A MIXED METHOD INVESTIGATION OF PREDICTORS OF PAIN AND DISABILITY IN PATIENTS WITH LUMBAR SPINAL STENOSIS.

by

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ABSTRACT

This study identified characteristics associated with pain and disability in LSS at entry to treatment and factors contributing to long-term reduction of pain and disability. It also revealed how patients with LSS appraise the stressors of pain and disability and use coping resources. This study used qualitative and quantitative methods to address the dearth of research in the LSS literature regarding factors associated with severity of pain and disability upon entry to treatment and the influence of coping resources on post-treatment outcomes. A cohort of 34 patients was evaluated to understand the relative contribution of perceived health, self-efficacy, and social support on the stressors of pain and disability using a combination of bivariate and multivariate regression analyses and patient interviews.

Several key findings emerged from this research. First, there was an inverse relationship between perceived physical and mental health and severity of disability upon entry to treatment. In interviews, patients with LSS described a variety of sources contributing to stressors of pain and disability including physical limitations, reduced confidence, lack of control, vulnerability, mental health concerns, reduced social participation, frustrations at needing support, and financial limitations. Better perceived physical health had the greatest contribution to reduced levels of pain and disability post-treatment. In interviews, a variety of behaviors were described that improved coping including a greater understanding of limitations and needs along with beliefs for pushing through and remaining positive. In line with the Stress and Coping Model, patients with stronger coping behaviors and more resources reduced the severity and improved outcomes of pain and disability associated with LSS.
There is an increased need for research improving the quality of life in later years particularly when faced with a chronic disabling condition such as LSS. Early identification of those at risk for higher pain and disability as well as support for positive coping behaviors post-treatment can help patients with LSS maintain a higher level of participation in society. The factors uncovered in this study serve to inform translational research, clinical practice, and policy recommendations, which may ultimately add to treatment and resources for reducing pain and disability associated with LSS.

The form and content of this abstract are approved. I recommend its publication.

Approved: Susan L. Dreisbach
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LIST OF ABBREVIATIONS

ADLs  Activities of Daily Living
BDI  Beck Depression Index
COMIRB  Colorado Multiple Institutional Review Board
ESI  Epidural steroid injection
EXSE  Exercise Self-Efficacy subscale of the LoBACS
FSE  Functional Self-Efficacy subscale of the LoBACS
ICF  International Classification of Functioning
IRB  Institutional Review Board
LBP  Low back pain
LoBACS  Lower Back Activity Confidence Scale
LSS  Lumbar spinal stenosis
MCID  Minimal Clinically Important Difference
MCS  Mental Component Summary of the SF-36
MOS SSS  Medical Outcomes Survey Social Support Scale
MRI  Magnetic resonance imaging
MrOS  Osteoporotic Fractures in Men Study
NPRS  Numeric Pain Rating Scale
NPRSbb  Numeric Pain Rating Scale back and buttock subscale
NPRStl  Numeric Pain Rating Scale thigh and leg subscale
OA  Osteoarthritis
ODI  Oswestry Disability Index
PCS  Physical Component Summary of the SF-36
PT  Physical therapy
RA  Rheumatoid arthritis
RCT  Randomized clinical trial
SCT  Social Cognitive Theory
SF-36  Short Form 36 from the Medical Outcomes Survey
VAS  Visual Analog Scale
WHO  World Health Organization
CHAPTER I

BACKGROUND AND SIGNIFICANCE

Low Back Pain

Low back pain (LBP) occurs at epidemic proportions in the United States, affecting 60-90% of individuals during their lifetimes.\(^1\) Total healthcare expenditures in the U.S. incurred by patients with LBP are 90 billion dollars annually, 60% higher than in individuals without LBP.\(^2\) Next to the common cold, the complaint of LBP is the most common reason individuals visit a physician’s office.\(^3,4\) Approximately 40% of individuals have experienced LBP for a day or more within the last 12 months, with 40% of them having consulted their primary care provider. Because of the substantial impact of LBP on healthcare, there is a need to identify effective management strategies to reduce the pain and disability associated with diagnoses of LBP.

Lumbar Spinal Stenosis

A US national survey of physician visits identified back pain as the most commonly reported musculoskeletal symptom and third most frequently reported symptom in patients over 75 years of age.\(^5\) Lumbar spinal stenosis (LSS) is a subgroup of LBP that clinicians can identify through age and symptom related factors. LSS is a prevalent and disabling musculoskeletal condition in the aging population that often results in substantial stress and physical burden for individuals with the disorder, and is associated with significant healthcare costs.\(^6,8\) Physicians diagnose LSS in an estimated 13-14% of patients who seek help from a specialty physician, and 3-4% who seek care from a general practitioner for LBP.\(^8,9\) Elderly patients with LSS as a source of their back and leg pain suffer from significant functional disability,\(^10,11\) and many eventually seek surgical intervention. The Osteoporotic Fractures in Men Study (MrOS) examined a multi-center community cohort of 5995 men, 66 years and older, and found 65% of the men had at least 1 episode of LBP in the past year and 26% had clinically relevant LBP which occurred more than
3 times in the prior year at a pain level of moderate to severely bothersome. In addition, the authors found that approximately 10% of the group with clinically relevant LBP had symptoms that were similar to those with LSS.

Definition, pathoanatomy, and clinical presentation of LSS. Degenerative lumbar spinal stenosis (LSS) is defined as a focal narrowing of the spinal canal, although there are varying opinions about the precise amount of narrowing that must occur before the canal is considered stenotic. LSS is classified as an arthritic condition. Postaccini and other scholars apply the general term “spinal stenosis” to 3 root compression mechanisms alone or in combination: (1) disk protrusion or herniation, (2) osteotic overgrowth into the spinal canal or the foramina through which the roots pass laterally, and (3) vertebral slippage or spondylolisthesis.

Because degenerative changes are the predominant etiology of LSS, affected individuals tend to be older, typically at least 50 years of age, with a prolonged history of low back pain. Leg pain, either unilateral or bilateral, is also reported in about 90% of patients seeking medical attention. Chronic compression of the spinal nerve roots can also lead to sensory, reflex and/or strength changes in the lower extremities. Fifty percent of patients report these neurological changes. Acute cauda equina syndrome is rare, but clinicians have reported it.

The hallmark finding of patients with LSS is the postural-dependency of the symptoms. Patients have reported that symptoms typically worsen with standing or walking, and can be relieved or diminished by sitting or bending forward. Neurogenic claudication frequently accompanies LSS, defined by clinicians as poorly localized pain, paresthesias, and cramping in one or both lower extremities that is of a neurological origin, brought on by walking and relieved by sitting. Walking tolerance can become substantially limited in patients with LSS, with pain and reduction in walking capacity often cited as a reason for seeking medical intervention.

Incidence and impact of LSS. Although there is literature on the burden of disease of LBP in general, only 1 study has addressed the societal burden of disease related to functional loss and disability specifically for patients with spinal stenosis. A Swedish study by Johnsson,
that defined spinal stenosis as a canal of 11 mm or less, described the annual incidence of LSS among patients referred to orthopedic departments as approximately 50 per 100,000 inhabitants. This 1995 population study of 2 regions in Sweden reported that, with a LSS incidence of about 50 per 100,000, between 42% and 58% of these patients had claudication (leg pain or weakness upon standing or walking). From these data, Johnsson calculated the incidence as about 25 per 100,000 inhabitants for spinal-stenosis-associated claudication. More severe stenosis can result in cauda equina syndrome, which is characterized by the loss of sexual function and urinary and/or fecal incontinence. This same study reported that cauda equina syndrome had an incidence of less than 1 per 100,000. If untreated, clinicians commonly believe severe LSS has the potential to lead to symptoms that become permanent and unresponsive to medical or surgical treatment.11, 13, 29-34

Review articles23, 35, 36 and textbooks32, 37 provide some evidence that patients with symptomatic spinal stenosis typically have chronic LBP and pain and weakness in the legs that limits functional tasks such as standing and walking to brief durations and short distances. These physical impairments place stressors on the individual, particularly limitations on the ability to carry out self-supporting, daily activities as well as work, social, and recreational activities, that would be defined as sources leading to disability in the person with LSS.

Patients with LSS often report decreases in physical health.38-40 Decreased physical health either real or perceived can impact an individual in many ways. Overall, it is known that those who have decreased physical health reduce or eliminate participation in daily living, social, and recreational activities. A lack of activity has been shown to lead to other stressors such as obesity and general physical deterioration that may eventually result in further disability with the onset of cardiovascular and other serious health problems.41 Activity restrictions may also lead to low self-confidence, fear or avoidance behaviors, depression and other psychological problems that further restrict the person with LSS from participation in activities of daily living (ADLs), recreational activities, social activities, and community functions.32, 42, 43
Limitations in the current literature for LSS. While the substantial societal impact of LSS is apparent, there continue to be controversies in the literature regarding the effectiveness of both surgical and non-surgical management of LSS.\textsuperscript{5, 11, 19, 44-47} Suboptimal research designs along with other factors such as incomplete reporting of patient characteristics and unmeasured psychosocial factors that may influence coping behaviors in managing the stressors of pain and disability account for some of the gaps in current research on LSS. The interaction between the stressors of pain and limited physical function, limited participation in activities, and altered patient behaviors in relationship to intrapersonal and interpersonal coping factors is complex and has been poorly studied in patients with LSS. This research study fills an important gap in the literature by using a novel approach to evaluate the relative contribution of self-efficacy, social support, and self-reported physical and mental health when managing the stressors of pain and disability in LSS.

Rationale

The Institute of Medicine has recognized LBP as a top 15 priority condition, calling for health care organizations to develop new evidence-based care process models.\textsuperscript{48} Current practice guidelines for LBP in primary care recommend a stepped care approach with an initial treatment of education and advice that focuses on remaining active throughout care. For a subgroup of patients with LBP diagnosed with LSS, evidence shows success for conservative treatment that includes informational education, advice for physical activity, epidural steroid injections and physical therapy.\textsuperscript{49-51} Identifying the multiple factors resulting in heightened pain and disability is the first goal in clinical management. Identifying factors for successful clinical outcomes is the next goal. Success in treatment is measured by reduction in pain and disability for this subgroup of patients with LSS. Several studies have indicated that psychosocial factors such as depression and fear avoidance behaviors are negative influences on the stressors of pain and disability and result in declines in treatment success in LBP in general.\textsuperscript{52-54} Studies have shown that depression
and fear avoidance behaviors correlate with reduced participation in functional daily tasks indicating higher risk for disability. Studies have also shown that depression and fear avoidance scores can improve during LBP management and result in positive changes in patient outcomes of pain and disability. Overall, research has demonstrated that using an enhanced or multimodal team approach to treatment results in improved patient outcomes for LBP. Although the general LBP literature can provide some insight into management of LSS, identifying factors contributing to higher pre-treatment pain and disability as well as determining what factors help improve treatment outcomes for patients with LSS continues to be incomplete. Due to a lack of reporting and a limited understanding of what influences the stressors of pain and disability, there are gaps in LSS literature about the influence of psychosocial factors on the severity and outcomes in LSS. Rarely has LSS research examined the intrapersonal and interpersonal influences in this chronic condition. No other study to date has examined the relative contribution of self-efficacy and social support in predicting the severity and outcomes of pain and disability in patients with LSS. As the population continues to age and the provision of medical care for patients with LSS requires considerable healthcare resources, it is important to identify and understand factors that impact pain and disability and thereby improve successful treatment of patients suffering from this spinal disorder.

Research Question and Specific Aims

The current study addressed the following research question: **What is the relative contribution of self-efficacy, social support, perceived physical health, and perceived mental health to pain and disability in individuals with LSS?** Three Specific Aims guided the investigation of this overarching research question.
Aim 1: To determine the relative contribution of self-efficacy, social support, self-rated physical health, and self-rated mental health to the severity of pain and disability among patients with LSS upon entry to treatment of LSS.

H1A: Lower levels of self-efficacy, social support, perceived physical health and perceived mental health will each independently predict higher disability at entry to treatment.

H1B: Lower levels of self-efficacy, social support, perceived physical health and perceived mental health will each independently predict higher pain at entry to treatment.

H1C: Lower levels of self-efficacy, social support, perceived physical health and perceived mental health will together predict higher disability at entry to treatment.

H1D: Lower levels of self-efficacy, social support, perceived physical health and perceived mental health will together predict higher pain at entry to treatment.

Aim 2: To determine the relative contribution of self-efficacy, social support, self-rated physical health, and self-rated mental health to the outcomes of pain and disability among patients with LSS in the year following treatment of LSS.

H2A: Higher levels of self-efficacy, social support, perceived physical health and perceived mental health will each independently predict lower disability after treatment of LSS.

H2B: Higher levels of self-efficacy, social support, perceived physical health and perceived mental health will each independently predict lower pain after treatment of LSS.

H2C: Higher levels of self-efficacy, social support, perceived physical health and perceived mental health will together predict lower disability after treatment of LSS.

H2D: Higher levels of self-efficacy, social support, perceived physical health and perceived mental health will together predict lower pain after treatment of LSS.
Aim 3: Explore how self-efficacy, social support, perceived physical health and perceived mental health contribute to a patient’s lived experience with LSS and influence meanings of pain and disability.

Research Goals

The goal of this dissertation research project was to determine the relative contribution of self-efficacy, social support, and self-rated physical and mental health to pain and disability in patients with LSS upon entry to treatment and long term post-treatment. This goal requires a greater understanding of the role of self-efficacy, social support, and self-rated health beyond what currently exists in the literature for patients with LSS. This project also sought to uncover additional unknown factors that contribute to the stressors of pain and disability and identify any additional coping resources that might be available to patients with LSS. These research findings will improve the understanding of how stressors, particularly pain and disability, are appraised in a population of individuals with LSS. In addition, this research will help identify the role of self-efficacy, social support, self-rated physical health and self-rated mental health in coping with LSS and determine their contribution in predicting outcomes of pain and disability. Results from this study will help direct clinical management and future research in this patient population.
CHAPTER II

REVIEW OF THE LITERATURE

Pain and Disablement in LSS

Research illustrates that the LSS condition results in significant stressors for individuals with LSS in the form of pain and disability.\textsuperscript{58, 59} Research also confirms that after treatment, many with LSS continue to have multiple stressors related to pain and disability with basic activities such as standing and walking.\textsuperscript{60, 61} Similar to those living with chronic conditions such as cancer, osteoarthritis, and diabetes, it is likely that persons with LSS experience challenges with psychological, social, medical, and financial limitations in addition to basic physical functioning limitations.\textsuperscript{59, 62-65}

It is clear that somatic symptoms related to body structure or function has the most recognition in the current literature for LSS. Low back pain, leg pain and spinal canal narrowing are the top 3 reported factors contributing to disability in the LSS population.\textsuperscript{6, 39, 58, 60, 66} Severity of LSS is almost exclusively determined by pain and spinal canal narrowing on imaging and are the most recognized factors for surgical decision making.\textsuperscript{67, 68} However, imaging of spinal canal narrowing has not been found to be a reliable way to identify severity in LSS.\textsuperscript{61, 69, 70} Also, problems with other somatic factors in addition to pain have been reported including neurogenic claudication, neurological changes, decreased lumbar spine motion particularly in extension, and decreased range of motion of most of the joints and soft tissues in the lower extremity and trunk.\textsuperscript{40, 51}

Alterations in activity due to pain and weakness are frequently reported factors contributing to disablement in LSS. The top 3 reported factors related to changes in activities or participation includes limitations in walking and standing but increased activity of sitting.\textsuperscript{6, 59, 60, 66} These 3 activity/participation factors have become part of the clinical diagnosis for LSS.\textsuperscript{39} Other
functional problems seem to be present such as stair climbing or general activities of daily living (ADLs) but these have been widely under-reported.

Identification and measurement of pain and disability in patients with LSS has been almost exclusively documented by physical examination or patient self-report. Condition-specific instruments have been used often in the LSS literature to indicate the severity of disability by quantification with measures like the Oswestry Disability Index (ODI) and the Roland-Morris Disability Questionnaire.\textsuperscript{71, 72} In addition, more generic health status instruments have been frequently used to report general health in LSS such as the Medical Outcomes Study Short Form 36 (SF-36) and the Nottingham Health Profile.\textsuperscript{73, 74} Pain specific instruments such as the Numeric Pain Rating Scale (NPRS), the Visual Analog Scale (VAS) and other dimension specific instruments such as the Beck Depression Index (BDI) have also been used to identify specific issues in patients with LSS.\textsuperscript{75-78} All of these condition-specific, general, and dimension specific instruments have collectively been used to address the stress related experience of pain and disability in patients with LSS although with little standardization in the use and comparison among studies.

**Previous Literature: Psychosocial Factors**

Previous research on patients with arthritis and other health conditions has identified that persistent psychosocial needs can decrease the effectiveness of medical treatment, general health status and quality of life while increasing health care costs.\textsuperscript{64, 79, 80} Although unidentified in the LSS literature, unaddressed personal and social needs may contribute to reduced compliance with treatment and follow-up recommendations, diminished self-care, and reduced overall health management.\textsuperscript{81} Similar to other health conditions, the daily lives of patients with LSS likely involve unanticipated challenges. Patients with LSS must learn to navigate life with the stress of chronic LBP, cope with continued side effects of reduced functioning, experience continued
limitations to their physical and social abilities, manage through decreased activities and abilities, and face fears about recurrence or worsening of their condition.

The American College of Physicians and the American Pain Society published clinical guidelines that recommend clinicians conduct a focused history and physical exam with patients with LBP. This focused history is recommended to include assessment of psychosocial factors which predict risk for chronic disabling back pain. Psychosocial factors and emotional distress have been found to be stronger predictors of LBP outcomes when compared to physical exam findings or severity of pain alone. Psychosocial factors that predict poorer LBP outcomes include presence of depression, passive coping strategies, higher disability levels, or somatization. Psychosocial factors often delay recovery and identification can help to target interventions. It is recommended that patients with chronic LBP who do not improve with self-care options would benefit from non-pharmacological therapy including interdisciplinary rehabilitation, exercise therapy, spinal manipulation, and cognitive-behavioral therapy.

Only a few studies have examined the presence of psychosocial factors and the relationship to severity of pain and disability in patients with LSS. Moreover, only a few have examined the association between psychosocial factors and outcomes of treatment for patients with LSS. Depression, low sense of coherence, life dissatisfaction, and fear or avoidance behaviors have all been described to be present in baseline examination of some individuals with LSS and have been linked to worse treatment outcomes in LSS. Specifically, Wood et al identified that patients with LSS have higher fear of reinjury and activity avoidance. Individuals with higher depression scores also had greater disability at baseline and had worse surgical outcomes in the treatment of LSS. In one study, Turner et al found that lower depression after surgical treatment was related to reduced disability scores but not pain scores. However, Katz et al found that depression scores pre-treatment were associated with higher pain scores 6 months post-surgical intervention. In another study by Katz et al, higher depression
scores were also associated with poorer patient satisfaction post-surgery in bivariate but not multivariate analysis.

Several studies examined the relationship between life dissatisfaction and other clinical baseline measures and post-surgical outcomes in LSS. Sinikallio et al found that 25% of the pre-operative patients with LSS reported life dissatisfaction. In the general population, life dissatisfaction has been recorded in 13% of the healthy population and in 25% of those with illnesses. Therefore, patients with LSS have more life dissatisfaction than the general population but are similar to patients with other chronic illnesses. Sinikallio et al also found that dissatisfied patients with LSS had lower coping resources, elevated alexithymia, and elevated depression scores. Two follow up studies by Sinikallio et al found that both pre-operative and post-operative life dissatisfaction was independently correlated with disability and sense of coherence, a measure of coping. Pain, however, was not associated with life dissatisfaction either pre-operatively or post-operatively.

Patients with LSS remain a vulnerable population who often find themselves in need of general information, guidance, and social support. Only 1 study by Katz et al examined social support in patients with LSS using a single question: 1-5 Likert scale related to the amount of contact with friends and family, ranging from daily contact to no contact in the past month. The results of this study did not find significant correlations between pre-operative contact amounts with friends and family and post-operative outcomes of pain from surgery for LSS.

Previous Literature: General Health Status

General health status and health related quality of life has been minimally investigated in the population of patients with LSS. General or self-rated health measures have often been related to quality of life. Battie et al examined health related quality of life and comorbidities associated with LSS and noted that individuals with LSS have health related quality of life issues 4 times that of the general population. Gunzburg et al identified that patients with LSS have high
baseline rates of non-organic symptoms reflecting the potential significance of illness behaviors in this population. In addition, these authors found that better pre-operative self-rated health (scale: excellent, good, fair, poor) was associated with better post-surgical outcomes of walking capacity, symptom severity, and treatment satisfaction.

In the general LBP literature, Fanuele et al\textsuperscript{10} investigated the Medical Outcomes Survey SF-36 physical component scores (PCS) in a prospective sample of 17,774 patients with spinal disorders. They found that the patients with LBP had a mean PCS score of 30.4 \( \pm \) 9.95 (SD) compared with 50.0 \( \pm \) 10.00 for the general United States population. This indicates that the PCS score is greatly reduced in patients with spinal disorders in general and is similar to other patient population PCS scores such as chronic heart failure (31.0), Chronic Obstructive Pulmonary Disorder (33.9), Systemic lupus erythematosus (37.1), cancer (38.4), primary total hip arthroplasty (29.0), primary total knee arthroplasty (32.6), and glenohumeral degenerative joint disease (35.2).\textsuperscript{10}

Individuals with LSS often self-report worse physical health when compared to the population at large. In the MrOS study, Vogt et al\textsuperscript{12} found that men with LBP symptoms similar to LSS had SF-12 self-reported scores for the physical component summary (PCS) of 38.3 out of 100, ranking them at the 14\textsuperscript{th} percentile for physical health compared to the US population with a mean ranking of 50\textsuperscript{th} percentile.\textsuperscript{12,73} In addition, patients with LSS enrolled in the National Spine Network registry had PCS scores of 32.92 out of 100, ranking them in the 8\textsuperscript{th} percentile for physical health compared to the US population with an mean ranking of 50\textsuperscript{th} percentile.\textsuperscript{10} Patients in an RCT investigating both surgical and non-surgical intervention found patients with LSS to have mean SF-36 PCS values between 34.3 and 35.4 \( \pm \) 22 (SD) compared with 50.0 \( \pm \) 10.00 for the general United States population indicating similarly low PCS scores comparable to the other studies sited.\textsuperscript{38} Although there appears to be an association between LSS and self-rating of physical health, this relationship and its impact on pain and disability is not clearly understood.
Pahl et al\textsuperscript{95} examined the impact of health status in 4,442 patients with LBP including a subpopulation of patients with LSS. Although not specific to LSS, they found that self-ratings of physical health measured by the PCS, ranked patients with LBP lower than normative values for matched age groups. Pahl et al also found that individuals over 40 years old with LBP also had poorer mental health status and declines in vitality or energy and other social functioning domains compared to their matched age group norms. Overall, this evidence illustrates that both perceived physical and mental health are likely contributing factors to the outcomes of pain and disability in LSS and warrant further investigation.

**Previous Literature: Research Design in LSS**

Literature in LSS almost exclusively uses quantitative methods for determining health care outcomes, providing minimal depth of understanding about sources for and appraisal of stressors as well as coping resources available to those with LSS. Standardized measurements cannot capture the complete experience of pain and disability with LSS. Qualitative methods can provide a more detailed account of a patient’s experience with a stressful health condition like LSS and provide insight into the coping resources available to those individuals. These insights can help direct health care resources for treatment of individuals with LSS.

Although several authors in the current literature indicate they used qualitative methods, these authors all describe qualitative assessment by a clinician for MRI imaging, disc protrusion measurement, and nerve root involvement. Two authors described qualitative assessment as self-report of the number of analgesic medications used during the study,\textsuperscript{96} and self-report of limitation in walking distance (yes/no) along with the self-report of limitation in ADLs performed (yes/no).\textsuperscript{97} Two additional studies mentioned the use of patient interviews for measurement of post-operative outcomes. One of these studies, Sharma et al\textsuperscript{97} used 2 questions to inquire if the patient was satisfied with the outcomes of surgery (yes/no), and any significant limitation in ADLs (yes/no) although the methodology is unclear. The other study, Slosar et al\textsuperscript{98} interviewed
patients using questions from a standardized outcomes measurement tool but added no additional information from these interviews beyond the survey questions. Orlin et al\textsuperscript{99} used a novel approach in preoperative interviews asking 209 patients with LBP (50 with LSS) 8 questions about bladder, anal and sexual function and dermatome sensitivity in the only study published on urinary voiding dysfunction with patients undergoing lumbar spine surgery from both lumbar disc lesions and spinal stenosis. Results from this study illustrate that 68\% of these patients undergoing lumbar spine surgery have baseline urinary voiding dysfunction. This study clearly illustrates that patients with LSS have other concerns other than just standing and walking difficulty.

Only 1 additional study by Sekiguchi et al\textsuperscript{100} actually used a more comprehensive qualitative methodology with patients with LSS in designing a new questionnaire to rate symptoms of LSS based on quality of life constructs. In this study, a team of 2 orthopedic specialists and 1 psychometric specialist devised several constructs of the new scale and operationalized the constructs as they related to the overall measurement of quality of life in patient with LSS. Next, they asked 10 patients with LSS (7 men, 3 women) divided into 2 focus groups to discuss their pain, disabilities and difficulties with ADLs. Finally, 1 group was asked to confirm their understanding of the meaning of the items of the scale and if it appropriately described what was bothering the patient. The results confirmed specific quality of life issues for patients with LSS that include: 1) limitations on going out, 2) sleeping problems, 3) burden imposed by hospital visits and treatment, 4) urination problems, 5) walking problems, 6) limitations in everyday activities, and 7) emotional burdens. This study adds unique clinical implications that behavioral concerns are important to patients with LSS. Unfortunately this symptom scale has not been tested nor is it used in clinic or in LSS research.
Previous Literature: Summary

While the substantial societal impact of LSS is apparent, there are controversies in the literature regarding the identification of subgroups according to patient characteristics, effectiveness of treatment, and general management in LSS. Suboptimal research designs also account for some of the gaps in current research on LSS, along with other factors such as incomplete reporting of many patient characteristics, poorly measured psychosocial factors that may influence treatment as well as outcomes of treatment, and limited research design leading to a lack of understanding of the larger issues of pain and disablement in this population. Rarely has research in this area evaluated the contribution of intrapersonal and interpersonal factors such as self-efficacy and social support or explored the meanings of self-rated health in understanding the experience of pain and disability in the management of LSS.

Theoretical Perspectives

Integrating Theory in LSS

Like people with other medical conditions, individuals with chronic and recurring LSS may need to adjust their habits and lifestyles while trying to maintain basic physical, social, vocational, and recreational activities. To manage the condition of LSS, patients must try to understand the nature of their problem, create self-care strategies for dealing with pain flare-ups, manage and attempt to overcome functional problems, and identify and utilize available support and resources wisely. This process underscores the behavioral component of coping with LSS. To date the general LSS literature lacks a theoretical foundation for this behavioral component, particularly in comparison to research on other areas of chronic disease. Therefore, this study was developed from a theoretical perspective to better understand the traditionally biomedical characterized condition of LSS. This study was guided by the Stress and Coping
Model\textsuperscript{107} to identify predictors associated with 2 main sources for stress in individuals with LSS: pain and disability. In addition, this study was designed using mixed methodology with the aim to uncover the appraisals and coping mechanisms identified and used by individuals with this disabling condition.

**Theoretical Framework**

The present study used the underlying theoretical concepts in the Stress and Coping Model\textsuperscript{107} to define both stress and coping as well as identify the relationship of these concepts in the condition of LSS. Two primary stressors have been identified in previous LSS literature: pain and disability. Differing experiences with LSS result in different appraisals of the stressors of pain and disability. Individuals with LSS also have different outcomes related to the experience of pain and disability. Two guiding theories will be used to understand the experience of pain and disability in patients with LSS including the Stress-Diathesis Model\textsuperscript{108, 109} and the ICF Framework of Health and Disablement.\textsuperscript{108, 110} Finally, the Stress and Coping Model\textsuperscript{107} will be used to identify what coping behaviors and resources preserve well-being in patients with LSS while facing stressful experiences with this chronic condition. Specifically, the study will explore the construct self-efficacy proposed as a personal resource in LSS. The concept of self-efficacy originates from Bandura’s work in Social Cognitive Theory.\textsuperscript{111, 112} A second construct, social support, will be examined as a social resource for health as identified by Lazarus and Folkman in the Stress and Coping Model.\textsuperscript{107} and expanded in health application by Schwarzer and Leppin.\textsuperscript{113} Finally, the constructs of self-rated physical and mental health will also be explored from the perspective of the Stress and Coping Model.\textsuperscript{107}

**Stress and Coping Model**

Within the Stress and Coping Model,\textsuperscript{107} stress involves the relationship between an individual and his or her environment. This relationship or transaction between individuals and
their environment indicates that stress is more than an external stimulation or specific pattern of physiological, behavioral, or subjective reactions (see Figure 2.1). This relationship also views two processes as mediators within the person-environment transaction: cognitive appraisal and coping effort. Cognitive appraisals and coping efforts are influenced by moderators such as personal and situation factors that result in the outcome of adaptation of the individual on many levels impacting their health.

Figure 2.1. Stress and Coping Model and stressful health conditions. Adapted from Glanz114
Cognitive appraisal. The cognitive appraisal or evaluation by the individual is paramount to determining if the stress is threatening to his/her well-being or surpassing his/her resources. Upon appraising a stressor, the theory asserts that people engage in coping, defined as fluctuating behavioral exertions, in an effort to manage that stressor. The cognitive appraisal process helps an individual determine both the controllability and availability of coping resources identified as necessary to manage the stressor(s).  

Cognitive appraisal is a necessary component of dealing with a stressor. It accounts for the different ways in which individuals react to similar events. Health conditions such as those resulting in pain provocation and disability like LSS can cause stress in nearly every person, yet people vary in their reactions and interpretations of the same event and condition. A health condition is a general stressor but the different ways individuals respond to the same health condition can depend on their cognitive appraisals. This variability in cognitive appraisals can change a person’s level of vulnerability during a stressful health condition. Vulnerability is closely related to appraisal since vulnerability increases as a person appraises that he/she has reduced coping resources available. Vulnerability reflects the inability of individuals to withstand adverse impacts from multiple stressors to which they are exposed. It can be associated with a pattern of thought that is believed to predispose the individual to psychological problems and feelings of hopelessness. In addition, the variability of individual appraisals as well as his/her responses helps to explain why some individuals experience similar health conditions but have differing quality, intensity, and duration of physical, social, and emotional outcomes.

Personal and situational factors. Two types of factors influence the cognitive appraisal process: personal factors and situational factors. Personal factors consist of the personal values that motivate individuals to make certain decisions and beliefs that give the individual a personal sense of control. Therefore, at the individual-level, commitments and beliefs are all part of an individual’s process of appraisal. Commitments are expressions of what is important to a person and can be related to vulnerability. The deeper a person’s commitment, the greater potential for
threat, but also the greater the push toward ameliorative action and hope. Beliefs are also important in determining how a person evaluates a stressful event or health condition. Beliefs of personal control over situations can relate to how an individual believes internal self-responses to situations can be controlled. General control beliefs relate to the extent that the person believes the health related outcomes can be controlled.

Another influence to the appraisal process is situational factors which play a critical role in determining the external controllability of the stressor and what ameliorative action can be taken. Situational factors can include predictability and uncertainty, temporal and life course factors, and ambiguity. Because patients with LSS are often in their later stages of life, aging related concerns are a component of situational factors in LSS. Situational factors can also influence how and to what extent the stressor can be managed. Maximum uncertainty is often extremely stressful for an individual experiencing a health condition like LSS. The uncertainty can have immobilizing effects on anticipatory and actual coping processes and can cause mental confusion in the individual. Overall, it is important to evaluate both situational factors and personal factors in order to understand what ultimately influences the level of stress related to pain and disability in patients with LSS.

**Different appraisals.** While differences between individuals under similar circumstances are inevitable due to various personal and situational factors, the Stress and Coping Model emphasizes that all individuals evaluating a stressor undergo a cognitive appraisal process involving primary appraisal, secondary appraisal and/or reappraisal. Primary appraisals involve assessment of the magnitude and significance of a stressor or traumatic event. During primary appraisal, the individual will assess the actual harm, loss, threat, or challenge that must be encountered with a stressful health condition. When an individual first experiences a health condition or a reoccurrence of a chronic condition like with LSS, primary appraisal takes place. Individuals with LSS are often in the process of primary appraisal when they seek out medical care and treatment.
Secondary appraisal refers to an individual’s assessment of the degree to which the stressor or traumatic event can be controlled and the available coping resources. Secondary appraisals are a judgment about what might and can be done in the situation. Secondary appraisals include an evaluation about whether a coping option will accomplish what it is supposed to do as well as the consequences in the context of other internal and/or external demands and constraints. Appraisals of controllability of a health condition can be stress-reducing if the outcome is believed to be controllable or that one has the coping resources to manage the outcomes. However, appraisals of controllability can also heighten threat and give rise to negative emotions and beliefs about coping if control and resources are diminished. For example, individuals with LSS will use secondary appraisals when their chronic LBP has reoccurred and their activities have been limited. This in turn motivates some to seek treatment to control their pain and disability as part of the coping process if they have the necessary access and resources.

Reappraisal is the final feature of the appraisal process which entails an altered or revised version of a previous appraisal. Reappraisals can occur multiple times for reasons such as changes in the environment or the health condition. Reappraisals can also occur when an individual has gone through the cognitive coping process and has altered the assessment of the available coping resources. Because the complete process of appraisal is dynamic, a patient with a chronic disease such as LSS is likely to appraise and reappraise the stressors of pain and disability and respective coping resources before, during, and after treatment multiple times and with each successive chronic episode.

**Coping.** Coping is intimately related to the concept of cognitive appraisal and the person-environment relationship. Coping involves the cognitive and behavioral efforts to address external and internal demands on the person experiencing a stressful encounter. Coping can either be focused on changing the person-environment problem behind the stress, or be directed toward changing the appraisal of the situation. Moreover, coping can be focused toward trying to reduce a negative emotional state of the situation.
There are 2 types of coping research in the literature: trait oriented and state oriented. Trait oriented coping research aims to identify individuals whose coping behaviors are diminished due to the demands of the stressful encounter. Early identification of individuals who have reduced coping behaviors could help target certain factors and resources needed to improve coping behaviors. For example in patients with LSS, early identification of individuals who have negative appraisals and reduced coping can help direct clinicians to increase cognitive-behavioral efforts to improve patient beliefs, motivation, and participation in treatment. State oriented coping on the other hand, centers on understanding which coping strategies an individual actually chooses and uses during stressful events. State oriented coping explores the relationship between coping strategies and the outcome variables. Variables of interest include coping efficiency, emotional reactions, and variables of adaptive outcome (e.g., health status) that accompanies certain coping efforts. In patients with LSS, understanding coping behaviors in relationship to health outcomes can be important to identify and prioritize health care resources for individuals with this chronic condition. In general, state oriented coping research strategies tend to lay the foundation for resource allocation and targeted programs to improve outcomes. This study identifies a combination of both trait and state oriented coping by determining coping behaviors at entry to treatment and actual coping efforts during the management period by individuals with LSS. The overall intention in exploring the coping resources and behaviors of individuals with LSS is to create a foundation for early identification of coping strategies and resource allocation for future LSS treatment programs.

**Application of the Stress and Coping Model to LBP.** There are no current studies using Lazarus and Folkman’s Stress and Coping Model\textsuperscript{107} in the treatment of LSS. Previous studies on LBP and other chronic diseases have emphasized the importance of appraisal of the stressor, typically conceptualized as general challenges with pain management, normal function, and coping resources (or perception of resources) available to allow for adjustment to life during and after treatment completion.\textsuperscript{115-117} This dissertation study defined specific stressors, pain and
disability, within the global stressor of the health condition of LSS, as reflected in the Specific Aims. This dissertation study aimed to further understand the stressors of pain and disability in LSS to better identify and understand coping behaviors and resources appraised by individuals with LSS in order to manage their pain and disability.

Managing Stressors: Pain

The experience of pain is often described as stressful by an individual and identified as a source of stress for individuals in previous literature. In recognizing the role of pain as a stressor, it is necessary to explore and expand upon an understanding of the factors contributing to an individual’s experience of pain. The traditional biomedical model of pain dates back hundreds of years when pain was understood to be a primarily sensory experience resulting from the stimulation of noxious sensory receptors usually from physical damage or injury. This theory of pain describes primarily nociceptive pain, defined as pain elicited when sensory receptors specialized to sense mechanical, thermal, or chemical pain react when stimulated past a sensory threshold. This simplistic view suggests that pain only comes from specific physical pathology and is often called the biomedical model of pain. It does not take into account how pain is experienced by the individual, involving additional psychological, social and behavioral mechanisms of injury and illness. Due to the narrow scope of the biomedical model of pain, it is often criticized for being reductionist and exclusionary. In the condition of LSS for example, patients with LSS often experience pain that is unrelated or only partly due to their radiographic severity or lumbar segmental level of pathology, illustrating that their pain experience is greater than the pure pathophysiologic processes involved.

Biopsychosocial Models of Pain

To encompass a broader view of pain, Turk and Flor described a biopsychosocial approach to pain which addresses many of the shortfalls found in traditional biomedical models.
In this approach, it is recognized that the experience of pain is the reciprocal and dynamic interaction of biological, psychological, and social factors. It is based on the concept that the experience of pain arises from illness behavior although it is initiated and/or has contributions from nociceptive pain. Illness behavior is a term used to describe the ways in which given symptoms may be differently perceived, evaluated, and acted or not acted upon by different kinds of persons. Illness behavior is believed to be a dynamic process that allows for the role of the biological, psychological and social factors to change in chronic conditions and as the condition evolves.

In the 1980’s, Waddell et al applied the construct of illness behavior to LBP (see Figure 2.2). Their view was that persons with chronic LBP experienced illness behaviors and not just nociceptive pain. This view represented a broader biopsychosocial model of pain stemming from physiological impairment but with broader cognition, affective and social factors resulting in the experience of pain perceived and reported by individuals with chronic LBP.

![Figure 2.2. Biopsychosocial model of pain. Cross sectional representation of the Glasgow model representing the role of fear-avoidance beliefs in chronic low back pain and disability. Adapted from Waddell et al.](image-url)
**Stress-Diathesis Model of Pain**

Asmundson and Wright\(^{125}\) conceptualized a stress-diathesis model of pain and disability that stems from the biopsychosocial framework and can be applied to chronic pain conditions resulting in disability (see Figure 2.3). It is this evolved theory of pain that describes how an initial physical pathology or injury is recognized as nociception and leads to a cycle of appraisal of the stress and coping factors needed to manage the health encounter. Also key to this model is the construct of diathesis which is described as a pre-dispositional vulnerability of the individual. This vulnerability as demonstrated in the model can be influenced by both internal and external factors. Along the pathway there are physical, cognitive, social, cultural and behavioral processes that contribute to the cycle and associate with the pain-specific distress. The combination of the distress and the diathesis contributes to a larger cycle of pain resulting in apprehension, avoidance, and overall disability (see Figure 2.3).

![Figure 2.3. The Stress-Diathesis Model of pain and disability. An integrated stress-diathesis model of chronic pain adapted from Asmundson et al.\(^{125}\)](image-url)
**Pain appraisals.** A key part of the stress-diathesis model is the issue of appraisal. Pain appraisal refers to the meaning ascribed to pain by an individual.\(^{126}\) In accordance with the Stress and Coping Model,\(^{127}\) a distinction can be made between primary appraisal of pain in terms of it being threatening, benign, or irrelevant and secondary appraisal which evaluates the controllability of pain and one's coping resources. Primary appraisal of a threat or harm/loss is indication of a stressor. Therefore, pain as described as threatening by the stress-diathesis model is inherently stressful. The degree of the stress depends on the other factors of vulnerability, social and cultural influence, and assessment of coping resources.

**Pain beliefs.** Pain beliefs and therefore reports of the pain experience develop both during the lifetime of an individual as well as throughout the duration of a chronic illness such as with LSS. Appraisal and beliefs about pain can have a big impact on an individual's affective and behavioral response to pain. If a pain signal is interpreted as harmful and appraised as a great threat, then it may be perceived as intense and unpleasant and may evoke escape or avoidance behavior. An example of this is the rating of pain associated with cancer described as more unpleasant than labor pain, even though the actual rating of intensity is equivalent.\(^{128}\)

Studies show that pain appraisal and beliefs are also determinants of adjustment to chronic LBP.\(^{129}\) After treatment, a large majority of patients with LBP believed that a wrong movement could have serious negative consequences for their back and further associated this belief with reduced activity levels and increased disability.\(^{130}\) Using the Stress-Diathesis Model, it is reasonable to expect that through the appraisal process, there are larger biopsychosocial influences that impact perception and a patient’s quantification of pain. The combination of actual physical limitations, environmental resources and barriers, and perceived physical, mental, and emotional characteristics influencing actual behaviors by the individual may in turn impact a person’s quantification of pain.
Managing Stressors: Disability

As we see in the Stress-Diathesis Model, pain is only one factor in a more complex set of factors resulting from pain but contributing to disability. Pain sensations, appraisal of the threat from the pain, vulnerability factors and even social and cognitive factors all contribute to the individual’s experience of somatic pain in this model. An individual’s responses and beliefs related to pain can play a large role in how he/she acts or fails to act when participating in many of life’s activities and therefore can magnify his/her level of disability.

Understanding disability has been an evolving process in health and health care literature. Multiple models have been proposed that have developed the complex understanding we have today about disability and the factors that contribute to disability. Understanding this complex process of disability is an important component of this research study as this study sought to uncover factors beyond somatic or physical factors that relate to disability in the population of patients with LSS.

Disablement Model

Over the years, multiple frameworks have been developed to explain a broader concept of disability. One of the earliest frameworks for disability was proposed in the 1960’s by the sociologist Saad Nagi called the “Disablement Model” that illustrates a disease pathway that is still used by health care professionals (see Figure 2.4). The Disablement Model describes a pathway comprised of 4 inter-related but separate constructs that contribute in a linear fashion to disability.131 The model starts with pathology as the underlying disease condition that eventually leads to impairments, functional limitations, and disability. Impairments are abnormalities in structure or function of the body’s systems, which can either be associated with pathology or remain after the pathology has resolved. Functional limitations are limitations in a person’s ability to perform tasks and ADLs such as self-care. Therefore, limitation in performance reduces the function of the individual. Finally, disability, as described by Nagi, is the pattern of behavior
that starts with pathology but develops with chronic impairments and functional limitations (see Figure 2.4).

**Figure 2.4. The modified Disablement Model.** Representation of the pathway from pathology to disability with environment contributing to both functional limitations and overall disability. Adapted from Saad Nagi’s disablement model.  

**Expanded Disablement Model.** A component of this model that is extraneous to the biomedical pathway of the original Nagi model is the environment. The Institute of Medicine revised its model to include disability as a function of the interaction of individuals with the influence of social and physical environments. As a result, the revised Disablement Model describes environment as including the natural environment, the built environment, culture, the economic system, the political system, and psychological factors. The less supportive the environment is to an individual from both a physical and social perspective, the greater the resulting disability. It is important to identify this transition in health literature as this initial recognition of environment in disability marked a turning point for health care in understanding a more complex disablement concept. This expanded disablement concept is particularly important to this dissertation study as the focus was to examine factors pertaining to the personal and social environment as they interact to define disability in patients with LSS.

Because the traditional Disablement Model illustrates a linear biomedical framework, it is unclear to what degree the ability or disability of an individual is a direct result of the disease process versus the contributing environment. Moreover, the ability to manage functional
limitations and disability often depends on the personal and social resources available to the individual, but these resources are only grossly reflected by the environment in this model. When using this model, it is difficult to direct resources or even identify specific environmental factors that impact disability.

Verbrugge and Jette\textsuperscript{133} expanded on the Disablement Model and conceptualized additional factors that may affect the pathway from pathology to function. Included in this expansion was the concept of risk factors which are predisposing factors that could affect either the presence or severity of the impairments, functional limitations or disability in the individual. These factors could include medical care, external supportive actions or systems, activity accommodations, or what is described as “intra-individual factors” such as lifestyle, behavior changes, and psychosocial attributes such as coping strategies. These factors are of particular interest to this research study as they identify that specific behavioral and social factors may interact during the coping process and contribute to disablement in patients with LSS.

Moreover, Verbrugge and colleagues\textsuperscript{133, 134} proposed that life activities include much more than those of the traditional medical model which included only ADLs. In this new definition, life activities could be grouped in 3 categories: obligatory, committed, and discretionary activities. Obligatory activities are those required for survival and self-sufficiency, including activities such as personal care, sleep, rest, walking and local transportation traditional referred to as ADLs. Committed activities include principle productive roles, such as paid work, and household management, such as food preparation, repairs, yard maintenance, shopping, and child or elder care. Discretionary activities are free-time activities that could include socializing with family and friends, entertainment away from home, hobbies, physical recreation, volunteer service, religious activities or other adult educational activities. Until this new conceptualization of the Disablement Model, the majority of disability research had only focused on obligatory activities and few committed activities but had ignored discretionary activities as important in the disablement process.\textsuperscript{133, 135} These concepts of expanded activity are important to this dissertation.
study as they identify multiple areas of activity that are important in individuals lives that when disrupted have the potential to result in disability. This dissertation study looked closely at limitations in activity beyond obligatory activities of daily living recognizing that social and emotional behaviors and roles can be impacted to a greater degree during committed and discretionary activities.

**Social model of disability.** An alternative model of disability, called the social model of disability offered an opposing view that disability is primarily a socially created problem and not an attribute of the individual. In this model, an unaccommodating physical environment creates the problems of disability through negative attitudes and other negative features of the environment. Although, the social model of disability was never intended to be an all-encompassing model of disability, it illustrates the need for reframing the idea of disability from the biomedical model to include issues of social interaction and social values that to contribute to disablement. This dissertation study has emphasized that the role of social function in the lives of patient with LSS is critical to fully understand the coping behaviors and resources of these individuals.

**ICF Framework**

To combine all of these models and contributions to the concept of disability, a new model was developed by the World Health Organization (WHO) and the Committee on a US National Agenda for the Prevention of Disabilities. This new framework called the World Health Organization’s International Classification of Functioning, Disability and Health (WHO-ICF) elucidates the larger biopsychosocial components of disablement. Known more commonly as ICF, this framework is a universal classification system to define and measure health and disability. It describes health and health-related domains from body, individual, and societal perspectives by means of 2 domains: Functioning and Contextual Factors. Each domain can be used to describe different changes and the impact of those changes that occur in the individual
and his/her usual environment due to health related states. The domains characterize different factors that interact with the individual to facilitate or hinder functioning and/or disability. Changes to different factors often result in a decrement of health and thereby can be used to describe disability in the individual.

**Functioning.** Similar to the Disablement Model, the ICF has components that encompass pathology, impairment and functioning. These are seen in the domain called “Functioning”. The functioning domain includes 4 components called body function, body structure, activity, and participation. Body functions are defined as the physiological and psychological functions of body systems. Body structures are defined as the anatomical parts of the body. Problems in both body function and structure are together usually termed impairments by health professionals and defined as deviations or loss of structure or function. The other 2 components of activity and participation encompass a larger concept of functioning. Activity and participation are similar concepts although each has a slightly different definition. Activity is defined as the action or task performance by an individual. Participation represents the involvement in life activities. Problems in an individual’s ability to participate in activities will result in participation restrictions and limit actual activity. For individuals with LSS, activities that are limited may include activities such as walking, climbing steps, or lifting objects. When a person with LSS cannot perform activities such as walking or stairs, it often precludes his/her participation in many social, recreational, and daily chores that require the functional ability and the confidence to execute these activities.

**Contextual factors.** As previously seen in the Disablement Model, the ICF describes the environment as a contributor to disability in a larger domain called “Contextual Factors”. Contextual factors in the ICF are classified as either personal or environmental factors that influence health through functioning and disability. As previously described, environmental factors are defined as exerting an influence on external domains that in turn influence a person’s functioning and disability. Environmental factors refer to all aspects of the external or extrinsic
world that form the context of an individual’s personal life that have an impact on a person’s functioning. Environmental factors can be both facilitators that can assist a person’s functioning or barriers that hinder or limit a person’s functioning. Because of the inclusion of environmental factors in the original Disablement Model, literature related to environmental factors in relation to disability has been extensive. In addition, the contribution of the social model of disability in the literature has added increased emphasis that persons with disabilities have reduced access to full participation in life and society.\(^ {138}\)

The other type of contextual factor, personal factors, can include anything that is an internal influence on a person’s functioning and disability. This includes individual characteristics like age, sex, social status, and life experiences.\(^ {139}\) Personal factors have been described in the literature as comprising 2 broad categories of demographic information and personality traits.\(^ {140}\) Personality traits are of particular interest to the present dissertation research study. These can include personality traits such as coping styles, lifestyle, habits, social background, past experiences, self-esteem, self-advocacy, and other psychological assets that are not directly related to the health condition. These personality traits can influence how a person responds to possible limitations secondary to disability. Some individuals may have difficulty with assertiveness or have a negative outlook, regardless of the health condition and corresponding disability. Others may have a sense of positive optimism or self-determination that persists regardless of the disability. Therefore, personal factors are those attributes within the person that are not caused by or have nothing to do with the disabling condition but may influence the person’s overall disability. Researchers have described these factors as those traits that would still be there even if the health condition and disability were suddenly gone. The recognition of personal factors in the ICF framework illustrates that a person is more than simply the sum of his/her physical functioning. The ICF framework and its components are displayed in Figure 2.5.
Contextual factors of the person and the environment interact and modify the impact of changes to body functions, body structures, activities, and participation of the individual with a health condition. The degree of impact these factors have in relation to the health condition help to describe the degree of disability in an individual with the health condition. The greater the challenges to the person’s functions or contextual factors, the greater the potential physical and psychological stress that is placed on the individual. Applying the Stress and Coping Model, if health related factors of the person or the environment are appraised as taxing or exceeding the individual’s resources or well-being, the health state will be viewed as stressful and therefore disabling to the individual. Contextual factors are of particular interest to this research study as
they identify both person and environmental factors that are potential moderators in the relationship between coping and outcomes of LSS. The ICF as a culmination of defining disablement provides a framework to identify both intrapersonal and interpersonal factors that may be interacting to exacerbate or diminish disability in patients with LSS.

**Application of disablement models in LBP.** The models of disablement described above serve to illustrate the complex and multifactorial nature of disability as currently understood by clinicians, researchers, and the public health community. As previously identified, LBP is a significant cause of disability in our society. Waddell in 1980 revolutionized the clinical perspective of LBP by illustrating that there were many nonorganic and behavioral components to individual’s experience of LBP. The work to revise the concept of disablement along with continued research in LBP has resulted in a more complex understanding of the typical spectrum of problems of functioning in patients with nonspecific LBP. A variety of studies have used the ICF framework to assist in understanding the complexity of nonspecific LBP. Psychosocial and environmental risk factors have been identified in the development and management of nonspecific chronic LBP. Although not focused on the condition of LSS, these studies show the complexity of chronic LBP beyond somatic symptoms and support the multifactorial disablement models in LBP. Using the Stress and Coping Model in combination with the ICF framework and the Stress-Diathesis Model, respective coping processes and resources can be better identified that describe the experience of pain and disablement in patients with LSS. Ultimately, these theoretical contributions serve to support the goal of understanding and improving the allocation of resources to reduce the consequences of disability in persons with LSS.

**Resource Theories of Stress and Coping**

In order to fully understand the experiences of pain and disablement in LSS, it is important to investigate whether and how intrapersonal and interpersonal factors interact to
influence the severity and the clinical outcomes of LSS. Intrapersonal and interpersonal influences would be classified as part of the contextual factor category in the ICF framework; namely personal and environmental factors. To further understand how personal and environmental factors contribute to disablement in a chronic condition like LSS, theoretical constructs have been identified at the personal and environmental in a number of resource theories of stress and coping. In other health conditions, social and personal constructs have been proposed to serve as coping resources that address stressful person-environmental transactions. It is unknown what social and personal constructs are important in coping by patients with LSS. Four specific constructs are explored in this research study including the personal constructs of self-efficacy, self-rated physical health, self-rated mental health, and the social construct of social support.

**Social Cognitive Theory and the Construct of Self-Efficacy**

At the clinical level, it may be important to identify risk factors for heightened pain and disability and whether individual influences affect or alter outcomes in identical treatment protocols for patients with LSS. There is evidence that individual factors related to stress, coping, and cognitive mechanisms can influence aging-related health in general,\textsuperscript{149} although currently no evidence exists on the role of these individual factors on the severity or the health outcomes of pain and disability in patients with LSS.

Social Cognitive Theory (SCT),\textsuperscript{112,150} originally called Social Learning Theory by Miller and Dollard and expanded by Bandura,\textsuperscript{112,151,152} addresses the psychosocial aspects of individual health behavior as well as methods of promoting behavioral change. According to SCT, individuals possess a self-system that enables them to exert control over their thoughts, feelings, motivations, and actions.\textsuperscript{152} SCT is a theory of human behavior that emphasizes the importance of personal beliefs as key components of control and personal agency. In this theory, individuals are viewed both as products and as producers of their own environments and social systems.
SCT hypothesizes that people’s beliefs in their capabilities mediate how they behave in situations such as participating in treatment for a health condition. Treatment provides an environment in which there are opportunities for physical and psychosocial support by a health professional, family, or friends which can in turn affect their beliefs about their capabilities. Both external support and treatment itself may help to improve an individual’s beliefs about his/her capacity to perform functional tasks. At this time, it is unknown how personal beliefs or external support can influence appraisals and coping behaviors in a patient with LSS.

**Self-efficacy.** The construct of self-efficacy is a key concept within the SCT framework. Self-efficacy is an intrapersonal factor defined as a person’s belief in one’s capacity to “organize and execute the courses of action required to produce given attainments.” It is a context-specific assessment of one’s competence to perform a specific task or range of tasks in a given domain. Bandura describes self-efficacy as influencing 4 areas: 1) the choices that are made, 2) the effort put forth in task specific roles, 3) the time one persists when there are obstacles, and 4) one’s feelings of confidence in performing specific tasks in specific situations.

Depending on what is being managed, the tasks over which personal influence is exercised may entail regulation of one's motivation, thought processes, affective states and actions, or changing environmental conditions. Self-efficacy beliefs are sensitive to these contextual factors. Therefore, they differ from other expectancy beliefs in that self-efficacy judgments are more task and situation specific and individuals make use of these judgments in reference to the type of goal. Self-efficacy can refer to sub-skills required to organize actions that are governed by broader self-regulatory skills such as knowing how to diagnose task demands or constructing and evaluating alternative strategies. Possessing these self-regulatory sub-skills can permit individuals to improve their performances across varied activities particularly when faced with sensations of pain during activity performance. Self-efficacy can generalize across skills when commonalities are cognitively structured across activities. For example, physical exercises and motor skills practiced in health care treatments may transfer to
other activities performed in daily living as their confidence to perform these types of tasks increase.

People make and shape self-efficacy beliefs in the context of performing a specific goal or task. Theoretically, self-efficacy beliefs might influence a patient’s experiences of pain, functional limitations, and disability with LSS. A patient in treatment practicing functional activities like walking could increase their task specific self-efficacy for walking just by practicing and as a result, increase their confidence and activity outside of treatment. Moreover, a patient who enters treatment with high self-efficacy for functional tasks might have even greater belief that he/she could organize and execute all of the actions needed to successfully complete tasks required in treatment. Theoretically, a patient with higher self-efficacy could have heightened beliefs about accomplishing tasks that include positive health behaviors such as attending regularly scheduled clinical appointments, following medical instructions, executing a series of home and clinic exercises, and performing positive avoidance behaviors to minimize pain and discomfort. Overall, high self-efficacy beliefs lead to setting challenging individual goals and maintaining strong commitment to these goals that ultimately could affect outcomes of treatment.

In addition, researchers think self-efficacy beliefs in part determine outcome expectations. Individuals who expect success in a particular task often produce successful outcomes in that task. The opposite is also true of those who lack such confidence in task performance; those who doubt their success will produce failed outcomes. Patients undertaking tasks such as those found in treatment would have similar anticipatory outcome expectations about performing the specific tasks required for the process of treatment and transfer these beliefs to similar skills outside of treatment.

Issues of self-efficacy in the elderly population often center on reappraisals and misappraisals of their capabilities. Because biological conceptions of aging focus extensively on declining abilities, many physical functions can decrease as people grow older and require
reappraisals of self-efficacy for activities in which biological functions have been significantly affected. When a therapist teaches an older adult to use his/her intellectual and physical capabilities, his/her improvement in cognitive and physical functioning more than offsets the average decrement in performance over 2 decades.\textsuperscript{153} Therefore, elderly persons who invest the necessary effort can function at higher levels comparable to some younger adults. Although never studied in previous LSS research, it is possible that perceived self-efficacy may affect the level of involvement in activities and theoretically mitigate the decline seen from chronic disease processes such as LSS.

**Application of self-efficacy.** What is unknown is if self-efficacy can maintain or improve in the presence of pain and disability perceived by the patient with LSS. It is known that pain can impede or prevent patients from participating in an activity because of the actual physical sensations of pain, the fear and or avoidance behaviors that preempt participation, and the cognitive appraisals or reappraisals that are made after activities have repeatedly resulted in painful experiences. Reductions in function can also lower an individual’s self-confidence, and as a result continue to lower the level of activity in which an individual participates in daily life.

In laboratory experiments, self-efficacy beliefs predict tolerance levels to pain.\textsuperscript{157} From a physical perspective of pain, perceived self-efficacy has been shown to affect the body's opioid and immune systems.\textsuperscript{158} In patients with chronic pain disorders related to LBP, self-efficacy positively affects physical and psychological functioning.\textsuperscript{159} Evidence shows that self-efficacy influences pain and function after acute physical interventions like surgery.\textsuperscript{160, 161} Prospective studies in patients who underwent orthopedic surgery demonstrated that high self-efficacy before the start of treatment and larger increases over the course of treatment speed recovery and predict better long-term outcomes.\textsuperscript{162-164} It is possible that individuals with high self-efficacy may be more motivated to engage in health promoting behaviors and adhere better to treatment recommendations because they have higher performance success expectancies. In addition, it is believed that people with high self-efficacy are less likely to give up an activity when faced with
barriers such as pain and are therefore less likely to become trapped in the negative spiral of activity avoidance, physical deconditioning, loss of social supports and depression.

**Application of self-efficacy during treatment.** In rehabilitation literature, self-efficacy is measured by using task-specific constructs relevant to the chronic disease process and specific rehabilitation treatments being studied. Research indicates that task specific self-efficacy can improve during the treatment process. Scherer and Schmieder\textsuperscript{165} demonstrated improved task specific self-efficacy with patients who participated in treatment for dyspnea due to chronic obstructive pulmonary disease. Patients who completed educational and exercise training had significant increases in their self-efficacy scores to manage or avoid breathing difficulty. In addition, patients increased their self-efficacy expectations for exercise endurance.\textsuperscript{165} Carlson et al\textsuperscript{166} showed that cardiac rehabilitation treatment involving physical exercise improved patient’s post-treatment self-efficacy beliefs for independent exercise. Another study by Jeng and Braun\textsuperscript{167} found that those with greater success in functional outcomes from cardiac rehabilitation treatment correlated with higher exercise specific self-efficacy scores. Finally, Rejeski et al\textsuperscript{168} found that when patients undergo aerobic and strength training exercise for knee osteoarthritis (OA) those who actively engaged in physical exercises compared to controls had increased self-efficacy outcomes for stair climbing, a task-specific limitation for patients with knee OA.

Research has demonstrated that self-efficacy is also an important factor in improved coping and psychological outcomes.\textsuperscript{169-171} Taal et al\textsuperscript{103} surveyed patients with rheumatoid arthritis (RA) to determine their level of self-efficacy in relationship to function, pain, and disability when coping with RA. Higher self-efficacy scores correlated with improved coping abilities independent of pain, disease status and functional abilities. Moreover, Strahl et al\textsuperscript{172} found that higher self-efficacy levels in patients with arthritis were predictive of better outcomes related to psychological functioning.

An investigation of self-efficacy for patients with chronic LBP found that initial self-efficacy beliefs predicted functional abilities. In a study by Lackner and Carosella\textsuperscript{173} that included
patients with chronic LBP, 100 patients rated their confidence to perform load lifting tasks before any examination or treatment. Next, these patients underwent a subsequent physical exam and physical performance test for lifting loads. The results indicated a significant association between self-efficacy beliefs and lifting higher loads and higher physical performance. Lackner and Carosella did not find an association between pain perceptions or measures of psychological distress and the physical performance measures.

Overall, these studies indicate that self-efficacy is an important construct in health care management. Two of the studies found significant relationships that demonstrate self-efficacy beliefs have an impact on the outcomes of pain and disability for patients with chronic disease processes. In addition, no studies have examined the impact of self-efficacy beliefs during treatment of patients with LSS. Although the role of self-efficacy in the treatment process warrants more investigation, these studies indicate that heightened patient beliefs regarding the ability to perform specific tasks might also raise the functional, psychological, and overall coping behaviors of patients during and post-treatment and therefore help to decrease overall perceptions of pain and disability. Although the role of self-efficacy is unknown in LSS, this research study sought to investigate the impact of self-efficacy in the appraisal of pain and disability and coping behaviors of patients with LSS.

Social Relationships and Health

In addition to individual level factors such as self-efficacy, there is considerable evidence that interpersonal factors play a role in disease prevention, disease management, and health outcomes. At this time, it is unknown the role of interpersonal factors play in the health and management of patients with LSS. In general, researchers studying aging have determined that people with social support and social ties, regardless of their source, live longer than people who are isolated. People with a close network of ties with other people maintain better health, resist disease and deal more successfully with problems they encounter. People who are socially
isolated and have fewer social relationships have been found to have mortality rates 2 to 5 times higher than those with good social relationships, regardless of gender, race, ethnic background and socioeconomic status.\textsuperscript{176, 177}

There are several terms used to describe social relationships as they relate to health. Social integration refers to the existence of social ties.\textsuperscript{176} Social network describes the interconnectedness of social relationships that surround an individual.\textsuperscript{177} Together, social integration and social networks describe the existence and quantity of social connections that an individual has available. Social support on the other hand is a concept that illustrates not only the existence of a social relationship but also the positive function of that social connection and its potential to play a supportive role in an individual’s health.\textsuperscript{113, 178} Social support is defined as the degree to which a person’s basic social needs are met through interaction with other people.\textsuperscript{179} It includes tangible and intangible resources, emotional support, informational and instructional support, as well as a person’s perception of assistance in times of need. When measuring supportive functions in health, measurement should include support that one believes is available if needed (perceived support) or functions that one reports and is recently provided (received support).\textsuperscript{113, 177} This research study focused on identifying both perceived and received support in patients with LSS.

**Social support.** The role of social support has evolved in health research and is believed to be a social construct that protects and preserves well-being of an individual in the face of a stressful encounter such as a negative health condition.\textsuperscript{177} Social support is believed to contribute to global self-evaluations of health.\textsuperscript{180} In addition, social support serves as a social resource that can assist an individual in his/her capability to cope with stress.\textsuperscript{107} Even though social support comes from an external source, this external support is believed to be able to help protect people from the adverse effects of stress (Figure 2.6). In the stress and coping literature, social support is a coping resource that can alter beliefs and commitments that can in turn alter how one appraises a stressful situation.\textsuperscript{107}
When considering the role of social support, stressors are believed to act on 2 different pathways. One pathway is through appraisals of available social support (Figure 2.6). The perception that social support is available may protect people from the adverse effects of stressors by leading them to appraise or interpret stressful situations less negatively. For example, a patient with LSS with high perceived social support might interpret his/her pain and disability less negatively than a person with low perceived social support and therefore approach the process of treatment and self-management differently. Hypothetically, patients’ interpretations of support may moderate their experience of pain and disability before, during and after the treatment process.

![Figure 2.6. Social support interactions with Stress and Coping Model. Interactions between perceived support with appraisals as well as received support with coping to modify the relationship of a stressor on health.](image)

The other pathway social support is believed to assist in coping is by actual supportive actions, or received support. Received social support is the actual assistance by others during stress.\textsuperscript{181, 182} Received support is believed to interact and alter a person’s coping abilities in times of stress. This improved coping due to increased received support is theorized to reduce the
impact of stress on a person’s health.\textsuperscript{177} When a person can reduce the impact of stress on his/her health, it is theorized that this could be measured through improved health outcomes such as reduced pain and/or disability. A way clinicians have measured social support is by quantifying the frequency or number of supportive actions a person reports as well as his/her perception of the quality of that received support.\textsuperscript{183} Retrospectively identifying the frequency and quality of support received during a specific time period of treatment, identifying the supportive actions, and rating how this support was helpful or unhelpful are all ways that patients might report received social support for a health condition.

**Application of social support in treatment.** Evidence exists on the importance of overall social support in the treatment of chronic diseases, particularly in the treatment of cardiovascular disease\textsuperscript{184, 185} and stroke.\textsuperscript{186-189} These studies have shown that improvements in physical functioning and psychological adjustment in older adults in cardiovascular and stroke recovery were greater among those with higher sources of social support.\textsuperscript{185-191} Moreover, other studies have shown that social support from all sources positively correlated with increased perceived general health and quality of life after stroke.\textsuperscript{192-194} Researchers have also shown lack of social support in general to be associated with negative health consequences including suicidal thoughts,\textsuperscript{195} depression,\textsuperscript{104} length of hospital stay,\textsuperscript{196} discharge to rehabilitation and nursing home facilities,\textsuperscript{197} and reduced physical functioning.\textsuperscript{198, 199}

There is additional evidence that patients with a variety of chronic disease processes benefit from social support from all sources. In one study, Littlefield et al\textsuperscript{200} found patients with Type II Diabetes Mellitus had improved function with higher total social support scores but worse function with higher depression scores. In another study, Yates\textsuperscript{201} surveyed patients with cardiovascular disease who reported that both emotional support and tangible aid from health care providers and the patients’ spouses were important sources of support for coping with their disease process and improving overall physical recovery. Additionally, Gulick\textsuperscript{202} conducted research involving patients with multiple sclerosis and found that higher total social support
scores correlated positively with ADL function scores and inversely correlated with depression scores.

Research specifically investigating arthritis found that social support does mediate the response to the treatment process and function of the patient. In patients with RA, Taal et al\textsuperscript{103} found tangible or instrumental support by caregivers corresponded positively with improved patient reported health status and participation in daily physical activities. However, emotional support did not relate to patients’ reported health status for this sub-group of patients with RA. Weinberger et al\textsuperscript{203} illustrated in research involving patients with OA with concurrent functional limitations that both older age and lower levels of tangible support from caregivers, friends, or family associated directly with greater physical disability. Moreover, greater psychological disability was associated in patients with OA with lower levels of emotional support from all sources.

Little research has directly examined the association between treatment for LBP and social support. Masters et al\textsuperscript{183} investigated whether patients received social support in the treatment process for LBP. Retrospectively, the researchers asked patients who participated in treatment for LBP to indicate which sources of social support they received and whether this support was helpful or unhelpful. Out of the 50 patients surveyed, 43\% indicated that they received tangible support from a physical therapist and physician that was helpful. Thirty-three percent of the patients indicated they received helpful emotional support from physical therapists, family, and friends. Twenty-three percent of the patients additionally reported that they received helpful informational support from physical therapists. However, 50\% of the patients also reported that they received unhelpful emotional support from their family and friends during the treatment process. Additionally, 37\% reported receiving unhelpful informational support and 10\% reported receiving unhelpful tangible support from their physicians during the treatment process. Unfortunately, the researchers did not evaluate the relationship of support to other general health, physical function or psychosocial measures. In addition, the researchers did not evaluate the
relationship of social support to the outcomes of pain and disability in treatment for LBP. Overall, this study illustrates that social support sources are available and are identified as both helpful and unhelpful in treatment for LBP. Yet understanding how social support impacts the experience of pain and disability in LBP, particularly in LSS, continues to be lacking in the literature.

**General Health Status**

Self-rated health is another way to identify a patient’s perspective of his/her health condition and may contribute to poor coping behaviors as well as improvement in health outcomes. Self-ratings of health are used frequently in health literature and have shown to be predictors of morbidity and mortality. Self-rated health has also been proven sensitive to improvements and declines in many health related outcomes. Self-rated health measures assess subjective well-being related to physical and mental domains of health. These measures are used extensively in clinical trials and in health services research where they have shown evidence of reliability, validity, and responsiveness. Yet, researchers have only a limited understanding of how these self-evaluations are reached or their implications for health behaviors. In addition, few studies have examined changes in self-rated health over time and in specific health conditions such as LSS.

The perception of health status during a negative health experience is believed to be just as relevant to health outcomes as the actual somatic state of the individual. Even though most medical treatment still focuses on a person’s actual physical state as it relates to pain and illness, perceived health may largely contribute to a person’s well-being and function. Cross-sectional studies have typically shown that general self-rated health is closely related to the experience of physical symptoms. Moreover, a 5 year study by Gold et al of health outcomes in the community determined that both functional ability and self-rated health were independent predictors of health outcomes. Those with initial low functional scores also had greater decline in self-rated health over time reflecting the physical component in self-evaluations of health.
Appraisal of health. Self-rated health, both physical and mental health, is likely to be part of the appraisal process when faced with a stressful health condition. Health perceptions may also be part of coping processes when an individual faces a specific illness. When an individual has a better perception of their overall health, they have a greater potential for these health beliefs to bolster positive coping behaviors during illness experiences. It has been shown that older adults’ overall perception of health can be predictive of their use of active coping strategies to deal with age-related health challenges.²¹⁰ Research has also shown that those who don’t have a positive health perception may engage in sick role behaviors that can lead to self-destructive behaviors during illness.¹²² One reason for this is that self-rated health is believed to be a reflection of an enduring self-concept of a healthy or unhealthy person.²¹¹ Therefore this self-concept of health may act as a moderator when engaging in positive or negative illness behaviors.

Variance in physical measures and outcomes have also been shown to be related to respondents’ previous self-rated health.²¹¹ Longitudinal studies have illustrated that those with initial lower self-rated health predict poor functional ability and increased health care utilization over time.²⁰⁶, ²¹² Negative self-rated health has been found to predict long term disability and health decline in the general population.²¹² Change in self-rated health have been shown to coincide with long-term changes in physical health, mental health, perceived social support, and performance related behaviors.²¹¹ Moreover, self-rated health has been shown to vary according to whether respondents intended to improve specific health-related behaviors in the future.²¹¹ These findings suggest that self-rated health is both a current assessment of one's health status, similar to a self-concept, and a reflection of efforts to achieve relatively important health-related goals.

During illness, perceived health status may be determined in part by an individual’s level of emotion and distress during illness. Individuals have been found to experience different physical bodily responses based on their differing emotional states.²¹³, ²¹⁴ Some previous research has indicated that psychological function and perceived mental health are related to functional
status.\textsuperscript{215} Using the Stress-Diathesis Model, vulnerability or diathesis is an integral component in the experience of pain and disability. Therefore, it is probable that components of perceived psychological function, or mental health, can also have proximate influences on the appraisal process and indirectly influence health outcomes.

**Application of self-rated health.** Measurement of perceived physical and mental health has been performed routinely in the health literature by several standardized tools.\textsuperscript{73, 209, 215, 216} These general health surveys have been designed to measure overall self-rated health with a broad range of questions covering a variety of aspects of physical and mental health. It is commonly felt that the usefulness of general measures is in their ability to allow comparisons among patients with the same condition as well as between patients with different conditions. In some cases, general health measures may be able to identify unsuspected issues from a diagnostic group that would be highlighted as scores deviating from population or disease specific norms. These self-rated indicators likely take into account the patient’s physical sensations such as bodily pain, the patient’s comparison of what he/she can perform in his/her daily life as compared to previously or as compared to his/her peers, as well as his/her psychological and social perception of functioning. Overall, understanding how a patient perceives his/her general physical and mental health may add to the larger role of intrapersonal and interpersonal level influences on outcomes of pain and disability.

**Theoretical Summary**

Improvements in levels of pain and disability are routinely monitored and measured in treatment programs; however the influences mediating the severity and outcomes of these clinical variables are not fully understood. This study examined if personal factors at an individual or intrapersonal level, specifically self-efficacy, and social factors at an interpersonal level, specifically social support, contribute to a greater understanding of the experience of pain and disability in patients with LSS. Because there is some evidence that individual factors such as
stress, coping, and cognitive mechanisms can influence aging-related health in general, it was important to include a measure of perceived physical health and perceived mental health to the understanding of the experience of pain and disability. Although self-efficacy and social support have been previously studied in stroke, cardiovascular disease, arthritis and LBP, the contribution and association of self-efficacy and social support to understanding the experience of pain and disability in patients with LSS has not been studied.

Gaps Filled

The goal of this study was to understand how the influences of intrapersonal and interpersonal factors contribute to the experience of pain and disability in LSS. This study addressed multiple gaps in the LSS literature. Gaps in the LSS literature include a broader understanding of the experience of pain and disablement in this population, understanding appraisals and coping used by patients with LSS, and the use of mixed methods research. This study aimed to fill some of the gaps in the literature by evaluating the experience of pain and disability, particularly identifying the contribution of self-efficacy, social support, and perceived health status in management of patients with LSS.

This study tested existing measures of self-efficacy, social support, perceived physical health, and perceived mental health in a unique population before and after clinical treatment. This study added to a body of literature on how coping behaviors operate in the context of health and disease. Ultimately, this study aimed to identify factors not recognized in the current literature that contribute to the experience of pain and disability in patients with LSS. By using a mixed methods research design, a more complete picture was developed that will inform clinical practice as well as future research and policy recommendations for this patient population. As information is revealed, future research will need to determine how to best identify, monitor, and possibly intervene using concepts of self-efficacy, social support, general health perceptions, and any novel factors uncovered during the study period.
CHAPTER III

EXPERIMENTAL DESIGN AND METHODS

Research Design

The study used a subset of a larger data set from an ongoing randomized clinical trial (RCT). This study used a longitudinal, cohort design with mixed quantitative and qualitative methods. The subset of patients with LSS studied participated in 1 of 2 non-surgical treatment programs (Figure 3.1). Patients were evaluated upon entry to treatment and the time period between 6 months and one year post-treatment. Treatment effects were not evaluated in this sub-study and will be evaluated upon completion of the larger RCT. The sample in this subset is similar to the larger population of patients with LSS. All patients in this subset and in the larger RCT are at a similar stage of chronic disease as they have been diagnosed with LSS upon entry to the study and display signs and symptoms consistent with the diagnosis of LSS. All patients in this subset and in the larger RCT have been randomized to treatment including epidural steroid injection (ESI) and low back education, with half the subjects receiving additional physical therapy (PT) (Figure 3.1). Both ESI and PT represent the standard of care for current clinical practice. Although both non-surgical treatment options have been found to be helpful, at this time neither have been found to be superior in determining clinical outcomes of LSS.
Figure 3.1. Design of the randomized clinical trial for non-surgical treatment of LSS.
Research design illustrating baseline procedure, randomization, and treatment groups.

Within the larger RCT, there are opportunities to answer many questions. However, the focus of this dissertation research was to investigate if behavioral and social factors such as self-efficacy, social support, and self-rated health had an impact on standard clinical intake measures of pain and disability. In addition, this dissertation research sought to identify the role of self-efficacy, social support, and self-rated health in predicting positive outcomes of pain and disability in patients with LSS long-term. Understanding treatment effects is an important component in management of patients with LSS; however, unless we look closer at behavioral and social factors in the management process, we can’t draw complete or sound conclusions regarding patient severity or outcomes. In addition, understanding the role of behavioral and social factors in the long-term management of LSS can help direct clinical resources to address the specific needs of the patient. Future studies will need to test the findings from this study in an
intervention trial that uses strategies which target significant influencing behavioral and social factors in order to improve outcomes in patients with LSS.

**Subset of the RCT**

For this study, a subset of the study population from the RCT was selected for both quantitative, repeated measures survey and qualitative open-ended interviews. A cohort study design involves participants who meet specified criteria such as a specific health outcome or membership in a group of interest.\(^{217}\) In this case, persons with LSS who enter conservative treatment are the persons of interest and the entry point to treatment and the outcomes of their treatment related to pain and disability scores are the outcomes of interest.

All patients participated in self-report surveys of general health, condition specific pain and disability as well as specific intrapersonal and interpersonal domain measures of self-efficacy, social support, and self-rated health at entry to treatment and at long-term follow-up. Follow-up surveys were mailed at approximately 6 months post entry to treatment to 22 participants who completed treatment. Twenty subjects that completed treatment and the survey packets were included in the post-treatment measurement. The individual response time for follow up of post-treatment measurement in the 20 subjects was between 6 and 12 months. The same 20 subjects who completed treatment and follow up surveys participated in a 30-50 minute interview. All subjects received the same non-surgical treatment protocol for low back education and epidural steroid injection (ESI), with approximately half of the subjects receiving additional physical therapy treatment (ESI+PT). All procedures for the RCT treatment protocols are located in the Manual of Standard Operating Procedures (MOSP, Appendix A). Figure 3.2 depicts the study design.
Figure 3.2. Longitudinal, cohort study design using mixed methods. The quantitative analysis sample consisted of 34 patients at entry to treatment and 20 patients at follow-up. The qualitative interview sample consisted of the same 20 participants at follow-up. All participants were part of a subset of the ongoing RCT sample of patients.

Mixed Method Design

Mixed methods approach to inquiry was selected over other study designs because it enables the researcher to capture both empirical measures and patients’ accounts of the lived experience of pain and disability with the chronic condition of LSS. By combining quantitative and qualitative data collection techniques, mixed methods allows for a rich, complex, and more complete understanding of the phenomenon under study. Mixed methods utilizes the strengths of both quantitative and qualitative methods to offset the weaknesses inherent in each individual method and enhances validity of the findings. For the chronic condition of LSS, previous literature has not fully explored the meanings of pain and disablement. Although a narrow and focused understanding of pain and disability in patients with LSS is present in the current
literature, the addition of qualitative research to the quantitative data provides different perspectives on the experience of both pain and disability.

This mixed methods study employed a semi-convergent parallel design, capturing quantitative data at entry to treatment but then both quantitative and qualitative data at relatively the same time period post-treatment, as shown in Figure 3.2. Quantitative methods were used to explore questions and test hypotheses regarding the factors associated with pain and disability in LSS. Qualitative methods were used to enhance and expand upon the quantitative findings, give the patients a voice, and explore the nuances and meanings of pain and disability related to the lived experience of LSS. The purpose of the semi-convergent design is to obtain different but complementary data on the same topic to pull together the strengths of both quantitative and qualitative methods. This design is often used to triangulate findings by directly comparing and contrasting quantitative statistical results with qualitative findings for corroboration and validation purposes as well as to develop a more complete understanding of a phenomenon, in this case, the experience of pain and disability in individuals with LSS.

Finally, the mixed method approach allows for multiple worldviews in research related to LSS. Since a large portion of the research to date in LSS is hypothesis driven and uses a single method, the primarily focus has been a paradigm of positivism. The addition of other worldviews including paradigms from both post-positivism and constructivism in understanding pain and disability in this population is warranted. Since a single worldview currently exists in the literature investigating LSS but the pain and disability literature uses multiple worldviews, a pragmatism worldview was used in this study. Pragmatism is a set of ideas that draws on diverse approaches and uses both objective and subjective knowledge. According to Teddlie and Tashakkori, using a pragmatism approach in mixed methods places the research question as the primary focus rather than the method or the philosophical worldview that underlies the method. The pragmatism approach is well suited to answer the study’s research question by combining 2
types of data sources to uncover a more complete story about the experience of pain and disability in patients with LSS.

**Data Collection**

In order to corroborate and compare the information from both quantitative and qualitative data sources, this study included data from the same 20 participants at post-treatment. Parallel data collection questions were conducted across both the quantitative and qualitative data sources. Equal weight was given to both quantitative and qualitative data. In addition, results of the longitudinal data collection was conducted using repeated measures surveys at entry to treatment (n= 34) and post-treatment (n=20) and corroborated with in-depth, open-ended interviews (n=20) collected post-treatment from the RCT titled Epidural Steroid Injection versus Epidural Steroid Injection and Manual Physical Therapy and Exercise in the Management of Lumbar Spinal Stenosis; a Randomized Clinical Trial. (NCT00786981). IRB approval was completed by COMIRB and Hawkins Foundation (see Appendix B).

**Sampling and participants.** Figure 3.3 provides a visual representation of the process for sampling. The population for the study included individuals 50 years of age and older with a diagnosis of LSS in Colorado and South Carolina who entered conservative treatment for this chronic condition. The study used a subset of 43 of the total 80 subjects planned to be enrolled into the larger RCT using convenience sampling of individuals who sought treatment either at the Spine Center at the University of Colorado or the Steadman Hawkins Clinic of the Carolinas. These sites were located in 2 different geographic areas in the United States and represented a broader view of the population of LSS.

**Subject randomization, baseline examination, and treatment procedures.** Patients who sought medical care at the 2 clinical sites, met the inclusion criteria (see Table 3.1), and consented to participate were enrolled in the RCT. All patients were required to have health care insurance coverage (private insurance, Medicare, or Medicaid) to cover the standard treatment
protocols designed for the RCT which included standard treatment with ESI and PT. All patients in the study had a diagnosis of LSS, had symptoms of neurogenic claudication or radicular pain, and were candidates for non-surgical treatment. For the purposes of this study, LSS was defined as evidence of narrowing of the spinal canal and/or intervertebral foramen demonstrated on diagnostic imaging studies (MRI or CT scan), and clinical signs and symptoms consistent with a diagnosis of LSS including patient-reported reduction in walking tolerance due to pain and/or cramping in the leg(s), defined as neurogenic claudication.

Table 3.1. Inclusion and Exclusion Criteria for the Nonsurgical RCT with Patients with LSS

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
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</thead>
<tbody>
<tr>
<td>1. Age greater than or equal to 50 years</td>
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<tr>
<td>2. MRI findings consistent with lateral foraminal and/or central lumbar spinal stenosis (evidence of compression of lumbar spinal nerve root(s) by degenerative lesions of the facet joint, disc, and/or ligamentum flavum)</td>
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<tr>
<td>3. Chief complaint of pain in the low back, buttock and/or lower extremity(s)</td>
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<tr>
<td>4. Presence of symptoms consistent with neurogenic claudication (numbness, tingling, cramping, and downward radiating pain which is not exacerbated with biking, uphill ambulation, and lumbar flexion but is not alleviated with standing; or does not include signs of pulselessness, paralysis, or pallor).</td>
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<tr>
<td>5. Rates sitting as a better position with respect to symptom severity than standing or walking</td>
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<td>6. Lives within one hour of a research site</td>
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<tr>
<td>7. Can attend 10 regular physical therapy appointments spread over 10 weeks and 4 examination appointments (baseline, end of treatment, 6 months, and 1 year)</td>
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<tr>
<td>8. Sufficient English reading and language skills and mental capability to complete self-report assessment questionnaires</td>
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<td>9. No contraindications to MRI</td>
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<table>
<thead>
<tr>
<th>Exclusion Criteria</th>
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</thead>
<tbody>
<tr>
<td>1. Severe vascular, pulmonary or coronary artery disease which limits ambulation (as determined by the referring physician or the therapist)</td>
</tr>
<tr>
<td>2. Other orthopedic conditions or physical impairments of unrelated nature which would limit ambulation or prevent the subject from fully participating in any other aspect of the rehabilitation exercises (as determined by the referring physician or the therapist)</td>
</tr>
<tr>
<td>3. Previous spinal surgery that included fusion of two or more vertebrae</td>
</tr>
<tr>
<td>4. History of spinal tumors, spinal infection, or lumbar vertebral fractures other than spondylolysis or spondylolisthesis</td>
</tr>
<tr>
<td>5. Signs/symptoms suggestive of potential non-benign or pathologic condition as the origin of symptoms</td>
</tr>
<tr>
<td>6. Presence of any absolute contraindications to sub-maximal treadmill testing per the American College of Sports Medicine (ACSM) standards.</td>
</tr>
<tr>
<td>7. Epidural steroid injection within the last 365 days.</td>
</tr>
</tbody>
</table>
A physician, resident, or physician’s assistant indicated whether the patient met the inclusion criteria to participate in the RCT. In addition, the physician or physician assistant explained the study, the risks and benefits for patients, and asked eligible patients who were interested in participating to sign 3 copies of the informed consent form (Appendix C). The physician, resident, or physician assistant, performed the general baseline examination. After the baseline physical examination, patients completed paper and pen self-reported questionnaires (Appendix D).

The RCT employed a random number generator to establish randomization lists prior to the initiation of the RCT. After all baseline procedures were completed including consent, physical exam, and baseline surveys, the patients were randomized to 1 of 2 treatment groups: epidural steroid injection only or epidural steroid injection plus physical therapy. The procedures for baseline examination, randomization, and group treatment procedures were standardized so that all patients in each treatment group and at each site received the same care (see MOSP: Appendix A).

Subjects. As of October 2012, 43 subjects were enrolled into the RCT. Of these 43 subjects, 12 subjects dropped out and 1 subject died after baseline enrollment. Of those 13 subjects who dropped out, only 9 had completed baseline paperwork, 11 had no or partial treatment, and 2 had completed treatment but were lost to follow up (see Figure 3.3). Eight of the 43 subjects were still in the process of treatment at the end of data collection for this sub-study on 10/31/2012. Two subjects who had completed treatment were not a part of the patient interviews. In total 34 subjects completed baseline information and were included in the sub-study data at entry to treatment. Twenty of these same 34 subjects completed follow-up surveys and a phone interviews during the post-treatment phase (see Figure 3.3). All quantitative data were collected and kept in a locked storage cabinet and were entered into a secure database in a password protected computer. All quantitative data were only accessible to the research investigators of the
RCT. Participants who completed baseline evaluation, treatment, and completed the follow up surveys between 6 and 12 months after enrolling in the study, received $50 in remuneration.

A total of 20 subjects who completed baseline evaluation, treatment, and follow up surveys were invited and verbally agreed by phone to an interview session consisting of a series of open-ended questions. Of these 20 subjects, 12 were in the ESI only group and 8 were in the ESI plus PT group. All interviews lasted approximately 30-50 minutes and were conducted by phone. Interviews were audio-recorded during the phone conversation and transcribed verbatim into word documents along with field notes made after the interview. Interview and field note data were kept in a password protected computer. All data collected during the interview were kept confidential and coded to the subject’s number given during the RCT randomization procedures. Patients who completed an interview received an additional $25 in appreciation for their time, effort, and sharing their experiences with LSS. Figure 3.3 illustrates subjects who participated in baseline evaluation and subsequent follow up surveys and phone interview post-treatment.
University Hospital Spine Clinic in Colorado recruitment* N = 230
- Screen Fails N = 206
- Enrollment N = 34
* as of 10/30/12

Hawkins Foundation in South Carolina recruitment*
N = 33
- Screen Fails N = 24
- Enrollment N = 9
* as of 10/30/12

Enrolled to RCT as of 10/30/12 N = 43

Baseline Assessment including baseline physical examination and survey packet N = 40

Randomized to treatment N = 38
ESI only: N = 20
ESI + PT: N = 18

Completed treatment N = 32*
ESI only: N = 16
ESI + PT: N = 16
- As of 10/30/12

Completed post-treatment follow up N= 22
- 8 patients still in Rx at 10/30/12

Completed post-treatment follow up survey packets N = 22

Drop out after consent but before baseline assessment N = 3

Drop out incomplete baseline assessment / non-randomized N = 2

Incomplete baseline / drop out post randomization N = 4

Drop out complete baseline / incomplete treatment N = 2
- Death, unrelated (1)
- Reaction to 1st ESI (1)

Loss to follow up N = 2
- unable to contact phone or mail

No phone interview N = 2
- patient had hip surgery declined interview
- not able to contact by phone

Figure 3.3. Subject enrollment, consent, treatment retention, and follow-up.
Research Question and Specific Aims

The current study addressed the following research question: What is the relative contribution of self-efficacy, social support, perceived physical health and perceived mental health to pain and disability in individuals with LSS? Three Specific Aims guided the investigation of this overarching research question.

Aim 1: To determine the relative contribution of self-efficacy, social support, self-rated physical health, and self-rated mental health to the severity of pain and disability among patients with LSS upon entry to treatment of LSS.

H1A: Lower levels of self-efficacy, social support, perceived physical health and perceived mental health will each independently predict higher disability at entry to treatment.

H1B: Lower levels of self-efficacy, social support, perceived physical health and perceived mental health will each independently predict higher pain at entry to treatment.

H1C: Lower levels of self-efficacy, social support, perceived physical health and perceived mental health will together predict higher disability at entry to treatment.

H1D: Lower levels of self-efficacy, social support, perceived physical health and perceived mental health will together predict higher pain at entry to treatment.

Aim 2: To determine the relative contribution of self-efficacy, social support, self-rated physical health, and self-rated mental health to the outcomes of pain and disability among patients with LSS in the year following treatment of LSS.

H2A: Higher levels of self-efficacy, social support, perceived physical health and perceived mental health will each independently predict lower disability after treatment of LSS.
**H2B:** Higher levels of self-efficacy, social support, perceived physical health and perceived mental health will each independently predict lower pain after treatment of LSS.

**H2C:** Higher levels of self-efficacy, social support, perceived physical health and perceived mental health will together predict lower disability after treatment of LSS.

**H2D:** Higher levels of self-efficacy, social support, perceived physical health and perceived mental health will together predict lower pain after treatment of LSS.

**Aim 3:** Explore how self-efficacy, social support, perceived physical health and perceived mental health contribute to a patient’s lived experience with LSS and influence meanings of pain and disability.

**Measures and Constructs**

**Measuring pain: Numeric Pain Rating Scale (NPRS).** The Numeric Pain Rating Scale (NPRS) asked subjects to rate their pain on an 11-point scale. The anchors were 0 and 10, with 0 representing “No Pain” and 10 representing “Worst Pain Imaginable.” Subjects rated their minimum, average, and greatest pain intensity during the last 48 hours for their thigh and leg symptoms (NPRStl) and their low back and/or buttock pain (NPRSbb). This method of recording pain has demonstrated only fair reliability. Older patients tend to prefer the NPRS and tend to exhibit fewer errors than with the use of the visual analog scale. Whitman et al have shown the minimal clinically important difference (MCID) for the NPRS in a patient population with LSS to be between 1.25 and 1.5 respectively. Additionally, the body diagram was used to assess the distribution of symptoms by categorizing the location of symptoms as low back, buttock, thigh, and/or leg (distal to knee).

**Measuring disability: Oswestry Disability Index (ODI).** The modified ODI is a region-specific disability scale focusing on the lower back and leg regions for patients with LBP.
The ODI consists of 10 items addressing different aspects of function, each scored from 0-5 with higher values representing greater disability. The modified ODI was used as the primary outcome measure of disability. Whitman et al\textsuperscript{225} found that the modified ODI exhibits excellent test-retest reliability in patients with LSS (ICC, 0.84). They also found the modified ODI to be more responsive (AUC = 0.84) than the Spinal Stenosis Scale symptom and function subscales (AUC = 0.74 and 0.75 respectively). The authors identified the minimum clinically important difference in a population receiving non-surgical management for LSS as 5\% points which means the change in ODI scores must be at least 6 points to be clinically significant in patients with LSS.

**Measuring self-efficacy: Low Back Activity Confidence Scale (LoBACS).** The LoBACS\textsuperscript{228} assesses confidence in performance of key functional activities and regular exercise in patients with histories of LBP and surgical interventions. Self-efficacy literature, LBP literature, and clinicians’ observations were all used to develop the LoBACS. Seven items pertain to self-efficacy for functional activity: self-confidence for carrying, lifting, pushing, sitting, standing, walking, and stair climbing. Three items address self-efficacy for self-regulation of back health, and 5 items relate to confidence for regular exercise. The 2 scales of the LoBACS have good test-retest reliability with Functional Self-Efficacy (FSE): ICC, 0.92 and Exercise Self-Efficacy (EXSE): ICC, 0.75. The FSE subscale is also strongly negatively correlated with disability using the ODI: $r = -0.86$, $p < .0001$. The EXSE subscale is moderately correlated with disability using the ODI: $r = -0.28$, $p = .044$. Both subscales are correlated to subjective quality of life measures (FSE: $r = 0.55$, $p < .0001$; EXSE: $r = 0.35$, $p = .010$).

**Measuring social support: Medical Outcomes Survey Social Support Scale (MOS SSS).** The MOS SSS is a brief, multidimensional, self-report survey developed for patients with chronic conditions in the Medical Outcomes Study.\textsuperscript{229} This survey was designed to be comprehensive addressing different dimensions of social support. Multi-trait scaling analyses support the dimensionality of 4 functional support scales (emotional/informational, tangible, affectionate, and positive social interaction) and the construction of an overall functional social
support index. These support measures are distinct from structural measures of social support and from other related health measures. The support measures are reliable (alpha >0.91), fairly stable over time, and illustrate construct validity.

**Measuring perceived health status: Medical Outcomes Survey Short Form 36 (SF-36).** General health surveys have been designed to measure overall self-rated health with a broad range of questions covering a variety of aspects of physical and mental health. The Medical Outcomes Survey SF-36 is one such multi-purpose, general health survey which yields psychometrically-based physical and mental health summary measures. In multiple studies, the SF-36 has been used for general and specific populations evaluating health outcomes, comparing the relative burden of diseases, and differentiating the perceived health benefits produced by a wide range of different treatments. The content validity of the SF-36 has been compared to that of other widely used generic health surveys. The SF-36 was judged to be the most widely evaluated generic patient assessed health outcome measure in a study published in the *British Medical Journal*. In addition, the SF-36 is widely used in studies of patients with LBP and has well established psychometric properties.

The SF-36 is 36-item, generic self-report measure of perceived health status covering 8 domains and 2 subscales. The 8 domains include physical functioning, role limitation as a result of physical health problems, role limitations as a result of emotional health problems, energy/fatigue, emotional well-being, social functioning, pain and general health perceptions (see Figure 3.4). Each subscale and domain is scored from 0 (poor health) to 100 (optimal health). The 8 domains are designed to capture the 2 major components of health, physical and mental, contained in the 2 subscales.
The 2 subscales provide a more concise measure of overall physical and mental health and are called the Physical Component Summary (PCS) and Mental Component Summary (MCS) respectively. These summary scales use the items on the SF-36 with the PCS heavily weighting physical measures and the MCS heavily weighting mental health measures. Reliability coefficients for the physical and mental summary scores exceed 0.90 in previous studies. The PCS and MCS are adjusted by the population mean and standard deviation to produce norm-based scores with a common mean of 50 and standard deviation of 10. Thus, any score below 50 represents a decrement from “normal” health and functioning.

The physical health subscale or Physical Component Summary (PCS) comprises half of the SF-36 items which include domains of perceived physical function, role-physical, bodily pain,
and general health (see Figure 3.4). It is important to note that the PCS does not actually measure physical performance, ability or function. Rather it is a tool to indicate the patient’s perception of physical function, physical role in his/her life, his/her interpretation of body pain, and his/her overall indication of general health.

The mental health subscale or Mental Component Summary (MCS) comprises the other half of the SF-36 items which include domains of vitality or energy, social functioning, role-emotional, and mental health (see Figure 3.4). The mental health subscale in its name is misleading as it represents dimensions of intrapersonal energy and emotional well-being but also interpersonal interaction and social and emotional function. Again, it is important to note that this scale represents the patient’s perceived levels of energy, emotional roles, social function, and mental health. Moreover, it is important to note that the mental health subscale is does not represent a tool for psychiatric diagnosis of a mental health condition. The mental health subscale has been used to screen for psychiatric disorders such as depression, but is not as such a diagnostic tool for any mental disorder.

Data Collection Aims 1 and 2: Quantitative

Quantitative data for Aims 1 and 2 were collected on 34 subjects upon entry into treatment and 20 of these 34 subjects who completed post-treatment measurements. Baseline and follow-up measures included demographics and information related to pain, disability, perceived physical health, perceived mental health, self-efficacy for low back related tasks, and social support. A summary of the quantitative data collection is below (Table 3.2). Copies of the surveys are located in Appendix D.
Table 3.2. Data Collection Summary. Summary of quantitative data collection at entry to treatment and post-treatment during long-term follow up period of 6-12 months after entry to study.

<table>
<thead>
<tr>
<th></th>
<th>Entry to Treatment</th>
<th>Post-Treatment</th>
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<tbody>
<tr>
<td>Demographics</td>
<td>X</td>
<td></td>
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<tr>
<td>NPRS</td>
<td>X</td>
<td>X</td>
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<tr>
<td>ODI</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>SF-36</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>LoBACS</td>
<td>X</td>
<td></td>
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<tr>
<td>MOS SSS</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

Data Analysis Aims 1 and 2: Quantitative

Prior to addressing specific Aims 1 and 2, the data were examined using descriptive statistics to describe demographics of the sample using grouped frequency distributions and measures of central tendency and variability at entry to treatment collected from the physical exam and the baseline survey instruments (n=34). All survey data at entry to treatment and post-treatment were converted to index scores and scored according to the literature for each measurement tool. For each survey index score, parametric analysis was most appropriate in meeting statistical assumptions for linearity, normally distributed errors, and uncorrelated errors. Parametric data analysis has been recommended in the literature as preferable as long as assumptions of linearity are met since parametric data analysis is more robust with small sample sizes when compared to non-parametric analysis.²³⁹

Paired t-tests were performed to determine if there were pre to post differences between demographics, survey measures of the dependent variables of pain and disability, and independent variables of self-efficacy, social support, perceived physical health, perceived mental health, and all the subscales of both self-efficacy and social support during the study period. Next, associations between the independent variables and dependent variables using Pearson’s correlation coefficient were identified. Correlation analysis was conducted between the independent variables of self-efficacy, social support, perceived physical health, perceived mental health, and subscales of both self-efficacy and social support in association with the dependent
variables of pain and disability at entry to treatment and post-treatment. Correlations between predictors of greater than .70 can lead to multicollinearity while correlations below .20 between predictor and outcomes may not support the assumption of a linear relationship.\textsuperscript{239} Therefore, the assumptions of linearity, normally distributed errors, and uncorrelated errors were checked and met before further analysis. In addition, tests for multicollinearity were performed and checked during multiple regression analysis procedures and reported.

**Bivariate regression analysis.** Next, a simple or bivariate linear regression was conducted to investigate whether the individual variables of self-efficacy, social support, perceived physical health, and perceived mental health independently predicted the dependent variables of pain and disability in patients with LSS. These preliminary analyses were used to determine the degree of individual association between the independent variables of self-efficacy, social support and general measures of perceived physical and mental health on the dependent variables of pain and disability in patients with LSS. Because these variables have largely been unexplored in the LSS literature, understanding the individual contribution or prediction of the criterion variables of pain and disability was an important first step.

**Multiple regression analysis.** It was estimated that each of the independent variables of self-efficacy, social support, perceived physical health, and/or perceived mental health status may not individually represent a strong association with pain and disability but collectively they could contribute to a proportion of variability in the dependent variables. Because the independent variables have not been explored together in the current literature for LSS, a further step of using a multivariate analysis procedure of multiple regression further tested these relationships in the clinical phenomena of pain and disability in patients with LSS. Multiple regression is supported for analysis of theoretical components of constructs particularly when the purpose is to better understand the factors associated with it.\textsuperscript{239} The theoretical constructs of self-efficacy measured by the LoBACS self-efficacy scale and social support measured by the MOS SSS social support scale along with perceived physical and mental health status measured by the SF-36 physical
health subscale (PCS) and mental health subscale (MCS) were all modeled a priori to determine what combination, if any, of these constructs contributed to pain and disability at entry to treatment and post-treatment in patients with LSS. The literature states 2 main purposes of the modeling approach in multiple regression analysis: (1) to achieve best single predictor model, or (2) to achieve an explanatory approach for developing new insights, exploring potentially causal/explanatory relationships and designing future research.\textsuperscript{240} Statistical literature has stated that the second approach to achieve explanation must necessarily simultaneously consider all possible models.\textsuperscript{240, 241} The second approach to developing new insights and exploring causal relationships underlies the multiple regression methods in this study.

The simultaneous multiple regression method or “enter” selection procedure for SPSS version 19 (IBM SPSS Inc., Chicago IL) using underlying theory to enter all independent variables in the model was chosen to test how the combination of self-efficacy, social support, and perceived physical and mental health all contribute to the understanding of pain and disability. This procedure tests all of the variables in a model at both time points of data collection to determine their group association to the dependent variables of pain and disability. A final step was taken if statistical significance was not found or if multicollinearity was found in the group model. This final step tested the most parsimonious combination of all variables using a “backwards” procedure in which the SPSS analysis program searches for the best fit with the largest $R^2$ and most significant F value.

A key methodological point is that all models were guided a priori by the existing theoretical framework of self-efficacy and social support in a novel approach to test the contribution of these factors in combination with the measures of general perceived physical health and perceived mental health in the modeling process. Because there is no literature comparing these variables in a similar sample of patients with LSS, there is no prior indication about which variables will create the best prediction equation. In addition, since there is a small set of predictors being tested, simultaneous regression is the best method to use to test the group...
of predictors. The models for Aims 1 and 2 include the combinations of self-efficacy, social support, perceived physical health, and perceived mental health to achieve the most clinically relevant and parsimonious combination predicting the dependent variables of pain and disability. Only significant model combinations are reported.

Since this is a relatively small sample with only 34 observed cases at entry to treatment and only 20 of the original 34 observed cases followed post-treatment, testing the sample with all 4 independent variables reached the minimum recommendations of observations to variables (5:1) cited in the literature for multiple regression analysis. An a priori alpha level of p= 0.05 was set to determine significance. The adjusted R² value, reflecting the goodness of fit of the linear model adjusted for the number of independent variables in the equation was calculated for each model. The significance using the F statistic for each model was determined. Standardized beta coefficients for each variable in the model were calculated and the significance of each was determined under the null hypothesis that the coefficient was not different from zero.

Sample size and power analysis. It was anticipated that entering the independent variables self-efficacy, social support, perceived physical health, and perceived mental health into the multivariate models would result in a moderate effect size (0.30). Using an a priori sample size calculator for multiple regression considering 4 independent variables, an alpha level equal to 0.05, and a desired power of 80%, a sample size of 42 subjects would be required. Therefore, 34 subjects at entry and 20 at follow-up was determined unlikely to provide adequate power and therefore increased the risk of a type II error on detection of the true impact of the independent variables in their contribution to pain and disability. However with a large effect size (0.50) as reported by Cohen, a sample size of 27 subjects would be adequate from the 34 observations at entry to treatment but still less than what was available in the follow-up data set of 20 observations. Caution is warranted in interpretation due to the potential of committing a type II error with the small sample size. Therefore, a post hoc analysis was run on all models to help identify the magnitude of the observed data. Because of the minimal evidence in the literature
regarding the contribution of self-efficacy, social support, and self-rated health in understanding the severity and outcomes of pain and disability in LSS, this study provided a foundation for future research and provided direction to further explore these variables with a larger data set.

Data Collection Aim 3: Qualitative

The focus of the interview was to explore the meanings of pain and disability in a sample of patients with LSS. This focus guided the open ended questions to probe the details and depth of identified factors of self-efficacy and social support using the theoretical constructs discussed in Chapter 2. In addition, a broader sense of patient identified factors such as general health perception was explored. Data collected in Aim 3 consisted of patient interviews and field notes that were recorded at post-treatment, the time period of 6 to 12 month from entry into the study. The quantitative data from Aims 1 and 2 were therefore supplemented by patient descriptions of physical, behavioral, and psychosocial factors specifically self-efficacy, social support, and self-reported health, as they related to perception of pain and disability upon entry into treatment and post-treatment. Patient narratives were transcribed and coded by the researcher to characterize the patient’s perceived status at entry to treatment and post-treatment related to pain and disability. The interview explored the lived experience with LSS. Specifically, questions explored the patient’s self-confidence for back related tasks as well as patient’s social support sources and if these support sources were perceived as helpful or non-helpful during treatment and post-treatment. The interview guide is included in Appendix E.

Data analysis Aim 3: Qualitative and Combined Methods

Identification, confirmation, or contradiction of factors related to self-efficacy, social support, and general health status and their contribution to the understanding of pain and disability were identified through analysis of qualitative interviews (n=20). Interviews were conducted using an iterative process in which the researcher continued to interview subjects until
no new themes or factors related to the experience of living with LSS, experience of treatment, or
the concepts of self-efficacy, social support, perceived physical health, perceived mental health,
pain, and disability were revealed.

Interview transcripts were analyzed to identify any factors, including self-efficacy and
social support that contributed to the patient’s perceived pain and disability upon entry into
treatment and post-treatment. Verbatim transcripts from interviews were imported into the
qualitative software package Atlas.ti v6 (GmbH; Berlin, Germany), and preliminary themes were
identified and coded. In the first phase, the focus was on discovery and comprehension, whereby segments of data in a quote, sentence, or paragraph were coded with words or phrases that identified a particular theoretical constructs related to general health status, self-efficacy, social support, pain, and/or disability. These codes were complemented by ‘de novo’ coding which represents new information. These initial codes reflected quotes using the informants’ original words, and captured the essential meaning of a concept, idea, or description. Each transcript was read for code specific phrases until no new codes were identified in the data.

While the coding process began with the deductive process of breaking the narrative down into small coded phrases, it ended with the inductive process of recognizing thematic commonalities and generating observations which described typical behavior patterns. Major concepts or domains in the data were used that linked back to groups of statements or quotes. Domains related to pain and disability were compared and contrasted and relationships between them were identified and recorded on the network diagram of Atlas.ti v6. This process focused on synthesizing the data to define and clarify the essential concepts related to pain and disability revealed by the informants.

In the final stage of data analysis, theories were incorporated that built working explanations about the patterns observed in the data. The Stress and Coping Model was used as the underlying theory for understanding the appraisals of the stressors of pain and disability and
coping processes and resources identified by patients with LSS. Additionally, the Stress-Diathesis Model\textsuperscript{125} representing a biopsychosocial approach to pain was also used to identify the experience of pain. The WHO ICF framework\textsuperscript{248} was used as the overarching theoretical framework of disability. Finally, the Social Cognitive Theory\textsuperscript{112, 153} and the Stress and Coping Model were used to interpret data pertaining to the constructs of self-efficacy, social support, general perceived health status, and any other uncovered coping resources. A diagram that outlines the association between beliefs and behaviors related to pain and disability was developed in the final combined methods procedures to illustrate if and how factors of self-efficacy, social support, general health perception as well as other uncovered factors contribute to the experience of pain and disability in patients with LSS.
CHAPTER IV

RESULTS

Descriptive Results

Complete data sets on 34 patients upon entry to treatment and the remaining 20 patients post-treatment are represented below in the demographic analysis of the subset of patients with LSS. Demographic characteristics were reported with mean and standard deviations for interval data and with frequencies for categorical data in Table 4.1. The average age of the patients was 68 years at entry to treatment with only a slight increase to 71 years for the 20 patients remaining at follow up. These ages represent the typical age group found in patients with LSS. There were no statistical differences between the entry to treatment sample of 34 patients and the remaining 20 patients at post-treatment except for prior history of leg pain where 76% in the entry to treatment sample had a history of leg pain but 90% of the remaining 20 subjects had previous leg pain. Across the study sample, approximately 55% of the patients were male and 45% were female at the 2 time points. The race distribution in the sample was predominately white (70%) with over half of the sample married with a spouse (55%). Only a quarter of the patients currently worked in some capacity with the approximately half of patients retired, although 15% of the patients were permanently unable to work due to work or disease related medical disability status.

All patients in the sample came to treatment complaining of LBP with approximately 95% complaining of pain into buttock and leg(s). Nearly all patients rated their pain best when sitting (95%), however a few reported sitting caused increased pain which conflicts with the clinical diagnostic criteria although it is possible depending on acuity and severity that they had pain in any position. The average pain duration upon entry to the study for this current episode of LBP was 12 months prior to entry, with most patients reporting a prior history of LBP (90%).
<table>
<thead>
<tr>
<th>Demographics</th>
<th>Entry to Rehab (n=34)</th>
<th>Post-Rehab (n=20)</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>68.382 (8.714)</td>
<td>70.737 (8.881)</td>
<td>0.193</td>
</tr>
<tr>
<td>Gender - male</td>
<td>18 (53%)</td>
<td>11 (55%)</td>
<td>0.921</td>
</tr>
<tr>
<td>Gender - female</td>
<td>16 (47%)</td>
<td>9 (45%)</td>
<td>0.921</td>
</tr>
<tr>
<td>Race - White</td>
<td>24 (73%)</td>
<td>14 (70%)</td>
<td>0.304</td>
</tr>
<tr>
<td>Race - Black</td>
<td>5 (15%)</td>
<td>4 (20%)</td>
<td>0.304</td>
</tr>
<tr>
<td>Race – Hispanic</td>
<td>1 (3%)</td>
<td>1 (5%)</td>
<td>0.304</td>
</tr>
<tr>
<td>Race – Asian</td>
<td>2 (6%)</td>
<td>0 (0%)</td>
<td>0.304</td>
</tr>
<tr>
<td>Race – Pacific Islander</td>
<td>1 (3%)</td>
<td>0 (0%)</td>
<td>0.304</td>
</tr>
<tr>
<td>Resting HR (bpm)</td>
<td>78.409 (17.220)</td>
<td>77.588 (16.915)</td>
<td>0.873</td>
</tr>
<tr>
<td>Resting BP -SBP (mmHg)</td>
<td>129.462 (21.424)</td>
<td>128.850 (23.623)</td>
<td>0.821</td>
</tr>
<tr>
<td>Resting BP - DBP (mmHg)</td>
<td>78.360 (11.665)</td>
<td>79.105 (12.679)</td>
<td>0.271</td>
</tr>
<tr>
<td>BMI</td>
<td>29.615 (4.880)</td>
<td>29.977 (5.152)</td>
<td>0.741</td>
</tr>
<tr>
<td>Single</td>
<td>2 (6%)</td>
<td>1 (5%)</td>
<td>0.441</td>
</tr>
<tr>
<td>Married</td>
<td>21 (62%)</td>
<td>11 (55%)</td>
<td>0.441</td>
</tr>
<tr>
<td>Divorced</td>
<td>4 (12%)</td>
<td>2 (10%)</td>
<td>0.441</td>
</tr>
<tr>
<td>Widowed</td>
<td>7 (21%)</td>
<td>6 (30%)</td>
<td>0.441</td>
</tr>
<tr>
<td>Smoke now</td>
<td>3 (9%)</td>
<td>1 (5%)</td>
<td>0.340</td>
</tr>
<tr>
<td>Smoked over 100 cigarettes in lifetime</td>
<td>17 (50%)</td>
<td>12 (60%)</td>
<td>0.186</td>
</tr>
<tr>
<td>Low back pain</td>
<td>34 (100%)</td>
<td>20 (100%)</td>
<td>1.000</td>
</tr>
<tr>
<td>Pain beyond buttock</td>
<td>33 (97%)</td>
<td>19 (95%)</td>
<td>0.227</td>
</tr>
<tr>
<td>Current episode LBP (months)</td>
<td>14.348 (19.905)</td>
<td>12.467 (9.372)</td>
<td>0.227</td>
</tr>
<tr>
<td>Prior history LBP</td>
<td>29 (85%)</td>
<td>19 (95%)</td>
<td>0.080</td>
</tr>
<tr>
<td>Prior history leg pain and numbness</td>
<td>26 (76%)</td>
<td>18 (90%)</td>
<td>0.010</td>
</tr>
<tr>
<td>Physical activity &lt;3 days/week</td>
<td>16 (47%)</td>
<td>9 (45%)</td>
<td>0.829</td>
</tr>
<tr>
<td>Physical activity 3-4 days/week</td>
<td>8 (24%)</td>
<td>5 (25%)</td>
<td>0.829</td>
</tr>
<tr>
<td>Physical activity 5 days/week</td>
<td>5 (15%)</td>
<td>4 (20%)</td>
<td>0.829</td>
</tr>
<tr>
<td>No physical activity</td>
<td>3 (9%)</td>
<td>2 (10%)</td>
<td>0.829</td>
</tr>
<tr>
<td>Education – high school</td>
<td>11 (32%)</td>
<td>5 (25%)</td>
<td>0.450</td>
</tr>
<tr>
<td>Education – some college</td>
<td>9 (26%)</td>
<td>6 (30%)</td>
<td>0.450</td>
</tr>
<tr>
<td>Education – graduated college</td>
<td>5 (15%)</td>
<td>3 (15%)</td>
<td>0.450</td>
</tr>
<tr>
<td>Education – some post graduate</td>
<td>2 (6%)</td>
<td>2 (10%)</td>
<td>0.450</td>
</tr>
<tr>
<td>Education – completed post graduate</td>
<td>7 (21%)</td>
<td>4 (20%)</td>
<td>0.450</td>
</tr>
<tr>
<td>Work – full time</td>
<td>6 (18%)</td>
<td>4 (20%)</td>
<td>0.386</td>
</tr>
<tr>
<td>Work – part time</td>
<td>1 (3%)</td>
<td>1 (5%)</td>
<td>0.386</td>
</tr>
<tr>
<td>Work – permanently unable</td>
<td>5 (15%)</td>
<td>3 (15%)</td>
<td>0.386</td>
</tr>
<tr>
<td>Work – retired</td>
<td>16 (47%)</td>
<td>10 (50%)</td>
<td>0.386</td>
</tr>
<tr>
<td>Work – Homemaker</td>
<td>5 (15%)</td>
<td>2 (10%)</td>
<td>0.386</td>
</tr>
</tbody>
</table>

*p<.05, **p<.01, ***p<.001
Dependent Variables

**Rating of pain.** Patients rated their pain at entry to treatment at varying levels of intensity. Mean score on the NPRS for the sample at entry to treatment was 5.27 (2.57) which represent a moderate level of pain (4-6/10). At entry to treatment, 46% of patients rated their current pain in the high category, 29% rated their current pain in the moderate category, 23% rated their current pain in the low category, and 3% or 1 patient rated he had no pain (see Table 4.2). Irrespective of treatment condition, pain scores decreased over the study period with mean pain score for the sample at entry to treatment 5.27 (2.57) and mean post-treatment score 4.14 (2.52) indicating reduced pain of 1.13 points post-treatment although this was not significant (see Table 4.4). Post-treatment, only 25% of patients rated their current pain in the high category (2 in ESI group, 3 in ESI+PT group), 25% in the moderate category (4 in ESI group, 1 in ESI+PT group), 40% in the low category (4 in ESI group, 4 in ESI+PT group), and 10% with no pain (2 in ESI group, 0 in ESI+PT group) (see Table 4.2).

Table 4.2. Pain Rating in Patients with Lumbar Spinal Stenosis Pre and Post-Treatment

<table>
<thead>
<tr>
<th>Pain Rating</th>
<th>No Pain</th>
<th>Low (1-3)</th>
<th>Moderate (4-6)</th>
<th>High (7-10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entry to Treatment (n=34)</td>
<td>1</td>
<td>3%</td>
<td>8</td>
<td>24%</td>
</tr>
<tr>
<td>Post-Treatment (n=20)</td>
<td>2</td>
<td>10%</td>
<td>8</td>
<td>40%</td>
</tr>
</tbody>
</table>

**Rating of disability.** Patients at entry to treatment all reported higher levels of disability as measured by the ODI. The mean disability score for the patients at entry to treatment was 40.34 out of 100 (13.89) which indicate borderline high disability (see Table 4.4). Patients reported their overall disability at entry to treatment as 61% in the moderate disability category, 26% in the severe disability category, and 12% in the crippled category indicating they were extremely limited in all daily activities (see Table 4.3 and Figure 4.1). Irrespective of treatment condition, mean disability scores significantly decreased post-treatment indicating improved function and reduced disability from entry to treatment 40.34 (13.89) to post treatment 29.29
(17.06) (see Table 4.4). Post-treatment, 25% of the patient reported disability in the low category (3 in ESI group, 2 in ESI+PT group), 40% in the moderate category (5 in ESI group, 3 in ESI+PT group), 25% in the severe category (3 in ESI group, 2 in ESI+PT group), and 10% in the crippled category (0 in ESI group, 2 in ESI+PT group) (see Table 4.3).

Table 4.3. Disability Rating in Patients with Lumbar Spinal Stenosis Pre and Post-Treatment

<table>
<thead>
<tr>
<th>Disability Rating</th>
<th>Low (1-19)</th>
<th>%</th>
<th>Moderate (20-40)</th>
<th>%</th>
<th>Severe (41-60)</th>
<th>%</th>
<th>Crippled (61+)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entry to Treatment (n=34)</td>
<td>0</td>
<td>0%</td>
<td>21</td>
<td>61%</td>
<td>9</td>
<td>26%</td>
<td>4</td>
<td>12%</td>
</tr>
<tr>
<td>Post-Treatment (n=20)</td>
<td>5</td>
<td>25%</td>
<td>8</td>
<td>40%</td>
<td>5</td>
<td>25%</td>
<td>2</td>
<td>10%</td>
</tr>
</tbody>
</table>

Figure 4.1. Oswestry Disability Index score at entry to treatment in patients with LSS. The majority of patients fall into the moderate disability category with severe disability next highest and crippling disability third highest category. No patients fell into minimal or no disability categories.

Mean scores for both disability and pain positively improved from entry to treatment to post-treatment however only the change in disability from entry to post-treatment was significant (p=.04) (see Table 4.4). In addition, a higher pain rating at entry to treatment was significantly correlated with a higher total disability score as indicated by the Oswestry Disability Index.
\( \rho = .444 \) (\( p = .016 \))(n=34). After treatment, patients with a lower pain rating were significantly correlated with having reduced disability scores \( \rho = .610 \) (\( p = .006 \))(n=20).

**Table 4.4. Means, Standard Deviations, and Paired T-test for Disability and Pain**

<table>
<thead>
<tr>
<th>Variable</th>
<th>M</th>
<th>SD</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Disability</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Entry to Treatment</td>
<td>40.338</td>
<td>13.891</td>
<td></td>
</tr>
<tr>
<td>Post-Treatment</td>
<td>29.286</td>
<td>17.056</td>
<td>0.040*</td>
</tr>
<tr>
<td><strong>Pain</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Entry to Treatment</td>
<td>5.265</td>
<td>2.574</td>
<td></td>
</tr>
<tr>
<td>Post-Treatment</td>
<td>4.143</td>
<td>2.516</td>
<td>0.18</td>
</tr>
</tbody>
</table>

*\( p < .05 \), **\( p < .01 \), ***\( p < .001 \)

Table 4.5 summarizes the correlation analysis results for disability. The independent variables of self-efficacy \( \rho = -.319 \) (\( p < .05 \)), social support \( \rho = -.343 \) (\( p < .05 \)), physical health status \( \rho = -.610 \) (\( p < .001 \)), and mental health status \( \rho = -.444 \) (\( p < .01 \)) are negatively and significantly correlated with disability upon entry to treatment, indicating that those with lower self-efficacy, lower social support, worse perceived physical health, and worse perceived mental health tend to have higher disability scores.

Only the variables of self-efficacy and social support were significantly correlated with disability post-treatment.\(^{243}\) Patients who increased or improved their self-efficacy scores were significantly more likely to reduce their disability scores \( \rho = -.620 \) (\( p < .01 \)). However, social support had a significant and positive correlation with disability \( \rho = .389 \) (\( p < .001 \)), indicating that those with reduced social support had an overall reduction in disability post-treatment.

**Table 4.5. Correlation Analysis Results for Disability**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Entry to Treatment</th>
<th>Post-Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disability</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self-Efficacy</td>
<td>-0.319*</td>
<td>-0.620**</td>
</tr>
<tr>
<td>Social Support</td>
<td>-0.343*</td>
<td>0.389**</td>
</tr>
<tr>
<td>Perceived Physical Health</td>
<td>-0.610***</td>
<td>-0.886</td>
</tr>
<tr>
<td>Perceived Mental Health</td>
<td>-0.444**</td>
<td>-0.085</td>
</tr>
</tbody>
</table>

*\( p < .05 \), **\( p < .01 \), ***\( p < .001 \)
Table 4.6 summarizes the correlation analyses for pain. Only the independent variable of perceived physical health had a significant negative association with pain upon entry to treatment \( \rho=-.550 \) (p<.05), indicating that those with higher pain scores upon entry to treatment had a worse perceived physical health status. The functional self-efficacy subscale \( \rho=-.332 \) (p<.05) and perceived physical health \( \rho=-.631 \) (p<.01) were both significantly and inversely correlated with pain post-treatment. This would indicate that a patient who had higher functional self-efficacy and better perceived physical health long-term tended to have lower pain scores.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Entry to Treatment</th>
<th>Post-Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pain</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self-efficacy subscales</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Functional Self-efficacy</td>
<td>-.420</td>
<td>-0.332*</td>
</tr>
<tr>
<td>Self-Regulation Self-efficacy</td>
<td>-.256</td>
<td>-0.082</td>
</tr>
<tr>
<td>Exercise Self-efficacy</td>
<td>-.190</td>
<td>0.014</td>
</tr>
<tr>
<td>Social Support subscales</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emotional Support</td>
<td>-.205</td>
<td>-0.004</td>
</tr>
<tr>
<td>Tangible Support</td>
<td>-.411</td>
<td>-0.0253</td>
</tr>
<tr>
<td>Affectionate Support</td>
<td>-0.089</td>
<td>0.214</td>
</tr>
<tr>
<td>Positive Social Interaction</td>
<td>-.179</td>
<td>0.007</td>
</tr>
<tr>
<td>SF-36 subscales</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perceived Physical Health</td>
<td>-.550*</td>
<td>-0.631**</td>
</tr>
<tr>
<td>Perceived Mental Health</td>
<td>0.038</td>
<td>0.012</td>
</tr>
</tbody>
</table>

*\( p<.05 \), **\( p<.01 \), ***\( p<.001 \)

**Independent Variables**

Upon entry to treatment, 16 of the 20 subjects who were followed post-treatment had moderate to high levels of self-efficacy. Four patients had low levels of self-efficacy, below 50 out of 100. Of those 4, 2 patients continued to have low self-efficacy but 2 increased their self-efficacy above 50. Additionally, 2 patients reduced their self-efficacy over the study period (Table 4.7). Regarding social support, 15 of the 20 subjects had moderate to high levels of perceived support. Five patients had low perceived support entering the study. Over the study period, 4 of the 5 patients with low social support increased their perceived support scores over 50%. However 1 patient continued to report low social support at follow-up. In addition, 1 patient
reduced her perceived support scores below 50 out of 100 during the follow up period (Table 4.7).

Table 4.7. Levels of Self-Efficacy and Social Support At Entry and Post-Treatment

<table>
<thead>
<tr>
<th></th>
<th>Entry to Treatment Mod-High &gt;50</th>
<th>Entry to Treatment Low&lt;50</th>
<th>Post-Treatment Mod-High &gt;50</th>
<th>Post-Treatment Low &lt;50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-efficacy</td>
<td>16</td>
<td>4</td>
<td>16</td>
<td>4*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*2 continued low</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*2 improved</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*2 reduced</td>
</tr>
<tr>
<td>Social support</td>
<td>15</td>
<td>5</td>
<td>18</td>
<td>2*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*1 continued low</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*1 improved</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*1 reduced</td>
</tr>
</tbody>
</table>

Tables 4.8 and 4.9 show the means and standard deviations for the independent variables of self-efficacy, social support, perceived physical health, perceived mental health, and the subscales of both self-efficacy and social support at the time points of entry to treatment and post-treatment. All of the mean survey scores for the sample positively changed or improved from entry to treatment to post-treatment. The only significant differences of score improvement were seen entry to post-treatment between the subscale measures of functional self-efficacy (p=.043), emotional support (p=.043) and positive social interaction (p=.040) (see Table 4.8 and 4.9).

Table 4.8. Means, Standard Deviations and Paired T-test of Predictor Variables of Self-efficacy, Social Support, Physical Health and Mental Health

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean</th>
<th>SD</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Self-Efficacy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Entry to Rehab (n=34)</td>
<td>59.519</td>
<td>20.484</td>
<td></td>
</tr>
<tr>
<td>Post-Rehab (n=20)</td>
<td>70.393</td>
<td>21.805</td>
<td>0.266</td>
</tr>
<tr>
<td>Total Social Support</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Entry to Rehab (n=34)</td>
<td>72.753</td>
<td>23.356</td>
<td></td>
</tr>
<tr>
<td>Post-Rehab (n=20)</td>
<td>81.674</td>
<td>18.376</td>
<td>0.106</td>
</tr>
<tr>
<td>Physical Health Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Entry to Rehab (n=34)</td>
<td>33.768</td>
<td>8.228</td>
<td></td>
</tr>
<tr>
<td>Post-Rehab (n=20)</td>
<td>41.171</td>
<td>8.903</td>
<td>0.102</td>
</tr>
<tr>
<td>Mental Health Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Entry to Rehab (n=34)</td>
<td>47.721</td>
<td>10.948</td>
<td></td>
</tr>
<tr>
<td>Post-Rehab (n=20)</td>
<td>52.01</td>
<td>8.702</td>
<td>0.073</td>
</tr>
</tbody>
</table>

*p<.10; **p<.05; ***p<.01
Table 4.9. Means, Standard Deviations, and Paired T-test for Predictor Variables of Subscales of Self-Efficacy and Subscales of Social Support

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean</th>
<th>SD</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional Self-efficacy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Entry to Rehab (n=34)</td>
<td>41.899</td>
<td>27.383</td>
<td></td>
</tr>
<tr>
<td>Post-Rehab (n=20)</td>
<td>53.698</td>
<td>32.21</td>
<td>0.043*</td>
</tr>
<tr>
<td>Self Regulation Self-efficacy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Entry to Rehab (n=34)</td>
<td>66.667</td>
<td>27.377</td>
<td></td>
</tr>
<tr>
<td>Post-Rehab (n=20)</td>
<td>76.481</td>
<td>23.556</td>
<td>0.639</td>
</tr>
<tr>
<td>Exercise Self-efficacy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Entry to Rehab (n=34)</td>
<td>76.059</td>
<td>20.606</td>
<td></td>
</tr>
<tr>
<td>Post-Rehab (n=20)</td>
<td>80.889</td>
<td>18.939</td>
<td>0.612</td>
</tr>
<tr>
<td>Emotional Support</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Entry to Rehab (n=34)</td>
<td>71.232</td>
<td>22.961</td>
<td></td>
</tr>
<tr>
<td>Post-Rehab (n=20)</td>
<td>84.375</td>
<td>18.006</td>
<td>0.043*</td>
</tr>
<tr>
<td>Tangible Support</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Entry to Rehab (n=34)</td>
<td>71.838</td>
<td>30.048</td>
<td></td>
</tr>
<tr>
<td>Post-Rehab (n=20)</td>
<td>82.721</td>
<td>21.025</td>
<td>0.407</td>
</tr>
<tr>
<td>Affectionate Support</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Entry to Rehab (n=34)</td>
<td>79.865</td>
<td>28.52</td>
<td></td>
</tr>
<tr>
<td>Post-Rehab (n=20)</td>
<td>90.741</td>
<td>15.095</td>
<td>0.363</td>
</tr>
<tr>
<td>Positive Social Interaction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Entry to Rehab (n=34)</td>
<td>74.755</td>
<td>29.764</td>
<td></td>
</tr>
<tr>
<td>Post-Rehab (n=20)</td>
<td>89.815</td>
<td>15.539</td>
<td>0.040*</td>
</tr>
</tbody>
</table>

*p<.10; **p<.05; ***p<.01

Aim 1: Entry to Treatment

Aim 1: To determine the relative contribution of self-efficacy, social support, self-rated physical health, and self-rated mental health to the severity of pain and disability among patients with LSS upon entry to treatment of LSS.

Aim 1: Hypothesis Testing A & B

**H1A:** Lower levels of self-efficacy, social support, perceived physical health and perceived mental health will each independently predict higher disability at entry to treatment.

**H1B:** Lower levels of self-efficacy, social support, perceived physical health and perceived mental health will each independently predict higher pain at entry to treatment.
Bivariate Regression Analysis: Pain and Disability at Entry to Treatment

A perception of worse physical health significantly predicted greater disability at entry to treatment, $F(1,32) = 18.935, p<.001$, adjusted $R^2 = .352$. Upon entry to treatment, the beta weights presented in Table 4.10 indicate when perceived physical health scores decrease or get worse by 1 unit, disability scores increase or get worse by 1.209 units. This relationship between perceived physical health and disability had adequate post-hoc observed power >80% and supports hypothesis H1A, therefore the null hypothesis can be rejected (see Table 4.10).

A perception of worse mental health significantly predicted greater disability at entry to treatment, $F(1,32) = 7.837, p<.01$, adjusted $R^2 = .197$. The beta weights presented in Table 4.10 indicate when perceived mental health scores decrease or get worse by 1 unit, disability scores increase or get worse by .563 units. This relationship supports hypothesis H1A and the post-hoc observed power is 81%; therefore the null hypothesis can be rejected.

Lower social support significantly predicted greater disability at entry to treatment, $F(1,32) = 4.253, p<.05$, adjusted $R^2 = .10$. The beta weights, presented in Table 4.10 indicate when social support scores decrease by 1 unit, disability scores increase or get worse by .204 units. This relationship supports hypothesis H1A. However, using a post-hoc observed power analysis, this relationship was underpowered at 30%. No other significant associations were found between the individual independent variables of self-efficacy, social support, perceived physical health, and perceived mental health and the dependent variable of disability upon entry to treatment.
Table 4.10. Bivariate Linear Regression Results for Greater Disability at Entry to Treatment

<table>
<thead>
<tr>
<th>Entry to Treatment</th>
<th>R²</th>
<th>Adjusted R²</th>
<th>F</th>
<th>B</th>
<th>SEB</th>
<th>B²</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-efficacy</td>
<td>0.102</td>
<td>0.073</td>
<td>3.617</td>
<td>-0.216</td>
<td>0.114</td>
<td>-0.319</td>
<td>0.066</td>
</tr>
<tr>
<td>Social Support</td>
<td>0.117</td>
<td>0.10</td>
<td>4.253</td>
<td>-0.204</td>
<td>0.099</td>
<td>-0.343</td>
<td>0.047*</td>
</tr>
<tr>
<td>Physical Health</td>
<td>0.372</td>
<td>0.352</td>
<td>18.935</td>
<td>-1.029</td>
<td>0.237</td>
<td>-0.610</td>
<td>0.000***</td>
</tr>
<tr>
<td>Mental Health</td>
<td>0.197</td>
<td>0.172</td>
<td>7.837</td>
<td>-0.563</td>
<td>0.201</td>
<td>-0.444</td>
<td>0.009**</td>
</tr>
</tbody>
</table>

*p<.05,**p<.01,***p<.001

Using the self-efficacy subscales, only the subscale of functional self-efficacy independently and significantly predicted greater pain at entry to treatment, F(1,32) =4.824, p<.05, adjusted R² = .104. The beta weights presented in Table 4.11 illustrate when functional self-efficacy scores decrease or get worse by 1 unit, pain scores increase or get worse by .034 units. This relationship supports the hypothesis H1B however using post-hoc observed power analysis this was underpowered at 52%.

Table 4.11. Bivariate Linear Regression Results for Higher Pain at Entry to Treatment

<table>
<thead>
<tr>
<th>Entry to Treatment</th>
<th>R²</th>
<th>Adjusted R²</th>
<th>F</th>
<th>B</th>
<th>SEB</th>
<th>B²</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional self-efficacy</td>
<td>0.131</td>
<td>0.104</td>
<td>4.824</td>
<td>-0.034</td>
<td>0.015</td>
<td>-0.362</td>
<td>0.035*</td>
</tr>
<tr>
<td>Self-regulation self-efficacy</td>
<td>0.012</td>
<td>-0.019</td>
<td>0.374</td>
<td>-0.01</td>
<td>0.017</td>
<td>-0.108</td>
<td>0.545</td>
</tr>
<tr>
<td>Exercise self-efficacy</td>
<td>0.012</td>
<td>-0.019</td>
<td>0.4</td>
<td>-0.014</td>
<td>0.022</td>
<td>-0.111</td>
<td>0.531</td>
</tr>
<tr>
<td>Emotional support</td>
<td>0.022</td>
<td>-0.008</td>
<td>0.724</td>
<td>0.017</td>
<td>0.02</td>
<td>0.149</td>
<td>0.401</td>
</tr>
<tr>
<td>Tangible support</td>
<td>0.011</td>
<td>-0.02</td>
<td>0.356</td>
<td>-0.009</td>
<td>0.015</td>
<td>-0.105</td>
<td>0.555</td>
</tr>
<tr>
<td>Affectionate support</td>
<td>0.016</td>
<td>-0.015</td>
<td>0.521</td>
<td>-0.011</td>
<td>0.016</td>
<td>-0.127</td>
<td>0.476</td>
</tr>
<tr>
<td>Positive Social Interaction</td>
<td>0.000</td>
<td>-0.031</td>
<td>0.004</td>
<td>0.01</td>
<td>0.015</td>
<td>0.011</td>
<td>0.942</td>
</tr>
<tr>
<td>Physical Health</td>
<td>0.070</td>
<td>0.041</td>
<td>2.415</td>
<td>-0.083</td>
<td>0.053</td>
<td>-0.265</td>
<td>0.130</td>
</tr>
<tr>
<td>Mental Health</td>
<td>0.007</td>
<td>-0.024</td>
<td>0.232</td>
<td>0.02</td>
<td>0.041</td>
<td>0.085</td>
<td>0.633</td>
</tr>
</tbody>
</table>

*p<.05,**p<.01,***p<.001

Aim 1: Hypothesis Testing C & D

H1C: Lower levels of self-efficacy, social support, perceived physical health and perceived mental health will together predict higher disability at entry to treatment.
**H1D**: Lower levels of self-efficacy, social support, perceived physical health and perceived mental health will together predict higher pain at entry to treatment.

**Multiple Regression Analysis: Disability and Pain at Entry to Treatment**

With self-efficacy, social support, perceived physical health and perceived mental health in the model, the combinations of all 4 variables significantly predicted higher disability at entry to treatment, $F (4, 29) = 6.920, p<.001, R^2=.488$, with only perceived physical and mental health significantly contributing to the prediction. The adjusted $R^2$ value was .418 indicating that 42% of the variance in disability at entry to treatment was explained by the model. The beta weights, presented in Table 4.12, suggest that worse perceived physical health and worse perceived mental health were the only significant contributors to predicting greater disability at entry to treatment. Post-hoc observed power analysis revealed that this relationship was adequately powered at 99% and there was no multicollinearity in the data. This relationship supports hypothesis H1C that a worse perception of physical health and a worse perception of mental health predict greater disability at entry to treatment.

**Table 4.12. Model 1: All Variables Contribute to Greater Disability at Entry to Treatment**

<table>
<thead>
<tr>
<th></th>
<th>B</th>
<th>SEB</th>
<th>B2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-Efficacy</td>
<td>-0.115</td>
<td>0.102</td>
<td>-0.17</td>
</tr>
<tr>
<td>Social Support</td>
<td>0.009</td>
<td>0.097</td>
<td>0.015</td>
</tr>
<tr>
<td>Physical Health</td>
<td>-0.829</td>
<td>0.242</td>
<td>-0.491*</td>
</tr>
<tr>
<td>Mental Health</td>
<td>-0.399</td>
<td>0.188</td>
<td>-0.315*</td>
</tr>
<tr>
<td>Constant</td>
<td>93.636</td>
<td>10.617</td>
<td></td>
</tr>
</tbody>
</table>

Note. $R^2=.488$; $F(4,29) = 6.920, p<.001$

*p<.05, **p<.01, ***p<.001

With 4 variables of self-efficacy, social support, perceived physical health and perceived mental health in the model, the only significant model using subscales of self-efficacy in predicting greater pain at entry to treatment included functional self-efficacy, total social support, perceived physical health and perceived mental health, $F (4, 29) = 2.717, p<.05, R^2=.273$, with
only the variable of functional self-efficacy significantly contributing to the prediction. The adjusted $R^2$ value was .172 indicating that 17% of the variance in pain was explained by the model. The beta weights, presented in Table 4.13, suggest that reduced functional self-efficacy predicted greater pain at entry to treatment supporting the hypothesis H1D. Post-hoc observed power analysis revealed that this relationship was underpowered at 76% and there was multicollinearity found in the data between social support and mental health.

Table 4.13. Model 2: All Variables Contribute to Higher Pain at Entry to Treatment

<table>
<thead>
<tr>
<th>Variable</th>
<th>B</th>
<th>SE</th>
<th>$B^2$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional Self-Efficacy</td>
<td>-0.046</td>
<td>0.018</td>
<td>-0.489*</td>
</tr>
<tr>
<td>Social Support</td>
<td>0.038</td>
<td>0.022</td>
<td>0.341</td>
</tr>
<tr>
<td>Physical Health</td>
<td>-0.082</td>
<td>0.053</td>
<td>-0.262</td>
</tr>
<tr>
<td>Mental Health</td>
<td>0.027</td>
<td>0.041</td>
<td>0.114</td>
</tr>
<tr>
<td>Constant</td>
<td>5.995</td>
<td>2.251</td>
<td></td>
</tr>
</tbody>
</table>

Note. $R^2$=.273; $F(4,29) = 2.717$, $p<.05$  
*p<.05, **p<.01, ***p<.001

Using the “backward” entry method, only the 2 variables of functional self-efficacy and social support were found to be most parsimonious in the model, significantly predicted greater pain at entry to treatment, $F (2, 31) = 4.080$, $p<.05$, $R^2=.208$, with only functional self-efficacy significantly contributing to the prediction. The adjusted $R^2$ value was .157 indicating that 16% of the variance in pain was explained by the model. Post-hoc observed power analysis revealed that this relationship was underpowered at 74% but there was no multicollinearity in the data. The beta weights, presented in Table 4.14, suggest that having reduced functional self-efficacy contributes to predicting greater pain at entry to treatment supporting hypothesis H1D.

Table 4.14. Model 3: Two Variables Optimally Contribute to Higher Pain at Entry to Treatment

<table>
<thead>
<tr>
<th>Variable</th>
<th>B</th>
<th>SE</th>
<th>$B^2$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional Self-Efficacy</td>
<td>-0.05</td>
<td>0.018</td>
<td>-0.532*</td>
</tr>
<tr>
<td>Social Support</td>
<td>0.036</td>
<td>0.021</td>
<td>0.326</td>
</tr>
<tr>
<td>Constant</td>
<td>4.796</td>
<td>1.344</td>
<td></td>
</tr>
</tbody>
</table>

Note. $R^2$=.208; $F(2,31) = 4.080$, $p<.05$  
*p<.05, **p<.01, ***p<.001
With 4 variables in the model, the only combination of subscales of social support that significantly predict greater pain at entry to treatment was the model with emotional support, total self-efficacy, perceived physical health, and perceived mental health, $F(4, 29) = 2.739, p<.05$, $R^2=.274$, with total self-efficacy significantly contributing to the prediction. The adjusted $R^2$ value was .174 indicating that 17% of the variance in pain was explained by the model. Post-hoc observed power analysis revealed that this relationship was under powered at 75% but there was no multicollinearity in the data. The beta weights, presented in Table 4.15, suggest that reduced total self-efficacy predicts greater pain at entry to treatment supporting hypothesis H1D.

**Table 4.15. Model 4: All Variables Contribute to Higher Pain at Entry to Treatment**

<table>
<thead>
<tr>
<th></th>
<th>B</th>
<th>SEB</th>
<th>B2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emotional Support</td>
<td>0.039</td>
<td>0.02</td>
<td>0.351</td>
</tr>
<tr>
<td>Self-Efficacy</td>
<td>-0.049</td>
<td>0.021</td>
<td>-0.391*</td>
</tr>
<tr>
<td>Physical Health</td>
<td>-0.093</td>
<td>0.054</td>
<td>-0.298</td>
</tr>
<tr>
<td>Mental Health</td>
<td>0.024</td>
<td>0.039</td>
<td>0.102</td>
</tr>
<tr>
<td>Constant</td>
<td>7.388</td>
<td>2.366</td>
<td></td>
</tr>
</tbody>
</table>

Note. $R^2=.274; F(4,29) = 2.739, p<.05$

*p<.05, **p<.01, ***p<.001

**Aim 2: Post-Treatment**

**Aim 2:** To determine the relative contribution of self-efficacy, social support, self-rated physical health, and self-rated mental health to the outcomes of pain and disability among patients with LSS in the year following treatment of LSS.

**Aim 2: Hypothesis Testing A & B**

**H2A:** Higher levels of self-efficacy, social support, perceived physical health and perceived mental health will each independently predict lower disability after treatment of LSS.
**H2B:** Higher levels of self-efficacy, social support, perceived physical health and perceived mental health will each independently predict lower pain after treatment of LSS.

**Bivariate Regression Analysis: Pain and Disability Post-Treatment**

The association between self-efficacy, social support, perceived physical health, and perceived mental health in relationship to pain and disability was followed up in 20 of the original 34 patients with LSS post-treatment. Higher total self-efficacy significantly predicted reduced disability post-treatment, $F(1,18) = 14.942, p<.01$, adjusted $R^2 = .423$. The beta weights, presented in Table 4.18 indicate when total self-efficacy scores increased by 1 unit, disability scores decreased by .484 units. Using a post-hoc observed power analysis, this relationship has adequate power at 95%. In addition, this relationship supports hypothesis H2A and the null hypothesis can be rejected for the post-treatment period.

Better perceived physical health significantly predicted reduced disability post-treatment $F(1,17) = 55.458, p<.05$, adjusted $R^2 = .765$. At post-treatment, when perceived physical health scores improved or increased by 1 unit, disability scores decreased by 1.681 units. This relationship between better perceived physical health and reduced disability had adequate post-hoc observed power 99% and supports hypothesis H2A, therefore the null hypothesis can be rejected (see Table 4.16). No other significant associations were found between the individual independent variables of total self-efficacy, total social support, perceived physical health and mental health and the dependent variable of disability post-treatment.
Table 4.16. Bivariate Linear Regression Results for Predicting Reduction of Disability Post-Treatment

<table>
<thead>
<tr>
<th>Post-Treatment</th>
<th>( R^2 )</th>
<th>Adjusted ( R^2 )</th>
<th>F</th>
<th>B</th>
<th>SEB</th>
<th>B2</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-efficacy</td>
<td>0.454</td>
<td>0.423</td>
<td>14.942</td>
<td>-0.484</td>
<td>0.125</td>
<td>-0.673</td>
<td>0.001**</td>
</tr>
<tr>
<td>Social Support</td>
<td>0.000</td>
<td>-0.055</td>
<td>0.003</td>
<td>-0.012</td>
<td>0.215</td>
<td>-0.014</td>
<td>0.954</td>
</tr>
<tr>
<td>Physical Health</td>
<td>0.765</td>
<td>0.752</td>
<td>55.458</td>
<td>-1.681</td>
<td>0.226</td>
<td>-0.875</td>
<td>0.000***</td>
</tr>
<tr>
<td>Mental Health</td>
<td>0.003</td>
<td>-0.056</td>
<td>0.049</td>
<td>-0.1</td>
<td>0.452</td>
<td>-0.054</td>
<td>0.828</td>
</tr>
</tbody>
</table>

*p<.05, **p<.01, ***p<.001

Only better perceived physical health independently and significantly predicted reduced pain post-treatment, \( F(1,7) = 6.931, p<.05 \), adjusted \( R^2 = .259 \). The beta weights, presented in Table 4.17 indicate when perceived physical health scores improve or increased by 1 unit, pain scores decreased by .157 units. This relationship supports hypothesis H2B that better perceived physical health can predict a reduction in pain however post-hoc observed power analysis reveals lack of power at 72%.

Table 4.17. Bivariate Linear Regression Results for Predicting Reduced Pain Post-Treatment

<table>
<thead>
<tr>
<th>Pain</th>
<th>( R^2 )</th>
<th>Adjusted ( R^2 )</th>
<th>F</th>
<th>B</th>
<th>SEB</th>
<th>B2</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-Treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Functional self-efficacy</td>
<td>0.177</td>
<td>0.125</td>
<td>3.436</td>
<td>-0.034</td>
<td>0.018</td>
<td>-0.42</td>
<td>0.082</td>
</tr>
<tr>
<td>Self-regulation self-efficacy</td>
<td>0.065</td>
<td>0.01</td>
<td>1.189</td>
<td>-0.025</td>
<td>0.023</td>
<td>-0.256</td>
<td>0.291</td>
</tr>
<tr>
<td>Exercise self-efficacy</td>
<td>0.036</td>
<td>-0.02</td>
<td>0.639</td>
<td>-0.023</td>
<td>0.028</td>
<td>-0.19</td>
<td>0.435</td>
</tr>
<tr>
<td>Emotional support</td>
<td>0.042</td>
<td>-0.022</td>
<td>0.659</td>
<td>-0.027</td>
<td>0.033</td>
<td>-0.205</td>
<td>0.43</td>
</tr>
<tr>
<td>Tangible support</td>
<td>0.169</td>
<td>0.117</td>
<td>3.252</td>
<td>-0.04</td>
<td>0.022</td>
<td>-0.411</td>
<td>0.09</td>
</tr>
<tr>
<td>Affectionate support</td>
<td>0.008</td>
<td>-0.05</td>
<td>0.137</td>
<td>-0.012</td>
<td>0.032</td>
<td>-0.089</td>
<td>0.716</td>
</tr>
<tr>
<td>Positive Social Interaction</td>
<td>0.032</td>
<td>-0.025</td>
<td>0.564</td>
<td>-0.027</td>
<td>0.036</td>
<td>-0.179</td>
<td>0.463</td>
</tr>
<tr>
<td>Physical Health</td>
<td>0.302</td>
<td>0.259</td>
<td>6.931</td>
<td>-0.157</td>
<td>0.06</td>
<td>-0.55</td>
<td>0.018*</td>
</tr>
<tr>
<td>Mental Health</td>
<td>0.001</td>
<td>-0.061</td>
<td>0.023</td>
<td>0.01</td>
<td>0.068</td>
<td>0.038</td>
<td>0.88</td>
</tr>
</tbody>
</table>

*p<.05, **p<.01, ***p<.001

Aim 2: Hypothesis Testing C & D

**H2C:** Higher levels of self-efficacy, social support, perceived physical health and perceived mental health will together predict lower disability after treatment of LSS.
**H2D:** Higher levels of self-efficacy, social support, perceived physical health and perceived mental health will together predict lower pain after treatment of LSS.

**Multiple Regression Analysis: Disability and Pain Post-Treatment**

At post-treatment with all 4 variables in the model, the combinations of all 4 independent variables significantly predicted the reduction in disability, $F(4, 14) = 13.268$, $p<.001$, $R^2=.791$, with only perceived physical health significantly contributing to the prediction. The adjusted $R^2$ value was .732 indicating that 73% of the variance in disability was explained by the model. The beta weights, presented in Table 4.18, suggest that a perception of better physical health predicts reduced disability supporting hypothesis H2C. Post-hoc observed power analysis revealed that this relationship was adequately powered at 99% and there was no multicollinearity in the data.

<table>
<thead>
<tr>
<th>Table 4.18. Model 1: All Variables Contribute to Prediction for Reduced Disability Post-Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>B</td>
</tr>
<tr>
<td>Self-Efficacy</td>
</tr>
<tr>
<td>Social Support</td>
</tr>
<tr>
<td>Physical Health</td>
</tr>
<tr>
<td>Mental Health</td>
</tr>
<tr>
<td>Constant</td>
</tr>
</tbody>
</table>

Note. $R^2=.791$; $F(4,14) = 13.268$, $p<.001$

With 4 variables in the model, there was no combination using subscales of self-efficacy that significantly predicted pain post-treatment. Using the “backward” entry method, the 2 variables of exercise self-efficacy and perceived physical health significantly predicted a reduction in pain post-treatment, $F(2,15) = 3.784$, $p<.05$, $R^2=.335$, with perceived physical health significantly contributing to the prediction. The adjusted $R^2$ value was .247 indicating that 25% of the variance in pain post-treatment was explained by the model. Post-hoc observed power analysis revealed that this relationship was under powered at 74% but there was no multicollinearity in the data. The beta weights, presented in Table 4.19, suggest that better
perceived physical health contributes to predicting reduced pain post-treatment supporting hypothesis H2D.

Table 4.19. Model 2: Two Variables Have Clinical Relevance in Contributing to Prediction for Reduced Pain Post-Treatment

<table>
<thead>
<tr>
<th></th>
<th>B</th>
<th>SEB</th>
<th>B2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exercise Self-Efficacy</td>
<td>0.025</td>
<td>0.03</td>
<td>0.19</td>
</tr>
<tr>
<td>Physical Health</td>
<td>-0.173</td>
<td>0.063</td>
<td>-0.605*</td>
</tr>
<tr>
<td>Constant</td>
<td>8.764</td>
<td>2.973</td>
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Note. $R^2=.335$; $F(2,15) = 3.784$, $p<.05$

*p<.05, **p<.01, ***p<.001

With 4 variables in the model, there was no combination using subscales of social support that significantly predicted a reduction of pain post-treatment. Using the “backward” entry method, the 2 variables of emotional support and perceived physical health significantly predicted a reduction of pain post-treatment, $F(2,13) = 4.485$, $p<.05$, $R^2=.408$, with perceived physical health significantly contributing to the prediction. The adjusted $R^2$ value was .317 indicating that 32% of the variance in pain was explained by the model. Post-hoc observed power analysis revealed that this relationship was adequately powered at 87% and there was no multicollinearity in the data. The beta weights, presented in Table 4.20, suggest that better perceived physical health contributes to predicting a reduction of pain post-treatment which supports the hypothesis H2D.

Table 4.20. Model 3: Two Variables Have Clinical Relevance in Contributing to Prediction for Reduced Pain Post-Treatment

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<tr>
<td>Constant</td>
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</tr>
</tbody>
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Note. $R^2=.408$; $F(2,13) = 4.485$, $p<.05$

*p<.05, **p<.01, ***p<.001
Aim 3: Qualitative and Combined Results

Aim 3: Explore how self-efficacy, social support, perceived physical health, and perceived mental health contribute to a patient’s lived experience with LSS and influence meanings of pain and disability.

The qualitative analysis was designed to complement the quantitative findings and to describe emergent themes that contribute to both the severity and reduction of pain and disability in order to capture the lived experience of LSS. The analysis expanded upon and contextualized the *a priori* factors of self-efficacy, social support, perceived physical health and perceived mental health in addition to emergent themes uncovered during the interviews.

Two theoretical frameworks informed the qualitative analysis. The Stress-Diathesis Model in conjunction with the Stress and Coping Model were used as an interpretive lens in analyzing the behaviors and perceptions of patients with LSS. Using the Stress and Coping Model, the qualitative interviews revealed multiple coping resources that were either absent upon entry to treatment when the patients’ pain and disability were at the highest or present post-treatment serving as coping resources to ameliorate the stressors of pain and disability. Many themes also complement the Stress-Diathesis Model such as feelings of vulnerability, anxiety, and the role of social influences on the patients’ experiences with LSS. In addition, the interviews uncovered themes that supported the roles of the *a priori* identified coping resources of self-efficacy, social support, perceived physical health, and perceived mental health. Finally, several novel themes emerged during the interviews that revealed more about the condition of LSS than previously demonstrated in the literature.

**Stressors: Pain and Disability**

At entry to treatment, the quantitative data indicated that all patients entered the study with some level of moderate to high pain in their low backs. The interviews also confirmed the patients’ experience of pain. In addition, all of the patients in this study entered with moderate,
severe or crippling levels of disability. Yet, some patients rated their pain and/or disability higher as well as described their experience as more intense than others and therefore perceived a higher burden related to pain and disability.

When patients were asked to describe what it is like to have LSS, all interviewees focused first on pain, particularly pain in the low back but also pain into legs with all activity. Patients noted that this pain had been on and off for at least a year, if not many years. Pain was the primary reason patients stated they sought medical care. However, even though all patients had complaints of pain, not all patients had the same descriptions of their pain. For some patients, their pain was the direct sensation in their back, buttock or leg(s). For some this also included numbness or tingling sensations. For others, their pain was tied to fatigue and weakness sensations. When probed further, meanings of pain often related to frustrations about not being able to perform activities they enjoyed, feelings of helplessness, and feelings of a loss of control and choices in their daily lives.

Across patient interviews, the experience of pain was not always directly connected with their limitations in functional tasks and activities related to disability. When asked, the actual term “disability” did not have meaning for these individuals. The term disability was something that they believed related to other people who were really “bad off”: bed bound or incapable of doing anything. However, patients with LSS recognized their limitations and described many frustrations related to their limitations in activities, but they did not associate these problems with having a disability or being disabled. The interviews revealed that the experience of disability and even pain was much more complex for these individuals than pure physical losses as previously described by literature.39, 142, 250

**Entry to Treatment: Greater Severity of Pain and Disability**

The overarching goal of the qualitative analysis was to elicit main factors that persisted to define patients’ experiences of pain and disability as well as identify sources of coping that were
either present or absent at entry to treatment contributing to these stressors. Eight themes emerged to help explain why some patients appraised a higher burden related to pain and disability: physical limitations, lacking confidence in tasks and activities, feeling a lack of control, reduced social participation, feelings of vulnerability, poor mental state, frustration about needing support, and financial limitations.

![Diagram showing physical, mental, social, and environmental limitations contributing to stressors of pain and disability.]

**Figure 4.2. Physical, mental, social and environmental limitations contributing to stressors of pain and disability.**

**Physical limitations.** The most commonly reported theme in all the interviews was limitations in physical abilities. Most of these physical limitations pertained to task specific activities related to the low back. Other physical limitations cited were more general in nature. In all instances, every patient expressed physical limitations as primary to their experience with
LSS. An example of one woman’s explanation of her physical limitations focused on some specific low back related tasks but also included general physical movement as well:

I think getting up in the morning is just really bad, getting moving, and sometimes getting up from a sitting position and then standing up for just a moment, it hurts a lot more. And I think, you know, doing about anything, just walking, getting up and the morning and standing from sitting position is the worse. (76-year-old female)

Another woman described her physical limitations related to recreational activities:

Walking for example; running, you can’t run. No way. Walking, you are limited to a couple of blocks. It seems like when I would walk, it was putting a lot of pressure on my lower buttocks. (67-year-old female)

Finally, one woman described her physical limitations in terms of general reduced energy:

I think it just kind of all went kind of like together with everything else. With the no energy and of course, having no energy, then you don’t do as much. When you don’t do as much, then your back is at its best [laughs]. (76-year-old female)

Lacking confidence in tasks and activities. The next most commonly reported theme was lacking confidence in tasks and activities. Although all patients expressed physical limitations, for some it was the uncertainty of their back pain and inability to respond to the pain and adjust for weakness and poor balance during specific activities that concerned them. The *a priori* identified coping source of self-efficacy was supported by this theme of lacking confidence in tasks and activities. Reduced belief that they could do specific tasks such as standing doing dishes, stair climbing, walking to the bathroom or to the mail box all were examples used by patients of tasks for which they had lower confidence upon entering treatment. These self-doubts illustrated patients’ reduced self-efficacy for these low back related functional tasks. Moreover, their reduced self-efficacy expression also included worry related to negative ramifications after the task performance. Even the simplest tasks of daily living such as toileting were noted as problematic. One man described his decreased confidence due to in walking short distances even to accomplish essential activities such as going to the bathroom:

I mean I could get up from the chair and go to the bathroom and take care of business there. And then I had to get right back in my chair, and then I was in excruciating pain by that time, from being on my feet. So I sat down and the pain kind of floated away, when I
sat down again. It would take a period of time, I don’t know, whether I would say 
seconds or minutes, a period of time for the pain to dissipate from my leg after I sat back 
down and took the weight off it. So if going to the bathroom is so bad I figured I couldn’t 
do much of anything. I’d have to figure out how far I was to sitting down no matter what 
I did. (60-year-old male)

In addition, other specific activities most frequently noted as reduced or eliminated due to 
lack of confidence in performing them included walking outside of their homes, shopping in large 
stores, stair usage, general house maintenance both inside and outside of the house, and lifting or 
carrying any object greater than about 5-10 lbs. Recreational participation tasks that were 
mentioned as given up were walking for exercise, fitness classes, golf, and hiking and other 
outdoor activities. One man described his decreased confidence in participating in recreational 
activities:

Yeah, I don’t do too much. A lot of the activities I like involve lots of walking, like 
hunting. I was going to try it this year, and it has been a year since I tried. I had to stop 
when my back got bad. But I guess, it has held me back. I’m just not sure I can do it and I 
am worried about making the back worse. Like working out: I used to work out a lot. I 
don’t do a whole lot of that since my back started up. (60-year-old male)

Patients’ perceptions of worse physical health contributed to their reduction in activities 
and were echoed in most interviews. Fatigue and fear of pain often contributed to the lack of 
confidence in their general physical abilities. In addition, since all of the patients with this 
condition were 50 years of age or older, age and age related declines in physical health 
interplayed with their overall perception or confidence with physical abilities. Although some 
patients expressed that they expected some decreases in energy and fatigue with aging, LSS made 
them feel older than their years. Due to these doubts in general physical function, pain seemed to 
only add to their concerns when engaging in general activity. As a result, multiple patients 
expressed fear of not being physically able to do something. They were afraid to do something 
and then end up not being able to finish or get “stuck” somewhere such as a big box store or the 
mall. One woman described her decreased confidence to do grocery shopping in the following 
manner:
Maybe I am just getting old, but 2 years ago, I was old and I think it doesn’t happen quite that fast. You slow down for sure but this back pain makes me feel old. By 2 or 3 in the afternoon, I really don't want to go to the grocery and walk back to the milk aisle. If I am in the produce and if I have to walk back to the milk, I don’t think I can make it so I don’t or I just hold my breath... I hold it in. (63-year-old female)

Lacking control. The next theme that patients expressed related to feelings of anxiety and a lack of control over their body and their pain experience. Approximately half of the patients with the highest rating of pain and disability reported feeling a lack of control in some manner. This feeling of a lack of control illustrated the variability in actual pain experience for these patients. For these individuals, pain perceptions manifested as something beyond just bodily pain and became anxiety expressions about not knowing what to expect when performing even the simplest tasks. These feelings of lacking control often combined with patients’ reduced confidence for performing tasks. This resulted in a general fear of going outside of the home or other safe areas due to the unknown quality of their condition. One woman stated:

It didn’t matter where I was, it [lower back] might go out anytime and then what? (69 year old female)

This woman illustrated that her anguish was not over the pain per se but not knowing when and why the pain returned combined with her inability to control the pain sensations. Her words show the physical nature of this feeling but also the mental component and anxiety produced by the lack of control. Similar sentiments were expressed by another female who described the unknown quality in relationship to her everyday activities:

Well it is a little bit hard dealing with it. It seems like it comes and goes, one day I can feel pretty good, and the next day I can’t do anything. It puts a limit on what I can do at work and that sort of thing, and so my house work is piled up, a lot of scrubbing and dusting. I did that a couple of days ago, now yesterday and today I am paying for it, I am stiff and sore and achy. (77-year-old female)

When asked what her back was like before treatment and why she thought she felt that way, another woman stated:

I didn’t have any control. It does what it does. I could keep diary after diary and there would be no correlation in my mind. (63-year-old female)
This woman is a good example of the uncertainty that comes with LSS. This uncertainty and lack of control created a large amount of anxiety in most patients which in turn led to a decrease in their overall participation in all types of activities. Anxiety is a key feature in the Stress-Diathesis Model as a factor contributing to pain and disability. Heightened uneasiness and worry about their condition, pain, and inability to do or control the outcome of activities are all potential reasons anxiety can lead from pain to disability in patients with LSS. Another woman described her anxiety about going to the grocery store:

I didn’t like going to the store by myself, doing things like bending over the steering wheel and then having to get out of the car by myself, so I would say ok when you go to the store let me know so I can go with you. I just didn’t want to go to the store by myself. In case something happened… I just felt like I might get stuck. (66-year-old female)

She managed her uncertainty by going grocery shopping only if someone was going with her. In this way, she used support to help diminish the anxiety of being stuck somewhere without help or an ability to get herself out of the situation.

**Reduction in social activities.** Another related theme driven by several patients’ lack of confidence, lack of control, and/or anxiety about participating in activities is the resulting reduction of social activities. Social activities were seen in many cases as non-essential activity that could be readily eliminated from everyday life. Stopping participating in social activities was one way that patients managed their feelings of loss of control and uncertainty. One woman who was in the highest pain and disability categories provided a good example of how those who perceived a worse experience made choices for a deliberate reduction in social activities:

I don't make plans too many times now. I had to cancel some long stays. I have this German friend, she picks me up and we go out to lunch every month. I had to cancel 4 or 5 times and she probably got mad at me but now she has pain herself and she knows what it is and she apologized. And I used to go to church every Sunday and now I can't go to church. This is, on the pew, it is hard, and when I cannot sit and listen to what is talked about, why do I go to church? So I stay home and watch it on TV, or pray by myself. (74-year-old female)

Social outings marked an added burden for this woman and she no longer felt that she could participate in these activities with her back condition. Another man described similar sentiments:
We used to like to get out more like on a light rail and go down to the symphony or something like that. We are not doing that anymore. (72-year-old male)

Finally, one woman described a reduction in social activities that seem to be connected largely to her change in emotional state. Throughout her interview she expresses a variety of thoughts such as a loss of interest in social activities that she once enjoyed, feelings of frustration that she was limited in her social outings, and even sadness at the loss of her life as she once knew it. All of these emotions were tied to her decrease in social activities:

I guess I am suffering from a lack of social activity but it is because I think I am usually peppier. I am sure I am not the same and I think that shows to the people I am close to. (67-year-old female)

**Feelings of vulnerability.** Some patients also expressed mental health issues related to hopelessness and vulnerability. Vulnerability was a stronger theme than expected across the patients with over 1/3 (7 out of 20) expressing fears related to vulnerability and six of these in the highest pain and disability categories. Of the seven patients expressing concerns about vulnerability, four of these patients communicated a lack of perceived sources of support for many of their daily needs.

When talking to the patients, most expressed their feelings of vulnerability as helplessness. Vulnerability is a key feature in Stress-Diathesis Model as a factor contributing to pain and disability. Evidence of feelings of vulnerability was pervasive in all parts of patient’s lives. These feelings rendered them incapable to do even the simplest activities as expressed by one woman:

I couldn’t stand up long enough to do anything and then I would just feel so much pain, it just affected my doing every day household work. Going to the store was very, very hard ‘specially when I just had to bend over and then I got scared because right now the area where I live in is not the best and I was afraid people would see me like this and beat me up for something that I don’t even have. I was just that scared because I couldn’t stand up straight. I felt totally helpless. (66-year-old female)
Many of the patients felt a variety of frustrations leading to reduced confidence about managing their daily lives. These feelings often interacted with perceptions of vulnerability. An example is when one woman echoed the sentiments of helplessness, frustration, and reduced confidence as she described how her helplessness put her in a position that she must rely on her family and friends:

Yes, I felt totally helpless. And I didn’t like the fact that my girlfriends and my sister had to help me out a lot with things. It was bad, really bad. (53-year-old-female)

Finally another woman described how her back problems left her completely vulnerable and unable to deal with flu related symptoms. She ended up needing her family to support her in multiple ways:

At one time in the beginning it was so bad that I felt that I had a touch of the flu, getting up in and out of the bed was very painful. The doctor had told me to come to the emergency room. I really had the flu so bad that I couldn’t get up. I had diarrhea and vomit and I couldn’t even get up from the bed to go to the bathroom. And my brother, I couldn’t even get down the stairs, so he told me, he said if you don’t come down the stairs, I am going to kick in your door, so I sat on the stairs and just kind-of scooted down the stairs and let my brother in so he could take me to the hospital. I was so dehydrated by the time I did get to the hospital and totally humiliated because my brother had to clean up all the mess. I never, ever want to go through anything like that again. I felt terrible, the flu was bad and I felt worse because as I said, I just couldn’t get out of the bed. (66-year-old-female)

**Poor mental state.** Only a few patients expressed concerns with mental health and depression related to their back pain and disability, however those few who did were in the highest categories for pain and disability. Statements related to mental health ranged from specific mood changes to more general feelings of poor mental state. One woman expressed how her LBP resulted in depression type symptoms:

You feel depressed, you feel down. You are not happy about how you feel, you always carry a little burden with you, a little sadness with you. Can you cope with it? Yes. Would you rather not? Yes. (63-year-old female)

Two patients expressed their poor mental condition by revealing their previous thoughts of suicide when their low back problems were really bad before they sought treatment. For example,
one woman expressed how poor her mental state was before she sought help for her back
condition:

I don’t know if I should tell you this or not but after I had fallen I was in so much pain,
and I went to bed and the dog, he was never let on the bed because that was a cat
territory. I went to bed at night, I was lying there and I was in so much pain, hurting so
badly, I was down there and I thought to myself, I can’t live like this, so I planned to get
up, take the dog and the cat, get into the garage and hope the car didn’t run out of gas
before we all expired. But instead the little doggie hopped on the bed, put his back to my
back and I went to sleep and woke up the next morning, sometime during the night or so.
He was gone of course. But somehow he knew that I was in a great deal of pain, and he
took his life into his hands hopping on the bed, and he did that and my pain went away
that night and after that I realized that wasn’t what God intended me to do and I started
looking for alternative treatments. … It was the only time in my life time I ever, ever
contemplated suicide. I am 80 years old [in my eighties] and that is pretty good I might
say. (87-year-old female)

Another woman simply described how poor her mental state was before seeing the spine
physician:

I want to thank the people that really helped me, I really appreciated them, and you have
no idea. Prior to going to Dr. A., I just didn’t care anymore, I just wanted to die. (66-
year-old-female)

**Frustration about needing support.** One repeated theme that was uncovered was
patients’ reluctance to ask for help from friends, family, neighbors, and even health care
providers. Six individuals expressed that they were frustrated by the idea of needing help and
were reluctant to ask for help from close family or friends or even health care professionals. Four
others seemed to be frustrated that they could not avoid asking for help. Those who had to ask for
help from different sources expressed feelings of frustration tied to their feelings of vulnerability.

For those individuals who wanted to avoid asking for help, some of their frustration
revolved around the anxiety that they might need to ask for help at some point. This anxiety about
needing support also confirmed their beliefs about vulnerability due to factors such as their age
and their decline in abilities. A few individuals even discussed their resistance to giving in stating
that they were not ready to be old, helpless, and dependent.
For those individuals who had experiences asking for help, their frustrations revolved around feelings of being a burden for those around them. A few stated they used to be the one who helped others, such as a mother or sibling, and therefore did not like the role reversal. The others stated their support sources did not have the time or ability to support them but they did not have other options. One woman described how she ended up getting support from her family:

I don’t like people cleaning up my house, I do that for myself. I will let people do certain things for me, and that is so silly. My dad used to tell me pride is going to kill me one of these days. But I like to do things for myself. And whatever I could try to do for myself I would do and they would try to help me, but let me do it for myself because if I don’t then I won’t be able to stay in my house. So they would try… I didn’t want to move any of the furniture around, to help me get up and down the stairs. My sister, she just put her foot down, oh no, we are not doing that. We are going to have to do that. I have to use the walker and I just wanted everything to stay the same, but she wouldn’t let me. (66-year-old female)

All of these factors led to support being more of a frustration and source of anxiety rather than a positive factor appraised by these patients.

**Financial limitations.** A novel theme that emerged related to financial limitations. Several individuals had reduced or no treatment when their current episode of LBP started due to financial reasons. For three patients, these financial reasons reflected limited or no insurance coverage for LBP treatment. Being underinsured or uninsured resulted in a decrease in the amount of care or a delay in care for their LSS condition. It is important to note that because all of the subjects in this study eventually received insurance and therefore enrolled in the RCT, the interviews only minimally reflect the issues of the underinsured and uninsured. However, one key individual had absolutely no insurance or financial means when he first began his current episode of LBP before being involved in the study. He described in his interview how a lack of insurance caused him delay in seeking medical care. He described how he first tried to self-manage his condition for a while:

I tried using some over-the-counter medicine, something I got on my own. I wasn't prescribed any medication. I didn't have any insurance and I couldn't afford to go to the doctor, $275 for a 10 minute visit. I did the best I could. That is the way it is, because I couldn’t get medical care, so I didn’t have any choice about it I just had to keep going along. (57-year-old-male)
Then he described how he finally went into the Emergency Department once his back pain got so bad that he couldn’t cope:

It got to the point to where I had to go to the ER, I couldn’t walk. I went at 9:00 in the morning and I didn’t get out until 11:30 at night. They started me out with liquid valium, then morphine and then topped it off with dilaudid. When they were finally convinced I wasn’t there to do drugs, they moved me over until I ended up in the CIC (Colorado Indigent Care) program and it was very helpful to me. Then my health got bad in another aspect because I have pulmonary disorders. I had to take social security early because I was at a point where there was nothing left. I had to go on early social security, so I could get the benefits, and start seeing doctors. (57-year-old male)

In addition to lacking insurance, LSS resulted in financial implications related to work and earning an income. Due to their older age, many patients were retired but there were still a few who had job related impacts as a result of LSS. For those who were younger and had no source of retirement income, trying to keep a job and health insurance compounded their issues related to their LSS. One woman described how she tried to keep her job as long as possible despite her LBP:

I was able to deal with it for a while. I was able to work but my job required me to stand all day and it got to the point where I wasn’t able to stand so I was losing a lot of time. Because it hurt so much I had to go home, so I was losing a lot of time at work. Because I couldn’t stand I ended up losing my job. (53-year-old-female)

This woman, similar to the 57-year-old man quoted above, not only couldn’t work but also lost her health insurance when she lost her job. Both of these individuals were too young for Medicare, without other resources, and therefore both eventually ended up on Social Security disability benefits before entering treatment for this study.

Finally, about half of the patients cited other tangible sources of support that they felt they needed but lacked due to diminished financial resources. These missing paid support sources included examples such as the inability to hire a driver to go to the grocery store as well as the inability to hire someone to help around the home in cleaning, maintenance, or yard work. For a few individuals with highest levels of self-reported pain and/or disability, having financial
limitations often kept them home bound and decreased their options for self-management such as with exercise or seeking alternative care. One woman described how her reduced financial resources resulted in her not participating in any exercise:

What my doctor always tells me, walking is the best exercise. Or swimming. I can’t afford to go to a place where you go swimming and I don’t drive anymore. I used to swim a lot but now with me not driving anymore and the YMCA or whatever, that is too expensive I don’t have the money to go there. (74-year-old female)

As an emergent theme, the spectrum of financial limitations that patients experienced with LSS was complex and contributed to differing levels of pain and disability in this population. Age and age-related general health decline interacted with some of these financial limitations and increased need for help and assistance. Others who were too young fell into a reverse age-related gap where they were not old enough to get the support of financial resources such as Medicare. Many of the different issues expressed concerning financial limitations co-occurred in the patients who expressed financial concerns as contributing to their health problems (see Figure 4.3).

Figure 4.3. Factors related to financial limitations. Patients with LSS describe sources of financial limitations related to greater pain and disability pre-treatment.
Post-Treatment: Improving Outcomes of Pain and Disability

Improved outcomes of pain and disability are the main clinical goals of treatment for LSS. These goals for reduced pain and improved function were also clearly expressed by all patients during the interviews. However, not all patients reduced pain and improved function and therefore had outcomes of reduced disability. Out of the 20 patients interviewed, 10 patients (8 ESI group, 2 ESI+PT group) had a self-reported reduction of pain on the Numeric Pain Rating Scale during the course of treatment and the post-treatment period (see Table 4.2). 13 patients (8 ESI group, 6 ESI+PT group) had a self-reported decrease in disability on the Oswestry Disability Index during the treatment and post-treatment period (see Table 4.3). Interviews explored coping behaviors by these patients who were able to reduce pain and disability.

For those who did have a reduction in pain and a decrease in disability, many still had some limitations in daily activities, social activities, and recreational activities. Some patients remarked that they were still limited compared to what they wanted to do. However, most of the patients noted they had been able to get back to doing light housework, light yard work, walking in the community, using stairs more frequently, and going out to social events that did not include much strenuous activity and allowed for sitting during the event.

Patients used different strategies to balance activities with their pain levels. Some believed that to manage pain they had to eliminate all activities. Some believed to manage pain they had to modify how they performed certain activities. And others believed that they just needed to push through the pain. Regardless of the strategy used to manage their condition, all expressed that they would manage the repercussions of participation once they were home and could rest, take medications, or use other learned self-management techniques.

The overarching goal of the qualitative analysis of the post-treatment period was to determine what factors contributed to diminished stressors, namely pain and disability during the management period. Multiple themes emerged that provided insight into why some patients were able to reduce their pain and disability 6 to 12 months after entering treatment. These themes
included having greater confidence, knowing limitations, learning how to manage, having a push through attitude, having support, and having a positive outlook (see Figure 4.4).

**Figure 4.4. Factors related to improved outcomes.** Patients with LSS describe six factors that contribute to improved outcomes of lower pain and reduced disability post-treatment.

**Greater confidence.** Improving confidence in both specific tasks and general activities was a key theme reported by patients who had improvement during the study period. Three big areas of improved confidence after treatment were related to physical function: walking tolerance and distance, stair tolerance, standing tolerance and time spent standing. Improving confidence in these key activities helped many increase their normal daily activities but also allowed them to increase their recreational and social activities to some degree.

For some, the return to basic ADLs was very satisfying and they did not aspire to do more. These individuals were confident and content with what they could do, though still limited. For others, having the improved performance of basic ADLs did not satisfy them. For these individuals, some continued to either have goals for return to social or sport activity or had frustration about not returning to social or sport activity though they were more confident with many activities. When asked “what was the biggest factor that contributed to your improvement?”, one man described the moment he remembered feeling more confident about doing basic everyday tasks that he could not do previously:
Probably the biggest factor, that probably after I walked the steps in therapy and that really seemed to have a surprising positive impact on my being able to sit and walk and all that kind of stuff. That would be it. (60-year-old male, ESI+PT)

One woman who had progressively increased all of her activity discussed how she improved. In addition she commented on the goal setting she was doing with recreational activities:

I definitely have done more and I monitored it, for the last year now. Just on different things that I would do, what I can do, what is good for me and what is bad for me. And actually, going up and down stairs is great for me. Because that does keep you moving. Walking I find that I am doing better walking too. And hopefully at least by fall I will be able to go back to walking. In the weekend I was doing 5 and 10 miles, over the weekend before my back got bad. (67-year-old female, ESI+PT)

Knowing limitations. Some patients were able to manage their condition by understanding their limitations in performing specific tasks and activities. This knowledge of their limits seemed to empower a number of individuals. Their self-determination was improved when they felt a degree of understanding of their limitations with activities. One man described his abilities and limitations in this manner:

Golf is what I can get out and do. I can’t walk around a course because my back and my knee and the arthritis in my right foot. But I can play the game, I can ride in the cart, I can do well enough to not be terribly embarrassed. There are people my age that could certainly beat the socks off of me, but the people I play with are roughly my skill level. It is more fun that way. (66-year-old male, ESI+PT)

Another man described how he was able to manage outings out of the home:

When I do something I make myself take breaks. Stopping to sit always helps. I’ve sat on some interesting things at the grocery store. A pile of bottled water. Once I sat on this box and it turned out to be potato chips and that wasn’t a great idea. So that’s the way it goes, but we are doing ok. (72-year-old male, ESI+PT)

Finally, one man illustrated his knowledge of his limits by restricting where he goes and what he does:

I don’t go shopping any more than I have to, though. And I try to stay away from big box stores. Because I don’t really care to have to walk a mile in one of those big stores. I’d rather go to a regular grocery store than a club or something. So I am, I guess you call that managing pain by managing where you go. (66-year-old male, ESI+PT)
**Learning how to manage.** Some patients found a routine or strategy that helped them manage their condition. For these patients, learning how to manage their daily lives gave them a sense of control that they previously lacked. Often participation in activities was managed with rest breaks, sitting, or doing specific stretches that they learned were successful and allowed them to manage any reoccurrence of pain or increase in fatigue. One man described how he had a routine to get his day going:

> I know if I want to reduce the pain, each morning, as I am getting up, it is best if I lay there in bed and do the stretching exercises before I get up. I know that is going to reduce the pain. So it is for my benefit to do that. So I do that. It doesn’t eliminate the pain but it reduces the pain. (72-year-old male, ESI+PT)

Medication and exercise were factors described across most interviews as techniques used related to pain management. There was a consensus among patients who had higher pain scores that medication was essential to management. Although many patients who lowered their reported pain and disability mentioned using medications at some point, only about 1/3 of the patients who had improved scores mentioned using regular pain medication in their routine post-treatment. On the other hand, more than half of the patients who improved in pain and disability talked about exercise as helpful to manage their daily condition. Some of the patients who described doing exercise learned how to do exercises in physical therapy. Many patients mentioned doing exercise in the past and therefore tried to incorporate their previous exercise that they were familiar with. A few patients even created exercises and stretches on their own from trial and error of different movements. An example of all of these is seen when one man talked about what he does to manage his condition including medication and exercise as well as different stretches he developed while golfing:

> I still take a medicine I don’t know what it is numbs the numbness in my foot. I guess you could say it camouflages it. It doesn’t stop it, it just makes you don’t know it. As opposed to an anti-inflammatory, which reduces the inflammation and reduces the pain by reducing the inflammation. But anyway, the exercises are certainly an important part of it, and some of it is exercises and some of it is me going over to the fitness center and doing the lower back and the abs exercise. And there was one where you stand up and you pull one leg up behind you and stretch your thigh. That one helps. There are, the
main ones that you lay on your back, pulling your legs up in the air, towards you to stretch out that way. Turning, laying, trying to keep your shoulders flat on the air and turning your hips so one leg is pulled over and the other leg out to the right or left, one leg stretching, sort of to stretch I guess your hips or your side or something like that. When I am golfing, I will frequently either kneel down and lean forwards to stretch my back or I will stand up straight and reach down and touch my toes and stay in that position for a few seconds to stretch it out. I know I need to do those kinds of things, and I know that is part of it, that unless I have back surgery I have no choice. Unless I want to live with more pain, then I continue doing those kinds of exercises. (66-year-old male, ESI+PT)

Another man explained how the physical therapist helped him and how he added exercise to part of his daily management routine:

I guess it´s probably the main benefit that came out of that [physical therapy treatment] was exercise, that I got from him, that I did in the morning that made it a little easier for me to navigate during the day. If I didn’t do these exercises, the system, the back, the hips, whatever, then I was even worse off... I guess I still don’t fully understand the relationship between the back and the stenosis, but there is also back pain per se and the exercises, the work that he did and the exercises that he gave me allowed me to feel, I don’t know, feel better to be more able to get around. (72-year-old male, ESI+PT)

Patients often designed different strategies to manage their lives with LSS. One commonly discussed strategy was changing activities by spacing them out, taking rest breaks or changing positions, particularly by sitting. One man discussed how he learned to manage keeping his lawn mowed:

I space things out to make it work. In other words I mow the front yard first so it looks good, and the next day I do the back yard, instead of doing it all in one day. (68-year-old male, ESI)

Another woman talked about how she used trial and error to figure out what she could manage:

I think I have learned by trial and error. Can I do this? Or maybe I better leave this alone, or maybe not so intense with what I am doing. I used to do a lot of garden work and would pick up these bags of dirt. That’s one of my problems. I am picking up the heavy dog food regularly and in the summer I was doing the dirt and the fertilizer and I think this was aggravating it so I learned I need to stop and say no, you need to wait and get some help with that, don’t pick that up. (77-year-old female, ESI)

Finally, some patients described how changing focus or deciding on what was important and what they could ignore were helpful strategies to manage their daily lives. One woman described her
strategy of ignoring or placing less emphasis on things that she used to focus on in her daily activities:

I don’t feel confident that I can go up on a stool. I am tall so I can reach but if it is the corner on the window isn’t clean, I let it be. That’s about it. I just cut out some things, play dumb, you know what I mean, just ignore it. That’s all. (73-year-old female, ESI)

**Push through attitude.** About half of the patients who improved in pain and disability scores described that they had a “grin and bear it” attitude that they attributed to managing their LSS condition. They noted that they were able to increase their ability to do activities because they pushed through the pain, weakness, fear, or other factors that were keeping them inactive. Because of this attitude, many noted a return to functional and recreational activities that they felt was important or that they enjoyed. One man described this attitude as an internal drive learned from his grandmother:

I think it is something internal. I just learn that I always do hard work, and I always see my grandmother in my mind. She lived to be almost 103 and she had arthritis real bad, she had the arthritis hands and she lived by herself until she was about 98 and she dealt with it, she didn’t take anything, she lived by herself until she fell and broke her hip. But I just see her and I knew she had to be in some kind of pain because I had never seen her go to the doctor or take medicine. But I don’t know, I just learned to deal with it. So yes, it is pain and it would be nice not to have it but I have also learned that if that is the way it is, it is the way it is. (60-year-old male, ESI)

Another male patient described his motivation to push through as something that was part of him and his personality.

You always push on, because you are pushed from the inside. So you just keep living your life and doing what you are doing. Bend over, sit down, and get up and do it, just keep going. That is the point. (73-year-old male, ESI)

For these individuals who pushed through the pain, doing activity was thought to be better than not doing activity despite pain. In addition, some felt they had to keep going because no one was available to help them in daily activities around the home or outside the home. One woman with multiple comorbidities described improvement from the actual treatment as well as the support she received from health care professionals. In this quote she described how her attitude to keep going got her through the worst part of the condition and still kept her going:
I am a very strong person which is what everybody tells me. Whether I am in excruciating pain or not, I still do my daily chores. I don’t vacuum anymore. I wash my dishes like I used to and sometimes I stop in between and have to sit down, but I force myself. And a lot of times I cry but I will make my bed and sometimes I have to stop two or three times before I finish but I am determined I am going to do it. (74 year-old female, ESI)

One woman described her need to push through as a necessity. Her ability to push herself was driven by her greater need to be independent. She stated:

What got me through was the fact that I wasn’t going to go stay with my son. And I knew that if I didn’t do better, I couldn’t stay by myself. And I wasn’t going to go stay with my son and his wife, that wasn’t, that’s out. And so that’s why I say, anything to make me feel better. And I am a very independent person; I want to do things for myself. I don’t like not being able to do certain things, I try to push myself, you know, I’ll just try to push myself. I am used to being by myself and I am used to doing things for myself. So it is embarrassing for me to ask my girlfriends and my sisters to help me. (66-year-old female, ESI+PT)

Some individuals stated it was their nature to work hard and keep going regardless of the consequences. One man described his ability to push through as a result of his male pride and military mindset:

We are at the category of male pride. So you keep doing it. I was once hurt from a hard landing in a helicopter in Vietnam. Sitting on the floor, the floor in the helicopter was metal, to keep the bullets from getting through. And it slammed to the ground and I was sitting on the floor. And I was just getting ready to retire: I was 25 years in the army. I felt it, and I banged my tailbone. I think that is when my back problems originally started. Shortly after that. So that gives you a rough idea. It went on for several years. But because of the male pride, you don’t ask for help. All my friends went to the chiropractor. No, you give them 40 dollars and all you get is them to rub your back. The real impact, if you could get into the military mind, you never stick your arm out and have somebody help you. I would just keep doing. You never complain, never let them see you sweat, that whole business. It never goes away. (73-year-old male, ESI)

This “grin and bear it” attitude was not reported by all patients. There were some who believed you had to do certain things, like exercise, because it was good for you regardless of pain. This final thread that was seen in the theme for pushing through kept some patients exercising, doing chores, and other things they thought were essential despite pain. Therefore, having a push through attitude was not always helpful. Several patients who had higher levels of pain post-treatment discussed how they pushed through their pain because of their beliefs that
they should be exercising, moving, and completing other obligations. One woman described this belief like this:

And I think if I was to give advice to anybody, they need to keep moving and exercise. I don’t care how much pain you are in, if you don’t get up and move around, you are going to be in more pain. That is my experience. And I don’t care how old you are, at least, you know I was given some good years before my back really got bad and I was thankful, and like my Doctor said, thank goodness you were as active as you were, because if you weren’t, you would be in much worse shape. And that’s why I would take their advice and keep going. (67-year-old female, ESI+PT)

**Having support.** Social support was one of the most disparate topics across all patients. Most patients reported having some type of support during the study period. Some patients reported that support was helpful and important for management of their condition. Some expressed they did not want to ask for support and therefore did not feel support was important to manage their condition. Even a few described support as unhelpful during the management period.

However, a consistent theme emerged as patients who reduced pain and disability reported having support as a positive and helpful resource during the post-treatment period. For those patients who did find that support positively contributed to their experience, social support was helpful to improve activities of daily living. One woman stated this as she saw having support as helpful motivation during her recovery:

It does make a lot of difference. When you see that someone is in your corner, and someone is trying to help you, yes that makes me feel very good about myself, it makes me try much harder. I would feel so bad sometimes, I didn’t want to get out of my bed, and sometimes I didn’t. I didn’t want to do anything. I feel like I can do things now... It was really important to have the support.(66-year-old female, ESI+PT)

When questioned, patients revealed perceived and received support from a variety of sources including tangible support, informational support, positive social interaction, and emotional support. The most frequently cited support received across all subjects was tangible support. Examples of tangible support include someone performing an errand, a car ride to the
store, or help doing some form of ADL. The provider of this support usually came from friends, family, neighbors, or hired individuals to do the shopping or give a car ride.

The next commonly discussed type of support was informational support. Patients received information from a variety of individuals, although most informational support was reported to be received from health care professionals. When asked which health care professional provided support, there was a range of answers. Most patients noted they received informational support that was helpful from both their physician and physical therapist if they also had physical therapy treatment. Patients noted mixed amounts of education about their condition from providers with examples including a guideline of what activities they could do or precautions about what they should avoid. Some in both treatment groups reported feeling educated about their condition by their physician. Two patients with injection and physical therapy treatment felt that their physician did not take enough time to talk to them about their condition and what they could and couldn’t do in their daily life. These two patients noted that the physical therapist did more to educate them about their condition and provided more suggestions about activities than their physician or other health care professionals. Three subjects with injection only treatment noted they received some of their information and education from the internet or other private pay sources such as a chiropractor or massage therapist. Overall, the majority of information came from health care providers rather than family, friends, other media or ancillary care services. One man noted he received support from family and friends, but support from medical professionals helped him improve his ability to do things and reduce his back pain:

My friends and family have been helpful but particularly I found help from medical people, from the orthopedic division at the VA, your division there at university doing the research, you were all contributing [to my getting better]. (80-year-old male, ESI)

In contrast, 2 subjects particularly noted their distress that their physician (a primary care physician and a spine physician) did not listen to them or acted cold and unsympathetic to their
problems. These individuals expressed general despair about having any solution to their problems which seemed to be complicated by the issue that they did not receive supportive gestures from their health care provider. However, these patients said they did receive very beneficial support from the physical therapist. Both patients described the physical therapist as providing motivation and emotional support as well as helped to educate the patients about their ability to advocate for their health and health care services. One of these patients found a new physician who was reported to provide much higher levels of support and in turn gave this individual more confidence and a better outlook for her condition overall.

Most patients expressed that they did not want to burden the people around them with complaints of their low back and/or leg pain. They did not want to complain about what they couldn’t do in their lives and a few stated that “others have it a lot worse off” noting they thought they should not complain about pain or lacking in ability to do things. Only a few patients mentioned that they received emotional support from friends and occasionally a family member or even a health care professional. Those who were married did acknowledge that their spouses provided emotional support although a majority of patients who were married also stated that they didn’t want to burden their spouse with complaints or emotional needs related to their LBP. For these patients receiving emotional support, it was important in order to feel “better” about their back problems as well as their daily life. One woman reflected on her ability to ask her family members for support:

If I needed, it was always there, I just had to ask. I hate to ask all the time…you don't want to wear out a good thing, but they are there if I need it. (69-year-old female, ESI)

Even when asked directly, there were only a few patients who stated emotional support was important to their recovery. Friends were discussed by both female and male patients as indirect sources of support, but not specifically for their LBP. Female patients more often than male patients did state friends were their main sources of emotional support even though some found that friends didn’t really understand what they were going through. For this reason, the few
patients who talked about positive emotional support related to their management of LSS were also patients who had higher levels of pain and disability post-treatment. One woman who lives in low income housing for people who are on disability described how the people around have supported her:

Well, living in this building, there are a lot people who are suffering. Many in wheelchairs. I have a good friend, named Randy; he lives two floors under me. He used to be a truck driver, but he had an accident driving his truck and messed up his lower back and he is in a wheelchair now, but he is huge, maybe 400 pounds. But we became good friends… He has always been very supportive to me. Some of the people in the office that work here, some of the staff, they are very supportive. My family, yes. Especially when I became a diabetic, like 8 years ago. My daughter in Connecticut…she has been my rock or whatever you call it. Whenever I feel really bad, I call her. And then we have a few people in here who have back problems also, and we talk about it. One thing I have to say, I have a lot of people here who support me and I support them. (74-year-old female, ESI)

All of these complexities captured by the patients’ voices helped to demonstrate the inconsistent role social support had in the lives of those with LSS. As a result, support had both positive and negative connotations to these individuals. A woman described this as she reflected the mixed role of support since she had it available and helpful but doesn’t want to ask for it. She described these competing interests regarding support in this way:

My friends, I don’t say too much to them, and that is probably because I don’t want them to think that I am getting old. But my son and my daughter are pretty supportive, if we are going to do something, they make sure if I need to rest and my back is hurting, they are understandable. They understand, mom stay here, we will get this for you and of course I do not like to be waited on, so I once in a while let them do it, but mostly I am “no, no, I am fine, don’t baby me. I need to walk.” But they are really supportive, they understand, and of course I am their mother and they don’t want to see me hurting. But I should be the one taking care of them. My younger brother is pretty good, my older brother, he’s got a wife that has MS so I don’t go to too much with him, they don’t need to hear about my poor little back. But they are really supportive, and my friends understand. They know. If you have a back problem, you have a back problem. We all have different problems going on. (67-year-old female, ESI+PT)

Positive outlook. Some patients seemed resigned to the fact that they could not and will not be able to do activities as they had done in the past. These individuals seemed to re-define what activities they could do now and what they believed they will be able to do in the future. For
some this was a positive recognition of limitations in order to better self-manage their condition over the long term. Others actively engaged in goal setting, determined to return to some of the activities that they had to give up during their period of back pain. One man described his positive attitude as his motivating factor:

I am sure part of it is that I have a positive attitude. I am not thinking about killing myself or any stuff like that. And my positive attitude comes from having a good wife, good kids, being reasonably financially sound. I am retired so I am not worried about losing my job. But I love to play golf. And that doesn’t come without some pain. But I love to golf so much that I am willing to do all of that is necessary to enable me to get out there and play golf. (66-year-old male, ESI+PT)

He continued on to describe his ability to push through and manage pain due to his military training, his financial circumstances, and his family. When asked about how he manages, he stated:

First of all, yes I do deal with pain. But there are a lot of people that have a lot worse fates in life than I do. And I am retired from the Air Force, as a Colonel, that means that I am very fortunate that I have a pension that is better than many other people have. That doesn’t mean that I am rich, but it doesn’t mean I am going to go into the poor house either. I am retired in a school district, I have social security, my wife’s got a good job, and she is going to have a good pension. So there is a lot to live for. I am not going to lose my house; I am not standing in the food line or anything like that. In a very bad time in your country, my family and I are very fortunate. And when you are fortunate, if no other thing good is going on, but if you are fortunate like that, you have something to live for. I had kids late, so I don’t have grandkids yet. I’d like to be a grandfather before I croak. So I’ve got all kinds of things to look forward to. (66-year-old male, ESI+PT)

When asked to describe the main thing that helped her get better, one woman stated how her positive attitude made all the difference:

Do you want to know what the number one is? My dad used to say, she is a tough old bird. You know, you have to go with the flow, you have to deal with what comes and I think God has been very good to me. If I have pain I have pain. I take what I have to take to relieve it as much as possible. I don’t commit myself to anything that I know is going to be stressful or strenuous because I just be asking for it. So now, I live a very sedate life. And stuff like that. But that’s ok. I’ve had a good life and I am not complaining, but I think it’s my attitude, and I am not being braggadocious or anything like that, I have a very positive attitude. I have two beautiful granddaughters. I have my sons and I try to be an example for them. (87-year-old female, ESI+PT)
Quantitative and Qualitative: Combined Results

Patients with LSS reported a variety of types of coping behaviors that mediated both the severity and reduction of pain and disability including the a priori sources, self-efficacy, social support, perceived physical health and perceived mental health. Many related factors emerged from the patient interviews, including physical limitations, lack of confidence in tasks and activities, feeling a lack of control, reduced social participation, feelings of vulnerability, poor mental state, frustration at needing support, and financial limitations. The main factors that increased the severity of pain and disability at entry to treatment are illustrated in Figure 4.5. In addition, many factors identified by patients contributed to the reduction of pain and disability in the post-treatment period, including having greater confidence, knowing limitations, learning how to manage, having a push through attitude, having support, and having a positive outlook. The main coping behaviors found to mediate the reduction in pain and disability post-treatment are illustrated in Figure 4.6.
Figure 4.5. Factors increasing severity for pain and disability at entry to treatment.

Key:
- = association with disability in multivariate analysis
- = association with disability in bivariate analysis
= association with pain in multivariate analysis

*indicates subscale of total index
Figure 4.6. Factors mediating the reduction of pain and disability post-treatment.

Key:
- = association with pain and disability in bivariate and multivariate analysis
- = association with disability in bivariate analysis

Note: # In different patients, push through attitude contributed to both reducing and increasing pain and disability
CHAPTER V

DISCUSSION

This study aimed to identify predictors of perceived pain and disability in patients with LSS both upon entry to treatment and post-treatment, 6 to 12 months after entry into the study. In addition, this study aimed to describe sources of stress and respective coping as described by patients in their own words. Particular emphasis was placed on self-efficacy, social support, and general health perceptions as they contribute to pain and disability, using a theoretical framework from the Stress and Coping Model and the Stress-Diathesis Model.107, 112, 125, 141, 248

This research sought to fill several important gaps in the LBP literature, particularly the lack of research investigating the contribution of psychosocial factors such as self-efficacy and social support in identifying severity for and reduction of pain and disability in patients with LSS. In addition, this research has added greater understanding of the extent to which perceptions of physical and mental health contribute to the severity and outcomes of pain and disability. Finally, this research used a novel mixed methods design to uncover the patient’s lived experience with LSS. The overall outcome of this study was to inform translational research, clinical interventions, and policy recommendations, which may ultimately serve to identify treatment needs and provide additional resources for reducing pain and disability and improving the quality of life for patients with LSS.

Key Findings: Quantitative Summary

Multiple key findings emerged from this mixed methods study. The quantitative data illustrate that patients with LSS enter conservative treatment with high levels of pain and disability, indicating the importance of reducing these stressors of pain and disability in this population as an important clinical priority. Upon entry to treatment, 75% had experienced pain in the moderate or high category (4-10/10) with 44% in the high pain category (7-10/10) and all
of the patients had moderate or greater levels of disability with almost 40% at the severe or crippling level of disability.

The data also illustrated that multiple factors interacted positively during the treatment and post-treatment period to reduce pain and disability. Post-treatment, the mean disability score was at the low end of moderate range (29.3) compared to borderline high range (40.3) at entry to treatment. A quarter of the patients were in the low disability range (25%) post-treatment compared to none upon entry to treatment, but similar numbers at 25% in the severe range and 10% in the crippled range of disability for both pre and post-treatment. Similar results were seen for pain as the mean pain post-treatment was at the low end of moderate range (4.14/10) compared to 5.27/10 upon entry to treatment. Post-treatment, 60% of patients had either no pain or were in the low pain category (1-3/10) compared to only 27% at entry to treatment, while 10% were still in the high pain category up to 1 year post-treatment.

Next, a profile emerged from this sample indicating patients experiencing greater disability upon entry to treatment had worse perceived physical health, worse perceived mental health, and lower social support. As hypothesized, with three quarters (75%) of patients with LSS reporting elevated levels of disability, patients who perceived they had worse physical and mental health experienced an even more disproportionate burden of disability. The independent predictors for greater levels of disability upon entry to treatment emerged, with worse perceived physical health independently explaining 35.2% of the variance in disability, worse perceived mental health independently explaining 17.2% of the variance in disability, and lower social support independently explaining 10% of the variance in disability. With all 4 variables of self-efficacy, social support, perceived physical health and perceived mental health in the model, 48.8% the variance in disability was explained by a perception of worse physical health and worse mental health predicting greater levels of disability upon entry to treatment. With almost half the variance in baseline disability explained by self-perceived health status, this is an important contribution to the LSS literature.
The only significant predictors of pain at entry to treatment were functional self-efficacy and total self-efficacy. Reduced functional self-efficacy was the only significant independent predictor of higher pain, predicting 10% of the variance in pain upon entry to treatment. Significant but underpowered multivariate relationships emerged with the first model including significant contribution from reduced functional self-efficacy explaining 15.7% of the variance in pain. The second model had significant contribution from reduced total self-efficacy explaining a total of 17.4% of the variance in pain. Both models identifying higher pain at entry to treatment are only exploratory at this stage and need to be interpreted with caution due to the risk for error. Because these findings are preliminary in nature, additional follow-up analysis is warranted to examine these and additional factors related to severity of pain in the larger RCT data as well as in future studies.

Lastly, a profile emerged identifying predictors associated with outcomes of disability post-treatment. Specifically, having a better perception of one’s physical health independently explained 76.5% of the variance in disability which is quite an important contribution alone. In addition, total self-efficacy was a second important predictor independently explaining 42.3% of the variance in disability post-treatment. The group model resulted in better perceived physical health as the only significantly contributor to predicting less disability; accounting for 73% of the total variance in disability post-treatment.

Predicting a reduction in pain post-treatment resulted in 2 significant models. Only 1 model was adequately powered and explained approximately one third of the total variance in pain. This model only had significant contribution from better perceived physical health explaining 31.7% of the variance in pain post-treatment. A second significant but underpowered model emerged, with a better perceived physical health again explaining 24.7% of the variance in pain post-treatment. Given the small sample size and preliminary nature of the quantitative results, the qualitative results were used to triangulate the quantitative findings and contribute new insights associated with stressors and coping in patients with LSS.
Key Findings: Combined Summary

The qualitative component of this study used patient interview in order to better understand the constructs of self-efficacy, social support, perceived physical health, and perceived mental health as they relate to pain and disability in the eyes of patients with LSS. Emergent themes not tested by the quantitative surveys were also uncovered. Interview transcripts were analyzed for themes that represent patient beliefs and coping behaviors. These expressions by the patients supported, clarified, and added to the survey results regarding the stressors and coping behaviors of patients with LSS.

Similar to what was found in the quantitative data, pain was a key focus by many patients when describing why they sought treatment. In expressing pain and issues related to pain, patients also described components of disability such as problems with body structure or function, issues with personal factors, influences of environmental factors, and limitations in activity and participation that reflected a more complete concept of disability supported by ICF framework. Although the ICF framework uses a broad lens in which to interpret disability, it was not a helpful model to use to narrow down factors related to pain and disability in LSS. The Stress-Diathesis Model resulted in a much more accurate framework in understanding pain and associated disability in LSS. Using this model, patients described overlapping factors that related to the stressors of pain and disability and confirmed the importance of the appraisal and coping process. Because degenerative LSS is a chronic and re-occurring LBP condition, pain is complex and not isolated from issues of disability in these individuals and supports the use of the Stress-Diathesis Model in LSS.

In examining behaviors and experiences of the patients, multiple messages regarding the influence of self-efficacy, perceived physical health, perceived mental health as well as conflicting meanings for social support were found that confirm the importance of these constructs in management of LSS. Patients in this study were similar to most patients with LSS who are older and generally have more co-morbidities found in later stages in life. As a result
patients with LSS have many limitations in discretionary, committed, and obligatory activities that are tied to multiple factors. The clinical outcomes of pain and disability are used exclusively as markers for severity and outcomes in the literature, yet little work has gone into understanding what factors impact these outcomes other than treatment. Therefore goal for the mixed methods design was to help clinicians better understand how physical, mental, and social factors impact the severity and clinical outcomes of pain and disability in patients with LSS.

Entry to Treatment: Increased Pain and Disability

The patients’ experiences with LSS at entry to treatment shed light on a variety of personal and environmental factors that relate to perceived pain and disability in the LSS population. Based on the available data collected from this cohort, three predictors (perceived physical health, perceived mental health, social support) contribute to the variance of disability and one predictor (self-efficacy) contributes to the variance of pain at entry to treatment. These personal and environmental factors described by patients are supported by the ICF and the Stress-Diathesis Model as factors that help to define the stressors of pain and disability and describe coping in patients with LSS. Additionally, eight themes were identified by patients as reasons for increased perceptions of pain and disability upon entry to treatment. These themes included physical limitations, lacking confidence in tasks and activities, feeling a lack of control, reduced social participation, feelings of vulnerability, poor mental health, frustration about needing support, and financial limitations. In line with the Stress and Coping Model, these themes confirmed that patients who had negative appraisals and fewer coping resources all experienced higher levels of pain and disability.

Perceived physical health. The largest statistical contributor to the variance in disability at entry to treatment was perceived physical health. The quantitative results illustrated a clear inverse relationship between a worse perception of physical health and increased disability at entry to treatment. The interviews confirmed that patients had general health worries as well as
concerns across all activities due to their LSS condition. Patients expressed general concerns about diminished physical health that revolved around their inability to keep up with prior levels of activity and/or levels of activity of their peers. The perception of declining physical health may be particularly noticeable in this population of patients with LBP because of the high likelihood of concurrent age-related declines and comorbidity factors as compared with other types of LBP.  

However, aging and illness related perceptions of physical decline in older adults do not always result in the perception of poor physical health. Tobin and Lieberman and Rosow found that many older adults that are physically ill and moderately incapacitated still appraise their health status and life circumstances positively. These concepts support the Stress and Coping Model and the study findings that specific patients who held beliefs of declining physical health contributed to negative appraisal of the stressors of pain and disability and resulted in poor adaptational outcomes.

Patients with LSS described concerns with general physical function, bodily pain, problems with physical roles across a spectrum of activities, and decreased general physical health. These areas of concern are consistent with the areas measured by the PCS subscale of the SF-36. The negative perceptions of physical health reported in interviews were expressed in terms of losses related to participation in daily activities, recreational activities or social activities, as well as the perceived inability to fulfill certain roles (such as spouse, friend, or parent) because of fatigue and general physical loss. In addition, many patients revealed that the role of physical health may have a strong link to social functioning which seemed to permeate their perception of physical health status. This result is consistent with literature on other chronic health conditions.

At entry to treatment when LBP was at the greatest acuity, many of the patients also noted altered perceptions in physical health that combined with their ability to perform specific tasks. It is unclear at this time if the inability to do specific tasks contributed to eroding their
confidence in their physical health or if their perceived declining physical health status due to LSS contributed to the lack of confidence in task performance. It is likely that both played a role in augmenting and confirming fears of poor physical health due to the chronic condition of LSS.

Even in this condition-specific population of older adults, there were differences in perceived physical health that were revealed both in the PCS scores and in the patient interviews. Those who had a worse perception of their health also communicated greater limitations in their lives. For example, one man described his inability to do most anything since most tasks required walking: “Yeah, I don’t do too much. A lot of the activities I like involve lots of walking.” Or another man who had difficulty getting to the bathroom every day equated his inability to do this specific task of walking to the bathroom with his inability to do general physical activity: “So if going to the bathroom is so bad I figured I couldn’t do much of anything.” The uncertainty and absence of control over both the performance and the outcome of engaging in physical activities seemed to erode patients’ confidence and therefore actual performance of a general group of activities. An example of this uncertainty is illustrated as one woman stated: “Well it is a little bit hard dealing with it. It seems like it comes and goes, one day I can feel pretty good, and the next day I can’t do anything.” All of these sentiments describing a reduced confidence in physical health supports prior research that self-rated health is an important factor to consider and has direct links to disability.107

Unexpectedly, perceived physical health was not a significant predictor of pain at entry to treatment. In contrast to existing literature showing that perceived physical health is a powerful predictor of pain, this study did not find such a strong relationship in this cohort.264, 265 The patients’ experiences did not shed any additional light on this relationship between general physical health perceptions and pain except indirectly during interviews as a contributor to physical limitations. This is surprising as many of the biomedical theories for pain involve a large focus on physical components of pain.125, 226, 266 It may be that the experience of pain in this population with LSS is different than other types of LBP due to older age and chronicity which
has been shown in previous literature to affect one’s perception of pain.\textsuperscript{10, 116, 226} It also may be because perceived physical health as measured by the PCS and as describe by the patients’ was a broader construct than just bodily pain and represented a component of illness behavior. Previous research has shown that somatic functioning has a large role to play in illness behaviors but it is the sum of the physical, psychological and social contributions to illness behaviors that result in health perceptions and outcomes.\textsuperscript{122, 267} These findings would support the Stress-Diathesis Model where pain is in the pathway towards disability but perceptions of physical health contribute after appraisals of pain and interact much closer to anxiety and disability constructs. These findings warrant further investigation and suggest the need for a closer look into the experience of pain in older adults with the chronic condition of LSS.

It is important to recognize that measures of self-rated physical health in the SF-36 PCS overlap with disability measurement using the ODI as both represent domains of physical pain and functioning. The ODI is a condition-specific scale which measures low back related pain as it impacts function whereas the PCS, the physical health subscale of the SF-36, measures physical function but also encompasses measurement of general physical health. In addition to specific physical function and bodily pain, the PCS measures the physical roles of an individual and general health belief regarding one’s physical status which are not represented on the ODI.

The strong association between the SF-36 and the ODI found in LSS at entry to treatment may in part be due to the similar domains of bodily pain and physical function in these two measurement tools. At this time, the nature of this relationship specifically in this cohort of patients with LSS cannot be determined due to the small sample size. However using the ICF framework to define disability, body structure and function represent only one area of disability. Disability according to this framework also includes personal and environmental influences. Similar to what was found in the data, additional contributions from perceived mental health and social support and qualitative data supporting self-efficacy were also associated with disability in
patients with LSS at entry to treatment. These factors combined to represent a larger picture of disability in LSS as described by patients at entry to treatment.

**Perceived mental health.** The perception of poor mental health was another factor associated with greater disability at entry to treatment supported by both the quantitative and qualitative data. This study’s findings corroborate the results of several studies that found that patients with LSS have mental health issues pre-treatment.\textsuperscript{76, 86, 88} An important contribution of this study is the finding that a having a worse perception of mental health significantly contributed to determining elevated levels of disability upon entry to treatment. The qualitative findings supported this as well, suggesting that poor mental health and feelings of vulnerability contribute to concerns of patients with LSS and serve to increase their levels of stress and burden of disease.

Patient interviews helped to clarify the role of mental health status as a contributor to the experience of disability at entry into treatment. The interviews revealed that in 5 of 9 patients with higher pain and higher disability scores, a general poor mental state and depression contributed to their condition severity. This poor mental state ranged from a depressed mood to thoughts of suicide by 2 patients during a period of intense LBP before seeking treatment. These expressions of poor mental health illustrate mental health issues in the lives of patients with LSS and the relationship of mental health to pain and disability in this population.

Another theme related to general mental health, vulnerability, emerged from the qualitative data. Previous literature has not identified feelings of vulnerability as contributing to increased pain and disability in LSS. However supported by the Stress-Diathesis Model, feelings of vulnerability can modify the appraisal of pain and magnify the trajectory towards disability. This is consistent with patients’ narratives describing the effects of pain but focusing on their vulnerability resulting from functional limitations.\textsuperscript{125}

Patients also described a lack of control which contributed to mental health beliefs as it not only identified physical concerns but also revealed a high level of anxiety patients had about
daily living. These anxieties about control over events in their daily lives resulted in some degree of increased vigilance regarding pain and activity performance. These patient’s descriptions regarding control, anxiety, and vulnerability as components of mental health are supported by the Stress and Coping Model as an essential theme linking emotional states to appraisals of harm, threat, and challenge. Overall, the emotional states described by patients with LSS support a link between perceptions of worse mental health and the negative appraisal of pain and disability.

It is not clear to what extent emotional states and mental health contribute to experiences of pain and disability, versus how much the experience of pain and disability contribute to emotional states and perceptions of mental health. In this study, patients with expressed poor mental health status on the MCS also had a higher burden of disability. The interviews reinforced the quantitative findings that perceived mental health factors contributed to disability in LSS and supported the Stress-Diathesis Model. Future studies should explore these relationships using additional tools to compare measures of perceived health and emotional states with outcomes of pain and disability. This is one of the first studies to explore this issue in LSS and it confirms that a perception of worse mental health is a concern for patients with LSS and contributes to their severity of disability.

**Social support.** A small but significant inverse relationship was found between decreased amounts of social support contributing to greater disability in bivariate regression analysis. Supporting the Stress and Coping Model, a reduction of social support equates to the reduction of a coping resource. Under this model, having different sources of support should protect an individual from the adverse effects of stress. However these results were not supported by the multiple regression analysis as social support was not significantly associated with pain or disability at entry to treatment. These inconsistent results for social support emphasize the need for exploring this factor in the context of the patient’s perspective.

One key theme from the patient interviews was the expressed frustration of patients at having to rely on others. These strong feelings of frustration about relying on others’ for support
may be interacting with patient’s perceptions about social support resources and the role of these resources. As stated previously, the Stress and Coping Model describes having support available as a positive coping resource that can reduce stressors. However, in this population, having to rely on others for support itself seemed to be a stressor. The frustrations expressed by patients for needing support and even more by patients who had to use support illustrates the possible mixed messages that revolved around social support, particularly when most vulnerable at entry to treatment. In the literature, Doeglas et al\textsuperscript{268} demonstrated that satisfaction with supportive transactions was more important for patients’ well-being than the existence or frequency of supportive transactions. Therefore, patients with LSS may have reduced satisfaction with support as a coping resource and as a result, having social support was less helpful in ameliorating their pain and disability.

**Self-efficacy.** Surprisingly, the quantitative data revealed that self-efficacy was not a predictor of disability and only contributed to experiences of pain upon entry to treatment. Since self-efficacy reflects one’s confidence in physical tasks, one might expect self-efficacy to be related to disability when physical function has declined. However in this cohort, issues with self-efficacy at entry to treatment were only reflected by an association to pain. In line with the Stress and Coping Model, those with lower appraised total and functional self-efficacy as measured by the LoBACS survey experienced a disproportionate burden of pain compared to those with higher total self-efficacy in bivariate and multivariate analysis, although these relationships were underpowered in the current sample. The qualitative findings confirmed the role of self-efficacy contributing to the severity of pain but also support a larger role for self-efficacy in contributing to disability at entry to treatment.

When patients spoke about their beliefs regarding organizing and executing necessary actions for life activities, they would most readily use words like “confidence” for tasks and discuss what tasks they thought they could or could not perform. In the patient’s words, the a priori identified construct of self-efficacy was a theme that emerged most strongly as lacking
confidence in tasks and activities. Specific tasks such as standing doing dishes, stair climbing, walking to the bathroom or to the mailbox all were examples used by patients of tasks for which they expressed lower confidence upon entering treatment.

In addition, the theme of lacking control, particularly over specific physical tasks was pervasive across interviews. This theme reflected the patients apprehensions for participating in tasks before treatment, especially low back related tasks such as ADLs that included standing, walking, lifting, bending, and stair climbing. According to Bandura, self-efficacy beliefs reflect confidence for performing tasks but only while regulating one's own motivation, thought processes, affective states and actions, or changing environmental conditions. When patients expressed a feeling of a lack of control over tasks, it reflected their motivation and thought processes for executing specific actions. Patients described their lack of control as being unsure of their bodies' performance or whether they would have pain during the performance of a task. This uncertainty helped to erode patients' confidence for performing low back related tasks. Overall, those patients with feelings of a lack of control as well as a reduced self-confidence represented the construct of reduced self-efficacy and subsequently reported higher amounts of pain with activity supporting the quantitative results.

In addition, the qualitative findings emphasize that reduced self-efficacy is possibly more pervasive upon entry to treatment than found in the survey data. It is possible that expressions of reduced self-efficacy for specific tasks were overshadowed upon entry to treatment by stronger concerns for an individual's overall physical and mental health as seen in the quantitative data. Self-reported health may be more reflective of one’s perception of disability during acute episodes of a chronic condition such as LSS, and concepts of self-efficacy may be more narrowly defined during this time to pain provocation during specific task performance. More research is warranted to explore these relationships in patients with LSS.
Entry to Treatment: Emergent Theme

Financial limitations. The role of financial limitations was an unexpected factor reported by patients that contributed to the experience of greater pain and greater disability that was not tested in the quantitative data. Those patients who had previously been unable to receive timely medical care or had received reduced care due to financial limitations expressed greater levels of perceived pain and disability. In these instances, financial limitations represented environmental constraints to coping resources. Many patients complained of limited financial resources for ADLs that they could no longer do on their own such as home maintenance, yard maintenance, and transportation services. These limited financial resources were particularly present in those individuals who were retired and on fixed incomes. Those few who still worked had fewer financial limitations but their problems seemed to revolve around trying to keep their job. In several cases, LBP became problematic to their work abilities and led to a loss of work time and even the loss of their job.

Post-Treatment: Improving Outcomes of Pain and Disability

Patients with LSS described a variety of sources contributing to a reduction in the stressors of pain and disability post-treatment. These related to the a priori identified constructs of perceived physical health and total self-efficacy for low back related tasks. Additional themes from the patient interviews help explain some of the additional variance in pain and disability post-treatment unexplained by the quantitative models. Post-treatment, patients talked about their coping behaviors through the themes of knowing limitations, learning how to manage, having a push through attitude, having a positive outlook, and having social support. In line with the Stress and Coping Model, patients who described more coping resources and improved coping behaviors post-treatment compared to pre-treatment reported better outcomes of pain and/or disability and subsequently reduced the effect of stressors from this chronic condition.

Perceived physical health. The most significant factor contributing to the variance in
both pain and disability post-treatment was perceived physical health. Better perceived physical health on the SF-36 PCS was both a bivariate and multivariate predictor explaining approximately three quarters of the variance in disability outcomes. In addition, the perception of better physical health significantly contributed to the group model explaining 40% of the variance in pain post-treatment.

The qualitative data supported the findings that a perception of better physical health was related to improvements in pain and disability post-treatment. During interviews, many patients expressed a greater confidence in their overall physical abilities and physical stamina. Improved perceptions of general physical health seemed to greatly improve patients’ motivation for coping efforts leading to a reduction the severity of their experience of pain and disability. The literature has shown that holding positive beliefs about one’s health increases resilience and the ability to cope with stressors.\textsuperscript{269} Positive self-rating of health has also been shown to predict active coping strategies in health challenges 4 years later.\textsuperscript{210}

Patients’ general physical health beliefs were bolstered when specific tasks were performed or thought to be attainable. Specific tasks become a proxy for a general class of activities that the patients’ wished to perform. Often these were activities patients used to engage in before their back got worse. Returning to some of their “normal” functions post-treatment seemed to greatly improve patients’ perception of their physical health. However, in the interviews it was unclear whether beliefs for improving physical health led to increased confidence and control over specific tasks or if specific task performance led to better perceptions regarding patients’ physical health status. It would be warranted as evidenced from these preliminary findings, to explore the relationship between self-efficacy beliefs and perceived physical health in patients with LSS in future studies.

What is clear from the strong associations between the PCS scores and pain and disability scores in triangulation with patient statements is that improved perceptions of physical health was important for improving outcome expectations. This confirms that a positive perception of
physical health contributes to improved coping behaviors in LSS. These themes for improved physical health were repeated often by patients who expressed a greater pain relief and a better overall ability to manage their low back condition. The interviews illustrated how perceived control over one’s health situation resulted in better outcomes of pain and disability. Supported by previous literature in aging, the findings in this cohort of patient with LSS support the importance of self-rated physical health in relationship to better long-term outcomes of pain and disability.

As discussed above at entry to treatment, it is possible that the SF-36 PCS and the ODI overlap in the constructs each measure related to physical function and bodily pain. This is one potential reason why there is such a strong relationship between these two measures. In addition, LSS may represent a population where the focus of disability is largely characterized by physical function over the long-term. Other studies have found differences among groupings of conditions such as rheumatic conditions where different domains of the SF-36 PCS represents some rheumatic conditions better than others. The usefulness of general measures such as the SF-36 and its subscales, is in their ability to allow comparisons among patients with the same condition as well as between patients with different conditions. However, condition-specific measures such as the ODI has been reported to be more responsive to change in the condition under study, such as when comparing outcomes among individuals with LSS.

Previous literature in LBP has found general health measures to be both more responsive, and less responsive than condition specific measures such as the ODI and the Roland Morris Disability Index. The ODI had been shown to be most sensitive to change compared to other measures in patients with LBP who have low function, such as what is found in LSS. Other studies have shown similar responsiveness between generic health measures and condition specific measures in different types of health conditions. However, the SF-36 has been found less responsive when representing condition-specific problems. Specifically in LSS, Stucki et al found that a condition-specific measure was determined to be more
responsive in measuring outcomes of physical function and symptom severity in LSS than
general health measures, although neither the ODI or the SF-36 were specifically tested making
comparisons difficult.

Typically it is recommended that both condition-specific and general measures be used
clinically and for research. Utilization of both types of surveys, however, increases respondent
burden, creates redundancy, and adds to data collection and analysis burdens. If a general
measure such as the SF-36 PCS was as responsive as a condition-specific measure such as the
ODI for LSS, the benefits of the general measure could be maintained without risk of losing
information. General health measures like the SF-36 include broader questions related to health
related quality of life and therefore potentially represent more than what is routinely measured to
determine clinically relevant change for a specific condition. Literature in other health conditions
have found generic measures such as the SF-36 are important to describe overall health and
compare against other health conditions but condition-specific disability measures are important
to compare outcomes within specific conditions such as LSS. At this time, the nature of the
relationship between perceived physical health and disability in LSS using the SF-36 and ODI
cannot be answered accept to acknowledge the strong association post-treatment. Future research
needs to explore the relationships between these measures of perceived physical health and the
outcomes of disability as well as the emphasis on physical function in LSS.

**Self-efficacy.** The quantitative results demonstrated a significant relationship between
higher self-efficacy and reduced disability post-treatment in bivariate analysis but not
multivariate models. The qualitative results supported the bivariate results and added further
nuances regarding the role of self-efficacy as a coping behavior in patients with LSS. Three
themes helped explain patient’s increased confidence for specific low back related tasks and
contributed to the importance of increased total self-efficacy in the cohort of patients with LSS:
greater confidence, knowing limitations, and learning how to manage.
Overall, patients expressed a greater confidence post-treatment in performing specific tasks. This confidence originated from treatment experiences as well as alternative health and self-motivated experiences in which they were able to do specific physical and social activities successfully. In addition, patients frequently stated that with treatment, information, and trial and error they developed a self-system of knowing what and when they reached or came close to their physical, mental, and fatigue related limitations. Identifying what helps improve patient confidence, a key aspect of self-efficacy, may be important to investigate in future research in the reduction of disability in LSS and the proportion of variance not explained by the statistical model.

Social support. At post-treatment, there were no significant quantitative relationships between social support and outcomes of perceived pain and disability. However, in the qualitative data, social support emerged as a theme related to improvements post-treatment. Yet even in the qualitative data, only some of the patients who had reduced pain and disability described social support as helpful in improving their condition. Other patients described social support as not helpful in improving their outcomes. These conflicting results underscore the need to explore and understand the role of social support as a coping resource as described by patients with LSS.

Overall, the interviews illustrated a complex association between social support and the outcomes of pain and disability post-treatment. One theme emerged as several individuals with improved pain and disability outcomes did express social support as being helpful to their recovery. These patients found social support helpful particularly when it related to tangible support such as treatment from a health care professional and help around the house from family and friends. Others found helpful informational support from health care providers. Less frequently mentioned was emotional support which was found to be helpful for a few patients from sources such as health care providers, family, or friends to keep them motivated for recovery. These views of social support expressed by the patients with LSS are similar to the positive effects of support as a stress buffer that has been described in the literature.107, 280, 281
However, some patients’ descriptions of social support as well as their evaluations of support depicted a different role for social support. For these individuals, support was something they tried to avoid. Inherent in the definition of social support is the supportiveness of the relationship(s). These patients expressed embarrassment or reluctance about supportive functions. For those individuals who found support carried negative connotations, social support indicated weakness or helplessness. Asking and receiving support was expressed as being a burden for their family and friends. Some stated that even though they might have support sources, they would ask for and use support only if absolutely necessary. This response to support was due to pride, the need for independence, and even due to anxiety about family or friend relationships. Still others found health care professionals’ support ineffective or disingenuous. For these individuals, just getting treatment did not indicate a role for support nor did they see the supportive nature of health care assistance.

In addition, a number of patients with diminished pain and reduced disability post-treatment stated they did not need or want to ask for support. These individuals described themselves as having a push through attitude. For these individuals, the reluctance for emotional support and the desire not to be a burden on others seemed to overshadow the positive role social support could play as a coping resource. It is possible that these conflicting views of support and self-reliance illustrate why the underlying theories for social support as a positive coping resource were not supported in this research. These conflicts have been recognized in the literature as negative effects of social support.

In addition, some of the patients who had the most severe ratings of pain and disability post-treatment were the ones who found social support a positive coping resource. It is possible that those with higher disability needed to draw on relationships more frequently and therefore rated their support higher than those who possibly had the support available but did not need to use support for assistance in times of need. According to Lazarus and Folkman, social support is a resource that must be cultivated and used. Therefore it is possible that an individual who has
a chronic illness such as LSS who perceives he/she has a worse health status and greater need of support might cultivate and use his/her supportive resources more often regardless of the type of support. The qualitative findings confirm this explanation as those who reported greater functional limitations and reduced ability to leave their house talked about how they created supportive relationships with family, friends, and neighbors to help provide them with the support they needed to go to medical appointments, get groceries, or just go on outings.

All of the negative and positive effects of social support described by patients’ with LSS illustrate the differing perceptions of individuals while engaged in cultivating and using social supports. Although no consensus on support was reached in this study, the conflicting results are consistent with what has been uncovered in other studies and underscores the need to identify individual perceptions of social support as a part of the treatment planning process and determine the availability and acceptance of social support as a coping resource.281, 282

**Post-Treatment: Emergent Themes**

Several emergent themes were uncovered in the interviews that expressed reasons for patients’ relative improvements in perceived pain and disability post-treatment. These themes included having a *push through attitude* and a *positive outlook*. Both of these themes reflect belief systems generalized by patients. According to Lazarus and Folkman,127 beliefs served to modify appraisals of a stressful situation and enhance coping behaviors. These two themes expressed by patients with LSS were ways that these patients described how and why they improved post-treatment.

**Push through attitude.** Particularly those individuals who had decreases in disability scores post-treatment reflected the theme of pushing through. This is similar to the “just do it” or “grin and bear it” attitude recognized in our society as toughing it out despite pain or other obstacles. Some, but not all, who had lower pain scores post-treatment also talked about having this attitude. This inconsistency may be in part due to the fact that those who pushed through had
increases in pain at times but kept going nevertheless. For those who were able to push through, their words indicated that they had returned to more activities and had higher belief that they were able to do things. For these individuals, this mentality seemed to bolster their overall confidence and perspective on returning to “normal” or some degree of their previously held lifestyle.

However, there were a few patients with a push through attitude that did not show improved outcomes of pain or disability. These patients commented on pushing through out of necessity either due to the lack of support or lack of resources, particularly financial, at their disposal. For these individuals, pushing through irritated their condition, eroded their confidence, and often they resigned to doing less as a management strategy.

Positive outlook. Finally an emergent theme of having a positive attitude or outlook on their situation was helpful for many with LSS. Having a positive outlook seemed to be a beneficial complement in improving pain and disability. The sense of positivity has been found to be a component of motivation and helps to prevent negative states such as depression and anxiety. \(^{251}\) Supported by the Stress and Coping Model and the ICF framework, positive beliefs are a personal factor that can influence positive appraisals of stressors and the availability of coping resources. In research by Chipperfield, \(^{283}\) health optimists who tended to overstate their health, even with a number of health conditions, were significantly more likely to live longer indicating a bias for survival and strong coping behaviors. It is unclear if patients with LSS who expressed a positive outlook were health optimists, but it illustrates that these individuals did possess some sort of resilience which may have influenced their coping behaviors. Patients’ stories about their positive attitudes along with the theoretical framework of the Stress and Coping Model suggests that maintaining a positive health outlook may serve as a cognitive buffering mechanism to protect the self from negative changes that can occur with health conditions such as LSS.
CHAPTER VI

CONCLUSIONS

Using existing theoretical frameworks, this study explored appraisals and coping behaviors related to the stressors of pain and disability in a sub-set of patients with LSS. The mixed methodology in this study enabled results of the qualitative analysis to enhance the findings from the quantitative analysis. This unique approach in studying perceptions of pain and disability in patients with LSS generated possible explanations not found in the statistical models.

Guided by the Stress and Coping Model, this study confirms the hypotheses that perceived physical health has an inverse relationship with the degree of disability both prior to and long-term after treatment. In addition, it confirms that perceived mental health contributes to and has an inverse relationship with disability at entry to treatment and self-efficacy has an inverse relationship to disability post-treatment. Taken together, these results demonstrate that a perception of worse physical health and worse mental health contributed to the overall burden for disablement in this population. Improvements in disability were seen when complemented by coping behaviors for improving physical health beliefs as well as confidence for specific low back related tasks.

Little evidence supported the role for social support as a coping resource in LSS. Patients with LSS expressed a mixed need, availability, and satisfaction with social support. Patients who did express positive support described tangible and informational support in the form of advice and treatment from health care professionals. In addition, patients stated a preference for tangible support from family and friends for obligatory, committed, and discretionary activities. Several patients discussed the availability of emotional support from family or friends but only a few stated they sought emotional support for their LSS condition. Moreover, most patients expressed not wanting to ask for or receive support for multiple reasons such as pride, being a burden, and a preference for pushing themselves internally. These inconsistencies in social support can be
found in literature citing both the positive and negative effects of social support as a coping resource. Overall, the study results regarding social support as a coping resource might be clarified by further qualitative investigation as well as a closer investigation in a larger sample of patients with LSS before any conclusions can be drawn.

The qualitative analysis identified several emergent themes that complemented the a priori constructs of self-efficacy, social support, perceived physical health and perceived mental health. Eight themes helped to explain why a patient perceived greater pain and disability: physical limitations, lacking confidence in tasks and activities, feeling a lack of control, reduced social participation, feelings of vulnerability, poor mental health, frustrations about needing support, and financial limitations. In addition, 6 themes described patients’ views on what helped them reduce the burden of pain and disability post-treatment. These included having greater confidence, knowing limitations, learning how to manage, having a push through attitude, having support, and having a positive outlook. These emergent themes, conceptualized as a reflection of coping resources and behaviors at entry and post-treatment related to overall appraisals of the stressors of pain and disability in patients with LSS. Patients’ descriptions of these appraisals and coping in accordance with the Stress and Coping Model may help to explain some of the variance that remained unexplained in the data, offering future directions for intervention and management in patients with LSS.

**Limitations**

This study had several limitations that must be acknowledged. The largest limitation of this study was the small sample size. Although proposed research was originally planned with larger samples recruited for an RCT, challenges in recruitment and retention resulted in having far fewer subjects than intended. Consequently, this study involved a cohort of 34 patients at entry to treatment and 20 patients at follow-up.

The smaller sample size introduces a few important limitations. First, findings from
small samples may not be statistically generalizable to the population, with greater chance of Type II errors (i.e., failing to detect an association when there is one). In this study, an a priori sample size determination was calculated based off of information from previous studies. Inferential statistics were computed on the results: particularly correlation, bivariate regression, and multiple regression. Some quantitative results were underpowered based on the a priori sample size determination. Therefore, there was a reduced ability to draw strong conclusions regarding self-efficacy, social support, and self-rated physical and mental health as they contribute to a patient’s perception of pain and disability in LSS. To reduce the possibility of a Type II error, this study employed a post hoc analysis on all models to help identify the magnitude of the observable data. Post-hoc analysis has some advantages as it determines the power estimates based off of the actual sample size and results of this study. However, the danger in being confident of the findings is when in fact the findings represent error. As with any finding, the strength of the results would be improved by achieving the same results in a separate repeat study. In addition, repeating the same analysis once the RCT is completed will determine if the results are substantiated in a larger data set.

In addition, the small sample only allowed a limited number of relationships to be examined. Treatment was not one of the main variables of interest in this study. However, it is possible that the behavioral and social factors of interest in this study act as moderators in the relationship between treatment and outcomes of pain and disability. Therefore, the interaction of treatment type needs to be investigated upon completion of the larger RCT data set. Other important variables in addition to treatment that were not tested in this study include the effects of age, gender, comorbidity, and socioeconomic status. Moreover, there may be other potentially confounding variables (e.g. self-esteem) that should be included when examining the relationships between patient characteristics, coping behaviors and outcomes. Some of these limitations in sample size were moderated by the richness of the dataset, using both quantitative
surveys, 34 pre-treatment and 20 post-treatment, combined with 20 open-ended patient interviews.

Multiple statistical comparison procedures were conducted on this sample in an effort to determine the effects of the independent variables of self-efficacy, social support, and self-rated health on the outcomes of pain and disability. Although the Type I error rate was set at alpha level of .05, it is possible with multiple comparisons to increase the chance of erroneously finding a statistically significant impact. This could inflate the Type I error rate for the combined multiple tests. The procedures that control for multiplicity to reduced Type I error rate also result in reduced statistical power. Due to the reduced statistical power already present with the small sample, correction for multiple testing was not conducted. Analysis focused on either the bivariate model independently examining each independent variable or the multivariate group model including all 4 independent variables of interest. Upon completion of the larger RCT data set, these analyses will need to be compared and correction procedures for multiple testing can be performed to appropriately reduce the chance for Type I error.

Another important limitation is that all of the measures were self-report. While the intent of using measures of pain and disability was to capture the patients’ perspective, comparing perceptions of pain and disability to actual physical measure of pain and/or disability in the future may also improve the understanding of patient perceptions in LSS. In addition, repeat assessments were performed at the 2 time points (entry and post-treatment). At this time, change scores were not analyzed to determine if there was a change in scores across the treatment and self-management period. Even though each time point was analyzed separately, there was the potential for learning effect by the patients on the repeat assessments. In addition, the use of self-report instruments creates certain limitations such as issues with patients’ memory being incorrect, incomplete memory, and misrepresentations due to patients attempting to show themselves positively. Patients may also have difficult interpreting questions and may unintentionally answer items incorrectly. In order to reduce these errors, the addition of the
qualitative interviews helped to triangulate the results and uncover patient beliefs, concerns, and their lived experience with LSS which enhanced the analyses in this study.

There were also limitations based on the type of analysis used in this study. Previously validated quantitative measures for self-efficacy, social support and perceived physical and mental health status were used to capture appraisal of these factors pre-treatment. The survey items were totaled and each measurement tool was converted to a total index score. This allowed the data to be examined through bivariate and multiple regression analysis and multicollinearity was not found to be present among the predictor variables, except in 1 of the significant findings which was eliminated. Both bivariate and multiple regression analyses were used since the factors examined have been minimally examined in other studies with patients with LSS. Bivariate analysis allowed for determining effect in isolation to identify the strength of the predictor. Next, multivariate regression was used as it is more clinically appropriate since patients rarely present with single factors in isolation. However, a closer investigation of the significant variables and their interactions is warranted as there was possible overlap between the measurement tools. A follow up study looking at individual items in the surveys would allow for a better understanding of the nature of the interactions uncovered in this study.

Only individuals who were referred to or self-referred to 2 spine clinics in Denver, Colorado and Greenville, South Carolina entered the study. Therefore, a crisis of representation was present since the small sample was not randomly selected from the larger population. The representation of findings is limited to patients in communities of similar geography, social, cultural and economic makeup. Since health insurance is not equally distributed locally or across the United States, all individuals with LSS did not have equal opportunity for participation. This sample reflects predominately Caucasians (73%) who were moderate to highly educated (42% graduated college) although only 18% worked full time and most were on a fixed income including social security benefits, military benefits, and a few with job related retirement income. This clearly does not represent all individuals with LSS, particularly those who lack access or
ability to engage in health care services due to limited financial resources or lack of knowledge of treatment options. However, having multiple sites does help to broaden the application of the study to capture a larger clinical representation of patients with LSS. In addition, the sample was well-matched to the actual LSS population in terms of diagnostic symptoms, gender, and median age.

Information gathered from qualitative interviews was collected and analyzed by only one researcher who was also a clinician and could therefore be biased. Using multiple perspectives from a qualitative research team would make the analysis even richer. However, triangulating the survey instruments with the patient interviews helped to confirm findings as well as uncover interpretations that would not be present in a single method design. In addition, the strength of adding the qualitative interviews allows the reader to make connections between the different elements of the study and their own experiences with negative health conditions. This allows for a more complex discourse by researchers, clinicians and policy makers regarding the many contributors to severity and health outcomes of pain and disability in LSS.

Finally, there were limitations based on the research design. Although validated measures were used, it is difficult to understand the phenomena observed from only a quantitative standpoint. The addition of qualitative data post-treatment helped to decipher appraisal and coping factors as they relate to the stressors of pain and disability. In addition, the qualitative data post-treatment allowed for the exploration of the meanings of these concepts in the patient’s own words. However, given the design of the study, any reports by the patients regarding pre-treatment appraisals were based on memory of their experiences upon entry to treatment and therefore subject to recall bias. An optimal design for a follow-up study would capture patients’ meanings of these concepts upon entry to treatment as well as post-treatment. Future research is warranted to further examine the expressions of patients with LSS at entry to treatment and all components of the Stress and Coping Model including primary appraisal, secondary appraisal, reappraisal and processes of coping.
Significance and Future Directions

As life expectancy and the number of older adults in our communities continue to increase, so does the need for research into improved treatment and effective support for patients with lumbar spinal stenosis. LSS is a chronic and disabling condition that cannot be eliminated but must be managed in the lives of those who have the condition. The effectiveness of treatment options is still in question particularly due to the limited contributing factors that have been identified up to this point related to the severity and outcomes of pain and disability in these individuals.

This study found that measurement of perceived physical and mental health upon entry to treatment may be an effective way to assess severity for heightened disability in LSS. In addition, assessing perceived physical health and self-efficacy for low back related tasks post-treatment may be particularly useful in terms of understanding coping behaviors in LSS to direct resources and improve outcomes. Increased education, physical therapy, counseling, and motivational support are all ways that these improved coping behaviors can be encouraged.

To date, this is the first study that has had the specific goal of understanding the appraisal and coping processes of patients with LSS. In addition, no intervention study has measured the levels of self-efficacy, self-rated health, and social support before and after treatment to determine the level of pain and disability that can be attributed to these factors alone. The empirical evidence demonstrating that perceived physical health and perceived mental health have been identified as significant predictors of pain and disability at entry to treatment, with perceived physical health and self-efficacy contributing post-treatment can be used as a starting point for intervention development. In addition, the role of social support needs to be further explored with interventions targeted to individuals during management of this chronic disease.

Current recommendations for clinical practice guidelines for LBP include the use of active pain coping strategies that decrease fear and catastrophizing,\textsuperscript{284} as well as psychosocial intervention.\textsuperscript{285, 286} At this time, these recommendations are for nonspecific LBP and none exist
for the chronic condition of LSS. The qualitative findings of this study can help to inform further qualitative investigation into psychosocial factors. This can include focus groups and other exploratory research in preparation for the development of an LSS intervention study. Additional qualitative research might use focus groups to confirm, challenge, or enhance findings from this study and/or identify novel factors that are of most relevance to patients with LSS. Added interviews or focus groups could also help to determine management strategies for patients needing greater self-efficacy, improved perceptions of their health as well as identifying and altering appraisals of social support as a coping resource.

More research is needed to determine the degree to which the findings of the present study are applicable to the broader population of patients with LSS, including different clinical sites, geographic locations and a wider variety of patients with differing socioeconomic status and insurance coverage. Also, future research should stratify subjects by treatment type to determine if psychosocial factors interact as moderators in the outcomes of pain and disability. Finally, additional research is needed to identify and determine effective ways to support patients with LSS using cognitive-behavioral and social strategies throughout the management continuum.

While substantial previous research into physical intervention has been completed in LSS, little is known about the long-term burden of pain and disability in this patient population including all factors that contribute to or ameliorate pain and disability in these individuals. Given limited resources, management programs that meet important psychosocial needs of patients with LSS effectively and efficiently can be developed at the entry and post-treatment periods. While more research is needed, the results of this study provide groundwork for identifying the psychosocial needs of patients with LSS through appraisals of the stressors of pain and disability and identification of supporting coping behaviors for this chronic and disabling condition.
REFERENCES


213. Lazarus RS. Patterns of adjustment. 1976.


APPENDIX A

MANUAL OF STANDARD OPERATING PROCEDURES

SUBJECT RECRUITMENT PROCEDURES:
Identify potential patients with low back pain (LBP) and lower extremity symptoms. These will only be patients who are referred to the physician and diagnosed with lumbar spinal stenosis (LSS). Do not “cold-call” previous patients to participate in this study or invite individuals who may call about the possibility of participating. Only take patients from physicians at the University Spine Clinic. The physician will describe the study to the patient and invite them to participate.

INFORMED CONSENT:
Have subjects read and sign the Informed Consent document. All subjects must complete the Informed Consent document prior to any data collection procedures can begin. Any of the participating clinicians may consent a patient to participate; however, no other individuals may consent a patient into the study. Ensure the patient initializes all pages of each of the two copies of the Informed Consent document (except for the last page where their signature will be present). Both copies should then be signed by one of the participating clinicians in the “Investigator’s Signature” block and by another clinic staff member in the “Witness Signature” block. Do not have a friend or family member of the subject sign in the “Witness Signature” block. Hand one copy of the Informed Consent document to the subject for them to keep and place the other copy of the Informed Consent document in the unmasked folder in a secure location that is separate from the masked study folder which contains the majority of the subject’s data collection records. Patients are considered enrolled into the study once they sign this statement.

INCLUSION/EXCLUSION CRITERIA:
The physician, resident, or physician’s assistant will screen subjects according to the inclusion/exclusion criteria.

Inclusion Criteria:
In order to be eligible for participation an individual must satisfy all of the criteria listed below:

1. Lumbar spinal stenosis identified by MRI or CT scan and interpreted by a radiologist independent of the study. The criteria of Boden et al\textsuperscript{287} will be used to define LSS on MRI: non-discogenic loss of signal in the epidural fat with compression of neural tissues.
2. Chief complaint of pain in the low back, buttock, and/or lower extremity(s). The patient must have LE symptoms consistent with neurogenic claudication or radicular pain.
3. Patient-reported difficulty walking due to lower extremity pain and/or cramping.
4. Rates sitting as a better position with respect to symptom severity compared to standing or walking.
5. Consent of the patient to undergo education, epidural steroid injection(s), and attend specified physical therapy sessions.
6. Individuals with no language barrier, that are cooperative, have transportation to the Spine Center, and who sign an informed consent form.
7. Age greater than or equal to 50 years.

Exclusion Criteria:

An individual meeting any one of the following criteria will not be eligible for participation:

1. Patients with organic brain syndrome or dementia.
2. Severe vascular, pulmonary or coronary artery disease which limits ambulation.
3. Recent myocardial infarction (within last 6 months).
4. Spondylolisthesis requiring surgical fusion (i.e., greater than 5mm of slippage).
5. Previous spinal surgery that included fusion of two or more vertebrae.
6. Severe osteoporosis as defined by multiple compression fractures or a fracture at the same level as the stenosis.
7. Metastatic cancer.
8. Excessive alcohol consumption or evidence of non-prescribed or illegal drug use.
9. Other orthopedic conditions or physical impairments of unrelated nature which would limit ambulation or prevent the subject from fully participating in any aspect of the rehabilitation exercises.
10. Epidural steroid injection within the last 365 days.
11. Vascular or other non-musculoskeletal condition other than LSS suspected to be the primary source of the patient’s symptoms.

Be sure to keep track of subjects that you screen but who do not meet the eligibility criteria on the “Tally Sheet for Subject Ineligibility/Refusal” tracking form provided. It is designed so all that is need to place a tick mark next to the pertinent inclusion/exclusion criteria. Next the patients will undergo the baseline examination. The research packet includes the following forms:

**NOTE:** Once the baseline physical exam is completed by the physician, the patient will meet with an office assistant who will assist with completion of the following.

1. 3 copies of the Informed Consent document
2. Subject ID-Name Link
3. Numeric Pain Rating Scale (NPRS)
4. Oswestry Disability Questionnaire (OSW)
5. Spinal Stenosis Scale (SSS) form
6. Medical Outcomes Study (MOS) SF-36 form
7. Beck Depression Index (BDI) form
8. MOS Social Support Survey
9. Low Back Confidence Scale (LoBACS)
10. Demographic Information form
11. Physical Examination form

**COMPLETION OF FORMS**

Be sure that subjects and clinicians complete every form and all items of every form. It is easy to skip over questions and components of the form, and some of these items may be key pieces of
information necessary to properly analyze the data. I would recommend that you verify the completeness of every form as subjects hand them back to you and after clinicians complete any forms. By doing this, if an item is missing, you can immediately have them complete the item, rather than having them recall the information several days after the form was completed.

**Guide to the Baseline Physical Examination Performed by Physician:**

**Date of onset:** The subject has already recorded this once on p. 1 of the Demographic Information form; however, please ask this question again to confirm the subject gives you the same answer. The date of onset should be with respect to the most recent episode for which they are currently presenting, not the date at which they first ever had an episode of back pain.

**I. Historical Information**

**1. Mode of Onset:**

Three options are available, only one may be chosen:

1. Gradual - Patient is unable to identify a discrete moment when LBP or buttock/leg pain began.
2. Sudden (Minimal/No Perturbation) – LBP or buttock/leg pain began at a discrete moment in time, but was not associated with any abnormal movements or trauma, or was associated with an routine activity that involves very low stresses (e.g. picking up a light object from the floor)
3. Traumatic - LBP or buttock/leg pain began at a discrete moment, and was associated with an event or activity involving moderate or high stress on the spine.

Chose the most appropriate option describing the circumstances surrounding the onset, or select other and explain.

**2. Distribution of Symptoms:**

This information should be gathered from the pain diagram and confirmed by asking the patient if the diagram accurately reflects the symptoms that he or she experiences. Each of the five anatomical areas should be specified with the appropriate symptom distribution or marked as “No Symptoms”. The options for the type of symptoms, location, and nature are mutually exclusive, thus only one option may be selected for each area.

1. Lumbar spine is defined as the area at or above the lumbosacral junction. Central symptoms occur at or very near the spinal column. Bilateral symptoms occur to both sides, but occur outwards from the spinal column. Right or left refer to symptoms occurring out from the spinal column on one side only.

2. Buttock refers to the area below the lumbosacral junction and above the gluteal fold. Central symptoms occur along or very near the sacrum spinal processes. Bilateral symptoms occur to both sides, but occur outwards from the sacral spinous processes. This would include the region of the PSIS and sacral sulcus. Right or left refer to symptoms occurring out from the sacral spinous processes, including the regions of the PSIS and sacral sulcus but on one side only.
3. Groin refers to the inguinal region of the proximal anterior thigh.

4. Thigh is the area below the gluteal fold and above the popliteal fold of the knee on the posterior aspect of the leg.

5. Lower leg/foot is the area below the popliteal fold of the knee.

The nature of the symptoms in each of the anatomical areas is described in one of three ways, only one option may be chosen for each anatomical region:

- Constant - Always present with no variation in intensity
- Intermittent - Present at times, completely absent at other times
- Variable - Always present, but intensity varies

3. Ordering of Symptoms:

The patient is asked to identify which posture (sitting, standing, and walking) is the worst and best with regards to symptoms. More than one posture may be selected for each category (best and worst); however, the same posture should not be checked for both categories. A posture may only be identified for one of the categories, with the other left blank (e.g. walking is clearly the worst, and sitting is identified as best).

4. Prior History of LBP or buttock/leg pain:

a. The patient is asked about prior episodes of pain that have caused him to reduce his functional activity level. If the answer is no, the subsequent questions are not answered.

b. The number of prior episodes is established into one of the four categories listed.

c. The frequency of prior episodes is established into one of the three categories listed.

d. The location of symptoms of previous episodes is established. If any of the prior episodes involved leg pain, this option is marked. Both options may be marked.

e. The events leading up to prior episodes are determined; more than one option may be selected if the patient has had multiple prior episodes.

f. The patient is questioned regarding any treatments attempted for previous episodes. If a treatment has been used, the response to the treatment is ascertained.

II. Neurological Screening

1. Sensory Examination:

Sensory examination is carried out with pin prick examination in the specified anatomic areas bilaterally, while the patient has his eyes closed. The patient is asked if the sharp sensation is of equal intensity on both sides (WNL), or if one side feels more dull than the other (Diminished), or if one side is unable to be felt (Absent).

2. Motor Examination:
Manual muscle testing is performed bilaterally. Grading is either WNL (equal bilaterally) or diminished (less strength than the other side). Each movement is also assessed as painful or not painful during testing. All testing is performed with the patient seated:

- **Hip flexion** - the hip is flexed to near end range and pressure is applied to the anterior thigh into hip extension.
- **Knee extension** - The knee is placed in a position slightly less than full extension. One hand stabilizes the patient’s thigh, while the other applies pressure on the anterior tibia into knee flexion.
- **Dorsiflexion** - The foot is placed in full dorsiflexion with some inversion. One hand stabilizes the distal tibia, while the other hand applies pressure on the dorsum of the foot into plantar flexion with some eversion.
- **Plantarflexion** – The foot is placed in full plantarflexion with some eversion. One hand stabilizes the distal tibia, while the other hand applies pressure on the sole of the foot into dorsiflexion with some inversion.
- **Hallux Extension** - With the shoes off, the great toe is placed in extension. One hand stabilizes the foot, while the other hand applies pressure on the dorsum of the distal phalanx of the great toe into flexion.

### 3. Deep Tendon Reflexes:

Reflexes of the lower extremity are tested bilaterally with the patient seated. The quadriceps reflex is tested by tapping the patellar tendon and observing for knee extension. The ankle (Achilles) reflex is tested by grasping the patient’s foot and placing it into slight dorsiflexion. The Achilles tendon is tapped and the examiner observes and feels for ankle plantar flexion. Reflexes are graded as “WNL” when equal to the other side, “Diminished” if a response is of reduced vigor as compared to the other side, or “Absent” if no response is elicited.

### 4. Tension Signs:

1. **Straight Leg Raise** is performed with the patient supine and the head relaxed on a pillow and both hips and knees extended resting on the table. The examiner grasps under the ankle on the side to be tested and passively lifts the leg. The leg should remain straight and in neutral hip rotation. The leg is lifted until the patient reports that pain is produced. A test is considered positive when raising the leg less than 45° reproduces pain in the lower extremity (below the knee).

2. **Slump Test** is performed with the patient in sitting. The patient begins the test sitting in an upright position. The examiner passively flexes the patient’s spine and neck. The examiner then passively extends the patient’s knee and dorsiflexes the patient’s ankle. The examiner notes any report of pain from the patient. The test is repeated on the contralateral lower extremity. The test will be coded as 1) no reproduction of familiar symptoms, 2) reproduction of the patient’s LBP, 3) reproduction of patient’s LE symptoms proximal to the thigh, 4) reproduction of patient’s LE symptoms distal to the thigh.

3. **Femoral Nerve Stretch** is performed with the patient prone or prone with a pillow under the abdomen if the patient can not tolerate flat prone lying. The examiner passively flexes the
patient’s knee and notes any report of pain from the patient. The test is considered positive if pain is reproduced in the patient’s anterior thigh. This is determined by evaluating the location and nature of the pain produced during the test movement. If the anterior thigh symptoms are reproduced, the test is judged to be positive. However, if pain is reproduced only in the back, the test is judged to be negative.

III. Additional Physical Examination

1. Postural Observation:

The posture is observed. Postural deformities should be considered as postural adaptations to injury or pain, not normal variants of posture frequently observed in both healthy and symptomatic individuals (e.g. reduced or accentuated lumbar lordosis). Three options are possible. Both an acute kyphosis and a lateral shift may be present in the same individual:

1. WNL – This should be the selection if and acute kyphosis and a lateral shift are not present. In other words, if you are having to debate about the presence of an acute kyphosis or a lateral shift, mark it as WNL.
2. Acute Kyphosis - A frontal plane deformity in which the patient adopts a flexed posture due to injury or pain.
3. Lateral Shift - A sagittal plane deformity in which the shoulders are notably displaced to the left or right in the frontal plane with reference to the pelvis. The direction of the lateral shift is determined by the direction of the shoulders relative to the pelvis.

2. Range of Motion Provocation:

The patient will be taken through a range of motion for the lumbar spine, SI joint, and hip joint to determine pain provocation in both supine and standing positions. A positive pain provocation is indicated when the patient reports pain during the ROM testing procedure. The position of the joint range and the pain severity from 1-10 will be recorded for any pain provocation test.

3. Distal Pulses, Vital Signs:

The distal pulses and vital signs of the subjects will be taken. Distal pulses will include pulses found on the dorsal portion of the foot (dorsalis pedis) and behind the ankle (posterior tibial). Pulses will be recorded as normal, abnormal, or absent. Vital signs will include resting heart rate and resting blood pressure.

4. Body Mass Index:

The Body Mass Index (BMI) will be recorded by measuring the weight (lbs) and height (inches) of the subjects. These values will be calculated and compared to normative values based off of the 2007 American College of Sports Medicine Guidelines.

ASSIGNMENT OF SUBJECT ID
Once the baseline physical examination, and the MRI has been read, and the inclusion/exclusion criteria has been verified, assign the patient a Subject ID. Then, once the patient completes the Informed Consent document they will report to one of the office staff at the Spine Center and will be given the questionnaires listed above. Once the questionnaires are completed they will be randomly assigned to either the ESI or ESI+PT group.

### RANDOMIZATION

Once the patient completes the self-report measures, the office staff member will open the randomization envelope indicating the patient’s treatment group assignment that corresponds to the patient’s unique identification number. A random number generator will be used to establish randomization lists prior to the initiation of the study. Individual randomization assignments will be concealed according to the following procedure: 1) The group assignment will be recorded on a label that is affixed to a 3.5 X 5 inch index card; 2) This card will be folded in half such that the label with the patient’s group assignment will be on the inside of the fold; 3) The folded index card will then be placed inside the envelope, and the envelope will be sealed.

Assign subject ids in a consecutive order as subjects are enrolled into the study. In other words, just take the next envelope on top of the stack. Do not skip envelopes for any reason. Upon opening the envelope, the office staff will instruct the patient to either 1) schedule an appointment with the physician for their first epidural injection (ESI group), or 2) schedule an appointment with the physician for an epidural injection and schedule an initial physical therapy visit (ESI+PT group). Patients in the ESI group will follow-up within 10 days with the treating physician for ESI. Patients in the ESI+PT group will follow-up within 10 days with the treating physician for ESI and schedule an appointment with a licensed physical therapist. Patients will be monitored to confirm they have made their follow up appointments by the study coordinator. Patients who do not schedule their appointments as instructed will be called by the study coordinator to assist the patient in progressing to the treatment stage.

### TREATMENT PROCEDURES

#### Epidural Steroid Injection Group (ESI)

**Epidural Steroid Injection Treatments:**

Patients in the ESI Group will be treated with 2-3 epidural steroid injections, standardized educational support, and general care by the treating physician. Prior to the injection, the physician will verbally confirm that the patient does not have any allergies and is not taking blood thinners. Standardized technique as described by Botwin et al. will be used for all epidural steroid injections. Plain radiographs in the anteroposterior and lateral views will be taken after all injections to document both the contrast pattern and needle placement. All patients will be monitored by pulse oximetry, blood pressure, and electrocardiogram before, during, and after the procedure. Patients will be transferred to the recovery unit for 40 min. All patients will be seen by the physician who performed the injection and by a registered nurse before discharge. Patients will be instructed to perform activity as tolerated throughout the time of the study. A maximum of two to three ESI will be given in total to each patient throughout the study according to a clinical
### Algorithm for ESI Treatment

The number of injections received by each individual and any medications taken will be recorded and analyzed to determine similarities between groups. The patient will receive maximum of 2-3 epidural steroid injections during the RCT for lumbar spinal stenosis following the algorithm listed below:

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Make verbal confirmation</td>
<td>Before starting treatment, make verbal confirmation that the patient 1) does not have any allergies, and 2) is not on any blood thinning medications.</td>
</tr>
</tbody>
</table>
| 2. 1<sup>st</sup> Injection | Identify the level of greatest stenosis pathology according to MRI or CT scan that correlates the most to the patient’s symptoms. 
- Use a transforaminal approach at the level identified. 
- Determine if bilateral sites (2 injections at both sides of the level identified) or unilateral site (1 injection on only one side of the level identified). If >90% of the patient’s symptoms are one only one side, perform unilateral site injection. Otherwise, perform bilateral site injection. 
- Utilize exactly 1.5ml of steroid at each site injected. |
| 3. Re-assess 3-4 weeks for possible 2<sup>nd</sup> injection | If patient reports >90% improvement in overall symptom; discontinue injections. 
- If patient reports 50-90% improvement in overall symptoms; repeat injection #1 procedure at the same level indicated. 
- If patient reports <50% improvement in overall symptoms; change levels to above or below 1<sup>st</sup> injection determined by stenosis pathology indicated at other levels on MRI or CT scan and patient symptoms. |
| 4. Re-assess 3-4 weeks for possible 3<sup>rd</sup> injection | If patient reports >90% improvement in back/buttock/leg pain; discontinue injections. 
- If patient reports 50-90% improvement in back/buttock/leg pain; repeat injection #1 procedure at the same level indicated. 
- If patient reports <50% improvement in back/buttock/leg pain; change levels to above or below 1<sup>st</sup> and 2<sup>nd</sup> injection determined by stenosis pathology indicated at other levels on MRI or CT scan. |
| 5. Re-assess 3-4 weeks after 3<sup>rd</sup> injection | Determine the level of patient reported improvements in back/buttock/leg pain at this time and document overall symptom improvements or changes. 
- No further epidural steroid injections at this time. |
ESI + Physical Therapy Group (ESI + PT)

Epidural Steroid Injection Treatments (same as ESI group above)

Physical Therapy Examination that Therapists will Use to Determine Progression of Interventions:

I. Standing Examination

1. Single Movement Testing and Status Change with Trunk Movements:

Active range of motion is tested with the patient standing. Single movement testing is performed. The patient is first asked about his symptoms while standing, prior to any movement testing. The patient is instructed that these symptoms will serve as a baseline level, and it is the change in symptom location and/or intensity that should be reported. The range of motion values are measured in the following manner:

Single Movement Testing:

- Total Flexion - The center of the inclinometer is centered over the spinous process of T12. The inclinometer is zeroed. The patient is instructed to bend forwards as far as possible without bending the knees.
- Left and Right Sidebending - The spinous process of T12 is identified. The center of the inclinometer is placed just above this point parallel to the axis of the spinal column, and is zeroed. To measure right sidebending, the inclinometer is placed on the left side and to measure left sidebending, the inclinometer is placed on the right side. The patient is instructed to bend to the right or left as far as possible with the fingertips reaching as far down the side of the thigh.
- Extension - The center of the inclinometer is centered over the T12 spinous process. The inclinometer is zeroed. The patient is instructed to run their hands down along the back of the thighs while bending backwards. The patient is to bend backwards as far as possible without bending the knees. After this movement, have the patient bend perform an easing movement (bend forward, sit, etc) until any symptoms elicited ease.
- Sustained extension (up to 15 seconds) or repeated movements (up to 5) to assess production of symptoms (ask specifically if symptoms are above or below the gluteal folds)
- From the active movement testing, determine an “asterisk” sign that will be utilized for reassessment.
- Quadrant testing with overpressure may also be used (extension with side bending and rotation to the same side). The treating therapist would most often opt to perform this test if other ROM and provocative testing has not reproduced the patient’s familiar symptoms.

Status Change with Trunk Movements:

With each movement performed, the examiner makes a judgment as to whether the patient’s symptoms are improved or worsened after each movement. The examiner should also record whether the improvement or worsening in status is due to changes in pain (“My pain is worse.”) or “Now my pain is less.”) or changes in the location of the symptoms (“My symptoms have moved up my leg closer to my back” or “My symptoms have moved closer to my foot.”). Centralization
of symptoms should indicate an improvement in status, and peripheralization of symptoms with movement should indicate a worsening in status. Only one term (“Improve” or “Worsen”) can be used with each movement tested. However, it is possible that with flexion, for example, the patient’s symptoms may centralize (i.e. improvement in status), but the patient may describe their pain as getting worse. If this is the case, alterations in paresthesias take precedence over alterations in pain, thus this patient would be judged to have improved with this movement, and the improvement would be marked as occurring because of centralization. Improvement and worsening in status are defined below:

1. **Worsen** -
   a. Symptoms present (or produced) increase in intensity with the test movement. When the neutral position is resumed the intensity remains higher than baseline for at least 30 seconds after completion of the movement.
   b. Or, a paresthesia is produced which was not present prior to the movement,
   c. Or, a pain or paresthesia moves distally away from the spine
2. **Improve** -
   a. Symptoms present are diminished or abolished during the movement. When the neutral position is resumed, the symptoms remain decreased in intensity for at least 30 seconds.
   b. Or, a paresthesia present at rest is abolished.
   c. Or, a pain or paresthesia moves centrally towards the spine.
3. **Status Quo (ISQ)** -
   a. Test movement does not cause improving or worsening of symptoms

II. **Seated Examination**

1. **Motor:**
   The following key muscles will be tested:
   - Hip flexion (L1-L2) - the hip is flexed to near end range and pressure is applied to the anterior thigh into hip extension.
   - Knee extension (L2-L4) - The knee is placed in a position slightly less than full extension. One hand stabilizes the airman’s thigh, the other applies pressure on the anterior tibia into knee flexion.
   - Dorsiflexion (L4-L5) – The best way to test dorsiflexion is with heel walking. For a non-weightbearing test, the foot is placed in full dorsiflexion with some inversion. One hand stabilizes the distal tibia, the other hand applies pressure on the dorsum of the foot into plantarflexion with some eversion.
   - Great Toe Extension (L5) - With the shoes off, the great toe is placed in extension. One hand stabilizes the foot, the other hand applies pressure on the dorsum of the distal phalanx of the great toe into flexion.
• Ankle Eversion (S1-S2) - The foot is placed in full eversion and plantarflexion. One hand stabilizes the distal tibia, the other applies pressure on the lateral aspect of the foot into dorsiflexion and inversion.
• Ankle Plantarflexion (S1-S2) – The foot is placed in full plantarflexion. One hand stabilizes the distal tibia, the other applies pressure on the plantar aspect of the foot into plantarflexion.

2. Muscle Stretch Reflexes:
The Achilles’ reflex is performed to test the integrity of the S1-S2 nerve roots. The patient is seated and relaxed with the ankle supported at approximately neutral dorsiflexion. The Achilles tendon is struck with the reflex hammer and reflexive plantarflexion is felt with the supporting hand. The patellar tendon reflex is performed to test the integrity of the L2-L4 nerve roots. The patient is seated with the knee flexed to approximately 90°. The patellar tendon is struck with the reflex hammer and reflexive knee extension is observed.

3. Babinski Test:
The Babinski responses will be tested bilaterally to assist in ruling out upper motor neuron disease. The test is performed with the patient sitting and relaxed. The examiner places a moderately sharp object (end of the handle of a reflex hammer) at the lateral plantar surface of the foot near the heel and, with moderate pressure, strokes the foot on the lateral surface to the ball of the foot medially. Extension of the great toe and fanning of the other toes is considered a present Babinski Sign, which is considered abnormal in mature adults.

4. Sensation:
Evaluation for sensory loss is performed by lightly brushing the hand over key dermatomal regions. Any deficit noted should be tested further with the use of a pin to clearly map out the area of sensory deficit.
• Inguinal area (L1)
• Anterior mid-thigh (L2)
• Distal anterior thigh and medial knee (L3)
• Medial lower leg and foot (L4)
• Lateral lower leg and foot (L5)
• Posterior calf (S1)
• Medial calcaneus (S2)

III. Supine Examination

1. Capsular mobility of the hip:
The passive accessory mobility of the hip will be assessed by applying passive glides to end range into:

- Distraction
- Caudal glide
- Posterior glide

3. **Modified Thomas Test:**

The patient is supine sitting on the edge of the table with the pelvis level and square to the trunk. The patient flexes both hips (with the help of the examiner) and brings the thighs up towards the trunk. The pelvis is stabilized by placing a hand under the patient's lumbar spine. The patient holds one leg to his/her chest and lets the other leg lower down until it is flat on the table. If the thigh does not reach horizontal, the psoas major or the rectus femoris may be tight. The knee is then extended. If the hip extends further, the test is positive for a tight rectus femoris, if it does not extend to neutral, then at least the psoas is tight (and perhaps the rectus femoris is tight, too).

4. **Hip Flexion Test:**

With the subject in the supine position, the primary examiner passively flexes the hip to 90° and zeroes the inclinometer at the apex of the knee. The hip is then flexed until the opposite thigh begins to rise off of the table (be sure to adjust the patient’s clothing so that tight or restrictive clothing does not interfere with the test). A measurement is taken. The hip is then passively moved into end range flexion with gentle overpressure. The effect on symptoms is recorded.

5. **Quadrant test of the hip:**

With the subject in the supine position, the examiner passively flexes, adducts and internally rotates the hip such that the knee is guided towards the contralateral shoulder while applying gentle overpressure and compression through the axis of the femur. The amount of motion and the degree of patient discomfort is noted.

6. **FABER Test:**

The FABER test is administered with the subject in supine, the heel of the lower extremity to be tested placed over the opposite knee. If the patient does not have enough mobility for this position, rest the ipsilateral foot on the table just medial to the contralateral knee) The hip joint is passively externally rotated and abducted by placing pressure over the ipsilateral knee, while stabilizing the contralateral innominate. After being zeroed against a wall, an inclinometer is placed on the medial tibia of the lower extremity to be tested, just distal to the medial tibial condyle. The range of motion is measured at the point of maximal passive resistance or at the point where the subject stops the test secondary to pain.

7. **Transversus abdominis (TrA) testing:**
The therapist will palpate the muscle medial and inferior to the ASIS and ask the subject to slowly draw their navel up and in towards the table. Therapist should feel a tensioning under their fingers with retraction of the abdominal wall posteriorly without a “bulging” sensation which would indicate contraction of the internal oblique. Patients will be instructed in TrA exercises as described below.

IV. Sidelying Examination

1. Hip abduction strength:

In sidelying, the therapist will passively lift the subject’s leg into end range abduction while maintaining the hip in a neutral sagittal plane position. The patient will then be asked to hold the leg up against gravity. If the patient is able to hold the leg up, the therapist will assess the strength by attempting to push the leg down towards the table. A judgment will be made as to whether the hip abductors are normal or weak.

V. Prone Examination

1. Spring Testing of the Thoracic and Lumbar Spine:

Spring testing in prone (can use up to two pillows) is performed over the spinous processes of the thoracic and lumbar vertebrae and the sacrum. Spring testing is both a provocation test and a test of segmental mobility. The following options are available for each level tested:

- Normal Mobility - Passive mobility is judged to be normal.
- Hyper/Hypomobile - Judgments based on the passive mobility of the tested segment relative to adjacent segments and the expectation of the examiner. One of the two options may be selected.
- No Pain - No painful symptoms are produced.
- Pain - Judgment based on the provocation of pain. Local refers to pain produced directly under the examiner’s hand, whereas distant pain refers to provocation at an anatomical area not directly under the examiner’s hand. One of the two options may be chosen.

Spring testing is performed by placing the hypothenar eminence of the hand over the spinous process of the segment to be tested. With the elbow and wrist extended, the examiner applies a gentle but firm, anteriorly-directed pressure on the spinous process. Interpretation of whether a segment is hypomobile should be based on the examiner’s anticipation of what normal mobility would feel like at that level and compared to the mobility detected in the segment above and below. In previous studies of similar subjects, it was unusual for examiners not to identify at least one hypomobile segment.

3. Measurement of hip internal rotation (IR) and external rotation (ER):

The patient lies prone. The examiner places the opposite leg of the leg to be measured in 30° of hip abduction to enable the tested hip to be freely moved into external rotation. The lower extremity of the side to be tested is kept in line with the body, and the knee on that side is flexed to 90° with the ankle in the neutral position, and the leg in the vertical position. The inclinometer is first zeroed on a vertical surface and then placed on the distal aspect of the fibula in line with the bone. The leg should be oriented in such a fashion that the inclinometer reads zero degrees.
Measurement of hip IR (hip rotated in a lateral direction [leg moved toward the edge of the plinth) and ER (hip rotated in a medial direction [leg moved toward the middle of the table]) is recorded at the point in which the pelvis first begins to move. The measurement should be recorded bilaterally. The effect of overpressure at end range will also be assessed.

4. Measurement of hip extension:

The patient lies prone (if tolerated). Stabilize the pelvis by using one hand to push the ischial tuberosity towards the table, and then passively extend the hip. Use up to 2 pillows under the abdomen if needed for comfort.

This should be performed bilaterally and the clinician should make a judgment if it is tight or restricted. If the hip does not extend to ≥ 10 degrees extension, the examiner should record this as restricted or limited hip extension. The effect of overpressure at end range will also be assessed.

5. Hip extensor strength:

In prone, the therapist will passively lift the subject’s leg passively into end range hip extension while maintaining the hip in neutral in regards to abduction and adduction and the knee in full extension. The patient will then be asked to hold the leg up against gravity. If the patient is able to hold the leg up, the therapist will assess the strength by attempting to push the leg down towards the table. A judgment will be made as to whether the hip extensors are normal or weak. Note that the clinician should take precautions against aggravating the patient’s LBP and LE symptoms while testing the patient as needed (have patient tighten the abdominal muscles, use a pillow under the abdomen, reduce the degree of hip extension for testing, etc).

Physical Therapy Treatment:

Patients randomly assigned to the physical therapy group will be treated in physical therapy for 8-10 weeks, with a frequency of 1-2 visits per week for the first 6 weeks and 1 visit every two weeks for the following 4 weeks with no more than 10 visits total. Each patient will also receive additional instruction in an individualized home exercise program that will be updated during the treatments. The algorithm for physical therapy treatments can be found below:

The patient will receive interventions targeting lumbo-pelvic impairments on day one. Other interventions indicated based on the algorithm below and will be provided no later than the end of the third visit. Prioritization is as follows: 1) lumbo-pelvic spine, 2) hips / hip flexors; 3) abdominal muscles / ‘stabilization’ exercise; 4) thoracic spine mobility.

SUBJECT PAYMENT

Subjects will be paid $50.00 for each of the five re-evaluation packets of the study, for a total of $250.00 compensation. Additionally, subjects who participate in the qualitative interview with the PI will receive an additional $25 for completion of the interview. Subjects will receive one check at the end of their participation in the study for the degree of the study completed. Remind
subjects that payment usually takes from 6-8 weeks from the time the therapist faxes me the completed payment form.

**DATA MANAGEMENT**

*Completed* study folders will be packaged in a box and picked up by the PI, Amy Hammerich. Make sure the folders will not be able to excessively move inside the box, or it could become difficult to re-organize the data back to the correct subject.
APPENDIX B

IRB APPROVALS

1. COMIRB – University of Colorado Multidiciplinary Investigator Review Board
2. Hawkins Foundation – Greenville Hospital System
Certificate of Approval

07-Apr-2009

Investigator: Venu Akuthota
Sponsor(s): American Physical Therapy Association
Subject: COMIRB Protocol 09-0075 Initial Application
Effective Date: 03-Apr-2009
Expiration Date: 02-Apr-2010
 Expedited Category: S
Title: Epidural Steroid Injection Versus Epidural Steroid Injection, Manual Physical Therapy, and Exercise in the Management of Lumbar Stenosis: A Randomized Clinical Trial.

All COMIRB Approved Investigators must comply with the following:

- For the duration of your protocol, any change in the experimental design/consent and/or assent form must be approved by the COMIRB before Implementation of the changes.
- Use only a copy of the COMIRB signed and dated Consent and/or Assent Form. The Investigator bears the responsibility for obtaining from all subjects "Informed Consent" as approved by the COMIRB. The COMIRB REQUIRES that the subject be given a copy of the consent and/or assent form. Consent and/or assent forms must include the name and telephone number of the Investigator.
- Provide non-English speaking subjects with a certified translation of the approved Consent and/or Assent Form in the subject's first language.
- The Investigator also bears the responsibility for informing the COMIRB immediately of any Unanticipated Problems that are unexpected and related to the study in accordance with COMIRB Policy and Procedures.
- Obtain COMIRB approval for all advertisements, questionnaires and surveys before use.
- Federal regulations require a Continuing Review to renew approval of this project within a 12-month period from the last approval date unless otherwise indicated in the review cycle listed below. If you have a restricted high-risk protocol, specific details will be outlined in this letter. Non-compliance with Continuing Review will result in the termination of this study.

You will be sent a Continuing Review reminder 75 days prior to the expiration date. Any questions regarding this COMIRB action can be referred to the Coordinator at 303-724-1095 or UCHDC Box F-490.

Sincerely,

UCD Panel B
November 9, 2012

Thomas Denninger, DPT, CSCS
Attn: Allyson Sandago, MPH, ATC
The Hawkins Foundation
200 Patewood Drive, Suite C-100
Greenville, SC  29615

RE: IRB File #Pro00013317

Study Title: Epidural Steroid Injection versus Epidural Steroid Injection and Manual Physical Therapy and Exercise in the Management of Lumbar Spinal Stenosis: A Randomized Clinical Trial

Items Submitted for IRB Review: Protocol and Consent Form Continuing Review

Dear Dr. Denninger:

On November 5, 2012, the Chairman of the Institutional Review Board/Committee-A (IRB) of the Greenville Hospital System reviewed the continuation of your above-mentioned study. Expedited approval was given for one year.

Your study will expire on November 4, 2013. It is the investigator’s responsibility to make sure the proper reapproval information is submitted to the IRB. This information must be submitted to the IRB in October 2013.

The same requirements as previously outlined for you by the IRB remain in effect as long as the study is ongoing. Please refer to your initial approval letter for these requirements. Thank you for your assistance in this matter. If you have any questions, please feel free to call the IRB Office at 455-4984.

Sincerely,

Christopher C. Wright, MD, Chairperson
Institutional Review Board / Committee-A
900 West Faris Road
Greenville, SC  29605
APPENDIX C

INFORMED CONSENT

1. University of Colorado
2. Hawkins Foundation
Consent Form Approval

Date: APR 3 2009

Valid for Use Through: 04/02/10

COMIRB

Study Title: Epidural Steroid Injection versus Epidural Steroid Injection, Manual Physical Therapy, and Exercise in the Management of Lumbar Spinal Stenosis; a Randomized Clinical Trial

Principal Investigator: Venu Akuthota, MD
COMIRB No: 09-0075
Version Date: 3-27-09
Version #: 3

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don’t understand before deciding whether or not to take part.

Why is this study being done?

You have been asked to consider participation in this study because you have the type of lower back pain and / or leg pain that may come from lumbar spinal stenosis. The purpose of this study is to determine the effectiveness of various treatment techniques for spinal stenosis. Spinal stenosis is a type of spinal problem that is caused by a narrowing of the spaces around the nerves in your lower back. Individuals with spinal stenosis typically have some lower back pain and symptoms that go into the buttocks, thigh, or lower leg. This study is designed to provide information on factors which may help predict who will respond to non-surgical treatment for spinal stenosis and to compare different forms of testing and treatment for individuals with this condition.

Other people in this study

Up to 80 people from your area will participate in the study over a period of 3 years. As a participant, you will be randomly assigned to one of two treatment plans. Randomization is a process like flipping a coin and means you will have a chance of being assigned to either of the treatment plans.

What happens if I join this study?

As a participant, you will undergo a standard evaluation by a Physician including obtaining a current magnetic resonance image (MRI) of your lower back. MRI is a test that uses radio waves and magnetic field to provide detailed images of particular parts of the body. There is no exposure to x-ray radiation with MRI. It is extremely common for individuals with lower back pain and leg pain to be evaluated with this test. You will answer questionnaires regarding your back and leg pain before you start treatment. You will be required to attend anywhere from two to fifteen regular outpatient visits at the Spine Center at the University of Colorado and the Physical Therapy Program at

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Anschutz Medical Center for a maximum of 12 weeks. After 3 months, 6 months, 12 months, 24 months and 36 months after completion of the treatment, you will be asked to answer multiple questionnaires regarding your pain and functional abilities to do daily activities. The total number of appointments required will be one for evaluation by a specialist and up to fourteen visits for testing and treatment by clinicians.

If you are in Group One, you will be instructed in exercises designed to improve the motion of your spine and hips. You will be asked to continue your exercises at home as well as start an aerobic conditioning program either walking or cycling. Also, you will receive a book of instructions on how to take care of your lower back and avoid motions that will irritate your lower back. In addition, you will receive 1-3 epidural steroid injections from your physician that will help reduce your lower back pain and allow you to continue physical activity.

If you are in Group Two, you will be instructed in exercises designed to improve the motion of your spine and hips. Also, you will receive a book of instructions on how to take care of your lower back and avoid motions that will irritate your lower back. You will receive 1-3 epidural steroid injections from your physician that will help reduce your lower back pain and allow you to continue physical activity. You will also undergo an individualized manual therapy and exercise program that will help improve motion in your spine and hips. The manual therapy consists of joint mobilization using a variety of techniques commonly employed by physical therapists. In these treatments, the therapist will manually stretch various joints, to include your lower back and your hip joints. The therapist will also help you stretch muscles in your buttocks and legs. You will see the therapist 1-2 times per week for a maximum of ten weeks for treatment. In addition, you will walk on a treadmill or ride a bicycle 1-2 times per week. Personnel from the Physical Therapy department will supervise your aerobic program.

Upon completion of the treatment program, individuals from both treatment groups will be asked to fill out the same questionnaires you completed prior to the treatment program. All treatments are standard care procedures with known beneficial effects for patients with lumbar spinal stenosis.

What are the possible discomforts or risks?

Individuals with pacemakers, nerve stimulators, or any biomedical implants, such as cochlear implants or aneurysm implants, cannot be scanned in the MRI. Also, if you were ever a metal worker or have done metal-work as a hobby, you may have small metal fragments / shavings in your eye and should not undergo the MRI procedure. Lastly, if you are claustrophobic, your doctor may need to give you some sedative medication to help you get through the test. When you go to the hospital for your MRI appointment, the MRI clinic staff will explain any specific risks based on your medical history and answer any questions you have on this procedure.

Potential Risks with Epidural Steroid Injections: It should first be recognized that participants eligible for this study are those that have been identified as appropriate candidates for ESI, and referred to the Dept of Physical Medicine and Rehabilitation for consideration for this procedure. Therefore regardless of your participation in the study,
the treating physician would recommend an ESI for you as is generally accepted current standard of care in the US. Hence, the reality is that the actual clinical trial adds no more risk than that which would occur with routine care. ESI is routinely performed on patients with LSS who do not have contraindications to injection material or procedures. Lumbar epidural anesthesia and analgesia, generally regarded as safe procedures, are widely used during obstetric, gynecologic, urologic, orthopedic, and general surgical procedures, and for postoperative pain control. Adverse effects or complications per injection might include pain at injection site, facial flushing, transient non-positional headache, insomnia the night of the injection, and fever the night of the procedure.93

Risks Associated with Physical Therapy: The risks associated with physical therapy treatment are minimal. The examination and procedures used in this study are routinely used by physical therapists as the standard of care treatment for patients with LSS. However, there are a few small risks to be considered. First, you may experience an increase in pain intensity from completing the exercise due to a muscle or ligament injury. It is also possible that you will experience mild muscle soreness after manual therapy techniques are performed. However, this soreness typically resolves within 1-48 hours after the manual therapy. The physical therapists participating in this study already routinely use manual therapy in the management of patients with LSS. Based on our clinical experience, the chances of this are unlikely, occurring in less than 25% of individuals. Most instances of increased pain or muscle soreness are transient, lasting less than 24 hours. We will attempt to minimize this risk by having licensed physical therapists specifically trained in the study procedures carry out all treatments.

There is also a potential risk of psychological distress for you, the patient, while answering self-report questions about the impact of low back pain on various aspects of your life. Based on our clinical experience, the chance of this happening is rare, which means it occurs in less than 1% of people. To minimize this risk, patients will be told that they are not expected to answer any questions that are upsetting to them.

You will be required to exercise regularly over the next year. There are always slight risks associated with exercise. Because your health care provider has cleared you and you will be screened by physician prior to initiation of exercise and treatment, there is very little risk involved in participation in this program. However, as with any muscle assessment, exercise training, or stretching, you may develop slight soreness of your lower back or legs.

What are the possible benefits of the study?

There is no guarantee you will receive any benefit from this study other than knowing that the information may help future patients with lumbar spinal stenosis.

Are there alternative treatments?

Choosing not to participate in this study is your alternative to volunteering for the study. If you choose not to participate, you may pursue similar treatments as this study or other
Consent Form Approval

alternative treatments with your physician for lumbar spinal stenosis such as surgery, orthoses, modalities, and acupuncture.

Who is paying for this study?
This study is self-funded at this time. We have received grants to support the study from the Orthopedic Section of the American Physical Therapy Association and the Bob Doctor Research Program.

Will I be paid for being in the study?
You will be paid $50.00 for each re-evaluation at 3 months, 6 months, 12 months, 24 months, and 36 months. This will add up to a total of $250.00 if you complete all of the follow up questionnaires. In addition, you will be paid $25 for a 30-45 minute interview with one of the study coordinators. If you leave the study early, or if we have to take you out of the study, you will be paid only for the re-evaluation packets or interviews you have completed. It is important to know that payments for participation in a study are taxable income.

Will I have to pay for anything?
As this study is evaluating two standard treatment procedures for persons with lumbar spinal stenosis, you will be required to cover all medical expenses provided by the Spine Center with your personal medical insurance. If you are randomized to group two (which includes the physical therapy), the physical therapy will be provided free of charge to you.

Is my participation voluntary?
Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If you leave this study, you will still receive your normal medical care. The only medical care that you will lose is the medical care you are getting as part of this study. You might be able to get that same kind of medical care outside of the study. Ask your study physician.

Can I be removed from this study?

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The study physician may decide to stop your participation without your permission if the study physician thinks that being in the study may cause you harm, or for any other reason.

What happens if I am injured or hurt during the study?

If you have an injury while you are in this study, you should call Dr. Venu Akuthota, MD. immediately. His phone number is 720-848-2031. We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Venu Akuthota, MD. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Akuthota at 720-848-2031 or Dr. Paul Mintken, PT, DPT at 303-724-9545. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Akuthota or Dr. Mintken. You can also call the Colorado Multiple Institutional Review Board (COMIRB). You can call them at 303-724-1055.

Who will see my research information?

We will do everything we can to keep your records a secret. It cannot be guaranteed. Records your participation in this study may only be disclosed in accordance with federal law. By signing this document, you give permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further medical science. You will not be personally identified; all information will be presented as anonymous data.

Both the records that identify you and the consent form signed by you may be looked at by others. They are:

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study physician and physical therapists and team of researchers.
- Officials at University of Colorado who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.
Consent Form Approval

We will ask you to sign a different form that talks about who can see your research records. That form is called a HIPAA form. It will mention companies and universities who will see your research records.

You have the right to request access to your personal health information from the Investigator. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study has been completed.

This authorization does not expire. However, you may withdraw this authorization for use and disclosure of your personal health information by providing written request to the Investigator. If you withdraw this authorization, the Institution, the Investigator, the research staff, and the research Sponsor will no longer be able to use or disclose your personal health information from this study, except so far as that they have already relied on this information to conduct the study.

Agreement to be in this study

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I know that being in this study is voluntary. I choose to be in this study: I will get a copy of this consent form.

Signature: ___________________________ Date: ______

Print Name: ___________________________

Consent form explained by: ______________ Date: ______

Print Name: ___________________________

Investigator: _________________________ Date: ______

Witness: __________________________________ Date: ______
Witness of Signature □
And/or
Witness of consent process □

COMIRB # 09-0075 2/17/09 PI: Venu Akuthota MD Page 6 of 6
Consent to Participate in a Research Study

Epidural Steroid Injection vs. Epidural Steroid Injection, Manual Physical Therapy, and Exercise in the Management of Lumbar Spinal Stenosis: A Randomized Clinical Trial

Study to be Conducted at: Steadman Hawkins Clinic of the Carolinas
200 Patewood Drive, C100
Greenville, SC 29615

Proaxis Therapy
111 Doctors Drive
Greenville, SC 29607

Sponsor Name: American Physical Therapy Association (Orthopedic Section) and the Bob Doctor Research Program

Principal Investigator: Thomas Denninger, PT, DPT
(864) 797-7020

INTRODUCTION
You are being asked to participate in a research study. The Institutional Review Board of the Greenville Hospital System has reviewed this study for the protection of the rights of human participants in research studies, in accordance with federal and state regulations. However, before you choose to be a research participant, it is important that you read the following information and ask as many questions as necessary to be sure that you understand what your participation will involve. Your signature on this consent form will acknowledge that you received all of the following information and explanations verbally and have been given an opportunity to discuss your questions and concerns with the principal investigator or a co-investigator.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

PURPOSE
You are being asked to participate in a research study because you have the type of lower back pain and/or leg pain that may come from lumbar spinal stenosis. Spinal stenosis is a type of spinal problem that is caused by a narrowing of the spaces around the nerves in your lower back. The purpose of this study is to determine the effectiveness of various treatment techniques for spinal stenosis. This study is designed to provide information on factors which may help predict who will respond to non-surgical treatment for spinal stenosis and to compare different forms of testing and treatment for individuals with this condition.

There will be 80 patients asked to participate in this study. The total amount of time you will be involved in this study is three years.

PROCEDURES
If you choose to participate in this study, you will be randomized (assigned to a treatment group by chance, like flipping a coin) to receive one of two options for your treatment after your injection. You will answer questionnaires regarding your back and leg pain before you start treatment (injection plus, potentially, physical therapy). The questionnaires should take 30-45
You will answer these same questionnaires again at 3 months, 6 months, 12 months, 24 months and 36 months after completion of the treatment. There will also be a qualitative interview at 12 months to determine any factors that contribute to both success and obstacles for success in a physical rehabilitation program, as well as any factors that may have limited your success due to any social or home environment obstacles. The total number of appointments will be one for evaluation by a specialist and up to fourteen visits for testing and treatment by clinicians.

If you are randomized to Group One, you will be instructed in exercises designed to improve the motion of your spine and hips. You will be asked to continue your exercises at home as well as start an aerobic conditioning program, either walking or cycling. Also, you will receive a book of instructions on how to take care of your lower back and avoid motions that will irritate your lower back. In addition, you will receive 1-3 epidural steroid injections from your physician that will help reduce your lower back pain and allow you to continue physical activity.

If you are randomized to Group Two, you will be instructed in exercises designed to improve the motion of your spine and hips. Also, you will receive a book of instructions on how to take care of your lower back and avoid motions that will irritate your lower back. You will receive 1-3 epidural steroid injections from your physician that will help reduce your lower back pain and allow you to continue physical activity. You will also undergo an individualized manual therapy and exercise program that will help improve motion in your spine and hips. The manual therapy consists of joint movement/motion using a variety of techniques commonly used by physical therapists. In these treatments, the therapist will manually stretch various joints, to include your lower back and your hip joints. The therapist will also help you stretch muscles in your buttocks and legs. You will see the therapist 1-2 times per week for a maximum of ten weeks for treatment. In addition, you will walk on a treadmill or ride a bicycle 1-2 times per week.

Both treatments are standard care procedures with known beneficial effects for patients with lumbar spinal stenosis. We are investigating which post-injection procedure provides the better outcome for the patient through a series of questionnaires given at the indicated follow-up schedule.

POSSIBLE RISKS
Any treatment has possible side effects. The treatments and procedures used in this study may cause all, some, or none of the side effects listed. There is always the risk of very uncommon or previously unknown side effects happening. There may be risks or side effects which are unknown at this time. Side effects may be mild or very serious. You should always talk to the Principal Investigator about any side effects that you have while taking part in the study so he may properly monitor your health.

It should first be recognized that participants eligible for this study are those that have been identified as appropriate candidates for Epidural Steroid Injections (ESI), and referred to the co-investigator for consideration for this procedure. Therefore, regardless of your participation in this study, the treating physician would recommend an ESI for you as is generally accepted current standard of care. Potential adverse effects with the injection include pain at the injection site, facial flushing, headache, insomnia (inability to sleep), and fever.

The risks associated with physical therapy treatment are 1.an increase in pain intensity from completing the exercises and 2.mild muscle soreness after manual therapy techniques are performed. We will attempt to minimize these risks by having a licensed physical therapist specifically trained in the study procedures carry out all treatments. There is also a slight risk
associated with the exercises you will be asked to perform at home, including muscle soreness in your lower back or legs.

Some of the questions you will answer may be of a personal nature, including questions about the impact of low back pain on various aspects of your life. You do not have to answer any questions you do not feel comfortable answering.

**EXCLUSIONS**
You cannot participate in this study if you have or have had the following:
- Less than 50 years of age
- Organic brain syndrome (decreased brain function due to a medical disease) or dementia
- Severe vascular, pulmonary or coronary artery disease which limits movement
- Recent heart attack (within last 6 months)
- Spondylolisthesis (degeneration or slippage of part of the spine) requiring surgical fusion
- Pervious spinal surgery that included fusion of two or more vertebrae
- Severe osteoporosis as defined by multiple compression fractures or a fracture at the same level as the stenosis (narrowing of area in the spine)
- Metastatic cancer (cancer spread throughout various regions in the body)
- Excessive alcohol consumption or evidence of non-prescribed or illegal drug use
- Other orthopedic conditions or physical impairments of unrelated nature which would limit ambulation (moving/walking) or prevent you from fully participating in any aspect of the rehabilitation exercises
- Epidural steroid injection within the last year
- Vascular or other non-musculoskeletal condition other that LSS suspected to be the primary source of your symptoms
- Pregnancy during the period of the study

**POSSIBLE BENEFITS**
It is not possible to know whether or not you may benefit from participating in this study. Future lumbar spinal stenosis patients may benefit from the results of this research.

**ALTERNATIVE (OTHER) TREATMENTS**
You can still receive evaluation and treatment for your condition if you do not participate in this study. Discuss any alternative treatments with your regular doctor and/or the study doctor before you decide to participate in the study. Some alternative treatments for your condition include surgery, orthopedic support(s) tools to decrease pain/inflammation (cold/hot pack, electrical stimulation, etc) and acupuncture. Your decision is entirely up to you. If you decide not to participate in the study, you will not be penalized or lose any benefits and your decision will not affect your relationship with your doctor or hospital.

**COSTS TO YOU FOR PARTICIPATING IN THIS STUDY**
You and/or your insurance company will be billed for the cost of those procedures which are considered to be normal and usual medical practice for someone with your condition (including the injection). You will be responsible for all other charges, including your office visits and physical therapy.

**PAYMENT FOR PARTICIPATION**
*To You:* You will be paid $50 for each re-evaluation at 3, 6, 12, 24, and 36 months, for a total of $250 if all follow-up questionnaires are completed. You will also be paid $25 for a 30-45 minute
interview at 12 months. If you have to leave the study early, or if we have to remove you from the study, you will be paid only for the re-evaluation packets or interviews you have completed. It is important to know that payments for participation in a study are taxable income.

**To Investigators:** The investigators will not be paid for participating in the study.
**To Institution:** The Greenville Hospital System and Proaxis Therapy are not being paid for this study.

**COMPENSATION FOR INJURY AS A RESULT OF STUDY PARTICIPATION**
If you get hurt or sick because of treatment you have received in this study, emergency medical treatment is available but will be provided at the usual charge. The study sponsor may or may not pay for this treatment. You will be responsible for any charges not paid for by the sponsor.

No financial compensation (payment) will be available to you from the study sponsor, the Greenville Hospital System or the investigators. You or your insurance company will be charged for continuing medical care and/or hospitalization. You understand that you have not given up any of your legal rights by signing this consent form.

**VOLUNTARY PARTICIPATION**
Participation in this study is completely voluntary (your choice). You may refuse to participate or withdraw from the study at any time. If you refuse to participate or withdraw from the study, you will not be penalized or lose any benefits. Your decision will not affect your relationship with your doctor or hospital.

**NEW INFORMATION**
During this study, you will be told of any important new information that may affect your willingness to participate in this study. You will be informed of any new findings that might change your decision to be in this study.

**AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION**
As part of this research study, your study doctor and his/her research team will keep records of your participation in this study. These study records may be kept on a computer and will include all information collected during the research study, and any health information in your medical records that is related to the research study. Your study doctor and his/her research team will use and disclose (release) your health information as they conduct this study. To evaluate the results of the study and for compliance with federal and state law, your health information may be examined and copied by the Food and Drug Administration (FDA), other governmental regulatory agencies, the Institutional Review Board of the Greenville Hospital System, the study sponsor and the sponsor’s authorized representative(s). This study may result in scientific presentations and publications, but steps will be taken to make sure you are not identified.

Under federal privacy laws, your study records cannot be used or released for research purposes unless you agree. If you sign this consent form, you are agreeing to the use and release of your health information. If you do not agree to this use, you will not be able to participate in this study. The right to use your health information for research purposes does not expire unless you withdraw your agreement. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.
Once your health information has been released, federal privacy laws may no longer protect it from further release and use. If you have any questions about the privacy of your health information please ask your study doctor.

CONTACT FOR QUESTIONS
For more information concerning this study and research-related risks or injuries, or to give comments or express concerns or complaints, you may contact the principal investigator, Thomas Denninger, PT, DPT, at (864) 797-7020. You may also contact a representative of the Institutional Review Board of the Greenville Hospital System for information regarding your rights as a participant involved in a research study or to give comments or express concerns, complaints or offer input. You may obtain the name and number of this person by calling (864) 455-8997.

A survey about your experience with this informed consent process is located at the following website:  


Participation in the survey is completely anonymous and voluntary and will not affect your relationship with your doctor or the Greenville Hospital System. If you would like to have a paper copy of this survey, please tell your study doctor.

CONSENT TO PARTICIPATE

*My study doctor, _________________________________, has explained the nature and purpose of this study to me. I have been given the time and place to read and review this consent form and I choose to participate in this study. I have been given the opportunity to ask questions about this study and my questions have been answered to my satisfaction. I have been given a copy of my study doctor’s Notice of Privacy Practices. I agree that my health information may be used and disclosed (released) as described in this consent form. After I sign this consent form, I understand I will receive a copy of it for my own records. I do not give up any of my legal rights by signing this consent form.*

Printed Name of Participant

_______________________________  ___________________________  __________

Signature of Participant  Date  Time

_______________________________  ___________________________  __________

Signature of Witness  Date  Time

INVESTIGATOR STATEMENT

I have carefully explained to the participant the nature and purpose of this study. The participant signing this consent form has (1) been given the time and place to read and review this consent form; (2) been given an opportunity to ask questions regarding the nature, risks and benefits of participation in this research study; and (3) appears to understand the nature and purpose of the study and the demands required of participation. The participant has signed this consent form prior to having any study-related procedures performed.

_______________________________  __________

Signature of Investigator  Date  Time

Principal Investigator: Thomas Denninger, PT, DPT  (864) 797-7020
Co-Investigators: Thomas Jarecky, MD  (864) 454-7422
APPENDIX D

STUDY QUESTIONNAIRES

1. Demographic survey
2. Modified Oswestry Disability Index
3. Numeric Pain Rating Scale
4. Lower Back Activity Confidence Scale
5. Medical Outcomes Survey Social Support Scale
6. Medical Outcomes Survey SF-36
Demographic Information

Thank you for completing this questionnaire. This questionnaire will help us to better understand your general health and any problems related to bone and muscle conditions. Your responses will be held in the strictest confidence. Please answer every question. Some questions may look like the others, but each one is different. There is no right or wrong answer. If you are not sure how to answer a question, just give the best answer you can.

Subject ID: ____________________________  Today’s Date: _____/_____/____

mm           dd

yy

Date of Birth: _____/_____/

Weight:_________

Height:_________

mm         dd         yy

Gender:  Male

Female

Race:  Hispanic

American Indian

Asian

Pacific Islander

Black or African American

White or Caucasian

Other ________________

Do you expect you will be able to complete all treatment sessions over a 10-week period (i.e. not going on vacation, no extended business trips scheduled, etc.)?  No  Yes
1. Are you presently seeking treatment from any other specialists for your back pain?
   No
   Yes (If yes, please check all that apply below:

   | Acupuncturist | Osteopath |
   | Chiropractor  | Pain Clinic |
   | Emergency Room| Physical Therapist |
   | General       | Rheumatologist |
   | Practitioner  | Work Hardening Clinic |
   | Internist     | Nurse Practitioner |
   | Massage Therapist | Other:__________________________ |
   | Neurosurgeon  | |

2. Prior to your coming to the physician, what treatment(s) have you had for this episode of your low back pain? (Please mark all that apply.)
   None
   Surgery (Date and type of surgery:______________________________)
   Physical/Occupational Therapy
   Medication (Date and type of medication:________________________)
   Chiropractic
   Massage Therapy
   Splint, Brace, or Cast
   Shoe Inserts
   Other (Please specify:______________________________________________)

1. If you had to spend the rest of your life with the low back symptoms you have right now, how would you feel about it?
   Very dissatisfied
   Somewhat dissatisfied
   Neutral
   Somewhat satisfied
   Very satisfied
2. What results do you expect from your treatment? (Check one response on each row.)

<table>
<thead>
<tr>
<th></th>
<th>Definitely yes</th>
<th>Probably yes</th>
<th>Not sure</th>
<th>Probably not</th>
<th>Definitely not</th>
<th>Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete relief from symptoms (pain, stiffness, swelling, numbness, weakness, instability)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate relief from symptoms (pain, stiffness, swelling, numbness, weakness, instability)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>To do more every day household or yard activities</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>To sleep more comfortably</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>To go back to my usual tasks</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>To exercise and do more recreational activities</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>To prevent future disability</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. During the past week, how bothersome have these symptoms been? (Check one response on each row that best describes your average symptoms over the past week.)

<table>
<thead>
<tr>
<th></th>
<th>Not at all bothersome</th>
<th>Slightly bothersome</th>
<th>Somewhat bothersome</th>
<th>Moderately bothersome</th>
<th>Very bothersome</th>
<th>Extremely bothersome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low back and/or buttock pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leg pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Numbness or tingling in leg and/or foot</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
1. What is your current marital status?
   - Single
   - Married
   - Living with significant other
   - Divorced/separated
   - Widowed

2. What level of education have you completed?
   - Less than high school
   - Graduated from high school
   - Some college
   - Graduated from college
   - Some post-graduate course work
   - Completed post-graduate degree

The following is a list of common health problems. In the first column please indicate if you currently or have ever had any of the problems in the past. In the second column please indicate if you are currently receiving treatment for the problem. In the last column please indicate if the problem limits any of your daily activities.

<table>
<thead>
<tr>
<th>Health Problem</th>
<th>Do you or have you had the problem?</th>
<th>Do you currently receive treatment for this problem?</th>
<th>Does this problem limit your daily activities?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osteoporosis</td>
<td>Yes No</td>
<td>Yes No</td>
<td>Yes No</td>
</tr>
<tr>
<td>Spinal Compression Fracture</td>
<td>Yes No</td>
<td>Yes No</td>
<td>Yes No</td>
</tr>
<tr>
<td>Heart Disease</td>
<td>Yes No</td>
<td>Yes No</td>
<td>Yes No</td>
</tr>
<tr>
<td>High Blood Pressure</td>
<td>Yes No</td>
<td>Yes No</td>
<td>Yes No</td>
</tr>
<tr>
<td>Low Blood Pressure</td>
<td>Yes No</td>
<td>Yes No</td>
<td>Yes No</td>
</tr>
<tr>
<td>Lung Disease</td>
<td>Yes No</td>
<td>Yes No</td>
<td>Yes No</td>
</tr>
<tr>
<td>Diabetes</td>
<td>Yes No</td>
<td>Yes No</td>
<td>Yes No</td>
</tr>
<tr>
<td>Condition</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>-----</td>
<td>----</td>
<td>-----</td>
</tr>
<tr>
<td>Ulcer or Stomach Disease</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kidney Disease</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liver Disease</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anemia or Other Blood Disease</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cancer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Seizures</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Fainting</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dizziness or Vertigo</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nerve Disease or Disorder</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Muscle Disease or Disorder</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hearing Loss</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eye Disease or Injury</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin Disease</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Medical Problems</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(please specify)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. Are you currently taking any medications (over the counter and/or prescribed)?
   No
   Yes (If yes, please list the medications that you are currently taking.)
<table>
<thead>
<tr>
<th>Name of Medicine</th>
<th>Dose (Milligrams)</th>
<th>How many pills?</th>
<th>How many times per day?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

2. During the **past week**, how often have you taken pain medication, including narcotics or over-the-counter medications **for your low back pain**?
   - Not at all
   - Once a week
   - Once every couple of days
   - Once or twice a day
   - Three or more times a day

3. Have you smoked at least 100 cigarettes in your lifetime?
   - No
   - Yes

4. If you smoked more than 100 cigarettes in your lifetime (**Proceed to the lifestyle section if you have not smoked more than 100 cigarettes in your lifetime**):

5. On average during all of the years that you have smoked, how many cigarettes did you usually smoke per day?
   - 1 - 10
   - 11 - 20
   - 21 - 40
   - More than 40

6. Do you smoke cigarettes now?
   - No
   - Yes

7. Except for the times that you quit, how many years all together have you smoked cigarettes?
   - 0 - 5
   - 6 - 10
11 - 20
More than 20 years

**Lifestyle**

1. Which statement best describes the work you do? (If retired, answer based on everyday activities.)
   - Mostly sedentary
   - Sedentary, substantial amount of walking required
   - Moderately active; walking, some lifting, and carrying
   - Demanding physical activity, heavy lifting, and carrying

2. Describe your employment status.
   - Work regular duty full time
   - Work regular duty part time
   - Work light duty or modified position full time
   - Work light duty or modified position part time
   - Temporarily unable to work due to health status
   - Permanently unable to work or retired due to health status
   - Retired (not due to health status)
   - Unemployed
   - Homemaker (not working outside the home)
   - Student (not currently working)

3. How much physical activity do you do in a typical week.
   - Less than 3 days a week
   - 3 to 4 days a week
   - 5 days a week
   - Greater than 5 days a week

4. Mark the type of physical activity you participate in:
   - Very light level.
   - Light activity.
   - Moderate level activity.
   - Vigorous level of activity.
   - I do not participate in physical activity.
Indicate by circling the comment next to the treatment that corresponds to your amount of agreement with the following statement. Substitute each treatment into the blank as you consider your response.

I believe ________________ will significantly help to improve **this episode** of my back pain.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>completely disagree</th>
<th>somewhat disagree</th>
<th>neutral</th>
<th>somewhat agree</th>
<th>completely agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rest</td>
<td>completely disagree</td>
<td>somewhat disagree</td>
<td>neutral</td>
<td>somewhat agree</td>
<td>completely agree</td>
</tr>
<tr>
<td>Surgery</td>
<td>completely disagree</td>
<td>somewhat disagree</td>
<td>neutral</td>
<td>somewhat agree</td>
<td>completely agree</td>
</tr>
<tr>
<td>Epidural Steroid Injections</td>
<td>completely disagree</td>
<td>somewhat disagree</td>
<td>neutral</td>
<td>somewhat agree</td>
<td>completely agree</td>
</tr>
<tr>
<td>Massage</td>
<td>completely disagree</td>
<td>somewhat disagree</td>
<td>neutral</td>
<td>somewhat agree</td>
<td>completely agree</td>
</tr>
<tr>
<td>Joint Manipulation</td>
<td>completely disagree</td>
<td>somewhat disagree</td>
<td>neutral</td>
<td>somewhat agree</td>
<td>completely agree</td>
</tr>
<tr>
<td>Traction</td>
<td>completely disagree</td>
<td>somewhat disagree</td>
<td>neutral</td>
<td>somewhat agree</td>
<td>completely agree</td>
</tr>
<tr>
<td>Aerobic exercise (i.e. walking, stationary cycling, Stairmaster, etc.)</td>
<td>completely disagree</td>
<td>somewhat disagree</td>
<td>neutral</td>
<td>somewhat agree</td>
<td>completely agree</td>
</tr>
<tr>
<td>Range of motion exercises (i.e. stretching)</td>
<td>completely disagree</td>
<td>somewhat disagree</td>
<td>neutral</td>
<td>somewhat agree</td>
<td>completely agree</td>
</tr>
<tr>
<td>Strengthening exercises</td>
<td>completely disagree</td>
<td>somewhat disagree</td>
<td>neutral</td>
<td>somewhat agree</td>
<td>completely agree</td>
</tr>
</tbody>
</table>
MODIFIED OSWESTRY LOW BACK PAIN DISABILITY QUESTIONNAIRE

Section 1: To be completed by patient
Age: ______ Date: ________ Gender: Male / Female

Section 2: To be completed by patient
This questionnaire has been designed to give your therapist information as to how your back pain has affected your ability to manage in every day life. Please answer every question by placing a mark on the line that best describes your condition today. We realize you may feel that two of the statements may describe your condition, but please mark only the line which most closely describes your current condition.

### Pain Intensity

- The pain is mild and comes and goes.
- The pain is mild and does not vary much.
- The pain is moderate and comes and goes.
- The pain is moderate and does not vary much.
- The pain is severe and comes and goes.
- The pain is severe and does not vary much.

### Personal Care (Washing, Dressing, etc.)

- I do not have to change the way I wash and dress myself to avoid pain.
- I do not normally change the way I wash or dress myself even though it causes some pain.
- Washing and dressing increases my pain, but I can do it without changing my way of doing it.
- Washing and dressing increases my pain, and I find it necessary to change the way I do it.
- Because of my pain I am partially unable to wash and dress without help.
- Because of my pain I am completely unable to wash or dress without help.

### Lifting

- I can lift heavy weights without increased pain.
- I can lift heavy weights but it causes increased pain.
- Pain prevents me from lifting heavy weights off of the floor, but I can manage if they are conveniently positioned (ex. on a table, etc.).
- Pain prevents me from lifting heavy weights off of the floor, but I can manage light to medium weights if they are conveniently positioned.
- I can lift only very light weights.
- I cannot lift or carry anything at all.

### Walking

- I have no pain when walking.
- I have pain when walking, but I can still walk my required normal distances.
- Pain prevents me from walking long distances.
- Pain prevents me from walking intermediate distances.
- Pain prevents me from walking even short distances.
- Pain prevents me from walking at all.

### Sitting

- Sitting does not cause me any pain.
- I can only sit as long as I like providing that I have my choice of seating surfaces.
- Pain prevents me from sitting for more than 1 hour.
- Pain prevents me from sitting for more than 1/2 hour.
- Pain prevents me from sitting for more than 10 minutes.
- Pain prevents me from sitting at all.
Section 2 (cont): To be completed by patient

**Standing**
- I can stand as long as I want without increased pain.
- I can stand as long as I want but my pain increases with time.
- Pain prevents me from standing more than 1 hour.
- Pain prevents me from standing more than 1/2 hour.
- Pain prevents me from standing more than 10 minutes.
- I avoid standing because it increases my pain right away.

**Sleeping**
- I get no pain when I am in bed.
- I get pain in bed, but it does not prevent me from sleeping well.
- Because of my pain, my sleep is only 3/4 of my normal amount.
- Because of my pain, my sleep is only 1/2 of my normal amount.
- Because of my pain, my sleep is only 1/4 of my normal amount.
- Pain prevents me from sleeping at all.

**Social Life**
- My social life is normal and does not increase my pain.
- My social life is normal, but it increases my level of pain.
- Pain prevents me from participating in more energetic activities (ex. sports, dancing, etc.)
- Pain prevents me from going out very often.
- Pain has restricted my social life to my home.
- I have hardly any social life because of my pain.

**Traveling**
- I get no increased pain when traveling.
- I get some pain while traveling, but none of my usual forms of travel make it any worse.
- I get increased pain while traveling, but it does not cause me to seek alternative forms of travel.
- I get increased pain while traveling which causes me to seek alternative forms of travel.
- My pain restricts all forms of travel except that which is done while I am lying down.
- My pain restricts all forms of travel.

**Employment/Homemaking**
- My normal job/homemaking activities do not cause pain.
- My normal job/homemaking activities increase my pain, but I can still perform all that is required of me.
- I can perform most of my job/homemaking duties, but pain prevents me from performing more physically stressful activities (ex. lifting, vacuuming)
- Pain prevents me from doing anything but light duties.
- Pain prevents me from doing even light duties.
- Pain prevents me from performing any job or homemaking chores.

Section 3: To be completed by physical therapist  
SCORE:_________ or ___________%

---

Pain Diagram and Pain Rating

Name:_______________________________ Date:_____/____/_____

Please use the diagram below to indicate the symptoms you have experienced over the past 24 hours. Use the key to indicate the type of symptoms.

Key: 
- Pins and Needles = 000000
- Burning = xxxxxx
- Stabbing = /////
- Deep Ache = zzzzzz

Please rate your current level of pain on the following scale (check one):

0 1 2 3 4 5 6 7 8 9 10
(no pain) (worst imaginable pain)

Please rate your worst level of pain in the last 24 hours on the following scale (check one):

0 1 2 3 4 5 6 7 8 9 10
LOW BACK ACTIVITY CONFIDENCE SCALE

The following items are designed to determine what types of activities you can do easily, which are more difficult, and which you cannot do successfully. Please indicate your level of confidence, at the present time, in doing the activity in question by circling the appropriate percentage. Select the response that most closely matches your own, remembering that there are no right or wrong answers.

For example, in question #1 if you have almost complete confidence that you could carry a box that weighs 25 lbs. from a car into your home, you might circle 90%. If, however, you had no confidence that you could carry a box that weighs 25 lbs. from a car into your home, you would circle 0%.

<table>
<thead>
<tr>
<th>0%</th>
<th>10%</th>
<th>20%</th>
<th>30%</th>
<th>40%</th>
<th>50%</th>
<th>60%</th>
<th>70%</th>
<th>80%</th>
<th>90%</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO CONFIDENCE</td>
<td>MODERATE CONFIDENCE</td>
<td>COMPLETE CONFIDENCE</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

I believe that I can …

1. carry a box that weighs 25 lbs. from a car into my home.
   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

2. move a heavy phone book from an overhead cabinet to a low shelf.
   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

3. push a sofa 10 feet into a new location across carpet.
   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

4. sit for a 6-hour plane trip.
   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

5. climb 3 flights of stairs.
   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

6. walk 1 mile (10 city blocks) non-stop.
   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

7. stand in a slow-moving line for 3 hours.
   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
I believe that I can …

8. do what I have to do to take care of my back.

9. control my low back problem in such a way that I can do the things I enjoy.

10. find strength within myself to deal with the frustration of low back pain.

11. continue to do my exercise program even when I have pain or discomfort.

12. continue to do my exercise program even if I have no current symptoms of my low back problem.

13. exercise regularly even if I was bored by the program or activity.

14. exercise when there is no one around to offer encouragement.

15. exercise when I need to start up with the program again after lapsing.
People sometimes look to others for companionship, assistance, or other types of support. How often is each of the following kinds of support available to you if you need it? Circle one number on each line.

<table>
<thead>
<tr>
<th>MOS Social Support Survey</th>
<th>None of the time</th>
<th>A little of the time</th>
<th>Some of the time</th>
<th>Most of the time</th>
<th>All of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Someone you can count on to listen to you when you need to talk</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Someone to give you information to help you understand a situation</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Someone to give you good advice about a crisis</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Someone to confide in or talk to about yourself or your problems</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Someone whose advice you really want</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Someone to share your most private worries and fears with</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Someone to turn to for suggestions about how to deal with a personal problem</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Someone who understands your problems</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Someone to help you if you were confined to bed</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Someone to take you to the doctor if you needed it</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Someone to prepare your meals if you were unable to do it yourself</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Someone to help with daily chores if you were sick</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Someone who shows you love and affection</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Someone to love and make you feel wanted</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>------------------------</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Someone who hugs you</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Someone to have a good time with</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Someone to get together with for relaxation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Someone to do something enjoyable with</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Someone to do things with to help you get your mind off things</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Instructions for Completing the Questionnaire

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Please answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

Your Health in General

1. **In general, would you say your health is (check one):**
   - Excellent: O
   - Very good: O
   - Good: O
   - Fair: O
   - Poor: O

2. **Compared to one year ago, how would you rate your health in general now? (check one)**
   - Much better now than one year ago: O
   - Somewhat better now than one year ago: O
   - About the same as one year ago: O
   - Somewhat worse now than one year ago: O
   - Much worse now than one year ago: O
3. The following questions are about activities you might do during a typical day. Does your HEALTH now limit you in these activities? If so, how much? (check one on each line)

<table>
<thead>
<tr>
<th>Activity</th>
<th>Yes, limited a lot</th>
<th>Yes, limited a little</th>
<th>No, not limited at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>b) Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>c) Lifting or carrying groceries</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>d) Climbing several flights of stairs</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>e) Climbing one flight of stairs</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>f) Bending, kneeling, or stooping</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>g) Walking more than a mile</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>h) Walking several blocks</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>i) Walking one block</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>j) Bathing or dressing yourself</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>
4. During the PAST WEEK, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health? (check one on each line)

<table>
<thead>
<tr>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a) Cut down on the amount of time you spent on work or other activities

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 WEEK, how much of the time 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)? (check one on each line)

<table>
<thead>
<tr>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a) Cut down on the amount of time you spent on work or other activities

b) Accomplished less than you would like

c) Did work or other activities less carefully than usual
6. During the PAST WEEK, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? (check one)

Not at all | Slightly | Moderately | Quite a bit | Extremely
--- | --- | --- | --- | ---
○ | ○ | ○ | ○ | ○

7. How much **bodily pain** have you had during the PAST WEEK? (check one)

None | Very mild | Mild | Moderate | Severe | Very severe
--- | --- | --- | --- | --- | ---
○ | ○ | ○ | ○ | ○ | ○

8. During the PAST WEEK, how much did pain interfere with your normal work (including both work outside the home and housework)? (check one)

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 WEEK. 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 WEEK... (check one answer on each line)

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

a) Did you feel full of life?  ○ ○ ○ ○ ○
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 WEEK, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)? (check one)

<table>
<thead>
<tr>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

11. How TRUE or FALSE is each of the following statements for you? (check one answer for each line)

<table>
<thead>
<tr>
<th></th>
<th>Definitely true</th>
<th>Mostly true</th>
<th>Don't know</th>
<th>Mostly false</th>
<th>Definitely false</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) I seem to get sick a little easier than other people</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>b) I am as healthy as anybody I know</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>c) I expect my health to get worse</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>d) My health is excellent</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE!
APPENDIX E
INTERVIEW GUIDE

The Patient Interview Questions
I am going to ask you a series of open ended questions about your experiences with having lumbar spinal stenosis. I want to hear in your words what your feelings are and experiences have been with this condition. Feel free to elaborate or explain your thoughts as you feel necessary. At the end, if there is anything I haven’t asked you that you would like to share, I would like you to have the opportunity to share this information.

Main disease problems.
Tell me in your own words what it is like to have LSS.

Describe to me how your life is different now that you have LSS.

Does having LSS impact your interactions? For example:
- Your perceptions about yourself and what can do
- Your relationships
- Your ability to do daily activities
- Your ability to do social or recreational activities

Rehabilitation Treatment
Tell me about your experiences with Epidurals

Tell me about your experiences with physical therapy

Tell me about what factors made your experience in physical rehabilitation (ESI and PT)
- Supportive
  - Positive – helpful
  - Negative – helpful
- Challenges

Describe any education or advice you were given.

Describe any tasks you were given.
- Did you experienced problems with adhering to these and why?

Describe how your pain was improved or got worse during rehabilitation.
- What factors do you think contributed to the change in your pain?

Contextual Factors.
In General/Everyday:
What do you think influenced your ability to manage LSS the most?

Rehab:
What do you think influenced your ability to participating in rehabilitation (either ESI or PT) the most?
Do you remember being confident or not confident to participate in rehabilitation before you started your treatment program?

Confidence with Tasks:
Describe any task you originally felt you were not confident to perform physically, mentally, or socially.

Are there now tasks you feel you can now perform?
• Describe how this relates to your back problems

Are there any tasks you feel you now cannot perform?
• Describe how this relates to your back problems

Support Sources
What did your family or friends think of all of this?

• Did they support you?

• Was it helpful or not helpful?

Who do you think influenced you the most during this time?

Were any friends or family members, neighbors or anyone else sources of support during his stressful health experience?

Did you feel you had:
• Emotional support?
• Informational support?
• Tangible support?
• Affectionate support?
  o Describe who provided this support.
  o Describe if the support was either helpful or unhelpful