EARLY INTERVENTION OPTIONS FOR ACUTE LOW BACK PAIN PATIENTS:

A PROSPECTIVE ONE-YEAR FOLLOW-UP STUDY

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To my wife and best friend, Elizabeth

EARLY INTERVENTION OPTIONS FOR ACUTE LOW BACK PAIN PATIENTS: A PROSPECTIVE ONE-YEAR FOLLOW-UP STUDY

by

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The University of Texas Southwestern Medical Center at Dallas, 2009

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This study represents a continuation of research that has focused on the treatment of acute low back pain (ALBP) patients using techniques designed to address the psychosocial, as well as physical, aspects of pain. Initially, an algorithm was developed by Gatchel et al. (1995a) to identify patients suffering from ALBP who were at high-risk for developing chronic low back pain (CLBP). An interdisciplinary early intervention program was then implemented by Gatchel et al. (2003) to discourage the progression of ALBP to CLBP. Previous studies demonstrated the effectiveness of the early intervention program in

reducing levels of pain and disability as compared to those not receiving additional treatment. Another advantage that the treatment group had, relative to the "treatment as usual" group, was cost-effectiveness, as evidenced by lower levels of healthcare utilization, time away from work and medication costs.

Due to the important position that work status holds in a discussion of disability and costs associated with injury, a work transition component was added to the early intervention program. Individuals considered high-risk for developing LBP were randomly assigned into one of four groups: early intervention (EI); early intervention with work transition (EI/WT); work transition (NI/W); and non-intervention (NI). A one-year prospective study looked at how these groups differed regarding outcome measures designed to evaluate pain level, coping abilities and work status (Holberg & Gatchel, 2007). Earlier findings were confirmed regarding the effectiveness of early intervention programs at addressing these issues, but a small sample size did not allow for conclusive results.

The current study expanded upon previous research by utilizing additional instruments in the measurement of the physical and psychosocial status of those at high risk for developing CLBP, including cortisol analyses intended to demonstrate the interplay between the physical and mental aspects of pain. In addition to these measures, an increase in sample size allowed for greater statistical power and more definitive statements regarding the long-term efficacy of early intervention interdisciplinary programs for the treatment of ALBP.

TABLE OF CONTENTS

PRIOR PUBLICATIONS

Haggard, R., Whitfill, T., & Gatchel, R.J. (In Press). Predictors of poor prognosis for chronic pain patients: The MMPI Disability Profile and high Pain Medication Questionnaire scores. *Journal of Opioid Management* .

Garofalo, J.P., Robinson, R., Gatchel, R.J., & Whitfill, T. (2009). Hypothalamic-pituitary-adrenocortical activity in older adults with low back pain. *The Clinical Journal of Pain*, 10(1), S74.

Whitfill, T., Haggard, R., & Gatchel, R.J. (2008). *Early intervention options for acute low back pain patients: A prospective one-year follow-up study*. Poster session presented at the Graduate Student Organization annual poster session.

Robinson, R.C., Crasilneck, H., Garofalo, J.P., & Whitfill, T. (2006). Examining sympathetic nerve activity with microneurography during hypnosis: Untangling the effects of central command. *International Journal of Clinical and Experimental Hypnosis, 54*(4), 448-456.

Robinson, R.C., Whitfill, T., & Wang, Z. (2005). *Central command's effects on vasculature*. Poster session presented at the Annual Meeting of The American Society of Hypertension.

Robinson, R.C., Crasilneck, H., Wang, Z., & Whitfill, T. (2005). Hypnosis' effect on skin sympathetic nerve activity during static handgrip exercise. *American Journal of Hypertension , 18*(5), A48 - A49.

Gatchel, R.J., Robinson, R.C., & Whitfill, T. (2005). Tailoring psychosocial treatment for patients with occupational disability. In I.Z. Schultz & R.J. Gatchel (Eds.), *Handbook of complex occupational disability claims: early risk identification, intervention and prevention* (pp. 151-165). New York: Kluwer Academic.

LIST OF FIGURES

LIST OF TABLES

LIST OF ABBREVIATIONS

ACTH	Adrenocorticotropic hormone
ALBP	Acute low back pain
ANOVA	Analysis of variance
BDI	Beck Depression Inventory
CBT	Cognitive-behavioral therapy
CLBP	Chronic low back pain
CPI	Characteristic Pain Inventory
CPP	Comprehensive pain program
CRH	Corticotropin-releasing hormone
df	Degrees of freedom
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders, Fourth edition
EI	Early intervention
EI/WT	Early intervention with work transition
EMG	Electromyography
η^2	Eta Squared
HPA	Hypothalamic-pituitary-adrenal
HR	High risk for developing chronic pain
IDET	Intradiscal electrothermal therapy
IRB	Institutional Review Board
LBP	Low back pain
LOCF	Last observation carried forward
LR	Low risk for developing chronic pain

μ	Mean
MIC	Minimal important change
MVAS	Million Visual Analog Scale
MMPI-2	Minnesota Multiphasic Personality Inventory, Second edition
MPI	The West Haven-Yale Multidimensional Pain Inventory
NI	Non-intervention
NI/W	Work transition
NSAIDS	Nonsteroidal anti-inflammatory drugs
ORQ	Obstacles to Return-to-work Questionnaire
RTW	Return-to-work
n	Sample size
p	Significance level
SC	Standard care
σ	Standard deviation
SCID	Structured Clinical Interview for DSM-IV, Non-patient version
SF-36	Medical Outcomes Short Form 36-Health Survey
SPS	Stanford Presenteeism Scale
SSDI	Social security disability income
T	Treatment
VAS	Visual Analog Scale for Pain
WC	Worker's compensation
WOC	Ways of Coping Questionnaire
χ^2	Pearson's Chi-Square

CHAPTER ONE
Introduction

Individuals suffering from chronic pain endure a variety of financial and psychosocial hardships. The monetary costs to society are significant, with healthcare costs alone resulting in billions of dollars spent per year. This study represents a continuation of research that has focused on the treatment of acute low back pain (ALBP) patients using techniques designed to address the psychosocial, as well as physical, aspects of pain. Initially, an algorithm was developed by Gatchel et al. (1995a) to identify patients suffering from ALBP who were at high-risk for developing chronic pain. An interdisciplinary early intervention program was then implemented by Gatchel et al. (2003) to prevent the progression of ALBP to chronic low back pain (CLBP). Previous studies demonstrated the effectiveness of the early intervention program in reducing levels of pain and disability, as compared to those not receiving additional treatment. Another advantage that the treatment group had, relative to the "treatment as usual" group, was cost-effectiveness, as evidenced by lower levels of healthcare utilization, time away from work and medication costs.

Due to the important position that work status holds in a discussion of disability and costs associated with injury, a work transition component was added to the above early intervention program. Individuals considered high-risk for developing LBP were randomly assigned into one of four groups: early intervention (EI); early intervention with work transition (EI/WT); work transition (NI/W); and non-intervention (NI). A one-year prospective study looked at how these groups differed regarding

outcome measures designed to evaluate pain level, coping abilities and work status (Holberg & Gatchel, 2007). Earlier findings were confirmed regarding the effectiveness of early intervention programs at addressing these issues, but a small sample size did not allow for sufficient statistical power. In that study, the work transition group did not show significant improvements regarding return-to-work status.

The current study expanded upon previous research by utilizing additional instruments in the measurement of the physical and psychosocial status of those at high risk for developing CLBP. An additional psychological measure was the Structured Clinical Interview for DSM-IV Axis I & II Disorders (SCID-I), which allowed for a comparison of specific psychiatric diagnoses at baseline and one-year. In an attempt to better understand the interplay between the physical and psychosocial aspects of pain, cortisol levels were measured as a physiological correlate of distress. In addition to these measures, a significant increase in sample size allowed for greater statistical power and more definitive statements regarding the long-term efficacy of early intervention interdisciplinary programs for the treatment of ALBP.

CHAPTER TWO
Review of the Literature

Scope of the Problem

Low back pain (LBP) is one of the most pervasive musculoskeletal disorders in the world, affecting approximately 50% to 80% of the adult population sometime during their lifetime. At a given point in time, it is estimated that 12% to 30% of adults in Western countries suffer from LBP (Andersson, 1997; Kelsey, 1980; Picavet, Schouten, & Smit, 1999; Von Korff et al., 2005). Fortunately, the majority of these cases are self-limited and resolve without major disruptions to the lives of the individuals or those around them (Carey et al., 1996). For roughly one in four individuals suffering from LBP, however, the experience lasts for more than one day and may eventually result in consultation with a medical professional (Deyo, Mirza, & Martin, 2006). Among this smaller group of LBP sufferers who seek medical assistance, the majority will show rapid improvement and be largely symptom free within a month's time (Pengel, Herbert, Maher, & Refshauge, 2003).

Although most individuals suffering from LBP see their symptoms resolve with little or no medical care, a small portion go on to develop more prolonged and significant impairment. Close to one-third of LBP patients report continued pain at moderate to severe levels 1 year after an initial episode, with 20% reporting significant physical limitations (Von Korff & Saunders, 1996). Within a given year, it is estimated that three to four percent of the population in all industrialized countries suffers a temporarily

disabling LBP injury, and that greater than one percent of the population is involved in an accident that results in total and permanent disability for the individual (Gatchel et al., 1995a). Although specific causal factors cannot be identified with certainty, some evidence suggests a long-term increase in the occurrence of LBP. Within the past century, reports of LBP incidents have outpaced the relative rise in population, with LBP disability occurring at a rate 14 times greater than population growth from 1957 to 1976 (J. W. Frymoyer, 1991).

Disability resulting from low back injuries is the most costly benign condition in industrialized nations (Mayer & Gatchel, 1988). It is estimated that Americans spend between $50 billion and $100 billion every year for low back-related costs. These costs are composed of direct expenses, such as medication and co-pays, as well as indirect expenditures, including lost wages and legal fees (National Center for Health Statistics, 2005). Healthcare costs represent the largest direct expenditure associated with LBP, surpassing $25 billion in 1998 (Luo, Pietrobon, X Sun, Liu, & Hey, 2004). Low back pain is the fifth most common reason for all physician visits (Deyo et al., 2006; Hart, Deyo, & Cherkin, 1995), and its treatment represents more than half the costs associated with the diagnosis and care of all musculoskeletal trauma (Holbrook, Grazier, Kelsey, & Stauffer, 1984).

Healthcare costs associated with medication alone, for individuals with back pain, are estimated to range from $5,000 to $10,250 per person (De Lissovoy, Brown, Halpern, Hassenbusch, & Ross, 1997; Straus, 2003). Nearly half of all LBP expenses can be

attributed to surgery, with approximately 317,000 lumbar surgeries performed every year (Holbrook et al., 1984; National Center for Health Statistics, 1997). At an average cost of $15,000, expenses attributed to back surgery approach $5 billion annually (J.W. Frymoyer & Durett, 1997). Surgeries of this nature increased by 55% between 1985 and 1995, contributing to an overall increase in the cost of LBP (Deyo & Phillips, 1996).

A major factor in the high costs associated with LBP is the amount of time individuals miss from work as a result of their injury. According to the United States Department of Labor (2007), four out of every ten days away from work can be attributed to sprains or strains, the leading cause of injury and illness in the U.S. population. The trunk area, including the shoulders and back, make up a significant proportion of these cases; with back-specific injuries accounting for 62% of all trunk-related missed workdays.

Low back pain is the most common cause of job-related disability in the United States, and back injuries are estimated to result in 1,400 missed workdays per 1,000 workers every year (Deede & McGovern, 1987; National Center for Health Statistics, 2005). Similarly, 10-15% of missed work days in Europe are due to back-related injuries, with 12.5% of those who are both unemployed and disabled in the United Kingdom citing LBP as the precipitating factor (Andersson, Pope, & Frymoyer, 1984; Elliott, Smith, Penny, Smith, & Chambers, 1999).

Gatchel, Polatin and Mayer (1995b) found LBP to be the primary cause of disabling injuries among individuals under age 45. When members of this typically robust

population become disabled, productivity suffers and the possibility arises for long-term costs to society in the form of social security disability income (SSDI). The average age for an individual with CLBP to begin receiving SSDI is less than 40, meaning they are likely to draw these checks for decades to follow (Mayer et al., 1987).

Payments made by non-governmental sources to persons unable to work as a result of low back-related injuries are considerable. The workers' compensation (WC) system in the United States spends approximately $11 billion annually on LBP disability claims, and compensated roughly 2% of the workforce for back-related injuries (Andersson, 1999). Back injury claims account for 30-40% of WC costs even though they make up only 15% to 25% of the claims. Direct costs associated with WC include lost wages, medical care and expenses such as legal fees. Indirect costs are more difficult to measure (e.g., costs associated with claim processing, worker-replacement training, company productivity and personal suffering), but are clearly a major contributor to the overall financial load (Webster & Snook, 1990). Similar burdensome costs are shared throughout the world, with 11% of Sweden's short-term sick leave payments and 13% of their early retirement pensions going to individuals suffering from back pain (Ekman, Johnell, & Lidgren, 2005).

The literature presented has clearly illustrated the magnitude of the problem presented by CLBP. The lives of numerous individuals are disrupted by the financial burdens associated with being unable to work, as well as the physical and psychosocial distress associated with a longstanding disability. Although private and governmental institutions

exist to lessen the strain on those suffering from CLBP, the resources of these organizations are limited, and the demands placed on them great. There are many treatment modalities designed to address the pain associated with CLBP. The most effective treatment program would attend to the various aspects of the problem in a way that improved productivity, lessened individual suffering, and reduced the financial burden to individuals as well as organizations.

Biopsychosocial Approach to Pain and Disability

In response to the considerable financial and personal costs resulting from chronic pain, a great number of research studies have explored the issue, and have advanced our knowledge of its causes, assessment approaches and treatment (Gatchel, Peng, Peters, Fuchs, & Turk, 2007). The consensus among healthcare providers is that an effective treatment plan for chronic pain must move away from the traditional biomedical model and adopt an approach that considers factors beyond the physical. The biomedical model operates under the assumption that the mind and body are wholly separate entities that do not act upon each other in any significant way. The experience of pain is viewed as a secondary response to the underlying physiological damage, and it is assumed that injuries of equal magnitude will result in identical levels of pain. Under this model, pain intensity should subside in proportion to the amount of healing that occurs in the body, and any pain that remains after this point is likely to be labeled psychogenic by the treating physician (Gatchel, 1996).

Alternatively, the biopsychosocial model recognizes that the interaction of social, psychological and biological factors ultimately affect the experience, severity and maintenance of pain. This approach is positioned to explain why individuals sometimes continue to experience pain well after the observable damage to the body has been "fixed", as well why individuals with similar injuries report drastically dissimilar levels of pain. The concept that factors beyond the physical may play a role in the exacerbation and maintenance of pain developed slowly over several years. Melzack and Wall (1965) built upon previous research that questioned the wisdom of the biomedical approach, and helped popularize the Gate Control Theory of Pain, the concept that emotions and cognition affect the subjective experience of pain. Many others, including Engel (1977), Gatchel and Baum (1983), and Turk and Rudy (1987), developed the biopsychosocial model following numerous research studies that demonstrated the vital role that psychosocial factors play in the development, maintenance and exacerbation of pain (D. A. Fishbain, Goldberg, Meagher, Steele, & Rosomoff, 1986; Flor & Turk, 1984).

Two important concepts to consider in any discussion of the biopsychosocial model are "disease" and "illness", with disease being the observable biological disruptions of bodily tissue historically addressed by the biomedical model. Illness moves beyond the physical features and incorporates the psychosocial factors that affect the subjective experience of pain and illness (Gatchel et al., 2007). A holistic approach, as represented by the concept of illness, must consider all possible contributors and avoid the temptation to dismiss subjective reports of pain as psychogenic or "not real".

The biopsychosocial model views pain as a complex interactive phenomenon, which may be precipitated by physical injury, but ultimately reflects numerous personal characteristics of the injured individual that may aggravate the injury or prolong recovery. Serious injury can significantly affect the social and psychological experiences of the injured individual. These changes in lifestyle and outlook can then play a role in delaying recovery, resulting in a mutually harmful relationship that can ultimately lead to chronic pain. Due to the biomedical model's inability to address the complex nature of chronic pain, which exacts great personal and financial tolls, the biopsychosocial model has taken the lead in developing and implementing an integrated approach to the treatment of chronic pain that addresses all known factors.

Acute versus Chronic Pain

Although arbitrary in some respects, duration of pain is typically divided into one of three categories for ease of study (i.e., acute, subacute and chronic). This classification is particularly helpful for those attempting to better understand pain's occasional progression from a temporary inconvenience to a permanent disability. Several standards are practiced, but Hardin (1998) stipulates that acute pain lasts up to seven days, subacute can last from seven days up to seven weeks, and that pain lasting for more than seven weeks be labeled chronic. Greater than 90% of back pain incidents resolve in a short amount of time regardless of whether a particular treatment plan is implemented (Deyo, 1983). Roughly one-half of all patients suffering from low back pain, for example, are no longer disabled after a 2-week period, 70% are disability free by 1 month and 90% will

have recovered within 3 to 4 months (Mayer & Gatchel, 1988). Although the large majority of cases will not persist, and will be labeled ALBP, most of the cases lasting longer than four months will endure for more than two years (J. W. Frymoyer, 1991). This small number of CLBP patients is very costly, with roughly 5% of those with back pain disability accounting for 75% of the costs (J. W. Frymoyer & Cats-Baril, 1991).

In order to better understand how individuals progress from acute to chronic pain, the physical and mental processes involved must be recognized. A three-stage model, which includes a "mental deconditioning" component, was developed by Gatchel (1991, 1996) to illustrate contributions that are not physical in nature. The mental processes described occur simultaneously, and in concert with physical processes, resulting in chronic pain. The first stage of mental deconditioning occurs soon after an injury and involves emotional reactions, including worry, anxiety and fear. These emotions are understandable and a natural reaction to pain, which is evolutionarily associated with harm, and typically dissipate within two months.

If the pain persists for two-to-four months following the initial injury, the patient may progress into the second stage of mental deconditioning. In this subacute stage, a number of behavioral and psychosocial problems may emerge, including somatization, learned helpless, depression, anger and anxiety. These non-physical components of the progression from acute to chronic pain are the result of both premorbid personality characteristics, as well as current social conditions such as economic and interpersonal stressors. Thus, an individual with premorbid depression who recently lost his or her job,

and has no support from friends or family, would be more likely to progress to this stage than a high functioning individual in a supportive environment with no significant stressors.

In situations where the pain does not subside for several months, in the presence of these complicating psychosocial factors, the patient may progress into Stage 3. The most notable feature of this third stage is adoption of the "sick role", in which individuals see themselves, and are perceived by others, to be incapable of carrying out activities previously performed. Social engagements, work responsibilities and physical activities are discontinued due to the perception that the person is incapable of resuming their previous lifestyle. Social and economic factors, including disability pay, may serve as an additional incentive to remain disabled and dependent on others to perform these tasks.

The physical factors that enable pain to progress from the acute stage to chronic disability are varied and complex, but the primary component involves physical deconditioning of the muscle from inactivity and disuse. Avoiding activities that result in pain is a common reaction to an injury. However, the resulting atrophy to the muscle decreases strength and endurance, creating an obstacle to rehabilitation. The stage of injury must be considered when judging the appropriateness of an action. Suspension of work activities, and even bed rest in more severe cases, are appropriate recommendations during the acute stage. However, treatment interventions of this nature at the chronic stage would only serve to reinforce physical deconditioning and decrease the odds of recovery (Gatchel, 1996).

Predictors of Chronic Pain

The description of the biopsychosocial model, and discussion of the factors that often lead to chronic pain, illustrate the complex nature of pain. The significant financial burdens on institutions and society, along with the psychosocial and physical suffering of individuals, require that an effective model for predicting and treating low back pain be developed. Due to the complex interactions that occur among pain, tissue damage and psychosocial factors, causal relationships are often hard to delineate, especially when an overly simplistic, unidirectional model is utilized to explain the relationship.

Risk factors for developing and maintaining pain are varied and numerous, but can be divided into the following groups: medical, psychological, social, compensation, demographic and occupational (Wright & Gatchel, 2002). Kumar (2001) suggests that the demands placed on workers today are incompatible with the evolutionary development of humans. Repetitious activities, high force exertion and prolonged postural demands are relatively new to our species, as are the psychosocial demands inherent in most work places. Factors including job dissatisfaction, heavy manual work, repetitiveness, exposure to vibration, employee/employer relationship and fatigue have all been linked to low back pain (Andersson, Svensson, & Oden, 1983; Biering-Sorensen, 1984; J. W. Frymoyer et al., 1983; Hales & Bernard, 1996; Lancourt & Kettelhut, 1992). Wright and Gatchel (2002) found higher levels of disability, pain and depression in a population of workers receiving monetary compensation for their injuries, allowing for

the possibility that injured workers receiving nothing have less of an incentive to remain disabled.

Certain physical and demographic characteristics, such as age, body size and spinal canal size, can also affect the likelihood of musculoskeletal injury. Medically, risk factors include previous low back problems, severity of injury and previous surgeries (Kumar, 2001). Social risk factors that can increase the chances of an acute injury developing into chronic pain include conflict with friends and family, as well as any significant changes in one's living arrangement that results in stress (Lancourt & Kettelhut, 1992; Proctor, Gatchel, & Robinson, 2000).

Psychosocial factors are an accepted component in the progression from acute to chronic pain, but establishing whether an injury causes or results from psychopathology can be difficult. Pulliam, Gatchel and Gardea (2001) found a higher prevalence of poor coping skills and Diagnostic and Statistical Manual (DSM) Axis I disorders in patients deemed as high-risk for developing chronic pain. In a study of 200 CLBP patients, Polatin, Kinney, Gatchel, Lillo and Mayer (1993) used the Structured Clinical Interview for the Diagnostic and Statistical Manual of Mental Disorders-III-Revised (SCID) to investigate psychopathology. The study found that 77% of the patients met lifetime criteria for a psychological disorder, and over half met criteria for an Axis II personality disorder. Of those who met criteria for a lifetime psychiatric disturbance, 54% were diagnosed as having major depression. Very high rates of substance abuse (94%) and anxiety disorders (95%) were also found. Based on the patients' self-report, the majority of these

diagnoses existed prior to their injury, supporting the position that such factors may precipitate chronicity. However, a recent study by Dersh, Mayer, Theodore, Polatin, and Gatchel (2007) found that psychiatric disturbance did not contribute significantly to the development of chronic disabling occupational spinal disorders: 38.7% of the participants had one or more pre-existing psychological disorders, while 98.9% went on to develop such a disorder following their injury (57.9% when excluding pain disorder). These findings are in line with reviews of research that focused on the order in which patients experience depression and chronic pain. Of the 13 studies that addressed the issue, only 3 took the position that depression preceded chronic pain. All of the studies reviewed supported the position that depression often develops following an injury (D. A. Fishbain, Cutler, Rosomoff, & Rosomoff, 1997). Other psychosocial factors, including anger, pain-related fear, guarding and perception of self-efficacy, have also been linked to chronic pain (Busch, Goransson, & Melin, 2007; Leeuw et al., 2007; Prkachin, Schultz, & Hughes, 2007; Schwartz, Slater, Birchler, & Atkinson, 1991).

Although a number of psychosocial factors have been associated with an increased risk for developing chronic pain, a cohesive approach that combines the most salient factors is needed in order to accurately identify patients in need of intervention. An inclusive approach of this nature was undertaken by Gatchel, Polatin and Kinney (1995a), and followed up soon after by a similar study with a larger number of participants (Gatchel et al., 1995b). In the second study, a battery of psychosocial assessment tests was administered to 421 participants who had experienced ALBP for less than 6 weeks. Measures included the Structured Clinical Interview for Diagnostic and Statistical

Manual of Mental Disorders, Third Edition Revised (Spitzer, Williams, Gibbon, & First, 1988); Minnesota Multiphasic Personality Inventory (Hathaway & McKinley, 1943); and Million Visual Analog Scale (Million, Hall, Haavik, Baker, & Jayson, 1982). Physical measures were also evaluated. These measures were used to assess personality factors, psychosocial contributors and vocational status at baseline and one-year follow-up.

Several factors were deemed highly relevant in this effort to identify patients most likely to develop chronic pain and disability, as measured by their work status one-year following the injury. The factors that increased the odds of future chronicity included female gender, high self-reported pain and disability, elevated scores on Scale 3 of the MMPI and participation in compensation programs through an employer. An algorithm was subsequently developed based on the data obtained from these measures, and was able to predict which patients would eventually develop chronic pain with 90.7% accuracy. The data also suggested that previous psychopathology, such as depression and substance abuse, was not predictive of future disability due to pain.

Gatchel and colleagues (2003) provided further support for the predictive algorithm. Participants in this later study included nearly 700 ALBP patients who were classified as "high risk" (HR) or "low-risk" (LR) for developing chronic pain based on algorithm results. Participants deemed HR were then randomized into one of two groups, early intervention with interdisciplinary treatment (HR/I), or a nonintervention group (HR/NI). Not only was the early intervention program successful in treating the HR participants, as evidenced by fewer work days missed and fewer healthcare visits, but the usefulness of

the algorithm was supported by the relatively poor outcomes of the HR/NI participants in relation to those in the LR group.

Treatment of Chronic Low Back Pain

Numerous techniques have been devised and implemented in the treatment of chronic pain, some of which were specifically designed to treat CLBP. These approaches vary in several ways, including cost, invasiveness, time duration and effectiveness. Competing literature can be found for nearly every treatment modality regarding efficacy, but the incremental nature of scientific study has resulted in more support for some than others. Although interdisciplinary treatment was implemented in the current study, alternative means of treatment must be understood in order to place this approach in context and to better assess its efficacy. The number of treatment options for CLBP is too great to cover fully, so the following discussion is limited to the most commonly implemented and researched methods.

Medication

Psychopharmacology is the most frequently recommended form of treatment for ALBP, and is the only intervention needed in most cases (Mayer & Polatin, 2000; Vogt et al., 2005). Symptom relief, as opposed to addressing the source of the pain, is the primary goal of drug interventions (Deyo, 1996). Results from one study determined that 80% of primary care patients suffering from low back pain were prescribed one or more medications on their initial visit, with 34% receiving 2 or more medication prescriptions

(Cherkin, Wheeler, Barlow, & Deyo, 1998). As with all medication use, the potential benefits must be weighed against possible side effects. Since the benefits of medication have not been clearly established for the treatment of back pain, the potential for harmful reactions should not be ignored (Chou & Huffman, 2007a). Nonsteroidal anti-inflammatory drugs (NSAIDS), acetaminophen, opioid analgesics and skeletal muscle relaxants are the most frequently prescribed medications for low back pain, with antidepressants, benzodiazepines, systemic corticosteroids and antiepileptic drugs less commonly recommended (Cherkin et al., 1998). Research on the efficacy of medications for the treatment of acute and chronic low back pain is abundant. For example, Deyo (1996) found good evidence for the use of NSAIDS, and fair evidence for skeletal muscle relaxants in the treatment of ALBP. The evidence was less clear regarding medication use for the treatment of CLBP, with considerable controversy surrounding the use of narcotic analgesics. Van Tulder, Koes and Bougher (1997) found limited evidence for the effectiveness of analgesics and muscle relaxants in the treatment of CLBP, and moderate evidence against the effectiveness of antidepressants. NSAIDS were deemed moderately effective, with no meaningful differences among the various types.

A more recent analysis of medications was conducted by Chou and Huffman (2007a) in connection with a larger review commissioned by the American Pain Society and the American College of Physicians intended to guide recommendations for the treatment of low back pain. This article is composed of data from previously conducted reviews on medications including acetaminophen, NSAIDS (nonselective, cyclooxygenase-2 selective and aspirin), antidepressants, benzodiazepines, antiepileptic drugs, skeletal

muscle relaxants, opioid analgesics, tramadol and systemic corticosteroids. Due to the large number of studies considered and the complex nature of quantifying a "successful" trial, consensus was not reached in regard to which drug was most desirable. However, the comprehensive nature of this review increases the likelihood that the data reflect our current understanding of the relationship between medication and low back pain.

Chou and Huffman (2007a) reviewed several studies that focused on acetaminophen, ultimately finding it to be less effective than NSAIDS in the treatment of both CLBP and osteoarthritis not limited to the back (Hickey, 1982; Lee et al., 2004; Towheed et al., 2006; Zhang, Jones, & Doherty, 2004). Adverse effects associated with the use of acetaminophen for low back pain were poorly documented in most studies, including serious harm such as gastrointestinal bleeding and myocardial infarction (Chou & Huffman, 2007a). Berry and colleagues (1982) found the NSAID, ibuprofen, superior to placebo for the treatment of CLBP. However, NSAIDs were also found to be no more effective than placebo in the treatment of sciatica (Vroomen, de Crom, Slofstra, & Knottnerus, 2000). The benefits credited to the use of NSAIDs for the treatment of CLBP were no greater than those found with opioid analgesics or muscle relaxants (M. W. Van Tulder, Scholten, Koes, & Deyo, 2000). However, the evidence for potential harm stemming from the use of NSAIDs in the treatment of CLBP is not sufficient to make conclusive statements (Derry & Loke, 2000; D. P. Evans, Burke, & Newcombe, 1980; McQuaid & Laine, 2006).

Antidepressants have been used for many years in the treatment of CLBP. Some believe these medications are effective in reducing pain by addressing the symptoms of depression, such as negative cognitions and inactivity, which can exacerbate the experience of pain. This hypothesis is weakened by the fact that antidepressant dosages used for the purpose of pain relief are significantly lower than those used for the treatment of depression (M.J. Sullivan, Reesor, Mikail, & Fisher, 1992). Several studies have supported the efficacy of trycyclic antidepressants in the treatment of pain associated with CLBP (Salerno, Browning, & Jackson, 2002; Staiger, Gaster, Sullivan, & Deyo, 2003). However, antidepressants that do not inhibit the uptake of norepinephrine have had similar effects to placebo, and functional outcomes have been inconsistent for all antidepressants. Moreover, adverse effects have been documented in connection with the use of antidepressants compared to placebo (22% vs. 14%), but typically include less serious events such as dizziness, dry mouth, constipation and drowsiness (Salerno et al., 2002).

Benzodiazepines were found to have neutral or negative effects on pain relief for the treatment of CLBP, and were frequently associated with disturbances of the central nervous system resulting in fatigue and light headedness (Basmajian, 1978; M. W. Van Tulder, Touray, Furlan, Solway, & Bouter, 2003). Mixed results were found in a review of skeletal muscle relaxants in the treatment of CLBP (Browning, Jackson, & O'Malley, 2001; Thomas J. Schnitzer, Ferraro, Hunsche, & Kong, 2004; Vroomen et al., 2000). Although serious complications were rare, adverse events of the central nervous system were reported with the use of skeletal muscle relaxants (M. W. Van Tulder et al., 2003).

The efficacy of opioid analgesics in the treatment of CLBP cannot be established due to conflicting accounts, but pain relief was found in several studies (Baratta, 1976; Hale, Dvergsten, & Gimbel, 2005; Kalso, Edwards, Moore, & McQuay, 2004). Tramadol, an atypical opioid, has been moderately effective in providing short-term pain relief and increased functional status for those suffering from CLBP (T.J. Schnitzer, Gray, Paster, & Kamin, 2000). Along with the more serious dangers presented by opioids are the less hazardous side effects of constipation and sedation (Hale et al., 2005). Some studies have attempted to combine various drugs used in the treatment of CLBP in an attempt to amplify the positive effects, but hybrids have not yielded any consistent beneficial results (Chou & Huffman, 2007a).

In summary, acetaminophen and NSAIDs are typically prescribed early in the treatment of low back pain. Although NSAIDs have generally proven more effective in pain relief, they also present a greater risk for side effects such as gastrointestinal bleeding and cardiovascular trouble. Individuals experiencing a greater level of discomfort in connection with their back pain may decide that the increased risk is a reasonable tradeoff for the potential relief. A similar decision-making process occurs when assessing the positive and negative aspects of opioids, which have traditionally been reserved for the treatment of severe and intractable pain. The possibility of increased function and pain relief may outweigh the risks of addiction and other adverse events (Chou & Huffman, 2007a). Due to the temporary nature of pharmacological pain relief, medications are

typically not used in isolation. Instead, they are a potentially useful tool in a treatment plan that may incorporate a number of methods.

Invasive Procedures

Every year, approximately 300,000 individuals suffering from back pain choose the option of surgery (Taylor & Taylor, 2005), and many more decide to pursue other invasive procedures. Due to the widely held traditional belief that physiological damage is the sole cause of pain, it is understandable that invasive procedures are seen as an expedient and effective course of treatment for those suffering from CLBP. The decision to administer a particular procedure is determined by the physical abnormality observed or believed to exist based on presentation. Due to the complex nature of specific back injuries, and the large number of procedural options, the following is a very basic introduction to some of these treatments and the existing literature on their efficacy.

There are several injection procedures used to address low back pain, including trigger point, sclerosant, facet joint and epidural. In a systematic review of treatments for CLBP, Van Tulder and colleagues (1997) found moderate evidence to support the use of epidural steroid injections to reduce short-term pain. However, the overall effectiveness of injections in the treatment of CLBP has been inconclusive due to conflicting results (M. W. Van Tulder, Koes, Seitsalo, & Malmivarra, 2006).

Some of the surgical options for the treatment of CLBP include electrothermal modulation, discectomy, spinal fusion and laminectomy. Randomized studies have not

yet been conducted on some of the recently introduced procedures, but others have been more thoroughly investigated. The largest number of studies have been conducted on spinal fusions, a surgical technique in which two or more vertebrae are fused in order to eliminate movement that has become painful. Fritzell and colleagues (2001) conducted a multi-centered randomized controlled trial on a population suffering from low back pain for greater than two years. Patients were randomly assigned to either a non-surgical group that received physical therapy and various forms of education, or one of three groups that received a form of surgical fusion. These latter three groups were later merged to form a single group. At two-year follow-up, outcomes were assessed based on levels of pain, disability and depression, as well as work status, patient satisfaction and an independent assessment by a separate spinal surgeon. It was found that the lumbar fusion group experienced significantly greater reductions in back pain, disability, return-to-work and patient/observer satisfaction.

However, different results were found by Fairbanks et al. (2005) in a randomized study comparing the efficacy of surgical fusion with an intensive rehabilitation program. Although the surgical group showed significant improvement in the areas of pain reduction and disability, the difference between groups was not deemed significant enough to outweigh the potential risk and additional costs associated with surgery. In a meta-analysis of randomized controlled trials comparing surgical fusion to non-surgical intervention, Ibrahim, Tleyjeh and Gabbar (2008) also concluded that the differences among groups were negligible and did warrant the risk of surgical complications.

Some early results for intradiscal electrothermal therapy (IDET) have been promising regarding pain reduction, but the lack of controlled trials comparing outcomes with other forms of treatment limits conclusions regarding relative efficacy. The partial removal of a vertebral disc, known as discectomy, is a common surgical treatment for the treatment of CLBP. Although this procedure can take a variety of forms, a review of research conducted on percutaneous lumbar discectomies found insufficient evidence of its efficacy (Nezer & Hermoni, 2007). Similarly, conflicting evidence exists for the effectiveness of artificial disks, analgesic pumps, laminectomy or implanted stimulators.

Biofeedback

A technique increasingly used in conjunction with other modalities in the treatment of CLBP is biofeedback. Physiological processes, such as heart rate, muscle tension and body temperature are monitored and observed in real time by the client and therapist, allowing for a better understanding of their typical levels and situational range. Relaxation training and behavior modification techniques are then employed to help reduce negative physiological reactions that may result from the pain and anxiety associated with long-term disability (Sherman, 2006).

Since biofeedback is typically used in conjunction with other treatments, randomized controlled trials addressing the effectiveness of unimodal biofeedback treatment are rare. However, Natour and colleagues (2001) looked exclusively at biofeedback in the treatment of a population of CLBP patients. Outcome measures included severity of pain, level of disability and levels of emotional distress in the form of depression and

anxiety. The treatment group utilizing biofeedback techniques out-performed the control group in the areas of pain and anxiety, but performed similarly on the quality of life measure and did not match the improvements of the control group in levels of depression.

Several attempts have been made to gauge the efficacy of biofeedback in the treatment of low back pain by reviewing previously conducted studies. Van Tulder (1997) determined that the existing studies on biofeedback were of low quality due to small sample size, and offered little evidence to support its efficacy as a sole treatment modality for nonspecific CLBP. Nielson and Weir (2001) revisited some of these studies in their examination of the efficacy of several biopsychosocial approaches to the treatment of chronic pain. Five of these studies specifically addressed the use of biofeedback in the treatment of low back pain. Van Tulder (1997) considered three of these studies to be of moderate quality, and three to have yielded positive results. A more recent review (Chou & Huffman, 2007b) found similarly mixed results. The dearth of well-controlled studies, as well as the heterogeneous nature of research, limits the ability to draw conclusions based on comparative analysis.

Flor and Birbaumer (1993) conducted a randomized controlled trial that compared the efficacy of electromyography (EMG) biofeedback, cognitive-behavioral therapy and conservative medical treatment in a population experiencing musculoskeletal pain. The outcome measures included pain severity, pain-related healthcare utilization, emotional distress, stress reactivity in the affected muscles and amount of active coping self-statements. Although each of the treatment groups showed significant improvement post-

treatment, the most notable changes were found in the EMG biofeedback group. Even more noteworthy is the fact that the biofeedback group alone maintained these improvements at 6 and 24 months following treatment, possibly due to the improved relaxation skills the participants acquired through practice.

Due to the relatively small number of randomized studies that have examined the efficacy of biofeedback in the treatment of CLBP, it is difficult to determine the reasons for the inconsistent results. Despite the occasional findings that biofeedback can serve as an effective stand-alone treatment for CLBP, this method is typically employed as a component of a more comprehensive treatment plan.

Cognitive-Behavioral Therapy

Although pain is typically accompanied by, and the result of, physical pathology, emotional, behavioral and ideational components can exacerbate and prolong its experience. Cognitive-behavioral therapy (CBT) recognizes this and attempts to address negative thoughts and behaviors that are counterproductive to recovery. Specific beliefs related to the severity of the injury, likelihood of recovery and capacity to cope with disability all contribute to the individual's physical and emotional well-being (M. J. Sullivan, Feuerstein, Gatchel, Linton, & Pransky, 2005). If the sensation of pain is interpreted as a harmful event associated with potentially permanent tissue damage, the individual will likely experience that pain more intensely and engage in unhelpful behaviors such as avoidance. Ironically, this avoidance can result in the outcomes most feared; extended duration of pain, decreased functioning and an increase in long-term

sick leave (Gatchel et al., 2007). A broad variety of interventions fit under the heading of CBT, including self-instructions (e.g., imagery and motivational self-talk), coping strategies (e.g., assertiveness training, minimization of negative thoughts, graded exposure and distraction) and goal setting (Gatchel & Okifuji, 2006).

In their review of biopsychosocial approaches to the treatment of chronic pain that incorporated the results of 12 randomized trials focused specifically on CBT, Nielson and Weir (2001) determined that moderate evidence exists for the use of cognitive-behavioral techniques within multimodal biopsychosocial treatments in the intermediate to long term. Morley, Eccleston and Williams (1999) found similarly favorable results in their meta-analysis of 18 randomized trials that compared CBT to the use of placebo, with significant improvement in the areas of pain reduction, disability and functioning. Results were not as favorable in a systematic review of randomized controlled trials conducted by van Tulder and colleagues (1997) that addressed the efficacy of CBT in the treatment of chronic nonspecific low back pain. Based on the results of 11 studies, it was determined that limited evidence exists to support the use of CBT for short-term treatment, and no evidence exists to suggest that a particular type of CBT therapy is superior to others.

A randomized controlled trial was conducted by Linton and Ryberg (2001) in order to assess the efficacy of a cognitive-behavioral program in a population suffering from back and neck pain. A total of 253 patients were randomly assigned to the experimental group, which consisted of a standardized 6-session CBT program or treatment as usual

group for the purpose of comparison. An analysis at 1-year found that the group receiving CBT showed improvement on 26 of the 33 outcome measures, including sick leave, pain-free days and fear-avoidance behaviors. A five-year follow-up study of the same data conducted by Linton and Nordin (2006) demonstrated that these physical, mental, behavioral and economic benefits were maintained over time. Brox et al. (2003) conducted a randomized study in which the effectiveness of lumbar spinal fusion was compared to CBT among a population of 64 back pain patients with documented pathophysiology. Both treatment groups showed significant improvement on a broad range of clinical measures, with no significant differences found between groups. These findings have been supported by more recent studies, including Fairbank et al (2005) and Brox et al. (2006).

A recent meta-analysis of randomized controlled trials investigating psychological interventions for CLBP was carried out by Hoffman, Papas, Chatkoff, and Kerns (2007). Twenty-two studies were included for analysis that implemented psychological techniques, either in isolation or as a component of a multidisciplinary intervention. The outcomes measured for this review included physical functioning, pain intensity, emotional functioning, employment status and healthcare utilization. When psychological interventions were compared with wait-list controls, moderate effect sizes were found for pain intensity, work-related disability and health-related quality of life, while smaller effect sizes were noted for the reduction of pain interference. CBT was a notably effective psychological intervention, demonstrating moderate to large positive effects on pain intensity.

Exercise

Due to the negative effects of deconditioning, which often occurs in chronic pain situations, the maintenance and reconditioning of muscle groups through physical exercise is critical. Avoidance of activities that cause pain or discomfort is often counterproductive and can ironically lead to greater disability and distress due to loss of strength and an increased sense of helplessness. Workers who remain active following a back injury have been found to return to work sooner than those who avoid exercise (Butterfield, Spencer, Redmond, Feldstein, & Perrin, 1998). Although this method of treatment is typically used in conjunction with other modalities, the efficacy of exercise as a unimodal treatment for CLBP has also been assessed. In one review of randomized controlled trials investigating the efficacy of physiotherapy exercise for the treatment of chronic back pain, Koes et al. (1991) concluded that the available research was of low quality, and ultimately neutral on the position of effectiveness. Faas (1996) later conducted a similar review and determined that exercise therapy was effective compared with a placebo or waiting list. However, the observed increase in functioning was not present after 12 months. In a review of non-surgical treatments for acute and chronic nonspecific low back pain, van Tulder (1997) reviewed 16 trials pertaining to exercise therapy, 3 of which were of high quality. The number of studies reporting positive and negative results was evenly divided, but the higher quality studies were unanimous in their support of exercise therapy. Nine of these trials investigated specific exercises in the treatment of low back pain, with no evidence found to support one exercise over another.

A meta-analysis conducted by Kool et al. (2004) investigated the efficacy of exercise, both alone and within a larger treatment program, in reducing the number of sick days at one-year follow-up among patients with non-specific CLBP. Evidence was found for the efficacy of exercise in reducing the duration of sick leave within the first year, specifically in severely disabled patients. However, these effects were not maintained past the one-year mark. Moreover, roughly half of the studies contained considerable methodological problems, and the evidence for exercise treatment alone was negligible. In their examination of therapies used to treat acute and chronic low back pain, Chou and Huffman (2007a) identified 79 unique trials utilizing exercise. Slight to moderate evidence was found in support of exercise therapy over no treatment for pain relief, but no effects were observed for functional outcomes.

Although the effectiveness of exercise as a unimodal treatment for CLBP has not been well established, its utility within the framework of a multidisciplinary program is largely accepted. However, some evidence suggests that certain exercise programs, such as low impact aerobics, can be implemented more efficiently and less expensively than more conventional treatment modalities (Mannion, Muntener, Taimela, & Dvorak, 2001).

Interdisciplinary Treatment

An approach to the treatment of CLBP that combines several of the previously mentioned techniques is appropriately known as multidisciplinary or interdisciplinary treatment. Predicated on the biopsychosocial model of pain and disability, this method understands

that a complex combination of physiologic, social and psychological factors play a role in an individual's unique experience of pain. Cognitive distortions, physical disabilities, psychosocial disorders and functional deficits are all experienced at higher rates by those suffering from chronic pain (Gatchel et al., 2007). Whereas the biomedical model views pain as a direct physiological occurrence that can be "cured" or "blocked", the mission of comprehensive pain programs (CPPs) is to reduce pain levels to a manageable level by also addressing the psychosocial factors. Functional restoration is one type of CPP used to treat CLBP by focusing on practical outcome measures, such as return-to-work, rather than pain levels alone. It addresses issues unique to chronic pain, including physical deconditioning, while also focusing on acute issues that decrease overall level of functioning such as pain avoidance and cognitive distortions (Gatchel & Okifuji, 2006).

Mayer and colleagues (1987) conducted a two-year follow-up study investigating the effectiveness of a functional restoration program for a population suffering from low back injuries. It was found that 87% of the functional restoration treatment group had returned to work at 2 years, while only 41% of the non-treatment group was working. The number of spine surgeries and active worker's compensation cases among the non-treatment group was nearly double that of the functional restoration group, and significantly higher rates of re-injury and healthcare utilization were noted. The efficacy of this specific program was later supported in separate studies by Hazard et al. (1989) and Patrick, Ahmaier and Found (2004), with a number of comparable randomized controlled trials from around the world showing similar results (Bendix et al., 1996;

Corey, Koepfler, Etlin, & Day, 1996; Hildebrandt, Pfingsten, Saur, & Jansen, 1997; Jousset et al., 2004; Shirado et al., 2005).

Over the past two decades, with increased support for the effectiveness of interdisciplinary pain management, the concept of "levels of care" has gained acceptance. *Primary care*, including electrical stimulation and temperature modulation, is a passive mode of treatment used to address acute injuries. When injuries do not resolve quickly, treatments such as exercise and education are introduced in the next phase known as *secondary care*. Injuries that are resistant to the previously mentioned levels of care are considered problematic to the majority of pain clinics, and are often referred to an interdisciplinary program for *tertiary care* (Mayer & Polatin, 2000).

Interdisciplinary programs combine the skills of multiple healthcare providers in a collaborative setting, with the goal of reducing pain, disability, healthcare utilization and days away from work. Nurses, psychologists, physical therapists, physicians and occupational therapists are typically included in such a treatment team, providing services such as medication management, cognitive-behavioral therapy, physical reconditioning, biofeedback and educational groups. These providers conduct case conferences at regular intervals in order to ensure that the patients' goals and progress are monitored collaboratively (Gardea & Gatchel, 2000).

A long-term study was conducted by Jensen et al. (2005) investigating different treatment modalities for a population of service workers on sick leave due to back and neck pain.

A randomization process placed participants into one of four groups: treatment as usual, physical therapy, cognitive behavioral therapy (CBT) and an interdisciplinary group consisting of both physical therapy and CBT. A three-year follow-up revealed that the participants within the interdisciplinary group were less likely to miss work or retire early, and experienced an improvement in their quality of life. This effect was especially strong among women, possibly due to greater compliance to treatment suggestions compared with men. Women within the interdisciplinary group also showed the most improvement in cost effectiveness over the control group, with significant differences in the areas of disability pension and sick leave. Including intervention costs, individuals within the interdisciplinary group averaged roughly half the costs as the treatment as usual group.

Altmaier and colleagues (1992) studied the effectiveness of an interdisciplinary treatment program for a population consisting of low back pain patients. Both treatment groups included education, exercise, an attempt to reduce medication and the goal of involving family members post-treatment. One group also incorporated a psychological component that involved relaxation training and coping skills. Each group was effective in reducing medication, increasing functioning and decreasing pain six months following treatment. A follow-up study was conducted on these same patients 13 years later by Patrick et al. (2004), demonstrating the long-term efficacy of interdisciplinary programs for the treatment of CLBP. Treatment gains were maintained in the areas of pain intensity/interference, physical functioning, mood and general health.

Finally, a review of nonpharmacologic therapies for CLBP by Chou and Huffman (2007b) studied the results of 28 unique trials and 4 systematic reviews assessing the efficacy of interdisciplinary treatment. Intensive treatments, defined as greater than 100 hours, were deemed moderately superior to non-interdisciplinary rehabilitation in regards to functional status. Pain outcomes three to four months following treatment were also considered moderately superior, with inconsistent long-term results. Meta-analysis conducted by Hoffman and colleagues (2007) found that interdisciplinary treatment was particularly effective in the area of long-term behavioral outcomes, such as return-to-work, but less so in other areas. Similar results were reached by Flor and colleagues (1992).

Return-to-Work

Many of the financial and emotional costs of low back pain are associated with an individual's inability to work. Businesses are negatively affected by reduced productivity, individuals may lose their primary source of income if they are unable to work and society assumes a myriad of indirect costs. Psychosocial issues, such as depression and anxiety, often result from prolonged absences from work and contribute to difficulty transitioning back to work (Kendall & Thompson, 1998). For many researchers and practitioners in the area of low back pain, return-to-work (RTW) outcomes have come to be seen as equally, if not more, important than traditional measures of pain relief. RTW interventions typically incorporate various components (e.g., education, behavioral elements and ergonomic measures) in a number of

combinations. Factors that help determine the extent to which a low back injury affects RTW can include individual traits and ideas, as well as forces in the workplace that are outside the person's control.

Factors Specific to the Individual

An individual's personality, ideas and perceptions all influence the experience of pain. Researchers investigating RTW outcomes in LBP populations have explored these factors in order to better predict how an individual's work attendance may be affected. Traditional biomedical models proved inadequate in explaining why some individuals returned to work while others did not. An early prospective study by Gallagher and colleagues (1989) revealed that several psychosocial variables effectively predicted work status at six months, while little evidence existed for similar predictive power among biomechanical and physical measures. Further support for the relevance of psychosocial factors in RTW interventions has accumulated since.

In a replication of an earlier study investigating job perception's effect on RTW among a chronic pain population, Fishbain and colleagues (1997) found that perceptions of job stress, work danger, physical demands and role conflicts helped to correctly classify 79.49% of participants regarding RTW at a 1-month time point. Similar research has supported this finding that fears and beliefs related to work have a significant effect on total days missed (S. J. Linton & Hallden, 1998; Waddell, Newton, Henderson, & Somerville, 1993). Van der Giezen and colleagues (2000) investigated predictive factors for RTW among a CLBP population out of work for three to four months due to their

injury. Potential predictive factors measured included health status, socioeconomic variables, job characteristics and information about previous low back injuries. At one-year follow-up, the patients' job satisfaction, perception of health and "bread winner" status (i.e., primary economic provider to family) were more predictive of RTW than were physical aspects of disability or the physical requirements of the job.

In a screening questionnaire developed by Du Bois and Donceel (2008), intended to quickly assess the risk of non-RTW among newly injured workers, an individual's prediction of RTW was one of the primary predictive factors found. A separate attempt at predicting non-RTW through the use of testing was undertaken by Kool, Oesch and de Bie (2002). In this research, a group of CLBP patients was administered several measurements, including the Pain Rating Scale, Behavioral Signs Test, the Step Test and the Pseudo Strength Test; the latter two tests measuring precipitous cessation on a relatively easy task. A regression analysis revealed that positive scores on two or more of these tests resulted in a predictive value of 0.97 for non-RTW.

External Factors

Although many of the factors that affect RTW among a CLBP population are unique to the individual, others are determined by outside forces such as an employer. In a review of 164 interdisciplinary rehabilitation programs designed to treat chronic pain patients, Fishbain et al. (1993) identified 26 that commented on predictive variables for RTW. Occupational variables proved equally important as individual factors in the search for variables that affected patients' ability to RTW. Specific job factors found to be

associated with improved RTW included timely modification of duties following injury (Briand, Durand, St-Arnaud, & Corbiere, 2008; Crook, Moldofsky, & Shannon, 1998; Franche et al., 2005; Frank et al., 1998; Hogg-Johnson & Cole, 2003; Soucy et al., 2006), ergonomic interventions (Loisel et al., 1997) and employee reassurance (Loisel et al., 2001).

Hoogendoorn and colleagues (2000) found low social support from coworkers and/or supervisors to negatively affect RTW, while research from Krause and colleagues (2001) identified high physical/psychological job demands, low job control and low job satisfaction as poor RTW predictors. A qualitative study was undertaken by Muenchberger and colleagues (2008), with the goal of comparing RTW factors being reviewed in the literature with factors deemed pertinent to clinicians. Although workplace-related factors received relatively little attention by researchers, occupational processes were considered paramount to clinical experts who monitor RTW status and what issues affect it.

Challenges Associated with Return-to-Work Research

Although a considerable amount of research has been undertaken to better understand RTW issues and to improve upon interventions, progress in the areas of implementation, cost reduction and rates of disability has been poor (Pransky, Gatchel, Linton, & Loisel, 2005). The previously mentioned research that came to different conclusions regarding primary contributors (i.e., individual vs. external) to RTW status illustrates the lack of consensus. In 2004, a group of researchers from various countries convened to discuss

the current state of RTW research, with the goal of formulating a plan and direction for future research. A key weakness in past research was that the definition of RTW as an outcome measure varied by study. Although many studies considered basic measures of RTW, such as number of sick leave days, others included less objective outcome measures, including psychological and physical functioning, pain intensity and healthcare utilization (Pransky et al., 2002). These are just a few of the reasons for the contradictory evidence found in research that assessed the relative importance of internal vs. external factors. Issues surrounding work-related injuries are complex and not always measurable regardless of well-planned methodology. For example, economic and personal factors might cause an injured worker to resume his/her job while mildly disabled, resulting in decreased productivity for the company and an exacerbation of the injury (Burton, Pransky, Conti, Chen, & Edington, 2004).

The Role of Cortisol in the Experience of Pain

The biopsychosocial model of pain is based on the principle that biological, psychological and social factors are constantly interacting to produce the subjective experience of pain. A potential component of this complex interaction is the breakdown of biological structures as a result of social and psychological stressors. The sympathetic nervous system, as well as the hypothalamic-pituitary-adrenal (HPA) axis, is activated during times of stress. The HPA axis involves a complex set of interactions among the hypothalamus, the pituitary gland (located below the hypothalamus) and the adrenal glands (located on top of the kidneys).

Upon experiencing stress, the hypothalamus produces corticotropin-releasing hormone (CRH) which, in turn, causes the pituitary gland to secrete adrenocorticotropic hormone (ACTH). When the adrenal glands are exposed to ACTH, they respond by producing glucocorticoid hormones (primarily cortisol) which are released into the blood stream and saliva (Biondi & Picardi, 1999). Short-term cortisol elevations promote recovery from stress by increasing glucose levels, lowering sensitivity to epinephrine and norepinephrine, and preventing the immune system from depleting resources. However, prolonged exposure to this stress hormone can result in an impaired immune system, cardiovascular abnormalities and poor metabolic functioning. In the majority of individuals, cortisol levels fluctuate naturally throughout the day. The highest levels are reached within an hour of waking up, followed by another spike late in the afternoon before a gradual decline to the lowest levels during sleep (de Kloet & DeRijk, 2004).

There are a number of stress-inducing situations that can result in the production of cortisol. Major depression, and negative affect in general, have been associated with increased levels of cortisol (Buchanan, al'Absi, & Lovallo, 1999; Cowen, 2002). The high correlation between pain and stress-related psychopathology (e.g., depression, anxiety, substance abuse and personality disorders) further complicates the relationship between pain and cortisol (Dersh, Polatin, & Gatchel, 2002). Research regarding this relationship is mixed, but evidence is generally supportive of its existence. An early study by Shenkin (1964) found elevated cortisol levels in patients with identifiable organic injuries, but not in those suffering from pain identified as psychogenic in nature.

A later study of chronic pain patients found elevated cortisol levels regardless of etiology (Lascelles, Evans, Merskey, & Sabur, 1974). Geiss and colleagues (1997) found lower early-morning cortisol levels in patients with persistent sciatic pain than in pain-free participants; and Tennant and Hermann (2002) found cortisol levels in chronic pain patients to vary drastically prior to treatment, only to normalize afterward.

Evans and colleagues (2008) evaluated the relationship among depression, pain intensity and salivary cortisol levels in a population (n=18) receiving multidisciplinary pain management. Cortisol levels were recorded prior to and following a four-week pain management program. Self-report measures of depression and pain severity were also completed by participants. Pain intensity, as well as depression severity, were found to correlate with waking cortisol levels. Neither depression nor pain level affected the other's positive relationship with cortisol levels, supporting the position that cortisol may serve as an effective marker for pain.

In recent years, researchers have begun to examine the relationship between psychological/medical conditions and the variability of cortisol rather than mean cortisol levels (Blackburn-Munro, 2004; Dessein, 2000; Ehlert, Gaa, & Heinrichs, 2001; J.P. Garofalo, Robinson, Gatchel, & Wang, 2007; McEwen, 2005; Okifuji & Turk, 2002). Conditions such as CLBP can result in long-term activation of the HPA axis thought to cause cortisol dysregulation. Researchers have even begun to assess the effects of treatment modalities on cortisol variability. In a study examining cortisol variability among a group of patients at high risk for developing chronic jaw-related pain, Robinson,

Garofalo and Gatchel (2006) found significant decreases in cortisol variability within the treatment group and significant increases in the variability of participants receiving standard care. A study by Garofalo, Robinson and Gatchel (2006) even found evidence for greater cortisol variability within the first two weeks among a group at high risk for developing temporomandibular disorders as compared to the low risk group; suggesting a possible link between psychosocial determinants and biological mechanisms.

Scope of the Present Study

The purpose of this investigation was to evaluate the efficacy of an interdisciplinary early intervention program in the treatment of patients suffering from ALBP. In addition to interdisciplinary treatment intended to address the biopsychosocial needs of the patient, a work transition component was added in order to specifically address return-to-work issues. The ultimate goal was to prevent ALBP from developing into CLBP as demonstrated by a variety of outcome measures.

The initial step was to identify individuals in the acute stage of low back pain who were likely to develop CLBP. This was accomplished with the aid of an empirically-supported algorithm developed by Gatchel et al. (1995a) that identified individuals deemed "high risk" (HR) for developing CLBP. Participants considered acute and HR were then randomized into one of the four following groups: 1) Early intervention (EI); 2) Work transition (WT); 3) Early intervention plus work transition (EI/WT); and 4) Standard care

(SC). The participants' pain levels, work status and level of disability were then monitored periodically over the following year.

The following hypotheses were proposed for this study:

1) High risk ALBP participants randomly assigned to one of the three treatment groups (i.e., EI, WT, or EI/WT) were expected to have lower rates of CLBP at one-year follow-up than those in the standard care group (SC).
2) Membership in one of the treatment groups was expected to result in lower levels of disability, improved return-to-work status, and reduced levels of pain, as compared to those in SC group.
3) The combined treatment group (EI/WT) was expected to show the most significant improvement at one-year follow-up in all areas measured, including pain level, work status, level of disability and overall chronicity.

CHAPTER THREE
Methodology

Participants

Participants involved in this investigation consisted of 994 patients who met the following criteria: English speakers between the ages of 18-65; the onset of an original case of LBP within two months of involvement in the study; no current illnesses or diseases at initial evaluation that directly caused or exacerbated the experience of pain (such as lupus or arthritis); not have experienced more than one episode of disabling pain during the past two years; and not currently in need of a surgical procedure. Finally, between the time of injury and inclusion in the study, participants were required to have experienced uninterrupted pain on a daily basis while performing their usual activities.

Participant recruitment took several forms, including advertisements, flyers, private practice groups and contributions from local physicians. A description of the study was placed in a weekly newspaper (i.e., The Dallas Observer), and flyers were placed throughout area universities, including The University of Texas Southwestern Medical Center at Dallas (UT Southwestern), Southern Methodist University and The University of Dallas. Referrals from area physicians included Orthopedic Associates in Lewisville, Texas, and several Concentra Medical Clinics operating in the Dallas-Fort Worth area. A low back insurance database was also utilized through a partnership with Liberty Mutual Center for Disability Research.

Procedure

At initial contact, the participants were asked a brief set of questions in order to establish that basic criteria were met for inclusion in the study (e.g., age, date of onset and existence of comorbid pain-exacerbating conditions). The participants were then offered a range of $25 to $50 to complete an initial screening evaluation packet. Included in the packet was a HIPAA consent form, informed consent for the study, payment voucher, basic demographic form, and the high-risk screening questionnaire developed by Gatchel and colleagues (1995a). Scores from the questionnaire were then entered into the previously mentioned statistical algorithm developed by Gatchel and colleagues (1995a). Results from the algorithm were used to determine if participants were at "high risk" (HR) or "low risk" (LR) for developing CLBP. Participants deemed HR were then randomized into one of four following groups: 1) Early intervention (EI); 2) Work transition (WT); 3) Early intervention plus work transition (EI/WT); and 4) Standard care (SC).

HR participants meeting criteria for inclusion were then contacted and given the option of participating in a baseline evaluation for which they would be compensated $50. The baseline evaluation involved the gathering of more demographic information, administration of the Structured Clinical Interview for DSM-IV Axis I and II Disorders, as well as the completion of various measures [(i.e., Obstacles to Return-to-Work, ORQ; (Marhold, Linton, & Melin, 2002); Stanford Presenteeism Scale, SPS; (Koopman et al., 2002); Million Visual Analog Scale, MVAS; (Million et al., 1982); Characteristic Pain

Inventory, CPI; (Dworkin & LeResche, 1992); The West Haven-Yale Multidimensional Pain Inventory, MPI; Ways of Coping, WOC; Beck Depression Inventory, BDI; Pain Visual Analog Scales, PAINVAS; and 36-item Short Form Health Survey Summary, SF-36; (Ware, Snow, Kosinski, & Gandek, 1993)]. These were re-administered at later dates for outcome purposes. Each participant included in the study, regardless of whether he or she received treatment or standard care, was asked to collect saliva samples once during every two-week period. The study provided cotton, plastic tubes and instructions regarding the collection and storage of the samples. The saliva samples were used to assess levels of cortisol, a stress-related hormone and ultimately analyzed for differences across groups.

Selected measures were administered at post-treatment, six-month follow-up and nine-month follow-up. One year following intake, participants were offered $50 to complete a follow-up evaluation that mirrored the baseline evaluation. Baseline and one-year follow-up evaluations took place at The Eugene McDermott Center for Pain Management or the Spine Center at UT Southwestern, and were conducted by licensed clinical psychologists, Master's level clinicians, pre-doctoral clinical psychology interns, or Master's level students.

Participants randomized into one of the two groups that included early intervention (i.e., EI/WT and EI) initially received a physician examination and the opportunity to attend up to six to nine physical therapy and six to nine behavioral medicine sessions. The physician evaluation involved the collection of basic medical information, including vital

signs and medical/surgical history. Physical therapy sessions were modified to fit the needs of the patient, but generally took a sports medicine approach involving stretching and exercise in an attempt to improve strength, endurance and range of motion. The behavioral medicine sessions lasted 45 minutes each and followed a specific protocol focusing on biofeedback and pain management. Relaxation and stress management skills were taught, including progressive muscle relaxation and diaphragmatic breathing. Interdisciplinary team conferences were held at baseline and discharge.

Participants randomized into one of the two groups incorporating the work transition component (i.e., WT and EI/WT) were allowed up to 6, 45-minute sessions and one or more case management sessions. The goal of the WT sessions was to aid in the transition back to work or help address current work conditions that may aggravate the injury. Modifications related to schedules, tasks and ergonomics are examples of areas that might benefit from adjustment. A manualized workbook was given to each participant and used in didactic lessons tailored to specific situations.

Depending on several factors, including group assignment and number of sessions scheduled, the course of treatment lasted 4-10 weeks. In an attempt to limit potential bias, groups were similar regarding exposure to therapists. The early intervention and work transition treatment components were administered by licensed professionals trained in their respective fields. This study was funded by the National Institutes of Health through The University of Texas at Arlington and subcontracted through UT Southwestern. The Institutional Review Boards (IRBs) at each institution approved of,

and oversaw, the current study, requiring that all members of the research team complete the necessary training regarding ethical treatment of human participants.

Instruments and Outcome Measures

Beck Depression Inventory (BDI). The BDI (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961) is a 21-item self-report inventory designed to assess the physical and emotional symptoms of depression. Individual items are multiple-choice, with a range of zero to three. All items are summed to produce a total score between 0 and 63. A total score of 0 to 9 is considered below the depression threshold; 10 to 15 is considered mild depression; 16 to 19 reflects mild to moderate depression; 20 to 29 represents moderate to severe depression; and greater than 30 indicates severe depression. In a meta-analysis of various studies, Beck, Steer and Garbin (1988) found the internal consistency reliability coefficient to be .81 for non-psychiatric patients. Test-retest reliability coefficients ranged from .60 to .83, and the BDI's validity was supported by a .60 correlation coefficient in comparisons with other measures of depression.

Characteristic Pain Inventory (CPI). The CPI (Dworkin & LeResche, 1992) is a self-report measure that assesses aspects of pain over the past three months. The current study assessed self-reports of participants' pain levels at the time of self-report. The pain ratings are made on a scale of 0 to 10, with 10 representing "most intense pain" and 0 representing "no pain".

Medical Outcomes Short Form 36-Health Survey (SF-36). The SF-36 (Ware et al., 1993) is a 36-item self-report questionnaire that assesses health-related quality of life based on 2 summary scales: the Mental Component Score (MCS) and the Physical Component Score (PCS). These summary scales are composed of eight smaller health concept scales that can be informative regarding specific areas of physical and mental health. The SF-36 is often used for the assessment and monitoring of health-related outcomes due to its high reliability rates and internal consistency.

Million Visual Analog Scale (MVAS). The MVAS (Million, Hall, Haavik, Baker, & Jayson, 1981) is a 15-item self-report measure assessing the participants' perception of pain and disability. Responses are given on a horizontal line representing a score range of 0 to 10, with 0 being represented by a dash on the far left side of the line. The items are then totaled to produce a disability score between 0 and 150, with 150 representing the highest possible levels of pain and disability. The manual provides ranges that represent mildly, moderately and severely disabling pain, but a review by Anagnostis, Mayer, Gatchel and Proctor (2003) put forth a system based on six categories that provide more specificity. Under this system, 0 represents no reported disability; scores ranging from 1 to 40 represent mild disability, scores ranging from 41 to 70 represent moderate disability; scores ranging from 71 to 100 represent severe disability; scores ranging from 101 to 130 represent very severe disability; and scores ranging from 131 to 150 represent extreme disability.

Obstacles to Return-to-Work Questionnaire (ORQ). The ORQ (Marhold et al., 2002) is a 55-item self-report questionnaire designed to identify risk factors associated with work-related pain. The measure is divided into psychosocial risk factors, such as low job satisfaction and insufficient social support, as well as physical risk factors, including heavy work and uncomfortable postures. Marhold and colleagues reached the conclusion that individuals' perceptions of work affect their recovery from injury and return to work. These perceptions are represented by nine separate dimensions within the ORQ: depression, pain intensity, difficulties at work return, physical workload and harmfulness, social support at work, worry due to sick leave, work satisfaction, family situation and support and perceived prognosis of work return. A total score based on the participants' overall response pattern is also produced, with higher scores representing a greater number of perceived occupational obstacles.

Salivary Cortisol Collection. Regardless of group assignment, participants were asked to collect salivary samples once every two weeks for a one-year period. Participants were provided cotton, plastic tubes and instructions regarding the collection and storage of the samples. The saliva samples were used to assess the amounts of cortisol present in the body, with the ultimate goal of analyzing the results for variability across treatment groups.

Stanford Presenteeism Scale (SPS). The SPS (Koopman et al., 2002) is a six-item self-report measure designed to quantify the concept of presenteeism, defined as the amount of work not completed by a worker due to an injury or illness. This term sounds similar

to “absenteeism”, a better known concept in the area of injury-related lost productivity, which represents a total absence from the worksite. The items are arranged in the form of a Likert Scale with a range of one through five, with one representing “Strongly Agree” and five representing “Strongly Disagree”. Total scores have a range of 0 to 30, with higher scores representing a lower degree of presenteeism and a higher level of performance.

Structured Clinical Interview for DSM-IV-Non-Patient Version (SCID-NP). The SCID/NP (First, Spitzer, Gibbon, & Williams, 2005) is a highly structured clinical interview designed to identify current and lifetime DSM-IV diagnoses. The SCID/NP includes a brief background section, a general inquiry portion used to focus the interview and detailed questions tailored to match specific criteria for diagnoses. Test-retest reliability was found to be moderately high for both current (.61) and lifetime (.69) Axis I diagnoses in previous versions (Williams, Gibbon, First, & Spitzer, 1992), and kappa values ranged from .9 to 1.0 in a study measuring inter-rater reliability (Kinney, Gatchel, Polatin, & Fogarty, 1993).

Structured Clinical Interview for DSM-IV Personality Disorders (SCID-II). The SCID-II is a structured interview used in the diagnosis of Axis II disorders as set forth in the DSM-IV. Specific diagnoses are organized by clusters, including: Cluster A representing odd or eccentric individuals; Cluster B representing dramatic, emotional, or erratic individuals; and Cluster C representing anxious or fearful individuals (2000). Inter-rater

reliability was deemed fair to good (kappa values of .63 to .72) on previous versions of the SCID-II (Spitzer et al., 1988).

Visual Analog Scale (VAS). The VAS is a self-report measure used to assess severity of pain. The measure consists of a single horizontal line 10 centimeters in length, with 6 equally spaced hash marks. The hash mark on the far left is represented by "No pain", while the far right hash mark represents "Worst possible pain". Participants are asked to place an "X" on the line location that most accurately represents their level of pain. The far left hash mark represents a score of 0, and the remaining hash marks represent increments of 2 with a high score of 10. McGeary, Mayer and Gatchel (2006) proposed categorizing individuals based on their scores in order to more easily interpret results across participants. VAS scores were broken into the following four groups: scores in the 0 to 3 range representing mild pain; scores in the 4 to 5 range representing moderate pain; scores in 6 to 7 range representing severe pain; and scores in the 8 to 10 range representing extreme pain.

Ways of Coping Questionnaire (WOC). The WOC is a 42-item self-report measure designed to assess the thoughts and behaviors utilized by an individual when faced with a stressful situation. The participant is asked to recall the most distressing event within the past year, and is presented with specific thoughts and behaviors common to stressful situations. Participants then state how often (i.e., never, rarely, sometimes or regularly) they used the particular technique in their stressful situation, and receive a score ranging from one to four per question. "Never used" responses receive 1 point, "Rarely Used"

receives 2 points, "Sometimes used" receives 3 points and "Regularly used" receives 4 points. Results are presented in the form of five subscales, including problem solving, problem seeking, self-blame, wishful thinking and avoidance.

The West Haven-Yale Multidimensional Pain Inventory (MPI). The MPI (Kerns, Turk, & Rudy, 1985) is a 56-item self-report inventory designed to gauge the effect chronic pain has on an individual. The measure is divided into three sections that examine how the pain is affecting the individual, how others are responding to the individual's communication of pain and to what extent the pain is affecting daily activities. The results of an individual's responses are organized into eight pain scales, and one of five coping styles is identified (i.e., adaptive, interpersonally distressed, dysfunctional, hybrid or anomalous). Internal consistency reliability estimates range from .70 to .90, and test-retest reliability ranges from ranges from .62 to .91. Various measures, including the BDI, were used to establish validity.

Return-to-Work Form. The Work form is a brief self-report questionnaire that inquires about the status and history of various employment-related issues. Examples of items include questions regarding present vocational status, numbers of work days missed and modified work conditions.

Summary of Design

This study was designed to evaluate the efficacy of interdisciplinary interventions, with and without a work transition component, in the treatment of an ALBP population at risk of developing CLBP. A total of 994 participants were screened for potential inclusion in this study. Of these 994 participants, 155 completed a baseline assessment on the basis of their high risk (HR) status for developing CLBP. This proportion of HR participants (15.6%) is consistent with previous studies that found an approximate rate of 10% within the overall population of individuals suffering from LBP (Mayer & Gatchel, 1988; Mayer & Polatin, 2000). The treatment phase of the study included a randomization of the HR participants into one of the 4 comparison groups, with the following distribution: 1) EI (*n*= 47); 2) WT (*n*= 13); 3) EI/WT (*n*= 43); and 4) SC (*n*= 52). The WT group was unable to acquire/retain adequate numbers during the course of the study due to a variety of factors, including concern on the part of participants that the work transition component would complicate their employment situation and a general perception that the treatment was ineffective. Therefore, the small amount of data collected for individuals within this group were excluded from the primary analyses, and will be reported separately.

Baseline and one-year follow-up scores from a variety of measures designed to assess psychopathology, pain levels and disability were then compared across groups in order to evaluate the relative efficacy of each.

Statistical Considerations

Baseline evaluations were conducted among the four original groups to assess for disparities among demographic variables, including gender, marital status, age, race and educational level since significant differences among groups could potentially affect outcomes and reduce the study's predictive ability. Chi square or ANOVA procedures were performed on these demographic groups depending on the type of variable being addressed (i.e., continuous or categorical). Demographic data and statistical analyses of these groups are presented in Table 1, with no significant differences found.

Demographic analyses were then conducted on the EI and EI/WT groups, with no significant differences found (Table 2). Therefore, these groups were combined into one group (T) in order to increase statistical power and more adequately address the basic question of relative efficacy between the treatment groups and the non-treatment (i.e., SC) group. Another group of statistical analyses were conducted to evaluate any potential differences in demographic variables between the T and SC groups. Demographic data are presented, along with statistical analyses showing no significant differences, in Table 3.

The distribution of scores among the outcome measures were assessed for normality. The two groups were compared at one-year follow-up on the basis of SCID I & II, MPI, WOC, Cortisol levels, BDI, CPI, PAINVAS, SF-36, MVAS, ORQ, SPS, and Return-to-Work form. Based on the type of variable being examined, and whether the data were

normally distributed, paired samples *t* tests, chi-square analyses, Fisher's Exact Tests, one-way analyses of variance (ANOVAs), or one-way repeated measures ANOVAs were conducted to evaluate significant differences between the groups on the various measures. Variations existed between the sample sizes of specific measures due to missing data. Although a uniform samples size across measures would be ideal, inclusion of all available data allowed for as complete an assessment as possible with a limited sample.

Last Observation Carried Forward

Participant non-compliance and attrition are unavoidable in a clinical study of this scope and duration, resulting in information-outcome gaps. The LBP population is particularly difficult to evaluate across time as compared to other pain populations (Pulliam, Gatchel, & Robinson, 2003). Attempts to maintain contact with uncooperative participants included phone messages, emails, and letters. A technique known as last observation carried forward (LOCF) was used to address missing data in this study. Based on the premise that the last received response from the participant is representative of future data, LOCF is commonly used in longitudinal trials to obtain missing data (Siddiqui & Ali, 1998).

Minimal Important Change (MIC)

The complexities associated with pain management for a CLBP population are apparent, and the goal of total pain reduction is rarely reasonable. As a result, the community of health specialists charged with addressing these challenges has taken steps towards

reaching consensus on what a clinically significant reduction in pain is. A literature review, expert panel, and workshop during the VIII International Forum on Primary Care Research on Low Back Pain resulted in a determination that 30% reduction in pain from baseline represented minimal important change (MIC) (Ostelo et al., 2008). This approach was applied to the MVAS used in the current study.

CHAPTER FOUR
Results

RETURN-TO-WORK/VOCATIONAL SELF-REPORT MEASURES

Return-To-Work Form

At baseline and one-year, participants were asked to state their current status of employment. Fisher's Exact Tests were conducted to determine if significant differences existed between the T and SC groups in this regard at these two points in time. No significant differences were found at baseline. However, a significantly larger portion of individuals within the T group were working at one-year as compared to the SC group, (p = .04, one-tailed Fisher's Exact Test) (Table 3). This result is visually represented in Figure 1.

Obstacles to Return-To-Work Questionnaire (ORQ)

Paired samples t tests were conducted to evaluate participants' perceptions of work limitations. A significant reduction in perceived work limitations was noted in the T group from baseline to 1-year, t (58) = 3.60, $p < .01$, while participants in the SC group did not show significant improvement, t (41) = 1.51, p = .14 (Table 4).

Stanford Presenteeism Scale (SPS)

In order to evaluate the effect LBP had on participants' work productivity, the SPS was administered. Paired samples *t* tests were conducted and a significant increase in work productivity was found in the T group from baseline to 1-year, t (56) = -2.53, p = .02, while participants in the SC group showed no such improvement, t (38) = -.23, p = .82 (Table 5).

SELF REPORT OF PAIN AND DISABILITY

Characteristic Pain Inventory (CPI)

Participants' ratings of "current pain" were analyzed to determine if significant differences existed between the T and SC groups. A one-way repeated measures ANOVA was conducted, and it was determined that current pain levels were significantly lower for participants who received treatment, than those who did not, from baseline to 1-year, F (1, 94) = 6.47, p = .01 (Table 6).

Million Visual Analog Scale (MVAS)

Analyses were conducted on MVAS scores to assess for clinically significant reductions in pain and functional disability from baseline to one-year. Due to the categorical nature of minimal important change (MIC) classifications, a chi-square analysis was performed

to determine if significant differences existed between the T and SC groups. A clinically significant reduction in pain was found in the T group as compared to the SC group, χ^2 (1, n = 101) = 3.66, p = .04 (Table 7).

Visual Analog Scale (VAS)

A one-way repeated measures ANOVA was conducted to determine if any significant differences existed between the T and SC groups from baseline to one-year for reported levels of pain. Participants within the T group reported significantly lower levels of pain than did participants within the SC group across these two points in time, F (1, 98) = 5.79, p = .02 (Table 8).

COPING MEASURES

Ways of Coping Questionnaire (WOC)

A one-way repeated measures ANOVA was conducted to evaluate the wishful thinking subscale of the WOC. The T group showed significant improvement from baseline to 1-year on this measure of unproductive avoidance, as compared to the SC group, F (1, 97) = 4.10, p = .046 (Table 9).

The West Haven-Yale Multidimensional Pain Inventory (MPI)

Although various scales are included in the results of an MPI that communicate how an individual is affected by their pain, the focus of this study was to assess individuals' coping styles. Anomalous coping styles are those that are significantly different than the three primary coping styles: Adaptive, Interpersonally Distressed and Dysfunctional. There are a variety of reasons for anomalous results, including carelessness or confusion on the part of the participant. Due to a surprisingly high percentage of Anomalous results, particularly at one-year (62%), analyses were limited by the small number of participants with valid coping styles. No significant findings resulted from these analyses.

OTHER PSYCHOSOCIAL MEASURES

Beck Depression Inventory (BDI)

A one-way repeated measures ANOVA was conducted to assess for differences between the T group and SC group regarding reported symptoms of depression. Participants receiving treatment showed significant improvement in reported mood levels as compared to the SC group, F (1, 92) = 8.76, $p < .01$ (Table 10). These results are visually represented in Figure 2.

Medical Outcomes Short Form 36-Health Survey (SF-36)

Analyses were conducted on both the Physical Component Score (PCS) and Mental Component Score (MCS) of the SF-36. A one-way repeated measures ANOVA was conducted to assess for change in PCS scores from baseline to one-year between the T and SC groups. The levels of reported physical functioning among the T group were significantly improved as compared to participants in the SC group, F (1, 93) = 4.31, p = .04 (Table 11). Analyses conducted on the participants' mental functioning did not find statistically significant differences between the T and SC groups.

Structured Clinical Interview, DSM-IV-Non-Patient (SCID-DSM-IV)

Chi-square analyses were conducted to assess for differences between the T and SC groups regarding Axis I and Axis II disorders as classified by the DSM-IV. Participants within the SC group were found to have significantly fewer symptoms of Axis II disorders than those in the T group at one-year. It is unclear why inclusion in the treatment group would result in a greater number of symptoms related to personality disorders, which are notably stable conditions, but discrepancies between raters were noted that may have affected the outcome. Chi-square analysis of Axis I disorders did not find any significant differences between the T and SC groups at one-year.

PHYSIOLOGICAL MEASURE (CORTISOL)

Many participants were unwilling or unable to collect and return the salivary samples required for cortisol analysis. Therefore, some of the following analyses incorporated data from both LR and HR participants. The large majority of these LR participants received risk scores that approached HR status, and were included in the cortisol collection process due to concerns about compliance among HR participants. Various analyses were run in order to ensure that no significant differences existed between the LR and HR groups that might affect results. The primary analysis assessed the percentage of change in cortisol variability from baseline to one-year between the T and SC groups. The means and standard deviations of cortisol levels were determined for individual participants, allowing for individual samples to be assigned standardized T scores with a mean of 50. The average variance from the mean was obtained for participants at baseline and one-year. Percentage of change was determined by dividing the average variance at one-year by the average variance at baseline.

A one-way ANOVA was conducted to assess for percentage of change in cortisol variability from baseline to one-year between the T and SC groups consisting of both LR and HR participants (n=25). The cortisol levels of participants receiving treatment displayed significantly less variability than those in the SC group, F (1, 23) = 5.32, p = .03 (Table 12), and is visually represented in Figure 3. A one-way ANOVA was also conducted to assess for differences between groups among HR participants (n=13). The

difference in variability between the T and SC groups did not reach significance, F (1, 11) = 3.76, p = .08, however, a large effect size was found η^2 = .26 (Table 13).

One-way ANOVAs were also conducted to assess for differences between the T group and SC group in regard to mean cortisol levels across all subjects and samples. The T group had significantly higher levels of cortisol for the total sample, F (1, 948) = 6.43, p = .01, as well as the group composed solely of HR participants, F (1, 517) = 5.79, p = .02 (Table 14).

WORK TRANSITION (WT)

It is not entirely clear why the WT participants were unwilling to enroll/remain in treatment, but anecdotal evidence suggests many were disappointed at not being assigned to one of the early intervention (i.e., EI or EI/WT) groups. Participants also voiced concern about the potential for complications that might arise at their workplace as a result of the intervention. Due to the small number of participants within this group and their poor completion rate (Table 15), separate analyses were run to assess for significant differences between baseline and one-year scores among the measures. No such differences were found.

CHAPTER FIVE
Discussion

Several previous studies provided the framework and impetus for the current research. The algorithm used in the current study to identify individuals at high risk for developing CLBP was developed by Gatchel et al. (1995a), and was employed in similar research that illustrated the efficacy of an early intervention program in decreasing levels of pain and disability (Gatchel et al., 2003). In addition to reducing the biopsychosocial effects associated with CLBP, treatment was shown to be cost-effective by reducing healthcare utilization, medication costs and time away from work. The current study builds directly upon the preliminary research by Holberg and Gatchel (2007), which implemented a work transition component intended to improve return-to-work status among participants. The current study benefited from increased sample size and greater statistical power, allowing for a more definitive assessment of the differences between treatment and non-treatment groups.

Return to Work/Vocational Self-Report Measures

The work transition (WT) component was a novel addition to the established interdisciplinary approach to the treatment of low back pain in this study. However, the WT group was unable to acquire/sustain adequate numbers due to concerns among participants that this component may lack efficacy or complicate their work situation. Therefore, the small amount of data collected for individuals within this group were excluded from the primary analyses. Participants within the group that combined the

early intervention and work transition components (EI/WT) showed few significant differences from the early intervention group (EI) regarding measures, and no significant demographic differences, so these two groups were merged to allow for a comparison between the treatment and non-treatment groups.

Among the vocational measures, work status at one-year follow-up was seen as an important marker due to its direct impact on the emotional and financial well-being of participants. Although the T and SC groups were similar at baseline regarding work status, a significantly higher number of participants within the T group were working at one-year. The retention problems encountered by the WT group also affected the EI/WT group, and may explain the general lack of statistical significance found between the EI and EI/WT groups. The effectiveness of traditional interdisciplinary treatment, in combination with the costs and difficulties associated with work transition interventions, suggests that treatment intended to reduce CLBP may not benefit from the addition of a work transition component.

In addition to return-to-work improvements found among participants receiving treatment, a decrease in perceived work limitations resulted. These perceptions, represented by ORQ scores, were significantly reduced from baseline to one-year. Work productivity, based on the concept of presenteeism as measured by the SPS, was significantly improved from baseline to one-year for participants within the T group, but not so for the SC group.

Self Report of Pain and Disability

All three measures designed to assess pain and disability included in this study showed significant improvements among participants receiving treatment. These results lend additional support to previous studies that found significant reductions in these areas for those who participated in an interdisciplinary early-intervention program (Gatchel et al., 2003; Jensen et al., 2005). The two measures that focus exclusively on pain (i.e., VAS and CPI) each showed significant pain reduction from baseline to one-year for the T group as compared to the SC group.

The MVAS provided information about the level of pain an individual experienced, as well as the ways in which the individual's activities were affected by the pain. The concept of minimal important change (MIC) provided the opportunity to practically assess the effects of treatment for LBP. Participants within the T group were significantly more likely to experience a 30% reduction in pain and disability than participants in the SC group.

Coping Measures

The cognitive-behavioral component of interdisciplinary treatment encourages participants to become aware of, and attempt to reduce, thoughts and behaviors that may interfere with the healing process. The WOC allows participants to report on a wide variety of such thoughts/beliefs, and its scores represent the participants' current ability

to handle potential problems. One aspect of positive coping involves the ability to accurately assess a problem and take steps to find a solution. Wishful thinking, a WOC subscale that is marked by avoidance and denial, was significantly decreased among the T group participants from baseline to one-year, with no such drop among participants within the SC group.

Other Psychosocial Measures

Due to the important mutual relationship between thoughts and the experience of physical pain, measures were given that assessed participants' depressive symptoms and beliefs related to their abilities. Symptoms of depression, as measured by the BDI, were significantly reduced for the T group as compared to the SC group from baseline to one-year. The Physical Component Score on the SF-36 represents the participants' beliefs regarding their ability to engage in various activities. The T group showed significant improvement from baseline to one-year as compared to the SC group in this regard. There is a complex interplay between the mind and body during the onset and maintenance of pain, so it is impossible to state if these improvements in psychosocial functioning are causing, resulting from or unrelated to changes in the physical experience.

Physiological Measure (Cortisol)

Salivary samples were collected from participants throughout the year in which they were involved in the study in order to measure levels of cortisol, a hormone that is released by the adrenal glands during times of stress. Cortisol data from LR participants were included in some of the analyses due to the poor compliance among the HR population, but no significant differences were found between these groups regarding variability or mean levels. Cortisol dysregulation, as measured by the variability at baseline and one-year, was significantly more pronounced in the SC group than in the T group for both the LR/HR combination group and group consisting solely of HR participants.

Although previous studies had noted a general increase in cortisol levels over time in both treatment and non-treatment groups (Robinson et al., 2006), the significantly higher mean cortisol levels within the T group, as compared to the SC group, was a novel finding. The reason for this association is not clear and should be pursued in future studies investigating the relationship between cortisol and pain. Conflicting data exists within the literature regarding the specific relationship between pain, stress and cortisol levels, but these findings provide additional support for a link between stress and cortisol levels and the efficacy of an interdisciplinary approach regarding regulation of the HPA axis.

Limitations and Directions for Future Research

There are several limitations to the current study. Primarily, the desired sample size was not obtained. A study of this length requires a high level of commitment on the part of participants who are often struggling in other areas of life as a result of their LBP. The limitation in sample size, and the occasional missing data points, necessitated the use of LOCF as a statistical technique, which may have resulted in fewer significant findings. Another aspect that may have reduced the ability to identify significant trends within the data set was the occasional delay in one-year follow-up data collection. Due to a variety of reasons, including occupational and personal obligations, some participants completed measures up to two years following the completion of the treatment period. It is possible that positive effects from treatment may have become less pronounced during the interval between one-year and the time of data completion.

One aspect of small sample size that affected the study's direction involved the removal of the WT group from the primary analyses. Although anecdotal, evidence suggested that participants placed into this group were disappointed that they would not be receiving some of the treatment modalities offered to members of the EI or EI/WT groups. Some participants also voiced concerns that their employers may look unfavorably on a process that involved input from outside the workplace.

Compliance among participants regarding cortisol collection was particularly poor. This is somewhat understandable considering the time commitment and relative complexity of

the task, but greater compliance would have allowed for analyses to be conducted exclusively on HR participants with completed data. Although a large effect size was obtained to support the case for reduced cortisol dysregulation among HR individuals within the T group, additional participants were required to reach statistical significance. This study went to great lengths to obtain the desired sample size by communicating the potential benefits of treatment and providing appropriate compensation, but future studies would benefit from continuing to search for creative solutions to overcome the obstacles inherent in such long-term commitment-heavy projects.

Conclusions

The results from this study further support the well-documented evidence for the efficacy of interdisciplinary programs in the treatment of low back pain. Pain, disability and coping ability all showed significant improvements within the T group from baseline to one-year. In addition, this study was able to demonstrate that early intervention treatment significantly improved return-to-work status and symptoms related to depression; and may have contributed to stabilizing activity within the HPA axis.

The separate analyses, consisting exclusively of participants within the WT group, found no significant improvements from baseline to one-year for the occupational or psychosocial variables measured. Although benefits may have become evident if a larger sample size had been obtained, the success of early intervention treatment supports the

position that additional work-specific interventions may be unnecessary due to the added costs and compliance issues.

APPENDIX A
FIGURE 1

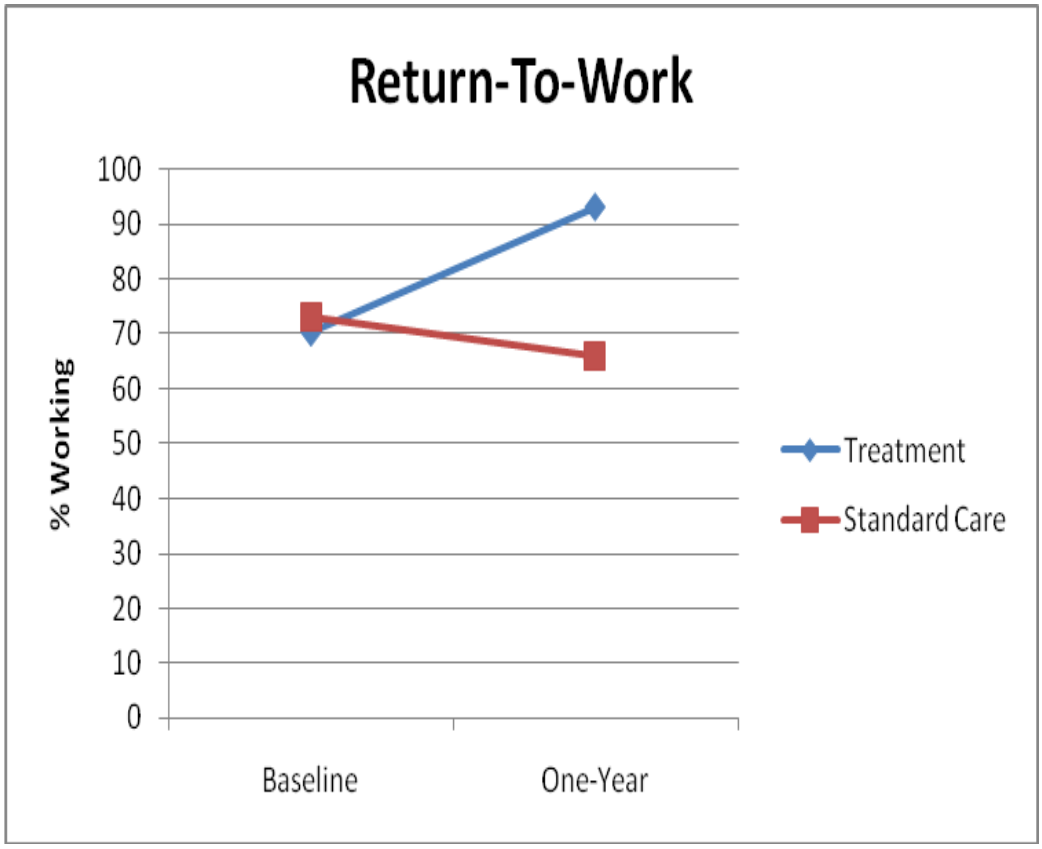


FIGURE 2

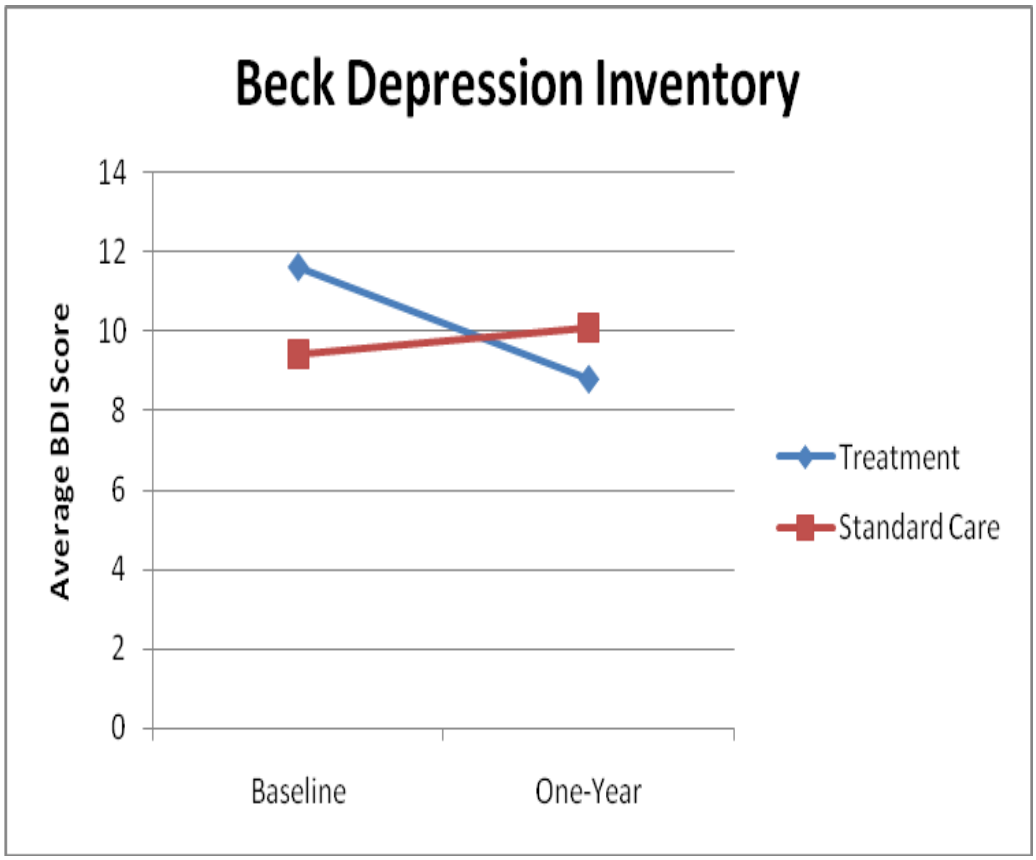
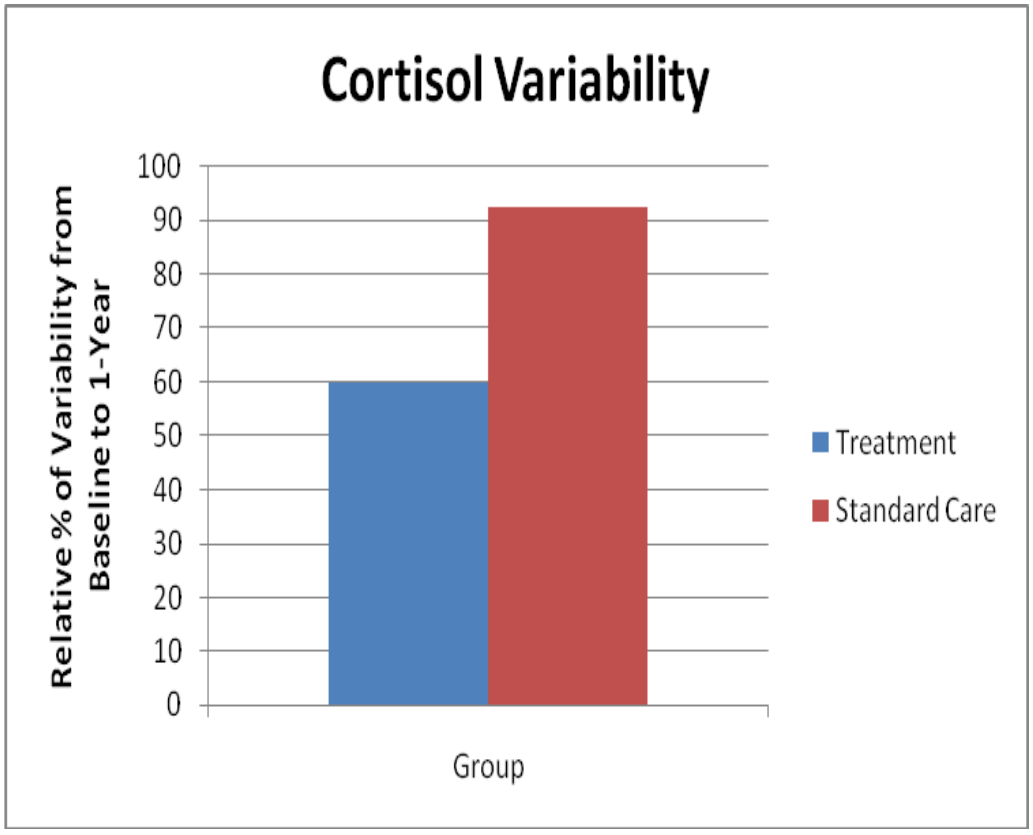

Beck Depression Inventory
Average BDI Score
14
12
10
8
6
4
2
0
Baseline
One-Year
Treatment
Standard Care

FIGURE 3


Cortisol Variability
Relative % of Variability from Baseline to 1-Year
100
90
80
70
60
50
40
30
20
10
0
Group
Treatment
Standard Care

APPENDIX B
TABLE 1

Demographic Comparison of Four Original Groups at Baseline

	EI (*n*=46)	EI/WT (*n*=43)	WT (*n*=13)	SC (*n*=52)	χ^2	*df*	*p*
Gender					5.08	3	.17
Male	61.7%	44.2%	69.2%	46.2%			
Female	38.3%	55.8%	30.8%	53.8%			
Ethnicity					21.77	15	.11
Caucasian	56.5%	51.2%	46.3%	48.1%			
Latino	10.9%	13.9%	7.6%	17.3%			
African American	32.6%	32.5%	23.1%	26.9%			
Asian	0.0%	2.3%	7.6%	5.8%			
Other	0.0%	0.0%	15.4%	1.9%			
Marital Status					7.94	9	.54
Single	28.3%	34.2%	30.8%	38.5%			
Married	52.2%	46.3%	69.2%	51.9%			
Divorced	19.5%	19.5%	0.0%	9.6%			
Level of Education					16.32	15	.36
No Degree	6.7%	7.2%	0.0%	5.8%			
G.E.D.	8.9%	14.3%	0.0%	15.4%			
High School	24.4%	28.6%	46.1%	46.2%			
Associate	13.3%	19.0%	23.1%	3.8%			
Bachelor	26.7%	19.0%	15.4%	17.3%			
Graduate	20.0%	11.9%	15.4%	11.5%			

	EI	EI/WT	WT	SC	μ	*σ*	*F*	*df*	*p*
Age	43.5	40.1	41.3	37.2	40.2	11.5	2.55	3	.06

TABLE 2

Demographic Comparison of EI and EI/WT Groups

	EI (*n*=46)	EI/WT (*n*=43)	χ^2	*df*	*p*
Gender			2.77	1	.07
Male	61.7%	44.2%			
Female	38.7%	55.8%			
Ethnicity			1.36	3	.72
Caucasian	56.5%	51.1%			
Latino	10.9%	14.0%			
African American	32.6%	32.6%			
Asian	0.0%	2.3%			
Other	0.0%	0.0%			
Marital Status			1.34	3	.72
Single	28.3%	34.1%			
Married	52.2%	46.3%			
Divorced	19.5%	19.6%			
Level of Education			2.57	5	.76
No Degree	6.7%	7.1%			
G.E.D.	8.9%	14.3%			
High School	24.4%	28.6%			
Associate	13.3%	19.0%			
Bachelor	26.7%	19.0%			
Graduate	20.0%	11.9%			

	EI	EI/WT	μ	*σ*	*df*	*F*	*p*
Age			41.8	11.2	1	2.05	.16
	41.8	11.2					

TABLE 3

Demographic Comparison of Treatment and Standard Care Groups

	T (*n*=58)	SC (*n*=44)	χ^2	*df*	*p*
Gender			.47	1	.32
Male	50.0%	43.2%			
Female	50.0%	56.8%			
Ethnicity			2.46	3	.48
Caucasian	51.7%	40.3%			
Latino	19.0%	20.7%			
African American	27.6%	32.0%			
Asian	1.7%	7.0%			
Other	0.0%	0.0%			
Marital Status			2.72	2	.26
Single	31.6%	38.6%			
Married	47.4%	52.3%			
Divorced	21.0%	9.1%			
Level of Education			6.69	5	.24
No Degree	7.1%	7.0%			
G.E.D.	10.8%	14.0%			
High School	26.8%	41.8%			
Associate	19.6%	4.6%			
Bachelor	25.0%	18.6%			
Graduate	10.7%	14.0%			

	T	SC	μ	*σ*	*df*	*F*	*p*
Age	42.3	37.6	40.3	12.1	1	3.79	.05

TABLE 4

Fisher's Exact Test for Return-To-Work*

	Treatment	**Standard Care**	Fisher's
			.57
Working at Baseline	19	11	
Not Working at Baseline	8	4	

	Treatment	**Standard Care**	Fisher's
			.04**
Working at 1-Year	25	10	
Not Working at 1-Year	2	5	

* Number of participants may differ from table to table for various reasons, including LOCF
** Statistically significant at the .05 level

TABLE 5

Paired Samples *t*-tests for Obstacles to Return-To-Work Questionnaire

	*n**	μ	*σ*	*df*	*t*	*p*
Treatment				58	3.60	.00**
Baseline	59	126.7	48.1			
1-Year	59	111.6	54.7			
Standard Care				41	1.51	.14
Baseline	42	114.9	38.0			
1-Year	42	109.8	45.2			

* Number of participants may differ from table to table for various reasons, including LOCF
** Statistically significant at the .05 level

TABLE 6

Paired Samples *t*-tests for Stanford Presenteeism Scale

	*n**	μ	*σ*	*df*	*t*	*p*
Treatment				56	-2.51	.02**
Baseline	57	17.2	5.9			
1-Year	57	20.4	10.4			
Standard Care				38	-.22	.82
Baseline	39	19.0	5.7			
1-Year	39	19.2	6.1			

* Number of participants may differ from table to table for various reasons, including LOCF
** Statistically significant at the .05 level

TABLE 7

One-Way Repeated Measures ANOVA for Characteristic Pain Inventory, Current Pain

	*n**	μ	*σ*	*df*	*Er. df*	*F*	*p*
Baseline				1	94	6.47	.01**
Treatment	56	5.2	2.5				
Standard Care	40	5.2	2.5				
1-Year							
Treatment	56	3.0	2.8				
Standard Care	40	4.3	3.0				

* Number of participants may differ from table to table for various reasons, including LOCF
** Statistically significant at the .05 level

TABLE 8

Chi-Square Analysis of Minimal Important Change for Million Visual Analog Scale*

	Not Significant	**30% Reduction**	χ^2	*df*	*p*
			3.66	1	.04**
Treatment	31	28			
Standard Care	30	12			

* Number of participants may differ from table to table for various reasons, including LOCF
** Statistically significant at the .05 level

TABLE 9

One-Way Repeated Measures ANOVA for Visual Analog Scale

	*n**	μ	*σ*	*df*	*Er. df*	*F*	*p*
Baseline				1	98	5.79	.02**
Treatment	58	6.0	2.1				
Standard Care	42	6.0	2.0				
1-Year							
Treatment	58	3.9	2.9				
Standard Care	42	5.1	2.8				

* Number of participants may differ from table to table for various reasons, including LOCF
** Statistically significant at the .05 level

TABLE 10

One-Way Repeated Measures ANOVA for Ways of Coping, Wishful Thinking

	*n**	μ	*σ*	*df*	*Er. df*	*F*	*p*
Treatment				1	97	4.10	.04**
Baseline	57	21.0	5.8				
1-Year	57	20.1	6.1				
Standard Care							
Baseline	42	17.7	6.2				
1-Year	42	18.0	6.5				

* Number of participants may differ from table to table for various reasons, including LOCF
** Statistically significant at the .05 level

TABLE 11

One-Way Repeated Measures ANOVA for Beck Depression Inventory

	*n**	μ	*σ*	*df*	*Er. df*	*F*	*p*
Treatment				1	92	8.76	<.01**
Baseline	57	11.6	9.3				
1-Year	57	8.8	9.5				
Standard Care							
Baseline	37	9.4	9.6				
1-Year	37	10.1	10.2				

* Number of participants may differ from table to table for various reasons, including LOCF
** Statistically significant at the .05 level

TABLE 12

One-Way Repeated Measures ANOVA for Medical Outcomes Short Form 36-Health Survey, Physical Composite Summary

	*n**	μ	*σ*	*df*	*Er. df*	*F*	*p*
Treatment				1	93	4.31	.04**
Baseline	57	33.0	8.1				
1-Year	57	40.5	11.5				
Standard Care							
Baseline	38	36.0	10.1				
1-Year	38	39.5	10.6				

* Number of participants may differ from table to table for various reasons, including LOCF
** Statistically significant at the .05 level

TABLE 13

One-Way ANOVA for Cortisol Variability (LR/HR Combination)

	*n**	μ	*σ*	*df*	*Er. df*	*F*	*p*
				1	23	5.32	.03**
Treatment	16	59.8	34.0				
Standard Care	9	92.7	34.8				

* Number of participants may differ from table to table for various reasons, including LOCF
** Statistically significant at the .05 level

TABLE 14

One-Way ANOVA for Cortisol Variability (HR Only)

	*n**	μ	*σ*	*df*	*Er. df*	*F*	*p*	η^2
				1	11	3.76	.08	.26
Treatment	7	59.29	29.31					
Standard Care	6	92.00	31.52					

* Number of participants may differ from table to table for various reasons, including LOCF

TABLE 15

One-Way ANOVAs for Cortisol Mean Levels (Total and HR)

	*n**	μ	*σ*	*df*	*Er. df*	*F*	*p*
Total Sample				1	948	6.43	.01**
Treatment	587	.51	.78				
Standard Care	363	.4	.31				
HR Participants				1	517	5.79	.02**
Treatment	277	.56	1.09				
Standard Care	242	.38	.35				

* Number of individual cortisol samples
** Statistically significant at the .05 level

TABLE 16

Completion Rate Among the Work Transition Participants

	Completed	**Not Completed**
One-Year	1	4
LOCF	2	6

APPENDIX C
Consent To Participate in Research

The University of Texas Southwestern Medical Center at Dallas

CONSENT TO PARTICIPATE IN RESEARCH

Title of Research: An Evaluation & Treatment Study of Low Back Disability II

Sponsor: ***National Institutes of Health***

Investigators	Tel. No.	Investigators	Tel. No
Samuel Bierner, M.D.	214-648-2240	Robert J. Gatchel, Ph.D.	214-645-8450
Anna W. Stowell, Ph.D.	214-536-5438	Deborah Buckingham	817-498-6917
Richard Robinson,Ph.D.	214-362-0278	Travis Whitfill	214-645-8741
Mark Rogerson	214-645-8741	Peter Polatin, M.D.	214-801-5001
Glenn Pransky, M.D.	508-497-0234	Jokae Ingram	214-645-8741
Amanda Buelow	214-645-8741	Maggie Perish, M.A.CL.	214-645-8741
		Robbie Haggard, M.S.,CRC, LPC Intern	214-645-8749

**** In an emergency ask to have study doctor paged by calling the same number listed above for each doctor.***

INVITATION: You are invited to participate in this research because you have had low back pain for 10 weeks or less. Medical research involves offering a plan of care to a group of patients, collecting and studying information about each patient's experience, and using that information to develop the best possible care for future patients. About 800 subjects are expected to be in this study.

PURPOSE: The purpose of this research is to assess the role of physical health and life events in your past and present to determine their effect on your back pain and discomfort. This will further allow for determination of which type of treatment is best at

reducing the duration and magnitude of your low back pain symptoms. The research will also assess the costs incurred by you for treatment of your pain in terms of finances, time, and convenience.

This research is being done because currently there are few non-invasive options for pain relief for people suffering acute back pain and the costs involved in traditional care are exorbitant. We aim to determine what type of early intervention is best suited for treating acute back pain and discomfort while reducing the overall financial and time burden.

PROCEDURES

Screening: During this screening phase you will complete a patient information form, requesting demographic information and basic information about your back pain and medical/surgical history. You will also complete two questionnaires, asking more detailed information about your pain, as well as physical and emotional functioning. The study doctor might contact you with clarifying questions about your health, medications you take for any health problems, and any surgical procedures you have had.

Randomization: If the study doctor believes that you qualify to participate in this research, you will be contacted at a later point in time and may be offered some additional treatment to help manage low back pain. You have a 1 in 5 (20%) chance of being invited for further evaluation and being enrolled in the study. The study assignment is made in advance by a process similar to drawing straws. Assignment is made to an early intervention group or a non-intervention group. Regardless of your study assignment, you will be contacted for follow-up. Of the 800 anticipated screens, we plan to have 135 in the intervention group and 45 in the non-intervention group. Participants in the non-intervention group will receive one evaluation by the study doctor, but will not receive additional treatment within the study and will be encouraged to pursue their normal course of treatment with their outside providers. All subjects who are screened, whether allocated to the intervention or non-intervention group, will be followed-up by telephone four times at three-month intervals for the period of one year. The telephone follow-up will be brief, and will essentially entail asking questions about the status of your back pain, if it is interfering with your life, as well as any treatment you have had to seek as a result of it.

Further Evaluation Phase: If the study doctor believes that you qualify to participate in this research, you will be invited to participate in a further evaluation, which would require an additional visit of about 2.5 hours. The evaluation will consist of an interview with the study doctor and completion of numerous questionnaires. These questionnaires will ask for in depth information about your pain level, physical and psychological functioning, and work demands. Should you be offered a further evaluation and you choose to participate, a separate informed consent process will be undertaken to cover the procedures and data gathered during this second phase of the project.

TREATMENT PHASE

Early Intervention: Early intervention treatment will be offered to half of the patients who enroll in the study, and will consist of a physician evaluation, physical therapy visits, and behavioral medicine visits.

Physician Evaluation: At the physician evaluation, the study doctor will perform a basic medical exam, collecting vital signs and asking you questions about your health, medications you take for any health problems, and any surgical procedures you have had. The physician will see you once at the start of the study and at the end of the study, unless further appointments are necessary. He will serve as a consultant to your outside providers, if any, and will recommend additional treatment options to you if he sees fit. He will not take over your care.

Physical Therapy: The physical therapist is an expert in pain management and is supervised by the study physician. The physical therapy regimen (approximately 6-9 visits) will take a sports medicine approach (involving stretching and exercise) to helping you improve physical functioning, strength, endurance, and range of motion.

Behavioral Medicine: The behavioral medicine component will involve sessions (individual and group) with mental health professionals (approximately 9 individual, and up to 9 group) to learn relaxation skills, stress reduction, and coping strategies for managing pain and reducing the effects of pain on life-functioning.

Work Transition: The work transition intervention will be offered to half of the patients enrolled in the study. Half of the patients in this group will also receive the Early Intervention treatment, in combination. Work Transition will consist of strategies to help ease your transition back into your job (if your low back pain has caused absence) or to help you make changes in your work place that will allow you to guard against further aggravation of your low back pain. These strategies will involve telephone consultation and/or meetings with a case manager who is an expert in work related injuries, and might include suggestions for improving the ergonomics of your work site or for modifying work activities to protect your back. Sometimes these activities might be facilitated by dialogue between the case manager and your employer. If the case manager makes this recommendation, you have the right to decline. If you do agree to have the case manager speak with your supervisor, you will be asked to sign a separate consent form. Work transition will also include meetings (approximately 4-6) with a mental health professional who will help you identify any obstacles for optimal functioning in the work place (or other aspects of life) and identify problem-solving strategies.

Saliva Collection: All study participants, whether in one of the intervention groups or non-intervention groups, will be asked to collect samples of saliva, every two weeks, by chewing a piece of cotton and placing the cotton in a plastic test tube. Both the cotton and the test tube will be provided by us. The purpose of this collection is to assess the amount of a stress related hormone (cortisol) that is naturally present in your saliva. This information will then be correlated to your self-reported level of pain. There is no discomfort associated with collecting these samples.

POSSIBLE RISKS & BENEFITS

Unforeseen risks: A previously unknown problem could result from your participation in this research. It is not possible to estimate the chances of such problems or how serious problems could be. Consequently we ask that you inform the study doctor of any problems that arise during this study and also inform your physician. You may discontinue any and all aspects of the treatment at any time during the study. Telephone numbers where you may reach the study personnel are listed on the front page of this consent form.

Possible benefits: Your back pain or discomfort may get better or go away; however your study doctor cannot guarantee that you will benefit from participation in this research. In the future, other people with back pain or discomfort may benefit from the results of this research. Information gained from this research may lead to improved treatment at a reduced cost and within a shorter period of time than is traditional. However, your study doctor will not know whether there are benefits to other people with back pain or discomfort until all of the information obtained from this research has been collected and analyzed.

ALTERNATIVES TO PARTICIPATION IN THIS RESEARCH: You do not have to participate in this research to receive care for your medical problem. Alternative care includes referrals to health care providers who regularly work with patients suffering from back pain and discomfort, such as orthopedists.

PAYMENT TO TAKE PART IN THIS RESEARCH: You will be paid $20 to participate in the screening phase of this research. We may also ask that you participate in the further evaluation mentioned above, and for this we will pay you an additional $50. As mentioned previously, should this occur, we will undergo a separate informed consent process to cover the procedures and data gathered during this second phase of the project. If you collect saliva samples, as mentioned above you will be paid $10 per collection.

If you are an employee of UT Southwestern, tax will be deducted from the payment given to you for your participation in the research.

UT Southwestern, as a State agency, will not be able to make any payments to you for your participation in this research if the State Comptroller has issued a "hold" on all State payments to you. Such a "hold" could result from your failure to make child support payments or pay student loans, franchise taxes, etc. Should this occur, UT Southwestern will be able to pay you for your participation in this research after you have made the outstanding payments, and the State Comptroller has issued a release of the "hold."

COSTS TO YOU: The sponsor will pay the expenses for the tests and materials that are part of this research. Expenses related to standard medical care for back pain and discomfort are your responsibility (or the responsibility of your insurance provider or government program). There are no funds available to pay for parking expenses,

transportation to and from the research center, lost time away from work and other activities, lost wages, or child care expenses, unless otherwise arranged with the study doctor.

COMPENSATION FOR INJURY: Compensation for an injury resulting from your participation in this research is not available from the University of Texas Southwestern Medical Center at Dallas. You retain your legal rights during your participation in this research.

VOLUNTARY PARTICIPATION IN RESEARCH: You have the right to agree or refuse to participate in this research. If you decide to participate and later change your mind, you are free to discontinue participation in the research at any time.

Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. Refusal to participate will not affect your legal rights or the quality of health care that you receive at this Center. In the case that you are affiliated with the University of Texas Southwestern Medical Center at Dallas, your status as a medical student, fellow, faculty, or staff in the medical center will not be affected in any way.

RECORDS OF YOUR PARTICIPATION IN THIS RESEARCH: You have the right to privacy. Any information about you that is collected for this research will remain confidential as required by law. In addition to this consent form, you will be asked to sign an "Authorization for Use and Disclosure of Protected Health Information for Research Purposes," which will contain more specific information about who is authorized to review, use, and/or receive your protected health information for the purposes of this study.

CERTIFICATE OF CONFIDENTIALITY: Samuel Bierner, M.D., Principal Investigator has obtained a Certificate of Confidentiality from the Federal government. This Certificate will help researchers protect your privacy. However, the Certificate will not protect your privacy if you consent in writing to the release of information about your participation in this research to anyone else.

For more information about a Certificate of Confidentiality, please read "More Information about This Research" at the end of this consent form.

YOUR QUESTIONS: Your study doctor is available to answer your questions about this research. The Chairman of the IRB is available to answer questions about your rights as a participant in research or to answer your questions about an injury or other complication resulting from your participation in this research. You may telephone the Chairman of the IRB during regular office hours at 214-648-3060.

YOU MAY HAVE A COPY OF THIS CONSENT FORM TO KEEP.

Your signature below certifies the following:

- You have read (or been read) the information provided above.
- You have received answers to all of your questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.

_____
Participant's Name (printed)

_____
Date

_____
Participant's Signature

_____
Legally authorized representative's name (printed)

_____
Date

_____
Legally authorized representative's Signature

Date

_____
Name (printed) of person obtaining Consent

_____
Date

_____
Signature of person obtaining consent

More Information about This Research

How long are my records kept? The investigators will keep your information in a research laboratory at this medical center until the study is completed. If your

information remains stored beyond your lifetime, it will be used as described in this document.

Could your information be used for other purposes? No one may use your information for purposes other than research without your permission or the permission of your legally responsible representative and the approval of the IRB at this medical center.

Will the results of the tests and interview be reported to you? The investigators will use your information only for research. They will not be reported to you and will not be used to plan your health care.

Will you be contacted in the future? You will be contacted every three months for the duration of one-year. Please keep in touch with the investigators and maintain a current address and telephone number on file. Please notify the investigators if your legal name changes.

The investigators may invite you to participate in other research in the future. Any new information which becomes available during your participation in the research and may affect your willingness to continue in the research will be given to you promptly.

What are some of the risks that could result from participation in this kind of research?

Stress: You could experience stress from participating in this kind of research. Knowing that researchers have personal information about you may trouble you.

What is a Certificate of Confidentiality? The Department of Health & Human Services issued a Certificate of Confidentiality for this research. This Certificate enables Samuel Bierner, M.D., and the other investigators associated with this project to withhold information about your participation. The protection afforded by this Certificate lasts forever. However, the Certificate will not provide protection if you consent in writing to the release of information about your participation in the research to anyone else.

Why is a Certificate of Confidentiality needed? Sensitive information about your health and psychiatric well-being will be collected and studied. The Certificate will help the investigators avoid having to release identifying information about you which could expose you and your family to unwanted financial, legal, emotional, and social consequences.

How does the Certificate of Confidentiality protect your privacy? All persons who are employed by or associated with the University of Texas Southwestern Medical Center at Dallas (and its contractors or cooperating agencies) and who have access to information about your participation in this research may withhold your name and other identifying information from all persons not connected with the conduct of that research.

This means that the investigators do not have to identify you as a participant in this research in any Federal, State, or local, civil, criminal, administrative, legislative, or other proceedings.

What are the limitations of the Certificate? This Certificate does not stop you or a member of your family from identifying you as a participant in this research.
For example, if an insurance provider or employer learns about your participation in this research and obtains your consent to receive research information, the investigators may not use the Certificate of Confidentiality to withhold this information.

It is important that you and your family actively protect your own privacy.

If the investigators determine that you could be harmful to yourself or to others, they must report such concerns to proper authorities for your safety or the safety of others.

A Certificate of Confidentiality does not represent an endorsement of this research project by the Department of Health & Human Services or any other Federal government agency.

Could there be problems if you or someone else in the family releases information?
If you or a member of your family receives private information about you and does not maintain the privacy of that information, there is no way to predict who will have access to that private information. There is no way to predict the risks or damage which could result from unwanted release of that information.

How do you stop your participation in the research? If you prefer to stop participation in this research, you may ask the investigators to destroy any record of your participation in this research and to destroy any information with your name on it. You will not be asked for further information. Your identity will be removed from all research records. However, the resulting data from the research will not be discarded

APPENDIX D
Project Summary for National Institutes of Health (NIH) - Funded Grant

PURPOSE: To empirically evaluate potential obstacles to safe and sustained return to normal occupational status within the context of a biopsychosocial assessment-treatment protocol (developed upon the basis of our earlier two NIH-funded projects) for high-risk ALBP patients.

BACKGROUND: The initial NIH-funded grant project in this series clearly isolated some significant psychosocial risk factors that successfully predicted the development of chronicity, with a 90.7% accuracy rate. These risk factors include gender, workers' compensation status, and various standardized indices of pain and psychological functioning. A statistical algorithm was developed that could be used to identify "high risk" ALBP patients who are prime candidates for early intervention in order to prevent chronicity. As an extension of these findings, the second funded grant project (2R01 MH46452) clearly revealed additional differences between the high-risk and low-risk groups. High-risk patients were then randomly assigned to one of two groups: an early intervention group or a non-intervention group. Overall, it was largely found that early intervention at the acute stage would prevent the development of chronic disability at one-year follow-up. Traditional medical modalities have been passive in nature, such as bedrest, NSAID medication, etc. One additional observation from this project was that, even in the successful early intervention group, there were sometimes problems encountered by certain patients when they were ready to return-to-work. Preliminary evaluations indicated that workplace factors may present some significant obstacles for certain of these patients to immediately return-to-work when they were ready to do so.

CONCISE SUMMARY OF PROJECT: A three-component model of early intervention will be used to evaluate potential obstacles to safe and sustained return to normal occupational status for high-risk ALBP patients: (1) the identification of high-risk status by use of our empirically-supported clinically-applicable algorithm; only approximately 5-10 % of subjects screened meet the high-risk criterion*, thus necessitating the screening of large numbers of subjects;(2) providing our empirically-supported successful early intervention program for high risk patients; (3) and then also introducing a back-to-work transition component in order to directly modify any potential workforce obstacles to maximize return-to-work effectiveness of the intervention. Explanation of these interventions is provided below. It is hypothesized that this latter interventional component will be the "final piece of the puzzle" in maximizing the prevention of chronicity in high-risk ALBP patients. This research will be conducted in partnership with the largest workers' compensation insurance company in the U.S. (Liberty Mutual). For this study, high-risk ALBP patients will be randomly assigned to one of the following 4 groups (45 patients/group): (1) early intervention plus workplace transition; (2) early intervention plus no workplace transition; (3) no early intervention plus workplace transition; (4) no early intervention plus no workplace transition. Comparison of Groups 2 and 4 will provide a replication test of results from our just completed project. Comparison of Groups 2 and 3 will evaluate whether appropriate workplace transition is as effective as early intervention in preventing chronicity. The

major hypothesis is that patients in Group 1 will do the best of patients in all groups in terms of earliest work return and maximizing the prevention of chronicity.
*Subjects' risk status is established through the use of a Screening packet, which includes a demographics form and two questionnaires (see attached.) Information derived from these forms is plugged into the algorithm (referenced above) for determining risk status for developing chronic lower back pain.

TREATMENT SUMMARY:

Early Intervention: Early intervention treatment will consist of a physician evaluation, physical therapy, and behavioral medicine. At the physician evaluation, the study doctor will perform a basic medical exam, collecting vital signs and information about medical usage and medical/surgical history. There is one physician visit at the start of treatment and one at the end of treatment, for a total of two physician visits, unless further appointments are deemed necessary. The physical therapy regimen (approximately 6-9 visits) will take a sports medicine approach (involving stretching and exercise) to helping improve patients' physical functioning, strength, endurance, and range of motion. The behavioral medicine component will involve sessions (individual and group) with mental health professionals (approximately 9 individual, and up to 9 group) to teach relaxation skills, stress reduction, and coping strategies for managing pain and its effects on life-functioning.

Work Transition: Work Transition will consist of strategies to facilitate patients' transition back to work and/or to facilitate accommodations in the work place to help guard against further aggravation of low back pain. These strategies will involve telephone consultation and/or meetings with a case manager who is an expert in work related injuries, and might include suggestions for improving the ergonomics of the work site or for modifying work activities. Work transition will also include meetings (approximately 4-6) with a mental health professional who will help the patient identify any obstacles for optimal functioning in the work place (or other aspects of life) and identify problem-solving strategies.

Saliva Collection: All study participants, whether in one of the intervention groups or the non-intervention group, will be asked to collect samples of saliva, every two weeks, by chewing a piece of cotton and placing the cotton in a plastic test tube. Both the cotton and the test tube are provided by the study. The purpose of this collection is to assess the amount of a stress related hormone (cortisol) that is naturally present in the patients' saliva and to correlate this with self-reported pain and anxiety levels.

CRITERIA FOR INCLUSION OF SUBJECTS: 1) English speaking and 18 years of age or older; 2) have no more than two months (8-10 weeks) since ALBP onset; 3) constant daily pain when performing activities, from initial onset to current evaluation; 4) decreased ability to perform normal job requirements because of the pain; 5) no history of chronic episodic back pain (i.e., two or more disabling episodes at least four to six months apart during the past two years, with fluctuating low grade discomfort between episodes); 6) no current need for surgery; 7) preferably fully employed at the time of their injury. All subjects are referred after their primary care physicians have released them following any acute crisis stabilization.

CRITERIA FOR EXCLUSION OF SUBJECTS: Subjects who do not meet all of the above inclusion criteria will be excluded. Non-English speaking people will be excluded because all assessment materials require comprehension of English. Also, the interdisciplinary treatment team only speaks English.

SOURCES OF RESEARCH MATERIAL: Data to be used in the research will be obtained via questionnaires and self-report measures, as well as review of medical and billing records. Prior to collecting or using any such information, all subjects will read and sign a consent form indicating exact data to be used and/or collected. See below.

RECRUITMENT OF SUBJECTS: Similar to the last grant projects, we will recruit patients from a number of clinical facilities in the Dallas area, with whom we have a well-established referral base. Moreover, because of our partnership with the Liberty Mutual Center for Disability Research, our referral base will greatly expand, as they will become our major referral source. They will help us recruit patients from their insurance claims database to improve the representativeness of the subject sample. Liberty Mutual will also help us in developing the work-transition phase for subjects. Consent procedures and the method for obtaining consent are discussed below.

PROCEDURES TO MAINTAIN CONFIDENTIALITY: Subjects will be required to sign a research consent form approved by the UT Southwestern Medical Center at Dallas Institutional Review Board. Clinical research assistants funded buy this project will be consenting the subjects. A copy of the signed consent form will be filed in the subject's medical record. The subject will also receive a copy. The subjects will be informed that they will be participating in a clinical research project focusing on ALBP disability. At the conclusion of the project, all subjects will be completely debriefed concerning the questions addressed by the study. Subjects participating in this project will be assigned experimental identification numbers that will be used on all test protocols. All data will be kept in locked file cabinets. Data will be entered into data files by identification number only. Subjects' names will be separated from the data, assigned a coded identification number, and kept in a locked file cabinet. Access to the file cabinet will be strictly controlled by the Principal Investigator. Subjects will also be asked permission for access to their clinical and medical charts relating to their LBP as an important part of the project. All self-report testing protocols, cortisol samples and other such materials will be kept under strict confidentiality, and they will be destroyed at the conclusion of the study.

POTENTIAL BENEFITS: Subjects' back pain or discomfort may get better or go away; however there is no guarantee that participants will benefit from participation in this research. Subjects' participation may will benefit science as a whole by the addition of new information to our understanding and knowledge of both acute and chronic low back pain disability syndromes, and may significantly aid in the development of early intervention treatment programs to prevent costly chronicity.

RISK/BENEFIT ASSESSMENT: In the past ten years that this study has been ongoing, there have been no reported adverse events associated with participation in this study. There have been, however, benefits to individual participants who have reported pain reduction and a return to a productive lifestyle. Society has benefited in terms of overall healthcare costs and healthcare utilization. Therefore, participation has benefited individuals and society, as well as the scientific community.

BIBLIOGRAPHY

Altmaier, E. M., Lehmann, T. R., Russell, D. W., Weinstein, J. N., & Kao, C. F. (1992). The effectiveness of psychological interventions for the rehabilitation of low back pain: a randomized controlled trial evaluation.[see comment]. *Pain, 49*(3), 329-335.

Anagnostis, C., Mayer, T. G., Gatchel, R. J., & Proctor, T. J. (2003). The million visual analog scale: its utility for predicting tertiary rehabilitation outcomes. *Spine, 28*(10), 1051-1060.

Andersson, G. B. (1997). The epidemiology of spinal disorders. In J. W. Frymoyer (Ed.), *The adult spine: Principles and practice* (2nd ed., Vol. 1, pp. 93-133). Philadelphia: Lippencott-Raven.

Andersson, G. B. (1999). Epidemiological features of chronic low back pain. *The Lancet, 354*(9178), 581-585.

Andersson, G. B., Pope, M. H., & Frymoyer, J. W. (1984). Epidemiology. In M. H. Pope & J. W. Frymoyer (Eds.), *Occupational Low Back Pain*. New York: Praeger.

Andersson, G. B., Svensson, H. O., & Oden, A. (1983). The intensity of work recovery in low back pain. *Spine, 8*(8), 880-884.

Association, A. P. (2000). *Diagnostic and statistical manual of mental disorders*. Arlington, VA: American Psychiatric Association.

Baratta, R. R. (1976). A double-blind comparative study of carisoprodol, propoxyphene, and placebo in the management of low back syndrome. *Current Therapeutic Research, Clinical & Experimental, 20*(3), 233-240.

Basmajian, J. V. (1978). Cyclobenzaprine hydrochloride effect on skeletal muscle spasm in the lumbar region and neck: two double-blind controlled clinical and laboratory studies. *Archives of Physical Medicine & Rehabilitation, 59*(2), 58-63.

Beck, A. T., Steer, R. A., & Garbin, M. G. (1988). Psychometric properties of the Beck Depression Inventory: Twenty-five years of evaluation. *Clinical Psychology Review, 8*(1), 77-100.

Beck, A. T., Ward, C. H., Mendelson, M. M., Mock, J., & Erbaugh, J. (1961). An inventory for measuring depression. *Archives of General Psychiatry, 4*, 561-571.

Bendix, A. E., Bendix, T., Vaegter, K., Lund, C., Frolund, L., & Holm, L. (1996). Multidisciplinary intensive treatment for chronic low back pain: a randomized, prospective study. *Cleveland Clinic Journal of Medicine, 63*(1), 62-69.

Berry, H., Bloom, B., Hamilton, E. B., & Swinson, D. R. (1982). Naproxen sodium, diflunisal, and placebo in the treatment of chronic back pain. *Annals of the Rheumatic Diseases, 41*(2), 129-132.

Biering-Sorensen, F. (1984). Physical Measurements as Risk Indicators for Low-Back Trouble Over a One-Year Period. *Spine, 9*(2), 106-119.

Biondi, M., & Picardi, A. (1999). Psychological stress and neuroendocrine function in humans: The last two decades of research. *Psychotherapy and Psychosomatics, 68*(3), 114-150.

Blackburn-Munro, G. (2004). Hypothalamo-pituitary-adrenal axis dysfunction as a contributory factor to chronic pain and depression. *Current Pain & Headache Reports, 8*(2), 116-124.

Briand, C., Durand, M., St-Arnaud, L., & Corbiere, M. (2008). How Well Do Return-to-work Interventions for Musculoskeletal Conditions Address the Multicausality of Work Disability? *Journal of Occupational Rehabilitation, 18*(2), 207-217.

Browning, R., Jackson, J. L., & O'Malley, P. G. (2001). Cyclobenzaprine and back pain: a meta-analysis. *Archives of Internal Medicine, 161*(13), 1613-1620.

Brox, J. I., Reikeras, O., Nygaard, O., Sorensen, R., Indahl, A., Holm, I., et al. (2006). Lumbar instrumented fusion compared with cognitive intervention and exercises in patients with chronic back pain after previous surgery for disc herniation: A prospective randomized controlled study. *Pain, 122*(1-2), 145-155.

Brox, J. I., Sorensen, R., Friis, A. P., Nygaard, O., Indahl, A., Keller, A., et al. (2003). Randomized Clinical Trial of Lumbar Instrumented Fusion and Cognitive Intervention and Exercises in Patients with Chronic Low Back Pain and Disc Degeneration. *Spine, 28*(17), 1913-1921.

Buchanan, T. W., al'Absi, M., & Lovallo, W. R. (1999). Cortisol fluctuates with increases and decreases in negative affect. *Psychoneuroendocrinology, 24*(2), 227-241.

Burton, W. N., Pransky, G., Conti, P. A., Chen, C. Y., & Edington, D. W. (2004). The association of medical conditions and presenteeism. *Journal of Occupational & Environmental Medicine, 46*, S38-S45.

Busch, H. B., Goransson, S. M., & Melin, B. P. (2007). Self-Efficacy Beliefs Predict Sustained Long-Term Sick Absenteeism in Individuals With Chronic Musculoskeletal Pain. *Pain Practice, 7*(3), 234-240.

Butterfield, P., Spencer, P., Redmond, N., Feldstein, A., & Perrin, N. (1998). Low back pain: predictors of absenteeism, residual symptoms, functional impairment, and medical costs in Oregon workers' compensation recipients. *American Journal of Industrial Medicine, 34*(6), 559-567.

Carey, T. S., Evans, A. T., Hadler, N., Lieberman, G., Kalsbeek, W. D., Jackman, A. M., et al. (1996). Acute Severe Low Back Pain: A Population-based Study of Prevalence and Care-seeking. *Spine, 21*(3), 339-344.

Cherkin, D. C., Wheeler, K. J., Barlow, W., & Deyo, R. A. (1998). Medication Use for Low Back Pain in Primary Care. *Spine, 23*(5), 607-614.

Chou, R., & Huffman, L. (2007a). Medications for Acute and Chronic Low Back Pain: A Review of the Evidence for an American Pain Society/American College of Physicians Clinical Practice Guideline. *Annals of Internal Medicine, 147*(7), 505-514.

Chou, R., & Huffman, L. (2007b). Nonpharmacologic therapies for acute and chronic low back pain: a review of the evidence for an American Pain Society/American College of Physicians clinical practice guideline.[summary for patients in Ann Intern Med. 2007 Oct 2;147(7):I45; PMID: 17909203]. *Annals of Internal Medicine, 147*(7), 492-504.

Corey, D. T., Koepfler, L. E., Etlin, D., & Day, H. (1996). A limited functional restoration program for injured workers: A randomized trial. *Journal of Occupational Rehabilitation, 6*(4), 239-249.

Cowen, P. (2002). Cortisol, serotonin and depression: All stressed out? *British Journal of Psychiatry, 180*(2), 99-100.

Crook, J., Moldofsky, H., & Shannon, H. (1998). Determinants of disability after work related musculoskeletal injury. . *Journal of Rheumatology, 25*, 1570-1577.

de Kloet, E., & DeRijk, R. (2004). Signaling Pathways in Brain Involved in Predisposition and Pathogenesis of Stress-Related Disease: Genetic and Kinetic Factors Affecting the MR/GR Balance. [References]. In R. Yehuda & B. McEwen (Eds.), *Biobehavioral stress response: Protective and damaging effects* (pp. 14-34). New York, NY: New York Academy of Sciences.

De Lissovoy, G., Brown, R. E., Halpern, M., Hassenbusch, S. J., & Ross, E. (1997). Cost-effectiveness of long-term intrathecal morphine therapy for pain associated with failed back surgery syndrome. *Clinical Therapeutics, 19*(1), 96-112; discussion 184-115.

Deede, B. A., & McGovern, P. M. (1987). Low back problems--etiology and prevention. *AAOHN Journal, 35*(8), 341-348.

Derry, S., & Loke, Y. K. (2000). Risk of gastrointestinal haemorrhage with long term use of aspirin: meta-analysis.[see comment]. *BMJ, 321*(7270), 1183-1187.

Dersh, J., Mayer, T. G., Theodore, B., Polatin, P., & Gatchel, R. J. (2007). Do Psychiatric Disorders First Appear Preinjury or Postinjury in Chronic Disabling Occupational Spinal Disorders? [Miscellaneous]. *Spine, 32*(9), 1045-1051.

Dersh, J., Polatin, P. B., & Gatchel, R. J. (2002). Chronic pain and psychopathology: Research findings and theoretical considerations. *Psychosomatic Medicine, 64*(5), 773-786.

Dessein, P. H. (2000). Neuroendocrine deficiency-mediated development and persistence of pain in fibromyalgia: a promising paradigm? *Pain, 86*(3), 213-215.

Deyo, R. A. (1983). Conservative therapy for low back pain. Distinguishing useful from useless therapy. *JAMA, 250*(8), 1057-1062.

Deyo, R. A. (1996). Drug Therapy for Back Pain: Which Drugs Help Which Patients? *Spine, 21*(24), 2840-2849.

Deyo, R. A., Mirza, S. K., & Martin, B. I. (2006). Back pain prevalence and visit rates: estimates from U.S. national surveys, 2002. *Spine, 31*(23), 2724-2727.

Deyo, R. A., & Phillips, W. R. (1996). Low Back Pain: A Primary Care Challenge. *Spine, 21*(24), 2826-2832.

Du Bois, M., & Donceel, P. (2008). A screening questionnaire to predict no return to work within 3 months for low back pain claimants. *European Spine Journal, 17*(3), 380-385.

Dworkin, S. F., & LeResche, L. (1992). Research diagnostic criteria for temporomandibular disorders. *Journal of Craniomandibular Disorders: Facial & Oral Pain, 6*, 301-355.

Ehlert, U., Gaa, J., & Heinrichs, M. (2001). Psychoneuroendocrinological contributions to the etiology of depression, posttraumatic stress disorder, and stress-related bodily disorders: the role of the hypothalamus-pituitary-adrenal axis. *Biological Psychology, 57*(1-3), 141-152.

Ekman, M., Johnell, O., & Lidgren, L. (2005). The economic cost of low back pain in Sweden in 2001. *Acta Orthopaedica, 76*(2), 275-284.

Elliott, A. M., Smith, B. H., Penny, K. I., Smith, W. C., & Chambers, W. A. (1999). The epidemiology of chronic pain in the community. *Lancet, 354*, 1248-1252.

Engel, G. L. (1977). The need for a new medical model: a challenge for biomedicine. *Science, 196*(4286), 129-136.

Evans, D. P., Burke, M. S., & Newcombe, R. G. (1980). Medicines of choice in low back pain. *Current Medical Research & Opinion, 6*(8), 540-547.

Evans, K. D., Douglas, B., Bruce, N., & Drummond, P. D. (2008). An Exploratory Study of Changes in Salivary Cortisol, Depression, and Pain Intensity After Treatment for Chronic Pain. *Pain Medicine, 9*(6), 752-758.

Faas, A. (1996). Exercises: which ones are worth trying, for which patients, and when?[see comment]. *Spine, 21*(24), 2874-2878; discussion 2878-2879.

Fairbank, J., Frost, H., Wilson-MacDonald, J., Yu, L., Barker, K., & Collins, R. (2005). Randomised controlled trial to compare surgical stabilisation of

the lumbar spine with an intensive rehabilitation programme for patients with chronic low back pain: the MRC spine stabilisation trial. *BMJ, 330*(7502), 1233.

First, M. B., Spitzer, R. S., Gibbon, M., & Williams, J. B. (2005). *Structured Clinical Interview for DSM-IV Axis I Disorders - Nonpatient Verison 2.0*. New York: New York State Psychiatric Institute.

Fishbain, D. A., Cutler, R., Rosomoff, H. L., Khalil, T. M., & Steele-Rosomoff, R. (1997). Impact of chronic pain patients' job perception variables on actual return to work. *Clinical Journal of Pain, 13*(3), 197-206.

Fishbain, D. A., Cutler, R., Rosomoff, H. L., & Rosomoff, R. S. (1997). Chronic pain-associated depression: antecedent or consequence of chronic pain? A review. *Clinical Journal of Pain, 13*(2), 116-137.

Fishbain, D. A., Goldberg, M., Meagher, B. R., Steele, R., & Rosomoff, H. L. (1986). Male and female chronic pain patients categorized by DSM-III psychiatric diagnostic criteria. *Pain, 26*, 181-197.

Fishbain, D. A., Rosomoff, H. L., Goldberg, M., Cutler, R., Abdel-Moty, E., Khalil, T. M., et al. (1993). The prediction of return to the workplace after Multidisciplinary Pain Center treatment. *Clinical Journal of Pain, 9*(1), 3-15.

Flor, H., & Birbaumer, N. (1993). Comparison of the efficacy of electromyographic biofeedback, cognitive-behavioral therapy, and conservative medical interventions in the treatment of chronic musculoskeletal pain. *Journal of Consulting & Clinical Psychology, 61*, 653-658.

Flor, H., Fydrich, T., & Turk, D. C. (1992). Efficacy of multidisciplinary pain treatment centers: A meta-analytic flow. *Pain, 49*(2), 221-230.

Flor, H., & Turk, D. C. (1984). Etiological theories and treatments for chronic back pain: I. Somatic models and interventions. *Pain, 19*, 105-121.

Franche, R. L., Cullen, K., Clarke, J., Irvin, E., Sinclair, S., & Frank, J. (2005). Workplace-Based Return-to-Work Interventions: A Systematic Review of the Quantitative Literature. *Journal of Occupational Rehabilitation, 15*(4), 607-631.

Frank, J., Sinclair, S., Hogg-Johnson, S., Shannon, H., Bombadier, C., & Beaton, D., Cole, D,. (1998). Preventing disability from work-related low-back pain: New evidence gives new hope -- if we can just get all the players on the same side. *Canadian Medical Association Journal, 158*(12), 1625-1631.

Fritzell, P., Hagg, O., Wessberg, P., & Nordwall, A. (2001). 2001 Volvo Award Winner in Clinical Studies: Lumbar fusion versus nonsurgical treatment for chronic low back pain: a multicenter randomized controlled trial from

the Swedish Lumbar Spine Study Group.[see comment]. *Spine, 26*(23), 2521-2532; discussion 2532-2524.

Frymoyer, J. W. (1991). Epidemiology of spinal disease. In T. G. Mayer, V. Mooney & R. J. Gatchel (Eds.), *Contemporary conservative care for painful spinal disorders* (pp. 10-23). Philadelphia: Lea & Febiger.

Frymoyer, J. W., & Cats-Baril, W. L. (1991). An overview of the incidences and costs of low back pain. *Orthopedic Clinics of North America, 22*(2), 263-271.

Frymoyer, J. W., & Durett, C. L. (1997). The economics of spinal disorders. In J. W. Frymoyer, T. B. Ducker, J. P. Kostuik, J. N. Weinstein & T. S. I. Whitecloud (Eds.), *The Adult Spine: Principles and Practice* (2nd ed., Vol. 1, pp. 143-150). Philadelphia: Lippincott-Raven.

Frymoyer, J. W., Pope, M. H., Clements, J. H., Wilder, D. G., MacPherson, B., & Ashikaga, T. (1983). Risk factors in low-back pain. An epidemiological survey. *Journal of Bone & Joint Surgery - American Volume, 65*(2), 213-218.

Gallagher, R. M., Rauh, V., Haugh, L. D., Milhous, R., Callas, P. W., Langelier, R., et al. (1989). Determinants of return-to-work among low back pain patients. *Pain, 39*(1), 55-67.

Gardea, M. A., & Gatchel, R. J. (2000). Interdisciplinary treatment of chronic pain. *Current Review of Pain, 4*(1), 18-23.

Garofalo, J. P., Robinson, R. C., & Gatchel, R. J. (2006). Hypothalamic-pituitary-adrenocortical axis dysregulation in acute temporomandibular disorder and low back pain: A marker for chronicity? *Journal of Applied Biobehavioral Research, 11*(3-4), 166-178.

Garofalo, J. P., Robinson, R. C., Gatchel, R. J., & Wang, Z. (2007). A pain severity-hypothalamic-pituitary-adrenocortical axis interaction: The effects on pain pathways. *Journal of Applied Biobehavioral Research, 12*(1), 35-42.

Gatchel, R. J. (1991). Early development of physical and mental deconditioning in painful spinal disorders. In T. G. Mayer, V. Mooney & R. J. Gatchel (Eds.), *Contemporary Conservative Care for Painful Spinal Disorders* (pp. 278-289). Philadelphia: Lea & Febiger.

Gatchel, R. J. (1996). Psychological disorders and chronic pain: Cause and effect relationships. In R. J. Gatchel & D. C. Turk (Eds.), *Psychological Approaches to Pain Management: A Practitioner's Handbook* (pp. 33-52). New York: Guilford.

Gatchel, R. J., & Baum, A. (1983). *An introduction to health psychology*. Reading, MA: Addison-Wesley.

Gatchel, R. J., & Okifuji, A. (2006). Evidence-Based Scientific Data Documenting the Treatment and Cost-Effectiveness of Comprehensive

Pain Programs for Chronic Nonmalignant Pain. *The Journal of Pain, 7*(11), 779-793.

Gatchel, R. J., Peng, Y. B., Peters, M. L., Fuchs, P. N., & Turk, D. C. (2007). The Biopsychosocial Approach to Chronic Pain: Scientific Advances and Future Directions. *Psychological Bulletin, 133*(4), 581-624.

Gatchel, R. J., Polatin, P. B., & Kinney, R. K. (1995a). Predicting outcome of chronic back pain using clinical predictors of psychopathology: A prospective analysis. *Health Psychology, 14*(5), 415-420.

Gatchel, R. J., Polatin, P. B., & Mayer, T. G. (1995b). The dominant role of psychosocial risk factors in the development of chronic low back pain disability. *Spine, 20*(24), 2702-2709.

Gatchel, R. J., Polatin, P. B., Noe, C., Gardea, M., Pulliam, C., & Thompson, J. (2003). Treatment- and cost-effectiveness of early intervention for acute low-back pain patients: a one-year prospective study. *Journal of Occupational Rehabilitation, 13*(1), 1-9.

Geiss, A., Varadi, E., Steinbach, K., Bauer, H. W., & Anton, F. (1997). Psychoneuroimmunological correlates of persisting sciatic pain in patients who underwent discectomy. *Neuroscience Letters, 237*(2-3), 65-68.

Hale, M. E., Dvergsten, C., & Gimbel, J. (2005). Efficacy and Safety of Oxymorphone Extended Release in Chronic Low Back Pain: Results of a Randomized, Double-Blind, Placebo- and Active-Controlled Phase III Study. *The Journal of Pain, 6*(1), 21-28.

Hales, T. R., & Bernard, B. P. (1996). Epidemiology of work-related musculoskeletal disorders. *Orthopedic Clinics of North America, 27*(4), 679-709.

Hardin, K. N. (1998). Chronic pain management. In P. M. Camic & S. J. Knight (Eds.), *Clinical handbook of health psychology: A practical guide to effective interventions* (pp. 123-165). Ashland, OH: Hogrefe & Huber Publishers.

Hart, L. G., Deyo, R. A., & Cherkin, D. C. (1995). Physician office visits for low back pain. Frequency, clinical evaluation, and treatment patterns from a U.S. national survey. *Spine, 20*(1), 11-19.

Hathaway, S. R., & McKinley, J. (1943). *Minnesota Multiphasic Personality Inventory*. Minneapolis, MN: University of Minnesota Press.

Hazard, R. G., Fenwick, J. W., Kalisch, S. M., Redmond, J., Reeves, V., Reid, S., et al. (1989). Functional restoration with behavioral support. A one-year prospective study of patients with chronic low-back pain. *Spine, 14*(2), 157-161.

Hickey, R. F. (1982). Chronic low back pain: a comparison of diflunisal with paracetamol. *New Zealand Medical Journal, 95*(707), 312-314.

Hildebrandt, J., Pfingsten, M., Saur, P., & Jansen, J. (1997). Prediction of success from a multidisciplinary treatment program for chronic low back pain. *Spine, 22*(9), 990-1001.

Hoffman, B. M., Papas, R. K., Chatkoff, D. K., & Kerns, R. D. (2007). Meta-Analysis of Psychological Interventions for Chronic Low Back Pain. *Health Psychology, 26*(1), 1-9.

Hogg-Johnson, S., & Cole, D. C. (2003). Early prognostic factors for duration on temporary total benefits in the first year among workers with compensated occupational soft tissue injuries. *Occupational & Environmental Medicine, 60,* 244-253.

Holberg, C., & Gatchel, R. J. (2007). *Treatment of early intervention for acute low back pain patients utilizing a "Back-to-Work Transition" component: A one-year prospective study.* The University of Texas Southwestern Medical Center, Dallas.

Holbrook, T., Grazier, K., Kelsey, J., & Stauffer, R. (1984). *The frequency of occurrence impact and cost of selected musculoskeletal conditions in the United States*. Park Ridge, IL: American Acadamy of Orthopedic Surgeons Press.

Hoogendoorn, W. E., van Poppel, M. N., Bongers, P. M., Koes, B. W., & Bouter, L. M. (2000). Systematic review of psychosocial factors at work and in the personal situation as risk factors for back pain. *Spine, 25,* 2114-2125.

Ibrahim, T., Tleyjeh, I. M., & Gabbar, O. (2008). Surgical versus non-surgical treatment of chronic low back pain: a meta-analysis of randomised trials. *International Orthopaedics, 32*(1), 107-113.

Jensen, I. B., Bergstrom, G., Ljungquist, T., Bodin, L., Jensen, I. B., Bergstrom, G., et al. (2005). A 3-year follow-up of a multidisciplinary rehabilitation programme for back and neck pain. *Pain, 115*(3), 273-283.

Jousset, N., Fanello, S., Bontoux, L., Dubus, V., Billabert, C., Vielle, B., et al. (2004). Effects of functional restoration versus 3 hours per week physical therapy: a randomized controlled study. *Spine, 29*(5), 487-493; discussion 494.

Kalso, E., Edwards, J. E., Moore, R. A., & McQuay, H. J. (2004). Opioids in chronic non-cancer pain: systematic review of efficacy and safety.[see comment]. *Pain, 112*(3), 372-380.

Kelsey, J. L. (1980). Epidemiology and impact of low-back pain. *Spine, 5*(2), 133-142.

Kendall, N. A., & Thompson, B. F. (1998). A pilot program for dealing with the comorbidity of chronic pain and long-term unemployment. . *Journal of Occupation Rehabilitation, 8*, 5-26.

Kerns, R. D., Turk, D. C., & Rudy, T. E. (1985). The West Haven-Yale Multidimensional Pain Inventory (WHYMPI). *Pain, 23*(4), 345-356.

Kinney, R. K., Gatchel, R. J., Polatin, P. B., & Fogarty, W. (1993). Prevalence of psychopathology in acute and chronic low back pain patients. *Journal of Occupational Rehabilitation, 3*(2), 95-103.

Koes, B. W., Bouter, L. M., Beckerman, H., van der Heijden, G. J., & Knipschild, P. G. (1991). Physiotherapy exercises and back pain: a blinded review.[see comment]. *BMJ, 302*(6792), 1572-1576.

Kool, J., deBie, R., Oesch, P., Knusel, O., & van den Brandt, P., Bachmann, S. . (2004). Exercise reduces sick leave in patients with non-acute non-specific low back pain: A meta-analysis. . *Journal of Rehabilitation Medicine, 36*, 49-62.

Kool, J. P., Oesch, P. R., & de Bie, R. A. (2002). Predictive tests for non-return to work in patients with chronic low back pain.[see comment]. *European Spine Journal, 11*(3), 258-266.

Koopman, C., Pelletier, K. R., Murray, J. F., Sharda, C. E., Berger, M. L., Turpin, R. S., et al. (2002). Stanford presenteeism scale: health status and employee productivity. *Journal of Occupational & Environmental Medicine, 44*(1), 14-20.

Krause, N., Dasinger, L. K., Deegan, L. J., Rudolph, L., & Brand, R. J. (2001). Psychosocial job factors and return-to-work after compensated low back injury: A disability phase-specific analysis. *American Journal of Industrial Medicine, 40*(4), 374-392.

Kumar, S. (2001). Theories of musculoskeletal injury causation. *Ergonomics, 44*(1), 17-47.

Lancourt, J., & Kettelhut, M. (1992). Predicting return to work for lower back pain patients receiving worker's compensation. *Spine, 17*(6), 629-640.

Lascelles, P. T., Evans, P. R., Merskey, H., & Sabur, M. A. (1974). Plasma control in psychiatric and neurological patients with pain. *Brain, 97*(3), 533-538.

Lee, C., Straus, W. L., Balshaw, R., Barlas, S., Vogel, S., & Schnitzer, T. J. (2004). A comparison of the efficacy and safety of nonsteroidal antiinflammatory agents versus acetaminophen in the treatment of osteoarthritis: a meta-analysis. *Arthritis & Rheumatism, 51*(5), 746-754.

Leeuw, M., Goossens, M. E., Linton, S. J., Crombez, G., Boersma, K., & Vlaeyen, J. W. (2007). The Fear-Avoidance Model of Musculoskeletal Pain: Current State of Scientific Evidence. *Journal of Behavioral Medicine, 30*(1), 77-94.

Linton, S. J., & Hallden, K. (1998). Can we screen for problematic back pain? A screening questionnaire for predicting outcome in acute and subacute back pain. *Clinical Journal of Pain, 14*, 209-215.

Linton, S. J., & Nordin, E. (2006). A 5-year follow-up evaluation of the health and economic consequences of an early cognitive behavioral intervention for back pain: A randomized, controlled trial. *Spine, 31*, 853-858.

Linton, S. J., & Ryberg, M. (2001). A cognitive-behavioral group intervention as prevention for persistent neck and back pain in a non-patient population: a randomized controlled trial. *Pain, 90*(1-2), 83-90.

Loisel, P., Abenhhaim, L., Durand, P., Esdaile, J. M., Suissa, S., Gosselin, L., et al. (1997). A population-based, randomized clinicl trial on back pain management. *Spine 22*, 2911-2918.

Loisel, P., Durand, P., Berthelette, D., Vezina, N., Baril, R., Gagnon, D., et al. (2001). Disability prevention- New paradigm for the treatment of occupational back pain. *Disease Management & Health Outcomes, 9*, 351-360.

Luo, X., Pietrobon, R., X Sun, S., Liu, G. G., & Hey, L. (2004). Estimates and Patterns of Direct Health Care Expenditures Among Individuals With Back Pain in the United States. *Spine, 29*(1), 79-86.

Mannion, A., Muntener, M., Taimela, S., & Dvorak, H. (2001). Comparison of three active therapies for chronic low back pain: results of a randomized clinical trial with one-year follow-up.[see comment]. *Rheumatology, 40*(7), 772-778.

Marhold, C., Linton, S. J., & Melin, L. (2002). Identification of obstacles for chronic pain patients to return to work: Evaluation of a questionnaire. *Journal of Occupational Rehabilitation, 12*, 65-76.

Mayer, T. G., & Gatchel, R. J. (1988). *Functional Restoration for Spinal Disorders: The Sports Medicine Approach*. Philadelphia: Lea & Febiger.

Mayer, T. G., Gatchel, R. J., Mayer, H., Kishino, N. D., Keeley, J., & Mooney, V. A. (1987). Prospective two year study of functional restoration in industrial low back injury. *JAMA, 258*(13), 1763-1767.

Mayer, T. G., & Polatin, P. B. (2000). Tertiary nonoperative interdisciplinary programs: The functional restoration variant of the outpatient chronic pain management program. In T. G. Mayer, R. J. Gatchel & P. B. Polatin (Eds.), *Occupational Musculoskeletal Disorders: Function, Outcomes & Evidence* (pp. 639-649). Philadelphia: Lippincott, Williams & Wilkins.

McEwen, B. S. (2005). Stressed or stressed out: what is the difference? *Journal of Psychiatry & Neuroscience, 30*(5), 315-318.

McGeary, D. D., Mayer, T. G., & Gatchel, R. J. (2006). High pain ratings predict treatment failure in chronic occupational musculoskeletal disorders. *Journal of Bone & Joint Surgery - American Volume, 88*(2), 317-325.

McQuaid, K. R., & Laine, L. (2006). Systematic review and meta-analysis of adverse events of low-dose aspirin and clopidogrel in randomized controlled trials. *American Journal of Medicine, 119*(8), 624-638.

Melzack, R., & Wall, P. D. (1965). Pain mechanisms: a new theory. *Science, 150*(699), 971-979.

Million, S., Hall, W., Haavik, N. K., Baker, R. D., & Jayson, M. I. (1981). Evaluation of low back pain and assessment of lumbar corsets with and without back supports. *Annals of the Rheumatic Diseases, 40*(5), 449-454.

Million, S., Hall, W., Haavik, N. K., Baker, R. D., & Jayson, M. I. (1982). Assessment of the progress of the back-pain patient. 1981 Volvo Award in Clinical Science. *Spine, 7*, 204-212.

Morley, S., Eccleston, C., & Williams, A. (1999). Systematic review and meta-analysis of randomized controlled trials of cognitive behavior therapy and behavior therapy for chronic pain in adults, excluding headache. *Pain, 80*, 1-13.

Muenchberger, H., Kendall, E., Grimbeek, P., & Gee, T. (2008). Clinical Utility of Predictors of Return-to-work Outcome Following Work-related Musculoskeletal Injury. *Journal of Occupational Rehabilitation, 18*(2), 190-206.

National Center for Health Statistics. (1997). *National Hospital Discharge Survey*. Washignton, D. C.: U.S. Department of Health and Human Services, Center for Disease Controlo. Document Number)

National Center for Health Statistics. (2005). Health, 2005. With Chartbook on Trends in the Health of Americans. Hyattsville, Maryland.

Natour, J., Sousa, K. F., Orfale, A. G., & Leite, J. R. (2001). Assessment of a biofeedback program to treat chronic low back pain. *Arthritis & Rheumatism, 44(9)*(Supplement), S357.

Nezer, D., & Hermoni, D. (2007). [Percutaneous discectomy and intradiscal radiofrequency thermocoagulation for low back pain: evaluation according to the best available evidence]. *Harefuah, 146*(10), 747-750.

Nielson, W. R., & Weir, R. (2001). Biopsychosocial approaches to the treatment of chronic pain. *Clinical Journal of Pain, 17*(4 Suppl), S114-127.

Okifuji, A., & Turk, D. C. (2002). Stress and psychophysiological dysregulation in patients with fibromyalgia syndrome. *Applied Psychophysiology & Biofeedback, 27*(2), 129-141.

Ostelo, R. W., Deyo, R. A., Stratford, P., Waddell, G., Croft, P., Von Korff, M., et al. (2008). Interpreting change scores for pain and functional status in low back pain: towards international consensus regarding minimal important change. *Spine, 33*(1), 90-94.

Patrick, L., Ahmaier, E., & Found, E. (2004). Long-term outcomes in multidisciplinary treatment of chronic low back pain: Results of a 13-year follow-up. *Spine, 29*, 850-855.

Pengel, L. H., Herbert, R. D., Maher, C. G., & Refshauge, K. M. (2003). Acute low back pain: systematic review of its prognosis. *BMJ, 327*(7410), 323.

Picavet, H. S., Schouten, J. S., & Smit, H. A. (1999). Prevalences and consequences of low back pain problems in the Netherlands, working vs non-working population, the MORGEN-study. *Public Health, 113*, 73-77.

Polatin, P. B., Kinney, R., Gatchel, R. J., Lillo, E., & Mayer, T. G. (1993). Psychiatric Illness and Chronic Low Back Pain: The Mind and the Spine-Which Goes First? *Spine, 18*, 66-71.

Pransky, G., Benjamin, K., Hill-Fotouhi, C., Fletcher, K. E., Himmelstein, J., & Katz, J. N. (2002). Work-related outcomes in occupational low back pain: A multidimensional analysis. *Spine, 27*, 864-870.

Pransky, G., Gatchel, R., Linton, S. J., & Loisel, P. (2005). Improving return to work research. *Journal of Occupational Rehabilitation, 15*(4), 453-457.

Prkachin, K. M., Schultz, I. Z., & Hughes, E. (2007). Pain Behavior and the Development of Pain-related Disability: The Importance of Guarding. *Clinical Journal of Pain, 23*(3), 270-277.

Proctor, T., Gatchel, R. J., & Robinson, R. C. (2000). Psychosocial factors and risk of pain and disability. In D. C. Randolph & M. I. Ranavaya (Eds.), *Occupational Medicine: State of the Art Reviews* (Vol. 15, pp. 803-812). Philadelphia: Hanley and Belfus, Inc.

Pulliam, C. B., Gatchel, R. J., & Gardea, M. A. (2001). Psychosocial Differences in High Risk Versus Low Risk Acute Low-Back Pain Patients. *Journal of Occupational Rehabilitation, 11*(1), 43-52.

Pulliam, C. B., Gatchel, R. J., & Robinson, R. C. (2003). Challenges to early prevention and intervention: Personal experiences with adherence. *Clinical Journal of Pain, 19*(2), 114-120.

Robinson, R. C., Garofalo, J. P., & Gatchel, R. J. (2006). Decreases in cortisol variability between treated and untreated jaw pain patients. *Journal of Applied Biobehavioral Research, 11*(3-4), 179-188.

Salerno, S. M., Browning, R., & Jackson, J. L. (2002). The effect of antidepressant treatment on chronic back pain: a meta-analysis.[see comment]. *Archives of Internal Medicine, 162*(1), 19-24.

Schnitzer, T. J., Ferraro, A., Hunsche, E., & Kong, S. X. (2004). A Comprehensive Review of Clinical Trials on the Efficacy and Safety of Drugs for the Treatment of Low Back Pain. *Journal of Pain and Symptom Management, 28*(1), 72-95.

Schnitzer, T. J., Gray, W. L., Paster, R. Z., & Kamin, M. (2000). Efficacy of tramadol in treatment of chronic low back pain.[see comment]. *Journal of Rheumatology, 27*(3), 772-778.

Schwartz, L., Slater, M., Birchler, G., & Atkinson, J. H. (1991). Depression in spouses of chronic pain patients: the role of patient pain and anger, and marital satisfaction. *Pain, 44*(1), 61-67.

Shenkin, H. A. (1964). The Effect of Pain on the Diurnal Pattern of Plasma Corticoid Levels. *Neurology, 14*, 1112-1117.

Sherman, R. A. (2006). What are Psychophysiological Assessment and Biofeedback? . Retrieved 07/20/2008, from http://www.aapb.org/files/public/Slides.pdf

Shirado, O., Ito, T., Kikumoto, T., Takeda, N., Minami, A., & Strax, T. E. (2005). A novel back school using a multidisciplinary team approach featuring quantitative functional evaluation and therapeutic exercises for patients with chronic low back pain: the Japanese experience in the general setting. *Spine, 30*(10), 1219-1225.

Siddiqui, O., & Ali, M. W. (1998). A comparison of the random-effects pattern mixture model with last-observation-carried-forward (LOCF) analysis in longitudinal clinical trials with dropouts. *Journal of Biopharmaceutical Statistics, 8*(4), 545-563.

Soucy, I., Truchon, M., Cote, D., Soucy, I., Truchon, M., & Cote, D. (2006). Work-related factors contributing to chronic disability in low back pain. *Work, 26*(3), 313-326.

Spitzer, R. L., Williams, J. B., Gibbon, M., & First, M. B. (1988). *Structured Clinical Interview for DSM-III-R*. New York, NY: New York State Psychiatric Institute.

Staiger, T. O., Gaster, B., Sullivan, M. D., & Deyo, R. A. (2003). Systematic review of antidepressants in the treatment of chronic low back pain.[see comment]. *Spine, 28*(22), 2540-2545.

Straus, B. N. (2003). Chronic benign pain syndromes: the cost of intervention. *Spine, 27*, 2614-2619.

Sullivan, M. J., Feuerstein, M., Gatchel, R. J., Linton, S. J., & Pransky, G. (2005). Integrating Psychosocial and Behavioral Interventions to Achieve Optimal Rehabilitation Outcomes. *Journal of Occupational Rehabilitation, 15*(4), 475-489.

Sullivan, M. J., Reesor, K., Mikail, S., & Fisher, R. (1992). The treatment of depression in chronic low back pain: Review and recommendations. . *Pain, 50*, 5-13.

Taylor, R. J., & Taylor, R. S. (2005). Spinal cord stimulation for failed back surgery syndrome: a decision-analytic model and cost-effectiveness analysis. *International Journal of Technology Assessment in Health Care, 21*(3), 351-358.

Tennant, F., & Hermann, L. B. (2002). Normalization of Serum Cortisol Concentration With Opioid Treatment of Severe Chronic Pain. *Pain Medicine, 3*(2), 132-134.

Towheed, T. E., Maxwell, L., Judd, M. G., Catton, M., Hochberg, M. C., & Wells, G. (2006). Acetaminophen for osteoarthritis.[update of Cochrane

Database Syst Rev. 2003;(2):CD004257; PMID: 12804508]. *Cochrane Database of Systematic Reviews*(1), CD004257.

Turk, D. C., & Rudy, T. E. (1987). Towards a comprehensive assessment of chronic pain patients. *Behaviour Research and Therapy, 25*(4), 237-249.

U.S. Department of Labor. (2007). Nonfatal occupation injuries and illnesses requiring days away from work, 2006, Publication USDL 07-1741. Washington D.C.: U.S. Department of Labor.

van Der Giezen, A. M., Bouter, L. M., & Nijhuis, F. J. (2000). Prediction of return-to-work of low back pain patients sick listed for 3-4 months. *Pain, 87*, 285-294.

Van Tulder, M. W., Koes, B. W., Seitsalo, S., & Malmivarra, A. (2006). Outcome of invasive treatment modalities on back pain and sciatica: an evidence-based review. *European Spine Journal, 15 Suppl 1*, S82-92.

Van Tulder, M. W., Scholten, R. J., Koes, B. W., & Deyo, R. A. (2000). Non-steroidal anti-inflammatory drugs for low back pain.[update in Cochrane Database Syst Rev. 2006;(2):CD000396; PMID: 17636636]. *Cochrane Database of Systematic Reviews*(2), CD000396.

Van Tulder, M. W., Touray, T., Furlan, A. D., Solway, S., & Bouter, L. M. (2003). Muscle relaxants for non-specific low back pain. *Cochrane Database of Systematic Reviews*(2), CD004252.

Van Tulder, N., Koes, B., & Bougher, L. (1997). Conservative treatment of acute and chronic non specific low back pain: A systematic review of randomized controlled trials of the most common interventions. *Spine, 22*, 2128-2156.

Vogt, M. T., Kwoh, C. K., Cope, D. K., Osial, T. A., Culyba, M., & Starz, T. W. (2005). Analgesic Usage for Low Back Pain: Impact on Health Care Costs and Service Use. *Spine, 30*(9), 1075-1081.

Von Korff, M., Crane, P., Lane, M., Miglioretti, D. L., Simon, G., Saunders, K., et al. (2005). Chronic spinal pain and physical-mental comorbidity in the United States: Results from the national comorbidity survey replication. *Pain, 113*(3), 331-339.

Von Korff, M., & Saunders, K. (1996). The Course of Back Pain in Primary Care. *Spine, 21*(24), 2833-2837.

Vroomen, P. C., de Crom, M. C., Slofstra, P. D., & Knottnerus, J. A. (2000). Conservative treatment of sciatica: a systematic review. *Journal of Spinal Disorders, 13*(6), 463-469.

Waddell, G., Newton, M., Henderson, I., & Somerville, D. (1993). A Fear-Avoidance Beliefs Questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. *Pain, 52*(2), 157-168.

Ware, J. E., Snow, K. K., Kosinski, M., & Gandek, B. (1993). *SF-36 Health Survey: Manual and Interpretation Guide*. Boston: The Health Institute, New England Medical Center.

Webster, B., & Snook, S. H. (1990). The Cost of Compensable Low Back Pain. *Journal of Occupational Medicine, 32*(1), 13-15.

Williams, J. B., Gibbon, M., First, M. B., & Spitzer, R. L. (1992). The Structured Clinical Interview for DSM-III--R (SCID): II. Multisite test-retest reliability. *Archives of General Psychiatry, 49*(8), 630-636.

Wright, A. R., & Gatchel, R. J. (2002). Occupational musculoskeletal pain and disability. In D. C. Turk & R. J. Gatchel (Eds.), *Psychological Approaches to Pain Management: A Practitioner's Handbook* (2nd ed., pp. 349-364). New York: Guilford.

Zhang, W., Jones, A., & Doherty, M. (2004). Does paracetamol (acetaminophen) reduce the pain of osteoarthritis? A meta-analysis of randomised controlled trials.[see comment]. *Annals of the Rheumatic Diseases, 63*(8), 901-907.