A COST UTILITY ANALYSIS OF INTERDISCIPLINARY EARLY INTERVENTION VERSUS TREATMENT AS USUAL FOR AN AT-RISK POPULATION WITH ACUTE LOW BACK PAIN

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Robert Gatchel, Ph.D.

Samuel Bierner, M.D.

Betsy Kennard, Psy.D.

Richard Robinson, Ph.D.

Deborah Wiebe, Ph.D.

For my family,

my friends,

and for Sarah

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by

MARK D. ROGERSON

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Mark D. Rogerson, Ph.D. Candidate

The University of Texas Southwestern Medical Center at Dallas, 2009

Supervising Professor: Robert J. Gatchel, Ph.D.

Chronic pain is a costly and debilitating condition that has proven difficult to treat solely with medical interventions due to the complex interplay of biological, psychological, and social factors in its onset and persistence. Many studies have demonstrated the effectiveness of interdisciplinary treatment that includes psychosocial interventions for low back pain. Nevertheless, these interventions continue to be under-utilized due to concerns of cost and applicability. The present study evaluated effectiveness and associated costs by using the objective, standard approach of a cost utility analysis. Individuals with acute low back pain that was considered at high-risk for becoming chronic (according to a previously-demonstrated algorithm) were randomized to either treatment as usual or an interdisciplinary early intervention program. Treatment

effectiveness was evaluated using a standard pain measure and quality-adjusted life years (QALYs) from pre-treatment baseline to 12-month follow-up, and associated medical and employment costs were gathered every 3 months for 1 year. Results indicated that subjects improved significantly from pre-treatment to one-year follow-up, and that the early intervention group reported fewer healthcare visits and missed workdays. A cost utility analysis was conducted utilizing 1,000 bootstrapped samples, and the majority of samples indicated the dominance of the early intervention program as being both more effective and less costly from a societal perspective. Within a generally-accepted range of acceptable costs, the early intervention treatment was the preferred option in 85% to 93% of samples. Sensitivity analyses indicated that these effects were robust to changes in estimated values for associated costs. These results indicate encouraging evidence for the cost-effectiveness of interdisciplinary intervention and the benefits of targeted treatment.

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LIST OF ABBREVIATIONS

ALBP	Acute low back pain
ANOVA	Analysis of variance
CE	Cost effectiveness
CEA	Cost-effectiveness analysis
CEAC	Cost-effectiveness acceptability curve
CU	Cost utility
CUA	Cost utility analysis
df	Degrees of freedom
EI	Early intervention
ICER	Incremental cost effectiveness ratio
ICUR	Incremental cost utility ratio
LOCF	Last observation carried forward
MCS	Mental Component Scale of the Short Form-36 Health-Status Survey
MVAS	Million Visual Analog Scale
MMPI-2	Minnesota Multiphasic Personality Inventory, Second Edition
NSAIDS	Nonsteroidal anti-inflammatory drugs
n	Sample size
p	Significance level
PCS	Physical Component Scale of the Short Form-36 Health-Status Survey
QALY	Quality-adjusted life year
r	Pearson correlation coefficient
SD	Standard deviation

SF-36	Medical Outcomes Short Form-36 Health Status Survey
TU	Treatment as usual
χ^2	Pearson's Chi-Square

CHAPTER ONE

INTRODUCTION

Chronic back pain is a debilitating and demoralizing condition that afflicts millions of Americans every year. It is caused by a complex interaction of physical, psychological, and social factors that combine to produce disabling symptoms and far-reaching consequences. Most acute low back pain resolves naturally, but as pain persists, its treatment becomes more difficult. Despite advances in knowledge, technology, and procedures, no medical treatment has been demonstrated to consistently and completely alleviate the chronic pain of all of those afflicted (Turk & Monarch, 2002). Many patients with chronic pain have unsuccessfully tried numerous interventions, and their symptoms become refractory as their discomfort persists. By the time that pain becomes chronic, it has already led to immense suffering and countess dollars in medical expenses, lost wages and productivity, and other indirect costs.

Interdisciplinary pain management programs employ treatments that include psychosocial interventions and have well-demonstrated treatment- and cost-effectiveness for chronic pain. Nevertheless, they continue to be under-utilized due to their labor-intensive nature. Such treatment may not be feasible for the entire chronic population, but Gatchel, Polatin, and Mayer (1995) identified a set of risk factors that could identify patients whose acute low back pain was at risk for persisting to become chronic. A subsequent study demonstrated that an interdisciplinary early intervention program was effective at preventing the development of chronic disability with a similarly identified group of at-risk patients (Gatchel et al., 2003). That study also demonstrated cost savings

as a result of the early intervention in the form of decreased healthcare utilization, medication use, and lost work days.

The current competition for scarce healthcare funds compels research that demonstrates effectiveness in terms of objective, comparable metrics of observed benefits and associated costs. The evaluation of pain—and particularly chronic pain—is complicated by the inherently subjective nature of the syndrome itself. Medical imaging and diagnostic testing are insufficient, because experienced pain and degree of disability are not simply a function of extent of tissue damage (Gatchel & Okifuji, 2006; Melzack & Wall, 1965). However, self-report can be fraught with bias, especially when reports are made on multiple occasions over time. Other outcome measures, such as return-to-work status or number of sick days, provide an objective assessment but may be affected by numerous other factors besides severity of pain.

In order to evaluate treatments, comparisons must also be made regarding the costs required to achieve any demonstrated benefit. The Panel of Cost-Effectiveness in Health and Medicine, convened by the United States Public Health Service, recommended the use of cost effectiveness analyses in order to compare potential treatments within and across health care disciplines, with objective health outcomes as the crucial measure (Weinstein, Siegel, Gold, Kamlet, & Russell, 1996). The Panel recommended the use of quality-adjusted life-years (QALYs) to provide a uniform, objective measure of health status. Brazier, Roberts, and Deverill (2002) have developed and demonstrated an algorithm for converting data from the Medical Outcomes Short Form-36 Health-Status Survey (SF-36) directly into QALYs. This algorithm has been used to demonstrate the cost-effectiveness of interdisciplinary treatment in a

heterogeneous chronic spinal pain population (Hatten, Gatchel, Polatin, & Stowell, 2006). The present study extends these results by examining the cost-effectiveness of an early intervention program for at-risk patients with acute low back pain.

CHAPTER TWO

REVIEW OF THE LITERATURE

Scope of the Problem

Chronic pain is among the most widespread and costly problems facing the Unites States today. Loosely defined as pain lasting longer than three months, researchers have estimated that 10% to 20% of adults experience chronic pain (Verhaak, Kerssens, Dekker, Sorbi, & Bensing, 1998), and 57% of all Americans reported experiencing some sort of recurrent or chronic pain within the past year (American Academy of Pain Management, 2003). An estimated 58% to 84% of the general population will be affected at some point in their lives by back pain, and at any point in time, 30% of adults are suffering from low back pain (Crombie, Croft, Linton, LeResche, & VonKorff, 1999).

In terms of economics, it is estimated that chronic pain costs Americans over $70 billion per year in healthcare expenditures (American Academy of Pain Management, 2003). Total costs of treatment, lost work days, and disability due to chronic pain in 1995 and 1996 were estimated to be between $150 billion (United States Bureau of the Census, 1996) and $215 billion (National Resource Council, 2001). Pain is second only to the common cold as the reason patients seek medical care (Jensen et al., 1994). An estimated 22% of patients seen in primary care settings report the occurrence of persistent

pain (Gureje, VonKorff, Simon, & Gater, 1998), and 2.9 million Americans (or 1.1%) annually are being treated by chronic pain specialists (Marketdata Enterprises, 1995). Chronic pain is responsible for half a million lost workdays every year (United States Bureau of the Census, 1996). About two million Americans are unable to work due to back pain, and another five million are partially disabled (National Institute of Neurological Disorders and Stroke, 2002). Chronic back pain produces the greatest amount of disability payments for workers under 45 years of age (Mayer & Gatchel, 1988). Chronic spinal pain is estimated to cost close to $50 billion per year in direct healthcare costs, disability compensation, and lost productivity (Gatchel, 2004). A broad cascade of indirect costs—including decreased productivity and tax revenues and increased risk for psychiatric conditions—underscores the breadth of the problem in addition to its magnitude. In short, chronic pain is a debilitating, widespread problem that produces enormous economic burdens and incalculable human suffering.

A Brief History of Pain

"Let no one persuade you to cure the headache until he has first given you his soul to be cured. For this is the great error of our day in the treatment of the human body, that physicians separate the soul from the body." —Hippocrates, 202 B.C.

Pain has been a ubiquitous yet constantly evolving concept throughout history. Perceptions of pain have both shaped and reflected beliefs about the soul, the body, illness, wellness, and life itself. The complexity of the phenomenon and its cultural

meaning has often complicated attempts to understand and alleviate it. Only recently have many of the disparate contributions to the pain experience been integrated into a comprehensive conceptualization, although much remains to be understood.

Classical Concepts

Pain is a universal component of the human condition. The meaning of pain has been a defining concept for much of humankind's philosophical and religious past. The presence of suffering was inevitable, but the meaning it was given is what defined life (Meldrum, 2003). Early cultures believed in animism, that pain and illness were the work of "spirits." The Greek physician Hippocrates maintained that the mind and body were intimately connected and that illness and temperament arose from dynamic balance and imbalance in four vital fluids. Thus, for many centuries, people perceived an intimate connection between the physical and the incorporeal (Gatchel, Baum, & Krantz, 1989).

Around the time of the Renaissance, a noticeable shift took place, separating the mind and the body into a duality most often associated with the philosopher Rene Descartes. The body was considered an empty vessel that was the domain of science and medicine, whereas the mind and soul were reserved for the sacrosanct realm of religion (Gatchel et al., 1989). Such a state helped to facilitate advancements in the field of medicine through the scientific discoveries of the Renaissance and Enlightenment, but it also revealed incomplete understanding and inconsistent treatment of one of medicine's oldest and most basic adversaries—pain.

Early physicians valued pain as a medical sign and considered it an indication of the patient's vitality. When the pain of surgery was first assuaged with the use of anesthesia, an extensive debate ensued over the ethics of operating on an unconscious

patient, as many believed that the relief from pain might retard the healing process. Some religious writers agreed, calling it a violation of God's law. Others considered it a divine blessing, and slowly the capability to alleviate pain was exercised. The use of opiates followed a similar uncertain course, as the desire to relieve pain was tempered by the fear of inducing addiction, and the act of vitiating one's pain through external means was believed to be associated with a loss of autonomy and admission of infirmity (Meldrum, 2003).

The Biomedical Model

Despite the interplay between cultural belief and medical procedure, physicians quickly became adept at ameliorating pain through the use of physical means and anatomical understanding. According to the biomedical model, illness was exclusively the result of physiological causes related to the body and disease. Other factors, such as psychological contributions, were deemed outside the purview of this conceptualization and irrelevant to the treatment of medical illness. Pain was the result of nociceptive input from damaged nerve cells that, in turn, signal the brain. By the early twentieth century, the abiding model taught in medical schools was *specificity theory*, which held that "true" pain resulted from a direct, proportional response to a specific noxious stimulus. It was a symptom of physical insult and nothing more. Patients who suffered from syndromes that could not be explained in these terms were considered to be delusional, malingerers, or drug abusers. Psychoanalysts regarded such symptoms as signs of mental or emotional disease, and physicians enacted drastic surgical remedies in an attempt to mollify the nerves (Meldrum, 2003).

In modern times, the physiological understanding of pain has inarguably advanced, and its medical treatment has obviously improved. Neurophysiologists have mapped out specific anatomical pathways by which nociceptive signals are processed. Pain receptors (called nociceptors) detect stimuli that can cause tissue damage, including mechanical disturbance, chemical exposure, temperature extremes, and oxygen deprivation. These signals are then transmitted to the brain via two separate routes: a rapid, sharp pain pathway through Aδ fibers; and slower, duller, longer-lasting signals through C fibers. Information about pain and temperature in the body is conveyed via the spinal cord to the thalamus and on to the cerebral cortex. The characteristics of peripheral and central mechanisms and interactions can give rise to such phenomena as: hyperalgesia, in which pain signals cause subsequent heightened sensitivity; referred pain, in which a visceral stimulus is perceived as a cutaneous sensation; and other ways in which pain signals are modulated (Bear, Connors, & Paradiso, 2001). Medical treatment of these physiological mechanisms has developed concomitantly, and nerve blocks, injections, and a variety of surgical procedures are commonly employed to address the biomedical nature of pain. However, even though the biomedical model continues to direct much of current pain practice, research has repeatedly shown that physical pathology does not reliably predict pain severity or level of disability. For instance, 64% of individuals with no reported back pain demonstrate abnormal lumbar disc findings on an MRI (Jensen et al., 1994). Furthermore, despite significant technological and scientific advances, there is no available treatment that consistently and completely addresses the chronic pain of all of those afflicted (Turk & Monarch, 2002).

The Biopsychosocial Model

Throughout history, certain types of pain have perplexed observers. Patients with amputated limbs often continue to experience pain in their "phantom limbs" (see Ramachandran & Hirstein, 1998). The persistence of pain that did not respond to treatment, and in the absence of pathology, represented a dilemma that confounded physicians. Close observers, though, strongly asserted the reality of their patients' affliction despite its unexplained and bizarre nature (Meldrum, 2003). In World War II, Henry Beecher observed that seriously wounded soldiers reported much lower levels of pain than civilian patients with comparable levels of injury. He concluded that for the soldiers, their injuries represented safety, because they would receive treatment and could escape from the stressors and horrors of war (Beecher, 1946). Thus, the meaning of pain plays a powerful role in its experience, and pain must be understood as a combination of a physical sensation as well as cognitive and emotional reactions.

Melzack and Wall (1965) provided the foundation for a major integration of physiological and psychological contributions with their *gate control theory* of pain. In it, they proposed spinal cord mechanisms by which pain sensations could be regulated and modulated through ascending stimulus pathways, descending central responses, and inhibitory interneurons that could effectively "close the gate." Such moderators include three systems: sensory-discriminative, motivational-affective, and cognitive-evaluative. For example, rubbing a nearby area and actively ignoring pain are two methods of moderating it. Thus, peripheral stimuli interact with cortical variables and psychological factors to produce and modify the pain experience (Turk & Monarch, 2002). This development challenged the idea of simple specificity between noxious stimulus and pain experience and postulated a neural mechanism for the process of modulation. Subsequent

work has added contributions for endogenous neurochemicals, learned responses of the nervous system, and individual coping behaviors (Meldrum, 2003). In addition, the theory gave rise to new treatments such as neural stimulation, pharmacological advances, behavioral treatments, and interventions targeting attentional and perceptual processes (Turk & Monarch, 2002).

Melzack (1999) extended the Gate Control Theory and incorporated Selye's (1950) theory of stress, resulting in a conception of pain as a multidimensional experience produced by characteristic patterns of nerve impulses in a distributed neural network in the brain known as the "body-self neuromatrix." This *neuromatrix theory* of pain proposes that these patterns activate perceptual, homeostatic, and behavioral programs subsequent to injury or pathology. Prior learning can shape the neuromatrix by influencing these behavioral and physiological response patterns (Turk & Monarch, 2002). One of the principle homeostatic programs involved is the stress response, and pain can be considered a significant stressor that induces the body to initiate regulatory mechanisms such as cardiovascular and endocrine responses to achieve a return to homeostasis. When a stressor becomes chronic, the extension of the initial acute reaction may lead to maladaptive consequences, including destructive effects on body tissues. Thus, the neuromatrix theory not only demonstrates a mechanism by which chronic pain may have physical consequences, but also provides a reasonable account of how psychological stressors may provide a basis for chronic pain. The body-self neuromatrix is modulated by the powerful functions of the stress system and cognitive operations of the brain in addition to traditional sensory inputs (Melzack, 1999). Such a model suggests

the clinical importance of limiting pain before it becomes chronic and leads to the further damaging effects of the stress system.

The current conceptualization of the nature of pain is represented by the *biopsychosocial model*, which recognizes pain as a complex perceptual experience influenced by dynamic and reciprocal interactions among biological, psychological, and sociocultural factors (Turk & Flor, 1999). Biological variables and responses interact with psychosocial influences including emotions, beliefs, attitudes, expectations, and social and environmental context in shaping a person's response to pain. The model assumes the presence of some sort of physical pathology or change that generates nociceptive input to the brain. The resulting perception is influenced by the person's appraisal of the stimuli, which is directed by the beliefs developed over the person's lifetime. Subsequent behaviors are shaped by these beliefs and appraisals, as well as the person's interpersonal role and the response of others.

The patient's beliefs are particularly important in the context of chronic pain, as worry about the future, the meaning of symptoms, and attributions of their onset play crucial roles (Turk & Okifuji, 2002). Severity of symptoms is greater with perceived traumatic onset than perceived insidious onset, even with equivalent severity of pathology (Turk, Okifuji, Sinclair, & Starz, 1996), and putative cause of pain onset affects the attitudes and behaviors of both patients and clinicians (Turk & Okifuji, 2002). Pain behaviors may be influenced by social learning and modeling processes, operant conditioning, and experience with reinforcement (Turk & Monarch, 2002). Pain-related anxiety, fear, and harm avoidance may actually intensify the pain experience in chronic pain, and fear of pain and responses to it are often more disabling than the pain itself

(Waddell, Newton, Henderson, Somerville, & Main, 1993). Self-efficacy, or a person's perceived ability to perform given behaviors and exert control over one's circumstances, mediates people's coping behaviors and influences reports of pain, disability, and depression in chronic pain patients (Lorig, Chastain, Ung, Shoor, & Holman, 1989). Psychosocial factors have been demonstrated to accurately predict pain severity and long-term disability (Turk & Okifuji, 2002).

The biopsychosocial model provides a comprehensive account of the various contributions and components of pain. It incorporates the findings of the gate control and neuromatrix theories with psychological and social factors that can mediate and exacerbate pain. People differ markedly in their responses to illness and to treatment (Turk & Monarch, 2002). Since pain and disability are more than just a function of physical pathology, psychosocial variables provide particularly valuable information for understanding the antecedents and consequences of chronic pain.

Interdisciplinary Treatment for Chronic Pain

The biopsychosocial approach views pain as a complex and dynamic interaction rather than a straightforward physical symptom that can be eradicated by blocking pain pathways through medication or surgery. This integrative approach is both more comprehensive and more accurate, as chronic pain can rarely be understood in terms of linear, nociceptive mechanisms. Currently, there are no definitive cures for the most prevalent chronic pain syndromes. Rather, rehabilitation and pain management are the most appropriate therapeutic goals (Gatchel & Okifuji, 2006). Conventional medical

efforts have done little to address the problem of low back pain and may even contribute to it through the focus on an elusive cure, the lack of consensus on appropriate care, and the concomitant continual escalation in prevalence and costs (Deyo, Cherkin, Conrad, & Volinn, 1991). Accordingly, more comprehensive treatment models are now being utilized to address the complex and recalcitrant problem of chronic pain.

The Interdisciplinary Treatment Model

The beginnings of interdisciplinary treatment might be considered to have started with a young anesthesiologist named John Bonica who worked at an army hospital during World War II. Confronted with pain problems he could not comprehend, he consulted with colleagues and found that they knew as little as he did, but that each of them benefited from discussion with the others (Meldrum, 2003). The idea behind interdisciplinary treatment is that pain is a complex phenomenon with multiple contributions. For such a truly biopsychosocial problem, multiple areas of expertise are necessary to address all of the various components. In addition, each member of the treatment team would benefit from interaction and consultation with the others. Dr. Bonica advocated for interdisciplinary care for the rest of his career, and he eventually founded and directed the interdisciplinary organization known as *The International Association for the Study of Pain* and its journal, *Pain*.

No single professional discipline is equipped to fully address the complex requirements of treating chronic pain. As a result, effective, comprehensive care requires the contribution of several specialties, such as a physician, nurse, psychologist, physical therapist, and an occupational therapist (Deschner & Polatin, 2000). *Multidisciplinary* treatment consists of several health care providers who participate in care but may not be

"under the same roof." Communication may therefore be limited. *Interdisciplinary* care, however, consists of multiple specialists housed in the same facilities who have frequent communication with each other and provide coordinated treatment interventions. Collaboration, cooperation, and a shared philosophy of rehabilitation are essential. Treatment goals should focus on realistic aims, such as symptom management, improved pain behavior, controlled use of healthcare services and medications, increased activity and productivity, and independent self-management. In addition, thorough and multidimensional assessment, outcome tracking, consistent communication, and regular staff conferences have been identified as crucial components to interdisciplinary care in order to minimize barriers to treatment and promote optimal outcome (Gardea & Gatchel, 2000; Gatchel & Turk, 1999). These comprehensive programs typically include cognitive-behavioral interventions specifically designed to address the various psychosocial characteristics of pain, including fostering effective coping skills and addressing the individual's interpretation, evaluation, and belief about the illness.

Empirical Evidence for Interdisciplinary Treatment

In a comprehensive meta-analysis of 65 published studies, Flor et al. (1992) concluded that multidisciplinary pain centers were superior to no treatment, waiting list, and single-treatment centers such as medical treatment or physical therapy only. The beneficial effects were stable over time and extended to measures of pain, mood, disability, and healthcare utilization. Even at long-term follow-up, patients treated in the multidisciplinary setting were functioning better than 75% of the sample undergoing either no treatment or conventional treatment. Furthermore, 68% of patients in the multidisciplinary group returned to work, compared to 36% of untreated patients. Other

research using patients with documented pathophysiology demonstrated comprehensive treatment including cognitive-behavioral therapy to be as effective as lumbar spinal fusion surgery (Brox et al., 2003).

Measures such as restoration of functioning and return-to-work represent both objective outcomes and important goals for both treatment programs and patients themselves. Research has consistently demonstrated the efficacy of interdisciplinary care on these practical outcomes, as 66% of patients returned to work after interdisciplinary treatment, whereas only 27% did so after conventional unimodal medical care. With regard to functional restoration, interdisciplinary treatment has been shown to be superior to conventional medical care, as demonstrated by an approximately 65% increase in physical activity compared to a 35% increase with conventional treatment (Flor et al., 1992).

These data are particularly impressive considering the fact that despite their demonstrated efficacy, interdisciplinary pain clinics have continued to be used as a treatment of last resort after more conventional treatments have failed, often repeatedly. Consequently, the patients seeking treatment at such centers and participating in such studies tend to have the most chronic and refractory pain. Interdisciplinary care is likely under-utilized as a consequence of the lengthy and labor-intensive nature of the treatment. However, data indicate that comprehensive care results in significantly reduced healthcare utilization in the form of fewer clinic visits, hospitalizations, and back surgeries in the following year (Gatchel & Okifuji, 2006). Overall, annual medical costs following interdisciplinary treatment are reduced by an estimated 68% (Simmons, Avant, Demski, & Parisher, 1988). Gatchel and Okifuji (2006) estimated a savings of

approximately $8,500 in healthcare costs per patient per year, and lifetime savings were calculated to be at least $272,000 per patient.

Based on the growing preponderance of research, there is unequivocal evidence for the effectiveness of integrated pain treatment. Despite the significant observed cost savings, third-party payers and policymakers have eschewed such programs in favor of conventional medical interventions, even as patients have sought relief from increasingly unconventional and non-medical treatments such as chiropractic care and acupuncture. One insurance company practice designed to cut costs is to "carve out" services to certain contracted providers. Robbins et al. (2003) demonstrated that such a practice of moving the location of the physical therapy component—thereby making the treatment multidisciplinary instead of interdisciplinary—significantly compromised the efficacy of the treatment at both short-term and one-year follow-up. As a result of attempts to limit expenses, fewer patients participate in these proven interventions, and the healthcare system is divested of millions of dollars of savings each year. Therefore, it is critical that research: (a) further demonstrate the cost-effectiveness of interdisciplinary care; and (b) determine ways of targeting such treatment to smaller subsets of patients who would achieve the greatest benefit.

Prevention of Chronic Disability

As back pain has increasingly been recognized as a vastly under-treated problem, and as clinicians have realized the difficulty in fully alleviating chronic pain, an increasing number of researchers and stakeholders are calling for an increased focus on

preventing disability. This represents a shift from a focus on disease—since pathological causes and tangible diagnoses are elusive—to a focus on disability, with an emphasis on functional restoration and self-management skills to minimize discomfort and dysfunction in spite of continued symptoms. In addition, prevention is increasingly emphasized, as the longer back pain persists, the greater its toll, the higher its costs, and the more difficult it becomes to treat. Only 10% of acute low back pain will persist to become chronic (Carey, 1999). However, these relatively few cases account for the majority of direct and indirect expenditures (Pulliam, Gatchel, & Gardea, 2001). Understanding the evolution of pain over time should help clinicians to hone interventions accordingly to maximize their benefits.

The Transition from Acute to Chronic

Gatchel and Oordt (2003) described a three-step process by which acute pain develops into chronic pain. In the first or acute phase, normal emotional reactions such as fear, anxiety, and worry develop in response to the individual's perception of pain. Such responses serve a protective function by prompting the individual to protect the injury and to seek medical attention if necessary. However, if the pain persists for longer than two to four months (generally considered the normal period for healing with most pain syndromes), the individual passes into the second stage. In this stage, physiological and behavioral problems become exacerbated, and symptoms such as learned helplessness, anger, distress, and somatization become more typical. Often, the stress of coping with pain may lead to an exacerbation of underlying psychosocial characteristics. According to this diathesis-stress model, a person's response is affected by preexisting personality characteristics as well as socioeconomic and environmental conditions.

In the third and final stage, the pain becomes chronic. The individual begins exhibiting complex interactions among physical, psychological, and social processes. In response to the significant and persistent pain and accompanying stress, the patient's life begins to revolve around the pain and the behaviors that maintain it. The individual becomes accustomed to reinforcers, such as the avoidance of responsibility, and adopts the "sick role." Activity is avoided, and mental and physical deconditioning becomes apparent. At this stage, the pain has become a complex and recalcitrant component of the patient's life, and any amelioration will itself be a large change with far-reaching implications. Clearly, the optimal response is to treat the pain before it can progress to become chronic.

Evidence for Identification and Intervention

Whereas 90% of patients with acute low back pain (ALBP) do not progress to the chronic stage (Carey, 1999), in order for early intervention to be feasible, it would have to be targeted to the 10% who are at risk. Accordingly, several studies have endeavored to identify variables that will accurately predict patients with acute back pain that is at an increased risk for becoming chronic. Gatchel, Polatin, and Mayer (1995) systematically evaluated 421 patients presenting with ALBP and evaluated the power of a comprehensive battery of psychosocial and personality measures in predicting chronicity. Patients were followed every three months for one year. The authors determined that a statistical model combining gender, self-reported pain and disability scores, Scale 3 on the Minnesota Multiphasic Personality Inventory – Second Edition (MMPI-2), and workers' compensation/personal injury litigation status accurately predicted 90.7% of the cases that became chronic. These results suggested the existence of a robust

"psychosocial disability factor" that is associated with injured patients whose pain is likely to progress from acute to chronic. Pulliam, Gatchel, and Gardea (2001) extended these results and determined that additional factors, including lower positive temperament, greater workaholic tendencies, an avoidant coping style, and an Axis I or Axis II psychological diagnosis (according to the *Diagnostic and Statistical Manual, 4th edition, text revision*, DSM-IV-TR, American Psychiatric Association, 2000) were associated with increased risk for chronic back pain. These factors predicted long-term status with 80.8% accuracy. While this model was not as accurate as the previous one, it underscores the importance of a broad biopsychosocial perspective in attempting to comprehensively conceptualize pain and disability.

Schultz et al. (2002) conducted a multivariate predictive analysis of workers with subacute (operationally defined as 4 to 6 weeks after injury) and chronic pain (6 to 12 months post injury) by investigating predictive validity and return-to-work status at a 3-month follow-up. The identified variables represented a broad sample of the biopsychosocial spectrum, including characteristics of the injury, physical ability, behaviors, perceptions, expectations, and feelings. The authors determined that cognitive factors were the most predictive and promising, and they recommended early intervention with cognitive-behavioral therapy.

After identifying patients who are at risk for developing chronic pain, the next step is designing what are known as *secondary prevention* interventions in order to prevent the initial pain condition from becoming a long-term disability (Turk & Okifuji, 2002). Linton and Andersson (2000) performed a randomized trial comparing a six-session cognitive-behavioral group intervention to two groups that received informational

packages of greater and lesser length. The authors found that the cognitive-behavioral intervention decreased the risk for long-term disability as determined by long-term sick absence, physician and physical therapy utilization, and self-perceived risk. The patients all had acute or subacute pain, but the only mechanism to screen for risk was self-report. All participants "had a self-perceived risk of a chronic problem developing" (p. 26).

Another study (Linton, Boersma, Jansson, Svard, & Botvalde, 2005) examined the effects in terms of preventing chronicity and disability of adding either a cognitive-behavioral intervention or the cognitive-behavioral intervention plus preventive physical therapy, compared with a minimal treatment group. With regards to health care utilization and work absenteeism, the risk of chronic disability was significantly lower with both of the study interventions that included cognitive-behavioral techniques. The addition of physical therapy had no significant impact. In this study, participants were described as being "at risk for developing long-term disability," (p. 111), but no mention is made of what criteria were used to designate them as such. In addition, the inclusion criteria included nonspecific back or neck pain, and they did not specify any diagnostic or temporal characteristics. Accordingly, although both of these studies are encouraging in their positive outcomes after early intervention with psychosocial intervention, neither were applied to a group adequately identified as having ALBP at risk for becoming chronic. Therefore, any resulting intervention will be confronted with the familiar problems of cost and applicability.

Gatchel et al. (2003) applied an early intervention treatment to a group of ALBP patients identified by a previous algorithm (Gatchel et al., 1995) as being at high risk for developing chronic disability. Subjects were included if they had a history of ALBP of

less than two months' duration, had no history of chronic back pain, were currently working full-time, and were identified as being high-risk. The low-risk subjects were assigned to a non-intervention group, and the high-risk subjects were randomly assigned to either a non-intervention group or a functional restoration early intervention group that involved an interdisciplinary team approach consisting of psychology, physical therapy, occupational therapy, and case management.

At 12-month follow-up, the high-risk subjects who had received the early intervention displayed significantly lower indices of chronic pain disability on a wide range of pain, healthcare, and work variables. The intervention group had significantly lower self-rated pain intensity (on average and most intense), had fewer healthcare visits (pain-related and other), were less likely to be taking medication (analgesics and psychotropics), were more likely to have returned to work, and had fewer disability days. In addition, the high risk group that did not receive intervention displayed significantly more symptoms of pain disability compared with the low risk group, thereby supporting the validity of the risk algorithm. Finally, the early intervention was shown to be cost-effective, as the cost savings due to decreased healthcare utilization and lost wages more than offset the cost of the intervention program. The average cost per patient over the course of the follow-up year was $12,721 for patients who received the intervention, compared to $21,843 for those who did not. Medical expenditures were $1,764 (not including the $3,885 cost of the intervention) compared with $2,892 for the non-intervention group. Lost wages due to disability days were $7,072 for the intervention group versus $18,951 for the non-intervention group.

It is interesting to note that the majority of cost savings were realized in the context of decreased absenteeism and lost wages at work. While clearly cost-saving overall, these results indicate that when considered solely in terms of medical expenses, the cost savings did not offset the cost of the treatment itself. When considering the fragmented healthcare system with various stakeholders and different payers for various expenses and timeframes, it is clear that what may be in the medical and economic best interests of society overall may not coincide with the economic interest of an individual payer. In sum, this study clearly demonstrated that early intervention with interdisciplinary treatment can successfully prevent the development of chronic low-back pain disability in identified at-risk patients. Furthermore, it suggested that targeted early intervention may result in significant cost savings.

Quantifying Effectiveness and Cost

With the multitude of treatment options and enormous demand for healthcare services, interventions must be evaluated in terms of their demonstrated benefits compared with the costs required to achieve them. In order to allocate limited budgets, policymakers must be informed by objective comparisons of the benefits of disparate treatments for different diseases with diverse outcomes (Dagenais, Haldeman, & Polatin, 2005). These evaluations are particularly relevant in the field of chronic pain, because outcomes are difficult to measure and the costs of treatment are astronomically high. Accurate measurement of pain is complicated by its inherently subjective nature. Objective medical findings and level of physiological pathology are not good indicators

of experienced pain. Nevertheless, self-report is unstandardized and can be fraught with response bias, and it becomes even more problematic when comparing across contexts or over multiple observations. Moreover, observable measures, such as return-to-work status and healthcare utilization, are indirect and may be confounded by external influences. In addition, they are approximations that do not represent the "complete picture" of pain and recovery. For example, interventions that return a patient to work most quickly may lead to more total disability in the long run due to incomplete healing and unnecessary strain. Therefore, well-validated, standard outcome measures are essential in comparing the efficacy of various treatments, particularly in a field with such diverse contributing factors and proposed interventions. Meanwhile, the stakes of pain treatment in terms of human suffering and economic expenditure are enormous. With such a prevalent and expensive problem, small improvements in efficacy can represent great potential for benefit. Accordingly, an objective method of comparing the effectiveness and associated costs of various treatments is immensely valuable.

Cost-Effectiveness Evaluations

Cost-effectiveness evaluations (CEAs) are decision-making tools that explicitly compare the benefits of an intervention with its costs. The total costs are represented in the numerator of the equation, and the observed outcomes are placed in the denominator. In conducting a CEA, costs are considered in terms of a societal perspective (Dagenais et al., 2005). Thus, total costs consist of the cost of the intervention but also include ancillary costs such as the time required for treatment and any associated expenses (e.g., the cost of a patient driving to an appointment, missing a day of work, etc.). The benefits are quantified using an accepted measure of health outcomes, such as symptom severity

or functional disability. The resulting value, called a cost-effectiveness (CE) ratio, represents the amount of money necessary to achieve a given unit of change:

$$\text{CE Ratio} = \frac{\text{(Intervention Cost – Cost Averted)}}{\text{Total Health Outcome}}$$

Next, in order to compare various interventions, an incremental cost-effectiveness ratio (ICER) can be calculated by determining the incremental costs and outcomes beyond those associated with an alternative option. The ICER provides information on the cost per unit of gain on the designated outcome measure.

$$\text{Incremental CE Ratio} = \frac{(\text{Total Cost}_B - \text{Total Cost}_A)}{(\text{Total Outcome}_B - \text{Total Outcome}_A)}$$

By comparing these ratios among treatment alternatives, one can evaluate their relative effectiveness and efficiency in achieving a desired health outcome (Haddix & Shaffer, 1996).

The QALY and Cost Utility Analyses

The outcome measures used in the denominators of CEAs vary depending upon the focus of treatment and are therefore difficult to compare across illnesses, disciplines, and interventions. For instance, it is unclear how much money per point of improvement on a depression scale is a good value, compared to a given change in blood pressure. The Panel on Cost-Effectiveness in Health and Medicine (Weinstein et al., 1996) recommended comparing treatments using a specific type of CEA known as a cost utility analysis (CUA). CUAs are calculated from a societal perspective and use a designated outcome measure known as a quality-adjusted life year, or QALY. The QALY provides

an objective measure of health-related quality of life by combining a measured health state with established preferences for a spectrum of possible health states. The quantified health state is multiplied by the period of time it was observed, thereby ensuring that the QALY accounts for both the quality and quantity of life. The equation for determining a cost-utility (CU) ratio is:

$$CU = \frac{\text{Total Cost of Treatment}}{(QALY_{\text{Post-Treatment}} - QALY_{\text{Pre-Treatment}})}$$

The incremental cost utility ratio (ICUR), or cost per QALY gained, is calculated as follows:

$$\text{Incremental CU Ratio} = \frac{(Cost_B - Cost_A)}{(\Delta QALY_B - \Delta QALY_A)}$$

In order to adequately quantify quality of life, a number of domains must be incorporated, including general health, physical functioning, bodily pain, mental health, and social functioning. Common measures for gauging health status include the Medical Outcomes Study, Short Form-36 Health-Status Survey (SF-36; Ware & Sherbourne, 1992) and the Sickness Impact Profile (Bergner, Bobbitt, Carter, & Gibson, 1981). With numerous domains and response levels, these measures can generate millions of discrete health states (Gold et al., 1996). In addition to a measure of health status, preference measures are used to assign corresponding values to the measured health states. Preference measures ask individuals to indicate their preferences for given health states based on descriptions of symptoms, pain, and impairment. These preferences may be obtained via response on a visual analog scale or through decisions that consist of either balancing a period of perfect health with a chosen period of imperfect health (the time-

tradeoff approach), or equating a given state with a chosen probability of perfect health versus the worst state (standard gamble).

After ascertaining the preferences of a broad sample of the population, an extensive hierarchy of health states is assembled and arranged onto a scale from 1.0 (indicating a perfect state of health and well-being) to 0.0 (indicating the worst possible state or death). Health economists have developed instruments that combine self-reported health state with societal preference weights, as well as algorithms for converting general health state data into a preference-based quality of life index (Gold et al., 1996). The design and implementation of brief, straightforward methods of obtaining health state values using common self-report measures represent a valuable advance in making meaningful comparisons of cost-effectiveness data.

Converting SF-36 Data into QALYs

The Medical Outcomes Short Form-36 Health-Status Survey (SF-36) is a measure with great utility due to its strong psychometric properties, broad subject domain, relatively brief administration, and widespread use. Pickard, Wang, Walton, and Lee (2005) assessed 10 published algorithms for converting SF-36 and SF-12 data into QALYs, and they concluded that Brazier, et al.'s (2002) model was preferable due to its strong methodological and theoretical basis and robust results. In order to construct their algorithm, Brazier, et al. (2002) first reduced the SF-36 from a questionnaire with 35 multiple-level items to a scale that incorporated 6 health dimensions, each with between 2 and 6 levels (the SF-6D), all while minimizing the loss of informative data. Using these six dimensions, a total of 18,000 health states can be defined. The authors then conducted a survey of a representative sample of the population of the United Kingdom using a

sample of 249 health states presented via a standard gamble task. Based on the responses, econometric methods were used to identify an optimal model for predicting health state values based on the SF-6D. This model is hypothesized to have strong sensitivity, particularly in groups with mild to moderate health problems and with assessments involving small differences or changes. The algorithm is copyrighted but is available from the authors free of charge.

Cost Utility Analyses of Back Pain Treatment

Using Brazier, et al.'s (2002) conversion algorithm and SF-36 data, Hatten, et al. (2006) performed a cost utility analysis of an interdisciplinary treatment program for patients with chronic back pain. Patients underwent treatment at a pain clinic and received one of four types of treatment as determined by their treating physician's clinical judgment and the availability of treatment due to managed care. The treatments consisted of: (a) an interdisciplinary program including medication management, psychotherapy, group education, and physical therapy; (b) interdisciplinary care plus anesthetic procedures; (c) medications alone; and (d) medications plus anesthetic procedures. At six-month follow-up, patients who received interdisciplinary care reported significantly greater improvement in pain intensity and perceived health state. When converting the outcome data to QALY values, both of the groups who received medication and no interdisciplinary care actually experienced a decline in health status. As a result, the corresponding CE ratios and ICERs were negative, which demonstrated that the interdisciplinary treatments were superior and more cost-effective. Both interdisciplinary interventions were considered to be good values according to established parameters, but few other comparisons could be made. Despite the practically-based,

non-random assignment of the patients, as well as the chronic and somewhat heterogeneous nature of their pain, this study represented an important development in applying an SF-36/QALY conversion algorithm to perform a cost utility analysis of interdisciplinary back pain treatment.

Rivero-Arias, et al. (2005) conducted a cost utility analysis comparing an intensive rehabilitation program that included cognitive-behavioral techniques with spine surgery for patients with chronic low back pain in whom conservative treatment had failed. The authors chose to use the EuroQol (EQ-5D) as the outcome measure for health utility. They concluded that spinal surgery was not a cost-effective first-line therapy. Whitehurst, et al. (2007) performed a cost utility analysis of an early intervention for acute low back pain that also used the EQ-5D. The authors compared a brief pain management program, incorporating biopsychosocial principles and administered by physiotherapists, with standard physical therapy (PT) for patients in primary care. At 12 months, the PT group was found to have marginally better outcomes, but with greater health care costs (other societal costs were not included). Thus, neither program was demonstrably superior, but the PT program was concluded likely to be the more cost-effective approach. This study acknowledged the practical limitations in applying clinically-proven interdisciplinary treatment to an entire primary care back pain population and attempted to provide some form of psychosocial intervention. However, instead of targeting the full treatment to a group of at-risk patients, they abbreviated the intervention and delivered it using physiotherapists with only rudimentary training. These studies demonstrate the growing trend toward cost utility analyses in back pain treatment,

but neither assessed the effectiveness of an interdisciplinary treatment to a targeted group of patients with acute low back pain.

Scope of the Current Investigation

As reviewed earlier, chronic back pain harms the physical and economic well-being of Americans enormously. Despite medical and technological advances, it continues to represent a painful and escalating burden on millions of people. As pain persists over time, its psychosocial components become progressively predominant, and treatment becomes increasingly difficult. Comprehensive interdisciplinary treatment programs have convincingly demonstrated their efficacy in treating chronic pain, but providers and insurance companies instead continue to employ conventional medical treatments with results that are questionable at best. Third-party payers contend that comprehensive care is too intensive and expensive to be implemented on the entire chronic pain population.

Recent research (Gatchel et al., 1995) has identified a system of variables that can predict those patients with acute low back pain who are at risk for developing chronic disability. By implementing an integrated early intervention with these relative few, an impressive amount of future pain and expenditures can be prevented (Gatchel et al., 2003). In today's competitive healthcare market, a multitude of treatments compete for limited financial resources, and in order to optimally allocate these budgets, policymakers require a clear representation of health gains for each dollar spent. Cost utility analyses provide a uniform, objective means of comparing disparate treatments and varying

healthcare contexts. Such analyses have evaluated the cost-effectiveness of interventions for chronic pain and using an abbreviated psychosocial intervention, but never has such an analysis been undertaken on an identified group of at-risk acute patients. The current study evaluates the cost-effectiveness of an interdisciplinary early intervention targeted to patients with acute low back pain who are at risk for chronic disability. In performing this study, the following hypotheses were proposed:

Hypothesis 1

Patients who receive the early intervention treatment will demonstrate greater improvement on measures of pain and health status (using QALY as an outcome measure) than those who receive medical treatment as usual (as demonstrated by Gatchel et al., 2003).

Hypothesis 2

The patients who participate in the early intervention will report decreased healthcare utilization and improved work attendance compared to those who do not receive early intervention.

Hypothesis 3

Treatment with the early intervention program will be more cost-effective than medical treatment as usual, as indicated by a lower ratio of cost per QALY gained. This value will be within the established limits to be considered a “good value” for allocation of healthcare resources.

CHAPTER THREE

METHODS

Participants

Participants were recruited from local pain clinics in the Dallas, Texas, metropolitan area and through print advertising. Inclusion criteria consisted of: (a) complaint of low back pain of less than ten weeks' duration; (b) no previous history of lower back injury or diagnosed chronic pain condition; and (c) high risk status as designated by the identification algorithm described by Gatchel, et al. (1995). Participants were paid $20 to $100 at each phase of data collection and received treatment free of charge.

Procedure

In the initial phase of the study, subjects filled out a screening packet consisting of a patient demographic sheet, the Million Visual Analog Scale (MVAS), and Scale 3 of the MMPI-2. Based on the previously identified risk algorithm (Gatchel et al., 1995), a risk score was calculated to identify those patients at high risk for chronic disability. Those who met this criterion were invited to return for a baseline appointment. At that time, they underwent a comprehensive clinical interview and completed a more extensive set of paperwork, including the SF-36, measures of pain severity and disability, and questionnaires pertaining to work status and healthcare and medication utilization.

Subjects were then randomly assigned to one of three groups: (a) an early intervention program consisting of cognitive-behavioral and physical therapy (EI), (b) a combined early intervention and work transition group (EI+WT), and (c) treatment as usual (TU). Cognitive-behavioral therapy was provided by a licensed clinical psychologist or professional counselor and included coping skills training, relaxation, and biofeedback. Physical therapy was provided by licensed providers. The work transition intervention consisted of one to three consultations with a counselor who specialized in workplace accommodations and ergonomics. All patients continued to receive medical treatment from their regular source of care. At the commencement of treatment, a physical examination was performed to ensure the safety of the participants, but no medical care or medication was provided as part of the study.

Treatment consisted of 6 to 9 sessions of both cognitive-behavioral and physical therapy, generally lasting approximately 3 months. At the end of the treatment phase (or after 3 months for those not in an early intervention group), and every 3 months for one year, the patients were mailed a follow-up packet with several questionnaires, including the MVAS and measures of healthcare utilization, medication use, and employment information. At one year post-treatment, the patients again completed an evaluation packet that included an SF-36. Patients who did not return packets via mail were contacted by phone and offered the opportunity to complete the measures over the phone or on a website.

Patient healthcare utilization and medication costs were calculated based on appropriate national averages (according to *Medical Fees in the United States*, 2008; *Red Book: Pharmacy's Fundamental Reference*, 2008). Cost of travel to the clinic was

calculated by using Google Maps (http://maps.google.com) to determine the distance traveled from the patient's home, then multiplied by a standard reimbursement rate and the number of trips that were made during the course of treatment. The compensation costs of missed workdays were assessed using self-reported wages.

Measures

Million Visual Analog Scale (MVAS)

The Million Visual Analog Scale (Million, Hall, Nilsen, & Baker, 1982) is a 15-item instrument designed to assess pain severity, disability, and physical functioning. It takes only five to ten minutes to complete, can quickly be scored, and is easy to administer, as the subject simply marks an "X" along a horizontal line that is labeled on one end with a minimal response and on the opposite with a maximal one and is marked with five hash lines at evenly-spaced increments in between. Test-retest and inter-examiner reliability coefficients are sufficient. The MVAS has been demonstrated to be valid and responsive to change (Hazard et al., 1989).

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

The SF-36 is a 36-item self-report inventory that assesses 8 dimensions of physical and mental quality of life. These dimensions are represented by eight individual domain scores: Physical Functioning, Role-Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role-Emotional, and Mental Health. Two summary scales can also be calculated, the Physical Component Scale (PCS) and Mental Component Scale (MCS). The SF-36 has been demonstrated to possess excellent psychometric

properties, including reliability and validity coefficients for all eight individual scales and two summary scales that far exceed the accepted standards. It correlates well with other measures of health-related quality of life and has strong predictive validity for health outcomes. The measure has been validated and normed for general and specific diagnosis populations in the United States, Sweden, Denmark, Germany, Australia, Italy, France, the Netherlands, and the United Kingdom and has been translated into over 40 languages (Ware, Kosinski, & Keller, 1994; Ware, Snow, Kosinski, & Gandeck, 1993).

Brazier, et al. (2002) SF-36 Conversion Algorithm, Model 10

Model 10 is a mean model conversion algorithm that maps SF-36 data onto the SF-6D classification, assigns preference weights to the resulting outcomes, then calculates an index of QALYs between 0.0 and 1.0, which makes it well-suited for cost utility analyses. Value weights are derived from a representative sample of the population of the United Kingdom. The model performs well on tests of fit. The conversion algorithm and all statistical analyses were conducted using SPSS.

Design and Analysis

The current study was designed to assess the cost-effectiveness of an early intervention program for acute low back pain versus medical treatment as usual using the specific methodology of a cost utility analysis and the standard measure of Quality Adjusted Life Years (QALY). Treatment outcomes were compared with the associated costs related to standard care and interdisciplinary early intervention. This comparison provides the most complete and accurate information on the research question of whether

early interdisciplinary intervention for acute low back pain is the optimal choice in preventing long-term disability when considering both efficacy and cost.

Treatment Groups

Since the main research question to be answered was the efficacy of interdisciplinary early intervention—and due to information from previous work with this patient cohort that indicated work transition counseling was associated with decreased observed follow-up rates and limited reported usefulness and demonstrated efficacy—treatment groups were collapsed into two groups: those who received the interdisciplinary early intervention (EI) and those who did not (TU). These two groups were compared on all outcome measures.

Efficacy of Treatment Modalities

In order to assess treatment change and outcome for each treatment group, scores on the MVAS were compared from baseline to 12-month follow-up using repeated-measures analyses of variance (ANOVAs). Data from the SF-36 were converted into QALYs and compared at baseline and at 12-month follow-up using repeated-measures ANOVAs. In addition, number of work days missed and number of healthcare visits were similarly assessed.

Cost Utility Analysis

All treatment costs, including outside medical visits and missed work days, were summed for each subject. A standard cost utility analysis was performed by dividing the total cost of each treatment by the change in the QALY index from baseline to 12-month follow-up. Cost utility (CU) ratios and incremental CU ratios were calculated and compared across treatments. Due to uncertainty related to sampling variation, 1,000 non-

parametric bootstrapped replications of the mean cost and outcome differences were computed (using quantitative instruments from Wood, 2004) and plotted onto cost-utility planes, where incremental QALYs are represented on the x-axis and incremental costs are located on the y-axis. The advantage of non-parametric bootstrapping is that it does not depend on parametric assumptions regarding the sampling distributions of the statistics of interest. Repeating the procedure over a large number of repetitions provides an empirical estimate of the sample's true distribution. Finally, a cost-utility acceptability curve was plotted to estimate the probability that a given intervention is cost-effective at given cost-per-QALY thresholds (see Fenwick & Byford, 2005; O'Brien & Briggs, 2002). Appendix A provides the observed CU ratios for some other common medical and social interventions as a point of reference (Center for the Evaluation of Value and Risk in Health).

Sensitivity Analysis

Due to imprecision in cost estimates, an exploratory sensitivity analysis was performed by which these estimates were systematically altered. The cost utility analysis was then repeated to determine whether the outcomes and conclusions are robust to changes in the estimated values.

Sample Size/Power Analysis

When planning a research project, it is important to estimate the appropriate sample size that will be adequate for discerning treatment effects while not being unnecessarily large and burdensome. However, there are currently no existing models for accurately determining necessary sample size for a cost utility analysis. When considering the central outcome measure of QALY, the crucial results consist of the

effects of two different treatments from baseline to follow-up. The standard method for analyzing such a design would be using a repeated-measures ANOVA. Using G*Power software, an *a priori* power analysis based on standard assumptions of an α level of .05 and a power of 0.8 indicated that a sample size of 34 subjects will be required to detect an effect that is medium in magnitude (0.25) according to widely accepted values for effect sizes with ANOVAs (Cohen, 1992). This type of *a priori* analysis makes generic assumptions about the nature of the population and relationships between the variables, however, and may not be specifically applicable to the present analysis. Accordingly, referring to previous research may provide the most appropriate guidance for determining an adequate sample size. Gatchel, et al. (2003) demonstrated the effectiveness of a comparable early intervention program with a very similar group of patients. This study revealed strong effects in terms of improved pain severity, disability, and economic outcomes after early intervention using a sample that included 22 subjects in the early intervention group and 48 subjects in the nonintervention group. Another study that performed a cost utility analysis of chronic spinal pain treatment (Hatten et al., 2006) used a sample of 121 patients split among 4 treatment groups.

CHAPTER FOUR

RESULTS

Demographic Information

The early intervention (EI) group was compared to the treatment-as-usual group (TU) on several demographic variables using independent-samples t-tests for continuous data and χ^2 tests for categorical variables. The results are shown in Tables 1 and 2. There were no significant differences observed for age, t (61) = 1.66, p = .102; gender, χ^2 (1, N = 63) = 1.725, p = .212; ethnicity, χ^2 (4, N = 63) = 3.007, p = .557; marital status, χ^2 (2, N = 63) = 2.097, p = .350; number of children living in the home, χ^2 (2, N = 63) = 2.641, p = .267; years of education, t (61) = -.366, p = .716; or yearly income, t (40) = .318, p = .752. The overall cohort of participants was on average 43 years old, had 14.5 years of education, and earned approximately $39,000 per year. Fifty-seven percent were male, 51% were Caucasian, 24% were African-American, 17% were Latino, 6% were Asian/Pacific Islanders, and 1% were Native American. Sixty-two percent were married, 25% were single, and 13% were divorced or separated. Seventy-five percent reported no children under 18 living at home.

In addition, no significant differences between the two groups were noted regarding weight, t (59) = .112, p = .912; number of previous surgeries, t (59) = -.108, p = .915; previous musculoskeletal injury, χ^2 (1, N = 63) = .019, p = .891; other health conditions, χ^2 (4, N = 59) = 1.936, p = .748; smoking status, χ^2 (1, N = 63) = .032, p = 1.000; or usual source of healthcare, χ^2 (4, N = 62) = 6.955, p = .138. The usual source of

healthcare of the EI group was found to be significantly farther from home than that of the TU group (12.8 miles vs. 5.2 miles), t (49) = 3.56, p = .001. Participants had an average of 1.4 previous surgeries, and 49% had previously experienced a musculoskeletal injury. A primary care physician was the usual source of healthcare for 79% of participants, and 10% used the emergency room as their usual source.

Heath Outcomes

Measures of Pain Outcomes

Subjects completed a wide variety of measures during each phase of the study, from screening to baseline, post-treatment, and 6-, 9-, and 12-month follow-ups. These measures encompassed such diverse outcomes as pain severity, physical disability, coping style, fear avoidance, and workplace characteristics. Analyses of these outcomes are comprehensively described by Whitfill (2009). For the present analysis, the primary outcome measures were pain severity and overall health status.

Pain severity was measured using the Million Visual Analog Scale (MVAS). Results are shown in Table 3. Analysis of pain severity across the 5 timepoints from baseline to 12-month follow-up using a repeated-measures analysis of variance (ANOVA) demonstrated a significant main effect for time. Pain severity for both treatment groups decreased from baseline to 12-month follow-up, F (4, 36) = 10.988, p < .001. In addition, a significant interaction was observed whereby the EI group demonstrated a more rapid improvement over time, F (4, 36) = 3.227, p <. 05. No

significant main effect was observed between treatment groups, F (1, 39) = .487, p = .489.

Health status was evaluated using the Physical Component Scale (PCS) and Mental Component Scale (MCS) of the SF-36 health status survey. Results are represented in Table 4. Comparisons were made between treatment groups at baseline and 12-month follow-up using repeated-measures ANOVAs. On the PCS, a significant main effect was noted for time, F (1, 39) = 32.064, $p < .001$, whereby both treatment groups improved from baseline to 12-months. The between-groups main effect, F (1, 39) = 1.432, p = .239, and interaction effect, F (1, 39) = .237, p = .629, were not statistically significant. On the MCS, main effects for time, F (1, 39) = .304, p = .585, and treatment group, F (1, 39) = 1.805, p = .187, were not significant. No significant interaction was observed, F (1, 39) = 1.722, p = .197.

Quality-Adjusted Life Years

Participants who met the criterion for high-risk status as described in (Gatchel et al., 1995), and who completed the SF-36 at baseline and 12 months post-treatment commencement, were compared using a repeated-measures ANOVA. This group consisted of 41 participants. First, the SF-36 data were converted to QALYs using the Brazier, et al. (2002) algorithm. Results are shown in Table 5 and Figure 1. Analysis of the QALY data indicated a statistically significant main effect for time, F (1, 39) = 32.843, $p < .001$, such that both the EI and TU group improved significantly from baseline to 12 months. There was a non-significant trend toward an interaction between treatment and time, F (1, 39) = 1.698, p = .200, in which the EI group showed a greater improvement over time than the TU group (the EI group had a mean improvement .058

QALYs greater than that of the TU group). The EI group had lower QALY scores at both baseline and 12 months, but between-group differences were not statistically significant, F (1, 39) = 2.860, p = .099.

Relationships between QALYs and Other Measures

Linear regression analysis was conducted to evaluate the association between QALY values (derived from the Brazier, et al. (2002) SF-36 algorithm) and the various pain outcome measures. Results are summarized in Table 6. Statistically significant Pearson product-moment correlations were observed between baseline QALYs and baseline scores on the SF-36 PCS, r = .657, p < .001; SF-36 MCS, r = .562, p < .001; and MVAS, r = .502, p = .001. Significant correlations were noted between QALYs at 12-month follow-up and 12-month scores on the SF-36 PCS, r = .799, p < .001; SF-36 MCS, r = .747, p < .001; and MVAS, r = .716, p < .001. Finally, significant correlations were observed on changes in QALYs from baseline to 12-month follow-up and similar change scores on the SF-36 PCS, r = .699, p < .001; SF-36 MCS, r = .449, p = .003; and MVAS, r = .380, p = .014. Figure 2 depicts a graphical representation of the relationship between change in QALYs and change in PCS.

Economic Costs: Healthcare Utilization

Healthcare utilization information was collected at baseline (utilization since the injury) and every 3 months thereafter for 12 months. Missing data were extrapolated using last observation carried forward (LOCF) (see Siddiqui & Ali, 1998). Nevertheless, data were often incomplete and thus encumbered analysis. As a result, economic costs

were derived from a larger group of participants that included subjects who did not meet such stringent inclusion standards regarding risk status. Thus, a number of low-risk subjects were included in the cost analyses, although most produced risk scores that did not depart drastically from the high-risk cut-off score. Despite this inclusion, the majority of subjects in the analysis met the criteria for high-risk status. All participants underwent an identical process of assignment to treatment groups and received the treatment interventions according to the same protocol. An attrition analysis was conducted to determine whether the subjects for whom complete data were available differed significantly from those with only partial data. Results indicated that a significantly higher percentage of the EI group (63%) had full data than those in the TU group (29%), χ^2 (1, N = 63) = 7.100, $p < .01$. Those with full data did not significantly differ from the remainder of the cohort on baseline QALY scores or any of the demographic variables. No significant differences on demographic variables were noted between the treatment groups within the larger sample, except for distance to usual source of healthcare, t (49) = 3.335, $p < .005$. No significant differences were observed between the EI and TU groups on percentage of included subjects who were considered low-risk, χ^2 (1, N = 63) = 1.517, $p = .218$.

Healthcare Visits

Total number of medical appointments for the EI and TU groups were compared using a repeated-measures ANOVA (2 groups x 5 time points), and the results are summarized in Table 7 and Figure 3. Main effects for time, F (4, 26) = .471, $p = .757$, and treatment group, F (1, 29) = 1.870, $p = .182$, were not statistically significant. A significant interaction between group and time was observed, F (4, 26) = 2.932, $p < .05$,

with the EI group's number of medical appointments generally decreasing over time, whereas the TU group's generally increased. Thus, healthcare utilization rates at baseline were comparable between the groups, and treatment effects became increasingly disparate over the course of the year.

Means of the overall sums of medical appointments for the entire 12 months were 14.6 for the EI group (SD=35.4) and 37.9 for the TU group (SD=49.6). Due to the large amount of variation and positively skewed nature of the data, numbers of appointments for each subject at each time point were collapsed into ordinal data for non-parametric analyses, with categories denoting: 0, 1-10, 11-99, and 100+ visits. As shown in Table 8 and Figure 4, using a χ^2 analysis for the 1-year medical visit sums, significant differences were observed between the EI and TU groups, χ^2 (3, N = 31) = 8.242, $p < .05$. Of the EI group, 40.9% of subjects had 0 medical visits for the year, 36.4% had between 1 and 10, 18.2% had between 11 and 99, and 4.5% had 100 or more. Of the TU group, 11.1% had 0 visits, 11.1% had between 1 and 10, 66.7% had between 11 and 99, and 11.1% had 100 or more. Thus, over 75% of the EI group had 10 or fewer appointments, and over 75% of the TU group had 11 or more.

Travel Costs

In a standard cost utility analysis, travel to and from medical appointments is included in the treatment costs. Distance to the study treatment site was calculated using Google maps, and subjects reported the distance to their usual source of care. Subjects in the EI group averaged approximately 20 one-way trips to the treatment site, which was located an average of 20 miles away. Analysis of travel to medical care, however, revealed that TU subjects lived significantly closer to their usual sources of care (5.2

miles vs. 12.8 miles), t (49) = 3.56, p = .001. TU subjects made an average of approximately 76 one-way trips to healthcare appointments over the year, and EI subjects made approximately 29 trips. Using a driving cost multiplier of $.40 per mile, the EI group averaged $302.13 in travel costs, whereas the TU group averaged $184.95. However, the observed difference in distance to medical treatment accounted for the majority of the cost discrepancy. When the overall mean distance to usual medical care (9.3 miles) was used in the calculations, the EI group costs averaged $269.42, whereas the TU group costs were $281.98. Thus, differences in travel costs were relatively small and largely due to differences in distance to the usual source of medical care. Since the primary aim of the present study was to compare early intervention to treatment as usual, and since different travel distances are unlikely to represent clinically relevant treatment effects, travel costs were not included in subsequent analyses.

Medication Use

Data regarding medication use and dosage were collected at each follow-up point over the course of the year. Medications were separated into three classes, consisting of: non-steroidal anti-inflammatory drugs (NSAIDs); narcotics / muscle relaxants / anxiolytics / neuroleptics; and antidepressants. Dosages were classified as mild, medium, or strong using information from a standard pharmaceutical periodical (*Monthly Prescribing Reference*, July 2006). Missing data were extrapolated using LOCF. Medication use at 12-month follow-up was assessed for each category using a χ^2 analysis. No significant differences were observed for the NSAID class, χ^2 (3, N = 63) = 4.223, p = .238; the antidepressant class, χ^2 (2, N = 63) = .436, p = .804; or the group of narcotics, muscle relaxants, anxiolytics, and neuroleptics, χ^2 (3, N = 63) = 3.589, p = .309.

Repeated-measures ANOVAs for each of the medication classes over the course of the year also failed to yield any significant differences or interactions between treatment groups. Since no systematic differences between groups were observed and specific dosage information was particularly incomplete, medication usage was not included in subsequent cost analyses.

Economic Costs: Missed Workdays

Participants reported the number of workdays missed since their injury at the beginning of the study and at every subsequent time point. Invalid data were removed, and missing data were extrapolated using LOCF. The subjects also reported their monthly wages, which were converted into daily wages for each individual. Average wages for the treatment group were used for subjects who failed to provide monthly income. Results are shown in Table 9 and Figure 5. Cumulative workdays missed at baseline and 12 months were compared using a repeated-measures (2 groups x 2 time points) ANOVA. Results indicated a non-significant trend toward an interaction between treatment and time, F (1, 59) = 2.201, p = .143. At 12 months, the EI group was observed to have an average of fewer workdays missed (13.6, SD=27.4) than the TU group (25.8, SD=54.4). Since the work data exhibited significant variability and positive skew, data were collapsed into 4 ordinal categories representing: 0 workdays missed, 1 to 10, 11 to 99, and 100 or more. These data were then analyzed using a repeated-measures ANOVA, which revealed a statistically significant interaction between time and treatment group, F (1, 59) = 4.012, p = .05. Using ANOVAs to evaluate ordinal data has been demonstrated

to be a valid alternative to non-parametric tests (see Lord, 1953; Stiger, Kosinski, Barnhart, & Kleinbaum, 1998).

Cost Utility Analysis

Total costs and QALY change scores were calculated for each individual subject, and group values are summarized in Table 10. Medical fees were calculated using cost data (from *Medical Fees in the United States*, 2008) for each reported healthcare appointment and surgical procedure. Total lost wages were calculated by multiplying the number of missed workdays reported by each individual by that subject's self-reported daily income. Total costs consisted of the sum of medical costs, lost wages, and the cost of the early intervention treatment, if applicable ($4,025). Although medical costs and lost wages for the EI group were lower than those of the TU group, independent-samples t-tests indicated that these difference were not statistically significant, t (29) = -1.304, p = .226 for medical costs; t (29) = -1.641, p = .112 for lost wages. No statistically significant differences were observed for total costs, t (29) = -.906, p = .373.

Since individual values for costs and QALY change led to some uninformative individual ratios as a result of zero or negative values, group means were used to calculate cost utility (CU) ratios for each group (see Table 11). The CU ratio for the EI group revealed a cost of $49,593 per QALY gained, whereas the CU ratio for the TU group indicated a cost of $71,001 per QALY gained. The incremental CU ratio is a measure for the number of dollars required to achieve a change of 1 QALY beyond that of a given treatment (see Table 12). Since the EI group realized a greater gain in QALYs *and* lower total costs than the TU group, the EI treatment is the dominant alternative, as

indicated by a negative incremental CU ratio (-$235,355). Since full data for costs and QALYs were only available for a relatively limited sample, similar ratios were calculated from means derived from all subjects, including those with partial data, in order to further corroborate the approximate magnitude and relative differences of the calculations for each group. With the inclusion of partial data, the CU ratio for the EI group was $53,906 per QALY gained, and the CU ratio for the TU group was $77,712 per QALY gained. The incremental CU ratio (-$34,072) again demonstrated the dominance of the EI treatment.

Bootstrapped Modeling

Due to statistical error and uncertainty in deriving cost utility data, a non-parametric bootstrapping model was utilized, in which 1,000 bootstrapped samples were calculated by randomly sampling with replacement from a population comprised of the observed values for both costs and QALY effects. An incremental cost utility plane is shown in Figure 6 and represents a graphical display of the incremental costs and QALYs that were observed for the EI group beyond those for the TU group. The QALY difference between the EI and TU groups is depicted on the x-axis, and the cost difference is displayed on the y-axis. Each point represents the combination of mean incremental costs and QALYs for each of the 1,000 bootstrapped samples.

Data points in the lower right quadrant indicate samples in which the EI treatment was both cheaper and more effective, thus representing the dominant choice. Approximately 56% of the samples were located in this quadrant. Data points in the upper left quadrant denote samples in which the EI treatment was both more costly and less effective and thereby dominated by the TU option. Approximately 3% of the samples

were located in this quadrant. Data points in the upper right and lower left quadrants indicate that the EI treatment was either (a) more expensive and more effective (approximately 4% of samples); or (b) less expensive and less effective (approximately 37% of samples).

Interpreting the distribution of sample CU estimates is complicated by several factors (see O'Brien & Briggs, 2002). Firstly, CU values are not distributed according to any comprehensive ordering system. Lower positive ratios are preferred, as they indicate lower costs per QALY. However, with negative ratios, miniscule treatment effects (in the denominator) will result in extremely low ratios but little practical benefit. Furthermore, negative ratios result from two quadrants with very different meanings. One indicates lower costs and treatment gains, and thus the dominance of the intervention under consideration. The other indicates higher costs and negative treatment effects, thus indicating the dominance of the control condition. Interpretation of positive ratios is also a complicated endeavor. With positive ratios in the upper right quadrant (cost increases and positive effects), lower magnitudes are preferable, due to lower costs per observed effect. However, with positive ratios in the lower left quadrant (cost savings and negative effects), higher magnitudes are indicative of lower costs per observed effect and are thus preferable. In sum, conventional comparisons, analyses, and interpretation are complicated by the complexity of ratio data both across and within quadrants of the incremental cost utility plane. The cost-effectiveness acceptability curve (CEAC) represents a preferable method for evaluating cost effectiveness by estimating uncertainty and probability rather testing parametric hypotheses.

The relative cost utility of the EI treatment in these samples is dependent upon the amount that society is willing to pay per QALY gained. Figure 7 shows a CEAC that provides a graphical depiction of the likelihood that EI is the preferred treatment at various thresholds of acceptable CU ratios. It is important to remember that this graph *does not* represent the amount of benefits achieved by investing money in a particular treatment (i.e., early intervention). Rather, if society is willing to pay $X for *any* treatment (including treatment as usual), the CEAC indicates which of 2 treatments would be a *more effective* use of those resources. Proportions of cost-effectiveness are calculated by determining the number of samples that fall below (cost-saving) and to the right of (more effective) a line with a given slope (cost/QALY) on the incremental cost utility plane. As shown in the figure, at $0/QALY gained, approximately 93% of samples indicate that EI is the preferred treatment. At a commonly-used threshold of $40,000/QALY, approximately 91% of samples indicate that EI is superior. At the upper limit of the range of generally-accepted values of $100,000/QALY, approximately 85% of samples indicate that EI is preferable. Thus, throughout the range of generally-accepted values (Brauer, Rosen, Olchanski, & Neumann, 2005), EI is overwhelmingly preferred, and dominance is actually greatest when willingness to pay is at its lowest value ($0/QALY), or when funding resources are most scarce.

Sensitivity Analysis

Due to the various estimations and extrapolations involved in the present calculations, a sensitivity analysis is beneficial in determining the overall effects of changes in these estimates and assumptions. The estimate that was most commonly used in cost calculations was the cost of a medical visit. A value of $116.48 was used, which

was derived from the median fee for evaluation and management (according to *Medical Fees in the United States*, 2008), adjusted for the higher costs in the area in which the study was conducted (using a multiplier of 1.04). This cost estimate is likely quite conservative, because it does not account for any diagnostic tests or treatment procedures. Since the TU group had more medical visits, any increases in the physician appointment cost estimate would lead to greater discrepancies in total costs and subsequent CU ratios. For example, increasing the estimate to $233 (a factor of 2) would result in CU ratios of $52,890 for the EI group and $80,823 for the TU group. Alternatively, if the estimated fee for physician appointments were reduced to $60 (a factor of 0.5), the resulting ratios would be $47,994 for the EI group and $66,240 for the TU group. There is no appointment fee low enough to eliminate the difference in CU ratios between the EI and TU groups. Multiplying the other medical fees (e.g., emergency room, physical therapy, chiropractic, massage) by a factor of 2 or 0.5 had little impact on the overall CU ratios. Other medical and surgical procedures similarly occurred too infrequently for changes in their cost estimates to appreciably alter the overall cost analysis.

Another value used in calculating total costs was daily wage. Observed mean for wages indicated that the annual salaries of the workers in the current sample were in the middle 20% of incomes in the United States but below the median household income in the U.S. and Texas (U.S. Census Bureau, 2008). Since the TU group demonstrated more workdays missed, increasing the daily wage value would increase the observed difference in CU ratios. For example, an increase for each subject to the state-wide median income of $46,013 per year would result in a CU ratio of $50,942 for the EI group and $98,753

for the TU group. There is no daily wage low enough to eliminate the difference in CU ratios between the EI and TU groups.

CHAPTER FIVE

DISCUSSION

Summary of Current Findings

Health Outcomes

There is a wealth of research data on treatment effects for patients with back pain. Treatment efficacy for targeted interdisciplinary intervention with at-risk acute low back pain has been demonstrated on standard pain measures with the present patient cohort (Whitfill, 2009) and a similar previous one (see also Gatchel et al., 2003). The present results suggested that early interdisciplinary intervention resulted in significantly improved outcomes over time as measured by the MVAS, but not the SF-36.

The current study is one of few that measure outcomes using the metric of quality-adjusted life years (QALYs), which is uniform and objectively comparable across different modalities, ailments, and treatments. In these results, both the EI and TU groups improved significantly from baseline to 12-month follow-up. The EI group improved an average of .0576 QALYs more than the TU group, although this difference was not statistically significant. The finding that both groups improved was surprising, given that these patients were all identified by a previously-established algorithm as being at high risk for chronic back pain. It may be that although objective health states may improve somewhat with standard care, subjective pain and perceived disability persist.

Alternatively, the SF-36 may not be the most responsive measure to changes in pain severity and disability.

QALY outcomes were found to be significantly related to scores on the other measures of pain and health status, and stronger correlations were observed between QALYs and SF-36 physical functioning than any other measure. The observed change in QALYs for the EI treatment group was substantial and compared favorably with previous observations of change in QALY for an interdisciplinary intervention with a more heterogeneous pain population (Hatten et al., 2006). In fact, the QALY change that was observed with interdisciplinary treatment in that previous study was of comparable magnitude with the *difference* in QALY change between the EI and TU groups in the present study. Thus, with regards to Hypothesis 1, although no statistically significant differences were noted between the groups regarding change in QALYs, the EI group did improve significantly from baseline to 12-month follow-up and demonstrated a trend toward a larger mean improvement than the TU group.

Economic Costs

From a treatment and policy perspective, a critical factor in evaluating observed changes in health states is the associated cost of achieving those changes. The total cost is comprised of multiple direct and indirect societal costs associated with pain and disability, including healthcare utilization and employment outcomes. A statistically significant interaction was observed in which healthcare appointments for the EI group tended to decrease over the course of the year, whereas appointments for the TU group tended to increase. In addition, a statistically significant difference was noted such that at 12-month follow-up, more than 75% of patients in the EI group reported utilizing 10 or

fewer appointments, whereas more than 75% patients in the TU group required 11 or more.

Travel costs associated with treatment and medication usage are typically included in cost utility analyses. In the present study, however, a statistically significant difference was observed between the two treatment groups regarding the distance traveled to the usual source of healthcare. This difference accounted for the small observed discrepancy between the groups for overall travel costs, and since the focus of the study was the relative cost-effectiveness between the two treatments, travel costs were excluded from the subsequent analysis. Similarly, no significant differences between the groups were noted regarding medication usage. Since no systematic differences contributed to overall relative costs, and since dosage information necessary for comprehensive individual calculations was often incomplete, medication costs were not included in the overall cost analysis.

Missed workdays, lost wages, and decreased productivity represent some of the most substantial societal consequences of chronic low back pain. Results from the present study suggested that missed workdays were higher for the TU group. Due to the high observed variance in the data and presence of notable outliers representing particularly poor outcomes, data were collapsed into ordinal categories. Analysis of these data indicated a significant interaction between treatment and time. Missed workdays appeared comparable through 6-month follow-up before diverging over the last 6 months of the year as the TU group missed work at a higher rate.

Overall, healthcare appointments and workdays missed appeared to be higher among the TU group than the EI group. These results corroborate Hypothesis 2, that early

intervention would result in decreased healthcare utilization and increased work attendance.

Cost Utility Analysis

Cost and QALY data for each individual were summed, and overall means for each treatment group were used to calculate total costs and changes in QALY. Although no statistically significant cost differences were observed, the EI group showed marginally lower medical costs, employment costs, and total costs. Indeed, the observed difference in medical costs in one year alone would cover the cost of the early intervention treatment program. Cost and QALY information were used to calculate cost utility (CU) ratios for each group. As predicted in Hypothesis 3, cost-effectiveness for the EI group was better than treatment as usual, as indicated by a lower CU ratio ($49,593/QALY vs. $71,001/QALY). Both CU ratios are considered to be "good values" according to established parameters. Generally, a CU ratio between $20,000/QALY and $100,000/QALY is considered a good value. Ratios lower than this range are considered an excellent value, and higher ones are considered "not the best value" (Brauer et al., 2005). Similar magnitudes and relative differences in CU ratios were noted when including the overall means for all subjects, including those with partial data, which suggests that these results are relatively robust to the individual and sample differences within the present study. Non-parametric bootstrapped modeling demonstrated that the majority of calculated samples (56%) represented both greater health outcomes *and* lower costs associated with the early intervention. Only 3% of samples suggested better costs and outcomes for treatment as usual. Throughout the generally-accepted range of societal cost-utility values, the early intervention treatment was consistently and overwhelmingly

preferred (from 85% to 93% probability of being cost-effective compared to treatment as usual). In addition, sensitivity analysis revealed that increasing the conservative estimate for physician fees or increasing daily working wage would magnify the observed discrepancy in CU ratios between the two groups and enhance the relative favorability of the early intervention group.

Limitations and Future Directions

As with any research, the present study possesses some limitations and presents areas for future elaboration. In conducting the analysis, the incomplete nature of follow-up data represented a formidable obstacle to statistical comparison. In addition, economic cost outcomes are highly skewed and variable by nature, as many subjects achieve reasonably good outcomes, but a significant few experience considerable exacerbations that require substantial further expenses. As a result of the limited sample and high variance, several of the analyses were likely underpowered to detect statistically significant results.

In attempting to increase the power of the calculations, a number of strategies were employed. The last observation carried forward (LOCF) method was used to extrapolate missing economic data. This technique likely minimizes observed longitudinal effects by inserting data from earlier observations into subsequent time points. In the present study, economic outcomes between the two groups appeared to diverge increasingly as the year progressed. Accordingly, the LOCF procedure is likely a conservative method that decreases the likelihood of a Type I error and may limit the

capacity to fully discern effects. In addition, economic costs were calculated using a broader sample that included some patients who did not meet such stringent criteria for high-risk status. Data from this sample represented the fullest, most accurate representation of cost outcomes, and its use is unlikely to differentially affect the two treatment groups.

The difficulty in accumulating complete data for each subject at each of six data points over the course of a year demonstrates some of the obstacles in performing research with an at-risk low back pain community population. Characteristics that predispose an individual to chronic pain also tend to exacerbate difficulties in coping and interpersonal interactions. Practical obstacles can interfere with follow-up contact and hinder data collection. These impediments are exacerbated by the comprehensive nature of the information required to perform a cost utility analysis. Extensive data from a variety of modalities must be integrated to arrive at an overall ratio of cost and utility. Several previous studies that have utilized cost utility analyses have benefited from healthcare systems in which patient treatments and outcomes are all incorporated in one system and can be tracked accordingly (Hatten et al., 2006; Rivero-Arias et al., 2005; Whitehurst et al., 2007). Costs outside of the system of clinical or national care are difficult to fully capture and require particular diligence. Fidelity procedures for validating self-report data would be beneficial in corroborating information and limiting the potential contributions of biased recall and responding.

Although the present work represents encouraging evidence for the relative cost utility of targeted interdisciplinary intervention, further extension of this research would be extremely beneficial in demonstrating the treatment effects and clarifying the various

outcomes. Studies with large, robust samples and particular attention to obtaining comprehensive follow-up information over time will be vital. In addition, longitudinal research that continues to follow subjects beyond one year will be beneficial, especially since chronic pain persists for so long and the present outcomes appeared to increasingly diverge over time. Also, further longitudinal studies in back pain and chronic pain using QALYs as an outcome measure will help to build upon the existing knowledge base and explicate the observed improvements for both groups over time. Finally, such research will help to standardize the assessment of pain and provide meaningful data regarding the relative effects of very different treatment approaches.

Conclusions

Chronic low back pain is a debilitating condition with enormous costs and few consistently effective treatments. Its prevalence underscores the complex biological, psychological, and social factors that interact in the persistence of pain. Interdisciplinary psychosocial treatment interventions have demonstrated impressive efficacy in helping to decrease symptoms and improve functionality (Flor et al., 1992). Nevertheless, such treatments continue to be under-utilized, ostensibly due to the impracticality of applying such a time- and cost-intensive treatment to such a large population. Indeed, the vast majority of acute pain will remit within a few months, but the few chronic cases represent an enormous amount of pain-related costs. Accordingly, Gatchel, et al. (1995) have identified a psychosocial risk algorithm to identify patients with acute low back pain that is at risk for becoming chronic, and early psychosocial intervention has been

demonstrated to be effective in improving outcomes and preventing chronicity with such patients (Gatchel et al., 2003; Whitfill, 2009).

In today's ever-changing healthcare field with increasing costs and limited resources, it is imperative to demonstrate objective results and account for associated costs. Cost utility analyses represent a method of comparing health outcomes and cost effectiveness using the QALY as a uniform and comparable outcome measure. This type of analysis represents a critical advance in evaluating the various modalities and outcomes of pain treatment. Previous research has used the cost utility analysis to assess interdisciplinary treatment of a heterogeneous pain population (Hatten et al., 2006), a chronic low back pain population with whom conservative treatment had failed (Rivero-Arias et al., 2005), and an entire acute low back pain population that received an abbreviated psychosocial intervention (Whitehurst et al., 2007). The present study is the first to conduct a cost utility analysis on an early intervention program targeted to prevent chronic low back pain in a sub-sample of patients identified as having increased risk. This methodology helps to address some of the most intransigent difficulties in pain treatment and research: using standard, objective measures of outcomes that can be compared across modalities; and targeting psychosocial interventions to more focused contexts that will result in greater applicability.

The present study demonstrated encouraging results regarding the utility of early interdisciplinary intervention for acute low back pain. Treatment resulted in significantly improved health states at 12-month follow-up, and the treatment group exhibited decreased healthcare utilization and missed workdays compared with the group that received medical treatment as usual. Better outcomes and lower costs resulted in cost

utility ratios that demonstrated the dominance of the early intervention treatment. Further research with more exhaustive data will be useful in bringing greater statistical power to bear in identifying effects and elaborating on these findings. By continuing to utilize the most effective analytical tools and research methodologies, effective treatments can be identified, practical applications can be implemented, and various disciplines can collaborate in assuaging the obstinate problem of chronic pain.

APPENDIX A

REFERENCE COST/UTILITY RATIOS

Cost per QALY (in 2002 dollars)	Intervention
Cost-saving, QALY-increasing	○ Flu vaccine for the elderly
	○ Elective Caesarian-section vs. vaginal delivery in HIV-infected pregnant women
$0 - $10,000	○ Beta-blockers after heart attack in high-risk patients
	○ Treatment with interferon alpha for 6 months vs. conventional management in 40-year-old patients with chronic hepatitis C
$10,000 - $20,000	○ Cervical cancer screening every 3 years
	○ Combination antiretroviral therapy for HIV patients
$20,000 - $50,000	○ Driver-side airbags
	○ Statin therapy to lower cholesterol for 75-year-olds with previous heart attacks
$50,000 - $100,000	○ Diabetes screening programs for adults
	○ Dialysis for end-stage renal disease
$100,000 - $500,000	○ Cervical cancer screening every year
	○ Annual depression screening in 40-year-olds
$500,000 +	○ CT and MRI for children with headache with an intermediate risk of brain tumor

(source - Center for the Evaluation of Value and Risk in Health)

APPENDIX B

TABLES AND FIGURES

Table 1. Demographic Variables

Variable	Total Sample[a]	EI[b]	TU[c]
Gender (%)			
Female	42.9	35.3	51.7
Male	57.1	64.7	48.3
Age (years)			
Mean (SD)	43.0 (11.2)	45.2 (11.4)	40.5 (10.6)
Minimum	19	19	25
Maximum	65	64	65
Race (%)			
Caucasian	50.8	52.9	48.3
African-American	23.8	23.5	24.1
Latino	17.5	20.6	13.8
Asian/Pacific Islander	6.3	2.9	10.3
Native American	1.6	0.0	3.4
Marital Status (%)			
Married	61.9	61.8	62.1
Single	25.4	20.6	31.0
Separated/divorced	12.7	17.6	6.9
Children at Home (%)			
0	74.6	67.6	82.8
1	19.0	26.5	10.3
2	6.3	5.9	6.9
Monthly Income ($)			
Mean (SD)	3,247 (3,199)	3,398 (3,972)	3,080 (2,142)
Minimum	600	600	1,000
Maximum	20,000	20,000	8,500
Years of Education			
Mean (SD)	14.6 (2.7)	14.4 (2.6)	14.7 (2.8)
Minimum	9	9	11
Maximum	20	20	20

[a] N = 63; [b] n = 34; [c] n = 29

Table 2. Healthcare Demographic Variables

Variable	Total Sample[a]	EI[b]	TU[c]
Previous Musculoskeletal Injury (%)	50.8	50.0	51.7
Other Health Condition (%)	18.6	19.4	17.9
Previous Surgeries			
Mean (SD)	1.39 (2.33)	1.36 (1.75)	1.43 (2.90)
Minimum	0	0	0
Maximum	15	6	15
Usual Source of Healthcare (%)			
PCP	79.0	78.8	79.3
Primary Care Clinic	4.8	6.1	3.4
ER	9.7	3.0	17.2
Military Provider (VA)	1.6	3.0	0.0
Other	4.8	9.1	0.0
Distance to Usual Source (miles)			
Mean (SD)	9.4 (9.0)	12.8 (10.2)*	5.2 (4.7)*
Minimum	0	1.5	0
Maximum	40	40	20
Weight (lbs)			
Mean (SD)	196.6 (47.7)	197.2 (49.5)	195.8 (46.3)
Minimum	112	120	112
Maximum	320	320	300
Smokers (%)	11.1	11.8	10.3

[a] N = 63; [b] n = 34; [c] n = 29

* $p = .001$

Table 3. Analysis of Pain Outcomes: MVAS

Time	Early Intervention (EI) (n=27)	Treatment as Usual (TU) (n=14)	Statistical Comparison
Baseline	80.15 (27.47)	71.07 (20.95)	ANOVA: F (4, 36) = 3.227, p = .023*
3 Months	55.04 (34.49)	70.21 (21.42)	
6 Months	55.22 (35.80)	62.50 (29.41)	
9 Months	55.48 (34.15)	72.00 (23.57)	
12 Months	41.67 (33.43)	42.07 (32.13)	

* $p < .05$

Table 4. Analysis of Pain Outcomes: SF-36

Component Scale	Treatment Group (n)	Baseline Mean (SD)	12-Month Mean (SD)	ANOVA
PCS	EI (27)	34.07 (8.23)	45.22 (9.98)	F (1, 39) = .237, p = .629
	TU (14)	38.11 (12.39)	47.50 (8.84)	
MCS	EI (27)	47.27 (13.74)	50.65 (10.69)	F (1, 39) = 1.722, p = .197
	TU (14)	54.44 (9.56)	53.05 (13.65)	

Table 5. Analysis of Health Outcomes

Measure	Treatment Group (n)	Baseline Mean (SD)	12-Month Mean (SD)	Incremental Change	ANOVA
QALY (derived from SF-36)	EI (27)	.6042 (.127)	.7596 (.161)	.1554	F (1, 39) = 1.698, p = .200
	TU (14)	.7036 (.125)	.8014 (.154)	.0978	

Figure 1. QALY Outcomes from Baseline to 12 Months

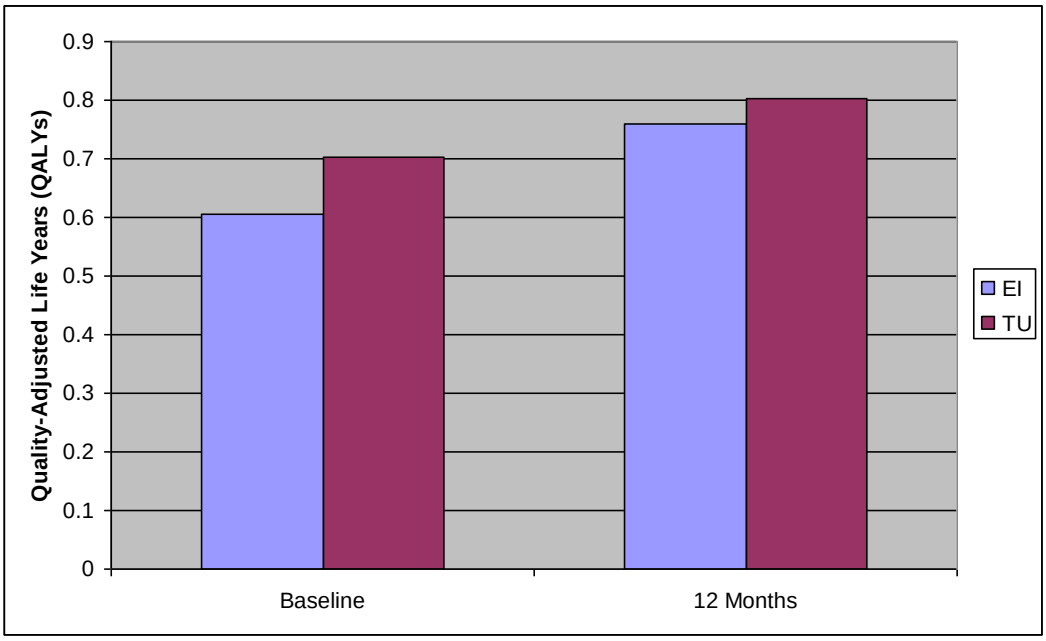


Table 6. Correlations between QALYs and other Outcomes

Time	Pearson's *r*		
	SF-36 PCS	SF-36 MCS	MVAS
Baseline	.657***	.562***	.502**
12-Month Follow-up	.799***	.747***	.716***
Change	.699***	.449**	.380*

* $p < .05$; ** P < .005; *** $p < .001$

Figure 2. Change in QALYs vs. Change in PCS (12-Month – Baseline)

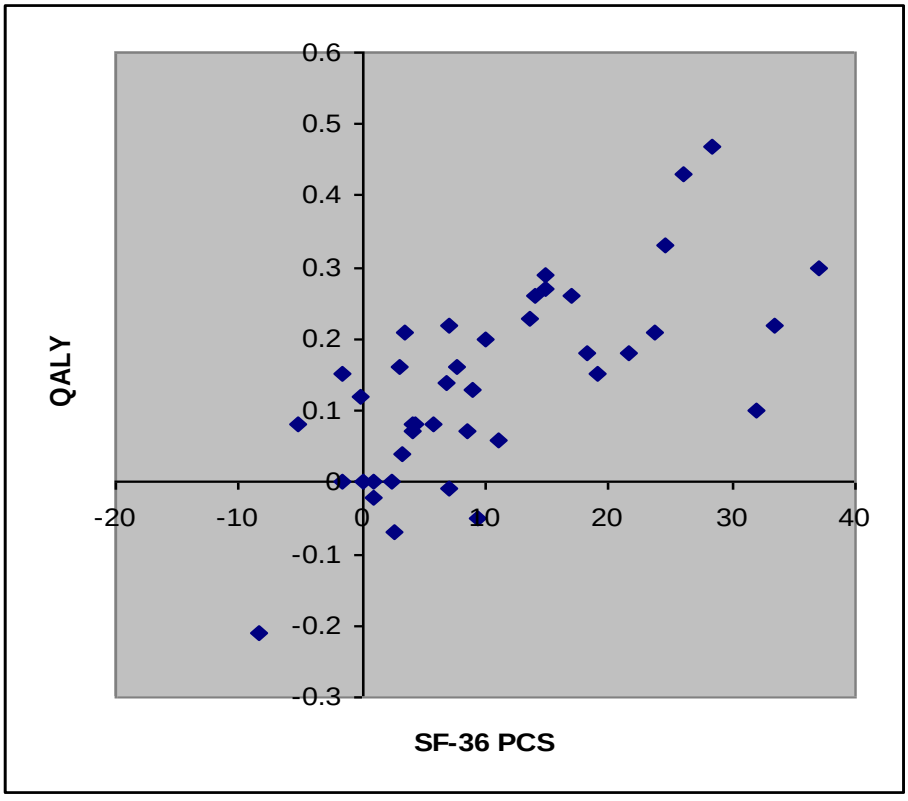


Table 7. Mean Healthcare Appointments

Time	Early Intervention (EI) (n=22)	Treatment as Usual (TU) (n=9)	Statistical Comparison
Baseline (since injury)	5.41 (5.24)	4.22 (4.12)	ANOVA: F (4, 26) = 2.932, $p < .05$*
Post-Treatment (3 Months)	5.50 (12.17)	8.22 (11.65)	
6 Months	4.23 (11.49)	10.22 (11.67)	
9 Months	3.64 (11.47)	8.89 (14.94)	
12 Months	1.23 (3.61)	10.56 (14.21)	
Total for Year	14.59 (35.40)	37.89 (49.59)	t-test: t (29) = 2.186, p = .150

Figure 3. Healthcare Utilization from Baseline to 12 Months

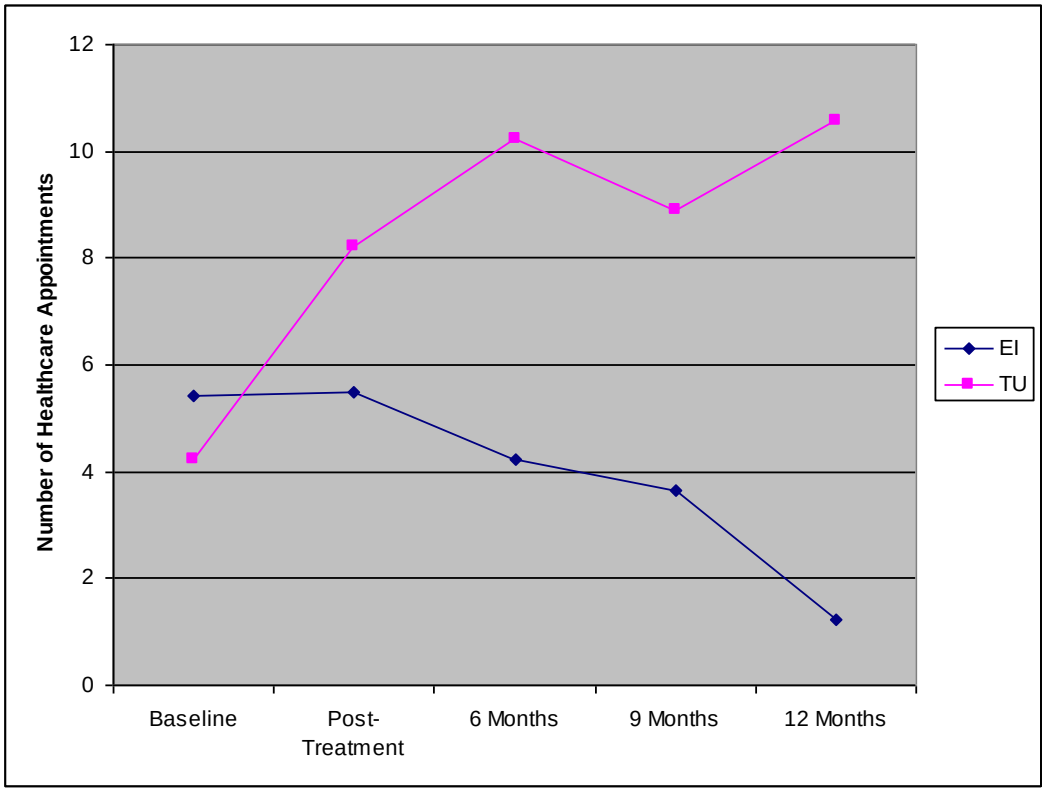


Table 8. Categorical Data for Healthcare Appointments

Treatment Group	Sum of Medical Visits for 12 Months			
	0	1-10	11-99	>99
EI (n=22)	9 (40.9%)	8 (36.4%)	4 (18.2%)	1 (4.5%)
TU (n=9)	1 (11.1%)	1 (11.1%)	6 (66.7%)	1 (11.1%)
Total (n=31)	10 (32.3%)	9 (29.0%)	10 (32.3%)	2 (6.5%)
Statistical Analysis	$\chi^2 = 8.242$	$df = 3$	$p < .05$*	

Figure 4. Categorical Healthcare Data (Number of Healthcare Visits after 1 Year)

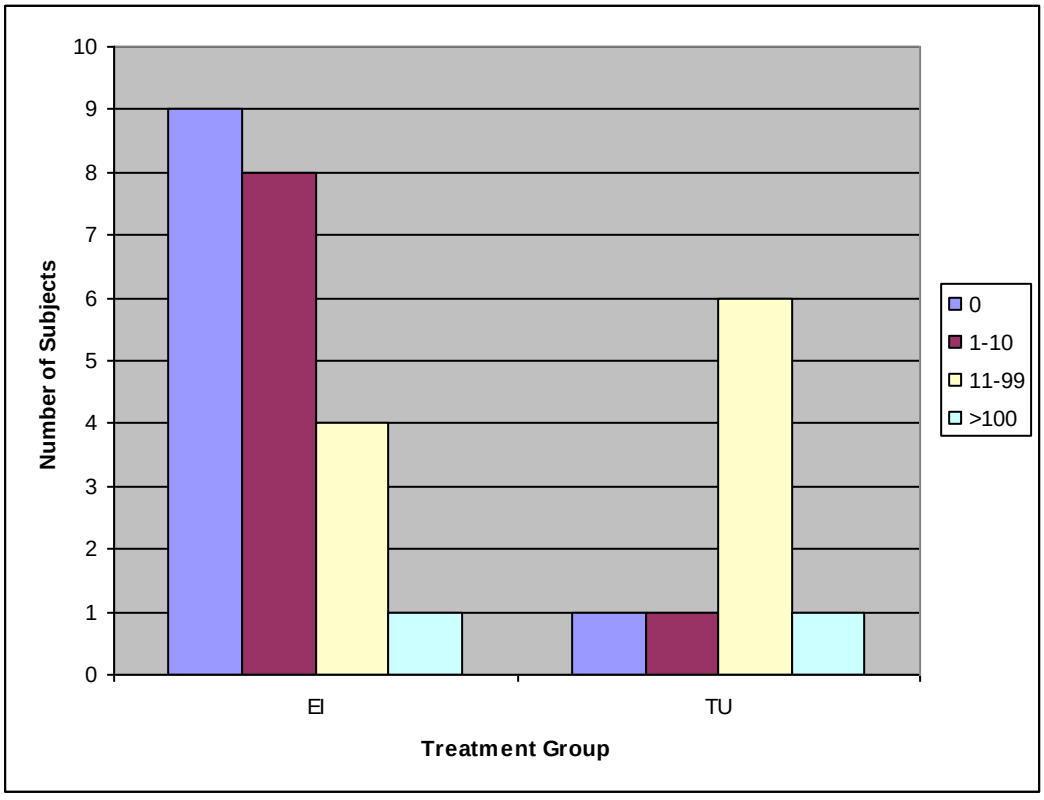


Table 9. Mean Cumulative Workdays Missed since Injury

Treatment Group	Time	
	Baseline	12 Months
EI (n=33)	6.70 (SD = 13.87)	13.55 (SD=27.44)
TU (n=28)	4.29 (SD = 7.83)	25.82 (SD=54.43)
ANOVA	F (1, 59) = 2.201	*p* = .143
ANOVA (with ordinal categories)	F (1, 59) = 4.012	*p* = .05*

Figure 5. Cumulative Workdays Missed

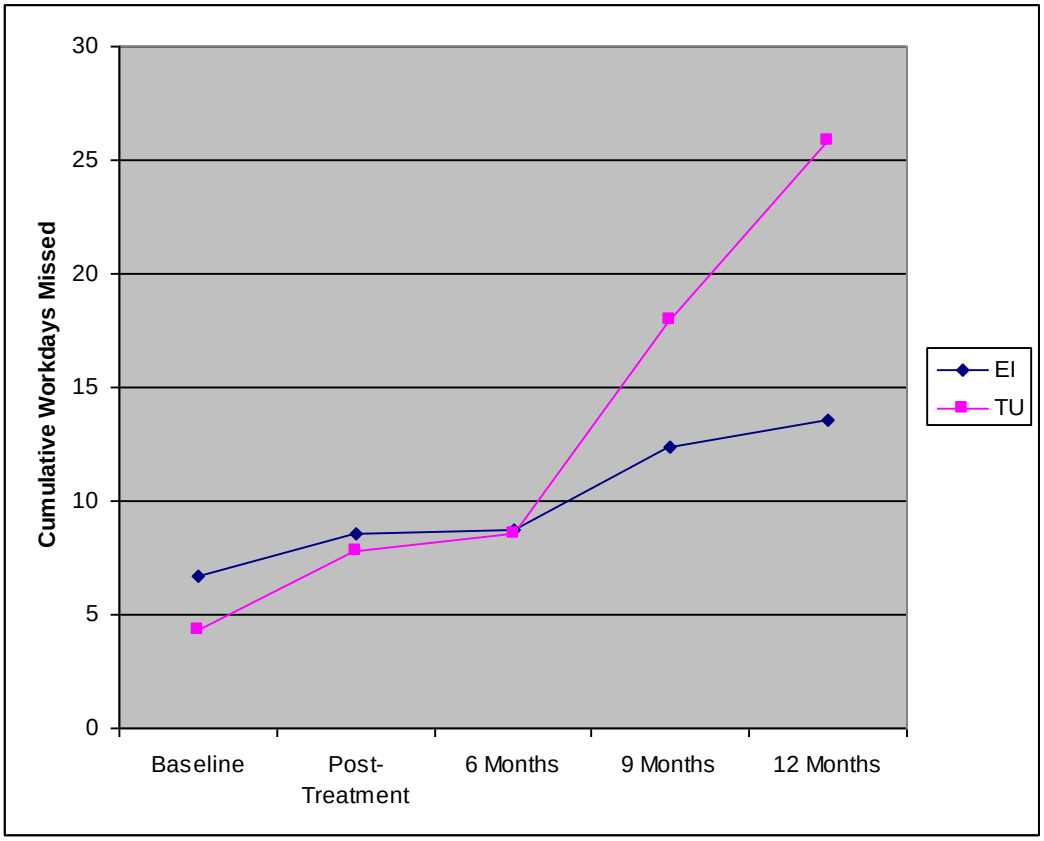


Table 10. Summary of Treatment Costs

Cost Source	Group (n)	Mean (SD)	T-Test
Medical Costs	EI (22) TU (9)	$1,413 (2,717) $5,501 (9,244)	*t* (29) = -1.304, *p* = .226
Treatment Costs	EI (22) TU (9)	$4,025 $0	
Employment Costs	EI (22) TU (9)	$1,731 (4,515) $4,044 (4,354)	*t* (29) = -1.641, *p* = .112
TOTAL COSTS	EI (22) TU (9)	$7,168 (5,544) $9,546 (11,135)	*t* (29) = -.906, *p* = .373

Table 11. Mean Cost Utility Ratio

Treatment Group	Mean Cost ($)	QALY Change Score	Mean CU Ratio ($/QALY)	CI (95%)
EI (22)	7,168	+.15	49,593	(26,426 to 101,110)
TU (9)	9,546	+.13	71,001	(42,065 to 152,737)

Table 12. Incremental Cost Utility Ratio

Treatment Group	Cost per Group ($)	Incremental Cost ($)	Incremental Utility (QALY Change Score)	Incremental CU Ratio ($/QALY)
TU (9)**	9,546	-----	----	----
EI (22)	7,168	-2,378	.02	-235,355

** Dominated Treatment Group

Figure 6. Incremental Cost Utility Plane

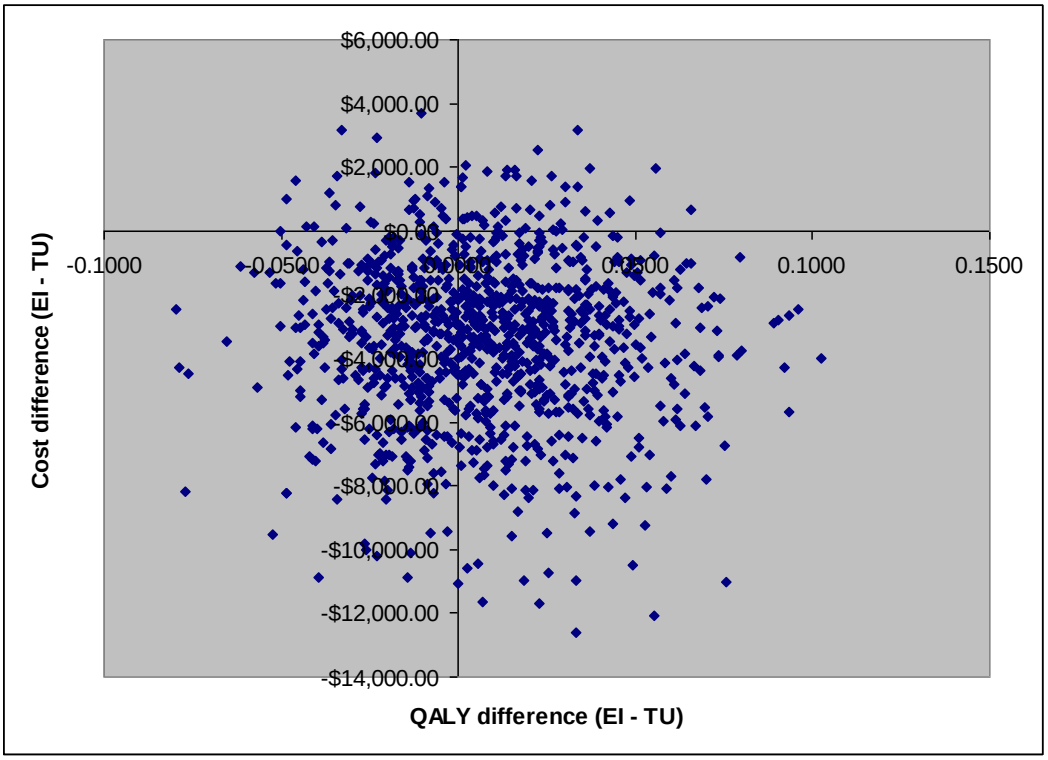
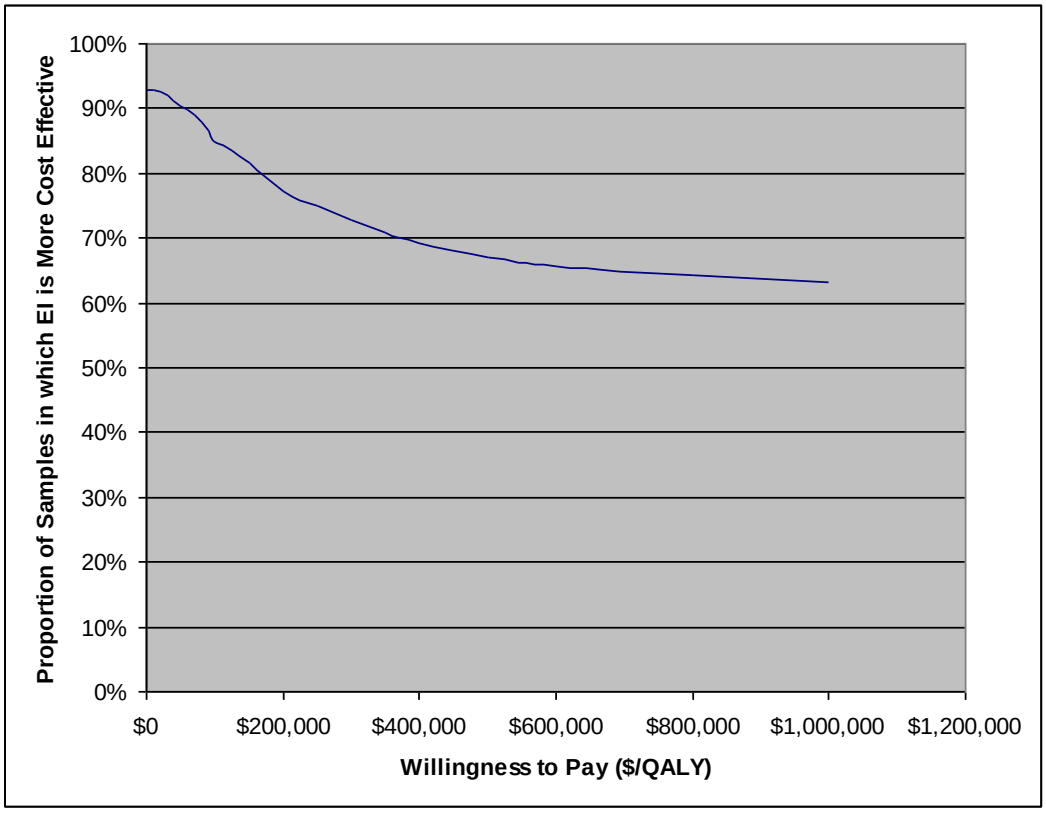


Figure 7. Cost Utility Acceptability Curve



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