medication early and have to call my doctor for refills.

- Never
- Occasionally
- Sometimes
- Often
- Always

[**PMQ.023**]

I find it useful to take additional medications (such as sedatives) to help my pain medication work better.

- Never
- Occasionally
- Sometimes
- Often
- Always

[**PMQ.025**]

How many times in the PAST YEAR have you run out of pain medication

How many times in the PAST YEAR have you run out of pain medication early and had to request an early refill?

- Never
- 1 time
- 2 times
- 3 times
- 4 times or more

[**PMQ.026**]

How many times in the PAST YEAR have you asked your doctor to increase your prescribed dosage of pain medication in order to get relief?

- Never
- 1 time
- 2 times
- 3 times
- 4 times or more

[**PMQ.027**]

How many times in the PAST YEAR have you accidentally misplaced your prescription for pain medication and had to ask for another?

- Never
- 1 time
- 2 times
- 3 times
- 4 times or more

[**PMQ.028**]

How many painful conditions (injured body parts or illnesses) do you have?

- 1 painful condition
- 2 painful conditions
- 3 painful conditions
- 4 painful conditions

- 5 painful conditions

Emotional Distress Anger – Calibrated Items

Please respond to each item by marking one box per row.

In the past 7 days...

		Never	Rarely	Sometimes	Often	Always
EDANG01	When I was frustrated, I let it show…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG03	I was irritated more than people knew….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG04	I felt envious of others……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG05	I disagreed with people……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG06	I made myself angry about something just by thinking about it……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG07	I tried to get even when I was angry with someone……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG09	I felt angry……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG10	When I was mad at someone, I gave them the silent treatment	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG11	I felt like breaking things……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days...

		Never	Rarely	Sometimes	Often	Always
EDANG15	I felt like I was ready to explode.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG16	When I was angry, I sulked……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG17	I felt resentful when I didn't get my way...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG18	I felt guilty about my anger……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG21	I felt bitter about things……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG22	I felt that people were trying to anger me…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG25	I stayed angry for hours……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG26	I held grudges towards others……...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG28	I felt angrier than I thought I should……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG30	I was grouchy……...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
EDANG31	I was stubborn with others……...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG35	I felt annoyed……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG37	I had a bad temper……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG42	I had trouble controlling my temper…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG45	I was angry when I was delayed……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG47	Even after I expressed my anger, I had trouble forgetting about it……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG48	I felt like I needed help for my anger…...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG54	I was angry when something blocked my plans…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG55	I felt like yelling at someone……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
		Not at all	**A little bit**	**Somewhat**	**Quite a bit**	**Very Much**
EDANG56	Just being around people irritated me…...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Emotional Distress - Anxiety – Calibrated Items

Please respond to each item by marking one box per row.

In the past 7 days...

		Never	Rarely	Sometimes	Often	Always
EDANX01	I felt fearful	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX02	I felt frightened	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX03	It scared me when I felt nervous.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX05	I felt anxious	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX07	I felt like I needed help for my anxiety	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX08	I was concerned about my mental health....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX12	I felt upset	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX13	I had a racing or pounding heart.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX16	I was anxious if my normal routine was disturbed	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
EDANX18	I had sudden feelings of panic.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX20	I was easily startled	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX21	I had trouble paying attention.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX24	I avoided public places or activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX26	I felt fidgety.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX27	I felt something awful would happen	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX30	I felt worried.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX33	I felt terrified	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX37	I worried about other people's reactions to me	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX40	I found it hard to focus on anything other than my anxiety	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
EDANX41	My worries overwhelmed me	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX44	I had twitching or trembling muscles	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX44	I felt nervous	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX47	I felt indecisive.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX48	Many situations made me worry.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX49	I had difficulty sleeping	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX51	I had trouble relaxing.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX53	I felt uneasy.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX54	I felt tense.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX55	I had difficulty calming down.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Emotional Distress - Depression – Calibrated Items

Please respond to each item by marking one box per row.

In the past 7 days...

		Never	Rarely	Sometimes	Often	Always
EDDEP04	I felt worthless……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP05	I felt that I had nothing to look forward to	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP06	I felt helpless……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP07	I withdrew from other people……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP09	I felt that nothing could cheer me up…	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP14	I felt that I was not as good as other people……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP17	I felt sad……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP19	I felt that I wanted to give up on everything…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP21	I felt that I was to blame for things……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
EDDEP22	I felt like a failure…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP23	I had trouble feeling close to people……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP26	I felt disappointed in myself…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP27	I felt that I was not needed……...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP28	I felt lonely……...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP29	I felt depressed…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP30	I had trouble making decisions…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP31	I felt discouraged about the future……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP35	I found that things in my life were overwhelming……...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP36	I felt unhappy……...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP39	I felt I had no reason for living…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
EDDEP41	I felt hopeless…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP42	I felt ignored by people……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP44	I felt upset for no reason……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP45	I felt that nothing was interesting……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP46	I felt pessimistic…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP48	I felt that my life was empty……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP50	I felt guilty…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP54	I felt emotionally exhausted……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Fatigue – Calibrated Items

Please respond to each item by marking one box per row.

In the past 7 days...

		Never	Rarely	Sometimes	Often	Always
FATEXP02	How often did you feel run-down?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP05	How often did you experience extreme exhaustion?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP06	How often did you feel tired even when you hadn't done anything?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP07	How often did you feel your fatigue was beyond your control?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP16	How often were you sluggish?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP18	How often did you run out of energy?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP19	How often were you physically drained?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP20	How often did you feel tired?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days...

		Never	Rarely	Sometimes	Often	Always
FATEXP22	How often were you bothered by your fatigue?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP24	How often did you have enough energy to enjoy the things you do for fun?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
FATEXP26	How often were you too tired to enjoy life?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP28	How often were you too tired to feel happy?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP29	How often did you feel totally drained?....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP31	How often were you energetic?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
FATEXP48	How often did you find yourself getting tired easily?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP49	How often did you think about your fatigue?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP54	How often did you have physical energy?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

In the past 7 days....

		Never	Rarely	Sometimes	Often	Always
FATIMP03	How often did you have to push yourself to get things done because of your fatigue?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP04	How often did your fatigue interfere with your social activities?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP05	How often were you less effective at work due to your fatigue (include work at home)?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP06	How often did your fatigue make you feel slowed down in your thinking?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP08	How often were you too tired to watch television? …….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP09	How often did your fatigue make it difficult to plan activities ahead of time?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP10	How often did your fatigue make it difficult to start anything new?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP11	How often did your fatigue make you more forgetful?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days...

		Never	Rarely	Sometimes	Often	Always
FATIMP13	How often were you too tired to do errands?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP14	How often did your fatigue make it difficult to organize your thoughts when doing things at work (include work at home)?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP15	How often did your fatigue interfere with your ability to engage in recreational activities?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP16	How often did you have trouble finishing things because of your fatigue?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP17	How often did your fatigue make it difficult to make decisions?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP18	How often did you have to limit your social activities because of your fatigue?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days...

		Never	Rarely	Sometimes	Often	Always
FATIMP19	How often were you too tired to do your household chores?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP20	How often did your fatigue make you feel less alert?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP21	How often were you too tired to take a bath or shower?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP22	How often did your fatigue make it difficult to organize your thoughts when doing things at home?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP24	How often did you have trouble starting things because of your fatigue?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP25	How often was it an effort to carry on a conversation because of your fatigue?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP26	How often were you too tired to socialize with your family?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP29	How often were you too tired to leave the house?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days...

		Never	Rarely	Sometimes	Often	Always
FATIMP30	How often were you too tired to think clearly?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP33	How often did your fatigue limit you at work (include work at home)?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP40	How often did you have enough energy to exercise strenuously? ……	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
FATIMP42	How often were you less effective at home due to your fatigue?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP53	How often were you too tired to take a short walk?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP55	How often did you have to force yourself to get up and do things because of your fatigue?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP56	How often were you too tired to socialize with your friends?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days...

		Not at all	A little bit	Somewhat	Quite a bit	Very much
AN1	I feel listless ("washed out")……...	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
AN2	I feel tired……...	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
AN3	I have trouble starting things because I am tired……	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
AN4	I have trouble finishing things because I am tired……...	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
AN5	I have energy……..	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
AN7	I am able to do my usual activities…...….	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
AN8	I need to sleep during the day……...……	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
AN12	I am too tired to eat……	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
AN14	I need help doing my usual activities……	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
AN15	I am frustrated by being too tired to do the things I want to do……...…	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

In the past 7 days...

		Not at all	A little bit	Somewhat	Quite a bit	Very much
AN16	I have to limit my social activity because I am tired……..	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
FATEXP12	To what degree did you feel tired even when you hadn't done anything?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP13	How bushed were you on average?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP21	How fatigued were you when your fatigue was at its worst?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP34	How tired did you feel on average?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP35	How much were you bothered by your fatigue on average?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP36	How exhausted were you on average?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP38	How fatigued were you on the day you felt most fatigued?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days...

		Not at all	A little bit	Somewhat	Quite a bit	Very much
FATEXP40	How fatigued were you on average?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP41	How run-down did you feel on average?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP42	How much mental energy did you have on average?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
FATEXP43	How physically drained were you on average?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP44	How energetic were you on average?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
FATEXP45	How sluggish were you on average?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP50	How fatigued were you on the day you felt least fatigued?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP51	How easily did you find yourself getting tired on average?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP52	How wiped out were you on average?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days...

		Not at all	A little bit	Somewhat	Quite a bit	Very much
FATIMP01	To what degree did you have to push yourself to get things done because of your fatigue?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP02	To what degree did your fatigue make you feel slowed down in your thinking?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP27	To what degree did you have trouble starting things because of your fatigue?...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP28	How hard was it for you to carry on a conversation because of your fatigue?....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP34	To what degree did you have to limit your social activities because of your fatigue?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP35	To what degree did your fatigue make it difficult to organize your thoughts when doing things at home?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP36	To what degree did your fatigue make it difficult to start anything new?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days...

		Not at all	A little bit	Somewhat	Quite a bit	Very much
FATIMP37	Due to your fatigue were you less effective at work (include work at home)?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP38	To what degree did your fatigue make it difficult to make decisions?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP43	To what degree did your fatigue make it difficult to organize your thoughts when doing things at work (include work at home)?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP44	To what degree did your fatigue make you more forgetful?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP45	To what degree did your fatigue interfere with your ability to engage in recreational activities?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP47	To what degree did you have to force yourself to get up and do things because of your fatigue?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP48	To what degree did your fatigue interfere with your social activities?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days...

		Not at all	A little bit	Somewhat	Quite a bit	Very much
FATIMP49	To what degree did your fatigue interfere with your physical functioning?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP50	Did fatigue make you less effective at home?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP51	To what degree did you have trouble finishing things because of your fatigue?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP52	To what degree did your fatigue make you feel less alert?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
HI7	I feel fatigued……...…….	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
HI12	I feel weak all over ……..……	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

In the past 7 days…

		None	1 day	2-3 days	4-5 days	6-7 days
FATEXP46	On how many days was your fatigue worse in the morning?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

		None	Mild	Moderate	Severe	Very severe
FATEXP56	What was the level of your fatigue on most days?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Pain Behavior – Calibrated Items

Please respond to each item by marking one box per row.

In the past 7 days....

		Had no Pain	Never	Rarely	Sometimes	Often	Always
PAINBE2	When I was in pain I became irritable.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE3	When I was in pain I grimaced.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE6	When I was in pain I would lie down	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE8	When I was in pain I moved extremely slowly……..…….….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE9	When I was in pain I became angry ..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE11	When I was in pain I clenched my teeth……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE13	When I was in pain I tried to stay very still……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE16	When I was in pain I appeared upset or sad.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE17	When I was in pain I gasped……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

In the past 7 days....

		Had no Pain	Never	Rarely	Sometimes	Often	Always
PAINBE18	When I was in pain I asked for help doing things that needed to be done	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE21	When I was in pain it showed on my face (squinting eyes, opening eyes wide, frowning)……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE22	Pain caused me to bend over while walking……...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE23	When I was in pain I asked one or more people to leave me alone…..…	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE24	When I was in pain I moved stiffly ...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE25	When I was in pain I called out for someone to help me	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE26	Pain caused me to curl up in a ball	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE27	I had pain so bad it made me cry	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE28	When I was in pain I squirmed.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

In the past 7 days....

		Had no Pain	Never	Rarely	Sometimes	Often	Always
PAINBE29	When I was in pain I used a cane or something else for support.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE31	I limped because of pain.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE32	When I was in pain I became quiet and withdrawn	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE33	When I was in pain I frowned	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE34	When I was in pain I asked for help when walking or changing positions …	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE35	When I was in pain I groaned.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE37	When I was in pain I isolated myself from others.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE38	When I was in pain I drew my knees up	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE39	When I was in pain I moaned, whined or whimpered	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

In the past 7 days....

		Had no Pain	Never	Rarely	Sometimes	Often	Always
PAINBE40	When I was in pain I flung my arms or limbs around.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE41	When I was in pain I screamed.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE42	When I was in pain my upper body would tense up.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE43	When I was in pain I walked carefully.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE44	When I was in pain I bit or pursed my lips	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE45	When I was in pain I thrashed	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE46	When I was in pain I protected the part of my body that hurt	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE47	When I was in pain my body became stiff.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE48	When I was in pain I clenched my jaw or gritted my teeth.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

In the past 7 days....

		Had no Pain	Never	Rarely	Sometimes	Often	Always
PAINBE49	When I was in pain I winced	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE50	When I was in pain I moved my limbs protectively	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE51	When I was in pain I avoided physical contact with others	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

Pain Interference – Calibrated Items

Please respond to each item by marking one box per row.

In the past 7 days…

		Not at all	A little bit	Somewhat	Quite a bit	Very much
PAININ1	How difficult was it for you to take in new information because of pain?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ3	How much did pain interfere with your enjoyment of life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ5	How much did pain interfere with your ability to participate in leisure activities?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ6	How much did pain interfere with your close personal relationships?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ8	How much did pain interfere with your ability to concentrate?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ9	How much did pain interfere with your day to day activities?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ10	How much did pain interfere with your enjoyment of recreational activities?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days…

		Not at all	A little bit	Somewhat	Quite a bit	Very much
PAININ11	How often did you feel emotionally tense because of your pain?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ12	How much did pain interfere with the things you usually do for fun?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ13	How much did pain interfere with your family life?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ17	How much did pain interfere with your relationships with other people?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ18	How much did pain interfere with your ability to work (include work at home)?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ19	How much did pain make it difficult to fall asleep?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ20	How much did pain feel like a burden to you?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ22	How much did pain interfere with work around the home?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days…

		Not at all	A little bit	Somewhat	Quite a bit	Very much
PAININ31	How much did pain interfere with your ability to participate in social activities?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ34	How much did pain interfere with your household chores?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ35	How much did pain interfere with your ability to make trips from home that kept you gone for more than 2 hours?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ36	How much did pain interfere with your enjoyment of social activities?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ48	How much did pain interfere with your ability to do household chores?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ49	How much did pain interfere with your ability to remember things?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ56	How irritable did you feel because of pain?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ14	How much did pain interfere with doing your tasks away from home (e.g., getting groceries, running errands)?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
PAININ16	How often did pain make you feel depressed?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ24	How often was pain distressing to you?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ26	How often did pain keep you from socializing with others?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ29	How often was your pain so severe you could think of nothing else?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ32	How often did pain make you feel discouraged?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ37	How often did pain make you feel anxious?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ38	How often did you avoid social activities because it might make you hurt more?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ39	How often did pain make simple tasks hard to complete?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ40	How often did pain prevent you from walking more than 1 mile?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
PAININ42	How often did pain prevent you from standing for more than one hour?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ46	How often did pain make it difficult for you to plan social activities?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ47	How often did pain prevent you from standing for more than 30 minutes?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ50	How often did pain prevent you from sitting for more than 30 minutes?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ51	How often did pain prevent you from sitting for more than 10 minutes?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ52	How often was it hard to plan social activities because you didn't know if you would be in pain?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ53	How often did pain restrict your social life to your home?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ55	How often did pain prevent you from sitting for more than one hour?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	In the past 7 days…	Never	Once a week or less	Once every few days	Once a day	Every few hours
PAININ54	How often did pain keep you from getting into a standing position?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Physical Functioning – Calibrated Items

Please respond to each item by marking one box per row.

		Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
PFA10	Are you able to stand for one hour?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA11	Are you able to do chores such as vacuuming or yard work?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA12	Are you able to push open a heavy door?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA13	Are you able to exercise for an hour?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA14	Are you able to carry a heavy object (over 10 pounds)?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA15	Are you able to stand up from an armless straight chair?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA16	Are you able to dress yourself, including tying shoelaces and doing buttons?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA17	Are you able to reach into a high cupboard?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

		Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
PFA18	Are you able to use a hammer to pound a nail?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA19	Are you able to run or jog for two miles?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA20	Are you able to cut your food using eating utensils?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA21	Are you able to go up and down stairs at a normal pace?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA22	Are you able to open previously opened jars?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA23	Are you able to go for a walk of at least 15 minutes?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA25	Are you able to do yard work like raking leaves, weeding, or pushing a lawn mower?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA28	Are you able to open a can with a hand can opener?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

		Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
PFA29	Are you able to pull heavy objects (10 pounds) towards yourself?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA30	Are you able to step up and down curbs?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA31	Are you able to get up off the floor from lying on your back without help?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA32	Are you able to stand with your knees straight?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA33	Are you able to exercise hard for half an hour?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA34	Are you able to wash your back?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA35	Are you able to open and close a zipper?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA36	Are you able to put on and take off a coat or jacket?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA37	Are you able to stand for short periods of time?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

		Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
PFA38	Are you able to dry your back with a towel?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA39	Are you able to run at a fast pace for two miles?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA40	Are you able to turn a key in a lock?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA41	Are you able to squat and get up?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA42	Are you able to carry a laundry basket up a flight of stairs?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA43	Are you able to write with a pen or pencil?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA44	Are you able to put on a shirt or blouse?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA45	Are you able to get out of bed into a chair?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA47	Are you able to pull on trousers?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

		Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
PFA48	Are you able to peel fruit?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA49	Are you able to bend or twist your back?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA50	Are you able to brush your teeth?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA51	Are you able to sit on the edge of a bed?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA52	Are you able to tie your shoelaces?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA53	Are you able to run errands and shop?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA54	Are you able to button your shirt?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA55	Are you able to wash and dry your body?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA56	Are you able to get in and out of a car?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA8	Are you able to move a chair from one room to another?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

		Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
PFA9	Are you able to bend down and pick up clothing from the floor?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB10	Are you able to climb up five steps?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB11	Are you able to wash dishes, pots, and utensils by hand while standing at a sink?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB12	Are you able to make a bed, including spreading and tucking in bed sheets?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB13	Are you able to carry a shopping bag or briefcase?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB14	Are you able to take a tub bath?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB15	Are you able to change the bulb in a table lamp?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB16	Are you able to press with your index finger (for example ringing a doorbell)?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

		Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
PFB17	Are you able to put on and take off your socks?....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB18	Are you able to shave your face or apply makeup?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB19	Are you able to squeeze a new tube of toothpaste?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB20	Are you able to cut a piece of paper with scissors?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB21	Are you able to pick up coins from a table top?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB22	Are you able to hold a plate full of food?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB23	Are you able to pour liquid from a bottle into a glass?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB24	Are you able to run a short distance, such as to catch a bus? ……...	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

		Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
PFB25	Are you able to push open a door after turning the knob?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB26	Are you able to shampoo your hair?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB27	Are you able to tie a knot or a bow?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB28	Are you able to lift 10 pounds above your shoulder?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB29	Are you able to lift a full cup or glass to your mouth?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB30	Are you able to open a new milk carton?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB31	Are you able to open car doors?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB32	Are you able to stand unsupported for 10 minutes?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB33	Are you able to remove something from your back pocket?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

		Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
PFB34	Are you able to change a light bulb overhead?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB36	Are you able to put on a pullover sweater?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB37	Are you able to turn faucets on and off?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB39	Are you able to reach and get down a 5 pound object from above your head?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB40	Are you able to stand up on tiptoes?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB41	Are you able to trim your fingernails?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB42	Are you able to stand unsupported for 30 minutes?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB56	Are you able to lift one pound (a full pint container) to shoulder level without bending your elbow?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

		Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
PFB8	Are you able to carry two bags filled with groceries 100 yards?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB9	Are you able to jump up and down?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC13	Are you able to run 100 yards?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC29	Are you able to walk up and down two steps.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC31	Are you able to reach into a low cupboard?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC32	Are you able to climb up 5 flights of stairs?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC33	Are you able to run ten miles?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC38	Are you able to walk at a normal speed?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC39	Are you able to stand without losing your balance for several minutes?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC40	Are you able to kneel on the floor?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

		Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
PFC41	Are you able to sit down in and stand up from a low, soft couch?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC43	Are you able to use your hands, such as for turning faucets, using kitchen gadgets, or sewing?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC45	Are you able to get on and off the toilet?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC46	Are you able to transfer from a bed to a chair and back?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC47	Are you able to be out of bed most of the day?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC49	Are you able to water a house plant?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC51	Are you able to wipe yourself after using the toilet?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC52	Are you able to turn from side to side in bed?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC53	Are you able to get in and out of bed?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

		Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
PFC6	Are you able to walk a block on flat ground?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC7	Are you able to run five miles?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

		Not at all	Very little	Somewhat	Quite a lot	Cannot do
PFA1	Does your health now limit you in doing vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA3	Does your health now limit you in bending, kneeling, or stooping?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA4	Does your health now limit you in doing heavy work around the house like scrubbing floors, or lifting or moving heavy furniture?.	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA5	Does your health now limit you in lifting or carrying groceries?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA6	Does your health now limit you in bathing or dressing yourself?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA7	How much do physical health problems now limit your usual physical activities (such as walking or climbing stairs)?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

		Not at all	Very little	Somewhat	Quite a lot	Cannot do
PFB1	Does your health now limit you in doing moderate work around the house like vacuuming, sweeping floors or carrying in groceries? ……...	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB3	Does your health now limit you in putting a trash bag outside?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB43	Does your health now limit you in taking care of your personal needs (dress, comb hair, toilet, eat, bathe)? ……	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB44	Does your health now limit you in doing moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB48	Does your health now limit you in taking a shower?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB49	Does your health now limit you in going for a short walk (less than 15 minutes)?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB5	Does your health now limit you in hiking a couple of miles on uneven surfaces, including hills?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

		Not at all	Very little	Somewhat	Quite a lot	Cannot do
PFB51	Does your health now limit you in participating in active sports such as swimming, tennis, or basketball?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB54	Does your health now limit you in going OUTSIDE the home, for example to shop or visit a doctor's office?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB7	Does your health now limit you in doing strenuous activities such as backpacking, skiing, playing tennis, bicycling or jogging?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC10	Does your health now limit you in climbing several flights of stairs?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC12	Does your health now limit you in doing two hours of physical labor?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC20	Does your health now limit you in walking one hundred yards?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC34	Does your health now limit you in walking several hundred yards?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC35	Does your health now limit you in doing eight hours of physical labor?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

		Not at all	Very little	Somewhat	Quite a lot	Cannot do
PFC36	Does your health now limit you in walking more than a mile?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC37	Does your health now limit you in climbing one flight of stairs?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC54	Does your health now limit you in getting in and out of the bathtub?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC56	Does your health now limit you in walking about the house?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

		No difficulty at all	A little bit of difficulty	Some difficulty	A lot of difficulty	Can't do because of health
PFB50	How much difficulty do you have doing your daily physical activities, because of your health?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

Satisfaction with Participation in Discretionary Social Activities - Calibrated Items

Please respond to each item by marking one box per row.

In the past 7 days…

		Not at all	A little bit	Somewhat	Quite a bit	Very much
SRPSAT05	I am satisfied with the amount of time I spend doing leisure activities…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT10	I am satisfied with my current level of social activity…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT19	I am satisfied with my ability to do all of the community activities that are really important to me	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT20	I am satisfied with my ability to do things for my friends…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT23	I am satisfied with my ability to do leisure activities……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT25	I am satisfied with my current level of activities with my friends…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT33	I am satisfied with my ability to do things for fun outside my home…….....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days…

		Not at all	A little bit	Somewhat	Quite a bit	Very much
SRPSAT34	I feel good about my ability to do things for my friends……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT36	I am happy with how much I do for my friends…….....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT37	I am satisfied with the amount of time I spend visiting friends……...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT48	I am satisfied with my ability to do things for fun at home (like reading, listening to music, etc.)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT52	I am satisfied with my ability to do all of the leisure activities that are really important to me……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Satisfaction with Participation in Social Roles – Calibrated Items

Please respond to each item by marking one box per row.

In the past 7 days…

		Not at all	A little bit	Somewhat	Quite a bit	Very much
SRPSAT06	I am satisfied with my ability to do things for my family……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT07	I am satisfied with how much work I can do (include work at home)……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT08	I feel good about my ability to do things for my family…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT09	I am satisfied with my ability to do the work that is really important to me (include work at home)……...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT21	I am satisfied with the amount of time I spend doing work (include work at home)……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT22	I am happy with how much I do for my family……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT24	I am satisfied with my ability to work (include work at home)…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days…

		Not at all	A little bit	Somewhat	Quite a bit	Very much
SRPSAT35	The quality of my work is as good as I want it to be (include work at home) ……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT38	I am satisfied with the amount of time I spend performing my daily routines…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT39	I am satisfied with my ability to do household chores/tasks…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT47	I am satisfied with my ability to do regular personal and household responsibilities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT49	I am satisfied with my ability to perform my daily routines……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT50	I am satisfied with my ability to meet the needs of those who depend on me……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT51	I am satisfied with my ability to run errands……..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Sleep Disturbance – Calibrated Items

Please respond to each item by marking one box per row.

In the past 7 days...

		Not at all	A little bit	Somewhat	Quite a bit	Very much
Sleep105	My sleep was restful.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Sleep106	My sleep was light.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep107	My sleep was deep	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Sleep108	My sleep was restless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep115	I was satisfied with my sleep.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Sleep116	My sleep was refreshing.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Sleep125	I felt lousy when I woke up.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep20	I had a problem with my sleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep44	I had difficulty falling asleep.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep65	I felt physically tense at bedtime.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days…

		Not at all	A little bit	Somewhat	Quite a bit	Very much
Sleep67	I worried about not being able to fall asleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep68	I felt worried at bedtime	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep69	I had trouble stopping my thoughts at bedtime	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep70	I felt sad at bedtime	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep71	I had trouble getting into a comfortable position to sleep.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep72	I tried hard to get to sleep.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep78	Stress disturbed my sleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep86	I tossed and turned at night.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep93	I was afraid I would not get back to sleep after waking up.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
Sleep110	I got enough sleep	☐ 5	☐ 4	☐ 3	☐ 2	☐ 5
Sleep42	It was easy for me to fall asleep.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Sleep45	I laid in bed for hours waiting to fall asleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep50	I woke up too early and could not fall back asleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep87	I had trouble staying asleep.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep90	I had trouble sleeping.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep92	I woke up and had trouble falling back to sleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days…

		Very poor	Poor	Fair	Good	Very good
Sleep109	My sleep quality was	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

Sleep Related Impairment – Calibrated Items

Please respond to each item by marking one box per row.

	In the past 7 days...	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
Sleep10	I had a hard time getting things done because I was sleepy	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep11	I had a hard time concentrating because I was sleepy	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep119	I felt alert when I woke up	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Sleep120	When I woke up I felt ready to start the day	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Sleep123	I had difficulty waking up	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep124	I still felt sleepy when I woke up	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep18	I felt tired	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep25	I had problems during the day because of poor sleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep27	I had a hard time concentrating because of poor sleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days...

		Not at all	A little bit	Somewhat	Quite a bit	Very much
Sleep30	I felt irritable because of poor sleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep33	I had a hard time controlling my emotions because of poor sleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep4	I had enough energy	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Sleep6	I was sleepy during the daytime	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep7	I had trouble staying awake during the day.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days...

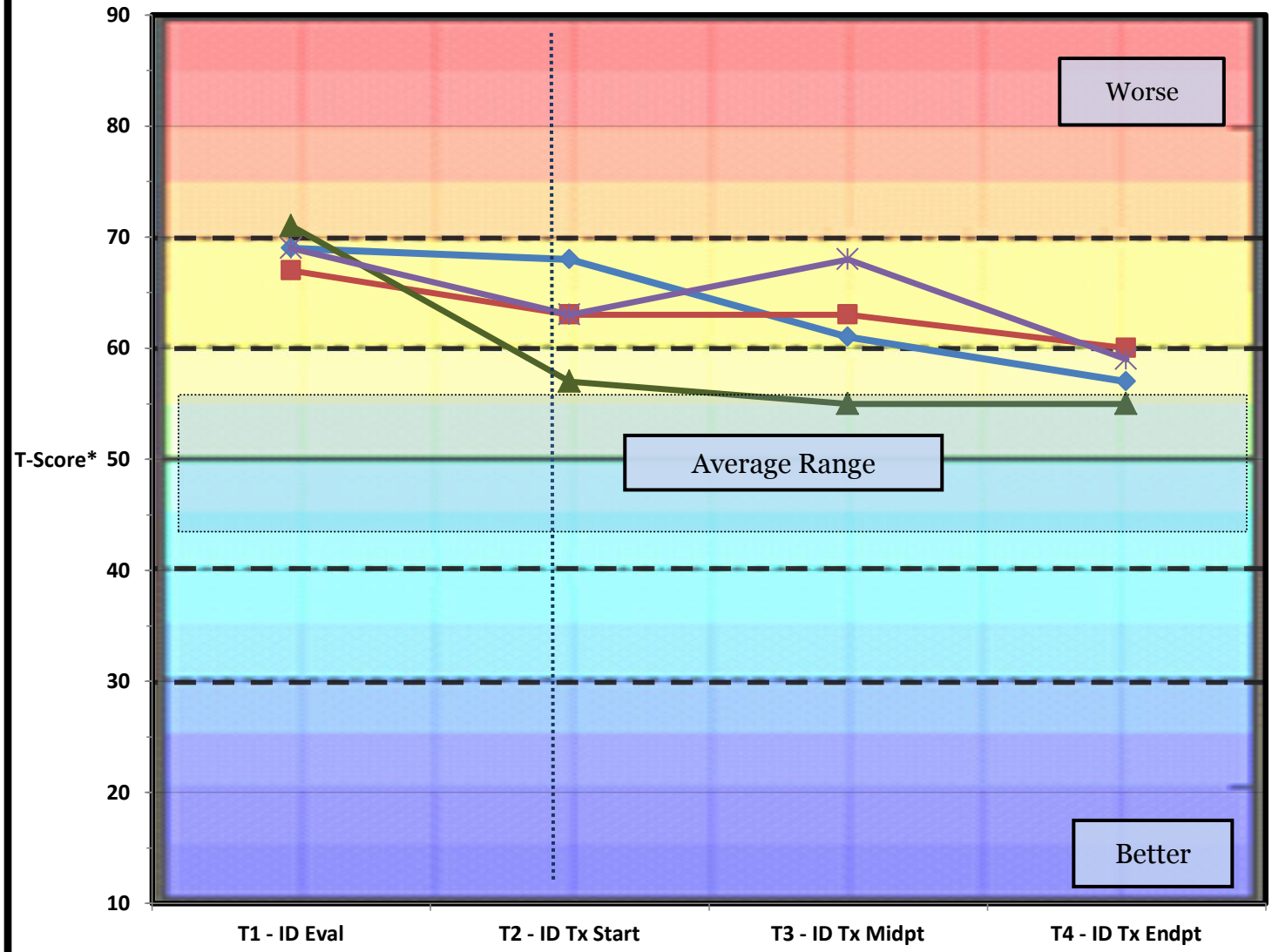
		Never	Rarely	Sometimes	Often	Always
Sleep19	I tried to sleep whenever I could	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep29	My daytime activities were disturbed by poor sleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Eric Swanholm
PhD Candidate in Clinical Psychology
Univ. of Texas Southwestern Med Center

McDermott Center for Pain Management:
Interdisciplinary Program Outcomes Research

Patient ID: *pid#*

Interdisciplinary Treatment Outcomes: Block 1



LEGEND

Outcome Measures

- Depressive Symptoms
- Anxiety Symptoms
- Anger
- Fatigue

Time-Point Reference

Time-point 1 (T1): Interdisciplinary (ID) Evaluation (3/11/11)

Time-Point 2 (T2): 1st Day of ID Treatment Program (4/5/11)

Time-point 3 (T3): Midpoint of ID Program (4/19/11)

Time-Point 4 (T4) : Endpoint of ID Program (4/29/11)

= Start of ID Treatment Program

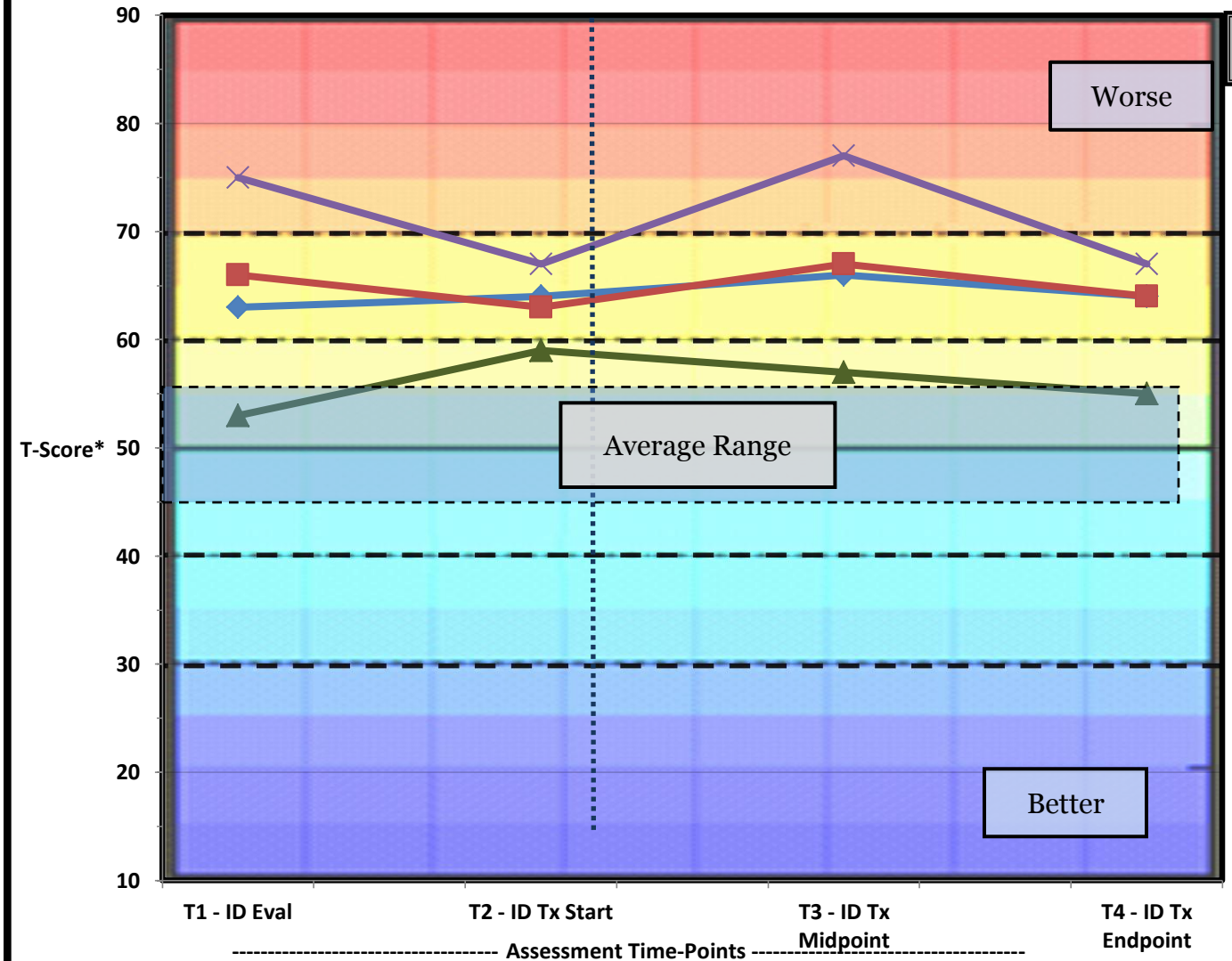
*Block 1 Measures are from the NIH Patient-Reported Outcomes Measurement Information System (PROMIS) Initiative www.nih-promis.org

Eric Swanholm
PhD Candidate in Clinical Psychology
Univ. of Texas Southwestern Med Center

McDermott Center for Pain Management:
Interdisciplinary Program Outcomes Research

Patient ID: *pid#*

Interdisciplinary Treatment Outcomes: Block 2



LEGEND

Outcome Measures

- Pain Behavior
- Pain Interference
- Sleep Disturbance
- Sleep-Related Impairment

Time-Point Reference

Time-point 1 (T1): Interdisciplinary (ID) Evaluation (3/11/11)

Time-Point 2 (T2): 1st Day of ID Treatment Program (4/5/11)

Time-point 3 (T3): Midpoint of ID Program (4/19/11)

Time-Point 4 (T4) : Endpoint of ID Program (4/29/11)

= Start of ID Treatment Program

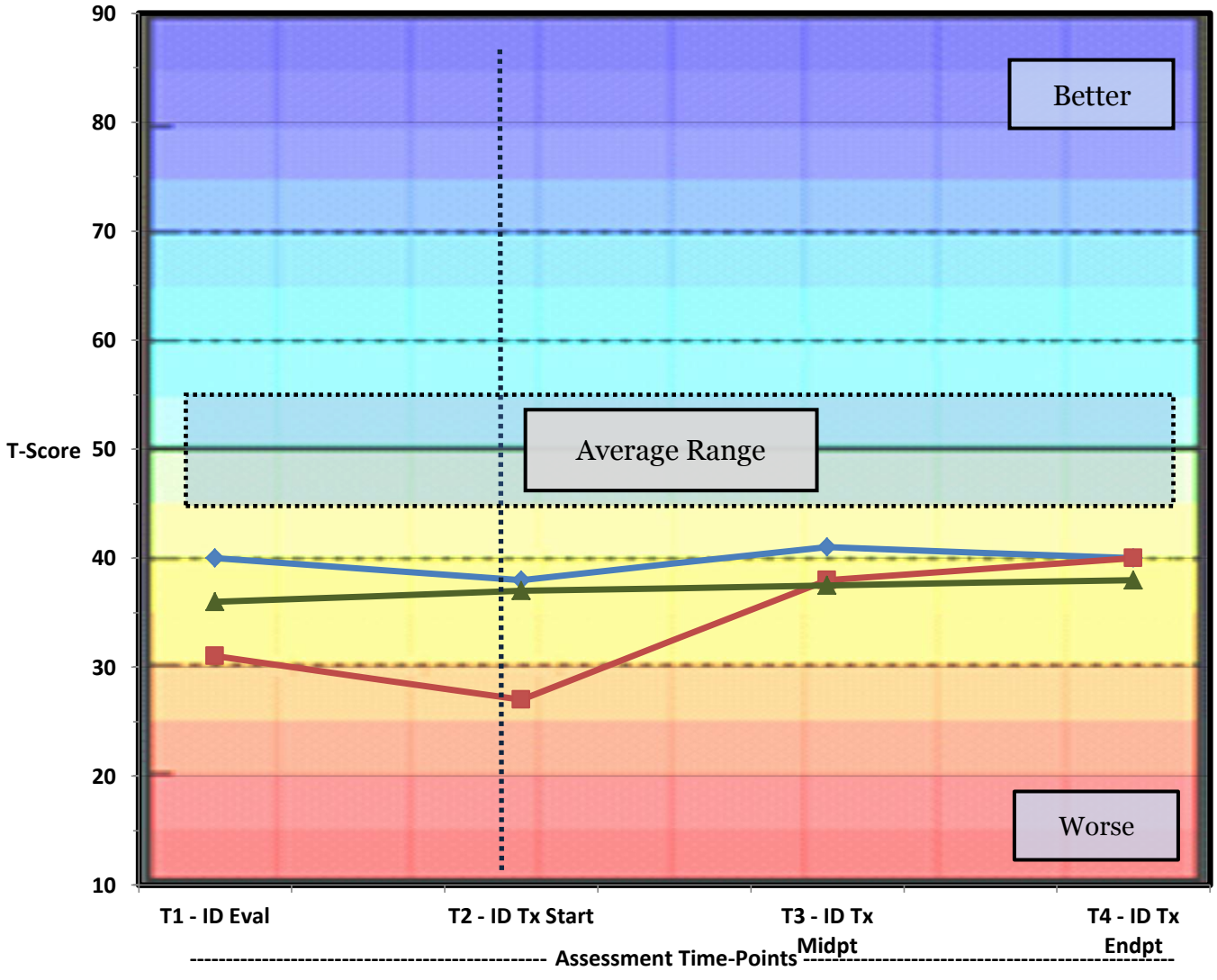
*Block 2 Measures are from the NIH Patient Reported Outcomes Measurement Information System (PROMIS) www.nih.promis.org

Eric Swanholm
PhD Candidate in Clinical Psychology
Univ. of Texas Southwestern Med Center

McDermott Center for Pain Management:
Interdisciplinary Program Outcomes Research

Patient ID: *pid#*

Interdisciplinary Treatment Outcomes: Block 3



LEGEND

Outcome Measures

- Physical Functioning
- Satisfaction with Discretionary Social Activities
- Satisfaction with Social Roles

Time-Point Reference

Time-point 1 (T1): Interdisciplinary (ID) Evaluation (3/11/11)

Time-Point 2 (T2): 1st Day of ID Treatment Program (4/5/11)

Time-point 3 (T3): Midpoint of ID Program (4/19/11)

Time-Point 4 (T4): Endpoint of ID Program (4/29/11)

= Start of ID Treatment Program

*Block 3 Measures are from the NIH Patient Reported Outcomes Measurement Information System (PROMIS) Initiative www.nih.promis.org

Interdisciplinary Patient Outcomes:

Block 4

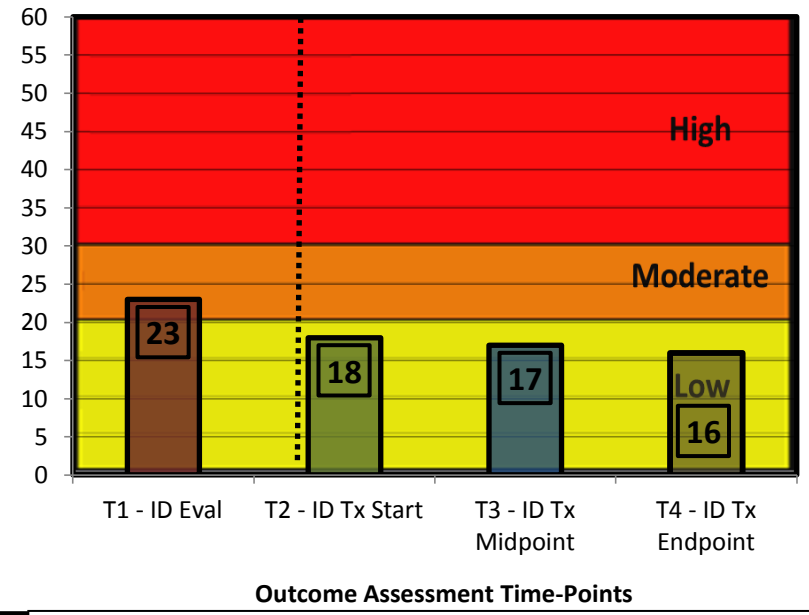
LEGEND

Time-point 1 (T1): Interdisciplinary (ID) Evaluation (3/11/11)
Time-Point 2 (T2): 1st Day of ID Treatment Program (4/5/11)
Time-point 3 (T3): Midpoint of ID Treatment Program (4/19/11)
Time-Point 4 (T4): Endpoint of ID Treatment Program (4/29/11)

..... = Start of ID Treatment Program

Opioid Misuse Risk

Pain Medication Questionnaire

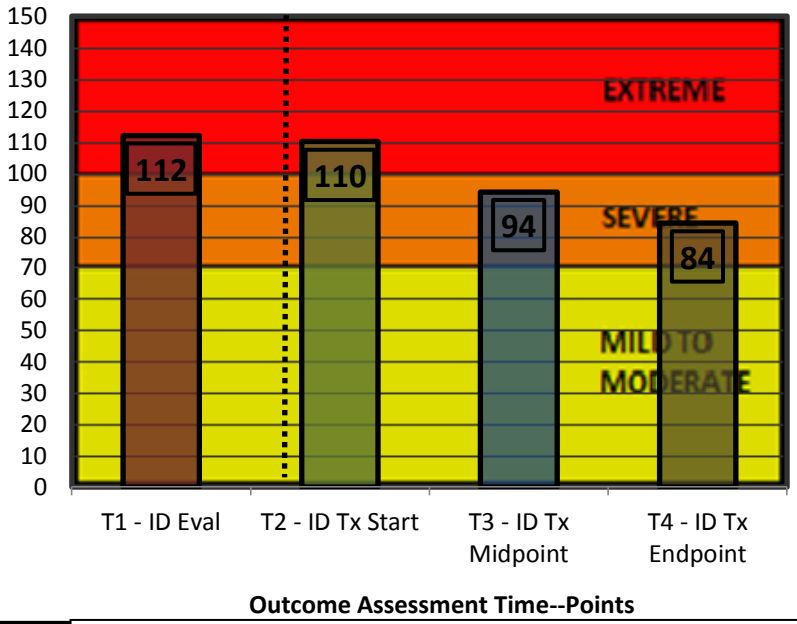


Outcome Assessment Time-Points

Pain Medication Questionnaire: Adams, Gatchel, Robinson et al., 2004

Pain-Related Functional Disability

Pain Disability Questionnaire



Outcome Assessment Time--Points

Pain Disability Questionnaire: Anagnostis, Gatchel, & Mayer, 2004

Eric Swanholm, PhD Candidate in Clinical Psychology
Univ. of Texas Southwestern Med Center

Questionnaire Summary Report

Your age: 28 **Your gender: Female**

Computerized Adaptive Tests: Anger, Anxiety, Depressive Symptoms, Fatigue, Pain Behavior, Pain Interference, Physical Function, Satisfaction with Discretionary Social Activities, Sleep-Related Impairment

For every questionnaire, the average score is 50 in the US general population.

Your estimated score on the Anger questionnaire is 62. Your estimated score indicates that your level of Anger is higher (worse) than:

- **90 percent of people in the general population**
- **82 percent of people age < 35**
- **89 percent of females**

Your estimated score on the Anxiety questionnaire is 56. Your estimated score indicates that your level of Anxiety is higher (worse) than:

- **74 percent of people in the general population**
- **64 percent of people age < 35**
- **70 percent of females**

Your estimated score on the Depression questionnaire is 60. Your estimated score indicates that your level of Depressive Symptoms is higher (worse) than:

- **84 percent of people in the general population**
- **75 percent of people age < 35**
- **81 percent of females**

Your estimated score on the Fatigue questionnaire is 68. Your estimated score indicates that your level of Fatigue is higher (worse) than:

- **96 percent of people in the general population**
- **96 percent of people age < 35**
- **95 percent of females**

Your estimated score on the Pain Behavior questionnaire is 63. Your estimated score indicates that your level of Pain Behavior is higher (worse) than:

- **92 percent of people in the general population**
- **94 percent of people age < 35**
- **91 percent of females**

Your estimated score on the Pain Interference questionnaire is 67. Your estimated score indicates that your level of Pain Interference is higher (worse) than:

- **94 percent of people in the general population**
- **97 percent of people age < 35**
- **93 percent of females**

Your estimated score on the Physical Function questionnaire is 33. Your estimated score indicates that your level of Physical Function is higher (better) than:

- **6 percent of people in the general population**
- **1 percent of people age < 35**
- **8 percent of females**

Your estimated score on the Social Activity questionnaire is 42. Your estimated score indicates that your level of Satisfaction with Discretionary Social Activities is higher (better) than:

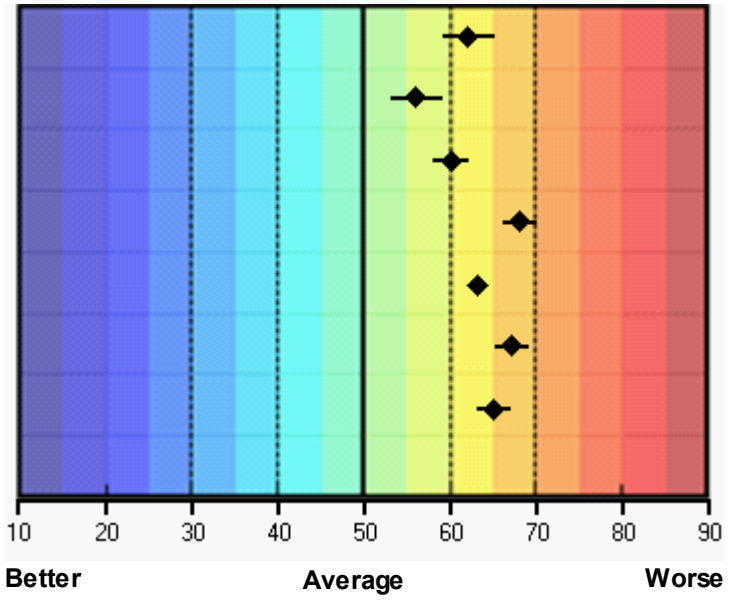
- **23 percent of people in the general population**
- **26 percent of people age < 35**
- **26 percent of females**

Your estimated score on the Sleep-Related Impairment questionnaire is 65. Your estimated score indicates that your level of Sleep-Related Impairment is higher (worse) than:

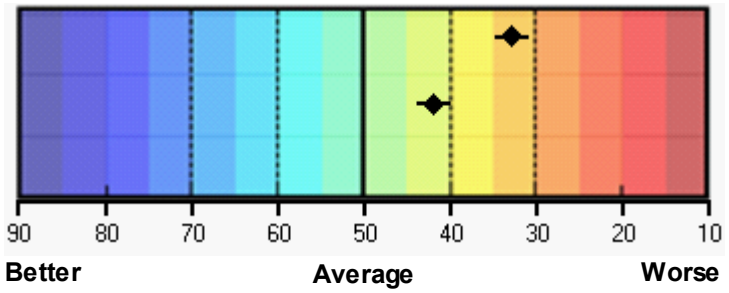
- **93 percent of people in the general population**
- **87 percent of people age < 35**
- **88 percent of females**

Your scores for the CATs you completed are shown below.

	Your Score	SE
Anger	62	3
Anxiety	56	3
Depressive Symptoms	60	2
Fatigue	68	2
Pain Behavior	63	1
Pain Interference	67	2
Sleep-Related Impairment	65	2



	Your Score	SE
Physical Function	33	2
Satisfaction with Discretionary Social Activities	42	2



The diamond is your estimated score. For each of the areas above, a score of 50 is average for the United States general population. Most people will score between 40 and 60 and almost all people will score between 30 and 70.
The Standard Error (SE) is a statistical measure of variance and represents a "margin of error" around your estimated score. The lines on either side of each diamond reflect the likely range of your actual score.