PSYCHOSOCIAL VARIABLES IN OUTPATIENTS

RECEIVING INTRATHECAL BACLOFEN OR

PAIN-PUMP THERAPY

APPROVED BY SUPERVISORY COMMITTEE

Robert Gatchel, Ph.D., ABBP

Martin Deschner, Ph.D.

Fatma Gul, M.D.

Cara Holmes, Ph.D.

Betsy Kennard, Psy.D.

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PSYCHOSOCIAL VARIABLES IN OUTPATIENTS RECEIVING INTRATHECAL BACLOFEN OR PAIN-PUMP THERAPY

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DEIDRE MARIE EDWARDS

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DEIDRE MARIE EDWARDS, M.S.

The University of Texas Southwestern Medical Center at Dallas, 2012

ROBERT J. GATCHEL, Ph.D., ABBP

Numerous studies have demonstrated that patients suffering from chronic health conditions are at an increased risk for experiencing psychosocial distress and developing psychological difficulties. Spasticity, a chronic condition generally defined as an increase in muscle tone while at rest, is frequently observed in a variety of medical populations. Spasticity is not only painful, it can also significantly impair mobility, daily functioning, and quality of life. Intrathecal baclofen and pain pump therapy have been viable treatment options for those patients with severe spasticity who have not responded to less invasive treatments. Several small studies have examined quality of life and

patient-reported efficacy for spasticity patients receiving implantable intrathecal baclofen (ITB) therapy. However, no research has examined what variables may play a role in quality of life outcomes for spasticity patients across and between the varied diagnostic populations treated with ITB or baclofen pain-pump therapy in a large sample. The proposed study examined several psychosocial variables (e.g. health-related quality of life [HRQOL], level of social functioning, self-reported levels of optimism/pessimism) and psychological variables (e.g. depressive and other psychiatric symptoms, as well as self-reported pain ratings) within a heterogeneous population of patients that receive ongoing care with intrathecal baclofen or baclofen pain-pump therapy. A sample of 125 adults, aged 19 - 82 years (M=49.06) who had been treated with ITB and other intrathecal pain medications, were assessed. Participants individually completed a packet of questionnaires measuring the primary study constructs. Analyses (One-way ANOVAs and t-tests) showed that the sample differed greatly from the normative population across measures of depression, quality of life, pain, and social functioning. Additionally, group differences were discovered between subgroups of spasticity patients. Multiple regression analyses showed that higher satisfaction with one's social roles, lower levels of feeling limited in one's roles by his/her emotional health, and higher rates of vitality were predictive of quality of life.

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Edwards, D.M., Gatchel, R.J., Adams, L.L., & Stowell, A.W. (2006). Emotional distress and medication use in two acute pain populations: Jaw and low back. *Pain Practice*, 6(4), 242-253.

Edwards, D.M., Hale, K.L., Maddux, R.E., & Rapaport, M.H. (2008). Anxiolytic Drugs. In A. Tasman, M. Maj, M.B. First, & J.A. Lieberman (Eds.), *Psychiatry* (3rd ed.) (pp. 2224-2253). New York: Wiley.

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LIST OF ABBREVIATIONS

ADLs – Activities of Daily Living

CHI – Closed Head Injury

CP – Cerebral Palsy

CSF – Cerebrospinal Fluid

DSM – Diagnostic and Statistical Manual of Mental Disorders

EMG - Electromyography

FDA – The U.S. Food and Drug Administration

GABA – Gamma-Amino Butyric Acid

HBI – Hypoxic Brain Injury

HRQOL – Health-Related Quality of Life

IRB – Internal Review Board at UTSW

ITB – Intrathecal Baclofen

LOT-R – Life Orientation Test – Revised

MS – Multiple Sclerosis

NIH – National Institute of Health

PID - Participant Identification Number

PM&R Clinic – Zale Lipshy Physical Medicine & Rehabilitation Clinic at UTSW

PROMIS – Patient Reported Outcome Measurement Information System

PROMIS-F – PROMIS Fatigue Item Bank Version 1.0

PROMIS-PB – PROMIS Pain Behavior Item Bank Version 1.0

PROMIS-PI – PROMIS Pain Interference Item Bank Version 1.0

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

PROMIS-SR – PROMIS Satisfaction with Social Roles Activities Item Bank Version 1.0

QALY - Quality-Adjusted Life Year

QIDS-SR – Quick Inventory of Depressive Symptoms – Self-Report

QOL – Quality of Life

QWB-SA – Quality of Well-Being Scale – Self-Administered

SCI – Spinal Cord Injury

SF-36 – The Short-Form Health Survey - 36

TBI – Traumatic Brain Injury

UTSW – University of Texas Southwestern Medical Center of Dallas

CHAPTER ONE

Introduction

Numerous studies have demonstrated that patients suffering from chronic health conditions are at an increased risk for experiencing psychosocial distress and developing psychological difficulties (Beasley and Beardslee, 1998; DiMatteo, Lepper, and Croghan, 2000; Merry, McDowell, Wild, Bir, and Cunliffe, 2004; Panzarino, 1998; President's New Freedom Commission on Mental Health, 2003; Wells et al., 1988). The presence of a comorbid psychological disorder has been shown to have a negative impact on health outcomes, including quality of life, self-care, adherence to medication regimens, and overall functioning (Bender, 2006; DiMatteo, Lepper, & Croghan, 2000; Dowson, Town, Frampton, & Mulder, 2004; Katon & Ciechanowski, 2002; Stein, Cox, Afifi, Belik, & Sareen, 2006; Whittemore, Kanner, Singleton, Hamrin, Chiu, & Grey, 2002). For example, research has shown that depressed patients are less adherent to medical regimens, more likely to miss clinic appointments, more likely to engage in health-risk behaviors such as smoking and drinking, report worse health-related quality of life, have more work absences, show higher levels of functional disability, and have higher healthcare utilization and healthcare costs compared to patients without psychological difficulties (Bender, 2006; DiMatteo, Lepper, & Croghan, 2000; Dowson, Town, Frampton, & Mulder, 2004; Katon & Ciechanowski, 2002; Stein, Cox, Afifi, Belik, & Sareen, 2006; Whittemore, Kanner, Singleton, Hamrin, Chiu, & Grey, 2002). Several studies have indicated that identification and treatment of psychological and psychosocial difficulties in medical illnesses positively influence medical outcomes and quality of life

(Benton, Staab, and Evans, 2007; Narasimhan, Raynor, and Blackmon Jones, 2008; Shemesh, Bartell, and Newcorn, 2002).

Spasticity, a chronic condition generally defined as an increase in muscle tone while at rest, is frequently observed in a variety of medical populations. Spasticity is not only painful, it can also significantly impair mobility, daily functioning, and quality of life. Intrathecal baclofen and pain pump therapy have been viable treatment options for those patients with severe spasticity who have not responded to less invasive treatments (Penn, 1992). Several small studies have examined quality of life and patient-reported efficacy for spasticity patients receiving implantable intrathecal baclofen (ITB) therapy (Rizzo, et al., 2004; Staal, Arends, & Ho, 2003). However, no research has examined what variables may play a role in quality of life outcomes for spasticity patients across and between the varied diagnostic populations treated with ITB or pain-pump therapy, nor have they examined this population in a larger sample size. Specifically, there is a dearth of research examining psychosocial factors in this population and their impact on quality of life with solid sample sizes.

CHAPTER TWO

Review of the Literature

SPASTICITY

Characteristics of Spasticity

Spasticity is a condition in which there is an abnormal increase in muscle tone or stiffness of muscle, which might interfere with movement and speech and has been associated with discomfort or pain (Barnes, 1998; National Institute of Neurological Disorders and Stroke, 2011). Spasticity is usually caused by damage to nerve pathways within the brain or spinal cord that control muscle movement. Symptoms may include increased muscle tone (hypertonicity), rapid muscle contractions (clonus), exaggerated deep tendon reflexes, muscle spasms, weakness and clumsiness of voluntary muscles, involuntary crossing of the legs (scissoring), and fixed joints (contractures) (Barnes, 1998; National Institute of Neurological Disorders and Stroke, 2011). The degree of spasticity varies from mild muscle stiffness to severe, painful, and uncontrollable muscle spasms and can be affected by a variety of factors, such as medication use or level of fatigue and stress (Barnes, 1998; National Institute of Neurological Disorders and Stroke, 2011). Spasticity can interfere with many aspects of patient functioning, including mobility, employment, activities of daily living, and sleep (Vanek & Menkes, 2010).

Common Conditions Related to Spasticity

Spasticity is frequently seen in patients with multiple sclerosis (MS), cerebral palsy (CP), stroke, spinal cord injury (SCI), hypoxic brain injury (HBI), and traumatic

brain injury (TBI). MS is a central nervous system disease that affects 40,000 people in the United States and 2.1 million people worldwide (National Multiple Sclerosis Society, website accessed October 5, 2010). Rizzo, Hadjimichael, Preiningerova, & Vollmer (2004) estimated that 34% of people with MS have spasticity that affects their daily functioning. A similar trend of impaired daily functioning is also seen in those diagnosed with CP, a movement and posture disorder caused by a defect to the developing brain that affects 764,000 Americans (United Cerebral Palsy, website accessed October 5, 2011). It is estimated that approximately 70 to 80% of people living with CP also have spasticity (CDC, website accessed October 5, 2011) and that at least 60% of those with spasticity experience functional limitations in their daily living (Kennes, et al., 2002).

Spasticity can also result from various injuries to the brain and spine. This includes the 1.17 million Americans who have suffered a traumatic brain injury each year (Center for Disease Control website: Cerebral Palsy, Accessed October 5, 2011). Spasticity occurs in approximately 53% of TBI patients who have a lesion in the mid-brain and in 17% of those who have no such lesion, and has been described as one of the most disabling aspects of brain injury (Wedekind & Lippert-Gruner, 2005). Another cause of spasticity is the occurrence of a stroke, which results when blockages in a blood vessel prevents blood from flowing to portions of the brain. Approximately 7 million people in the United States over the age of twenty have suffered a stroke (American Heart Association, website accessed October 5, 2010), with a reported 38% experiencing spasticity one year following the stroke (Watkins, Leathley, Gregson, Moore, Smith, & Sharma, 2002).

With regards to spinal injuries, there is an estimated 259,000 people in the United States who report having SCI (Foundation for Spinal Cord Prevention, Care, and Cure, website

accessed October 5, 2011). Severe spasticity has been described by 12% of this population (Anson & Shepherd, 1996).

Assessment of Spasticity

Physical examination is central to the assessment of spasticity and its severity (Mostoufi, 2009). Physical examination includes patient observation, affected limb palpitation, range of motion assessment, deep tendon reflexes evaluation, clinical tests, and spastic symptom detection (i.e., clonus, clasp-knife phenomenon, spastic catch; Mostoufi, 2009). Since spasticity symptoms fluctuate over the course of underlying etiology, serial examination with careful follow-up and treatment adjustment is often required.

Spasticity scales, such as the most commonly used Ashworth Scale or Modified Ashworth Scale, can define spasticity in measurable terms for monitoring treatment and detecting worsening of symptoms (Mostoufi, 2009).

Treatment Interventions

Treatment options for spasticity include therapeutic interventions (e.g., physical therapy, occupational therapy, speech therapy); physical modalities (e.g., ultrasonography, electrical stimulation, biofeedback); positioning or orthotics (e.g., taping, splints, wheelchairs, standers); surgical intervention (e.g., tenotomy, osteotomy, myelotomy, rhizotomy, spinal cord stimulator, neurosurgery); and medications (Moberg-Wolff, 2008). Because spasticity may be triggered by exacerbating factors, such as infection, pressure sores, painful stimuli, deep vein thrombosis, bladder distention, bowel

impaction, cold weather, seizure activity, stress, and poor positioning, treatment should include the prevention or control of exacerbating factors, (Moberg-Wolff, 2008).

Medication Interventions

Common oral medications for the treatment of spasticity include skeletal muscle relaxants (e.g., dantrolene, baclofen), tizanidine, and benzodiazepines (e.g., diazepam; Moberg-Wolff, 2009).

Dantrolene works by interfering with the release of calcium from the sarcoplasmic reticulum of skeletal muscle, thereby reducing muscle tone, clonus, and spasm. According to the Food and Drug Administration (FDA) approved labeling, dantrolene is indicated for controlling the manifestations of clinical spasticity resulting from upper motor neuron disorders; therefore, it is particularly effective in patients who have spasticity of supraspinal origin, such as traumatic brain injury or cerebral palsy (Vanek & Menkes, 2010).

The medication baclofen is considered by some clinicians to be the preferred drug for spasticity symptoms in spinal cord injury or multiple sclerosis. It is also useful for patients with cerebral palsy (Moberg-Wolff, 2008). The oral form of baclofen has FDA approval for the management of general spasticity, while intrathecal baclofen is recommended for severe spasticity. Baclofen is a synthetic agonist of the neurotransmitter gammaaminobutyric acid (GABA) that acts at the spinal cord level to inhibit the release of excitatory neurotransmitters thereby improving clonus, flexor spasm frequency, and joint range of motion (Vanek & Menkes, 2010), while simultaneously reducing spinal reflex action (Campbell, Ferrel, McLaughlin, et al., 2002). Results of

studies in patients with spasticity of spinal origin indicated that oral baclofen was able to improve spasticity in 70% to 87% of patients and spasms in 75% to 96% of patients (Dario & Tomei, 2004). Additionally, results of one study of oral baclofen in children with cerebral palsy (mean age of 7.4 years) found that it was significantly better than placebo in improving goal-oriented tasks in children with spastic quadriplegic cerebral palsy (Scheinberg, Hall, Lam, et al., 2006).

Tizanidine, a centrally-acting α_2 adrenergic agonist, is another oral agent with FDA approved labeling for the management of spasticity. Tizanidine improves spasms and clonus by decreasing excitatory input to alpha motor neurons (Vanek & Menkes, 2010). Research has shown that tizanidine is useful in the management of spasticity caused by multiple sclerosis, acquired brain injury, spinal cord injury, and stroke (Malanga, Reiter, & Garay, 2008). In a meta-analysis comparing tizanidine with oral baclofen and diazepam, tizanidine was found to have similar efficacy and greater tolerability (Groves, Shellenberger, & Davis, 1998).

Benzodiazepines are effective at enhancing the inhibitory effects of GABA, resulting in the reduction of spinal reflexes. The benzodiazepine diazepam has FDA-approved labeling for management of spasticity caused by upper neuron disorders and may improve passive ROM, and reduce hyperreflexia and spasms (Vanek & Menkes, 2010). Although, diazepam is primarily used in patients with spasticity of spinal origin, it has also been found to be useful in children with spastic cerebral palsy (Moberg-Wolff, 2008; Mathew & Mathew, 2005).

While several injectable medications have been used to abate the symptoms of spasticity, with the exception of intrathecal baclofen, none currently have FDA-approved

labeling for its treatment. An example of one such injection is the phenol nerve block. This medication lasts for approximately six months and works by temporarily demyelinating gamma fibers, resulting in a weakened muscle that can be stretched more easily (Botte, Abrams, & Bodine-Fowler, 1995). Phenol nerve block is most advantageous in the period immediately following traumatic brain injury or spinal cord injury, when increased muscle tone is often most severe (Botte, Abrams, & Bodine-Fowler, 1995). Another injection, botulinum toxin inhibits the presynaptic release of acetylcholine at the neuromuscular junction, thereby impairing muscle contraction. Its effects are temporary because collateral sprouting of the axon occurs after approximately three months (Moberg-Wolff, 2008). Despite controversy surrounding its safety and efficacy, the Academy of Neurology recommends offering botulinum toxin as a treatment option for both children and adults (Simpson & Gracies, 2008). This may be due in part to the finding of various clinical trials that support the use of botulinum toxin for the treatment of spasticity caused by cerebral palsy, multiple sclerosis, stroke, spinal cord injury, and brain injury (Vanek & Menkes, 2010).

INTRATHECAL BACLOFEN

Although oral baclofen is a mainstay of therapy for spasticity, it may not be effective for all patients, particularly for those patients with severe spasticity. This lack of therapeutic efficacy is likely due to inadequate penetration of the blood brain barrier by the oral formulation (Vanek & Menkes, 2010). Adverse events, such as sedation, ataxia, respiratory, and cardiovascular depression, preclude sufficient dosage escalations of oral

baclofen to levels that would alleviate spasticity in patients with severe spasticity (Vanek & Menkes, 2010).

Intrathecal baclofen provides a treatment alternative for patients whose spasticity is not controlled by oral medications. Intrathecal baclofen therapy bypasses the blood brain barrier and overcomes oral penetration issues by delivering the medication directly into the intrathecal space (Vanek & Menkes, 2010). With the intrathecal route, much smaller doses of baclofen are required, thus reducing adverse effects and enhancing therapeutic responses such as reduced muscle tone, spasms and pain, and improved mobility (Sadiq & Wang, 2006; Vanek & Menkes, 2010). Intrathecal baclofen is indicated in severe spasticity of spinal or cerebral origin, which includes the treatment of spasticity secondary to stroke, multiple sclerosis, cerebral palsy, and spinal cord injury (Deer, Raso, & Garten, 2007). Results of an 8-month study evaluating the efficacy of continuous intrathecal baclofen therapy in 30 patients with spasticity indicate that intrathecal baclofen had a beneficial effect on clinical response, QOL, pain, and patient satisfaction (Guglielmino, Sorbello, Fazzio, et al., 2006). No major adverse events were reported; however, one case of baclofen tolerance, which was resolved by a baclofen holiday, and one case of pump failure, which was resolved by pump replacement, were reported (Guglielmino, Sorbello, Fazzio, et al., 2006). Additional clinical studies have demonstrated long-term safety in patients with severe spasticity of spinal origin (age 8 years or older) and of cerebral origin (age 12 years or older; Penn, 1992; Albright, Gilmartin, Swift, et al., 2003).

Commercially available baclofen injection concentrate (Lioresal intrathecal, Medtronic, Minneapolis, MN) has FDA-approved labeling for intrathecal administration

via a compatible infusion device (Medtronic). Intrathecal baclofen may be administered through an implantable infusion pump that can be programmed to deliver therapeutic levels of active drug to the CSF. Programmable pumps are implanted in a subcutaneous pocket and are connected to a catheter, through which the medication is delivered. Constant or variable rate infusions are possible over long periods of time, while allowing for external control of the rate of drug delivery. Thus, the pumps can be programmed to provide a wide range of infusion rates, depending on a patient's specific needs (National Library of Medicine, 2009). When given intrathecally, baclofen reaches effective cerebrospinal fluid (CSF) drug concentrations with resultant plasma baclofen concentrations that are 100 times lower than that of oral administration (Medtronic).

To qualify for intrathecal baclofen therapy, a patient must have spasticity of spinal or cerebral origin that causes significant impairment and is unresponsive to treatment with oral medications, local injection therapy, and physical modalities (Ridley & Rawlins, 2006). In addition, the patient, family members, and healthcare providers must all agree that the patient's spasticity poses a significant problem that affects his/her functioning.

QUALITY OF LIFE IN SPASTICITY PATIENTS RECEIVING ITB

Several studies have examined quality of life and patient-reported efficacy for spasticity and pain in subjects receiving implantable intrathecal baclofen (ITB) and pain pump therapy. Results indicated that ITB therapy was cost-effective and likely to improve quality of life in patients with severe spasticity and disability (Becker, Harris,

Long, Ablett, Klein, & DeForge, 1995). One such study, compared a self-reported rating of quality of life between groups of MS spasticity patients who were receiving either ITB (n=198) or oral medications (n=315) (Rizzo, Hadjimichael, Preiningerova, & Vollmer, 2004). This study evaluated quality of life (QOL) using the Short-Form 36, a widely-accepted measure that assesses global and domain-specific QOL. This study of MS patients found that spasticity led approximately one-third to modify or eliminate daily activities, regardless of their medication group. Compared to the oral medication only group, ITB patients reported significantly greater quality of life in multiple domains, with the most notable differences on the physical component of the SF-36. Results also indicated that patient quality of life had a significant and inverse relationship with their severity of spasticity (Rizzo, Hadjimichael, Preiningerova, et al., 2004). An additional study reported that the majority of ITB therapy patients participating (88%) believed that their quality of life had improved with this treatment (Staal, Arends, & Ho, 2003).

A literature review published in 2003 examined study results in ITB therapy patients between 1984 and 2002 (Emery, 2003). The authors concluded that ITB therapy was related to improvement in patient functionality and quality of life. However, their review did not find studies that comprehensively examined QOL and other related psychosocial variables, i.e., what factors influence quality of life levels (Emery, 2003). Another literature review from 2002 reported that patients who had not responded to less invasive treatments gained worthwhile functional benefits from continuous intrathecal baclofen infusion (Sampson, Hayward, Evans, Morton, & Collett, 2002). In addition, a number of studies have reported that untreated spasticity in MS and spinal cord injury (SCI) patients significantly affects their general functionality (Gianino, York, Paice, &

Shott, 1998). Given that ITB therapy has been shown to dramatically reduce spasticity, it has been inferred that ITB therapy leads to parallel increases in patient QOL; however, there have been a limited number of studies that have expressly examined QOL or other psychosocial variables since 2003.

In contrast, a separate study from 2004 yielded results inconsistent with those from other studies in this area of research (Zahavi, et al., 2004). This 5-year observational study followed severe spasticity patients who were receiving intrathecal baclofen pump therapy. Findings indicated that long-term therapy resulted in improvements in clinical efficacy but not in the study patients' disability or perceived health status (Zahavi, Geertzen, Middel et al., 2004). The lack of improvement that was found in this long-term study highlights a shortage of consistency between studies of ITB, spasticity, and QOL. This discrepancy points to the need for additional studies that can begin to identify other significant variables that may play a role in QOL outcomes for spasticity patients receiving ITB so as to better understand these research discrepancies.

Another topic that emerged from a review of the literature was the sensitivity and general utility of QOL measures that have been used with spasticity patients receiving ITB. Multiple studies argued that the existing QOL measures were not precise enough to fully capture the difficulties that in this diverse patient population (Emery, 2003; Rizzo, et al., 2004; Staal, Arends, & Ho, 2003). Similarly, a study of spasticity patients using ITB indicated that a more targeted assessment of QOL can enhance measurement precision (Bramanti, D'Aleo, Rifici, Alagna, Cannata, Sessa et. al, 2004). Of the measures the authors examined, they concluded that the Quality of Well-Being Scale (QWBS) and the Self-Evaluation of Life Function may be more sensitive to the QOL and

general functionality of spasticity patients, respectively, given the nature of their questions.

As a comment on the general limitations of previous research with spasticity patients, Bramanti et al. wrote in 2004 that "outcomes of intrathecal baclofen treatment, in areas such as independence in daily activities and emotional state, are still unclear." Further, the majority of these previous studies have been limited by their assessment scope and/or a small sample size. Regardless of their study design, several of the existing studies are limited by small samples sizes, ranging from approximately 8 – 35 study patients (Staal, Arends, & Ho, 2003). While these studies have significantly contributed to this area of research, they are less statistically robust due to their small samples. Multiple studies limited their assessments to patient functionality and/or QOL-related measures (Emery, 2003; Rizzo, et al., 2004; Staal, Arends, & Ho, 2003). On the whole, these studies did not adequately assess psychiatric symptoms and/or other psychosocial variables beyond QOL. At present, there are no previous studies that examine HRQOL, common psychiatric symptoms, and additional psychosocial variables. Overall, there continues to be a dearth of research that comprehensively examines QOL and other psychosocial variables in spasticity patients receiving ITB.

CONCLUSIONS

Research has demonstrated that patients suffering from chronic health conditions are at an increased risk for experiencing psychosocial distress and developing psychological difficulties (Beasley and Beardslee, 1998; DiMatteo, Lepper, and Croghan, 2000; Merry, McDowell, Wild, Bir, and Cunliffe, 2004; Panzarino, 1998; President's New Freedom Commission on Mental Health, 2003; Wells et al., 1988). The presence of a comorbid psychological disorder has negative effects on quality of life, self-care, adherence to medication regimens, overall functioning, and worse health outcomes. Several studies have indicated that identification and treatment of psychological and psychosocial difficulties in medical illnesses positively influence medical outcomes and quality of life (Benton, Staab, and Evans, 2007; Narasimhan, Raynor, and Blackmon Jones, 2008; Shemesh, Bartell, and Newcorn, 2002).

Several small studies have examined quality of life and patient-reported efficacy for spasticity patients receiving implantable intrathecal baclofen (ITB) therapy. However, no research has examined what variables may play a role in quality of life outcomes for spasticity patients across and between the varied diagnostic populations treated with ITB or baclofen pain-pump therapy. Additionally, current research has utilized small sample sizes; new studies utilizing larger samples are needed. Specifically, there is a dearth of research examining psychological symptoms and psychosocial factors in this population and their impact on quality of life with solid sample sizes.

CHAPTER THREE

Aims and Hypotheses

OVERALL GOALS

The present study examined several psychosocial variables (e.g. global and population-specific health-related quality of life [HRQOL], level of social functioning, self-reported levels of optimism/pessimism) and psychological variables (e.g. depressive and other psychiatric symptoms, as well as self-reported pain ratings) within a heterogeneous population of patients that receive ongoing care with intrathecal baclofen or baclofen pain-pump therapy.

AIMS AND HYPOTHESES

Aim 1: Gain better understanding of patients' psychosocial and psychological well-being in patients receiving ITB therapy from a more robust sample size than has been previously collected.

Hypothesis 1: Patients receiving ITB therapy will differ from the normative population in the following ways: they will have decreased quality of life, lower levels of optimism, and lower levels of social functioning compared to the normative population.

Aim 2: To better understand the correlation between quality of life and the medical diagnoses, ITB medication, length of time with pump, level of pain, level of optimism, level of social functioning, and depressive symptoms or those utilizing ITB for spasticity or pain.

Hypothesis 2: There will be no discrepancy between quality of life ratings across differing diagnostic populations (such as TBI, CP, MS, paralysis, pain); Duration of treatment with the pump, increased level of social functioning will be correlated with higher levels of quality of life. Patients who report higher levels of pain and/or depressive symptoms and patients who report decreased levels of optimism will report lower levels of quality of life.

Aim 3: To determine what factors can predict a patient's quality of life rating.

Hypothesis 3: Optimism and perceived social support will have the greatest influence on patient's quality of life when controlling for diagnosis, length of time with pump, and levels of spasticity/pain.

CHAPTER FOUR

Methodology

STUDY DESIGN

Setting

This cross-sectional study examined several psychosocial and psychological variables within a heterogeneous population of adult outpatients that received ongoing care with intrathecal baclofen or pain pumps. This study was conducted with a population of outpatients seeking care for spasticity and/or pain at the Zale Lipshy Physical Medicine & Rehabilitation (PM&R) Clinic. Patients who participated in the study completed one-time study measures before or after their scheduled appointment. Located in Dallas, Texas, the Zale Lipshy Physical Medicine & Rehabilitation clinic (the PM&R Clinic) is a part of The University of Texas Southwestern Medical Center. The PM&R Clinic includes interdisciplinary care that specializes in diagnosis, treatment and prevention of disabilities in individuals affected by stroke, brain injury, spinal cord injury, neuromuscular disorders, musculoskeletal disease, pain and other conditions that limit mobility and function.

PARTICIPANTS

Inclusionary Criteria

Patients were recruited for the study in the waiting area of the PM&R Clinic or examination room during the 24-month recruitment period. Patients were invited to participate in the study if they were of adult age (18 and older), had $\geq$ 3 month utilization

of intrathecal baclofen or pain pump for the treatment of pain or spasticity, were receiving ongoing care at the PM&R Clinic, were capable of providing informed consent, could read and speak English, and were willing to allow access to their existing medical records.

Exclusionary Criteria

The PM&R Clinic provides care to an exclusively adult population (age ≥18 years). Thus, there was not a population of minors from which to draw for inclusion in the study. As such, minors (age <18 years) were excluded from the study. Due to the fact that validated Spanish versions are not available for all study measures, all participants needed to be proficient in English. Those who were not English-speaking were excluded from the study. Proficiency was determined by conversations held between the participant and the treatment provider/study staff.

MEASURES

Outcome variables were predominantly self-report measures. Additional variables examined were length of time with pump, diagnosis leading to pump use, medication type, age, gender, and race/ethnicity, and level of education. Outcome variables and other key study measures included global and population specific health-related quality of life, optimism/pessimism, level of depressive symptoms, scores on a psychiatric screening instrument, social health, and symptoms of physical health (e.g., level of fatigue, pain impact, pain behavior).

The Life Orientation Test – Revised

The Life Orientation Test (LOT) was developed to assess individual difference in generalized optimism versus pessimism (Scheier & Carver, 1985). This measure, and its successor The Life Orientation Test-Revised (LOT-R; Scheier, Carver, & Bridges, 1994), have been used in research on the behavioral, affective, and health consequences of the optimism/pessimism dimension. Studies have reported adequate coefficient alpha estimates (α = .85, Eid, Matthews, Meland, & Johnsen, 2005; α = .87, McPherson & Mohr, 2005). The correlation between the revised scale and the original scale is .95. The LOT-R consists of ten statements that patients have option to respond with *strongly disagree*, *disagree*, *neutral*, *agree*, or *strongly agree*. This measure was used as a primary outcome measure, as well as a predictor of quality of life.

The Patient Health Questionnaire

The Patient Health Questionnaire (PHQ) is a multiple-choice self-report inventory, used as a screening and diagnostic tool for depression, anxiety, alcohol, eating, and somatoform disorders (Spitzer, Kroenke, & Williams, 1999). It was designed for use in the primary care setting and lacks coverage for disorders seen in psychiatric settings. The PHQ is a self-administered version of the Primary Care Evaluation of Mental Disorders (PRIME-MD). The PHQ can be used to establish provisional diagnoses for the above mentioned DSM-IV disorders (Spitzer, Kroenke, & Williams, 1999). Agreement between PHQ diagnoses and those of independent mental health professionals resulted in 85% overall accuracy, 75% sensitivity, and 90% specificity, which is similar to the original PRIME-MD. An adequate coefficient alpha estimate has been reported (α = .84,

Spitzer, Kroenke, & Williams, 1999). Questions about mood, anxiety, eating behaviors, and alcohol use are assessed by yes/no responses, as well as the degree to which the symptoms has bothered them ("not at all," "several days," "more than half the days," and "nearly every day." To meet criteria for Somatoform Disorder a patient must endorse three of the thirteen available items at the most significant level, as well as lack an adequate biological explanation for these difficulties. To meet criteria for a depressive disorder, a patient must indicated little interest/pleasure in doing things and/or feeling down, depressed, or hopeless, as well as two to five additional DSM-IV symptoms of depression for more than half the days in the last four weeks. Bereavement and mania are also ruled out, as well as symptoms being attributed to a physical disorder, medication, or other drug, as the biological cause of the depressive symptoms. The PHQ defines Panic Disorder by the same means as the DSM-IV, i.e., patient must have experienced sudden fear/panic (anxiety attack) in the last four weeks, indicated previous episodes, indicated that they occur at random, and that the episodes are of concern to the patient. Additionally, the patient must endorse four or more other DSM-IV symptoms of panic disorder. Other anxiety disorders are combined into the Other Anxiety Syndrome, which required that a patient endorse feelings of nervousness, anxiety, worry, etc. more than half the days in a four week period, as well as endorse three or more additional anxiety symptoms. Regarding bulimia, a patient must endorse all of the following symptoms: feeling that one cannot control what or the amount he/she eats, eats an unusually large amount of food within in a 2-hour period, the behavior occurs at minimum twice weekly for a three month or longer period, and the behavior is done as an attempt to aid in weight loss. Binge Eating Disorder is similar but a patient would not

indicate that this behavior is done as a means to lose weight. Alcohol abuse is defined by the PHQ as a patient endorsing any of the following questions: drinking even though a medical professional has suggested that you stop, being drunk/high/hungover while working, missing work/responsibilities because of being drunk or hung over, and driving after having several drinks. The PHQ measure was used as a primary outcome measure and predictor of quality of life.

The Quality of Well-Being Scale – Self-Administered

The Quality of Well-Being Scale – Self Administered (QWB-SA; Sieber, Groessl, David, Ganiats, & Kaplan, 2008) is an updated, shorter version of the Quality of Well-Being Scale (QWB), which was designed as a comprehensive measure of health-related quality of life (Kaplan, Bush, & Beryy, 1975). The QWB and QWB-SA are some of the few measures that can help calculate the Quality-Adjusted Life Year (QALY), which is a standard measure of health-related quality of life (HRQOL) in medical cost-effectiveness research as an expression of health outcome (Gold, et al., 1996). QWB-SA has been extensively validated and its psychometric properties are well established (Kaplan, Anderson, and Ganiats, 1993). The format for the QWB-SA is made up of five sections. The first section assesses the presence/absence of 19 chronic symptoms or problems (e.g., blindness, speech problems). The chronic symptoms are followed by 25 acute (or more transient) physical symptoms (e.g., headache, coughing, and pain), and 14 mental health symptoms of behaviors (e.g., sadness, anxiety, irritation). The remaining sections include assessment of a person's mobility e.g., use of transportation), physical activity (e.g., walking and bending over), and social activity including completion of role

expectations (e.g., work, school, or home; Sieber, Groessl, David, Ganiats, & Kaplan, 2008). The QWB-SA can be administered in less than ten minutes (Sieber, Groessl, David, Ganiats, & Kaplan, 2008). This measure was used as a primary outcome measure.

Quick Inventory of Depressive Symptoms-Self Report

Participants will also complete the Quick Inventory of Depressive Symptoms-Self Report (QIDS-SR) to assess and compare their depressive symptoms at each of the study time points (baseline, week 6, and week 12). The QIDS-SR is a 16-item measure designed to assess the severity of depressive symptoms (Rush et al., 2003). Both clinician rated and self-report forms are available. It was derived from the 30-item Inventory of Depressive Symptomatology (IDS) and covers only the nine diagnostic symptom domains used to characterize a major depressive episode (Rush, Giles, Schlesser, Fulton, Weissenburger and Burns, 1986; Rush, Gullion, Basco, Jarrett, and Trivedi, 1996). The QIDS can be used to screen for depression or as a measure of symptom severity. It has proven sensitive to change among patients treated with medications, psychotherapy, or somatic treatments, making it useful for both research and clinical purposes. The QIDS measures, including the QIDS-SR, have shown satisfactory sensitivity to change in determining treatment response and remission (Brown et al., 2008; Rush et al., 2006). This study will utilize the QIDS-SR as a secondary outcome measure. The psychometric properties of the QIDS have been established in various study samples (Rush et al., 2003; Trivedi et al., 2004).

The Short Form Health Survey-36

The Short Form Health Survey-36 (SF-36) was derived from the General Health Survey of the Medical Outcomes Study by Stewart and colleagues (1988). It is a multi-purpose, short-form health survey with 36 questions. It yields an 8-scale profile of functional health and well-being scores as well as psychometrically-based physical and mental health summary measures and a preference-based health utility index. Accordingly, the SF-36 has proven useful in surveys of general and specific populations, comparing the relative burden of diseases, and in differentiating the health benefits produced by a wide range of different treatments. The reliability of the eight scales and two summary measures has been estimated using both internal consistency and test-retest methods. With rare exceptions, published reliability statistics have exceeded the minimum standard of 0.70 recommended for measures used in group comparisons in more than 25 studies (Tsai, Bayliss, & Ware, 1997); most have exceeded 0.80 (McHorney et al., 1994; Ware et al., 1993). The SF-36 is suitable for self-administration. It has been administered successfully in general population surveys in the U.S. and other countries (Ware, Keller, Gandek, Brazier, & Sullivan, 1995), as well as to young and old adult patients with specific diseases (McHorney et al., 1994; Ware et al., 1993). It can be administered in 5-10 minutes with a high degree of acceptability and data quality (Ware et al., 1993). This measure was used as a primary outcome measure.

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

Multiple measures from the PROMIS study were used to assess psychosocial and pain/health-related variables. PROMIS derived measures have all been shown to be unidimensional and to have high reliability and validity from large-scale testing (Cella, et al., 2007). All PROMIS-derived instruments used in this study are self-report. 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. Per design of the PROMIS study, all scores on PROMIS measures (e.g., 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 can be comparably analyzed (Cella, et al., 2010; Thissen & Mislevy, 2000). All PROMIS short-forms 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 PROMIS Pain Behavior Item Bank 1.0 utilizes six response options, which allows for the response-option of "*no pain*" (NIH; Cella, 2010).

PROMIS Fatigue

The PROMIS Fatigue Short-Form Instrument (PROMIS-Fg) contains 7 items that assess both the experience of fatigue (e.g., intensity, frequency and duration) and the influence 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 ADLs, impaired social functioning within family and social roles; D. Cella, et al., 2007; NIH; Cella, 2010). This measure was used as a secondary outcome measure.

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 Short-Form Instrument (PROMIS-PI). It is composed of 6 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 (Amtmann, et al., 2010). This measure was used as a secondary outcome measure.

Pain Behaviors

The second sub-domain is the PROMIS Pain Behavior Short-Form Instrument (PROMIS –PB). It is composed of 7 items that assess behaviors one engages in to avoid, minimize or reduce pain (Cella, et al., 2007). The PROMIS-PB demonstrated high internal reliability and unidimensionality (Cella, et al., 2010). This measure was also used as a secondary outcome measure.

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. 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 and unidimensionality (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 Short-Form Instrument (PROMIS-SPSR). It is composed of 7 items that assess satisfaction with usual social roles in life's situations and activities. This measure was used as a secondary outcome measure.

Satisfaction with Participation in Discretionary Social Activities

The second Social Health sub-domain is the PROMIS Satisfaction with Participation in Discretionary Social Activities Short-Form Instrument (PROMIS-SDSA). It is composed of 7 items that assess satisfaction with level of involvement in usual social

roles in life's situations and activities. This measure was used as a secondary outcome measure.

PROCEDURES

Prospective study patients were identified from existing patient lists of the M.D. co-investigators (Fatma Gul, M.D. and Benjamin Nguyen, M.D.). Those patients who met initial eligibility criteria (e.g. receiving ongoing intrathecal Baclofen or pain pump therapy) were approached regarding participation in the study prior to or after their already scheduled appointment with a member of the PM&R Clinic treatment team. During appointments that had already been scheduled with their providers, the treatment providers asked prospective study patients about participating in the study at the end of the appointment. If the patient agreed to participate, he or she met with one of the study personnel who are onsite. For those patients that agreed, a member of the treatment team from the clinic contacted the patient and asked that they speak with one of the research assistants, about participating in the study at the end of their next scheduled visit. Written informed consent was obtained from each study participant. No minors or individuals from special subject classes were included in the study. The informed consent documents were reviewed with the prospective study patients by either the project coordinator or one of the study's research assistants. Study patients signed two copies of the informed consent form. Both copies had a unique participant identification number that was used to represent that individual in the study's data files. One consent form was given to the patient to keep, while a member of the research team kept the

other. Following administration of any study measures, the study-copy of the consent form was stored in a folder labeled with the patients' previously assigned participant number. From there, the patients' folders were stored in a secure, locked environment. The primary storage location was in a locked cabinet within the office of Dr. Fatma Gul. During the consent process, study personnel created an initial timeline for the follow-up assessments, attempting to coordinate with any future appointments participants may have. Signed consents were assigned a unique participant identification number (PID) and stored in a locked office within the clinic.

Study measure completion required one encounter with consented participants, which lasted for approximately sixty minutes. Study procedures for initial participant contact included study notification (1-2 minutes), consent (5-10 minutes), and the completion of study questionnaires (20-40 minutes). Due to the self-report nature of the study measures and the individual participants' circumstances, overall visit time varied up to thirty minutes. Study notification refered to the treatment provider discussing potential participation with patients. After a patient agreed to participate, he or she met study personnel to complete the consent process, having questions answered as needed. Patients who indicated difficulty filling out the questionnaires (i.e., grasping/using a writing utensil) were informed that research personnel may mark their answers for them. It was emphasized that study participants must produce the answer by clearly indicating their answers, either verbally or nonverbally, to research personnel. Consented patients were given the study questionnaires and a writing utensil. They completed the forms in the exam room, which provided a comfortable writing surface upon which participants were able to complete the study questionnaires. Upon completion, participants were

asked if they have any additional questions or concerns. Participant data (e.g., consent, study questionnaires) was immediately stored in the participants designated folder and then placed in a locked cabinet within the Principal Investigator's office.

After the data was collected from the study participant, his/her data was entered into two separate databases. The first database was a key list that pairs the patients' names with their participant identification number. No data from study measures was entered into this database. The second database listed the participant identification numbers with corresponding study data. Both of these databases were saved on a password-protected computer.

DATA ANALYSIS

Categorical data, including gender, ethnicity, and level of education was examined using Pearson's chi-square statistical analysis of the 125 patients. T-tests and one-way ANOVAs were used to analyze the continuous variables, such as age, as well as to examine medical diagnostic group differences (TBI, CP, MS, paralysis, pain, etc.) on the following variables: quality of life, depressive symptomatology, pain, fatigue, social functioning, and levels of optimism. Correlations were obtained using the Holm Step-Down procedure (Holm, 1979; Huang and Hsu, 2007). Multiple regression was used to determine what variables are most predictive of quality of life. Hierarchical regression was used to control for diagnoses, duration of pump use, and pain level to predict quality of life, as determined by the QWB-SA.

CHAPTER FIVE

Results

DESCRIPTIVE STATISTICS

Demographic Data

Tables 1 and 2 present demographic data of all the patients that completed the study. One hundred and twenty five (n = 125) participants were evaluated in this study. The age range was 19 to 82 years with a mean age of 49 years (M = 49.06, SD = 13.60). The group had approximately equal gender distribution (49.6% male and 50.4% female). The ethnic makeup of the sample consisted of 83.2% Caucasian/Non-Hispanic, 9.6% African-American, 4.0% Hispanic, 0.8% Asian or Pacific Islander, 0.8% Native American, and 1.6% classified as "other" (a combination of two ethnicities). The sample was heavily weighted towards Caucasian individuals. In addition, the Hispanic population was underrepresented in this sample. This may be partially attributed to the exclusion of patients with limited English levels that did not permit them to complete the measures. The sample demonstrated a high level of education. Specifically, 44% of the participants completed some college and roughly 34% have completed 4 years of college or more. Please refer to Table 1 for more specific information on these demographics.

The sample had a broad range of medical diagnoses that lead to their use of intrathecal baclofen or pain pump therapy with 33.6% of patients suffering from chronic pain, 25.6% with spinal cord injuries, 18.4% with MS, 8.8% with a cerebrovascular accident/stroke, 7.2% with CP, 2.4% with TBI, and 1.6% with hereditary and/or familial spastic paraplegia, 0.8% with closed head injuries, 0.8% with dystonia, and 0.8% with another disorder. Of this sample, 68.8% of the participants were utilizing baclofen and/or

baclofen combination therapy, compared to 31.2% of participants who used other medications, such as morphine, ziconotide, bupivacaine, etc. Additionally, the sample had an average of 4.97 years with an ITB pump (SD=3.664, range 1 to 17 years).

Demographic Data of the Medication Groups

Tables 3 and 4 present demographic data by comparing the two medication groups (intrathecal baclofen/baclofen combination compared to intrathecal non-baclofen medications). As was previously reported, 68.8% of the participants were utilizing baclofen and/or baclofen combination therapy, with 31.2% utilizing another pain medication regimen. A significant difference was noted between the average age of the baclofen medication group (M=46.60 years, SD=13.35, N=85) compared to the other medication group (M=54.07 years, SD=12.83, N=39; t(122)=2.93, p=.004, d=.57). No statistically significant differences were found for gender, ethnicity, and education between these two groups. Please refer to Tables 3 and 4 for more specific information.

Demographic Data of Medical Diagnoses

Comparisons of the medical diagnoses that led to use of intrathecal baclofen or pain pump therapy indicate that age is significantly different between the diagnostic groups, $F(9, 115) = 6.35$, $p < .001$. Please refer to Table 5 to further examine how the mean age differs between these groups. Gender also differed at a statistically significant level between the different diagnostic groups, $X^2 (9, N = 125) = 25.181$, $p < .003$. No statistically significant difference was found for education level between these groups. Please refer to Table 6 for the demographic data on education level.

Sample Comparison to Normative Population

Measure	Study Sample					Normative Population			
	N	Mean	SD	Range					
Quick Inventory of Depressive Symptom	125	6.93	5.02	0	27	Very Severe	21-27		
						Severe	16-20		
						Moderate	11-15		
						Mild	6-10		
Life Orientation Test Revised (optimism)	124	15.82	4.50	2	24	Low	0-13		
						Mod	14-18		
						High	19-24		
						Medically Ill Population			
							Mean	t	p
QWB-SA	125	0.38	0.16	0.11	0.94	Poor	0.45	-4.7	<.001*
						Fair	0.54	-10.9	<.001*
						Good	0.64	-18.1	<.001*
						Very Good	0.70	-22.1	<.001*
						Excellent	0.76	-26.4	<.001*
SF-36						Mean	SD	t	p
Physical Functioning	125	28.12	26.17	0	100	84.2	23.3	2.059	0.04*
Mental Health	125	70.40	21.70	0	100	74.7	18.1	26.946	<.001*
PROMIS									
Satisfaction with Discretionary Social Activities	125	47.64	10.01	28.70	67.30	50	10	42.041	<.001*
Satisfaction with Social Roles	125	42.26	9.95	27.00	65.60	50	10	36.249	<.001*
Fatigue	125	56.14	8.45	36.90	74.80	50	10	61.049	<.001*
Pain Behavior	125	55.82	9.39	36.70	70.50	50	10	54.556	<.001*
Pain Interference	114	57.89	10.81	41.00	78.30	50	10	47.301	<.001*

a. *Degrees of Freedom (df) = 114 for all values, except the PROMIS-Pain Interference measure (df=113)

In Aim 1, it was hypothesized that spasticity patients will differ from the normative population in the following ways: they will have decreased quality of life, lower levels of optimism, and lower levels of social functioning compared to the normative population. Examination of the sample revealed that it differed from the normative population in several ways. The PHQ, a measure designed to facilitate the recognition and diagnosis of the most common mental disorders in primary care patients,

was used to assess the prevalence of psychiatric disorders in the sample population. The sample population had a 12.8% rate of MDD, defined as a patient indicating little interest/pleasure in doing things and/or feeling down, depressed, or hopeless, as well as five additional DSM-IV symptoms of depression for more than half the days in the last four weeks, compared to the 12-month prevalence of Major Depressive Disorder in the US, which is found to be 6.7% (http://www.nimh.nih.gov/statistics/1MDD_ADULT.shtml). Regarding anxiety disorders, the US 12-month US adult prevalence is 3.1% (www.nimh.nih.gov/statistics/1GAD_ADULT.shtml), compared to 8.9% of the sample population. Panic Disorder is also elevated in the sample population at 5.0% compared to 2.7% in the US population (www.nimh.nih.gov/statistics/1PANIC_ADULT.shtml). Binge Eating Disorder was also more prevalent in the sample population (2.4%) than in the US population (1.2%; www.nimh.nih.gov/statistics/1EAT_ADULT_RB.shtml). Interesting to note, alcohol abuse (2.4%) was under represented compared to the US prevalence data (4.65%; www.niaaa.nih.gov/NewsEvents/NewsReleases/NESARCNews.htm).

While 20.8% of the sample population met criteria for a depressive disorder as assessed by the PHQ as a little interest/pleasure in doing things and/or is feeling down, depressed, or hopeless, as well as two to four additional DSM-IV symptoms of depression for more than half the days in the last four weeks, the study sample's average QIDS score, a measure designed to assess the severity of depressive symptoms, was in the mild depression range. Interestingly, though, the average study sample score on the SF-36 Mental Health scale was similar to that of the general US population, thus

indicating that mental health, as described by the SF-36, was not significantly different. The study sample performed below the normative population on the SF-36 Role Limitations - Emotional Health scale, suggesting that emotional difficulties limited their life activity. It is important to note that although the score was lower it was still within a standard deviation. Interestingly, the sample population was reported to be moderately optimistic (M=15.82, SD=4.5), according to the LOT-R, a measure that assesses optimism/pessimism on a continuum.

Additional measures of the SF-36 were assessed for components of quality of life. The sample population fell two standard deviations below the normative average on the Physical Functioning scale, suggesting that the sample group had significantly more difficulty with their physical functioning. A significant discrepancy was noted on the PROMIS Pain Behavior ($t(124)=54.56$, $p<.001$) and Pain Interference ($t(113)=47.30$, $p<.001$) measures than the normative medically ill population.

Rates of energy and fatigue were also assessed using PROMIS Fatigue measure. A significant discrepancy was found between the study group and the normative medically ill population ($t(124)=61.05$, $p<.001$).

Social support was assessed using the PROMIS measures (Satisfaction Discretionary Social Activities and Satisfaction Social Roles). The sample population significantly differed from the normative medically ill population on the PROMIS - Satisfaction Discretionary Social Activities ($t(124)=42.04$, $p<.001$) and Satisfaction Social Roles measures ($t(124)=36.25$, $p<.001$). These findings are similar to the original hypothesis that the sample population would have lower levels of social functioning.

The sample population was also compared to the normative population using an overall measures of quality of life, the QWB-SA. The sample population's average QWB-SA score fell into the "Poor" range. These results indicate that the sample population has notably lower quality of life than the normative population.

Medical Diagnostic Group Differences on Self-Report Measures

In Aim 2, it was hypothesized that there would be no discrepancy between quality of life ratings across differing medical diagnostic populations (TBI, CP, MS, traumatic injury/paralysis, pain, etc.). However, significant differences were discovered between the medical diagnoses. The TBI subgroup had higher average Total QWB-SA scores compared to other diagnoses, $F(9,115) = 2.58$, $p = .01$. A similar result was also found when examining the QWB Self-Rated health, as TBI patients rated their health significantly above the other diagnostic groups, $F(9,115) = 2.73$, $p = .006$. A statistical difference occurred between the medical diagnostic groups on the SF-36 Vitality scale $F(9,115)=2.06$, $p = .039$, indicating that TBI and Closed Head Injury (CHI) groups reported high levels of energy and decreased levels of fatigue compared to the other diagnostic groups.

Similarly, statistical significance was also reported in the PROMIS Fatigue, Pain Behavior, and Pain Interference measures. The TBI and CHI subgroups reported less fatigue compared to the other medical diagnostic groups, $F(9,115)=2.04$, $p = .039$. The TBI and CHI groups also demonstrated lower pain behavior, while patients diagnosed with dystonia reported higher levels of pain behavior, $F(9,115)=3.87$, $p < .001$. TBI and

CHI patients also reported that pain interfered with their functioning at decreased levels when compared to the other medical diagnostic groups, $F(9,104)=3.98$, $p<.001$.

Differences were also revealed between the medication groups, baclofen/baclofen combo and other medications. Baclofen patients reported lower level of physical functioning on the SF-36 Physical Functioning scale, $t(122)=2.69$, $p=.008$, $d=.52$. Similarly, the baclofen group reported an increased level of pain and consequences of pain when compared to the other medication group on the PROMIS Pain Behavior measure, $t(122)=2.34$, $p=.019$, $d=.46$, and PROMIS Pain Interference measure, $t(111)=2.52$, $p=.013$, $d=.50$. No other differences were noted between baclofen and non-baclofen patients.

Correlations to Quality of Life

It was also hypothesized in Aim 2 that duration of treatment with the pump and higher levels of social functioning would correlate with higher ratings of quality of life, while those with higher levels of pain and depressive symptoms, as well as lower levels of optimism, will report decreased quality of life. Correlations were run using the Holm Step-Down correction procedure (Holm, 1979; Huang and Hsu, 2007). Duration of treatment with the pump had moderate to strong positive associations with PROMIS Satisfaction with Discretionary Social Activities ($r(125)=.41$, $p<.001$). The PROMIS Satisfaction with Social Roles ($r(125)=.55$, $p<.001$) and the PROMIS Satisfaction with Discretionary Social Activities ($r(125)=.41$, $p<001$) had moderate to strong positive relationship to the QWB. Small to strong negative associations were revealed when the

PROMIS Pain Behavior and Pain Interference were correlated to QWB (PROMIS-PB/QWB, r(125) = -.28, p =.002, PROMIS-PI/QWB, r(114) = -.36, p <.001).

Additional relationships between measures and/or constructs were also discovered. The QWB had a moderate positive association with the SF-36 Physical Functioning (r(125) = .338, p = .000) and the SF-36 Emotional Functioning scales (r(125) = .330, p = .000), indicating that higher levels of quality of life are associated with higher levels of physical and emotional functioning. A moderate negative association was found between the QWB and the QIDS (r(125) = -.368, p = .000), suggesting that higher quality of life is related to lower levels of depression. The QWB were also demonstrated a moderate negative association with the PROMIS-Fatigue measure (r(125) = -.399, p = .000), i.e., higher levels of quality of life relate to lower levels of fatigue. Examination of the relationship between level of optimism (LOT-R) and quality of life (QWB) indicated small positive associations (LOT-R/QWB, r(125) = .26, p =.003).

Interestingly, moderate to strong associations were found between the SF-36 Emotional Well-being measure and the rest of the measures, while only one small positive association was found between the SF-36 Physical Functioning score and the study measures. Specifically, a small positive association was found between the SF-36 Physical Functioning and the PROMIS-Satisfactions with Social Roles , r(125) = .27, p =.002).

The QIDS had moderate to strong relationships with several of the measures, including the LOT-R (r(125) = .-40, p =.000), PROMIS Satisfaction with Discretionary Social Activities (r(125) = .39, p =.000), PROMIS Satisfaction with Social Roles (r(125) = -.41, p =.000), PROMIS Fatigue (r(125) = -.63, p =.000), PROMIS Pain Behavior

(r(125) = -.38, p =.000), and PROMIS Pain Interference (r(125) = -.49, p =.000). Similarly, small to moderate associations were found between the LOT-R, a measure of optimism, and the additional measures. As expected the PROMIS measures also were associated with each other.

Quality of Life Predictors

To predict what variables affect quality of life (QWB-SA), a hierarchical (step-wise) regression was conducted. Medical and psychiatric diagnoses, duration of time with pump, and level of pain (SF-Bodily Pain, PROMIS Pain Behavior and Pain Interference) were controlled for to see what is predictive of higher quality of life. The results of the regression indicated that 41% of the variance (R_2=.41, F(18,59)=2.30, p =.009) was predicted by these variables. Twenty-nine percent of the variability was explained by the additional variables (R_2=.29, F(12,47)=3.78, p <.001). Specifically, it was found that the higher the satisfaction with one's social roles (PROMIS-Satisfaction with Social Roles, β = .012, p <.001), the lower the level of feeling limited in one's roles by his/her emotional health (SF-36 Role Limitations – Emotional Health, β = -.001, p<.05), and increased vitality (SF-36 Vitality, β = -.002, p <.05) are predictors of quality of life, as assessed by the QWB-SA.

CHAPTER SIX

Conclusions and Recommendations

DISCUSSION

The current study is one of the first to examine psychosocial and psychological variables in a large sample of spasticity patients. Additionally, it is one of the first to compare subgroups of differing diagnostic groups that are affected by spasticity using a large sample size. This study has relevance for treatment approaches. The sample population differed from the normative population on all measures of quality of life, depression, optimism, pain, and social functioning. Overall, the sample reported mild symptoms of depression, but had elevated rates of Major Depressive Disorder when compared to the normative population. The sample also had elevated rates of dysthymia, anxiety, panic, and binge eating disorders when compared to the normative population. Research suggests that the presence of a comorbid psychological disorder has negative effects on quality of life, self-care, adherence to medication regimens, overall functioning, and worse health outcomes. Several studies have indicated that identification and treatment of psychological and psychosocial difficulties in medical illnesses positively influence medical outcomes and quality of life (Benton, Staab, and Evans, 2007; Narasimhan, Raynor, and Blackmon Jones, 2008; Shemesh, Bartell, and Newcorn, 2002).

Given the high frequency of depressive symptoms and rate of depressive disorders, it is an interesting finding that the sample population fell into the moderately optimistic range (M=15.82, SD=4.5). This suggests that although there are significant psychological and psychosocial difficulties affecting this population, there is an element

of optimism. Examination of patient's level of hope might help further explain this finding.

Findings from the SF-36 and PROMIS measures differed on several constructs, including pain, physical health, energy/fatigue, and social functioning. Consideration should be given to the different designs of the measures. There are approximately two to four questions that substantiate the score for the SF-scales, the exception being physical health, compared to the average seven questions asked on the PROMIS measures. Additionally, the SF-36 uses the last four weeks as the time frame to base one's response, compared to 7-days on the PROMIS measures.

The sample population exhibited lower levels of physical functioning and felt limited in their daily lives by their physical health. A similar pattern was found on the Role Limitations – Physical Health scale. Given the disabling nature of spasticity, this finding was expected. The QWB-SA, a measure of overall quality of life, indicated that the sample population had significantly lower quality of life than the normative population. Relatedly, TBI and CHI patients were shown to have higher quality of life than other diagnostic groups. Further exploration of this finding is suggested for future research.

Differences were also found between the medication groups: baclofen/baclofen combo and other medications. Baclofen patients reported lower levels of physical functioning, increased pain level, and consequences of pain. No other differences were noted between baclofen and non-baclofen patients. This data suggests that baclofen patients in this sample reported increased levels of pain. Previously, researchers concluded that ITB therapy was related to improvement in patient functionality and

quality of life. However, their review did not find studies that comprehensively examined QOL and other related psychosocial variables, i.e., what factors influence quality of life levels (Emery, 2003). Results from this study, which examined several psychosocial variables as well as several quality of life scales, suggest that ITB did not relate to improved patient functionality or pain experience.

As was predicted, higher levels of social functioning correlated with higher ratings of quality of life, while those with higher levels of pain and depressive symptoms, as well as lower levels of optimism, reported decreased quality of life. These results support the current belief that comorbid psychological disorder has been shown to have a negative impact on quality of life, self-care, and overall functioning (Bender, 2006; DiMatteo, Lepper, & Croghan, 2000; Dowson, Town, Frampton, & Mulder, 2004; Katon & Ciechanowski, 2002; Stein, Cox, Afifi, Belik, & Sareen, 2006; Whittemore, Kanner, Singleton, Hamrin, Chiu, & Grey, 2002).

It is also important to note that duration of treatment with the pump had a small positive correlation with higher quality of life (SF-36 General Health), thus suggesting that longer pump use may improve quality of life. However, it is important to consider that patients who have used the pump for longer periods are receiving satisfactory spasticity/pain management and that those who have removed the pump have self-selected out of the group. This finding was an observation based on the length of time patient used a pump; future research should further explore this observation. Finally, higher satisfaction with social roles and vitality, in addition to lower levels of feeling limited because of emotional health, were predictive of higher levels of quality of life, when medical and psychiatric diagnosis, pain level, and length of pump were controlled

for. This finding highlights the importance of protective factors in improving quality of life spasticity patients. Specifically, it indicates that spasticity patients would benefit from social activities and maintaining active lifestyles to increase their energy levels, in addition to addressing mental health issues.

LIMITATIONS

There are several limitations to the current study. First, the study was a cross-sectional study designed to capture psychosocial and psychological descriptive data, as well as to look at this data across medical diagnostic subgroups. Groups were not matched for medical diagnosis and medication type, which resulted in unequal group size. Therefore, comparisons between groups were difficult to interpret. Additionally, the study only looked at one time point. It is possible that the variables of interest change over time periods. Most of the variables of interest were collected from self-report instruments. The subjective nature of these measures may increase the likelihood of changes in patient reporting over time. Second, the sample was ethnically homogenous and findings may not generalize to diverse populations covering a broad spectrum of racial and ethnic backgrounds. Spanish speakers were not included in the study due to limitations of the measures. The exclusion of this population may have limited the findings. Finally, the strong focus on quality of life rather than other dimensions of psychosocial or health outcomes may have limited the findings.

FUTURE DIRECTIONS AND IMPLICATIONS

Future research should further unravel the complexities of spasticity patients, particularly

regarding how quality of life affects their health outcomes. Though research has covered the gamut on quality of life in health populations, it is quite limited with regard to spasticity patients utilizing ITB therapy. This research study has demonstrated the level of quality of life in patients struggling with spasticity; however, research focusing more directly on the causal effects of quality of life on health outcomes would be beneficial in both treating the illness medically and working with the patients. Additionally, quality of life is just one factor to assess spasticity patients. Future research should explore other objective measures to gain better understanding of this complex population. Finally, research could further identify alternate approaches, such as specific therapeutic interventions, to help spasticity patients.

This research study was able to capture descriptive psychosocial and psychological data of a large sample of spasticity patients, as well as examine the relationships between these variables. Analyses were also conducted to assess for variables that are predictive of higher levels of quality of life. These associations may have important implications in both the medical and mental health fields with regard to treatment of spasticity patients. This may be especially relevant when disease management is going poorly as research has shown that identification and treatment of psychological and psychosocial difficulties in medical illnesses positively influence medical outcomes and quality of life (Benton, Staab, and Evans, 2007; Narasimhan, Raynor, and Blackmon Jones, 2008; Shemesh, Bartell, and Newcorn, 2002). In addition, the descriptive psychosocial and psychological data may offer treatment providers a new perspective to help them better understand spasticity patients.

In conclusion, this research study demonstrated that spasticity patients have higher levels of psychological difficulties and lower levels of quality of life. These difficulties remain consistent regardless of the medical diagnosis related to spasticity/pain or medication being used to treat the condition. Results of this research sets an important context from which medical and psychiatric diagnoses, duration of time with pump, and level of pain play significant roles among patient quality of life. Knowledge of the importance of these factors may provide a context in which future medical and psychological interventions may be focused, especially among those practitioners working towards improved illness management with spasticity patients.

CHAPTER SEVEN

TABLES

Study Tables

Table 1

Demographic Variables (All Subjects; n=125)

Variable		
n	125	
Age (years)	49.06	
Gender (% male/female)	49.6 / 50.4	
Race (% and frequency)		
Caucasian	83.2	104
African-American	9.6	12
Hispanic	4.0	5
Asian or Pacific Islander	0.8	1
Native American	0.8	1
Other	1.6	2
Education (n=124; % and frequency)		
Completed 8th grade	6.4	8
Completed high school	14.4	18
Some college	44.0	55
Completed 4-year college	25.6	32
Some graduate school	3.2	4
Completed graduate school	5.6	7

Table 2

Demographic Variables Continued

Variable		
Diagnosis Group (% and frequency)		
Chronic Pain	33.6	42
Spinal Cord Injury	25.6	32
Multiple Sclerosis	18.4	23
Traumatic Head Injury	2.4	3
Cerebral Palsy	7.2	9
Closed Head Injury	0.8	1
Dystonia	0.8	1
Hereditary and Familial Spastic Paraplegia	1.6	2
Cerebrovascular Accident/Stroke	8.8	11
Other	0.8	1
Medication Group (% and frequency)		
Intrathecal Baclofen/Baclofen Combo	68.8	85
Other intrathecal medications (no baclofen)	31.2	39
Years with ITB Pump (Mean and Range)		
Mean (SD)	4.97 (3.66)	
Range (years)	1 to 17	

Table 3

Demographic Variables of Medication Group

Variable	Baclofen	Other
n	85	39
Age (years)*	46.60	54.07
Gender (% male/female)	59.0 / 41.0	46.0 / 54.0
Gender (frequency male/female)	23 / 16	39 / 46
Race [frequency (%)]		
Caucasian	70 (82.4%)	33 (84.6%)
African-American	9 (10.6%)	3 (7.7%)
Hispanic	4 (4.7%)	1 (2.6%)
Asian or Pacific Islander	1 (1.2%)	0 (0%)
Native American	0 (0%)	1 (2.6%)
Other	1 (1.2%)	1 (2.6%)

*Significant finding: $t(122)=2.93$, $p=.004$, $d=.57$

Table 4

Demographic Variables of Medication Group Continued

Variable	Baclofen	Other
Education [frequency (%)]		
Completed 8th grade	3 (3.5%)	5 (12.8%)
Completed high school	11 (12.9%)	7 (17.9%)
Some college	39 (45.9%)	15 (38.5%)
Completed 4-year college	22 (25.9%)	10 (25.6%)
Some graduate school	3 (3.5%)	1 (2.6%)
Completed graduate school	1 (1.2%)	1 (2.6%)

Table 5

Demographic Variables of Medical Diagnosis Group

Medical Diagnosis	n	Age* (years)	Male^ [frequency]	Female^ [frequency]
Chronic Pain	42	56.5	24	18
Spinal Cord Injury	32	44.0	24	8
Multiple Sclerosis	23	51.4	7	16
Traumatic Brain Injury	3	40.7	2	1
Cerebral Palsy	9	31.4	4	5
Closed Head Injury	1	41.0	0	1
Dystonia	1	28.0	0	1
Hereditary/Familial Spastic Paraplegia	2	39.0	0	2
Cerebrovascular Accident/Stroke	11	29.0	1	10
Other	1	53.6	0	1

*$F(9,115) = 6.25$, $p<.001$

^Gender was significant, X^2 $(9, N = 125) = 25.181$, $p <.003$

Table 6

Demographic Variables of Medical Diagnosis Group Continued [frequency]

Medical Diagnosis	Completed 8th grade	Completed Some High School	Completed Some College	Completed 4-year College	Completed Some Graduate School	Completed Graduate School
Chronic Pain	4	8	20	8	1	1
Spinal Cord Injury	3	5	8	12	1	3
Multiple Sclerosis	1	1	12	8	1	0
Traumatic Brain Injury	0	0	0	2	0	1
Cerebral Palsy	0	2	6	0	0	1
Closed Head Injury	0	0	1	0	0	0
Dystonia	0	0	1	0	0	0
Hereditary/Familial Spastic Paraplegia	0	0	1	1	0	0
Cerebrovascular Accident/Stroke	0	2	5	1	1	1
Other	0	0	1	0	0	0

Table 7

Quality of Life Measures with Significant Difference between Medical Diagnostic Groups

MEDICAL DIAGNOSIS GROUP	N	QWB Score	SF-36 Vitality (Scale Score)	SF-36 Bodily Pain (Scale Score)	SF-36 General Health (Scale Score)	PROMIS Fatigue (T-Score)	PROMIS Pain Behavioral (T-Score)	PROMIS Pain Interference (T-Score)
Chronic Pain	42	0.38 ± 0.16	39.13 ± 22.55	37.32±25.28	47.80±21.42	56.81 ± 7.57	58.49 ± 6.54	61.86 ± 9.32
Spinal Cord Injury	32	0.34 ± 0.12	42.97 ± 26.36	45.00±27.03	49.22±24.20	56.75 ± 9.06	57.84 ± 7.21	61.15 ± 7.62
Multiple Sclerosis	23	0.37 ± 0.15	33.48 ± 17.67	61.85±24.35	45.22±14.65	58.90 ± 6.61	52.80 ± 10.69	53.86 ± 11.69
Traumatic Brain Injury	3	0.74 ± 0.27	71.67 ± 2.89	100.0±0.00	88.33±10.41	42.20 ± 4.69	36.70 ± 0.01	41.00 ± 0.01
Cerebral Palsy	9	0.42 ± 0.21	60.00 ± 29.58	66.11±35.09	72.22±23.06	50.84 ± 9.28	50.17 ± 13.53	49.98 ± 12.17
Closed Head Injury	1	0.20	90.00	100.00	90.00	43.90	36.70	41.00
Dystonia	1	0.58	35.00	67.50	50.00	59.20	67.40	65.50
Hereditary/Familial Spastic Paraplegia	2	0.34 ± 0.20	45.00 ± 14.14	77.50±17.68	80.00±7.07	56.40 ± 7.92	56.90 ± 4.24	45.90 ± 6.93
Cerebrovascular Vascular Accident	11	0.38 ± 0.13	39.09 ± 25.48	45.68±27.55	60.91±27.64	54.81 ± 9.89	56.10 ± 10.16	55.77 ± 11.58
Other	1	0.38	50.00	10.00	50.00	57.80	59.20	61.80

*All measures listed were significant at or below $p = .05$ level

Table 8

Psychological and Quality of Life Measures for No Baclofen vs. Baclofen

Measure	Group	N	Mean (x)	SD	t	p	d
QWB Score	- Baclofen	39	0.39	0.16	0.48	0.64	0.092
	+ Baclofen	85	0.38	0.16			
SF-36 Physical Functioning (Scale Score)	- Baclofen	39	37.44	24.25	2.69	0.01*	0.52
	+ Baclofen	85	24.18	26.07			
SF-36 Role Limitations Due to Physical Health (Scale Score)	- Baclofen	39	28.12	37.69	-1.01	0.31	-0.195
	+ Baclofen	85	35.88	39.99			
SF-36 Role Limitations Due to Emotional Health (Scale Score)	- Baclofen	39	59.83	43.40	-1.64	0.10	-0.317
	+ Baclofen	85	72.55	38.55			
SF-36 Energy/Fatigue (Scale Score)	- Baclofen	39	38.03	23.13	-1.26	0.21	-0.244
	+ Baclofen	85	43.94	24.73			
SF-36 Emotional Well-Being (Scale Score)	- Baclofen	39	68.82	22.71	-0.69	0.50	-0.108
	+ Baclofen	85	71.67	20.81			
SF-36 Social Functioning (Scale Score)	- Baclofen	39	57.05	33.79	0.52	0.61	-0.233
	+ Baclofen	85	64.22	29.29			
SF-36 Pain (Scale Score)	- Baclofen	39	38.21	25.95	-0.87	0.39	-0.587
	+ Baclofen	85	54.82	29.28			
SF-36 General Health (Scale Score)[b]	- Baclofen	39	98.77	21.39	1.24	0.22	-0.338
	+ Baclofen	85	55.24	23.55			
Life Orientation Test - Total (Scale Score)[a]	- Baclofen	39	15.26	4.73	-1.20	0.25	-0.226
	+ Baclofen	85	16.24	4.15			
QIDS – Total Score	- Baclofen	39	7.46	4.14	0.80	0.43	0.155
	+ Baclofen	85	6.68	5.40			
PROMIS – Satisfaction with Discretionary Social Activities (T-Score)	- Baclofen	39	47.35	10.29	-0.29	0.77	-0.057
	+ Baclofen	85	47.92	9.90			
PROMIS – Satisfaction w/ Social Roles (T-Score)	- Baclofen	39	42.94	10.82	0.43	0.67	0.083
	+ Baclofen	85	42.12	9.49			
PROMIS – Fatigue (T-Score)	- Baclofen	39	56.87	8.14	0.77	0.44	0.149
	+ Baclofen	85	55.62	8.50			
PROMIS – Pain Behavior (T-Score)[b]	- Baclofen	39	58.61	6.74	2.37	0.02*	0.458
	+ Baclofen	85	54.40	10.12			
PROMIS – Pain Interference (T-Score)[a]	- Baclofen	37	61.30	9.40	2.51	0.01*	0.504
	+ Baclofen	76	56.01	10.98			

a. Degrees of freedom (df) = 122 for all values, except Life Orientation Test (df = 121) for and PROMIS - Pain Interference (df = 111)

b. Equal variances assumed, with Levene's Test insignificant to $p > 0.05$ for all measures

c. Cohen's *d* was computed to determine effect size: small=0.20, medium=0.50, large 0.80

Table 9

Correlation of Psychosocial Measures (All subjects)

		QWB Score	SF-36 Physical Functioning (Scale Score)	SF-36 Emotional Well-being (Scale Score)	Life Orientation Test-Revised (Raw Score)	QIDS (Total Score)	PROMIS-Satisfaction Discretionary Social Activities (T-Score)	PROMIS-Satisfaction Social Roles (T-Score)	PROMIS-Fatigue (T-Score)	PROMIS-Pain Behavior (T-Score)
QWB Score	Pearson r									
	Sig. (2-Tailed)									
	N									
SF-36 Physical Functioning (Scale Score)	Pearson r	.338**								
	Sig. (2-Tailed)	.000								
	N	125								
SF-36 Emotional Well-being (Scale Score)	Pearson r	.330**	.130							
	Sig. (2-Tailed)	.000	.148							
	N	125	125							
Life Orientation Test-Revised Total (Raw Score)	Pearson r	.263**	.057	.522**						
	Sig. (2-Tailed)	.003	.527	.000						
	N	124	124	124						
QIDS (Total Score)	Pearson r	-.368**	-.043	-.642**	-.401**					
	Sig. (2-Tailed)	.000	.635	.000	.000					
	N	125	125	125	124					
PROMIS-Satisfaction Discretionary Social Activities (T-Score)	Pearson r	.407**	.173	.537**	.394**	-.523**				
	Sig. (2-Tailed)	.000	.054	.000	.000	.000				
	N	125	125	125	124	125				
PROMIS-Satisfaction Social Roles (T-Score)	Pearson r	.546**	.272**	.423**	.313**	-.413**	.788**			
	Sig. (2-Tailed)	.000	.002	.000	.000	.000	.000			
	N	125	125	125	124	125	125			
PROMIS-Fatigue (T-Score)	Pearson r	-.399**	-.108	-.520**	-.367**	-.626**	-.626**	-.549**		
	Sig. (2-Tailed)	.000	.230	.000	.000	.000	.000	.000		
	N	125	125	125	124	125	125	125		
PROMIS-Pain Behavior (T-Score)	Pearson r	-.275**	.116	-.460**	-.280**	-.380**	-.380**	-.294**	.519**	
	Sig. (2-Tailed)	.002	.197	.000	.002	.000	.000	.001	.000	
	N	125	125	125	124	125	125	125	125	
PROMIS-Pain Interference (T-Score)	Pearson r	-.358**	.000	-.531**	-.336**	-.494**	-.494**	-.411**	.615**	.808**
	Sig. (2-Tailed)	.000	.997	.000	.000	.000	.000	.000	.000	.000
	N	114	114	114	113	114	114	114	114	114

**. Correlation is significant at the 0.01 level (2-tailed).

Based on Holm step-down correction

CHAPTER EIGHT

APPENDIX A

Study Measures

FULL-LENGTH COPIES OF STUDY MEASURES

SF-36 QUESTIONNAIRE

(1992 -- Medical Outcomes Trust)

Patient Name: _____ **Date:** _____

1. In general, would you say your health is: (circle one)

   Excellent Very good Good Fair Poor

2. Compared to one year ago, how would you rate your health in general now? (circle one)

   Much better now than one year ago.

   Somewhat better now than one year ago.

   About the same as one year ago.

   Somewhat worse than one year ago.

   Much worse than one year ago.

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? (Mark each answer with an X)

ACTIVITIES	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
a. **Vigorous activities,** such as running, lifting heavy objects, participating in strenuous sports			
b. **Moderate activities,** such as moving a table, pushing a vacuum cleaner, bowling, or playing golf			
c. Lifting or carrying groceries			
d. Climbing **several** flights of stairs			
e. Climbing **one** flight of stairs			
f. Bending, kneeling or stooping			
g. Walking **more than a mile**			
h. Walking **several blocks**			
i. Walking **one block**			
j. Bathing or dressing yourself			

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? (Mark each answer with an X)

	YES	NO
a. Cut down on the **amount of time** you spent on work or other activites		
b. **Accomplished less** than you would like		
c. Were limited in the **kind** of work or other activities		
d. Had **difficulty** performing the work or other activities (for example, it took extra effort)		

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)? (Mark each answer with an X)

	YES	NO
a. Cut down the **amount of time** you spent on work or other activities		
b. **Accomplished less** than you would like		
c. Didn't do work or other activities as **carefully** as usual		

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors or groups? (circle one)

Not at all Slightly Moderately Quite a bit Extremely

7. How much bodily pain have you had during the past 4 weeks? (circle one)

None Very mild Mild Moderate Severe Very severe

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all A little bit Moderately Quite a bit Extremely

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks – (Mark each answer with an X)

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
a. Did you feel full of pep?						
b. Have you been a very nervous person?						
c. Have you felt so down in the dumps that nothing could cheer you up?						
d. Have you felt calm and peaceful?						
e. Did you have a lot of energy?						
f. Have you felt downhearted and blue?						
g. Did you feel worn out?						
h. Have you been a happy person?						
i. Did you feel tired?						

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? (circle one)

All of the time Most of the time Some of the time A little of the time None of the time

11. How TRUE or FALSE is each of the following statements for you?

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
a. I seem to get sick a little easier than other people					
b. I am as healthy as anybody I know					
c. I expect my health to get worse					
d. My health is excellent					

Quality of Well-Being Scale, Self-Administered, QWB-SA, V1.04

This survey asks about health problems that you have experienced in the last 3 days, not including today. Please answer all questions by filling in the appropriate circle with blue or black ink. Please do not use check marks or use text to pass. Thank you.

Today's date: ___ / ___ / ___ (MM / DD / YY)

Part I - Acute and Chronic Symptoms

1. **Please indicate whether you currently experience each of the following health symptoms or problems**

Do you have....

a. *blindness or severely impaired vision in both eyes?* Y○ N○
   blindness or severely impaired vision in only one eye? Y○ N○
b. speech problems such as stuttering, or being unable to speak clearly? Y○ N○
c. missing or paralyzed hands, feet, arms, or legs? Y○ N○
   missing or paralyzed fingers or toes? Y○ N○
d. any deformity of the face, fingers, hand or arm, foot or leg, or back (e.g. severe scoliosis)? Y○ N○
e. general fatigue, tiredness, or weakness? Y○ N○
f. a problem with unwanted weight gain or weight loss? Y○ N○
g. a problem with being under or over weight? Y○ N○
h. problems chewing your food adequately? Y○ N○
i. any hearing loss or deafness? Y○ N○
j. any noticeable skin problems, such as bad acne or large burns or scars on face, body, arms, or legs? Y○ N○
k. eczema or burning/itching rash? Y○ N○

Which of the following health aides do you use/have?

dentures? Y○ N○
oxygen tank? Y○ N○
prosthesis? Y○ N○
eye glasses or contact lenses? Y○ N○
hearing aide? Y○ N○
magnifying glass? Y○ N○
neck, back, or leg brace? Y○ N○

2. **For the following list of problems indicate which days (if any) over the past 3 days, not including today, you had the problem. If you have not had the symptom in the past 3 days, do not leave the question blank, please fill in "no days." If you have experienced the symptom in the past 3 days, please check which of the days you had it; if you experienced it on more than one of the days, fill in all days that apply.**

For example: if you had a headache yesterday and the day before that
A headache? ○ No Days ● Yesterday ● 2 days ago ○ 3 days ago

Did you have.... (please fill in all days that apply)

a. any problems with your vision not corrected with glasses or contact lenses (such as double vision, distorted vision, flashes or floaters)? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
b. any eye pain, irritation, discharge, or excessive sensitivity to light? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
c. a headache? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
d. dizziness, earache, or ringing in your ears? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
e. difficulty hearing, or discharge, or bleeding from an ear? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
f. stuffy or runny nose, or bleeding from the nose? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
g. a sore throat, difficulty swallowing, or hoarse voice? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
h. a tooth ache or jaw pain? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
i. sore or bleeding lips, tongue, or gums? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
j. coughing or wheezing? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
k. shortness of breath or difficulty breathing? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago

Did you have.... (please fill in all days that apply)

l. chest pain, pressure, palpations, fast or skipped heart beat, or other discomfort in the chest? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
m. an upset stomach, abdominal pain, nausea, heartburn, or vomiting? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
n. difficulty with bowel movements, diarrhea, constipation, rectal bleeding, black tar-like stools, or any pain or discomfort in the rectal area? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
o. pain, burning, or blood in urine? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
p. loss of bladder control, frequent night-time urination, or difficulty with urination? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
q. genital pain, itching, burning, or abnormal discharge, or pelvic cramping or abnormal bleeding? (does not include normal menstruation) ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
r. a broken arm, wrist, foot, leg, or any other broken bone (other than in the back)? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
s. pain, stiffness, cramps, weakness, or numbness in the neck or back? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
t. pain, stiffness, cramps, weakness, or numbness in the hips or sides? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
u. pain, stiffness, cramps, weakness, or numbness in any of the joints or muscles of the hand, feet, arms, or legs? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
v. swelling of ankles, hands, feet or abdomen? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
w. fever, chills, or sweats? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
x. loss of consciousness, fainting, or seizures? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
y. difficulty with your balance, standing, or walking? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago

3. **The following symptoms are about your feelings, thoughts, and behaviors. Please fill in which days (if any) over the past 3 days, not including today, you have had ...**

a. trouble falling asleep or staying asleep? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
b. spells of feeling nervous or shaky? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
c. spells of feeling upset, downhearted, or blue? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
d. excessive worry or anxiety? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
e. feelings that you had little or no control over events in your life? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
f. feelings of being lonely or isolated? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
g. feelings of frustration, irritation, or close to losing your temper? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
h. a hangover? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
i. any decrease of sexual interest or performance? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
j. confusion, difficulty understanding the written or spoken word, or significant memory loss? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
k. thoughts or images you could not get out of your mind? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago
l. to take any medication including over-the-counter remedies (aspirin-tylenol, allergy medications, insulin, hormones, estrogen, thyroid, prednisone)? ○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago

Please continue on other side.

Quality of Well-Being Scale, Self-Administered, QWB-SA, V1.04 - Page 2

Part I - Acute and Chronic Symptoms (continued)

3. *Question 3 continued .....*

m. to stay on a medically prescribed diet for health reasons?
○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago

n. a loss of appetite or over-eating?
○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago

4. *In the last 3 days did you have any symptoms, health complaints, or pains that have not been mentioned?*
○ Yes ○ No

If yes, what were they and on which days did you have them?

Symptoms	Days
A.	
B.	

Part II - Self Care

5. ***Over the last 3 days ... (please fill in all days that apply)***

a. did you spend any part of the day or night as a patient in a hospital, nursing home, or rehabilitation center?
○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago

b. because of any impairment or health problem, did you need help with your personal care needs, such as eating, dressing, bathing, or getting around your home?
○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago

Part III - Mobility

6. **Over the last 3 days ... (please fill in all days that apply)**

a. which days did you drive a motor vehicle?
○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago

b. which days did you use public transportation such as a bus, subway, Medi-van, train, or airplane?
○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago

c. which days did you either not drive a motor vehicle or not use public transportation because of your health, or need help from another person to use?
○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago

Part IV - Physical Activity

7. **Over the last 3 days did you ... (please fill in all days that apply)**

a. have trouble climbing stairs or inclines or walking off the curb?
○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago

b. avoid walking, have trouble walking, or walk more slowly than other people your age?
○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago

c. limp or use a cane, crutches, or walker?
○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago

d. avoid or have trouble bending over, stooping, or kneeling?
○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago

e. have any trouble lifting or carrying everyday objects such as books, a briefcase, or groceries?
○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago

f. have any other limitations in physical movements?
○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago

g. spend all or most of the day in a bed, chair, or couch because of health reasons?
○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago

h. spend all or most of the day in a **wheelchair**?
○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago

If in a wheelchair, on which days did someone else control its movement?
○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago

Part V - Usual Activity

8. ***Over the last 3 days ... (please fill in all days that apply)***

a. because of any physical or emotional health reasons, on which days did you avoid, need help with, or were limited in doing some of your usual activities, such as work, school or housekeeping?
○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago

b. because of any physical or emotional health reasons, on which days did you avoid or feel limited in doing some of your usual activities, such as visiting family or friends, hobbies, shopping, recreational, or religious activities?
○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago

c. on which days did you have to change any of your plans or activities because of your health? (Consider only activities that you did not report in the last 2 questions.)
○ No Days ○ Yesterday ○ 2 days ago ○ 3 days ago

If limited, please describe:

9a. Would you say that your health is:
○ Excellent ○ Very Good ○ Good ○ Fair ○ Poor

b. Compared to a year ago, how would you rate your health in general now:
○ Much better than a year ago
○ Somewhat better than one year ago
○ About the same as a year ago
○ Somewhat worse than a year ago
○ Much worse than a year ago

c. Think about a scale of 0 to 100, with zero being the least desirable state of health that you could imagine and 100 being perfect health. What number, from 0 to 100 would you give to the state of your health, on average, over the last 3 days?

0	10	20	30	40	50	60	70	80	90	100
○	○	○	○	○	○	○	○	○	○	○

10. **Please complete the following questions:**

Sex: ○ Male ○ Female

Age: ☐☐

What is your ethnicity?
○ African American
○ Asian/Pacific Islander
○ Caucasian - Non Hispanic
○ Hispanic
○ Native American
○ Other

Which of the following best describes your educational background?
○ 8th Grade Graduate
○ High School Graduate
○ Some College
○ College Graduate (B.S. or B.A. degree)
○ Some Graduate School
○ Completed Post-Graduate (M.A., M.D., Ph.D.)

Thank you for completing the QWB SA 1.04 Health Status Survey

Protocol Number ☐☐☐☐☐☐ Investigator Number ☐☐☐

Participant ☐☐☐☐☐☐

The revised life orientation test (LOT-R)

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.

Using the scale below, write the appropriate number beside each statement.

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

1) In uncertain times, I usually expect the best
2) It's easy for me to relax
3) If something can go wrong for me it will
4) I'm always optimistic about my future
5) I enjoy my friends a lot
6) It's important for me to keep busy
7) I hardly ever expect things to go my way
8) I don't get upset too easily
9) I rarely count on good things happening to me
10) Overall, I expect more good things to happen to me than bad

All data from this questionnaire will be kept in the strictest confidence.

Name:
Contact details:

The Quick Inventory of Depressive Symptomatology (16-Item) (Self-Report) (QIDS-SR16)

Name or ID: _____ Date: _____

CHECK THE ONE RESPONSE TO EACH ITEM THAT BEST DESCRIBES YOU FOR THE PAST SEVEN DAYS.

During the past seven days...

1. Falling Asleep:

☐ 0 I never take longer than 30 minutes to fall asleep.

☐ 1 I take at least 30 minutes to fall asleep, less than half the time.

☐ 2 I take at least 30 minutes to fall asleep, more than half the time.

☐ 3 I take more than 60 minutes to fall asleep, more than half the time.

2. Sleep During the Night

☐ 0 I do not wake up at night.

☐ 1 I have a restless, light sleep with a few brief awakenings each night.

☐ 2 I wake up at least once a night, but I go back to sleep easily.

☐ 3 I awaken more than once a night and stay awake for 20 minutes or more, more than half the time.

3. Waking Up Too Early:

☐ 0 Most of the time, I awaken no more than 30 minutes before I need to get up.

☐ 1 More than half the time, I awaken more than 30 minutes before I need to get up.

☐ 2 I almost always awaken at least one hour or so before I need to, but I go back to sleep eventually.

☐ 3 I awaken at least one hour before I need to, and can't go back to sleep.

4. Sleeping Too Much:

☐ 0 I sleep no longer than 7-8 hours/night, without napping during the day.

☐ 1 I sleep no longer than 10 hours in a 24-hour period *including naps.*

☐ 2 I sleep no longer than 12 hours in a 24-hour period including naps.

☐ 3 I sleep longer than 12 hours in a 24-hour period including naps.

During the past seven days...

5. Feeling Sad:

☐ 0 I do not feel sad.

☐ 1 I feel sad less than half the time.

☐ 2 I feel sad more than half the time.

☐ 3 I feel sad nearly all of the time.

Please complete either 6 or 7 (not both)

6. Decreased Appetite:

☐ 0 There is no change in my usual appetite.

☐ 1 I eat somewhat less often or lesser amounts of food than usual.

☐ 2 I eat much less than usual and only with personal effort.

☐ 3 I rarely eat within a 24-hour period, and only with extreme personal effort or when others persuade me to eat.

- OR -

7. Increased Appetite:

☐ 0 There is no change from my usual appetite.

☐ 1 I feel a need to eat more frequently than usual.

☐ 2 I regularly eat more often and/or greater amounts of food than usual.

☐ 3 I feel driven to overeat both at mealtime and between meals.

Please complete either 8 or 9 (not both)

8. Decreased Weight (Within the Last Two Weeks):

☐ 0 I have not had a change in my weight.

☐ 1 I feel as if I have had a slight weight loss.

☐ 2 I have lost 2 pounds or more.

☐ 3 I have lost 5 pounds or more.

- OR -

9. Increased Weight (Within the Last Two Weeks):

☐ 0 I have not had a change in my weight.

☐ 1 I feel as if I have had a slight weight gain.

☐ 2 I have gained 2 pounds or more.

☐ 3 I have gained 5 pounds or more.

The Quick Inventory of Depressive Symptomatology (16-Item) (Self-Report) (QIDS-SR16)

During the past seven days...

10. Concentration / Decision Making:

- ☐ 0 There is no change in my usual capacity to concentrate or make decisions.
- ☐ 1 I occasionally feel indecisive or find that my attention wanders.
- ☐ 2 Most of the time, I struggle to focus my attention or to make decisions.
- ☐ 3 I cannot concentrate well enough to read or cannot make even minor decisions.

11. View of Myself:

- ☐ 0 I see myself as equally worthwhile and deserving as other people.
- ☐ 1 I am more self-blaming than usual.
- ☐ 2 I largely believe that I cause problems for others.
- ☐ 3 I think almost constantly about major and minor defects in myself.

12. *Thoughts of Death or Suicide*:

- ☐ 0 I do not think of suicide or death.
- ☐ 1 I feel that life is empty or wonder if it's worth living.
- ☐ 2 I think of suicide or death several times a week for several minutes.
- ☐ 3 I think of suicide or death several times a day in some detail, or I have made specific plans for suicide or have actually tried to take my life.

13. General Interest

- ☐ 0 There is no change from usual in how interested I am in other people or activities.
- ☐ 1 I notice that I am less interested in people or activities.
- ☐ 2 I find I have interest in only one or two of my formerly pursued activities.
- ☐ 3 I have virtually no interest in formerly pursued activities.

During the past seven days...

14. Energy Level:

- ☐ 0 There is no change in my usual level of energy.
- ☐ 1 I get tired more easily than usual.
- ☐ 2 I have to make a big effort to start or finish my usual daily activities (for example, shopping, homework, cooking, or going to work).
- ☐ 3 I really cannot carry out most of my usual daily activities because I just don't have the energy.

15. Feeling Slowed Down:

- ☐ 0 I think, speak, and move at my usual rate of speed.
- ☐ 1 I find that my thinking is slowed down or my voice sounds dull or flat.
- ☐ 2 It takes me several seconds to respond to most questions and I'm sure my thinking is slowed.
- ☐ 3 I am often unable to respond to questions without extreme effort.

16. Feeling Restless:

- ☐ 0 I do not feel restless.
- ☐ 1 I'm often fidgety, wringing my hands, or need to shift how I am sitting.
- ☐ 2 I have impulses to move about and am quite restless.
- ☐ 3 At times, I am unable to stay seated and need to pace around.

PATIENT HEALTH QUESTIONNAIRE (PHQ)

This questionnaire is an important part of providing you with the best health care possible. Your answers will help in understanding problems that you may have. Please answer every question to the best of your ability unless you are requested to skip a question.

Name_____ **Age**_____ **Sex:** ☐ **Female** ☐ **Male** **Today's Date**_____

1. During the last 4 weeks, how much have you been bothered by any of the following problems?

	Not bothered	Bothered a little	Bothered a lot
a. Stomach pain	☐	☐	☐
b. Back pain	☐	☐	☐
c. Pain in your arms, legs, or joints (knees, hips, etc.)	☐	☐	☐
d. Menstrual cramps or other problems with your periods	☐	☐	☐
e. Pain or problems during sexual intercourse	☐	☐	☐
f. Headaches	☐	☐	☐
g. Chest pain	☐	☐	☐
h. Dizziness	☐	☐	☐
i. Fainting spells	☐	☐	☐
j. Feeling your heart pound or race	☐	☐	☐
k. Shortness of breath	☐	☐	☐
l. Constipation, loose bowels, or diarrhea	☐	☐	☐
m. Nausea, gas, or indigestion	☐	☐	☐

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

	Not at all	Several days	More than half the days	Nearly every day
a. Little interest or pleasure in doing things	☐	☐	☐	☐
b. Feeling down, depressed, or hopeless	☐	☐	☐	☐
c. Trouble falling or staying asleep, or sleeping too much	☐	☐	☐	☐
d. Feeling tired or having little energy	☐	☐	☐	☐
e. Poor appetite or overeating	☐	☐	☐	☐
f. Feeling bad about yourself, or that you are a failure, or have let yourself or your family down	☐	☐	☐	☐
g. Trouble concentrating on things, such as reading the newspaper or watching television	☐	☐	☐	☐
h. Moving or speaking so slowly that other people could have noticed. Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual	☐	☐	☐	☐
i. Thoughts that you would be better off dead, or of hurting yourself in some way	☐	☐	☐	☐

FOR OFFICE CODING: Score Dis if at least three of #1a–m are "Bothered a lot" and lack an adequate bad explanation. Maj Dep Syn if answer to #2a or b and five or more of #2a–i are at least "More than half the days" (count #2i if present at all). Other Dep Syn if #2a or b and two, three, or four of #2a–i are at least "More than half the days" (count #2i if present at all).

3. Questions about anxiety.

	NO	YES
a. In the <u>last 4 weeks</u>, have you had an anxiety attack—suddenly feeling fear or panic?		

If you checked "NO," go to question 5.

	NO	YES
b. Has this ever happened before?		
c. Do some of these attacks come <u>suddenly out of the blue</u>—that is, in situations where you don't expect to be nervous or uncomfortable?		
d. Do these attacks bother you a lot or are you worried about having another attack?		

4. Think about your last bad anxiety attack.

	NO	YES
a. Were you short of breath?		
b. Did your heart race, pound, or skip?		
c. Did you have chest pain or pressure?		
d. Did you sweat?		
e. Did you feel as if you were choking?		
f. Did you have hot flashes or chills?		
g. Did you have nausea or an upset stomach, or the feeling that you were going to have diarrhea?		
h. Did you feel dizzy, unsteady, or faint?		
i. Did you have tingling or numbness in parts of your body?		
j. Did you tremble or shake?		
k. Were you afraid you were dying?		

5. Over the <u>last 4 weeks</u>, how often have you been bothered by the following problems?

	Not at all	Several days	More than half the days
a. Feeling nervous, anxious, on edge, or worrying a lot about different things			

If you checked "Not at all," go to question 6.

	Not at all	Several days	More than half the days
b. Feeling restless so that it is hard to sit still			
c. Getting tired very easily			
d. Muscle tension, aches, or soreness			
e. Trouble falling asleep or staying asleep			
f. Trouble concentrating on things, such as reading a book or watching television			
g. Becoming easily annoyed or irritated			

FOR OFFICE CODING: Pan Syn if all of #3a-d are "YES" and four or more of #4a-k are "YES." Other Anx Syn if #5a and answers to three or more of #5b-g are "More than half the days."

6. Questions about eating.

	NO	YES
a. Do you often feel that you can't control *what* or *how much* you eat?	☐	☐
b. Do you often eat, *within any 2-hour period*, what most people would regard as an unusually *large* amount of food?	☐	☐

If you checked "NO" to either a or b, go to question 9.

	NO	YES
c. Has this been as often, on average, as twice a week for the last 3 months?	☐	☐

7. In the last 3 months have you *often* done any of the following in order to avoid gaining weight?

	NO	YES
a. Made yourself vomit	☐	☐
b. Taken more than twice the recommended dose of laxatives	☐	☐
c. Fasted (not eaten anything at all for at least 24 hours)	☐	☐
d. Exercised for more than an hour, specifically to avoid gaining weight after binge eating	☐	☐

	NO	YES
8. If you checked "YES" to any of these ways of avoiding gaining weight, were any as often, on average, as twice a week?	☐	☐
9. Do you ever drink alcohol (including beer or wine)?	☐	☐

If you checked "NO," go to question 11.

10. Have any of the following happened to you *more than once in the last 6 months*?

	NO	YES
a. You drank alcohol even though a doctor suggested that you stop drinking because of a problem with your health	☐	☐
b. You drank alcohol, were high from alcohol, or were hung over while you were working, going to school, or taking care of children or other responsibilities	☐	☐
c. You missed or were late for work, school, or other activities because you were drinking or hung over	☐	☐
d. You had a problem getting along with other people while you were drinking	☐	☐
e. You drove a car after having several drinks or after drinking too much	☐	☐

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

☐ **Not difficult at all** ☐ **Somewhat difficult** ☐ **Very difficult** ☐ **Extremely difficult**

FOR OFFICE CODING: Bul Ner if #6a,b,c and #8 are all "YES"; Bin Eat Dis the same but #8 is either "NO" or left blank; Alc Abu if any of #10a-e is "YES".

12. In the last 4 weeks, how much have you been bothered by any of the following problems?

	Not bothered	Bothered a little	Bothered a lot
a. Worrying about your health	☐	☐	☐
b. Your weight or how you look	☐	☐	☐
c. Little or no sexual desire or pleasure during sex	☐	☐	☐
d. Difficulties with husband/wife, partner/lover, or boyfriend/girlfriend	☐	☐	☐
e. The stress of taking care of children, parents, or other family members	☐	☐	☐
f. Stress at work outside of the home or at school	☐	☐	☐
g. Financial problems or worries	☐	☐	☐
h. Having no one to turn to when you have a problem	☐	☐	☐
i. Something bad that happened recently	☐	☐	☐
j. Thinking or dreaming about something terrible that happened to you in the past—like your house being destroyed, a severe accident, being hit or assaulted, or being forced to commit a sexual act	☐	☐	☐

13. In the last year, have you been hit, slapped, kicked, or otherwise physically hurt by someone, or has anyone forced you to have an unwanted sexual act?

NO ☐ YES ☐

14. What is the most stressful thing in your life right now? _____

_____

_____

15. Are you taking any medication for anxiety, depression, or stress?

NO ☐ YES ☐

16. FOR WOMEN ONLY: Questions about menstruation, pregnancy, and childbirth.

a. Which best describes your menstrual periods?

☐ **Periods are unchanged** ☐ **No periods because pregnant or recently gave birth** ☐ **Periods have become irregular or changed in frequency, duration, or amount** ☐ **No periods for at least a year** ☐ **Having periods because taking hormone replacement (estrogen) therapy or oral contraceptives**

	NO (or does not apply)	YES
b. During the week before your period starts, do you have a serious problem with your mood—like depression, anxiety, irritability, anger, or mood swings?	☐	☐
c. If YES, do these problems go away by the end of your period?	☐	☐
d. Have you given birth within the last 6 months?	☐	☐
e. Have you had a miscarriage within the last 6 months?	☐	☐
f. Are you having difficulty getting pregnant?	☐	☐

Developed by Drs Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke, and colleagues, with an educational grant from Pfizer Inc. For research information, contact Dr Spitzer at rls8@columbia.edu

Satisfaction with Participation in Discretionary Social Activities – Short Form 1

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
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
SRPSAT20	I am satisfied with my ability to do things for my friends	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT25	I am satisfied with my ability to do leisure activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT05	I am satisfied with the amount of time I spend doing leisure activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT26	I am satisfied with my current level of activities with my friends	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT10	I am satisfied with my current level of social activity	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT30	I am satisfied with my ability to do things for fun outside my home	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Satisfaction with Participation in Social Roles – Short Form 1

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
SRPSA706	I am satisfied with my ability to do things for my family	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSA750	I am satisfied with my ability to meet the needs of those who depend on me	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSA749	I am satisfied with my ability to perform my daily routines	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSA751	I am satisfied with my ability to run errands	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSA724	I am satisfied with my ability to work (include work at home)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSA738	I am satisfied with my ability to do household chores/tasks	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSA727	I am satisfied with how much work I can do (include work at home)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Fatigue - Short Form 1

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

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
FATEXP20	How often did you feel tired?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP6	How often did you experience extreme exhaustion?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP18	How often did you run out of energy?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP33	How often did your fatigue limit you at work (include work at home)?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP36	How often were you too tired to think clearly?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP21	How often were you too tired to take a bath or shower?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP40	How often did you have enough energy to exercise strenuously?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

Pain Behavior – Short Form 1

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
PAINBE5 When I was in pain I grimaced	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE8 When I was in pain I moved extremely slowly	☐ 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
PAINBE27 When I was in pain I isolated myself from others	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
PAINBE45 When I was in pain I thrashed	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

Pain Impact – Short Form 1

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
How much did pain interfere with your enjoyment of life?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
How much did pain interfere with your ability to concentrate?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
How much did pain interfere with your day to day activities?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
How much did pain interfere with your enjoyment of recreational activities?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
How much did pain interfere with doing your tasks away from home (e.g., getting groceries, running errands)?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	Never	Rarely	Sometimes	Often	Always
How often did pain keep you from socializing with others?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

CHAPTER NINE

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