

Treatment of Early Intervention for Acute Low Back Pain Patients
Utilizing a “Back-to-Work Transition” Component:
A One-Year Prospective Study

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DEDICATION

To my husband and my daughter,
thank you both for all of your support
and unlimited patience.

TREATMENT OF EARLY INTERVENTION FOR ACUTE LOW BACK PAIN
PATIENTS

UTILIZING A “BACK-TO-WORK TRANSITION” COMPONENT:
A ONE-YEAR PROSPECTIVE STUDY

by

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DISSERTATION

Presented to the Faculty of the Graduate School of Biomedical Sciences

The University of Texas Southwestern Medical Center at Dallas

In Partial Fulfillment of the Requirements

For the Degree of

DOCTOR OF PHILOSOPHY

The University of Texas Southwestern Medical Center at Dallas

Dallas, Texas

August, 2007

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ACKNOWLEDGMENTS

I must begin by expressing my gratitude to the members of my dissertation committee: Robert Gatchel, Ph.D., Anna Stowell, Ph.D., Peter Polatin, M.D., Martin Deschner, Ph.D., and Dana Bernstein, Ph.D. I thank Dr. Gatchel not only for being an exceptional research mentor, but also for all of his encouragement and guidance throughout my academic career. Without Dr. Gatchel's support none of this would have been possible. I thank Dr. Stowell for being an excellent model of what a psychologist should be. She has taught me the importance of not just doing a job, but doing a job well. Her reassurance and direction have helped me immeasurably in the completion of this project. I want to express my gratitude to Dr. Bernstein for all of her advice and encouragement. Her sincere interest in teaching and mentoring students is inspiring. I want to thank Dr. Deschner for his advice, professionalism, and his constant positive presence. Thank you, as well, Dr. Polatin for all of your medical expertise and input as well as your support of this project.

I am very appreciative to my fellow McDermott students including Whitney Worzer, Rob Haggard, and Renee Gilkey as well as the ALBP research team of Anna Goswami and Lisa Hernandez. The support of my fellow students and all of the hard work done by the ALBP research team, helped immensely with the completion of this project and made the "daily grind" of the last year bearable, and at times even enjoyable.

I must acknowledge all of my classmates as well. Over the last four years, they have all become a very special part of my extended family and I wish them all the best of

luck with all of their future endeavors. I feel that I am a better person for having the privilege of knowing them and working alongside them.

Of course, I owe an endless debt of gratitude to my parents, Wes and Linda Attaway for their unconditional love and support. I thank them both for insisting that I can achieve any goal I set my mind to and encouraging me even when I believed it impossible. To my late father, I express my appreciation for instilling in me the love of learning and a pervasive stubbornness that helped me persevere against all odds. To my mother, mere words cannot express how much I thank her. All of her love and support, especially over the last four years, have made all of this possible. She taught me the importance of empathy and helping others and her amazing strength and resilience has been inspirational.

To my daughter, who has given me the biggest reason of all to persevere, I thank you. It has amazed me how much the unconditional positive regard and love of a child can change your entire life. I thank her for all of her patience during the many hours of “mommy’s homework,” for being a willing “guinea pig” for the many child assessment batteries she has now endured, all the times she has lovingly smiled and said “just have fun mommy” as I left the house for a big exam, and for never letting me forget the “big picture.”

I would be remiss not to thank my husband, Jason Reed, whose encouragement and support have kept me relatively sane. I must thank him for the many hours of listening to me “vent” my frustrations and anxieties, and for making me laugh (quite frequently as myself). I thank him for convincing me that “having summers off” was not a good enough reason to drop out of graduate school in my 3rd year to pursue a career as a

kindergarten teacher and assuring me that it would be wiser to complete the program instead of pursuing a career as a pastry chef in my 4th year. I thank him for believing in me and for making me believe in myself.

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This study built upon previous research by Gatchel et al. (2003) which utilized an algorithm developed by Gatchel et al. (1995), to identify what patients with ALBP were at high-risk for developing chronic pain and then implemented an interdisciplinary early-intervention program in order to prevent the progression of ALBP to chronic low back pain (CLBP). The aforementioned authors were able to demonstrate the effectiveness of

the early-intervention program as measured by decreases on a number of pain and disability-related measures as compared to “treatment as usual.” In addition, they established the cost-effectiveness of such a program as compared to “treatment as usual” in terms of costs of medications, disability days, and healthcare utilization. The current study expanded upon the early-intervention program established by Gatchel et al. (2003) by adding a work transition component to better facilitate improved return-to-work and better work-related outcomes. In addition, the study set out to establish the effectiveness of the early-intervention and work transition component as well. After subjects were identified as being at high-risk for developing chronic pain, they were randomized into one of four treatment groups: early intervention (EI); early intervention with work transition (EI/W); work transition (NI/W); and non-intervention (NI), and followed-up for a period of 1-year.

A limitation of the study was small sample size and resulting reductions in statistical power. Despite this, the findings confirm prior studies that show early intervention with an acute pain population is important for achieving pain reduction, improved coping abilities, and return to work rates. Significant reductions in pain ratings were noted for the EI group from intake to 1-year. Overall, pain ratings for the EI, EI/W, and NI/W groups were observed to be comparable to one another and all were noted to be lower than NI group pain ratings at 1-year. In addition the EI, EI/W, and NI/W groups all demonstrated significant increases on a measure of coping that assesses an overall sense of control over physical well-being. Significant decreases and moderate decreases in functional disability were found for the EI group and EI/W group respectively from

intake to 1-year. Results on a measure of obstacles to return-to-work indicated a moderately improved prognosis for return-to-work for the EI group at 1-year.

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LIST OF DEFINITIONS

ADLs	Activities of Daily Living
ALBP	Acute Low Back Pain
ANCOVA	Analysis of Covariance
ANOVA	Analysis of Variance
CBT	Cognitive Behavioral Therapy
CLBP	Chronic Low Back Pain
CPI	Characteristic Pain Inventory
CPPs	Comprehensive Pain Programs
<i>df</i>	Degrees of Freedom
DFW	Dallas-Fort Worth
DSM-IV TR	Diagnostic and Statistical Manual -4 th Edition Text Revised
EI	Early Intervention
EI/W	Early Intervention + Work Transition
EMG	Electromyography
HIPAA	Health Insurance Portability and Accountability Act
HR	High Risk
HR/I	High Risk Intervention
HR/NI	High Risk Non-Intervention
IRB	Institutional Review Board
LBP	Low Back Pain
LOCF	Last Observation Carried Forward

LR	Low Risk
μ	Mean
MCS	Mental Component Score
MMPI-2	Minnesota Multiphasic Personality Inventory-2
MVAS	Million Visual Analog Scale
n	Sample Size
NI	Non-Intervention
NI/W	Work Transition
ORQ	Obstacles to Return to Work Questionnaire
p	Significance Level
PCS	Physical Component Score
RTW	Return to Work
σ	Standard Deviation
SF-36	36-Item Short Form Health Survey
SPS	Stanford Presenteeism Scale
SSDI	Social Security Disability Insurance
TMD	Temporomandibular Disorder
VAS	Visual Analog Scale
χ^2	Pearson's Chi-Square

CHAPTER ONE

Introduction

An overwhelming majority of people throughout the world will suffer from low back pain (LBP) at some period in their lives. While for most people the pain will resolve within a few weeks to a couple of months, for others, LBP can turn into a chronic disabling condition that extols enormous costs to the individual as well as to society as a whole. Low back pain-related expenditure in terms of lost productivity, litigation, and direct healthcare costs reach into the billions of dollars annually and it is one of the leading causes of disability and missed work days in industrialized countries (Frymoyer & Durett, 1997; National Center for Health Statistics, 2005).

The current study aims to build upon previous research by Gatchel, Polatin, Noe, Gardea, Pulliam, Thompson (2003) which utilized an algorithm developed by Gatchel, Polatin, and Kinney (1995), to identify what patients with acute low back pain (ALBP) were at high-risk for developing chronic pain in order to target those patients for an early-intervention program. The study then implemented an interdisciplinary early-intervention program in order to prevent the progression of ALBP to CLBP for those patients that would benefit most. In addition, those patients identified as low-risk were also followed in order to examine whether they go on to develop chronic pain and disability as well. The aforementioned authors were able to demonstrate the effectiveness of the early-intervention program as measured by decreases in a number of pain and disability related measures as compared to treatment as usual. Additionally, they were able to establish the

cost-effectiveness of such a program as compared to “treatment as usual” in terms of costs of medications, disability days, and healthcare utilization. Furthermore, those identified as low-risk showed no significant signs or symptoms of chronic disability at 1-year, further validating the usefulness of the algorithm and targeted intervention program (Gatchel et. al., 2003).

The current study aims to again identify participants at high-risk for progressing from ALBP to CLBP using the aforementioned algorithm. In contrast to the previous research, this study will only focus on those individuals identified as high risk for developing chronic pain. After subjects were identified as being at high-risk, they were randomized into one of four treatment groups: early intervention with work transition (EI/W); early intervention (EI); work transition (NI/W); and non-intervention (NI), and followed-up for a period of 1-year.

The current study expanded upon the early-intervention program established by Gatchel et al. (2003) by adding a work transition component to better facilitate return-to-work and improved work-related outcomes. The treatment conditions consisted of interdisciplinary treatment; interdisciplinary treatment with the addition of the work transition component; the work transition component alone, and no intervention (i.e. treatment as usual).

The four treatment groups were compared on measures of pain, pain-related disability, coping, and work-related measures at intake and 1-year with the aim of establishing the effectiveness of the intervention groups.

CHAPTER TWO

Review of the Literature

Scope of the Problem

Low back pain (LBP) is one of the most common musculoskeletal problems in the world and second only to headaches in terms of neurological ailments in the United States (National Institute of Neurological Disorders and Stroke, 2002). In 2003, LBP lasting more than one day was reported by 28% of adults, with the prevalence of LBP increasing with age (National Center for Health Statistics, 2005). An estimated 70-85% of people in industrialized countries will have LBP at some point in their lives (Andersson, 1999; Deyo R.A., Cherkin D., Conrad D., & Volinn E., 1991).

According to Gatchel, Polatin, and Mayer (1995b), LBP is the leading cause of disability in persons *under* age forty-five, which are considered to be the years when productivity is most crucial, and the third leading cause of disability in persons *over* the age of forty-five. The implications on the costs to society are further illustrated when considering that the average age for a chronic low back pain (CLBP) patient to begin receiving social security disability income (SSDI) is 35-40. The relatively young age of these SSDI recipients explained the large burden of expenditures on society since these people will then continue to collect disability benefits for many years (Mayer et al., 1987). Chronic low back pain, however, is reported by 2-7% of all adults in industrialized countries (Andersson, 1997). Keeping these estimates in mind, the economic costs of low back disorders are staggering. According to the National Center for Health Statistics

(2005), Americans spent between \$50 billion and \$100 billion each year on low back-related direct (i.e., direct patient costs such as co-pays, medications, etc.) and indirect costs (i.e., lost productivity and litigation). These figures were previously broken down by Frymoyer and Durett (1997), who estimated that annual costs for LBP related healthcare exceeded \$33 billion, with \$11 to \$43 billion spent on disability compensation, \$5 billion for legal services, and \$4.6 billion on lost productivity.

Low back pain is also a leading contributor to missed work days and the most common cause of job-related disability in the United States (National Center for Health Statistics, 2005). Deede and McGovern (1987) estimated that approximately 1,400 work days per 1,000 workers are lost each year due to back-related pain and disability in the United States. Similarly, Andersson, Pope, and Frymoyer (1984) estimated that in Europe, 10-15% of all absenteeism from work is attributable to back problems. Additionally, in the United Kingdom, LBP is cited as the reason for work-related disability by 12.5% of all unemployed persons (Elliott, Smith, Penny, Smith, & Chambers, 1999).

The U.S. Department of Labor and Statistics (2004) reported that the leading nature of all injuries and illnesses requiring days away from work (more than 4 out of 10 were sprains and strains), mostly involved the back. Sprains and strains accounted for more than half a million cases, making these diagnoses the leading cause of missed work days in every major area of industry. Work incidents involving the core trunk area of the body (i.e., shoulders and back) accounted for the highest number (35.5%) of work-related accidents and incidents, with back related problems accounting for 65% of all incidents involving the trunk (U.S. Department of Labor, 2004).

Of the staggering economic costs of low back pain, a significant share (about \$11 billion) arose from the worker's compensation system. The average cost of a worker's compensation claim for LBP was at least twice the average cost for all compensable claims combined (National Institute for Occupational Safety and Health, 1997). In addition, MacDonald and colleagues (1997) estimated that in the United States and Canada, 1-2% of all workers will file a worker's compensation claim for low back disability during their lifetime.

As highlighted by the literature presented, chronic pain, and more specifically CLBP, is a widespread epidemic associated with enormous amounts of suffering and economic costs for the individual, as well as society. The presented statistics illustrate the need for effective programs for preventing and treating these disorders. These programs are typically aimed at helping the individual experience less pain and disability to cut down on lost productivity, missed days of work, and healthcare-related costs.

Biopsychosocial Model of Pain and Disability

For most healthcare providers, the biopsychosocial model of pain currently prevails as the superlative model in terms of approaching and treating the chronic pain patient. Under the biomedical model, if a physician "cures" what is believed to be the physiological cause of the pain but the pain remains, the physician likely labels the patient as having a mental disorder (i.e., the pain must be psychogenic). The traditional biomedical model of treatment has focused on treating the underlying physiological damage or causes of pain and disability and has considered pain as simply a symptom of

secondary importance. The biopsychosocial model, on the other hand, attempts to address the interaction between biological, psychological, and social variables that maintain or exacerbate the patient's experience of pain and disability (Gatchel, 1996).

The biopsychosocial model was developed by Turk and Rudy (1987) after much research in the area of chronic pain illustrated that the dichotomous nature (psychogenic or physical) of the biomedical model's assessment of pain was insufficient to conceptualize chronic pain. Research has extensively demonstrated that psychosocial factors do play a significant role in maintaining pain, as well as in the severity and exacerbation of pain (Fishbain, Goldberg, Meagher, Steele, & Rosomoff, 1986; Flor & Turk, 1984; Polatin, Kinney, Gatchel, Lillo, & Mayer, 1993). The biopsychosocial model of pain asserts that while a biological precipitant, such as an injury, may initiate the individual's experience of pain, psychological factors may additionally influence how the individual perceives and appraises the physiological sensations of pain, and social factors may further act to influence the manner in which the person will react to their pain experience. As summarized by Turk (1996), no single factor alone (i.e., biological, psychological or social) can adequately account for the suffering and disability experienced by those with chronic pain.

This approach to the assessment of pain attempts to account for variances in the experience of pain that may not be explained by the biomedical model. For example, the same amount of physiological damage in individuals may be experienced with differing amounts of pain severity and may lead to differing degrees of disability depending on the psychological states of the individual, previous experiences of similar pain, and how the individual's social environment acts in response to the symptoms and reports of pain. To

further illustrate this point, Turk and Monarch (2002) found that pain severity and level of disability cannot exclusively be predicted from having diagnosable physiological pathology.

In addition, while the biomedical model cannot account for the persistence of pain (i.e., chronic pain) beyond that predicated by an initiating physiological cause, the biopsychosocial model attempts to explain this phenomenon in terms of the factors described above. The progression from acute to chronic pain is based, in part, on this model.

Progression from Acute to Chronic Pain

Low back pain is considered a time-limited condition (i.e., lasting only a brief amount of time) for approximately 90% of afflicted individuals. Within two weeks of onset of symptoms, about one half of the people reporting acute LBP (ALBP) are no longer disabled; by one month, 70% will have recovered; and within 3-6 months, 90% will have recovered (Mayer & Gatchel, 1988; Mayer & Polatin, 2000). However, the majority of the 10% whose symptoms continue after 6 months will still be disabled and unable to work at the end of 1-year (Wright & Gatchel, 2002). Likewise, the majority of those still disabled at 1-year will continue to be disabled at 2-years post the initial onset of symptoms (Wright & Gatchel 2002). These 10% of LBP patients, considered chronic, typically incur a disproportionate amount (80%) of the costs for extensive medical treatments, compensation costs, and settlements awards in a variety of industries (Spitzer, LeBlanc, & Dupuis, 1987).

In order to characterize the process by which an individual progresses from acute to chronic pain, Gatchel (1991; 1996) suggested a three-stage model, referred to as “mental deconditioning.” As proposed by Gatchel, the first, or acute, stage primarily consists of the individual’s emotional reactions to their pain including anxiety and fear. These emotions, often related to fear and worry, typically occur secondary to the association between sensation of pain and “harm.” Normally, these feelings dissipate over two months or less as the natural healing process ensues.

The patient may progress, though, into the next stage, if these emotional reactions continue past the expected amount of time necessary to heal. This process generally occurs as the pain persists 2-4 months past initial onset of pain. Stage Two, considered the sub-acute stage, is characterized by an intensification of the individual’s psychological and behavioral responses to their ailment (Gatchel, 1991). During this stage, more prominent feelings of anger, somatization, and learned helplessness may also emerge. Gatchel (1996) purports that the way in which an individual reacts to their pain is impacted by psychological functioning, personality characteristics, and environmental states, which existed prior to the onset of their pain. As such, the individuals may have certain predispositions that either help protect them or make them more susceptible to developing chronic pain. In addition, pre-existing difficulties may be exacerbated by the stress of coping with pain.

Once the patient has accepted the “sick role,” avoiding many activities including social responsibilities, work activities, and physical activities, progression into Stage Three, the chronic stage is evident. As the patient begins to see him/herself as innately

“sick” or “damaged,” he/she becomes more dependent on an existing social network to take over the above activities and responsibilities and for assistance with daily activities.

As observed by Mayer and Gatchel (1988), this progressive lack of activity results in physical deconditioning, muscular atrophy, and decreases in strength and endurance, all of which, play a role in the progression to chronic pain. This phenomenon of physical deconditioning interacts with the previously described “mental deconditioning” in a reciprocal manner (Gatchel, Baum, & Krantz, 1989), contributing to further deconditioning and further increasing the risk of developing chronic pain.

Predictors of Chronic Pain

With all of the associated costs of chronic pain, both to the individual, and to society, it is imperative that a model for predicting chronicity be developed and utilized effectively. According to Lawrence and colleagues (1998), legal, psychological, social and vocational factors may all play important roles in the duration of pain-related symptoms.

The risk factors for developing chronic pain may be categorized as follows: medical, job, compensation, social, demographic, and psychological (Wright & Gatchel 2002). Medical risk factors include medical history, particularly previous low back problems and/or surgery history, or lost work time due to LBP (Kumar, 2001). Other medical risk factors include persistently high subjective ratings of pain intensity (Proctor, Gatchel, & Robinson, 2000), a significant amount of pain behaviors, patient’s engaging in a pre-pain low activity lifestyle (Proctor et al., 2000), and avoidance of certain

activities due to the belief that the activities will exacerbate the pain (Geisser, Haig, & Theisen, 2000). Job dissatisfaction and significant levels of job-related stress coupled with intense job loads, hazardous working conditions, and poor relations between employees and employers are all considered risk factors for the development of chronic pain as well (Lancourt & Kettelhut, 1992; Proctor et al., 2000; Bigos et al., 1986). Research has shown that workers who receive compensation for their injuries, whether it occurs through continuous or lump sum payment, may behave differently and report higher levels of pain, depression, and disability than those who did not receive compensation (Wright and Gatchel, 2002). In terms of social risk factors, those individuals experiencing social (i.e., with family or other support networks) or personal difficulties concomitantly with their initial injury, are more likely to progress from acute to chronic pain (Lancourt & Kettelhut, 1992; Proctor et al., 2000). Psychological risk factors are generally characterized by passive coping strategies, psychopathology, and psychological distress. While these factors are important in assessing the risk of chronicity, few models have been developed that effectively incorporate these factors in a succinct manner in order to predict chronicity at the acute stages of pain.

One such model, proposed by Gatchel, Polatin, and Kinney (1995a), identified the type of acute patient who was more likely to become chronic and, therefore, should be targeted for early intervention programs. The model was based on an earlier study by Gatchel, Polatin, and Mayer (1995b) in which they evaluated 421 patients presenting with ALBP. The subjects were assessed using 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 Pain Scale (Million, Hall, Haavik, Baker, & Jayson, 1982), to evaluate vocational status, psychosocial, and personality factors at intake and then again at 1-year post-treatment. Based upon this study and previous research, researchers formulated a statistical algorithm that was able to predict, with 90.7% accuracy, which patients would progress from the acute to chronic stages of pain and disability. The algorithm variables were identified by Gatchel, Polatin, and Kinney (1995a) and included self-reported pain and disability levels, scores on Scale 3 of the MMPI-2, worker's compensation status, and gender.

This algorithm was further validated in a second study conducted by Gatchel and colleagues (2003). In this study, approximately 700 ALBP subjects were screened and classified as either "high-risk" (HR) or "low-risk" (LR) for developing chronic pain using the above mentioned algorithm. High risk subjects were then randomized into either an early intervention (HR/I) or no early intervention (i.e., standard care, HR/NI) group to assess the effectiveness of an early intervention program for the prevention of chronic pain. While the major goal of this study was to evaluate early intervention effectiveness, researchers were able to look at the differences in the HR/NI and LR groups in terms of chronicity at 1-year post-treatment in an attempt to re-examine the usefulness of the algorithm. At 1-year follow-up, the HR/NI group did, in fact, display significantly more indices of chronic pain disability, as measured by return-to-work status, healthcare utilization, medication usage, and self-reported pain, than the LR group, further establishing the algorithm's predictive utility.

Treatment of Chronic Low Back Pain

Various forms of treatment for chronic pain, and more specifically, CLBP, exist and many have been shown to be effective. Although interdisciplinary treatment is the treatment protocol used in the current study, it is important to understand the nature of the alternative treatments typically offered.

Drug Therapy

Typically, the first line of treatment offered to the patient presenting with LBP is drug therapy, which is effective for approximately 80% of individuals with ALBP (Mayer & Polatin, 2000). Drug therapies are able to provide relief from some symptoms of ALBP although, they do not typically “cure” or change the underlying physiological roots of the pain (Deyo, 1996). Commonly, narcotics, muscle relaxants, and psychotropic drugs are prescribed to treat chronic pain.

The effectiveness of using antidepressant medications in addressing chronic pain also continues to be examined. It has been argued that the effectiveness of antidepressant medications for chronic pain relief stems from alleviation of the underlying depression thought to maintain or exacerbate experienced pain. However, while depression is frequently a factor in chronic pain patients, the dosage of antidepressant medications typically used for pain relief is approximately one-fifth to one-third of the dosage indicated for the treatment of depression (Sullivan, Reesor, & Mikail, 1992).

Overall, studies on the effectiveness of antidepressant medications show some moderate pain relief over placebo, although results tend to be inconsistent across studies

(Turner & Denny, 1993). For example, Alcock, Jones, Rust, and Newman (1982) found that the use of imipramine produced significant improvements on most measures of pain relief over placebo. Earlier, Jenkins, Ebbutt, and Evans (1976) found imipramine to have no significant effects on pain relief over placebo. In general, it can be said that the overall results of these studies suggest that antidepressants are not consistently effective for the treatment of LBP.

In summary, while there is evidence that certain medications do provide some relief from the symptoms of chronic pain, clearly no specific medication works best for most people in most cases, or provides substantial long-term improvements when used as the only treatment modality. It is important to note, as well, that medications do not change the underlying physiological conditions that initiate the pain, but merely serve to relieve the pain experience temporarily. Therefore, drug therapy may provide temporary symptom relief, but is not a “cure” for chronic pain (Deyo, 1996). Drug therapy, therefore, may be partially beneficial to the chronic pain sufferer, but should be used in combination with other treatment modalities to facilitate longer-term improvements.

Exercise

While exercise remains a common treatment modality for LBP patients, few research studies have shown the benefits of exercise as a unimodal treatment for LBP. Further, while research has shown that exercise can improve functioning in LBP, the improvements do not tend to be long-term and are frequently extinguished by 1-year follow-up (Faas, 1996). Despite this, due to the aforementioned process of physical

deconditioning, exercise is likely a crucial component of a comprehensive LBP treatment program.

Kool and colleagues (2004) performed a meta-analysis, to examine whether exercise alone or treatment programs that included an exercise component, could reduce sick leave in patients with CLBP. While the authors claim to have found strong evidence that exercise reduces sick days at post-treatment follow-up, these findings did not persist at the 1-year follow-up, and most of the studies used in their analysis included exercise as one component of a multidisciplinary program. Few studies looked solely at the contribution of exercise alone. Of those studies examining exercise alone, most did not show exercise as having an impact on return-to-work or missed work days.

Similarly, van Tulder and associates (1997) conducted a systematic review of randomized control trials of treatment for acute and chronic LBP and concluded that exercise is a short-term efficacious treatment for LBP. A majority of the studies used in this review, however, lacked a control group or were not blinded to patients or researchers. While the review concluded that various types of exercises could be used effectively, most of the improvements noted had disappeared at 1-year follow-up. Thus, it is clear from the highlighted literature that exercise programs are a useful part of a chronic pain treatment program. This is found to be true, even though exercise alone has not proven to be effective for long-term improvements in chronic pain and disability.

Biofeedback and Relaxation Training

Biofeedback is a type of relaxation training and behavior modification technique used to treat many types of conditions, including chronic pain. Biofeedback educates

patients on how to monitor and control physiological reactions such as muscle tension, body temperature, and heart rate (The Association for Applied Psychophysiology and Biofeedback, 2006). Equipment, consisting of electrical sensors applied to special points on the patient's body and feedback units with displays, provide feedback to the patient regarding their progress. In a randomized control trial, Flor and Birbaumer (1993) compared electromyography (EMG) biofeedback, cognitive-behavioral therapy, or conservative medical treatment of musculoskeletal pain, including LBP. Subjects were randomized into one of the three groups listed above and were then assessed on measures of reductions in pain severity, interference, affective distress, pain-related use of the healthcare system, stress-related reactivity of the affected muscles, and an increase in active coping self-statements. While improvements were noted in all three treatment groups at post-treatment, the biofeedback group displayed the most significant changes. Likewise, at 6- and 24-months post-treatment, only the biofeedback group had maintained those improvements. The advances experienced by the biofeedback group, however, only applied to a specific subgroup of chronic pain patients (i.e., only those that displayed few physical disabilities).

In 2001, Neilson and Weir systematically reviewed 21 randomized control trials to examine the efficacy of various biopsychosocial treatments for chronic pain. Results of this review revealed limited evidence of the effectiveness of biofeedback in the treatment of chronic pain. While some studies suggested biofeedback was effective at three-months post-treatment, little evidence was provided for the long-term effectiveness of biofeedback in a chronic pain population.

Biofeedback has been shown to be an effective treatment for chronic temporomandibular disorder (TMD; Mishra, Gatchel, & Gardea, 2000). In a study done by Mishra and colleagues, 94 subjects with chronic TMD were randomized into one of four groups: a biofeedback treatment group; cognitive-behavioral skills training group; combined biofeedback and cognitive-behavioral skills training group; and non-intervention group (i.e. standard care). Subjects in all three treatment groups combined displayed significantly less self-reported pain at post-treatment as compared to pre-treatment measures. The non-intervention group, however, did not show such results. In addition, the biofeedback group showed significantly greater reductions in self-reported pain as compared to the non-intervention group. Researchers concluded that all three treatments were therapeutically effective for reducing pain in TMD patients. Although, the biofeedback treatment was shown to be the most effective of the three treatments. At 1-year follow-up, however, these reductions in pain were not maintained by the biofeedback treatment group (Gardea, Gatchel, & Mishra, 2001). In contrast, according to Gardea and associates, the only group from this original cohort that maintained a reduction in self-reported pain at 1-year was the combined biofeedback and cognitive-behavioral skills training group. Thus, overall, research regarding the effectiveness of biofeedback for treating chronic pain shows inconsistent results, and, at best, moderate improvements in chronic pain and disability. Despite the marginal findings supporting the use of biofeedback as an effective pain relieving technique, it is frequently used in conjunction with relaxation training as a component of a broader cognitive behavioral therapy approach to treating chronic pain.

Cognitive-Behavioral Therapy Interventions

Cognitive Behavioral Therapy (CBT) treatment procedures were specifically developed to help patients change cognitions and behaviors related to their ailment (Geisser & Colwell, 1999). Within CBT patients are taught relaxation techniques, stress management, and other ways to help patients cope with pain. CBT attempts to approach the treatment of chronic pain from the biopsychosocial model by acknowledging not only the influence of the underlying physiological pathology, but also the patient's cognitive, emotional, and behavioral responses to the experience of chronic pain

In a previously mentioned systematic review of biopsychosocial approaches to the treatment of chronic pain, Nielson and Weir (2001) illustrated the effectiveness of CBTs in this population. They examined 21 randomized control trials of biopsychosocial treatments for various chronic pain disorders and found that multimodal biopsychosocial treatments that included a cognitive behavioral component were effective for CLBP for intervals up to 1-year post-treatment. Similar results were found in a systematic review examining the efficacy of CBT versus placebo (Morley, Eccleston, & Williams, 1999). Morley and associates (1999) concluded from this review that CBT did result in significant improvements on a wide array of psychosocial measures including coping, activity, and social functioning.

Linton and Ryberg (2001) further investigated the effects of CBT in the prevention of chronic musculoskeletal pain. They examined 253 patients with complaints of persistent neck or LBP, and then randomly assigned them to either a cognitive-behavioral (group therapy) intervention or a non-intervention (i.e., standard care) group. At 1-year follow-up, the CBT group displayed significantly better results, as compared to

the standard care group, in terms of fear-avoidance beliefs, number of days missed from work, and number of pain-free days. In 2006, Linton and Nordin provided a 5-year follow-up on the same data presented above and found that, even after 5 years, the group that received CBT fared significantly better than the standard care group. These results illustrated that CBT is effective for both short- and long-term treatment of chronic pain and is associated with better socioeconomic outcomes in terms of fewer days missed from work and less losses in productivity.

Interdisciplinary Treatment

Functional restoration is an interdisciplinary treatment approach that consists of a blend of acute pain management and active physical rehabilitation based on a sports medicine approach to treating chronic pain (Gatchel & Mayer, 1988). These programs are time-limited treatments with the functional goal of return-to-work or to daily activities. They involve specific exercises in order to recondition the patient, coupled with education and cognitive-behavioral training. Functional restoration has repeatedly been found to be an effective treatment with, not only patients with acute pain, but those suffering from chronic pain as well (Bendix, Bendix, Labriola, & Boekgaard, 1998; Bontoux et al., 2004; Garcy, Mayer, & Gatchel, 1996; Kinney, Gatchel, Polatin, & Mayer, 1991; Moreno, Cunningham, Gatchel, & Mayer, 1991). Even the most disabled patients and worker's compensation patients with chronic musculoskeletal problems tend to have positive outcomes through the use of functional restoration programs (Garcy et al., 1996). Not only has functional restoration been found to be an effective treatment modality, it has also been proven to be cost-effective (Turk & Gatchel, 1999).

Interdisciplinary care is most appropriate for those patients whose pain has persisted despite passive attempts to control or alleviate the symptoms (i.e., primary care) and secondary treatment modalities such as physical and occupational therapy. For those few patients who still have found no relief through primary and secondary levels of care, it is then appropriate to refer them to tertiary levels of care, which includes interdisciplinary treatment programs (Mayer & Polatin, 2000).

Some of the typical features of an interdisciplinary treatment program are the inclusion of multiple treatment disciplines that focus on treating the chronic pain patient, such as a pain management physician, a physical therapist, an occupational therapist, and a psychologist (Wright & Gatchel, 2002). Most of these programs are set up in such a way that all treatment providers are “on-site,” resulting in consistency of care, as well as the collaboration of all providers in discussing the patient’s care, and identified concerns or obstacles. Interdisciplinary treatment programs are, therefore, consistent with the biopsychosocial model of pain, in that they are able to address the various components that contribute to pain. Deschner and Polatin (2000) describe the goals of interdisciplinary treatment teams as facilitating improved pain-related coping, reducing medication usage, aiding the patient’s to return-to-work, increasing levels of physical activity, and decreasing healthcare utilization.

In a study by Altmaier and colleagues (1992), patients with CLBP participated in an interdisciplinary treatment program that consisted of physical therapy, aerobic exercise, vocational counseling, and CBT. Researchers found a significant reduction in medication usage, improvements in overall functioning, and decreased self-report pain

and interference at 6-months post-treatment. In addition, 81% had returned to work or were participating in work-retraining programs at 6-months post-treatment.

Gatchel and Okifuji (2006) published a review of studies reporting outcomes for comprehensive pain programs (CPPs) that demonstrated the overall superiority of CPPs for the treatment of chronic pain relative to conventional medical treatment. CPPs were described as multidisciplinary treatment programs that focus on outcomes such as functional restoration of the chronic pain patient. Their review included studies that evaluated such as outcomes as self-reported pain, healthcare utilization and cost, return to work and other work-related factors, disability and function related to pain, medication usage, and insurance claims. Based on their review, Gatchel and Okifuji concluded that CPPs are the most effective treatment modality for patients with chronic pain.

Jensen and colleagues demonstrated the long-term effectiveness of interdisciplinary care for neck and back pain in 2005. Subjects in this study were randomized into a standard care group, a physical therapy group, a CBT group, or an interdisciplinary treatment group consisting of both physical therapy and CBT. At three years post-treatment, subjects in the interdisciplinary group had significantly fewer absences from work, less healthcare utilization and reported substantially better health than the remaining groups. In terms of cost for the intervention, sick leave, and pensions/disability payments, the interdisciplinary treatment group averaged \$51,000 per subject per year. This was significantly less than those in the standard care group who averaged \$94,000 per subject per year for intervention, sick leave, and pension/disability.

In 2004, Patrick and associates published findings from a 13-year follow-up study, further illustrating the long-term effectiveness of interdisciplinary treatment of

CLBP. These researchers contacted patients who had participated in the previously described Altmaier (1992) study in order to examine the lasting effects of interdisciplinary treatment for chronic pain. Patrick and colleagues found that patients maintained treatment gains in pain intensity and interference, mood, physical functioning, and general health even 13-years post-treatment. More than half of the subjects were employed and few of those that were unemployed reported this was due to back pain.

Return-To-Work

As previously outlined, LBP is a major cause of missed days of work and lost productivity. Missed days of work and/or a delay in return-to-work can amount to large costs to society. In addition research has suggested that extended absences from work due to illness or injuries may have a negative psychological impact on the patient and that the longer the patient is absent from work, the more difficult it may be for them to return-to-work (Frank et al., 1998; Kendall & Thompson, 1998; Verbeek, 2001). Keeping this in mind, there is an obvious need for effective treatments that facilitate improved return-to-work in a cost-effective manner. Interventions focusing on these aspects are termed “return-to-work” (RTW) interventions. These interventions focus on not only faster-return-to-work, but also fewer missed work days, and a reduction in the symptoms of chronic pain and prevention of disability in LBP patients (Staal et al., 2002).

Psychosocial Work-Related Factors

Through RTW studies, researchers have attempted to identify factors not only in the individual, but also in the workplace, that predict poor RTW outcomes in LBP patients. For example, researchers have identified a relationship between low social support from coworkers and/or supervisors (Hoogendoorn, van Poppel, Bongers, Koes, & Bouter, 2000), as well as high job demands, low job control, low work flexibility, high job strain (Krause, Dasinger, Deegan, Rudolph, & Brand, 2001), and absenteeism in patients with LBP. In addition, fears and beliefs about work have been found to have an impact on RTW and missed work days (Linton & Hallden, 1998; Waddell, Newton, Henderson, Somerville, & Main, 1993).

Fishbain and colleagues (1993) reviewed 164 studies of multidisciplinary rehabilitation treatment programs for chronic pain patients. Of these studies, 26 focused on identifying patient variables that predict RTW. Fishbain and associates concluded from these studies that work variables were equally as important in predicting RTW as the patient's individual variables. Researchers suggested further examination of the importance of work-related variables in predicting RTW in pain patients.

Van der Giezen and associates (2000) attempted to identify predictive factors for RTW of CLBP patients who had been sick-listed for three to four months. Researchers found that the patient's perception of overall health, job satisfaction, and family "bread winner" status (i.e. those that have an economic incentive to return-to-work) were more predictive of RTW at 1-year follow-up than the physical requirements of the job or type of industry. Researchers concluded that psychosocial aspects of work may have a large impact on RTW outcomes.

Objective Work-Related Variables (Non-Psychosocial)

While chronic pain disability has been shown to be related to psychosocial factors of the individual and the workplace, the individual's work environment may also play a role in determining RTW outcomes (Frank, Sinclair, Hogg-Johnson, Shannon, Bombadier, Beaton, & Cole, 1998; Loisel, Abenhaim, Durand, Esdaile, Suissa, Gosselin, Turcotte, Lemaire, 1997; Loisel, Durand, Berthelette, Vezina, Baril, Gagnon, Lariviere, C., & Tremblay, 2001) For example, modified work tasks have been shown to have an impact on RTW factors (Soucy, Truchon, & Cote, 2006). Workers who were allowed to make arrangements for the characteristics of their job (i.e., modified work hours, light work duties) returned to work faster than those not given the option of modified work tasks (Crook, Moldofsky, & Shannon, 1998; Hogg-Johnson & Cole, 2003).

Problems Facing Return to RTW Research

While much research has been done in the area of RTW in CLBP patients, there has not been a significant change in the rates of work disability (Pransky, Gatchel, Linton, & Loisel, 2005). One explanation for this finding is that the concept of RTW itself is often inconsistently defined across research studies (Pransky et al., 2005). RTW is frequently measured in a variety of ways such as sick leave, pain-intensity, physical functioning, psychological functioning, and healthcare utilization (Pransky et al., 2002). Defining RTW in these ways may be useful, but may also miss important factors needed to get a complete picture of the RTW process. For instance, many workers may stay on the job or return to work despite pain, but have difficulty (due to their pain) that causes

them to be less productive and still incurring costs in terms of healthcare utilization and lost productivity (Burton, Pransky, Conti, Chen, & Edington, 2004). Additionally, employers may discourage return to work due to fear of re-injury or pain exacerbation that may disrupt the already mended work flow (i.e., replacements may be performing well).

Cost Effectiveness

The National Center for Health Statistics (NCHS, 2005) estimated that complaints of LBP constitute approximately 3.6 million visits to healthcare providers each year in the United States. CLBP is associated with high medication usage and a substantial number of days missed from work as well (NCHS, 2005). All three of these findings suggest great costs to industry, to workers' compensation systems, and society as a whole. With this in mind, it is important that research and treatment programs address not only whether an intervention is effective for treating or preventing chronic pain, but also whether the treatment can significantly cut these costs.

Flor, Fydich and Turk (1992) attempted to address this important consideration by performing a systematic review and meta-analysis of interdisciplinary and multidisciplinary treatment programs for chronic pain. The review established not only the effectiveness of these treatment modalities, but also calculated the estimated costs savings for patients treated with interdisciplinary/multidisciplinary programs versus standard care. The authors estimated that within their sample of 2,318 patients treated

within an interdisciplinary or multidisciplinary program, there were cost savings of approximately \$18 million in terms of medical treatment in the year post-treatment.

Similarly, in the study presented earlier, Gatchel and colleagues (2003) examined cost savings comparisons in a cohort of subjects treated with an interdisciplinary early intervention program for ALBP. High-risk intervention (HR/I) subjects reported significantly fewer visits to healthcare providers, reduced medication usage, and fewer days missed from work than those in the high-risk non-intervention (HR/NI) group. Overall, this resulted in significantly reduced costs. For example, the average cost per subject per year in the High-risk intervention (HR/I) group was calculated as \$12,721 as compared to \$21,843 for subjects in the high-risk non-intervention (HR/NI) group. This calculation included costs for healthcare visits related to LBP, narcotic analgesic medications, psychotropic medications, work disability days, lost wages, and the early intervention program itself.

In addition, as presented earlier, Gatchel and Okifuji (2006) reviewed various systematic reviews, meta-analyses, and studies evaluating treatment outcomes for patients with chronic pain. Not only did Gatchel and Okifuji conclude that CPPs were the most efficacious treatment for chronic pain patients, they also determined CPPs to be more cost effective than conventional medical treatments.

Scope of Current Investigation

The purpose of the proposed project was to assess the efficacy of an early intervention program with an additional work-transition component within an ALBP

population. The aim was to prevent the progression to chronic pain and related disability and to facilitate improved return-to-work as assessed at 1-year follow-up.

These goals were accomplished by first screening study subjects for acute onset of LBP, as well as “at-risk” status using the previously established algorithm (Gatchel et al., 1995a). Those subjects found to be at “high-risk” (HR) for chronicity were entered into the study and then randomized into one of four groups. The groups were as follows: 1) Early intervention plus workplace transition (EI/W); 2) Early intervention alone (EI); 3) No early intervention plus workplace transition (i.e., standard care + work transition, NI/W); and 4) No early intervention plus no workplace transition (i.e., standard care alone, NI). Subjects were asked to complete measures to evaluate pain disability, and work status at baseline, as well as 1-year follow-up.

In the context of the above goals, the following hypotheses for this study were proposed:

- 1). The EI/W intervention was hypothesized to prevent the development of chronic pain in ALBP patients as measured by levels of self-reported pain and degree of chronic pain symptoms and disability. The addition of the work transition component was hypothesized to facilitate improved return-to-work rates. Therefore, at 1-year, EI/W group subjects were hypothesized to have had significantly lower levels of self-reported pain (Characteristic Pain Inventory; CPI; Dworkin & LeResche, 1992), display significantly fewer symptoms of chronic pain disability (Million Visual Analog Scale; MVAS; Million, Hall, Haavik-Nilson, Baker, & Jayson, 1982) and 36-Item Short Form Health Survey

Summary (SF-36; Ware, Snow, Kosinski & Grandeck, 1993), and would do better in terms of duration of time to return-to-work than the remaining groups (Obstacles to Return to Work Questionnaire; ORQ; Marhold, Linton, & Melin, 2002; Stanford Presenteeism Scale; SPS; Koopman et al., 2002; and return-to-work status), relative to the other three groups.

- 2) It was hypothesized that the work transition component alone (NI/W) would result in significantly improved return-to-work rates as compared to standard care (NI) by directly addressing any potential occupational obstacles that may prevent return-to-work. Therefore, at 1-year, NI/W group subjects were hypothesized to have significantly better return-to-work outcomes (ORQ, SPS and return-to-work status) and show fewer symptoms of chronic pain disability (CPI, MVAS, and SF-36) than the NI group.

CHAPTER THREE

Methodology

Subjects

Subjects were recruited from a number of sources, such as area physicians, private practice groups, insurance carriers, flyers, and advertisements. Area physicians included referrals from the group practice, Orthopedic Associates in Lewisville, Texas, and Concentra Medical Clinics located throughout the DFW area. Through a partnership with the Liberty Mutual Center for Disability Research, subjects were also referred from the low back insurance worker's database. Flyers were placed across the campus of The University of Texas Southwestern Medical Center at Dallas (UT Southwestern), and advertisements were placed in the Dallas Observer, a community newspaper.

Subjects were included if they were between the ages of 18-65, and had an onset of LBP no more than two months prior to entering the study. Subjects must also: have no other history of chronic episodic LBP as defined by two or more episodes of disabling pain during the last two years; not have been currently in need of surgery; and have had no pain-exacerbating physical condition (e.g., fibromyalgia or cancer) at the time of initial evaluation. In addition, subjects must have experienced constant daily pain when performing their normal activities from the time of initial onset of pain to the time of intake into this study, and must have been experiencing a decreased ability to perform their normal job requirements due to their LBP to qualify for study participation.

Procedure

Subjects were offered \$25 to complete an initial screening evaluation packet. The evaluation packet included an informed consent form, HIPAA consent form, a payment voucher, Million Visual Analog Scale (Million et al., 1982), Scale 3 items from the Minnesota Multiphasic Personality Inventory (MMPI-2; Dahlstrom, Welsh, & Dahlstrom, 1972), and a screening form asking for basic demographic information. Based upon the information collected in the screening packet, subjects were identified as either “high risk” (HR) or “low risk” (LR) for development of chronic pain based upon the previously described statistical algorithm identified in a prior study by Gatchel and associates (1995a). Those subjects identified as being HR were then randomized into one of four groups. The groups were as follows: 1) Early intervention plus workplace transition (EI/W); 2) Early intervention alone (EI); 3) No early intervention plus workplace transition (i.e., standard care plus workplace transition, NI/W); and 4) No early intervention plus no workplace transition (i.e., standard care alone, NI).

After completion of the initial screening packet, subjects were contacted and offered \$50 for further participation in the study evaluation process. Upon agreement to continue participation, all subjects were given a baseline evaluation that includes more detailed demographic information, vocational status (Stanford Presenteeism Scale; SPS; Koopman et al., 2002; Obstacles to Return to Work; ORQ; Marhold et al., 2002), and symptoms of pain disability (MVAS; Million et al., 1982; Characteristic Pain Intensity; CPI; Dworkin & LeResche, 1992; and 36-Item Short Form Health Survey Summary; SF-36; Ware, Snow, Kosinski & Grandeck, 1993).

Follow-up data was then collected for each participant at post-treatment, six-month past intake, and nine-months past intake. At 1-year following the initial date of intake, subjects were offered an additional \$50 to participate in a 1-year follow-up evaluation in which the aforementioned baseline measures were repeated. At each follow-up point, the subject was asked to indicate their current return-to-work status. Baseline and 1-year follow-up evaluations were conducted at The Eugene McDermott Center for Pain Management, at UT Southwestern by doctoral-level clinical psychologists, Masters' level clinicians, pre-doctoral Clinical Psychology interns or masters students from the Rehabilitation Counseling Psychology program at UT Southwestern.

For those subjects randomized into the EI/W and EI groups, the early intervention (EI) protocol consisted of the following: an intake and discharge physician examination, with additional visits if needed; up to 9 physical therapy sessions that are tailored to the needs of the patient; up to 9 behavioral medicine sessions lasting 45 minutes and consisting of biofeedback and pain management following a specific study protocol; and a minimum of an intake and discharge interdisciplinary team conference, with additional conferences if needed.

For those subjects randomized into the EI/W and NI/W groups, the workplace transition component protocol consisted of up to 6 sessions, lasting 45 minutes each and at least one case management session. These sessions focused on assisting subjects in directly addressing and modifying any potential occupational obstacles that may prevent return-to-work, by using problem-solving skills training. These problem-solving skills were taught using a manualized workbook provided to each subject.

Treatments were intended to be administered over a course of 4-10 weeks, depending on group assignment and the number of sessions in the subject's treatment plan. All treatments were administered by professionals licensed in their respective fields. This study is funded through The University Texas at Arlington and subcontracted through The University of Texas Southwestern Medical Center at Dallas. Therefore, all persons administering treatment in this study were employed by The Eugene McDermott Center for Pain Management, The University of Texas Southwestern at Dallas, and/or The University of Texas at Arlington. Research protocol was reviewed and monitored by the Institutional Review Boards (IRB) of both the University of Texas Southwestern Medical Center at Dallas, as well as The University of Texas at Arlington and all research personnel completed training in research involving human subjects in compliance with those IRBs.

Instruments and Outcome Measures

36-Item Short Form Health Survey Summary (SF-36; Ware, Snow, Kosinski & Grandeck, 1993). The SF-36 is a self-report questionnaire consisting of 36 items that contribute to 2 summary scales: the Mental Component Score (MCS) and the Physical Component Score (PCS). The MCS and PCS measure the subject's overall sense of control over mental and physical well-being, respectively. A higher rating on these two scales indicates a greater sense of control over mental and physical well-being.

Characteristic Pain Intensity (CPI; Dworkin & LeResche, 1992). The CPI is a self-report measure assessing levels of current pain, average pain, and highest pain during the preceding three months. The subject rates his/her pain on a scale of 0 to 100, with 100 being the “most intense pain” and 0 being “no pain.” These dimensions are scored by taking the average of these pain ratings and multiplying by 10.

Million Visual Analog Scale (MVAS; Million, Haavik-Nilson, Jayson & Baker, 1981). This 15-item, self-report measure was derived from the Million Visual Analog Scale and produces a total functional disability score ranging from 0 to 150, with greater scores representing more severe and disabling pain. The focus of this questionnaire is to assess not only self-reported pain intensity, but pain disability and function as well. Subjects’ ability to perform activities of daily living (ADLs) was assessed by having the subject mark a point on a 10 cm line, representing the range of possible answers from 0 to 10, which will then be added together to derive a total score. For the purposes of statistical analyses as well as in an attempt to better describe patient’s reported level of disability, patients were categorized into one of six categories based on their scores on the MVAS. Following previously established guidelines posited by Anagnostis, Mayer, Gatchel, and Proctor (2003), a rating of 0 was categorized as no reported disability; a rating of 1 to 40, as mild disability; a rating of 41 to 70 as moderate disability; a rating of 71 to 100 as severe disability; a rating of 101 to 130 as very severe disability; and a rating of 131 to 150 as extreme disability.

Visual Analog Scale (VAS). The VAS is a self-report measure used to help patients describe their degree of pain. The VAS consists of a horizontal line 10 centimeters in length with the left end of the line representing “No Pain” and the right end of the line representing “Worst possible Pain.” Patients are asked to mark an “X” along the line to represent where they perceive their pain to be. The VAS consists of equally spaced hash marks representing increments of 2, with the range of possible scores being 0 to 10. In order to more easily evaluate differences in patients’ experienced pain, patients were categorized into one of four groups based on their score on the VAS (McGeary, Mayer, & Gatchel, 2006). The groups were categorized as follows: a rating of 0 to 3 was categorized as mild pain; a rating a 4 to 5 was categorized as moderate pain; a rating of 6 to 7 as severe pain; and a rating of 8 to 10 was categorized as extreme pain.

Work Information Form. The subject was asked questions regarding their current vocational status (e.g. “have you returned to work”); whether they have been taken off work duty since their back injury; any modifications or accommodations their employer has made since returning to work; and how many days of work they have missed as a result of their back injury. Subjects were also asked whether they currently have pending litigation or a personal injury claim and whether they are currently receiving workers’ compensation as a result of their back pain or injury.

Obstacles to Return to Work Questionnaire (ORQ; Marhold, Linton, & Melin, 2002). This 55-item questionnaire is based upon epidemiological studies concerning psychosocial (e.g., high time pressure, low job satisfaction, and low social support) and

physical (e.g., uncomfortable work postures and heavy work) risk factors for pain in the workplace. Based on their research, Marhold and colleagues concluded that actual recovery and returning to work is impacted by the subject's perceptions about return-to-work and working. This measure was designed to tap into those perceptions and beliefs by calculating subjects' scores on 9 dimensions: 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 ORQ score is also calculated, with higher scores indicating an overall poorer prognosis in terms of return-to-work.

Stanford Presenteeism Scale (Koopman et al., 2002). While absenteeism from work is easily measured by tracking actual missed days from work, presenteeism is a newly described phenomenon that is more difficult to measure, but is just as costly in terms of lost productivity. Presenteeism refers to the lost productivity that results from the worker showing up to work but exhibiting reduced productivity secondary to illness. The SPS is a 6-item measure with, each item using a Likert Scale from one to five points, ranging from "Strongly Agree" to "Strongly Disagree." These questions assess the relationship between presenteeism, health problems, and productivity. The sum of these 6 items is calculated and results in the SPS-6 total score, which can range from 6 to 30. Lower scores indicate lower presenteeism and peak performance while higher scores indicate increased presenteeism and lower performance.

Study Design

At the time of this study, a total of 792 subjects had been screened for participation in this study. Of the 792 subjects screened, 86 were found to be at high risk for developing CLBP. Although 86 out of 792 subjects being identified as high risk may seem proportionately small, this proportion is consistent with earlier research indicating that approximately 10% of all people with LBP will likely go on to develop chronic pain (Mayer & Gatchel, 1988; Mayer & Polatin, 2000). Those identified as being high risk were then randomized into one of the 4 comparison groups for the treatment phase of the study, with an estimated distribution as follows: 1) EI/W ($n=15$); 2) EI ($n=23$); 3) NI/W ($n=7$); and 4) NI ($n=41$).

Subjects in all four groups (EI, EI/W, NI/W, and NI) were compared at baseline to evaluate differences in demographic variables such as age, gender, race, marital status, years of education, and duration of pain. These analyses were accomplished using ANOVAs or chi-square procedures, depending on the nature of the variable (continuous or categorical) to ensure no significant differences exist among the four groups that could influence the outcome of the study. Results of analyses on demographic variables are presented in the next chapter.

Statistical Considerations

At intake, the distributions of scores for each group on the various outcome measures were evaluated for normality. On those measures for which the distribution of

scores was determined not to be normal, non-parametric procedures were utilized to analyze differences among the four treatment groups. At one year follow-up, the four groups were compared on CPI, SF-36, MVAS, and return-to-work status (ORQ, SPS). Depending on the nature of the variable being examined and whether the data was found to be normally distributed, paired sample *t*-tests, Friedman's nonparametric two-way analysis of variance tests, or chi square analyses were conducted to assess significant differences among the four groups. In addition, effect sizes for the four treatment groups on the aforementioned outcome measures were calculated as well.

Last Observation Carried Forward

Missing data in the statistical analyses were handled through use of the last observation carry-forward technique (LOCF). Missing data was attributed to inconsistent data collection due to participant non-compliance and attrition. This method is specific to longitudinal data problems and involves replacing missing values for each individual by the last observed value of that variable (Shao & Zhong, 2003). A table summarizing all data points collected for each participant is provided (Tables 23-30).

CHAPTER FOUR

Results

The results of this study are presented in two major sections. Analyses of actual 1-year data are presented first in Chapter 4. The results of analyses utilizing LOCF techniques are presented second in Chapter 5. At the time that the following analyses were conducted, not all of the participants enrolled in the study had 1-year data available for analysis in this study. The distribution of subjects with available 1-year data used in the following analyses was as follows: EI/W ($n=5$); EI ($n=15$); NI/W ($n=3$); and NI ($n=8$). This study represents a preliminary examination of a larger ongoing study. It is important to note that, due to small sample size and the preliminary nature of the current study, a large number of statistical analyses were conducted. While this method is useful for finding trends in the data that are very important in the preliminary phase of a study, it also increases the likelihood of Type I errors. Thus, the results presented should be viewed with this caveat in mind.

DEMOGRAPHIC CHARACTERISTICS

The overall sample consisted of a total of 86 subjects at intake. Depending on the continuous or categorical nature of the demographic variables, Chi-square or ANOVA procedures were used to determine whether any significant differences in demographics existed among the four groups at baseline. No significant differences were found among the four groups for age, gender, ethnicity, education, or marital status (Table 1). In

addition, analyses were conducted to examine the duration of pain prior to intake into the study. No significant differences were found among groups in regards to duration of pain at intake (Table 1.2). Demographic variables were also analyzed for the group of participants that had 1-year data available for analyses for differences among the four treatment groups. No differences were found among the groups on any of the above mentioned demographic variables. These data are presented in Table 1.2. Additionally, demographic data for those participants that had 1-year data available for analyses following LOCF techniques were analyzed as well. No significant differences were found in terms of demographic variables for these data as well (Table 1.3).

PAIN MEASURES

Visual Analog Scale (VAS)

VAS ratings were found to not be normally distributed at intake for each of the four treatment groups. Due to the non-normal distributions found at intake, non-parametric procedures were conducted to examine overall differences among groups from intake to 1-year on VAS ratings. Analyses were conducted to examine whether VAS pain ratings were varied among groups at intake. No significant differences were found among groups at intake on VAS scores. The EI group was observed to have a significant decrease in pain rating from intake ($\mu = 5.9, \sigma = 2.2$) to 1-year ($\mu = 3.2, \sigma = 2.4$), $\chi^2 (1, n=15) = 5.3, p = .02$. In addition, the three intervention groups combined showed a

significant decrease in pain ratings from intake to 1-year, $\chi^2 (1, n=23) = 5.6, p = .02$.

These data are presented in Table 2.

Effect sizes for the four treatment groups on the VAS were also calculated. A large effect (.94) was found for the EI group on the VAS, as well as a medium effect for EI/W (.64) and NI/W group (.58). The NI group was found to have only a small effect (.29) on VAS ratings. These data are presented in Table 22.

VAS Categories

Pain ratings as measured by the VAS were further broken down into five categories which are as follows: mild pain (0-3); moderate pain (4 to 5); severe pain (6 to 7); and extreme pain (8 to 10). Due to the categorical nature of this variable, chi-square analyses were conducted in order to determine whether significant differences in reported levels of pain existed among the four treatment groups. Chi-square analyses did not reveal any significant differences among the groups' pain rating levels (Table 3).

Characteristic Pain Inventory

The CPI is comprised of three questions that ask the subjects to rate their pain in terms their "current pain" level; the "most intense pain" level experienced in a given time period; and the "average pain" level experienced in a specific time period. This study analyzed participant's "current" pain rating at intake and 1-year. CPI "current" pain ratings were found to be not normally distributed at intake for each of the four treatment

groups. In order to account for the non-normal distributions found at intake, non-parametric procedures were conducted to examine overall differences among groups from intake to 1-year on CPI “current” ratings.

No significant differences were found among the groups at intake on the CPI. Non-parametric tests confirmed that the EI group demonstrated a significant decrease in “current” pain ratings from intake ($\mu = 5.1, \sigma = 3.0$) to 1-year ($\mu = 2.4, \sigma = 2.5$), $\chi^2 (1, n=5) = 0.2, p = .015$. The three intervention groups combined also showed a significant decrease in “current” pain ratings from intake ($\mu = 4.5, \sigma = 2.7$) to 1-year ($\mu = 2.8, \sigma = 2.4$), $\chi^2 (1, n=15) = 3.6, p = .05$. No other significant differences were observed among groups in these analyses (Table 4).

Additionally, effect sizes for the four treatment groups on the CPI were calculated. A medium effect (.79) was found for the EI group and the NI/W group (.50) on the CPI “current” (Table 22).

COPING MEASURES

Short Form-36 (SF-36)

The two summary scales of SF-36 were utilized in this study. The Mental Component Score (MCS) measures the subject’s overall sense of control over mental well-being; and the Physical Component Score (PCS) measures the subject’s overall sense of control over their physical well-being. The raw scores of both the MCS and PCS were analyzed using non-parametric analyses to examine changes in reported sense of

control over mental and physical well-being within the four treatment groups at intake and 1-year-follow-up.

MCS Scores

Scores on the SF-36 MCS were found to be not normally distributed at intake for each of the four treatment groups. Due to the non-normal distributions found at intake, non-parametric procedures were conducted to examine overall differences among groups from intake to 1-year on MCS ratings. Non-parametric tests found no significant differences among groups in these analyses (Table 5).

Effect sizes for the four treatment groups on the MCS were calculated. Small effects were found for the EI/W group and the NI/W group on the MCS. The NI group was observed to have a medium effect (.65) on MCS scores.

PCS Scores

Scores on the SF-36 PCS were found to be not normally distributed at intake for each of the four treatment groups. Due to the non-normal distributions found at intake, non-parametric procedures were conducted to examine overall differences among groups from intake to 1-year on PCS ratings.

Analyses revealed no significant differences among the groups on PCS scores at intake. Results indicated that the EI group reported a significant increase in overall sense of control of physical well-being from intake ($\mu = 32.95, \sigma = 7.30$) to 1-year follow up ($\mu = 44.28, \sigma = 8.49$), $\chi^2(1, n=13) = 9.3, p = .00$. In addition, the EI/W group showed an

increase in overall sense of control of physical well-being, $\chi^2(1, n=4) = 3.0, p = .08$. The three treatment groups combined showed a significant increase in PCS scores from intake ($\mu = 33.3, \sigma = 7.8$) to 1-year ($\mu = 41.8, \sigma = 9.7$) as well, $\chi^2(1, n=20) = 8.9, p = .00$ (Table 6).

Effect sizes for the four treatment groups on the PCS were calculated. Large effects were found for the EI/W group (.95) and the EI group (.95) on the PCS. The NI/W group was observed to have a small effect (.20) on PCS scores and the NI group was found to have no effect on PCS scores (Table 22).

Million Visual Analog Scale (MVAS)

The MVAS is a measure of total functional disability with greater scores representing more severe and disabling pain. Results of the MVAS were found to be not normally distributed at intake for each of the four treatment groups. The non-normal distributions found at intake were taken into account by the use of non-parametric procedures to examine overall differences among groups from intake to 1-year on MVAS ratings.

Non-parametric procedures revealed the EI/W group reported significantly less functional disability from intake ($\mu = 82.4, \sigma = 27.9$) to 1-year ($\mu = 55.4, \sigma = 35.2$), $\chi^2(1, n=5) = 5.0, p = .03$ (Table 7). A moderate decrease in functional disability was also observed for the EI group as well as the three intervention groups combined from intake to 1-year, $\chi^2(1, n=15) = 3.3, p = .07$ and $\chi^2(1, n=23) = 3.5, p = .06$, respectively.

Additionally, effect sizes for the four treatment groups on the MVAS were calculated. Large effects were found for the EI/W group (1.20) and the NI/W group (1.11) on the MVAS. The EI group (.77) and the NI group (.57) were observed to have a medium effect on MVAS scores (Table 22).

MVAS Categories

MVAS raw scores were converted into categories in order to better describe subjects' reported levels of functional disability. Subjects are put into one of six categories that range from "no reported disability" to "extreme disability" based on their raw scores on the MVAS. These categories are described in more detail elsewhere in this text. Chi-square analyses were conducted to determine whether any significant differences in reported functional disability exist among the four treatment groups at intake or at 1-year follow-up. No significant differences were found among the four groups on the categorized MVAS at intake or at 1-year (Table 8).

VOCATIONAL MEASURES

Obstacles to Return to Work (ORQ)

ORQ scores were found to be normally distributed at intake for each of the four treatment groups. Due to the normal distributions found at intake, parametric procedures

were conducted to examine overall differences among groups from intake to 1-year on ORQ scores.

Total ORQ scores were compared at intake and at 1-year follow-up for each of the four treatment groups. Paired sample *t*-tests were conducted to examine differences in the total ORQ scores for each of the treatment groups. A significant decrease in the total ORQ scores was noted for the EI group from intake ($\mu = 122.8, \sigma = 57.8$) to 1-year ($\mu = 101.9, \sigma = 53.2$), indicating a better prognosis for return-to-work and better perceptions regarding working at 1-year, $t(14) = 2.1, p = .05$. All groups were noted to have some decrease in ORQ ratings from intake to 1-year (Table 9). Additionally, the three intervention groups combined showed significantly improved RTW outcomes from intake ($\mu = 130.6, \sigma = 56.4$) to 1-year ($\mu = 109.9, \sigma = 58.9$), $t(22) = 2.4, p = .02$.

The effect sizes for the four treatment groups on the ORQ were calculated as well. A medium effect was found for the EI group (.55) on the ORQ. Small effect sizes were noted for the EI/W group and NI/W group. The NI group was noted to have no effect on the ORQ (Table 22).

Stanford Presenteeism Scale (SPS)

Results of the SPS were found to be normally distributed at intake for each of the four treatment groups. Due to the normal distributions found at intake parametric procedures were utilized to examine overall differences among groups from intake to 1-year on SPS ratings.

Paired sample *t*-tests were conducted to evaluate changes in SPS scores within the four treatment groups from intake to 1-year follow-up. No significant changes were observed in SPS scores (Table 15). However, the EI group was observed to have moderately improved SPS rating from intake ($\mu = 17.5, \sigma = 4.8$) to 1-year ($\mu = 22.8, \sigma = 10.3$), $t(13) = -1.9, p = .06$. The three intervention groups combined showed an increase in SPS scores from intake ($\mu = 130.6, \sigma = 56.4$) to 1-year ($\mu = 109.9, \sigma = 58.9$) as well, $t(22) = 2.4, p = .025$. These results are summarized in Table 10.

The effect of the four treatment groups on the SPS was calculated as well. A medium effect was found for the EI group (.53) and the NI/W group (.65) on the SPS. A small effect size was observed for the NI group (.49) and the NI/W group showed no effect on the SPS (Table 22).

Work Information Form

Subjects were asked whether they had returned to work at intake and 1-year. Chi-square analyses were conducted to determine whether any significant differences in reported return-to-work status existed among the four treatment groups at intake or at 1-year follow-up. No significant differences were found. Approximately 83.3% of all participants were noted to have returned to work at 1-year follow-up (Table 11).

CHAPTER FIVE

Results: Last Observation Carried Forward Analyses

The following analyses were all conducted implementing a LOCF technique to compensate for missing data. Missing data was attributed to inconsistent data collection due to participant non-compliance and attrition. Tables 23 through 30 summarize all data points collected for each participant that were available for use in LOCF techniques. In addition, Table 1.3 summarizes the demographic variables for the group of participants used in LOCF analyses.

PAIN MEASURES

Visual Analog Scale (VAS)

Due to the small sample size available for these analyses, LOCF techniques were employed in the following analyses. VAS ratings were found to not be normally distributed at intake for each of the four treatment groups. Due to the non-normal distributions found at intake, non-parametric procedures were conducted to examine overall differences among groups from intake to 1-year on VAS ratings.

Non-parametric analyses revealed the EI group reported significantly less pain from intake ($\mu = 5.8, \sigma = 2.1$) to 1-year ($\mu = 3.0, \sigma = 2.3$), $\chi^2 (1, n=17) = 7.1, p = .00$. When the three intervention groups were combined, a significant decrease in pain ratings was observed from intake ($\mu = 5.5, \sigma = 2.0$) to 1-year ($\mu = 3.6, \sigma = 2.6$), $\chi^2 (1, n=32) = 6.8, p =$

.01. No other significant differences were noted among the other treatment groups (Table 12).

VAS Categories

As previously mentioned, pain ratings as measured by the VAS were broken down into five categories which are as follows: mild pain (0-3); moderate pain (4 to 5); severe pain (6 to 7); and extreme pain (8 to 10). Chi-square analyses were conducted to examine differences in reported levels of pain among the four treatment groups, but no significant differences were found (Table 13).

Characteristic Pain Inventory

Paired sample *t*-tests were conducted using a LOCF techniques in order determine whether any of the four treatment groups experienced significant changes in reported pain levels. Subjects were asked to rate their “current” pain levels over a specified time period at both intake as well as at 1-year follow-up. CPI ratings were found to not be normally distributed at intake for each of the four treatment groups. Due to the non-normal distributions found at intake, non-parametric procedures were conducted to examine overall differences among groups from intake to 1-year on CPI ratings.

Non-parametric analyses revealed significant reductions in “current” pain ratings for the EI group, $\chi^2(1, n=16) = 9.3, p = .00$, from intake ($\mu = 5.1, \sigma = 2.8$) to 1-year ($\mu = 2.1, \sigma = 2.3$). A significant reduction in “current” pain was also observed for the three

intervention groups combined from intake ($\mu = 5.0, \sigma = 2.6$) to 1-year ($\mu = 2.6, \sigma = 2.6$), $\chi^2(1, n=30) = 9.8, p = .00$. No other significant differences were noted. These data are presented in Table 14.

COPING MEASURES

Short Form-36 (SF-36)

Last observation carried forward techniques were utilized to analyze the MCS and PCS scales of the SF-36. The Mental Component Score (MCS) measures the subject's overall sense of control over mental well-being; and the Physical Component Score (PCS) measures the subject's overall sense of control over their physical well-being. Analyses were conducted to examine differences among the four groups at intake and 1-year-follow-up.

MCS Scores

The distribution of MCS scores was found to be not normally distributed at intake for each of the four treatment groups. In order to account for the non-normal distributions found at intake, non-parametric procedures were also conducted to examine overall differences among groups from intake to 1-year on the SF-36 MCS. Non-parametric analyses revealed no significant differences among the treatment groups at intake or 1-year (Table 15).

PCS Scores

LOCF techniques were utilized in combination with paired sample *t*-tests to examine whether any significant changes in overall sense of control of physical well-being existed among intake and 1-year within any of the four treatment groups. Scores on the SF-36 PCS were found to be not normally distributed at intake for each of the four treatment groups. Due to the non-normal distributions found at intake, non-parametric procedures were also conducted to examine overall differences among groups from intake to 1-year on PCS ratings.

Non-parametric analyses showed significant increases in overall sense of control over physical well-being for the EI group from intake ($\mu = 34.7$, $\sigma = 8.4$) to 1-year ($\mu = 46.4$, $\sigma = 8.7$), $\chi^2(1, n=17) = 13.2$, $p = .00$. A moderate increase in PCS scores was noted for the EI/W group from intake ($\mu = 31.8$, $\sigma = 9.2$) to 1-year ($\mu = 38.1$, $\sigma = 10.7$) $\chi^2(1, n=8) = 3.6$, $p = .06$. No other significant differences were found on the PCS among the four treatment groups at intake or 1-year (Table 16).

Million Visual Analog Scale (MVAS)

LOCF techniques were used in combination with paired sample *t*-tests analyses in order to examine changes in functional disability within the four treatment groups from intake to 1-year follow-up. Scores on the MVAS were found to be not normally distributed at intake for each of the four treatment groups. Due to the non-normal distributions found at intake, non-parametric procedures were conducted to examine overall differences among groups from intake to 1-year on MVAS ratings.

Significant decreases in functional disability were found for the EI/W group, $\chi^2 (1, n=9) = 5.4, p = .02$; the EI group, $\chi^2 (1, n=18) = 5.6, p = .02$; and the NI group, $\chi^2 (1, n=13) = 6.2, p = .01$, from intake to 1-year. Additionally, a significant decrease in functional disability was observed from intake ($\mu = 76.6, \sigma = 27.9$) to 1-year ($\mu = 51.1, \sigma = 31.4$), for the three intervention groups combined, $\chi^2 (1, n=33) = 8.8, p = .00$. The means and standard deviations for these analyses are provided in Table 17.

MVAS Categories

As previously described, the MVAS raw scores were converted into categories ranging from “no reported disability” to “extreme disability,” in order to better describe subjects’ reported levels of functional disability. Chi-square analyses were conducted to determine whether any significant differences in reported functional disability exist among the four treatment groups at intake or at 1-year follow-up. No significant differences were found among the four groups on the categorized MVAS at intake or at 1-year (Table 18).

VOCATIONAL MEASURES

Obstacles to Return to Work (ORQ)

ORQ scores were found to be normally distributed at intake for each of the four treatment groups. Due to the normal distributions found at intake, parametric procedures

were conducted to examine overall differences among groups from intake to 1-year on ORQ scores.

Total ORQ scores were compared at intake and at 1-year follow-up for each of the four treatment groups. Paired sample *t*-tests were conducted to examine differences in the total ORQ scores for each of the treatment groups. A significant decrease in the total ORQ scores was noted for the EI group from intake ($\mu = 122.80$, $\sigma = 57.8$) to 1-year ($\mu = 101.87$, $\sigma = 53.2$), indicating a better prognosis for return-to-work and better perceptions regarding working at 1-year, $t(14) = 2.11$, $p = .05$. All groups were noted to have some decrease in ORQ ratings from intake to 1-year (Table 19). Additionally, the three intervention groups combined showed significantly improved RTW outcomes from intake ($\mu = 130.6$, $\sigma = 56.5$) to 1-year ($\mu = 109.9$, $\sigma = 58.9$), $t(22) = 2.4$, $p = .00$.

Stanford Presenteeism Scale (SPS)

Changes in SPS scores within the four treatment groups from intake to 1-year follow-up were examined using a combination of LOCF techniques and parametric procedures. Results of the SPS were found to be normally distributed at intake for each of the four treatment groups. Due to the normal distributions found at intake parametric procedures were utilized to examine overall differences among groups from intake to 1-year on SPS ratings.

Paired sample *t*-tests were conducted to evaluate changes in SPS scores within the four treatment groups from intake to 1-year follow-up. No significant changes were observed. However, the EI group was observed to have moderately improved SPS rating

from intake ($\mu = 17.5, \sigma = 4.8$) to 1-year ($\mu = 22.8, \sigma = 10.3$), $t(13) = -1.9, p = .06$. The three intervention groups combined showed an increase in SPS scores from intake ($\mu = 130.6, \sigma = 56.4$) to 1-year ($\mu = 109.9, \sigma = 58.9$) as well, $t(22) = 2.4, p = .025$. These results are summarized in Table 20.

Work Information Form

Subjects were asked whether they had returned to work at intake and 1-year. Chi-square analyses in combination with LOCF techniques were conducted to determine whether any significant differences in reported return-to-work status exist among the four treatment groups at intake or at 1-year follow-up. No significant differences were found among the four groups in terms of work status at intake or at 1-year (Table 21).

CHAPTER SIX

Discussion

This study built upon previous research by Gatchel et al. (2003) which utilized an algorithm, developed by Gatchel et al. (1995), to identify what patients with ALBP were at high-risk for developing chronic pain, and then implemented an interdisciplinary early-intervention program in order to prevent the progression of ALBP to CLBP. The aforementioned authors were able to demonstrate the effectiveness of the early-intervention program as measured by decreases in a number of pain and disability related measures as well as to establish the cost-effectiveness of such a program as compared to “treatment as usual” in terms of costs of medications, disability days, and healthcare utilization. The current study expanded upon the early-intervention program established by Gatchel et al. (2003) by adding a work-transition component in order to facilitate improved RTW and better work-related outcomes. After subjects were identified as being at high-risk for developing chronic pain, they were randomized into one of four treatment groups (EI/W; EI; NI/W; NI) and followed-up for a period of 1-year.

Pain Measures

It was hypothesized the EI/W group would do significantly better on measures of self-reported pain and symptoms of chronic pain and disability relative to the EI, NI/W, and NI groups at 1-year. It was also hypothesized that the EI/W, EI, and NI/W groups would all do significantly better than the NI group at 1-year follow-up on the

aforementioned measures. The EI group and the intervention groups combined were noted to report significantly less pain from intake to 1-year on the VAS as well as the CPI. It was noted that the EI/W, EI, and NI/W groups exhibited comparable scores on the VAS at 1-year with the NI group VAS rating being somewhat higher than the others. It likely with a larger sample size, this trend would reach statistical significance. Overall, on a measure of self-reported pain, the EI group resulted in the most decreases in pain ratings. These results do, however, support the effectiveness of the interdisciplinary early-intervention program found by Gatchel et al. (2003) and those studies reviewed by Gatchel and Okifuji (2006).

Coping Measures

On measures of coping, significant increases in overall sense of control of physical well-being were found for the EI group and the three intervention groups combined. Additionally, a moderate increase was noted for the EI/W group on a measure of overall sense of control over physical well-being. The overall better results of the EI group as compared to the EI/W were surprising. Again, the EI group demonstrated significantly greater increases in coping as measured by the SF-36 PCS. Significant decreases in reported functional disability were seen in the EI/W group, whereas only moderate decreases were observed in the EI group.

LOCF analyses indicated a significant reduction in reported pain from intake to 1-year for the EI group, and EI/W group on the MVAS. Surprisingly, the NI group also demonstrated a significant decrease in pain rating from intake to 1-year. On the CPI, the

EI group again demonstrated the most decreases in pain from intake to 1-year. The three intervention groups combined also demonstrated significantly decreases in “current” pain rating from intake to 1-year.

Vocational Measures

It was hypothesized that the work transition component would facilitate better return-to-work and vocational outcomes, with the assumption that the NI/W and EI/W groups would demonstrate significantly improved RTW, decreased presenteeism, and a better perception about working than the EI and NI groups. However, no significant differences were found among the four treatment groups the SPS. Moderate improvements were seen on the SPS for the EI group as well as the three intervention groups combined. Analyses of the ORQ revealed significant improvements for the EI group and the three intervention groups combined, indicating a better prognosis for RTW. All groups were observed to have some improvement in terms of return-to-work prognosis from intake to 1-year. However, a large portion (83.3%) of the overall sample of participants in this study had returned to work at 1-year follow-up. It is hypothesized that the unusually large percentage of participants having returned to work by 1-year, in part, explains the reduction of significant findings on the vocational measures used in this study. Perhaps, an analysis of data collected at six- and nine-month follow-up points would give more substantial information regarding rates at which the four groups returned to work and would isolate significant differences among the groups on these

measures. Consistently collected six- and nine-month data for all participants, however, were unavailable for the current study.

LOCF Measures

In conclusion, only sparse evidence for some of the posited hypotheses was provided by the analyses conducted in the study. Very few significant findings were demonstrated by this very small sample. The problem of the overall small sample size was compounded by difficulties experienced in collecting long-term data. Frequently, subjects were missing data from one or more follow-up evaluation periods due to non-compliance with follow-up procedures. LOCF techniques were carried out in an attempt to compensate for these problems. However, due to the design of the current study, the intake, post treatment, and 1-year evaluations collect substantially more data than do the six- and nine-month follow-ups. Not all measures are collected at each time-point; therefore, LOCF analyses are limited in their usefulness in this 1-year follow-up study. Additionally, an attempt was made to recapture missing 1-year follow-up data for the current analyses. Consequently, some subjects were contacted and evaluated as late as 36 months past their intake date. These retrospective evaluations then rely upon the recollection of the participant for medications, healthcare visits, etc., for as far back as 24 months. The lack of significant findings on these measures may also, therefore, reflect inaccuracies in the retrospective reports of the participants.

Effect Size

Effect sizes were computed for each of the four treatment groups for all of the measures used in this study. Large effect sizes were found for the EI/W group on the SF-36 PCS and the MVAS. A moderate effect size was found for the EI/W group on the VAS as well. Large effect sizes were found for the EI group on the VAS and SF-36 PCS. Moderate effect sizes were found for the EI group on the CPI “current pain”, MVAS, ORQ, and SPS as well. Effects sizes for the NI/W group were found to be large for the MVAS and moderate for the VAS and CPI “current pain.” Additionally, moderate effect sizes were found for the NI group on the SF-36 MCS and the MVAS.

Limitations and Directions for Future Research

Various limitations presented themselves during the course of conducting this study. First and foremost, the small sample size of this study most likely had a significant effect on the results of the analyses. As a result, the four treatment groups were uneven in size. Future analyses with larger sample sizes will likely develop trends identified into significance.

Additionally, data were not consistently collected at all follow-up points due to participant non-compliance. Missing data posed a large challenge to these analyses. Many 1-year follow-ups were not completed due to difficulties with data collection. While an attempt was made to recapture the missing 1-year data, locating study subjects for long-term follow-up evaluation becomes increasingly difficult as each follow-up

period passes. Asking subjects to retrospectively answer follow-up questions increases the risk of inaccuracies as well. More effective methods of consistently collecting follow-up data have already been put into place in order to prevent data loss for the larger more comprehensive studies that will arise from this sample in the future.

In addition, the use of many analyses in this study increases the possibility that Type I errors occurred. However, this less conservative method of analyzing the data was used in order to identify any trends that might have existed in this preliminary study.

One last limitation identified in this study related to sample size and participant compliance. It was observed that patients randomized into the NI/W group tended to drop-out of the study at higher rates than the three other treatment groups. Anecdotally, it was noticed that some patients voiced their disapproval after being told they were randomized into the NI/W groups and made comments to research personnel that they had hoped they would be in the “full treatment” group (i.e. the EI/W group) or in the EI group. While great efforts are now made to retain participants in their respective randomized treatment groups, some attrition is unavoidable. Future research would do well to concentrate on retention and compliance issues throughout the study.

Conclusions

Despite the overall small sample size of the current study, significant findings as well as trends observed in the data demonstrated the effectiveness of an early intervention program in the prevention of the progression of acute to chronic pain. Overall, on measures of self-reported pain and disability as well as coping measures related to pain,

those subjects in the EI group showed improvement from intake to 1-year. The EI group, did better in terms of fewer symptoms of pain and disability as compared to the EI/W, NI/W, and NI groups. The EI/W group demonstrated some significant improvements on these measures from intake to 1-year, but the significance of the data was limited by the small sample size and lack of statistical power. As this is an analysis of preliminary results of a much larger ongoing study, the trends identified will likely build into significance for future analyses as the sample size enlarges.

APPENDIX A
TABLE 1

<u>Demographic Variables at Intake</u>				
	EI/W (n=15)	EI (n=23)	NI/W (n=7)	NI (n=41)
<u>Gender</u>				
Male	40.0%	56.5%	42.9%	43.9%
Female	60.0%	43.5%	57.1%	54.7%
<u>Ethnicity</u>				
Caucasian	60.0%	30.4%	28.6%	40.4%
Latino	13.3%	52.2%	71.4%	22.0%
African American	26.7 %	17.4%	0.0%	24.4%
Asian	0.0%	100.0%	100.0%	7.3%
Other	0.0%	22.7%	14.3%	2.4%
<u>Marital Status</u>				
Single	20.0%	30.4%	28.6%	36.6%
Married/Living Together as Married	73.3%	52.2%	71.4%	53.7
Divorced or Separated	6.7%	17.4%	0.0%	9.8%
<u>Age (at time of screening)</u>	43.8	43.0	43.4	38.3
<u>Years of Education</u>	14.2	14.4	13.5	13.4
<u>Days of Pain</u>	41.8	39.9	24.9	24.4

TABLE 1.2**Demographic Variables for Participants with 1-year Data**

	EI/W (n=5)	EI (n=15)	NI/W (n=3)	NI (n=8)
<u>Gender</u>				
Male	40.0%	60.0%	33.3%	25.0%
Female	60.0%	40.0%	66.7%	75.0%
<u>Ethnicity</u>				
Caucasian	80.0%	26.7%	33.3%	62.5%
Latino	20.0%	60.0%	66.7%	12.5%
African American	0.0%	13.3%	0.0%	0.0%
Asian	0.0%	0.0%	0.0%	25.0%
Other	0.0%	0.0%	0.0%	0.0%
<u>Marital Status</u>				
Single	40.0%	26.7%	33.3%	37.5%
Married/Living Together as Married	60.0%	60.0%	66.7%	50.0%
Divorced or Separated	0.0%	13.3%	0.0%	12.5%
<u>Age (at time of screening)</u>	39.7	41.9	41.2	46.1
<u>Years of Education</u>	14.6	14.3	12.7	14.6
<u>Days of Pain</u>	41.8	39.9	24.9	24.4

TABLE 1.3**Demographic Variables of Participants with 1-year Data Last Observation Carried Forward**

	EI/W (n=9)	EI (n=18)	NI/W (n=6)	NI (n=15)
<u>Gender</u>				
Male	33.3%	66.7%	33.3%	26.7%
Female	66.7%	33.3%	66.7%	73.3%
<u>Ethnicity</u>				
Caucasian	55.6%	27.8%	33.3%	60.0%
Latino	11.1%	50.0%	66.7%	6.7%
African American	33.3%	22.2%	0.0%	20.0%
Asian	0.0%	0.0%	13.3%	4.2%
Other	0.0%	0.0%	0.0%	0.0%
<u>Marital Status</u>				
Single	22.2%	27.8%	33.3%	26.7%
Married/Living Together as Married	66.7%	50.0%	66.7%	60.0%
Divorced or Separated	11.1%	22.2%	0.0%	13.3%
<u>Age (at time of screening)</u>	45.3	43.0	41.1	44.0
<u>Years of Education</u>	14.5	14.2	13.0	14.6
<u>Days of Pain</u>	38.8	39.6	17.0	14.4

TABLE 2

Friedman Non-Parametric Two-Way Analysis of Variance Visual Analog Scale
Intake to 1-year

VAS	<i>n</i>	μ	σ	<i>df</i>	χ^2	<i>p</i>
<u>EI/W</u>				1	1.8	.18
Intake	5	5.00	1.23			
12 Month	5	3.60	2.70			
<u>EI</u>				1	5.33	.02*
Intake	15	5.93	2.15			
12 Month	15	3.20	2.39			
<u>NI/W</u>				1	1.00	.32
Intake	3	2.67	1.15			
12 Month	3	3.33	2.31			
<u>NI</u>				1	0.67	.41
Intake	8	5.88	2.03			
12 Month	8	5.25	3.37			
<u>Combined Intervention</u>				1	5.60	.02*
Intake	23	5.3	2.1			
12 Month	23	3.3	2.3			

TABLE 3

Visual Analog Scale Categories Chi-Square

VAS		EI/W	EI	NI/W	NI	χ^2	df	p
	<u>Category</u>					4.41	9	.88
Intake	No Reported Pain	0.0%	0.0%	0.0%	0.0%			
	Mild Pain	11.1%	16.7%	22.2%	11.1%			
	Moderate Pain	16.7%	16.7%	55.6%	22.2%			
	Severe Pain	44.4%	37.5%	0.0%	40.0%			
	Very Severe Pain	0.0%	0.0%	0.0%	0.0%			
	Extreme Pain	27.8%	29.2%	26.7%	26.7%			
		EI/W	EI	NI/W	NI	χ^2	df	p
	<u>Category</u>					13.99	9	.12
1-year	No Reported Pain	0.0%	0.0%	0.0%	7.7%			
	Mild Pain	60.0%	73.3%	66.7%	37.5%			
	Moderate Pain	20.0%	0.0%	0.0%	0.0%			
	Severe Pain	0.0%	26.7%	33.3%	25.0%			
	Very Severe Pain	0.0%	0.0%	0.0%	7.7%			
	Extreme Pain	20.0%	0.0%	0.0%	37.5%			

TABLE 4

Friedman Non-Parametric Two-Way Analysis of Variance Visual Analog Scale Intake to 1-year Characteristic Pain Inventory "Current" Intake to 1-Year

<u>"Current" CPI</u>	<i>n</i>	μ	σ	<i>df</i>	χ^2	<i>p</i>
<u>EI/W</u>				1	0.20	.65
Intake	5	4.20	2.17			
12 Month	5	3.60	2.61			
<u>EI</u>				1	6.40	.01*
Intake	13	5.08	3.01			
12 Month	13	2.38	2.47			
<u>NI/W</u>				1	.33	.56
Intake	3	2.33	0.57			
12 Month	3	3.33	2.52			
<u>NI</u>				1	1.3	.28
Intake	7	5.00	2.38			
12 Month	7	4.00	3.46			
<u>Combined Intervention</u>				1	3.6	.06
Intake	21	4.5	2.7			
12 Month	21	2.8	2.4			

TABLE 5

Friedman Non-Parametric Two-Way Analysis of Variance SF-36 Mental
Component Scale Intake to 1-Year

MCS	<i>n</i>	μ	σ	<i>df</i>	χ^2	<i>p</i>
<u>EI/W</u>				1	.50	0.48
Intake	8	40.63	11.90			
12 Month	8	41.88	13.72			
<u>EI</u>				1	.06	0.80
Intake	17	48.29	15.71			
12 Month	17	48.65	11.60			
<u>NI/W</u>				1	.33	0.56
Intake	4	43.43	10.86			
12 Month	4	44.25	14.90			
<u>NI</u>				1	.14	0.71
Intake	7	52.80	11.63			
12 Month	7	47.14	17.75			
<u>Combined Intervention</u>				1	.00	1.00
Intake	29	45.51	14.18			
12 Month	29	46.17	12.54			

TABLE 6

Friedman Non-Parametric Two-Way Analysis of SF-36 Physical Component Scale Intake to 1-Year

PCS	<i>n</i>	μ	σ	<i>df</i>	χ^2	<i>p</i>
<u>EI/W</u>				1	3.0	.08
Intake	4	32.40	12.56			
12 Month	4	36.75	12.37			
<u>EI</u>				1	9.30	.00*
Intake	13	32.95	7.31			
12 Month	13	44.28	8.49			
<u>NI/W</u>				1	0.33	.56
Intake	3	36.03	2.95			
12 Month	3	37.91	10.56			
<u>NI</u>				1	.14	.71
Intake	7	42.17	13.86			
12 Month	7	43.29	10.23			
<u>Combined Intervention</u>				1	8.89	.00*
Intake	20	33.31	7.81			
12 Month	20	41.82	9.66			

TABLE 7

Friedman Non-Parametric Two-Way Analysis of Million Visual Analog Scale Intake to 1-Year

MVAS	<i>n</i>	μ	σ	<i>df</i>	χ^2	<i>p</i>
<u>EI/W</u>				1	5.0	.02*
Intake	5	82.40	27.86			
12 Month	5	55.40	35.18			
<u>EI</u>				1	3.27	.07
Intake	15	79.87	25.84			
12 Month	15	48.60	30.52			
<u>NI/W</u>				1	3.0	.08
Intake	3	40.33	16.26			
12 Month	3	52.67	19.73			
<u>NI</u>				1	2.0	.15
Intake	8	79.63	17.95			
12 Month	8	61.13	37.77			
<u>Combined Intervention</u>				1	3.52	.06
Intake	23	75.26	27.97			
12 Month	23	50.61	29.36			

TABLE 8

Million Visual Analog Scale Categories Chi-Square

MVAS		EI/W	EI	NI/W	NI	χ^2	<i>df</i>	<i>p</i>
	<u>Category</u>					9.96	12	.61
Intake	No Reported Disability	0.0%	8.0%	0.0%	0.0%			
	Mild Disability	5.6%	20.0%	22.2%	4.5%			
	Moderate Disability	16.7%	48%	33.3%	29.5%			
	Severe Disability	44.4%	24.0%	22.2%	45.5%			
	Very Severe Disability	33.3%	0.0%	22.2%	15.9%			
	Extreme Disability	0.0%	0.0%	0.0%	4.5%			
		EI/W	EI	NI/W	NI	χ^2	<i>df</i>	<i>p</i>
	<u>Category</u>					10.61	12	.56
1-Year	No Reported Disability	0.0%	0.0%	0.0%	12.5%			
	Mild Disability	40.0%	46.7%	33.3%	12.5%			
	Moderate Disability	20.5%	26.7%	66.7%	25.0%			
	Severe Disability	20.0%	26.7%	0.0%	37.5%			
	Very Severe Disability	20.0%	0.0%	0.0%	12.5%			

TABLE 9Paired Sample *t*-tests of Obstacles to Return to Work Total Intake to 1-Year

ORQ Total	<i>n</i>	μ	σ	<i>df</i>	<i>t</i>	<i>p</i>
<u>EI/W</u>				4	.95	.39
Intake	5	156.20	62.93			
12 Month	5	131.20	85.16			
<u>EI</u>				14	2.1	.05*
Intake	15	122.80	57.76			
12 Month	15	101.87	53.21			
<u>NI/W</u>				2	.61	.60
Intake	3	127.00	40.73			
12 Month	3	115.00	47.29			
<u>NI</u>				7	.24	.82
Intake	8	96.75	25.09			
12 Month	8	93.38	43.83			
<u>Combined Intervention</u>				22	2.41	.02*
Intake	23	130.61	56.45			
12 Month	23	109.96	58.94			

TABLE 10

Friedman Non-Parametric Two-Way Analysis Stanford Presenteeism Scale Intake to One Year

SPS	<i>n</i>	μ	σ	<i>df</i>	<i>t</i>	<i>p</i>
<u>EI/W</u>				3	-.075	.94
Intake	4	20.00	7.87			
12 Month	4	20.25	7.93			
<u>EI</u>				15	-1.09	.29
Intake	16	17.69	4.56			
12 Month	16	20.75	11.30			
<u>NI/W</u>				5	-1.45	.21
Intake	6	17.33	7.84			
12 Month	6	22.00	3.03			
<u>NI</u>				7	1.43	.19
Intake	8	22.63	5.58			
12 Month	8	19.63	5.75			
<u>Combined Intervention</u>				23	2.41	.02*
Intake	23	17.21	6.91			
12 Month	23	24.22	4.11			

TABLE 11

Vocational Status Chi-Square

		EI/W	EI	NI/W	NI	χ^2	<i>df</i>	<i>p</i>
<u>Status</u>						5.46	6	.48
Intake	Returned to Work	64.7%	82.6%	88.9%	66.7%			
	Not Returned to Work	35.3%	17.4%	11.1%	28.6%			
		EI/W	EI	NI/W	NI	χ^2	<i>df</i>	<i>p</i>
<u>Status</u>						1.57	3	.66
1-Year	Returned to Work	75.0%	90.0%	100.0%	71.4%			
	Not Returned to Work	25.0%	10.0%	0.0%	28.6%			

TABLE 12

Last Observation Carried Forward: Friedman Non-Parametric Two-Way Analysis of Variance Visual Analog Scale Intake to 1-Year

VAS	<i>n</i>	μ	σ	<i>df</i>	χ^2	<i>p</i>
<u>EI/W</u>				1	1.29	.26
Intake	9	5.67	1.73			
12 Month	9	4.56	2.69			
<u>EI</u>				1	7.14	.00*
Intake	17	5.76	2.14			
12 Month	17	3.00	2.32			
<u>NI/W</u>				1	.00	1.00
Intake	6	4.67	2.34			
12 Month	6	3.83	2.99			
<u>NI</u>				1	1.92	.17
Intake	15	5.87	1.73			
12 Month	15	4.20	3.23			
<u>Combined Intervention</u>				1	6.76	.00*
Intake	32	5.53	2.05			
12 Month	32	3.59	2.56			

TABLE 13

Visual Analog Scale Categories Chi-Square

VAS		EI/W	EI	NI/W	NI	χ^2	<i>df</i>	<i>p</i>
	<u>Category</u>					4.41	9	.88
Intake	No Reported Pain	0.0%	0.0%	0.0%	0.0%			
	Mild Pain	11.1%	16.7%	22.2%	11.1%			
	Moderate Pain	16.7%	16.7%	55.6%	22.2%			
	Severe Pain	44.4%	37.5%	0.0%	40.0%			
	Very Severe Pain	0.0%	0.0%	0.0%	0.0%			
	Extreme Pain	27.8%	29.2%	26.7%	26.7%			
		EI/W	EI	NI/W	NI	χ^2	<i>df</i>	<i>p</i>
	<u>Category</u>					13.99	9	.12
1-Year	No Reported Pain	0.0%	0.0%	0.0%	7.7%			
	Mild Pain	60.0%	73.3%	66.7%	37.5%			
	Moderate Pain	20.0%	0.0%	0.0%	0.0%			
	Severe Pain	0.0%	26.7%	33.3%	25.0%			
	Very Severe Pain	0.0%	0.0%	0.0%	7.7%			
	Extreme Pain	20.0%	0.0%	0.0%	37.5%			

TABLE 14

Last Observation Carried Forward: Friedman Non-Parametric Two-Way Analysis of Variance Visual Analog Scale Intake to 1-Year Characteristic Pain Inventory
 “Current” Intake to 1-Year

“Current” CPI	<i>n</i>	μ	σ	<i>df</i>	χ^2	<i>p</i>
<u>EI/W</u>				1	2.00	.15
Intake	9	5.22	2.49	.		
12 Month	9	3.22	3.23			
<u>EI</u>				1	9.31	.00*
Intake	16	5.06	2.79			
12 Month	16	2.06	2.35			
<u>NI/W</u>				1	.20	.65
Intake	5	4.40	2.88			
12 Month	5	3.40	2.51			
<u>NI</u>				1	3.60	.06
Intake	11	4.91	1.92			
12 Month	11	3.18	2.99			
<u>Combined Intervention</u>				1	9.85	.00*
Intake	30	5.00	2.63			
12 Month	30	2.63	2.65			

TABLE 15

Last Observation Carried Forward: Friedman Non-Parametric Two-Way Analysis of Variance of SF-36 Mental Component Scale Intake to 1-Year

MCS	<i>n</i>	μ	σ	<i>df</i>	χ^2	<i>p</i>
<u>EI/W</u>				1	.50	.48
Intake	8	40.63	11.90			
12 Month	8	41.88	13.72			
<u>EI</u>				1	.06	.80
Intake	17	48.29	15.71			
12 Month	17	48.65	11.60			
<u>NI/W</u>				1	.33	.56
Intake	4	43.43	10.86			
12 Month	4	44.25	14.93			
<u>NI</u>				1	.14	.70
Intake	7	52.80	11.63			
12 Month	7	47.14	17.75			
<u>Combined Intervention</u>				1	.00	1.0
Intake	29	45.51	14.18			
12 Month	29	46.17	12.54			

TABLE 16

Last Observation Carried Forward: Friedman Non-Parametric Two-Way Analysis of SF-36 Physical Component Scale Intake to 1-Year

PCS	<i>n</i>	μ	σ	<i>df</i>	χ^2	<i>p</i>
<u>EI/W</u>				1	3.57	.06
Intake	8	31.77	9.18			
12 Month	8	38.05	10.68			
<u>EI</u>				1	13.23	.00*
Intake	17	34.68	8.39			
12 Month	17	46.38	8.69			
<u>NI/W</u>				1	.00	1.0
Intake	4	31.18	10.01			
12 Month	4	36.65	8.98			
<u>NI</u>				1	.14	.71
Intake	7	42.17	13.86			
12 Month	7	43.29	10.25			
<u>Combined Intervention</u>				1	14.28	.00*
Intake	29	33.39	8.63			
12 Month	29	42.74	9.99			

TABLE 17

Last Observation Carried Forward: Friedman Non-Parametric Two-Way Analysis of Million Visual Analog Scale Intake to 1-Year

MVAS	<i>n</i>	μ	σ	<i>df</i>	χ^2	<i>p</i>
<u>EI/W</u>				1	5.44	.02*
Intake	9	84.44	24.85			
12 Month	9	64.78	31.94			
<u>EI</u>				1	5.56	.02*
Intake	18	77.33	27.94			
12 Month	18	43.06	30.72			
<u>NI/W</u>				1	.00	1.00
Intake	6	62.67	31.77			
12 Month	6	55.17	29.68			
<u>NI</u>				1	6.23	.01*
Intake	13	78.23	19.42			
12 Month	13	48.38	35.45			
<u>Combined Intervention</u>				1	8.76	.00*
Intake	33	76.61	27.95			
12 Month	33	51.18	31.41			

TABLE 18

Million Visual Analog Scale Categories Chi-Square

MVAS		EI/W	EI	NI/W	NI	χ^2	<i>df</i>	<i>p</i>
	<u>Category</u>					9.963	12	.619
Intake	No Reported Disability	0.0%	8.0%	0.0%	0.0%			
	Mild Disability	5.6%	20.0%	22.2%	4.5%			
	Moderate Disability	16.7%	48.0%	33.3%	29.5%			
	Severe Disability	44.4%	24.0%	22.2%	45.5%			
	Very Severe Disability	33.3%	0.0%	22.2%	15.9%			
	Extreme Disability	0.0%	0.0%	0.0%	4.5%			
		EI/W	EI	NI/W	NI	χ^2	<i>df</i>	<i>p</i>
	<u>Category</u>					10.61	12	.563
1-Year	No Reported Disability	0.0%	0.0%	0.0%	12.5%			
	Mild Disability	40.0%	46.7%	33.3%	12.5%			
	Moderate Disability	20.5%	26.7%	66.7%	25.0%			
	Severe Disability	20.0%	26.7%	0.0%	37.5%			
	Very Severe Disability	20.0%	0.0%	0.0%	12.5%			

TABLE 19

Last Observation Carried Forward: Paired Sample *t*-tests of Obstacles to Return to Work Total Intake to 1-Year

ORQ Total	<i>n</i>	μ	σ	<i>df</i>	<i>t</i>	<i>p</i>
<u>EI/W</u>				4	.95	.39
Intake	5	156.20	62.93			
12 Month	5	131.20	85.16			
<u>EI</u>				14	2.1	.05*
Intake	15	122.80	57.76			
12 Month	15	101.87	53.21			
<u>NI/W</u>				2	.61	.60
Intake	3	127.00	40.73			
12 Month	3	115.00	47.29			
<u>NI</u>				7	.24	.82
Intake	8	96.75	25.09			
12 Month	8	93.38	43.83			
<u>Combined Intervention</u>				22	2.41	.02*
Intake	23	130.61	56.45			
12 Month	23	109.96	58.94			

TABLE 20

Last Observation Carried Forward: Friedman Non-Parametric Two-Way Analysis
Stanford Presenteeism Scale Intake to One Year

SPS	<i>n</i>	μ	σ	<i>df</i>	<i>t</i>	<i>p</i>
<u>EI/W</u>				3	-.07	.94
Intake	4	20.00	7.87			
12 Month	4	20.25	7.93			
<u>EI</u>				15	-1.09	.29
Intake	16	17.69	4.56			
12 Month	16	20.75	11.30			
<u>NI/W</u>				5	-1.45	.20
Intake	6	17.33	7.84			
12 Month	6	22.00	3.03			
<u>NI</u>				7	1.43	.19
Intake	8	22.63	5.58			
12 Month	8	19.63	5.75			
<u>Combined Intervention</u>				23	2.41	.02*
Intake	23	17.21	6.91			
12 Month	23	24.22	4.11			

TABLE 21

Last Observation Carried Forward: Vocational Status Chi-Square

		EI/W	EI	NI/W	NI	χ^2	<i>df</i>	<i>p</i>
<u>Status</u>						5.46	6	.48
Intake	Returned to Work	64.7%	82.6%	88.9%	66.7%			
	Not Returned to Work	35.3%	17.4%	11.1%	28.6%			
		EI/W	EI	NI/W	NI	χ^2	<i>df</i>	<i>p</i>
<u>Status</u>						1.57	3	.66
1-Year	Returned to Work	75.0%	90.0%	100.0%	71.4%			
	Not Returned to Work	25.0%	10.0%	0.0%	28.6%			

TABLE 22

Effect Sizes Treatment Group for Outcome Measures

	EI/W	EI	NI/W	NI
<u>VAS</u>	.64*	.94**	.58*	.29
<u>CPI</u>				
“Current”	.26	.79*	.50*	.29
<u>SF-36</u>				
MCS	.38	.13	.29	.65*
PCS	.95**	.95**	.20	.15
<u>MVAS</u>	1.20**	.77*	1.11**	.57*
<u>ORQ</u>	.42	.55*	.35	.09
<u>SPS</u>	.04	.53*	.65*	.49

**Large Effect Size

*Moderate Effect Size

Table 23

Available Data Points for Visual Analog Scale

Patient Identification Number	Intake VAS	Post VAS	6 Month VAS	9 Month VAS	12 Month VAS
1	✓
2	✓
10	✓	.	.	.	✓
11	✓	.	.	.	✓
12	✓
39	✓
40	✓
42	✓
60	✓	.	.	.	✓
63	✓
74	✓
122	✓
168	✓
235	✓	✓	.	.	✓
252	✓
265	✓	✓	.	.	✓
312	✓	✓	.	✓	.
314	✓
324	✓	.	.	.	✓
328	✓	✓	.	✓	✓
334	✓	.	.	.	✓
344	✓	✓	.	✓	.
352	✓	✓	.	.	✓
354	✓
355	✓
359	✓
361	✓	✓	✓	✓	✓
372	✓	✓	.	.	✓
377	✓	.	.	.	✓
394	✓
409	✓
419	✓
422	✓
438	✓
447	✓	✓	✓	✓	.
473	✓
484	✓	✓	.	.	✓
507	✓	✓	✓	.	✓
508	✓
509	✓	✓	.	.	✓
519	✓
520	✓
535	✓	.	✓	.	✓

Table 23.2

Available Data Points for Visual Analog Scale Continued

Patient Identification Number	Intake VAS	Post VAS	6 Month VAS	9 Month VAS	12 Month VAS
539	✓
541	✓	.	.	.	✓
543	✓	.	.	.	✓
556	✓	✓	✓	✓	.
564	✓	.	.	.	✓
576	✓	.	.	.	✓
582	✓	.	.	✓	.
590	✓	.	✓	✓	✓
597	✓
604	✓
622	✓	✓	✓	.	✓
637	✓
638	✓	.	.	.	✓
641	✓	✓	.	.	✓
647	✓
651	✓	.	.	.	✓
652	✓
653	✓	✓	.	.	✓
660	✓	✓	✓	.	✓
667	✓
670	✓	.	.	✓	.
676	✓
677	✓	.	.	✓	✓
680	✓	✓	.	✓	.
681	✓
682	✓	.	✓	.	.
684	✓
687	✓	✓	.	✓	✓
690	✓	.	.	✓	.
691
698	✓	.	.	.	✓
715	✓	.	.	.	✓
719	✓	✓	.	✓	.
723	✓	.	.	✓	.
724	✓
727	✓	.	.	✓	.
731	✓
732	✓	✓	✓	.	.
740	✓	.	✓	✓	.
765	.	✓	✓	.	.
767	✓	.	✓	.	.
780	✓
790	✓
792	✓	✓	.	.	.

Table 24

Available Data Points for Characteristic Pain Inventory

Patient Identification Number	Intake Current CPI	Post Current CPI	6 Month Current CPI	9 Month Current CPI	12 Month Current CPI
1	✓
2	✓
10	✓	.	.	.	✓
11	✓	.	.	.	✓
12	✓
39	✓
40	✓
42	✓
60	✓	.	.	.	✓
63	✓
74	✓
122	✓
168	✓
235	✓	✓	.	.	✓
252	✓
265	✓	✓	.	.	✓
312	✓	✓	.	.	.
314	✓
324	✓	.	.	.	✓
328	✓	✓	.	✓	✓
334	✓	.	.	.	✓
344	✓	✓	.	✓	.
352	.	✓	.	.	✓
354	✓
355	✓
359	✓
361	✓	✓	.	✓	✓
372	✓	.	.	.	✓
377	✓	.	.	.	✓
394	✓
409	✓
419	✓
422	✓
438	✓
447	✓	✓	.	.	.
473	✓
484	✓	✓	.	.	✓
507	✓	✓	.	.	✓
508	✓
509	✓	✓	.	.	✓
519	✓
520
535	✓	.	.	.	✓

Table 24.2

Available Data Points for Characteristic Pain Inventory Continued

Patient Identification Number	Intake Current CPI	Post Current CPI	6 Month Current CPI	9 Month Current CPI	12 Month Current CPI
539	✓
541	✓	.	.	.	✓
543	✓	.	.	.	✓
556	✓	✓	.	.	.
564	✓	.	.	.	✓
576	✓	.	.	.	✓
582	✓	.	.	.	✓
590	✓	.	.	.	✓
597	✓
604	✓
622	✓	✓	.	.	✓
637	✓
638	✓	.	.	.	✓
641	✓	✓	.	.	✓
647	✓
651	✓	.	.	.	✓
652	✓
653	✓	✓	.	.	✓
660	.	✓	.	.	.
667	✓
670	✓
676
677	✓	.	.	.	✓
680	✓	✓	.	.	.
681	✓
682	✓
684
687	✓	✓	.	.	✓
690	✓
691
698	✓	.	.	.	✓
715	✓	.	.	.	✓
719	✓	✓	.	.	.
723	✓
724	✓
727	✓	.	.	✓	.
731	✓
732	✓	✓	✓	.	.
740	✓	.	✓	✓	.
765	✓	✓	✓	.	.
767	✓	.	✓	.	.
780	✓
790	✓
792	✓	✓	.	.	.

Table 25

Available Data Points for SF-36 Mental Component Scale

Patient Identification Number	Intake MCS	Post MCS	6 Month MCS	9 Month MCS	12 Month MCS
1	✓
2	✓
10	✓	.	.	.	✓
11	✓	.	.	.	✓
12	✓
39	✓
40	✓
42	✓
60	✓	.	.	.	✓
63	✓
74	✓
122	✓
168	✓
235	✓	✓	.	.	✓
252	✓
265	✓	✓	.	.	✓
312	✓	✓	.	.	.
314	✓
324	✓	.	.	.	✓
328	✓	✓	.	.	✓
334	✓	.	.	.	✓
344	✓	✓	.	.	.
352	✓	✓	.	.	.
354	✓
355	✓
359	✓
361	✓	✓	.	.	✓
372	✓	✓	.	.	✓
377	✓	.	.	.	✓
394	✓
409	✓
419	✓
422	✓
438	✓
447	✓
473	✓
484	✓	✓	.	.	✓
507	✓	✓	.	.	✓
508	✓
509	✓	✓	.	.	✓
519	✓
520	✓
535	✓

Table 25.2

Available Data Points for SF-36 Mental Component Scale Continued

Patient Identification Number	Intake MCS	Post MCS	6 Month MCS	9 Month MCS	12 Month MCS
539	✓
541	✓	.	.	.	✓
543	✓	.	.	.	✓
556	✓	✓	.	.	.
564	✓	.	.	.	✓
576	✓	.	.	.	✓
582
590	✓
597	✓
604	✓
622	✓	✓	.	.	✓
637
638	✓
641	✓	✓	.	.	✓
647	✓
651	✓	.	.	.	✓
652	✓
653	✓	✓	.	.	✓
660	✓	✓	.	.	✓
667	✓
670	✓
676	✓
677	✓	.	.	.	✓
680	✓	✓	.	.	.
681
682
684	✓
687	✓	✓	.	.	✓
690	✓
691	✓
698	✓	.	.	.	✓
715	✓	.	.	.	✓
719	✓	✓	.	.	.
723	✓
724	✓
727	✓
731	✓
732	✓	✓	.	.	.
740	✓
765	✓	✓	.	.	.
767	✓
780	✓
790	✓
792	✓	✓	.	.	.

Table 26

Available Data Points for SF-36 Physical Component Scale Continued

Patient Identification Number	Intake PCS	Post PCS	6 Month PCS	9 Month PCS	12 Month PCS
1	✓
2	✓
10	✓	.	.	.	✓
11	✓	.	.	.	✓
12	✓
39	✓
40	✓
42	✓
60	✓	.	.	.	✓
63	✓
74	✓
122	✓
168	✓
235	✓	✓	.	.	✓
252	✓
265	✓	✓	.	.	✓
312	✓	✓	.	.	.
314	✓
324	✓	.	.	.	✓
328	✓	✓	.	.	✓
334	✓	.	.	.	✓
344	✓	✓	.	.	.
352	✓	✓	.	.	.
354	✓
355	✓
359	✓
361	✓	✓	.	.	✓
372	✓	✓	.	.	✓
377	✓	.	.	.	✓
394	✓
409	✓
419	✓
422	✓
438	✓
447	✓
473	✓
484	✓	✓	.	.	✓
507	✓	✓	.	.	✓
508	✓
509	✓	✓	.	.	✓
519	✓
520	✓
535	✓

Table 26.2

Available Data Points for SF-36 Physical Component Scale Continued

Patient Identification Number	Intake PCS	Post PCS	6 Month PCS	9 Month PCS	12 Month PCS
539	✓
541	✓	.	.	.	✓
543	✓	.	.	.	✓
556	✓	✓	.	.	.
564	✓	.	.	.	✓
576	✓	.	.	.	✓
582
590	✓
597	✓
604	✓
622	✓	✓	.	.	✓
637
638	✓
641	✓	✓	.	.	✓
647	✓
651	✓	.	.	.	✓
652	✓
653	✓	✓	.	.	✓
660	✓	✓	.	.	✓
667	✓
670	✓
676	✓
677	✓	.	.	.	✓
680	✓	✓	.	.	.
681
682
684	✓
687	✓	✓	.	.	✓
690	✓
691	✓
698	✓	.	.	.	✓
715	✓	.	.	.	✓
719	✓	✓	.	.	.
723	✓
724	✓
727	✓
731	✓
732	✓	✓	.	.	.
740	✓
765	✓	✓	.	.	.
767	✓
780	✓
790	✓
792	✓	✓	.	.	.

Table 27

Available Data Points for Million Visual Analog Scale

Patient Identification Number	Intake MVAS	Post MVAS	6 Month MVAS	9 Month MVAS	12 Month MVAS
1	✓
2	✓
10	✓	.	.	.	✓
11	✓	.	.	.	✓
12	✓
39	✓
40	✓
42	✓
60	✓	.	.	.	✓
63	✓
74	✓
122	✓
168	✓
235	✓	✓	.	.	✓
252	✓
265	✓	✓	.	.	✓
312	✓	✓	.	✓	.
314	✓
324	✓	.	.	.	✓
328	✓	✓	.	✓	✓
334	✓	.	.	.	✓
344	✓	✓	.	✓	.
352	✓	✓	.	.	✓
354	✓
355	✓
359	✓
361	✓	✓	✓	✓	✓
372	✓	✓	.	.	✓
377	✓	.	.	.	✓
394	✓
409	✓
419	✓
422	✓
438	✓
447	✓	✓	✓	.	.
473	✓
484	✓	✓	.	.	✓
507	✓	✓	✓	.	✓
508	✓
509	✓	✓	.	.	✓
519	✓
520	✓
535	✓	.	✓	.	✓

Table 27.2

Available Data Points for Million Visual Analog Scale Continued

Patient Identification Number	Intake MVAS	Post MVAS	6 Month MVAS	9 Month MVAS	12 Month MVAS
539	✓
541	✓	.	.	.	✓
543	✓	.	.	.	✓
556	✓	✓	✓	✓	.
564	✓	.	.	.	✓
576	✓	.	.	.	✓
582	✓	.	.	✓	.
590	✓	.	✓	✓	✓
597	✓
604	✓
622	✓	✓	✓	.	✓
637	✓
638	✓	.	.	.	✓
641	✓	✓	.	.	✓
647	✓
651	✓	.	.	.	✓
652	✓
653	✓	✓	.	.	✓
660	✓	✓	✓	.	✓
667	✓
670	✓
676	✓
677	✓	.	.	.	✓
680	✓	✓	.	.	.
681	✓
682	✓	.	✓	.	.
684	✓
687	✓	✓	.	✓	✓
690	✓	.	.	✓	.
691	✓
698	✓	.	.	.	✓
715	✓	.	.	.	✓
719	✓	✓	.	.	.
723	✓
724	✓
727	✓	.	.	✓	.
731	✓
732	✓	✓	✓	.	.
740	✓	.	✓	✓	.
765	✓	✓	✓	.	.
767	✓	.	✓	.	.
780	✓
790	✓
792	✓	✓	.	.	.

Table 28

Available Data Points for Obstacles to Return to Work

Patient Identification Number	Intake ORQ Total	Post ORQ Total	6 Month ORQ Total	9 Month ORQ Total	12 Month ORQ Total
1	✓
2	✓
10	✓	.	.	.	✓
11	✓	.	.	.	✓
12	✓
39	✓
40	✓
42	✓
60	✓	.	.	.	✓
63	✓
74	✓
122	✓
168	✓
235	✓	.	.	.	✓
252	✓
265	✓	.	.	.	✓
312	✓
314	✓
324	✓	.	.	.	✓
328	✓	.	.	.	✓
334	✓	.	.	.	✓
344	✓
352	✓	.	.	.	✓
354	✓
355	✓
359	✓
361	✓	.	.	.	✓
372	✓	.	.	.	✓
377	✓	.	.	.	✓
394	✓
409	✓
419	✓
422	✓
438	✓
447	✓
473	✓
484	✓	.	.	.	✓
507	✓	.	.	.	✓
508	✓
509	✓	.	.	.	✓
519	✓
520	✓
535	✓	.	.	.	✓

Table 28.2

Available Data Points for Obstacles to Return to Work Continued

Patient Identification Number	Intake ORQ Total	Post ORQ Total	6 Month ORQ Total	9 Month ORQ Total	12 Month ORQ Total
539	✓
541	✓	.	.	.	✓
543	✓	.	.	.	✓
556	✓
564	✓	.	.	.	✓
576	✓	.	.	.	✓
582	✓
590	✓	.	.	.	✓
597	✓
604	✓
622	✓	.	.	.	✓
637	✓
638	✓	.	.	.	✓
641	✓	.	.	.	✓
647	✓
651	✓	.	.	.	✓
652	✓
653	✓	.	.	.	✓
660	✓	.	.	.	✓
667	✓
670	✓
676	✓
677	✓	.	.	.	✓
680	✓
681	✓
682	✓
684	✓
687	✓	.	.	.	✓
690	✓
691
698	✓	.	.	.	✓
715	✓	.	.	.	✓
719	✓
723	✓
724	✓
727	✓
731	✓
732	✓
740	✓
765	✓
767	✓
780	✓
790	✓
792	✓

Table 29

Available Data Points for Stanford Presenteeism Scale Continued

Patient Identification Number	Intake SPS	Post SPS	6 Month SPS	9 Month SPS	12 Month SPS
1
2	✓
10	✓	.	.	.	✓
11	✓	.	.	.	✓
12	✓
39	✓
40	✓
42	✓
60	✓	.	.	.	✓
63	✓
74	✓
122	✓
168	✓
235	✓	.	.	.	✓
252	✓
265	✓	.	.	.	✓
312	✓
314	✓
324	✓	.	.	.	✓
328	✓	.	.	.	✓
334	✓	.	.	.	✓
344	✓
352	✓	.	.	.	✓
354	✓
355	✓
359	✓
361	✓	.	.	.	✓
372	✓	.	.	.	✓
377	✓
394	✓
409	✓
419	✓
422	✓
438	✓
447	✓
473	✓
484	✓	.	.	.	✓
507	✓	.	.	.	✓
508	✓
509	✓	.	.	.	✓
519	✓
520	✓
535	✓	.	.	.	✓

Table 29.2

Available Data Points for Stanford Presenteeism Scale Continued

Patient Identification Number	Intake SPS	Post SPS	6 Month SPS	9 Month SPS	12 Month SPS
539	✓
541	✓	.	.	.	✓
543	✓
556	✓
564	✓	.	.	.	✓
576	✓	.	.	.	✓
582	✓
590	✓	.	.	.	✓
597
604	✓
622	✓	.	.	.	✓
637	✓
638	✓	.	.	.	✓
641	✓	.	.	.	✓
647
651	✓	.	.	.	✓
652	✓
653	✓	.	.	.	✓
660	✓	.	.	.	✓
667	✓
670
676	✓
677	✓	.	.	.	✓
680	✓
681	✓
682
684	✓
687	✓
690	✓
691
698	✓	.	.	.	✓
715	✓	.	.	.	✓
719	✓
723	✓
724	✓
727	✓
731	✓
732	✓
740
765	✓
767	✓
780	✓
790	✓
792	✓

Table 30

Available Data Points for Work Information Form

Patient Identification Number	Intake Return to Work	Post Return to Work	6 Month Return to Work	9 Month Return to Work	12 Month Return to Work
1	✓
2	✓
10	✓	.	.	.	✓
11
12	✓
39	✓
40	✓
42	✓
60	✓	.	.	.	✓
63
74
122	✓
168	✓
235	✓
252	✓
265	✓
312
314	✓
324
328
334	✓
344	✓	.	.	✓	.
352
354
355
359	✓
361	✓	.	.	✓	.
372	✓	.	.	.	✓
377	✓	.	.	.	✓
394	✓
409	✓
419
422	✓
438	✓
447	✓
473	✓
484	✓	.	.	.	✓
507	✓	.	✓	.	.
508
509	✓
519	✓
520	✓
535	✓

Table 30.2

Available Data Points for Work Information Form Continued

Patient Identification Number	Intake Return to Work	Post Return to Work	6 Month Return to Work	9 Month Return to Work	12 Month Return to Work
539	✓
541	✓
543	✓	.	.	.	✓
556	.	.	.	✓	.
564	✓	.	.	.	✓
576	✓
582	✓	.	.	✓	.
590
597	✓
604	✓
622	✓	.	✓	.	✓
637	✓
638
641	✓
647	✓
651	✓	.	.	.	✓
652	✓
653	✓	.	.	.	✓
660	✓	.	✓	.	✓
667	✓
670	✓	.	.	✓	.
676	✓
677	✓	.	.	✓	✓
680	✓	.	.	✓	.
681	✓
682	.	.	✓	.	.
684	✓
687	✓	.	.	✓	✓
690	✓	.	.	✓	.
691
698	✓	.	.	.	✓
715	✓	.	✓	✓	✓
719	✓	.	✓	✓	.
723	✓	.	✓	✓	.
724	✓	.	✓	✓	.
727	✓	.	✓	✓	.
731	✓	.	✓	✓	.
732	✓	.	✓	✓	.
740	✓	.	✓	✓	.
765	✓	.	✓	.	.
767	✓	.	✓	.	.
780	✓
790	✓
792	✓

APPENDIX B

The University of Texas Southwestern Medical Center at Dallas

CONSENT TO PARTICIPATE IN RESEARCH

Title of Research: An Evaluation & Treatment Study of Low Back Pain II /Further Evaluation

Sponsor: National Institutes of Health

<u>Investigators</u>	<u>Tel. No.</u>	<u>Investigators</u>
Robert J. Gatchel, 214-648-0607*	Ph.D. 214-648-0701*	Anna Wright, Ph.D.
Peter Polatin, M.D. 214-648-5285	214-351-4111*	Lynn Wildenstein, M.A.
Deborah Buckingham 214-648-0701	817-498-6917	Kelly Robinson
Christine Holberg	214-648-0701	

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

PREVIOUS CONSENT: You have already signed an informed consent document for a portion of the current study. In this previously signed document, you were told why you were invited to participate in this research, and the purpose of the research. Screening and randomization procedures for allocation to the treatment or no-treatment groups were also covered. Essentially, it was explained that 20% of subjects completing the screen would be assigned to an intervention group, and would be followed-up by telephone for one year. All other subjects would simply receive four follow-up phone calls, one every three months, for one year. The events to be expected from participation in either the treatment or no-treatment groups were also covered. The fact that you would be contacted for further evaluation was discussed. Finally, your rights, the costs/benefits, and payment related to the research were also covered. Please ask your study doctor if you have questions regarding these procedures.

INVITATION: You are currently invited to participate in the “further evaluation” portion of the study, which entails an interview and questionnaires (described in more detail below) to obtain more information about different variables that might be related to the experience of low back pain.

PURPOSE: The current portion of the study (“further evaluation”) enables us to understand in more depth how different life variables (including experiences, coping styles and psychiatric and/or medical difficulties) relate to pain. This information is valuable because knowledge about life variables that co-exist with back pain enables practitioners to best augment medical treatment with other, research-based, interventions.

PROCEDURES

Further Evaluation: During this second phase of the project, you will be asked to complete a series of questionnaires. These questionnaires will ask questions about your pain experience, as well as how you generally handle life events that may be unrelated to your pain experience. In addition to the completion of

questionnaires, the evaluation will consist of a diagnostic interview with the study doctor. This interview will look at potential emotional difficulties and life experiences that you may or may not have had. It could potentially yield a psychological diagnosis. You do not have to answer any questions that make you feel uncomfortable. You will also be asked about your health care utilization related and unrelated to your back pain. This interview takes an average of one hour. Completion of the questionnaires takes approximately 1.5 hours, for a total visit duration of about 2.5 hours.

From time to time, health, family, transportation, and financial difficulties may make it difficult for some patients to obtain the medical care they need. To gain a better understanding of how you access healthcare and the cost involved, we will need to obtain information on the care you received from *all* health care providers you have seen for the *past year*, and from all healthcare providers you will see for the *next two years*. This means that we may look at the services you used for one year prior to today's date, and for the next two years, or a total period not to exceed three years. This information may be collected from your physicians, with your consent, after you have signed the following release form. The information collected will include the date and place of services, medical procedures done, diagnoses, and billing charges if any. All attempts will be made to maintain your confidentiality, and your name will be removed from all information collected. The information is being collected for verification purposes only, and will not be used in any way not described in this consent.

TREATMENT PHASE

Treatment will be offered to three-fourths of the participants enrolled in the study. Through a process of randomization, one quarter of the participants will receive the Early Intervention treatment, detailed below. Another quarter will receive Early Intervention and Work Transition, also detailed below. One quarter of the participants will receive both Early Intervention and Work Transition, and one quarter of participants will be assigned to a no-intervention group, and will be encouraged to pursue "treatment as usual," or whatever course of treatment they would normally pursue. You have a right to refuse participation in this study, along with treatment offered to you, after it is explained to you. The treatment has no known risks associated with it; however, it is not always possible to predict whether you will have problems or not.

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 patient 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.

For more information about the use of your test and interview information in this research, please read “More Information about This Research” at the end of this consent form.

POSSIBLE RISKS

The attached document (“**More Information about This Research**”) describes possible risks related to this type of research.

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.

What to do if you have problems: If you have a problem during this research, the investigators or your referring physician can recommend treatment. Please report the problem to the investigators or to your physician promptly. Call any one of the telephone numbers listed on the first page of this consent form.

POSSIBLE BENEFITS

To you: 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.

To others: The results of this research may help other people in the future. New information may lead to improvements in medical care for back pain. However, research tests using your questionnaire and interview data could possibly fail to produce useful information.

COMMERCIAL DEVELOPMENTS: Research tests using your questionnaire and interview data may possibly result in inventions or procedures that have commercial value and are eligible for protection by a patent.

Compensation for any future commercial developments is not available from the University of Texas Southwestern Medical Center at Dallas, its researchers or other facilities or researchers whose research may benefit from the use of your sample.

By agreeing to the use of your information in research, you are giving your information without expectation of acknowledgment, compensation, interest in any commercial value or patent, or interest of any other type. However, you retain your legal rights during your participation in this research.

PAYMENT TO TAKE PART IN THIS RESEARCH: You will be paid \$50 to participate in the Further Evaluation. Another \$50 will be paid to you at the end of one year, upon completion of a similar Follow-Up Evaluation. You will also be paid \$10 per collection of saliva, over the course of the year. 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 a physical injury or any other complication resulting from participation in this research is not available from the University of Texas Southwestern Medical Center at Dallas. However, 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: Dr. Robert Gatchel, 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: The 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. 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 in this consent form and in the attached document, "More Information about This Research."
- 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)

Participant's signature and date

Legally authorized representative's name (printed)

Legally authorized representative's signature and date

Name of person obtaining consent (printed)

Signature of person obtaining consent and date

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 Dr. Robert Gatchel 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

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VITAE

Christine Marie Holberg was born in Irving, Texas, the daughter of Linda Kay Attaway and Wesley Evan Attaway. After entering Southern Methodist University she worked in the experimental psychology research labs of Mathew Ansfield, Ph.D. and Alan Brown, Ph.D. She received the degree of Bachelor of Arts with a major in psychology from Southern Methodist University in December, 2000. During the following three years she was employed as a research assistant in the lab of health psychologist and pain researcher, Robert J. Gatchel. In December of 2001, her daughter, Hannah Elizabeth Holberg was born. In August, 2003 she entered the Graduate School of Biomedical Sciences at the University of Texas Southwestern Medical Center at Dallas. She was awarded the degree of Doctorate in clinical psychology in August, 2006. In 2006, she married Jason Travis Reed of Dallas. Her plans are to work as a Post-Doctoral Fellow in forensic psychology at the University of Southern California Institute of Psychiatry and Law.

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