Effectiveness of Low Back Pain Manipulative Therapy in Combination with Physical Therapy as Compared to Standard Physical Therapy

Heidi L. Venegas-Rios
UNTHSC, heidi.venegas1@upr.edu

Follow this and additional works at: http://digitalcommons.hsc.unt.edu/theses

Recommended Citation
Venegas-Rios, H. L., ‘Effectiveness of Low Back Pain Manipulative Therapy in Combination with Physical Therapy as Compared to Standard Physical Therapy’ Fort Worth, Tx: University of North Texas Health Science Center; (2009).
http://digitalcommons.hsc.unt.edu/theses/32

This Dissertation is brought to you for free and open access by UNTHSC Scholarly Repository. It has been accepted for inclusion in Theses and Dissertations by an authorized administrator of UNTHSC Scholarly Repository. For more information, please contact Tom.Lyons@unthsc.edu.
ABSTRACT


Low back pain (LBP) can interfere with an individual's ability to work, have a meaningful and active social life, and negatively affects overall quality of life. In recent years, new approaches have been considered as alternative treatments for LBP. Spinal manipulative therapy (SMT) is one of these new approaches to acute LBP treatment. Still, recent studies have found contradicting results in terms of the effectiveness of such alternative therapies. This study aimed to compare the effect of SMT in combination with standard physical therapy (SPT) versus SPT alone to treat chronic LBP. A randomized, controlled, parallel-group trial was undertaken in the Worker's Compensation System, in Puerto Rico. A total of 66 subjects were enrolled in the study. The intervention consisted of adding two consecutive SMT two days apart followed by SPT for a total period of one month. The main outcome measures were functional impairment in activities of daily living, disability and perceived level of pain intensity and frequency. Results showed that both interventions were moderately effective in managing pain and disability in patients with chronic LBP who participate in the Worker's Compensation Program, but that the addition of a SMT seemed to add minimal
supplemental benefit to standard treatment. Future studies should consider including subjective and objective outcome measures in order to maximize information and understand the psychological, as well as, the physical effect LBP has on functional activities. It is also recommended to take into consideration diagnosed and undiagnosed depression among participants as it might have a negative effect on treatment outcomes. Finally, considering a moderate to severe level of impairment and disability at baseline might be important in order to avoid a floor effect and detect improvement with treatment. Including patients at various levels of disability and chronicity might help determine for which level of disability and/or level of pain chronicity this type of treatment is effective.
EFFECTIVENESS OF LOW BACK PAIN MANIPULATIVE THERAPY IN COMBINATION WITH PHYSICAL THERAPY AS COMPARED TO STANDARD PHYSICAL THERAPY

Heidi L. Venegas-Ríos, M.S.

APPROVED:

Major Professor

Committee Member

Committee Member

Committee Member

Department Chair

Dean, School of Public Health
EFFECTIVENESS OF LOW BACK PAIN MANIPULATIVE THERAPY IN COMBINATION WITH PHYSICAL THERAPY AS COMPARED TO STANDARD PHYSICAL THERAPY

DISSERTATION

Presented to the School of Public Health
University of North Texas
Health Science Center at Fort Worth
In Partial Fulfillment of the Requirements

for the Degree of

Doctor of Public Health (Biostatistics)

By
Heidi L. Venegas-Ríos, M.S.
Fort Worth, Texas
May 2009
Copyright by

Heidi L. Venegas-Ríos

2009
ACKNOWLEDGEMENTS

The following printed pages on this dissertation embrace far more than the culmination of years of study. These pages also echo the interactions with many generous and inspiring people I have met since beginning my graduate work in Puerto Rico and later in Texas. The list is extensive, but I treasure each contribution to my development as a scholar and teacher: To my advisor Dr. Karan Singh, and committee members Dr. Sejong Bae, Dr. Shande Chen and Dr. John C. Licciardone for their encouraging words, thoughtful criticism, and time and attention during busy semesters. A special gratitude to Dr. Shande Chen and Dr. Sejong Bae whose expectation of me helped me extend myself beyond my limitations and achieve all I envisioned; you were an inspiration during my academic development.

To Ms. Alice Cord, UNT-HSC Department of Biostatistics’ Senior Administrative Assistant for assisting me with the administrative tasks necessary to complete my doctoral program.

To Dr. Marcus Martin, a gracious professor who showed me that rigorous scholarship can and must be accessible to everyone, that social change is central to intellectual work and, as such, scholars have a responsibility to use the privileges of academia to imagine and create a better world. Thank you for listening when I needed to be heard, and for letting me know that change is a matter of choice.
To Dr. Dwight Santiago, at the Clínica de Medicina Deportiva del Caribe
and all personnel whose collaboration and support at so many levels made this
research experience possible.
TABLE OF CONTENTS

LIST OF TABLES ........................................................................................................ VII

LIST OF FIGURES ....................................................................................................... XI

CHAPTERS

1. INTRODUCTION .................................................................................................. 1
   Research Problem
   Statement of the Purpose
   Hypotheses
   Delimitations
   Limitations
   Assumptions
   Definition of Terms
   Importance of the Study

2. LITERATURE REVIEW .................................................................................... 14
   Etiology and Prevalence
   Financial Burden
   Work-Related LBP
   Available Treatments
   Clinical Prediction rules

3. METHODOLOGY ............................................................................................... 24
   Study Design
   Sample Size
   Data Entry, and Data Cleaning and Reduction
   Missing Information and Data Imputation
   Data Analysis
4. RESULTS ................................................................................................. 48

Characterization of participants’ sociodemographics characteristics and medical history by study group at baseline
Characterization of pain, and levels of functional impairment and disability by study group at baseline
Characterization of pain, functional impairments and disability by study group at 1-week after treatment, and at 1-month follow-up
Characterization of treatment effect on pain intensity and frequency, levels of functional impairments and levels of disability
Clinical improvement by treatment group

5. DISCUSSION AND CONCLUSION .................................................... 92

Discussion
Conclusion
Strengths and Limitations
Recommendations

REFERENCES ............................................................................................ 113

APPENDICES ............................................................................................ 120

A. Targeted Objectives and Outcome Measures

B. Timeline Scheme

C. Institutional Review Board Approval Letter

D. Collaboration Letter

E. Informed Consent

F. Initial Evaluation and Follow-up Evaluations Questionnaires

G. Manipulation Techniques
LIST OF TABLES

TABLE 1.
SOCIO-DEMOGRAPHIC CHARACTERISTICS OF STUDY GROUPS .................................................. 51

TABLE 2.
DISTRIBUTION OF PRE-EXISTING SPINAL DISEASES/CONDITIONS BY STUDY GROUP ................. 52

TABLE 3.
BASELINE OSWESTRY FUNCTIONAL IMPAIRMENT LEVELS PER FUNCTIONAL ACTIVITY BY STUDY GROUP ......................... 54

TABLE 4.
BASELINE OSWESTRY AND ROLAND-MORRIS DISABILITY SCORES AND DISABILITY LEVEL BY STUDY GROUPS ............ 55

TABLE 5.
BASELINE FEAR AVOIDANCE BELIEFS QUESTIONNAIRE SCORES BY STUDY GROUP .......................... 56

TABLE 6.
PAIN EXPERIENCE BY STUDY GROUPS AT BASELINE ............. 57

TABLE 7.
BASELINE, 1-WEEK AFTER TREATMENT, AND 1-MONTH FOLLOW-UP IMPAIRMENT LEVEL BY FUNCTIONAL ACTIVITY BY TREATMENT GROUP ................................................. 60
TABLE 8.
BASELINE, 1-WEEK AFTER TREATMENT AND 1-MONTH FOLLOW-UP DISABILITY SCORES BY TREATMENT GROUP ..... 63

TABLE 9.
BASELINE, 1-WEEK AFTER TREATMENT, AND 1-MONTH FOLLOW-UP PERCEIVED LEVEL OF PAIN INTENSITY AND PAIN FREQUENCY BY TREATMENT GROUP ................................... 65

TABLE 10.
ASSOCIATION BETWEEN TREATMENT AND DEGREE OF IMPAIRMENT AT 1-WEEK AFTER TREATMENT AND 1-MONTH FOLLOW-UP ................................................................. 67

TABLE 11.
DIFFERENCES IN OSWESTRY DISABILITY SCORE CHANGES AT 1-WEEK AFTER TREATMENT, AND AT 1-MONTH FOLLOW-UP BY TREATMENT GROUP ............................................... 70

TABLE 12.
BASELINE, 1-WEEK AFTER TREATMENT, 1-MONTH FOLLOW-UP AND PERCENT CHANGE IN OSWESTRY DISABILITY SCORES BY TREATMENT GROUP – SINGLE-FACTOR REPEATED MEASURES ANOVA................................................................. 75
<table>
<thead>
<tr>
<th>Table</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table 13.</td>
<td>Differences in Roland-Morris Disability Score Changes at 1-week after treatment, and at 1-month follow-up by treatment groups ANOVA</td>
<td>76</td>
</tr>
<tr>
<td>Table 14.</td>
<td>Baseline, 1-week after treatment, 1-month follow-up and percent change in Roland-Morris Disability Scores by treatment group</td>
<td>78</td>
</tr>
<tr>
<td>Table 15.</td>
<td>Differences in changes in pain intensity at 1-week after treatment, and at 1-month follow-up by treatment group</td>
<td>81</td>
</tr>
<tr>
<td>Table 16.</td>
<td>Influence of treatment and time of evaluation on perceived level of pain intensity</td>
<td>83</td>
</tr>
<tr>
<td>Table 17.</td>
<td>Differences in mean changes in pain frequency at 1-week after treatment, and at 1-month follow-up by treatment group intensity</td>
<td>85</td>
</tr>
<tr>
<td>Table 18.</td>
<td>Influence of treatment and time of evaluation on perceived level of pain frequency</td>
<td>87</td>
</tr>
</tbody>
</table>
TABLE 19.

CLINICAL SUCCESS BY TREATMENT GROUP AT 1-WEEK AFTER TREATMENT ................................................................. 88

TABLE 20.

CLINICAL SUCCESS BY TREATMENT GROUP AT 1-MONTH FOLLOW-UP .................................................................................. 89

TABLE 21.

CLINICAL OUTCOME BY CLINICAL PREDICTION RULE STATUS IN THE COMBINED THERAPY GROUP ............................................. 90

TABLE 22.

CLINICAL OUTCOME BY CLINICAL PREDICTION RULE STATUS IN THE COMBINED THERAPY GROUP ............................................. 91
LIST OF FIGURES

FIGURE 1.
TOTAL SAMPLE SIZE AS A FUNCTION OF POWER (EFFECT SIZE OF 7.0) ........................................ 36

FIGURE 2.
POWER AS A FUNCTION OF EFFECT SIZE (TOTAL SAMPLE SIZE OF 66) ........................................... 38

FIGURE 3.
DISTRIBUTION OF PARTICIPANTS LOST TO FOLLOW-UP BY TREATMENT GROUP AND TIME OF ASSESSMENT ........................................ 43

FIGURE 4.
PARTICIPANTS’ ENROLLMENT AND RANDOMIZATION ............. 49
CHAPTER I

INTRODUCTION

The following chapter presents the research problem, the statement of purpose of the study, and the study hypotheses. It also presents a list of delimitations, limitations and assumptions, as well as, a list of definition of terms referred to on this research study. The importance of the present study is also presented.

Research Problem

Low back pain (LBP) is a symptom that cannot be validated by an external standard. It is a disorder with many possible etiologies, occurring in many groups of the population, and with many definitions (Manchikanti, 2000). In fact, in most instances, the cause is difficult to understand, and only in a minority of cases does a direct relationship to some defined organic disease exist. LBP lacking a known etiology has been termed non-specific LBP within the clinical arena. Non-specific LBP is one of the most common physical ailments affecting millions of people worldwide, and constitutes a significant public health problem. LBP affects approximately, 60%-80% of U.S. adults at some point in time during their lifetime, and up to 50% have back pain within a given year (Deyo et al., 1991). LBP can interfere with an individual’s ability to work, have a meaningful and active social life, and negatively affects overall quality of life (Dunn & Croft, 2004).
Its usual course is rapid improvement; however, 5-10% of patients develop persistent low back symptoms (Dunn & Croft, 2004). Unfortunately, acute LBP has a propensity to relapse; consequently, most patients will experience multiple episodes during their life span. Although acute (and under some classifications, sub-acute) episodes that last up to three months are the commonest presentation of LBP, chronic LBP ultimately is more disabling and dispiriting because of the physical impairments it causes and its psychosocial effects. Chronic LBP, which translates into pain lasting for more than 3 months, has been caught up in medical controversies, especially about what treatments are most appropriate.

Some of the medical and economic consequences for society associated to chronic LBP are not only in terms of diagnosis, treatment and medication which can amount to more than $20 billions annually, but also in terms of indirect costs which can go as high as $50 billions per year (Deyo et al., 1991). Chronic LBP has also been associated with reduced productivity at the work place (Maetzel & Li, 2002). In fact, even though this ailment usually has a benign course, LBP is the most common cause of employment-related disability, and a leading contributor to sick days at work (IJzelenberg & Burdorf, 2004; IJzelenberg et al., 2004; Meerdng et al., 2005).
Physical therapy treatment has been, for many decades, the most standard treatment for chronic LBP. Yet, a lack of evidence for some types of physical therapy interventions, and a shortage of cost-effectiveness data for treatment of LBP, has led to controversy and uncertainty within the medical and health allied professions (Rivero-Arias et al., 2006). Therefore, despite being identified as a serious health concern, effective means of managing chronic LBP still remains controversial (Boswell et al., 2005; Boswell et al., 2007; Manchikanti et al., 2003; Watson et al., 2004).

In recent years, and as a response to these concerns, new approaches have been considered as alternative treatments for LBP, specifically acute LBP. Spinal manipulative therapy is one of these new approaches to acute LBP treatment. Still, recent studies have found contradicting results in terms of the effectiveness of such alternative therapies (Assendelft et al., 2003; 2004; Bronfort et al., 2004; Margo, 2005). Several experts (Childs et al., 2004; Childs et al., 2003) have stated that these discrepant conclusions from clinical research of spinal manipulation therapy for acute LBP can be attributed to misclassification of patients. As a result, a group of clinical scientists (Flynn, T. et al., 2002) developed a Clinical Prediction Rule (CPR) to identify patients with LBP who are likely to improve with spinal manipulation.
Results from recent research studies considering the CPR developed by Flynn et al., 2002, have been more than confirmatory in terms of the faulty classification of patients most likely to benefit from this type of therapy (Childs et al., 2003; Cleland, Fritz, Childs et al., 2006). In fact, studies have reported that approximately 90% of all patients satisfying the CPR demonstrate a successful outcome within one week (Childs et al., 2003; Cleland, Fritz, Whitman et al., 2006; Flynn, T. et al., 2002) including two consecutive sessions of spinal manipulations. However, findings can only be generalized to patients suffering from acute LBP. Whether these findings are also valid for chronic back pain still remains unresolved.

Statement of the Purpose

The main purpose of the study was to evaluate the effectiveness of manipulative therapy in combination with standard physical therapy to treat chronic LBP compared to standard physical therapy alone, in a population of patients within the Worker's Compensation Program in Puerto Rico. The primary objectives were:

1. To determine if manipulative therapy combined with standard physical therapy is more effective than standard physical therapy alone in reducing functional impairments in terms of the following activities of daily living: pain, personal care (e.g. washing, dressing, eating), lifting, walking, sitting, standing, sleeping, social life, sexual activity and traveling.
2. To determine if manipulative therapy combined with standard physical therapy is more effective than standard physical therapy alone in reducing level of disability.

3. To determine if manipulative therapy combined with standard physical therapy is more effective than standard physical therapy alone in reducing perceived level pain, and pain frequency.

Secondary objectives were:

4. To determine the effectiveness of manipulative therapy in a sub-group of patients with LBP that satisfy the CPR’s developed by Flynn et al. (Flynn, T. et al., 2002).

5. To determine if the CPR’s are correctly predicting patients most likely to benefit from manual therapy from the sample receiving the combination of manipulative therapy with standard physical therapy.

Hypotheses

This study had the following primary hypotheses:

1. Patients receiving a combined therapy, which includes manipulative therapy and standard therapy, would significantly be more likely to have lower levels of functional impairments than patients receiving standard physical therapy alone at 1-week and 4-weeks after treatment.
2. Patients receiving a combined therapy would have a significantly higher
difference in mean Oswestry disability questionnaire (ODQ) score change
when compared to patients receiving standard physical therapy alone at 1-
week and 4-weeks after treatment.

3. Patients receiving a combined therapy would have a significantly higher
difference in mean perceived level of pain change when compared to
patients receiving standard physical therapy alone at 1-week and 4-weeks
after treatment.

4. Patients receiving a combined therapy would have a significantly higher
proportion of clinical successes than patients receiving standard physical
therapy alone at 1-week and 4-weeks after treatment.

Secondary hypotheses are:

5. Patients meeting the CPR's developed by Flynn et al. (Flynn, T. et al.,
2002) within the manipulation combined treatment group would have a
significantly higher proportion of clinical successes at 1-week and 4-weeks
after treatment, than patients not meeting the CPRs.

6. The CPRs would correctly identify patients most likely to benefit from
manual therapy from the sample of patients receiving the combined
therapy intervention.

**Delimitations**

The study was delimited by:

- Age (21-65 y/o)
New LBP referrals among Worker’s Compensation population in San Juan, Puerto Rico, USA

LBP NOT caused by systemic or organic diseases, cancers, or psychiatric disorders, central nervous system involvement (upper motor neuron lesion); and nerve root involvement (decreased sensation or reflexes).

LBP NOT associated to acute severe LBP needing immediate treatment or surgery, past back fractures or surgery

Women that are NOT pregnant

**Limitations**

The study was limited by:

- Cases referred from Worker’s Compensation program to specific clinic
- New Worker’s Compensation program referrals of LBP
- Self-reported outcomes measures
- Subjective outcomes measures
- Self-administered questionnaires

**Assumptions**

This study relied on the following assumptions:

- Patients would be able to read and answer the informed consent, baseline and follow-up questionnaires
Patients would answer the questionnaires truthfully and accurately

Patients would complete all sections of the questionnaires

Patients would complete treatment as assigned and will complete rehabilitation program prescribed (no drop outs)

Definition of Terms

The following are operational definitions of terms and outcomes measures in this study.

- **Manipulative Therapy (manual therapy, or spinal manipulation)** - is defined as a form of manual therapy, which involves movement of a joint passed its usual end range of motion, but not passed its anatomic range of motion (Shekelle, 1994).

- **Standard Physical Therapy** - is defined as a form of therapy, which involves massage, regulated exercise, water, light, heat, and electricity (Hsieh et al., 2006).

- **Combined Therapy** - is defined as a form of therapy, which involves both manual therapy and standard physical therapy.

- **Functional Impairment** – is defined as a difficulty that substantially interferes with or limits role functioning in one or more major life activities, including basic living skills (e.g. eating, bathing, dressing); instrumental living skills (e.g. maintaining a household, managing money, getting around in the community, taking a prescribed medication); and functioning in social, family and vocational/educational contexts (Roland & Fairbank,
2000). In this study, functional impairment will be determined based on scores from individual items on the ODQ. This questionnaire has ten questions with six ratings. Higher scores on individual items demonstrate higher functional impairment on that particular item (e.g. higher score on lifting demonstrates higher functional impairment in lifting activity). In addition, the total score within a single item (functional activity) will be divided into three levels of functional impairment, considering 0-2 as minimal functional impairment, 3-4 as moderate functional impairment, and 4-5 as severe functional impairment.

- **Level of Disability** – is defined as the temporary or long-term reduction of a person’s capacity to function. An impairment, in and of itself, does not necessarily constitute a disability: it must "substantially limit" these activities. In this study, level of disability will be determined based on the total sum of scores on the ODQ (for all 10 items) divided by 50, and expressed as a percentage. Higher percentages demonstrate higher levels of disability (Roland & Fairbank, 2000). The total raw score will be divided into five grades for measuring the degree of disability, taking 0-10 as minimal disability, 11-20 as moderate disability, 21-30 as severe disability, 31-40 as crippled, and ≥ 41 as bed bound (Hsieh et al., 2004).

- **Perceived Level of Pain** – is defined as the temporary or long-term feeling of physical hurt, discomfort, distress and/or agony perceived by individuals. It is subjective in nature. In this study, perceived level of pain
will be measured using the Visual Analog Scale (VAS). The VAS for pain is a straight line with one end meaning no pain and the other end meaning the worst pain imaginable. A patient marks a point on the line that matches the amount of pain he or she feels. It assigns numeric scores to the patients’ perceived level of pain by measuring the length in millimeters from the no pain end of the scale to the patients’ mark. The VAS is a scale that goes from zero, or no pain, to 100, which translates to worst pain imaginable (Bijur et al., 2001).

- **Perceived Frequency of Pain** – is defined as the frequency of physical hurt, discomfort, distress and/or agony perceived by individuals. It is subjective in nature. In this study, perceived frequency of pain will be measured using the Visual Analog Scale (VAS). The VAS is a scale that goes from zero, or occasional pain, to 100, which translates to constant pain (Bijur et al., 2001).

- **Clinical Prediction Rules (CPR)** – is defined as a clinical diagnostic and classification tool that quantifies the individual contributions that various components of the history, physical exam, and basic laboratory results make towards the diagnosis, prognosis or likely response to treatment in an individual patient (Laupacis et al., 1997). In this study, we will used the CPR’s developed by Flynn et al. (Flynn, T. et al., 2002). The developed CPR contains five variables: symptom duration of less than 16 days (pain chronicity), at least one hip with more than 35° of internal rotation (hip
internal rotation asymmetry), lumbar hypo-mobility, no symptoms distal to the knee (no radiculopathy), and a Fear Avoidance Beliefs Questionnaire work subscale (FABQ-W) score of less than 19 points. CPR are met if at least four of the five components are met (Flynn, T. et al., 2002).

  o **Pain Chronicity** – is defined as duration of pain in days (Flynn, T. et al., 2002).

  o **Hip Internal Rotation Asymmetry** – is defined as a range of motion test revealing at least one hip with greater than 35º of internal rotation range of motion (Flynn, T. et al., 2002).

  o **Lumbar Hypo-Mobility** – is defined as decreased anterior-posterior range of joint movement at the lumbar area of the spine (Flynn, T. et al., 2002).

  o **Radiculopathy** – is defined as symptoms of pain distal to the knee (Flynn, T. et al., 2002).

  o **Fear and avoidance beliefs** – defined as an individual's beliefs about the influence of physical activity or work on LBP. In this study, fear and avoidance beliefs will be determined using the FABQ. The FABQ seeks to quantify the level of fear of pain and beliefs about the need to change behavior to avoid pain in individuals with LBP. Each item of the FABQ is scored 0 to 6, with higher numbers indicating increased levels of fear avoidance beliefs. Higher scores on
each sub-scale represent increased fear-avoidance beliefs (Kovacs et al., 2006).

- **Minimum detectable difference** – was defined as a pre-post mean difference of 7.0 points on the ODQ between groups (Childs et al., 2004; Cleland, Fritz, Childs et al., 2006; Flynn, T. et al., 2002).

- **Clinical Improvement** – was defined based on the analysis of serial questionnaire scores. Change in OSW point score at each assessment will be calculated as $(\text{OWS score } t_2 - \text{OSW score } t_1)$ (Childs et al., 2004; Flynn, T. et al., 2002).

- **Percentage of Improvement** – was defined based on the analysis of serial questionnaire scores, and calculated as $(\text{OWS score } t_2 - \text{OSW score } t_1) / (\text{OWS score } t_1) \times 100\%$ (Childs et al., 2004; Flynn, T. et al., 2002).

- **Treatment Success** – was defined as a percentage of improvement ≥ 50% on the OSW within evaluations (Childs et al., 2004; Childs et al., 2003; Flynn, T. et al., 2002).

- **Treatment Failure** - was defined as a percentage of improvement < 50% on the OSW within evaluations (Childs et al., 2004; Childs et al., 2003; Flynn, T. et al., 2002).

*Importance of the Study*

This study’s aim was to determine if manipulative therapy constitutes a viable therapy for chronic LBP. Specifically, the study attempted to detect if patients receiving manipulative therapy were able to reduce their perceived level of pain,
reduce impairment, resume their activities of daily living, and reduce their level of disability.

Results from this study will help determine whether this type of therapy can be used as a tertiary prevention method to reduce long-term disability among LBP patients. Moreover, if this type of therapy proves to be beneficial, then its utilization in clinical settings will help reduced the proportion of low back disabled adults generally.
CHAPTER II

LITERATURE REVIEW

This chapter presents a detailed review of the literature about the epidemiology, etiology and treatment strategies information related to low back pain (LBP) and its management. It also presents the most current knowledge on manipulation therapy as a treatment for non-specific LBP.

Etiology and Prevalence

LBP is a global human experience that goes from acute to chronic onset that could result in prolonged disability (Cleland et al., 2006; Manek & MacGregor, 2005). While not a disease by itself, LBP is a major cause of disability (Manek & MacGregor, 2005) and activity limitation (Andersson, 1999). Clinically, two types – specific and non-specific - of LBP disorders can be identified. The prevalence of specific LBP is about 10% in North America and is attributed to conditions such as cancer, fractures, and arthritis, among others. On the other hand, the prevalence of non-specific LBP is about 90% (Manek & MacGregor, 2005). Non-specific LBP does not seem to have an identifiable cause (Manek & MacGregor, 2005).

It has been estimated that approximately 70%-85% of the population has suffered LBP at least once in their lifetime (Andersson, 1999). The impact of LBP has been so broad that is the 2nd reason for physician visits after the common cold, 3rd cause for surgical procedures, and 5th cause for hospital admissions.
(Andersson, 1999; Katz 2006). Furthermore, once a person develops LBP, the probability of recurrence is up to 85%.

Nearly 50% of physical therapy visits within the US are related to LBP (Fritz et al. 2007). The etiology of LBP is multifactorial in nature, with individual, psychological and occupational factors involved (Andersson, 1999; Manek & MacGregor, 2005). Some of the individual factors related to LBP are smoking (Frymoyer et al., 1983; Manek & MacGregor, 2005), obesity (Manek & MacGregor, 2005), socioeconomic status (Katz 2006) and low educational level (Rainville et al., 1997; Manek & MacGregor 2005, Katz 2006). Several of the most identifiable psychological risk factors for LBP are stress (Manek & MacGregor 2005; Katz 2006), depression (Rainville et al., 1997; Manek & MacGregor, 2005) and fear avoidance behaviors (Fritz et al. 2001, 2002, Manek & MacGregor 2005; George et al. 2008). Occupational risk factors comprised of medium/heavy labor (Frymoyer et al., 1983; Manek & MacGregor, 2005), job dissatisfaction (Manek & MacGregor, 2005), night shifts (Manek & MacGregor, 2005), repetitive lifting (Frymoyer et al. 1983; Manek & MacGregor, 2005), and whole-body vibration (Frymoyer et al., 1983; Manek & MacGregor, 2005).

Financial Burden

LBP has become a financial burden in the United States with $50 billion spent annually in medical care (Cleland et al., 2006). These costs have reached comparable proportions to other chronic diseases such as heart disease, depression and diabetes (Cleland et al., 2006). The working task force and
industries have been directly affected by LBP and its sequelae. It has been estimated that approximately 5% of injured workers never return to work due to their LBP (Katz, 2006) and seek disability compensation (Andersson, 1999). Approximately 70-76% of direct compensation costs are related to LBP alone (Fritz et al., 2001; Katz 2006, Godges et al., 2008) with 37% being associated to physical therapy services (Cleland et al., 2006). The indirect costs related to LBP in the task force rise up to approximately $20 billion, and these costs are primarily related to absenteeism, reduced productivity and care giving (Katz, 2006). Work related LBP is also multifactorial in nature, and relates to the type of job performed (Manek & MacGregor, 2005; Katz 2006), severity of symptoms (Manek & MacGregor, 2005), economical status of the individual affected (Manek & MacGregor, 2005; Katz, 2006), social behaviors (Manek & MacGregor, 2005; Katz 2006), treatment and therapy effectiveness (Manek & MacGregor, 2005), and to legal involved seeking compensation actions (Rainville et al., 1997; Manek & MacGregor, 2005; Katz, 2006).

*Work-Related LBP*

Work related LBP in patients receiving some kind of compensation is of great research interest due to all factors involved, and the profile of those suffering from it. The profile of those injured workers suffering from LBP receiving compensation for their injury when compared to injured individuals not receiving any type of compensation comprise of lower education level, greater medium/heavy labor, greater leg pain, greater neurological symptoms, greater...
depression, greater disability and lesser flexibility (Rainville et al., 1997). It has been reported that injured workers receiving compensation have a tendency to improve over time their physical function and disability, without significant improvements or minimal improvements in self-reported level and frequency of pain (Rainville et al., 1997; Werneke et al., 2008).

**Available Treatments**

There are several treatment strategies for the treatment of chronic LBP, with exercise, patient education and manual therapy being the most commonly used nowadays. Therapeutic exercises have been advocated as one of the best treatment strategies to reduce fear avoidance behaviors, facilitate functional mobility and reduce sick leave from work (Manek & MacGregor, 2005). The rationale behind early mobility and restoration of motion lies within the scope that dysfunctional motion is a consequence of pain (Simmonds, 2006). If motion can be restore and kept within functional levels, the impact of pain on quality of life will be significantly reduced (Simmonds, 2006). Educational resources such as brochures, lectures, and questions and answer sessions, among others, from part of the healthcare professional have shown to reduce fear avoidance beliefs, increase physical activity, and help patients return to work without restrictions (Godges et al., 2008). Although exercise and patient education have been advocated as good therapeutic interventions in the management of work-related LBP, it is the combination of both that have shown greater improvements from this ailment (Schonstein et al., 2003; Klaber & Moffat, 2004). Researchers have
shown that injured workers with LBP who participate in job conditioning programs including aerobic training, strengthening exercises and patient education present lower fear avoidance beliefs (Klaber Moffat et al., 2004), decrease disability (Klaber Moffat et al., 2004) and reduce sick leave from 45-243 days (Schonstein et al., 2003).

From all the interventions encompassed as part of a therapy approach for LBP, spinal manipulative therapy has been widely used on patients showing acute symptoms. It includes a high velocity, low amplitude (“thrust”) joint manipulation. This type of manipulative therapy is literally a "hands-on" approach in which professionally licensed specialists use leverage and a series of exercises to mobilize spinal structures and restore back mobility. These manipulative techniques have proven to be safe in patients with LBP; and, no more than 3% of patients have reported worsening with treatment (Childs et al. 2006). Spinal manipulation has been studied in many randomized controlled trials (RCTs), which are heterogeneous in size, design, and quality of performance. These trials have been summarized in numerous systematic reviews (Bronfort et al., 2004; Margo, 2005). Results from these systematic reviews have reached discordant results - some randomized trials have shown a benefit, while other trials have not - and have been less than encouraging (Assendelft et al., 2003; Bronfort et al., 2004; Margo, 2005), leading to uncertainty in regards to the effectiveness of spinal manipulative therapy as treatment for LBP patients (Assendelft et al., 2004). These conflicting
conclusions are reflected in the various recommendations in national clinical practice guidelines, with some recommending manipulation and others not (Koes et al., 2001).

Researchers have argued that part of these discrepant conclusions in clinical trials assessing spinal manipulation therapy for LBP is attributable to a failure to account for the importance of diagnosing and classifying patients. Broad inclusion criteria seemed to have resulted in heterogeneous sample of acute LBP patients, for whom this type of therapy offers little or no benefit, thus diluting treatment efficacy (Bouter et al., 1998). As a result, developing methods for matching patients with acute LBP to treatments that are most likely to benefit them has become an important research priority during the past decade (Childs et al., 2004). Today, CPR have become an important tool used to assist clinicians in decision making when caring for patients (McGinn et al., 2000; Childs et al. 2003; Fritz et al. 2007). These evidence-based guidelines and prediction rules improve decision-making and outcomes by matching interventions to those patients who are most likely to benefit from them (Childs et al., 2003; Fritz et al., 2007).

Clinical Prediction Rules

Recently, Flynn and colleagues (Flynn, T. et al., 2002) developed a clinical prediction rule model for identifying patients with acute LBP who are likely to improve with spinal manipulation. They examined a series of patients with non-radicular LBP who underwent a spinal manipulation intervention. They reported
that five factors formed the most parsimonious set of predictors for identifying patients who achieved at least 50% improvement in disability within one week with a maximum of two manipulation interventions. Researchers concluded that patients with LBP most likely to respond to spinal manipulation can be correctly identified \textit{a priori} ( Flynn, T. et al., 2002).

The developed CPR’s contains five dimensions: symptom duration of less than 16 days, at least one hip with more than 35° of internal rotation, lumbar hypo-mobility, no symptoms distal to the knee, and a Fear Avoidance Beliefs Questionnaire work subscale (FABQ-W) score of less than 19. Their results also showed that about 45% of patients were successfully treated without any attempt at prediction, but that satisfying at least four of the five criteria raised the probability of success to 95%. Patients satisfying at least three of the criteria were found to have a 68% probability of success.

Results from recent research studies considering the CPRs developed by Flynn et al., 2002, have been more than confirmatory (Childs et al., 2003; Cleland, Fritz, Childs et al., 2006). In fact, studies have reported that approximately 90% of all patients satisfying the CPR’s demonstrate a successful outcome within one week –success defined as a 50% reduction or greater in disability, as measured by the Oswestry Disability Questionnaire (ODQ) (Childs et al., 2003; Cleland, Fritz, Whitman et al., 2006; Flynn, T. et al., 2002) within two sessions of spinal manipulation.
The rationale behind these five clinical criteria lies on medical evidence suggesting that if the criteria are met, the probability for improvement, or resolutions of symptoms, might improve. The first criterion is based on symptom acuity, in which it is desirable that patients have less than 16 days of LBP symptomathology. Typically, patients suffering from LBP that does not resolve by four to eight weeks after initial episode or acute exacerbation have greater probability for increased disability levels and decreased likelihood for returning to work (Fritz et al., 2002; Werneke et al., 2008). Clinical trials have shown that patients with more acute LBP symptoms respond better to manipulative therapy (Flynn et al., 2002). Additionally, early intervention in patients with LBP has shown that 100% of patients could return to work without restrictions by 45 days after injury (Godges et al., 2008). The second criterion is based on ruling out hip pathology. Patients with 35 degrees or more are expected to be free from hip joint pathology that could refer pain to the low back and interfere with activities of daily living. The third criterion of pain distal to the knee joint identifies those patients with greater neurological signs and symptoms indicating greater neurological damage and greater possibility for disability (Frymoyer et al., 1983). Patients without radicular symptoms passed the knee joint are expected to present with a centralization effect helping in the resolution or improvement of their symptoms (Fritz et al., 2007). These patients are typically 17% of the cases within an age range from 18 – 45 years (Werneke et al., 2008). The fourth criterion is based on general lumbar spine mobility. It is based on the ability of
the spine to glide from posterior to anterior throughout its normal range of motion (Fritz et al., 2007). Patients with hypomobility (lack of motion) on their lumbar spine are considered to suffer from mechanical LBP. The use of localized treatment strategies restoring lumbar mobility has the ability of reinstating lumbar motion and decreased LBP (Flynn et al., 2002, Fritz et al., 2007). The previous four factors all together have proven to increase the probability for improvement when they are met (Fritz et al., 2000). The last and fifth criterion is based on patients’ fear avoidance beliefs. Fear avoidance beliefs are the most important predictor of absenteeism and no return to work in injured workers (Fritz et al. 2001; 2002). Elevated scores ($\geq 29$ points) on the FABQ work subscale represent maladaptive behaviors from part of the patient (Fritz et al., 2002). Maladaptive behaviors facilitate the development of exaggerated pain perception (Fritz et al., 2002). Once these behaviors are integrated, patients initiate avoiding activities that they anticipate will cause LBP (Fritz et al., 2002). Avoidance of activities of daily living or any other activity reduces general movement quantity and intensity, exacerbate fear, and prolong disability (Fritz et al., 2002).

Therefore, the purpose of this clinical study was to determine if manipulative therapy combined with standard physical therapy is more efficient than standard physical therapy alone in terms of reduction of functional impairments, disability and pain intensity and frequency levels on injured workers suffering from chronic LBP. In addition, we identified two sub-groups of patients among those who received the spinal manipulation therapy – those who satisfied
the CPR’s and those who did not satisfy the prediction rules as developed by Flynn et al. (Flynn, T. et al., 2002) in order to analyze treatment outcomes among these two subgroups.
CHAPTER III

METHODOLOGY

The following chapter presents the research methodology utilized in this study. It provides a detailed explanation of the study design, including an in depth description of the study participants, together with the inclusion and exclusion criteria used to determine the eligibility for the study. The chapter also describes the clinical evaluation and treatments considered to test the study hypotheses. As a final point, a detailed account of the statistical methods and techniques considered to the test the hypotheses is provided.

Study Design

This study was conducted as a two stage randomized clinical trial in which physiotherapists performing the evaluations were blinded to every participant’s treatment assignment and scores on all previous outcome questionnaires and physical measurements. The head physician at the “Clínica de Medicina Deportiva del Caribe, Inc. in San Juan, Puerto Rico” followed a randomization scheme developed by the principal investigator to ensure proper random treatment assignment to participants. The randomization scheme was developed a priori, and each treatment assignment was kept confidential in closed numbered envelopes. Treatment assignment envelopes were only opened after a participant had consented to participate in the study. The study head physician was also responsible for keeping a list of such randomization in a
secure file, under key, at the physical therapy department at the “Clínica de Medicina Deportiva del Caribe, Inc. in San Juan, Puerto Rico”. Only the head physician at the clinic and the study’s principal investigator had access to these files. After randomization to either group, physical therapy intervention was prescribed considering specific needs of each patient.

The first stage of the study consisted of a two parallel arms clinical trial to determine if manipulative therapy in combination with standard physical therapy was more efficient in reducing physical impairment, disability and perceived level of pain in patients suffering from chronic low back pain (LBP) than standard physical therapy alone. During this stage, participants were assigned to either of the two treatments, and were evaluated based on their improvement during and after their prescribed therapy program at 1 week, and 4 weeks after initiation of treatment.

The second stage of the study consisted of a post-treatment sub-classification of patients receiving the manipulative therapy intervention. These patients were categorized depending on whether they met or did not meet at least three of the five Clinical Prediction Rules (CPR) described by Flynn et al. (Flynn, T. et al., 2002). Further analysis determined if patients who satisfied the CPR’s had a better outcome than those not satisfying the criteria, and if the CPR’s were correctly identifying patients most likely to benefit from the manipulative therapy.
Physical therapists. Physical therapists participating in this study had, on average, about seven to ten years of professional experience in the area of orthopaedic, sports medicine and manual therapy. Two of the physical therapists participating in this study were trained by one of the principal investigators to perform the specific manipulative techniques used as experimental treatment in this study. Training included visual demonstrations, hands-on experience and technique evaluation. Each trainee was not considered suitable to perform these maneuvers until he/she could perform each one correctly in two attempts or less. Training continued until all physiotherapists had successfully mastered each technique. Physiotherapists performing the manipulative therapy reached training criteria within a two-week period. In addition, these two physical therapists were closely supervised by the physical therapist in charge for the first month to assure proper performance of manipulative techniques.

Study participants. Participants were referred by the Worker’s Compensation System (WCS) to the “Clínica de Medicina Deportiva del Caribe, Inc. in San Juan, Puerto Rico”. Referrals were recommended by the WCS physician or case manager. WCS contracts with the “Clínica de Medicina Deportiva del Caribe” to offer medical care and physical therapy services for LBP patients enrolled in the System. Inclusion criteria consisted of new referrals of patient with complaints of chronic LBP that were between the ages of 21 and 65 years of age. Exclusion criteria consisted of the following: low back pain patients on follow-up appointments, low back pain caused by systemic or organic
diseases such as lupus, rheumatoid arthritis, cancers, among others; psychiatric disorders, including diagnosed chronic major depression, bi-polar disorder, schizophrenia and fibromyalgia; pregnancy; acute severe pain needing immediate treatment or surgery; past back surgery, fractures, or osteoporosis; central nervous system involvement (upper motor neuron lesion); nerve root involvement as a consequence of a lumbar disc extrusion, or lumbar disc sequestration; and severely decreased deep tendon reflexes, severely decreased myotomal sensation, and severely decreased manual muscle test compared to contra lateral side.

All new LBP patients meeting the study’s inclusion and exclusion criteria were invited to participate in this study by the head physician at the “Clínica de Medicina Deportiva del Caribe”. All individuals willing to participate in the study were scheduled for a subsequent visit with one of the principal investigators where they received, read and signed the University of Puerto Rico IRB approved informed consent form. In addition, participants were given the opportunity to ask questions about the study’s purpose, procedures, risks and benefits, as well as, privacy and confidentiality issues. Patients that had agreed to participate in the study, and had read and signed the informed consent were randomly assigned to either of the two treatments. A pre-established randomization scheme was developed for treatment allocation for each enrolled patient a priori. Each treatment allocation was concealed in a numbered closed envelope that was opened only after a patient had signed the consent form.
Examination. After randomization, each participant received a questionnaire containing a variety of self-report measures, followed by a standardized history and physical examination by the researcher physical therapist. The questionnaire designed for this study had three sections, one section for personal information and medical history of the patient, a second section for the patients’ self-report measures in relation to the characterization of their LBP in terms of perceived level of pain, functional impairment and disability, and a final section about demographic information (See Appendix F).

Self-report measures included the Spanish version of the following questionnaires: the Modified Oswestry Disability Questionnaire (ODQ), the Roland-Morris Disability Questionnaire (RMDQ), the Visual Analog Scale (VAS), for perceived level of pain and pain frequency, the Fear Avoidance Beliefs Questionnaire (FABQ), and a body diagram to assess distribution of symptoms. The ODQ was the primary outcome in this study. The RMDQ, FABQ and VAS for pain constituted secondary outcomes. When evaluating the treatment efficacy, the modified Spanish version of the ODQ was used. Its validity has been well established, and reliability widely tested (Roland & Fairbank, 2000). This questionnaire has ten questions with six ratings. Higher scores on individual items demonstrate higher functional impairment on that particular item (e.g. higher score on lifting demonstrates higher functional impairment in lifting activity). In addition, the total score within a single item (functional activity) was divided into three levels of functional impairment, considering 0-2 as minimal
functional impairment, 3-4 as moderate functional impairment, and 4-5 as severe
functional impairment. The total sum of scores (for all 10 items) divided by 50
determined the disability percentage for each subject. Likewise, the total score
was divided into five grades for measuring the degree of disability, taking 0-10 as
minimal disability, 11-20 as moderate disability, 21-30 as severe disability, 31-40
as crippled, and ≥ 41 as bed bound.

The RMDQ is a disability measure in which greater levels of disability are
reflected by higher numbers on a 24-point scale. The validity and reliability of the
Spanish version have also been well established and reported elsewhere
(Kovacs et al., 2002). Percentage of disability for each patient was determined as
the total of items checked divided by 24 (total of items). The total scores
measured by the RMDQ were divided into three score scales for measuring the
degree of disability, taking 0-8 as minimal disability, 9-16 as moderate disability,
and 17-24 as significant disability (Kovacs et al., 2002).

Perceived level of pain was measured using the VAS. The VAS assigns
numeric scores to the patients’ perceived level of pain by measuring the length in
millimeters from the no pain end of the scale to the patients’ mark. The VAS is a
100-point scale that goes from zero, or no pain, to 100, which translates to worst
pain imaginable.
Perceived frequency of pain was measured using the VAS. The VAS assigns numeric scores to the patients’ perceived frequency of pain by measuring the length in millimeters from the no pain end of the scale to the patients’ mark. The VAS is a 100-point scale that goes from zero, or occasional pain, to 100, which translates to constant pain.

The Spanish version of the FABQ was used to assess the patient’s beliefs about the influence of activity on their chronic LBP. The Spanish version of the FABQ has good comprehensibility, internal consistency, and reliability (Kovacs et al., 2006). The questionnaire cannot be analyzed parametrically, but only non-parametrically due to its skewed distribution. The FABQ seeks to quantify the level of fear of pain and beliefs about the need to change behavior to avoid pain in individuals with LBP. Each item of the FABQ is scored 0 to 6, with higher numbers indicating increased levels of fear avoidance beliefs. Two subscales are contained within the FABQ: a seven-item work subscale (score range 0-42) and a four-item physical activity subscale (score range 0-24). Higher scores on each sub-scale represent increased fear-avoidance beliefs (Kovacs et al., 2006). This measure of fear-avoidance beliefs was used to categorize patients in the experimental treatment as satisfying, or not satisfying the CPR’s. Patients with a score of less than 19 points in the work subscale were categorized as satisfying the criterion of the CPR’s.
Currently, these outcome instruments are the standard for measuring LBP treatment effectiveness in all settings. Therefore, their use for the present study was paramount not only to validate our outcome measures, but also to make them comparable to earlier and future studies in the area of LBP treatment.

The patient’s history consisted of socio-demographic information including age, sex, educational level, marital status, employment status, occupation, and income. In addition, past medical history, location and nature of symptoms, smoking status, overall past treatment satisfaction, and date of onset of the most recent episode was collected. The date of onset was used to determine if the patient met the CPR’s criterion of less than 16 days duration.

Separate sets of questionnaires were used at baseline, at one-week after treatment, and at 1-month follow-up assessments. Sections on personal information, medical history of the patient and demographic information was only included at baseline during the initial examination. No information and questionnaire scores on previous assessments were disclosed to participants, or therapists, throughout the therapy intervention in order to reduce bias.

*Intervention.* All patients completed each of the self-report measures at baseline (first day), at end of the first week, and at 1-month follow-up. Physical examination was only gathered at baseline, and at the end of the prescribed rehabilitation program. Both groups received similar treatments of conventional physical therapy interventions, from the first session until termination of treatment, on a daily basis. Patients assigned to manipulative therapy received
the lumbar and sacroiliac manipulative techniques during to physical therapy sessions, one day apart during the first week of treatment (See Appendix #). From the third session on, both treatment groups received similar physical therapy interventions until the end of their prescribed rehabilitation program.

Two manipulative techniques were used as experimental intervention in this study. Both techniques are equally effective in treating non-specific acute LBP. CPR’s were developed using lumbo-pelvic thrust manipulation techniques. However, recent evidence suggests that different manual therapy techniques may result in similar outcomes (Cleland, Fritz, Whitman et al., 2006). Therefore, studies show that CPR’s is not manipulation-type-specific as previously thought.

In this study, one technique targeted, more specifically, the sacro-iliac area, while the other targeted the lumbo-pelvic area (see manipulative pictures on Appendix G). The sacro-iliac technique is performed with the patient in supine position. The therapist stands in the opposite side to be manipulated. The side to be manipulated was selected using the following algorithm: first, the side of tenderness during sacro-iliac and/or lumbar palpation; if this test was negative, the side reported by the patient to be more painful was manipulated. The legs of the patient were moved away from the therapist side. The hands of the patient were behind his head in a crisscross fashion. The trunk of the patient was moved away from the therapist. The trunk of the patient was slowly and passively rotated towards the therapist’s side and a quick posterior-inferior thrust was delivered to the anterior superior iliac spine.
After the manipulation, the therapist noted if a cavitation (audible pop) was felt during the maneuver. If a cavitation was not felt, the patient was repositioned, and the manipulation repeated a second time in the same side. If a cavitation was not felt on the second attempt, the process was repeated in the opposite side twice in the same manner. If the manipulation did not produce cavitation after four attempts (two at each side), the physical therapist proceeded with the lumbo-pelvic manipulation.

The lumbo-pelvic technique was performed after the sacro-iliac manipulation with the patient side lying. The side to be manipulated was selected with the same algorithm used for the sacro-iliac technique. First, the side of tenderness during sacro-iliac and/or lumbar palpation; if this test was negative, the side reported by the patient to be more painful was manipulated. Patients were side lying straight in the treatment table with both legs aligned on top of each other and bottom arm under shoulder. The therapist was standing facing the patient’s belly. The upper leg was flexed while the therapist palpated the patient’s lower back. The upper leg was flexed until the point the therapist felt movement of the lumbar spine. Then, the therapist took the patient’s bottom arm and rotated the patient, slowly and passively, upward, until movement was felt in the lumbar spine. After positioning was over, one of the therapist’s forearm rested on the patient’s shoulder, while the other and elbow rested on the patient’s greater trochanter and hip. After positioning was over, a high velocity, low amplitude thrust of the pelvis in an anterior direction was applied. After the
manipulation, the therapist noted if a cavitation (audible pop) was felt during the maneuver. If a cavitation was not felt, the patient was repositioned and the manipulation repeated a second time in the same side. If a cavitation was not felt on the second attempt, the process was repeated on the opposite side, twice in the same manner. If the manipulation did not produce cavitation after four attempts (two at each side), the physical therapist proceeded with the therapy prescribed to the patient by his/her doctor.

No additional effort was attempted in order to achieve cavitation during manipulation. It has been reported that perceived cavitation (audible “pop”) may not relate to improved outcomes from high-velocity thrust manipulation for patients with non-radicular LBP at either an immediate or longer-term follow-up (Flynn, T. W. et al., 2006). Participants assigned to standard physical therapy received physical therapy as prescribed by their physician. Treatments included, but were not limited to modalities such as electrotherapy, ultrasound, diathermy, and thermal agents for pain management, stabilization, strengthening and flexibility exercises, and soft tissue techniques as decided by the physical therapist. Manipulative techniques were always performed after modalities but before the sequence of therapeutic exercises.

Blinding. Blinding physical therapists providing the intervention and patients to manipulative therapy versus standard physical therapy was unfeasible; therefore, blinding occurred at the therapist level. Physiotherapists performing initial evaluation were blinded to the patients’ assigned treatment. In
addition, both the manipulative therapist and the physical therapist were blind to pre-treatment assessment. Patients were blind for pre-treatment pain scores and ratings when filling-out post-treatment questionnaires, and, blind to post-treatment pain scores and ratings when answering 1-month follow-ups.

Sample Size

The OSWdisability scores after one week of treatment was used as the primary outcome on the study. We sought to detect a mean difference in change (delta) of 7.0 points in raw scores between groups at one week after treatment, based on a two-sided two-independent samples t-test. Studies had suggested a common standard deviation of approximately 10.0 points for 1-week change in OSWscores (Cleland, Fritz, Childs et al., 2006). After considering a significance level of 5% (two-sided) and a statistical power of 80%, a minimum of 68 patients were considered for recruitment, with 34 participants in each arm. Participants were randomly assigned to treatment. Figure 1 presents the total sample size needed, as a function of power, to detect an effect size of 0.7.
Based on previous work (Cleland, Fritz, Childs et al., 2006; Cleland, Fritz, Whitman et al., 2006; Flynn, T. et al., 2002; Fritz et al., 2005), approximately 52% of all patients suffering from LBP are expected to meet at least four of the CPR's criteria. Therefore, we expected that about 17 of our study patients would fulfill at least four of the five criteria of the CPR per group. We considered a power of 80% and a significant level of 5%, assumed a common standard deviation of 10, and a 15-point difference in mean OSW scores, which is equivalent to the 50% improvement by patients who satisfy the CPR as suggested in previous studies (Cleland, Fritz, Childs et al., 2006; Cleland, Fritz, Whitman et al., 2006; Flynn, T. et al., 2002; Fritz et al., 2005). Consequently, a sample size of 9 patients per group was needed to detect a 15-point difference in mean OSW scores between those satisfying the CPR criteria and those who did not. The initial sample

![Figure 1. Total sample size as a function of power (effect size of 7.0)](image)
calculation provided adequate power to determine improvement based on the CPR without having to increase the sample size. A 10% dropout rate was considered; thus, sample size was increased to 76 subjects, 38 per arm. However, strict exclusion criteria significantly reduced the pool of potential study participants; therefore, slowing down and hampering the process of enrollment of patients into the study. As a result, only a total of 66 patients out of a total of 76 needed to achieve 80% power were invited to the study after an entire year of enrollment. The power achieved for the primary outcome of the study (difference in changes in OSW scores after 1-week of treatment between intervention groups) was 5.5%. The reduction in power was the result of a treatment effect much more lower than expected and reported by others (Cleland, Fritz, Childs et al., 2006). It is important to note that no previous studies have been conducted on a population of patients within the Worker’s Compensation Program. Figure 2 presents the power achieved for the primary outcome as a function of the effect size.
Data Entry, and Data Cleaning and Reduction

All data provided by the participants via questionnaires were transferred into an electronic replica of the paper-based questionnaire developed in the windows-based version of the EPI-INFO software. All physical function measurements collected by the head physical therapist were also transferred into the electronic database. The data was entered using double data entry method in order to increase its accuracy. All discrepancies encountered were resolved by authenticating the data with original questionnaire values.

Once the database was created it was transferred into SPSS® (Statistical Package for the Social Sciences) statistical software for data cleaning and reduction. The data cleaning process included the utilization of summary statistics, including distribution of frequencies for categorical variables, and measures of central tendency and dispersion for continuous variables. Out-of-
range values encountered during data cleaning were resolved by authenticating data with original questionnaire values.

Data reduction was initiated after data cleaning processes were finished. During this procedure both disability scores, the OSW disability and the RM disability scores, were calculated. Both disability scores were also categorized by levels of disability according to Hsieh et al., 2004 and Kovacs et al., 2002. The total OSW disability score was initially divided into five categories to measure the degree of disability, and considered scores of 0-10 as minimal disability, 11-20 as moderate disability, 21-30 as severe disability, 31-40 as crippled, and ≥ 41 as bed bound. Yet, only a very small number of participants reported disability scores corresponding to crippled or bed-bound levels of disability. Consequently, OSW disability scores were later categorized into two levels of disability: minimal to moderate disability (scores 0-20), and severe to extremely severe level of disability (scores 21-50). In addition, the total score within a single item (functional activity) had to be divided into two, instead of three levels of functional impairment, considering 0-2 as minimal to moderate functional impairment, and 3-5 as severe to extremely severe functional impairment.

Due to the small number of participants also reporting lower disability scores on the RMDQ, scores were also divided into only two categories, instead of three as described by Kovacs et al., 2002. Scores 0-12 were considered as minimal to moderate disability and 13-24 as severe to extremely severe disability.
**Missing Information and Data Imputation**

Two different types of missing information were contemplated before considering any statistical analysis of the data. First, missing information in terms of particular questions not answered by participants (item non-response) and second, missing information in terms of a particular questionnaire on the series of three not answered due to lost to follow-up (unit non-response). Item non-response was not a significant problem on this study. Almost all questionnaires were completed in their entirety. In fact, only a single question within the series of questionnaires had a percentage of missing values close to 10% (9.1%). The variable with missing values was that aimed at cataloging how the participant’s LBP affected their sexual activity. This particular question is part of the composite of functional activities considered to determine the OSWdisability score; therefore, it was important to consider imputation of such values. Further analysis revealed that the number of missing values for this particular question was similarly distributed across treatment groups (4/33, 12.1% within the combined treatment group, and 2/33, 6.1% within the standard treatment group). Additionally, it was observed that women had a higher tendency to leave this question unanswered when compared to men (5/33, 15.2% within women, and 1/33, 3.0% within men), but similarly across treatment groups. Therefore, missing values for this particular question were substituted by estimated mean values reported by participants within the same treatment group and of the same sex. Other questions on the composite of functional activities having a very small
percentage of missing values (< 4%) were substituted using similar methods. An additional form of item non-response resulted from questions answered at baseline, but that were left unanswered (skipped) during follow-up questionnaires. This type of item non-response was resolved by carrying over the last value reported for that same question by participants (last value carried over imputation method). Less than 2% of all variables in the study presented item non-response at follow-up questionnaires, and within these variables less than 1% had to be imputed by carrying over the last reported value.

This study followed the intention-to-treat (ITT) strategy. Analysis by ITT compares the study groups in terms of the treatment to which they were randomly allocated, irrespective of the treatment they actually received, or other trial outcomes. Regardless of protocol deviations and participant withdrawal or temporal loss to follow-up, analysis was performed according to the assigned treatment group. The random allocation scheme considered in this study was aimed at ensuring that study participants’ characteristics that may have affected the outcome under investigation were balanced between the allocated treatments. This was to ensure that any differences in outcomes observed between groups were actually a result of the combined intervention. Any analysis other than an ITT analysis (eg, one that excludes lost to follow-up participants) would have potentially compromise the balance of these characteristics, and introduce bias into the treatment comparisons. Therefore, ITT strategy was considered, even though it generally gives a conservative estimate of the
treatment effect compared with what would be expected if all participants completed all interventions and questionnaire series.

Unit non-response (uncompleted questionnaires due to loss to follow-up) represented a serious problem in terms of the ITT strategy and data analysis because of the repeated measures nature of the data. Yet, in order to act in accordance with the ITT strategy, participants lost to follow-up had to be considered during the analyses. Figure 3 presents the distribution of participants lost to follow-up by treatment group.

As observed on Figure 3 there was no noteworthy difference in terms of number of participants with unit non-response between treatment groups by time of assessment. At the 1-week after treatment assessment only one participant on the standard treatment group did not attend to the clinic to continue with the rehabilitation treatment. This particular participant dropped out of the rehabilitation program altogether, including its participation on the Worker’s Compensation program. All participants on the combined treatment group attended their rehabilitation treatment and completed the 1-week after treatment questionnaire. In addition to the participant on the standard treatment group who discontinued the rehabilitation program, two other participants on the same group were lost to follow-up and did not complete the 1-month follow-up questionnaire. Two participants on the combined treatment group did not return to the clinic to finish their treatment programs and did not complete the 1-month follow-up questionnaire. In order to act in accordance with the ITT strategy all uncompleted
questionnaires due to drop-out or loss to follow-up were imputed by carrying forward the last observation prior to drop-out or loss to follow-up as the observation from the last visit recorded for the participant.

**Figure 3.** Distribution of participants lost to follow-up by treatment group and time of assessment

*Data Analysis*

Summary statistics, including frequencies and percentages for categorical variables, and measures of central tendency and dispersion for continuous variables were calculated to summarize the data. Baseline socio-demographic
information was compared across treatment groups to evaluate the adequacy of the randomization. Two-sided two independent samples t-tests, Chi-square tests for homogeneity of proportions, and Fisher’s exact tests were used for this purpose. Statistical adjustments for baseline characteristics differing between treatment groups were considered. An intention-to-treat (ITT) analysis was utilized wherein all participants were analyzed in the group to which they were originally assigned, and uncompleted questionnaires due to drop-out or loss to follow-up were imputed by carrying the last observation recorded forward as values for the last visit. All drop-outs and the reason for dropping out of the study were reported. An a priori alpha level of 0.05 was used for all analyses. All data were screened to ensure they met all assumptions necessary for the inferential statistical techniques considered. On some cases alternate statistical techniques were considered when assumptions were not met.

The change in OSW scores after 1-week of treatment was the primary outcome of this study. Clinical improvement over time was determined based on the analysis of serial questionnaire scores. Change in OSW point score at each assessment was calculated as \((\text{OSW}_{t2} - \text{OSW}_{t1})\), and percentage of improvement was calculated as \((\text{OSW}_{t2} - \text{OSW}_{t1}) / (\text{OSW}_{t1}) \times 100\%\). Change in RMDQ point score and RMDQ percent of improvement were calculated using the same method.
In order to determine if the combined treatment was more efficient than the standard treatment in terms of reduction of disability a two-sided two-independent samples t-test on OSW changes after 1-week of treatment was considered. Differences in OSW changes at 1-month follow-up between treatment groups were also evaluated to determine the long term effect of treatment. Similar analyses were conducted considering RMDQ scores and pain level and frequency as dependent variables.

Secondary analyses to determine if the combined treatment was more efficient than the standard treatment in terms of reduction of disability included a two factors repeated measures analysis of variance (2-way RM-ANOVA) using the OSW score as the dependent variable, treatment group as the between groups factor (standard physical therapy vs. combined therapy) and time of evaluation (baseline, 1-week after treatment, and 1-month follow-up) as the within subjects factor. This type of statistical modeling provided an opportunity to determine if the treatment factor had a significant effect in reducing the level of disability, as well as, to determine if an immediate and/or long-term treatment effect existed. Yet, baseline OSW disability scores were statistically different. Consequently, a repeated measures analysis of covariance (RM-ANCOVA) adjusting for baseline disability scores was used. Two factors repeated measures analysis of variance (2-way RM-ANOVA) were conducted considering RMDQ scores and pain level and frequency as dependent variables.
Originally, ordinal logistic regression models were considered in order to determine if the combined treatment was more efficient than standard treatment in terms of reducing specific functional impairment. Yet, due to the small number of participants reporting greater levels of disability, scores had to be dichotomized into minimal to moderate disability and severe to extremely severe disability. Consequently, binary logistic models, instead of ordinal logistic models were considered. A different model was conducted for each functional impairment variable. These logistic models considered treatment as the independent variable and baseline functional impairment scores as a covariate when appropriate. Baseline characteristics differing between groups were also considered on all final models.

Treatment success was defined as a percentage of improvement ≥50%, and treatment failure as a percentage of improvement of <50%, as suggested by previous studies (Childs et al., 2004; Cleland et al., 2007; Cleland, Fritz, Childs et al., 2006; Cleland, Fritz, Whitman et al., 2006). Difference in the proportion of patients with a successful outcome between treatment groups were analyzed using the Chi-square test for homogeneity of proportions, or Fisher’s exact test, as appropriate.

Secondary analyses included categorization of patients randomized to combined therapy treatment with respect to the CPR’s developed by Flynn et al. (Flynn, T. et al., 2002). Patients satisfying four or more of the five criteria included in the CPR were categorized as those patients most likely to have had
benefited from the manual therapy, and those with less than four of the five criteria, as less likely to have had benefited from it. Again, patients were also categorized based on success (≥50% improvement) or failure (<50% improvement). Yet, no participants with a successful treatment satisfied at least four of the clinical prediction rules. Therefore, participants were re-categorized as those satisfying at least three of the prediction rules. Chi-square test for independence was used to determine if treatment success was dependent upon CPR's status. In order to determine if the CPR correctly identified patients most likely to benefit from manual therapy, Kappa analysis were conducted. The Kappa statistics determined the level of agreement between the CPR and the patients' observed outcomes.
CHAPTER IV

RESULTS

The following chapter presents the results of the research study. It provides a description of the study participants, and variables considered throughout the study. A comprehensive description of the effect of the combined treatment for non-specific chronic low back pain (LBP) will be presented.

Socio-Demographic Characteristics and Medical History by Study Group at Baseline

During the period of June 14, 2007 to June 14, 2008, a total of 480 individuals were referred by the study primary physician as potential participants. Out of the 480 individuals identified as potential participants, 72 met all inclusion and exclusion criteria. All but one individual were invited to participate in the study. One individual was withdrawn from the pool of potential participants because the complaint of LBP was only secondary to a neck pain compliant. Only five individuals refused to participate after being invited to the study. Reasons for refusals were: 1.) felt uncomfortable participating on a study (n=2, 40%), 2.) thought the experimental treatment could worsen the pain (n=3, 60%). Figure 4 shows the overall participation rate was 92.96% (66/71).
480 consecutive patients, 21-65 years of age, with non-specific low back pain, who were referred to physical therapy between May 1, 2007 – June 14, 2008 by the Worker's Compensation System in PR, were considered potential participants.

408 patients excluded due to out-of-range age, spinal fractures, spinal surgery, osteoporosis, central nervous system involvement, and/or mayor psychiatric disorder.

72 patients met all inclusion and exclusion

1 patient was not invited to participate due to multiple complaints in addition to lower back pain

71 were invited to participate in the study

5 patients refused to participate in the study

66 patients accepted to participate, signed informed consent, and were randomized into combined or standard treatment groups

33 patients randomized

33 patients randomized

Figure 4. Participants’ enrollment and randomization
Each individual was randomly assigned to either the experimental or control group after consenting to participate in the study in writing. During treatment randomization, 33 participants were assigned to each treatment. Table 1 presents the distribution of socio-demographic characteristics considered in this study. Most socio-demographic characteristics were evenly distributed across study groups.

In order to determine if differences in terms of socio-demographic characteristics between groups were statistically meaningful, some of the categories within variables were collapsed and recoded. The mean age within the experimental and control group was 40.69 ± 9.03 and 42.59 ± 10.62 years, respectively. The participants’ sex was evenly distributed between samples; about 50% of participants were women in both groups. About 60% of participants in the standard treatment group were either legally married or living in a marriage-like union, whereas 70% of participants in the combined treatment group were in such a marital situation. Educational attainment was moderately lower within the combined treatment group, than within the standard treatment group. Almost 30% of participants within the combined treatment group had 12 years of education or less; whereas, 20% in the standard treatment had that level of education. Yet, 90% of participants in the combined treatment group were employed (full-time and/or part-time); but, only 75% of those in the standard treatment were employed. In terms of family income, about 30% of both groups reported to earn more than $35,000 annually.
There were no significant differences between study groups in terms of general socio-demographic characteristics, such as age, sex, marital status, education level, employment status, and annual income (p-values > 0.05).

Table 1. Socio-Demographic Characteristics of Study Groups

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Combined treatment (n=33)</th>
<th>Standard treatment (n=33)</th>
<th>p-value&lt;sup&gt;d&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean ± SD)</td>
<td>40.69 ± 9.03&lt;sup&gt;a&lt;/sup&gt;</td>
<td>42.59 ± 10.62</td>
<td>0.555</td>
</tr>
<tr>
<td>Sex (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>16 (48.5)</td>
<td>17 (51.5)</td>
<td>0.806</td>
</tr>
<tr>
<td>Male</td>
<td>17 (51.5)</td>
<td>16 (48.5)</td>
<td></td>
</tr>
<tr>
<td>Marital status No. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Legally married/Living together</td>
<td>23 (69.7)</td>
<td>19 (57.6)</td>
<td>0.306</td>
</tr>
<tr>
<td>Divorced/Separated/Widowed/</td>
<td>10 (30.3)</td>
<td>14 (42.4)</td>
<td></td>
</tr>
<tr>
<td>Never married</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Education attainment No. (%)</td>
<td></td>
<td></td>
<td>0.566</td>
</tr>
<tr>
<td>High school graduate or less</td>
<td>9 (27.3)</td>
<td>7 (21.2)</td>
<td></td>
</tr>
<tr>
<td>Some college/College graduate/Graduate school</td>
<td>24 (72.7)</td>
<td>26 (78.8)</td>
<td></td>
</tr>
<tr>
<td>Employment status No. (%)</td>
<td></td>
<td></td>
<td>0.099</td>
</tr>
<tr>
<td>Employed full-time/part-time</td>
<td>30 (90.9)</td>
<td>25 (75.8)</td>
<td></td>
</tr>
<tr>
<td>Unemployed/Stay at home</td>
<td>3 (9.1)</td>
<td>8 (24.2)</td>
<td></td>
</tr>
<tr>
<td>Annual income No. (%)&lt;sup&gt;b, c&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; $15,000</td>
<td>13 (39.4)</td>
<td>10 (31.2)</td>
<td>0.757</td>
</tr>
<tr>
<td>$15,000 - $34,999</td>
<td>10 (30.3)</td>
<td>12 (37.5)</td>
<td></td>
</tr>
<tr>
<td>≥$35,000</td>
<td>10 (30.3)</td>
<td>10 (31.2)</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup> One subject did not report age.

<sup>b</sup> Unemployed subjects were excluded (combined treatment, n =31; standard treatment, n = 30).

<sup>c</sup> One subject in the standard treatment group did not report income.

<sup>d</sup> Comparisons based on $\chi^2$, or two-sided two-independent samples $t$ test.
Medical history and clinical characteristics reported at baseline were also evenly distributed across treatment groups. As presented on Table 2, the frequency of pre-existing diseases/disorders related to the spine was very low in both groups, as expected due to the exclusion criteria established on the study. None of the pre-existing conditions predominated within a single group. The most common spinal disease/disorder reported by the participants was having a diagnosis of herniated disks; however, both treatment groups reported a prevalence of 75.8%. The second most common spinal diseases/disorders reported were osteoarthritis, scoliosis and spinal stenosis; yet, the prevalence of these conditions were statistically equivalent between treatment groups.

Table 2. Distribution of Pre-Existing Spinal Diseases/Conditions by Study Group

<table>
<thead>
<tr>
<th>Characteristics, No. (%)</th>
<th>Combined treatment, (n=33)</th>
<th>Standard treatment, (n=33)</th>
<th>p-value (^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osteoporosis</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>-</td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>2 (6.1)</td>
<td>6 (18.2)</td>
<td>0.258</td>
</tr>
<tr>
<td>Lordosis</td>
<td>2 (6.1)</td>
<td>0 (0.0)</td>
<td>0.492</td>
</tr>
<tr>
<td>Scoliosis</td>
<td>5 (15.2)</td>
<td>3 (9.1)</td>
<td>0.708</td>
</tr>
<tr>
<td>Kyphosis</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>-</td>
</tr>
<tr>
<td>Herniated disk</td>
<td>25 (75.8)</td>
<td>25 (75.8)</td>
<td>1.000</td>
</tr>
<tr>
<td>Spinal stenosis</td>
<td>3 (9.1)</td>
<td>5 (15.2)</td>
<td>0.708</td>
</tr>
<tr>
<td>Spondylolysis</td>
<td>2 (6.1)</td>
<td>2 (6.1)</td>
<td>1.000</td>
</tr>
<tr>
<td>Spondilolisthesis</td>
<td>1 (3.0)</td>
<td>0 (0.0)</td>
<td>1.000</td>
</tr>
<tr>
<td>Fractured vertebra</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>-</td>
</tr>
</tbody>
</table>

\(^a\) Comparisons between treatment groups based on Fisher’s Exact test.
Functional Impairment, Disability and Levels of Pain by Study Group at Baseline

The distribution of level of functional impairment, level of disability and fear avoidance behavior adoption at work settings is illustrated on Tables 3 through 5. Table 3 shows that baseline OSW functional impairment levels were significantly different between study groups, in terms of time standing and sitting, and marginally different in terms of difficulty sleeping. The combined treatment showed significantly lower levels of impairments in these functional activities at baseline, as compared to the standard treatment group. As a result, the combined therapy group showed a lower mean raw OSW disability score at baseline, when compared to the standard therapy group (15.85 ± 6.05, vs. 19.82 ±7.15 group mean raw scores, respectively, p=0.018) (Table 5).

Categorization of OSW total raw scores into disability levels revealed that few subjects reported either a severe or extremely severe level of disability in both groups. Consequently, OSW levels of disability were re-coded as minimum to moderate disability, and severe to extremely severe disability. Treatment groups did not differ in terms of level of disability as measured by the ODQ.
Table 3. *Baseline Oswestry Functional Impairment Levels per Functional Activity* by Study Group

<table>
<thead>
<tr>
<th>Functional Impairments</th>
<th>Level of impairment</th>
<th>Combined treatment (n=33)</th>
<th>Standard treatment (n=33)</th>
<th>p-value$^a$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain intensity</td>
<td>Minimum to moderate</td>
<td>14 (42.4)</td>
<td>11 (33.2)</td>
<td>0.612</td>
</tr>
<tr>
<td></td>
<td>Severe to extremely severe</td>
<td>19 (57.6)</td>
<td>12 (66.7)</td>
<td></td>
</tr>
<tr>
<td>Standing</td>
<td>Minimum to moderate</td>
<td>27 (81.8)</td>
<td>19 (57.6)</td>
<td>0.059</td>
</tr>
<tr>
<td></td>
<td>Severe to extremely severe</td>
<td>6 (18.2)</td>
<td>14 (42.2)</td>
<td></td>
</tr>
<tr>
<td>Personal care</td>
<td>Minimum to moderate</td>
<td>28 (84.8)</td>
<td>29 (87.9)</td>
<td>1.000</td>
</tr>
<tr>
<td></td>
<td>Severe to extremely severe</td>
<td>5 (15.2)</td>
<td>4 (12.1)</td>
<td></td>
</tr>
<tr>
<td>Sleeping</td>
<td>Minimum to moderate</td>
<td>32 (97.0)</td>
<td>27 (81.8)</td>
<td>0.105</td>
</tr>
<tr>
<td></td>
<td>Severe to extremely severe</td>
<td>1 (3.0)</td>
<td>6 (18.2)</td>
<td></td>
</tr>
<tr>
<td>Lifting</td>
<td>Minimum to moderate</td>
<td>17 (51.5)</td>
<td>15 (45.5)</td>
<td>0.806</td>
</tr>
<tr>
<td></td>
<td>Severe to extremely severe</td>
<td>16 (48.5)</td>
<td>18 (54.5)</td>
<td></td>
</tr>
<tr>
<td>Sexual activity</td>
<td>Minimum to moderate</td>
<td>28 (84.8)</td>
<td>23 (69.7)</td>
<td>0.240</td>
</tr>
<tr>
<td></td>
<td>Severe to extremely severe</td>
<td>5 (15.2)</td>
<td>10 (30.3)</td>
<td></td>
</tr>
<tr>
<td>Walking</td>
<td>Minimum to moderate</td>
<td>30 (90.9)</td>
<td>27 (81.8)</td>
<td>0.475</td>
</tr>
<tr>
<td></td>
<td>Severe to extremely severe</td>
<td>3 (9.1)</td>
<td>6 (18.2)</td>
<td></td>
</tr>
<tr>
<td>Social life</td>
<td>Minimum to moderate</td>
<td>25 (75.8)</td>
<td>21 (63.6)</td>
<td>0.422</td>
</tr>
<tr>
<td></td>
<td>Severe to extremely severe</td>
<td>8 (24.2)</td>
<td>12 (36.4)</td>
<td></td>
</tr>
<tr>
<td>Sitting</td>
<td>Minimum to moderate</td>
<td>24 (72.7)</td>
<td>15 (45.5)</td>
<td>0.044</td>
</tr>
<tr>
<td></td>
<td>Severe to extremely severe</td>
<td>9 (27.3)</td>
<td>18 (54.5)</td>
<td></td>
</tr>
<tr>
<td>Traveling</td>
<td>Minimum to moderate</td>
<td>27 (81.8)</td>
<td>27 (81.8)</td>
<td>1.000</td>
</tr>
<tr>
<td></td>
<td>Severe to extremely severe</td>
<td>6 (18.2)</td>
<td>6 (18.2)</td>
<td></td>
</tr>
</tbody>
</table>

$^a$ Comparisons between treatment groups based on two-sided Fisher’s exact test.
The RMDQ was not able to detect any differences in mean raw disability scores between the combined and standard treatment groups (9.67 ± 4.31, vs. 10.39 ± 4.27 mean total raw scores, respectively, p = 0.493). As presented on Table 4, RM levels of disability were equally distributed across treatments. In fact, most of the participant in the combined and standard treatment groups reported minimal or moderate disability (72.7% and 69.7%, respectively, p > 0.05).

Table 4. *Baseline Oswestry and Roland-Morris Disability Scores and Disability Level by Study Group*

<table>
<thead>
<tr>
<th>Disability</th>
<th>Combined treatment</th>
<th>Standard treatment</th>
<th>p-value&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n=33)</td>
<td>(n=33)</td>
<td></td>
</tr>
<tr>
<td>Oswestry</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Raw disability score (mean±SD)</td>
<td>15.85 ± 6.05</td>
<td>19.82 ± 7.15</td>
<td>0.018</td>
</tr>
<tr>
<td>Level of disability No. (%)</td>
<td></td>
<td></td>
<td>0.408</td>
</tr>
<tr>
<td>Minimal to moderate</td>
<td>26 (78.8)</td>
<td>22 (66.7)</td>
<td></td>
</tr>
<tr>
<td>Severe to extremely severe</td>
<td>7 (21.2)</td>
<td>11 (33.3)</td>
<td></td>
</tr>
<tr>
<td>Roland-Morris</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Raw disability score (mean±SD)</td>
<td>9.67 ± 4.31</td>
<td>10.39 ± 4.27</td>
<td>0.493</td>
</tr>
<tr>
<td>Level of disability No. (%)</td>
<td></td>
<td></td>
<td>1.000</td>
</tr>
<tr>
<td>Minimal to moderate</td>
<td>24 (72.7)</td>
<td>22 (69.7)</td>
<td></td>
</tr>
<tr>
<td>Severe to extremely severe</td>
<td>9 (27.3)</td>
<td>10 (30.3)</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup> Comparisons between treatment groups based on two-sided Fisher’s Exact test or two-independent samples t test.
A direct comparison of frequency of disability levels between the ODQ and RMDQ revealed that both measures were arriving at similar results. Even though there was a highly significant correlation between OSW and RM raw disability scores \( (\rho = 0.70, p < 0.001) \), the ODQ seemed to discriminate better between treatment groups when considering raw scores. It appears that the OSW disability raw score was more sensitive when trying to identify differences between patients with lower levels of disability.

The fear avoidance beliefs' work section questionnaire revealed that both treatment groups had a tendency to adopt behaviors of activity evasion at the work place (Table 5). In fact, mean raw fear avoidance beliefs scores were not significantly different between study groups \( (p = 0.126) \).

Table 5. Baseline Fear Avoidance Beliefs Questionnaire Scores by Study Group

<table>
<thead>
<tr>
<th>Fear Avoidance Beliefs at the work place</th>
<th>Combined treatment ( (n=33) )</th>
<th>Standard treatment ( (n=33) )</th>
<th>( p )-value(^a )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score (mean ± SD)</td>
<td>27.27 ± 8.34</td>
<td>30.42 ± 8.17</td>
<td>0.126</td>
</tr>
</tbody>
</table>

\(^a\) Comparisons between treatment groups based on two-independent samples \( t \) test.

Table 6 depicts differences between groups in terms of pain characterization. There were no significant differences across study groups in terms of perceived level of pain, pain frequency, and pain location; except, for pain irradiating below the knee. The prevalence of pain irradiating below the knee
was considerably higher in the standard treatment group, than in the combined treatment group (42.4% vs. 18.2%, respectively, \( p = 0.059 \)). All other characteristics related to characterization of pain were similarly distributed across study groups.

Table 6. *Pain Experience by Study Group at Baseline*

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Combined treatment (n=33)</th>
<th>Standard treatment (n=33)</th>
<th>p-value (^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perceived level of pain (mean ± SD)</td>
<td>58.61 ± 20.69</td>
<td>55.52 ± 15.63</td>
<td>0.496</td>
</tr>
<tr>
<td>Frequency of pain (mean ± SD)</td>
<td>70.64 ± 27.13</td>
<td>73.15 ± 22.82</td>
<td>0.685</td>
</tr>
</tbody>
</table>

*Pain irradiating along the: No. (%)*

- **Spine**: 13 (39.4) vs. 14 (42.4) \( p = 1.000 \)
- **Thighs**: 5 (15.2) vs. 11 (33.3) \( p = 0.150 \)

*Pain irradiating to: No. (%)*

- **Hips/waist**: 31 (93.9) vs. 33 (97.0) \( p = 1.000 \)
- **Gluteus**: 9 (27.3) vs. 10 (30.3) \( p = 1.000 \)

*Pain irradiating below knee No. (%)*

- 6 (18.2) vs. 14 (42.4) \( p = 0.059 \)

\( ^a \) Comparisons between treatment groups based on two-sided Fisher’s Exact test or two-independent samples t test.
Functional Impairments, Disability and Level of Pain by Study Group at 1-Week after Treatment, and at 1-Month Follow-up

Oswestry functional impairments. Table 7 presents baseline, 1-week after treatment and 1-month follow-up levels of functional impairments by study groups. It is noticeable that in most functional activities, both groups reported to have very similar baseline levels of impairments, except for tasks such as standing, sitting and sleeping. Yet, their scores only were significantly different in sitting activities ($p = 0.044$), and marginally significant in standing activities ($p = 0.059$) (Table 3).

When evaluating the change in the percentage of subjects within each level of impairment between groups at 1-week of treatment, it was clear that both groups, regardless of type of treatment received, were able to reduce the level of impairment in almost all functional activities. Patients in the combined treatment group were not able to reduce their level of impairment in terms standing activities after 1-week of treatment. Furthermore, the combined treatment group increased their level of impairment when considering how their LBP disrupted their sleeping patterns. In contrast, the standard treatment group was not able to decrease their level of impairment in terms of walking activities. In addition, this group’s level of impairment increased in terms of activities related to personal care and traveling after 1-week of treatment.
At 1-month follow-up, both treatment groups were able to maintain the reduction in functional impairments gained at 1-week after treatment, or reduce even further their level of impairment. In fact, the combined treatment group was able to reduce even more the level of impairment in terms of standing, lifting, sitting and sexual activities. This group was also able to maintain a relatively stable level of impairment in terms of pain intensity and walking activities. Yet, this group increased considerably their level of impairment in terms of sleeping and traveling activities. In fact, the combined treatment group showed an increasing disability trend in terms of sleeping. The standard treatment group was able to reduce even further their level of impairments on all functional activities. In addition, this group was able to keep the same level of impairment reduction gained at 1-week after treatment in terms of sleeping and lifting activities, as well as, social life. There were no increases in functional impairment at 1-month follow-up in the standard treatment group.

Both treatment groups were able to reduce their impairment levels, or at least, keep the reduction in impairment gained after 1-week of treatment on most of the functional activities. Yet, some of the functional activities still remained at levels of impairment considerably elevated after treatment. The standard treatment group showed a reduction in impairment in terms of pain intensity, but more than 40% still reported levels of impairments that ranged from severe to extremely severe after 1 month. This group also reported a small reduction in
<table>
<thead>
<tr>
<th>Functional activity</th>
<th>Study group</th>
<th>Level of impairment</th>
<th>Baseline</th>
<th>1-week after treatment</th>
<th>1-month follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pain intensity</strong></td>
<td>Combined</td>
<td>Minimal to moderate</td>
<td>42.4</td>
<td>22 (66.7)</td>
<td>22 (66.7)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severe to extremely severe</td>
<td>57.6</td>
<td>11 (33.3)</td>
<td>11 (33.3)</td>
</tr>
<tr>
<td></td>
<td>Standard</td>
<td>Minimal to moderate</td>
<td>33.2</td>
<td>18 (54.5)</td>
<td>19 (57.6)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severe to extremely severe</td>
<td>66.7</td>
<td>15 (45.5)</td>
<td>14 (42.4)</td>
</tr>
<tr>
<td><strong>Standing</strong></td>
<td>Combined</td>
<td>Minimal to moderate</td>
<td>81.8</td>
<td>27 (81.8)</td>
<td>28 (84.8)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severe to extremely severe</td>
<td>18.2</td>
<td>6 (18.2)</td>
<td>5 (15.2)</td>
</tr>
<tr>
<td></td>
<td>Standard</td>
<td>Minimal to moderate</td>
<td>57.6</td>
<td>23 (69.7)</td>
<td>24 (72.7)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severe to extremely severe</td>
<td>42.2</td>
<td>10 (30.3)</td>
<td>9 (27.3)</td>
</tr>
<tr>
<td><strong>Personal care</strong></td>
<td>Combined</td>
<td>Minimal to moderate</td>
<td>84.8</td>
<td>30 (90.9)</td>
<td>29 (87.9)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severe to extremely severe</td>
<td>15.2</td>
<td>3 (9.1)</td>
<td>4 (12.1)</td>
</tr>
<tr>
<td></td>
<td>Standard</td>
<td>Minimal to moderate</td>
<td>87.9</td>
<td>28 (84.8)</td>
<td>29 (87.9)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severe to extremely severe</td>
<td>12.1</td>
<td>5 (15.2)</td>
<td>4 (12.1)</td>
</tr>
<tr>
<td>Functional activity</td>
<td>Study group</td>
<td>Level of impairment</td>
<td>Baseline</td>
<td>1-week after treatment</td>
<td>1-month follow-up</td>
</tr>
<tr>
<td>---------------------</td>
<td>-------------</td>
<td>---------------------------</td>
<td>----------</td>
<td>------------------------</td>
<td>------------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sleeping</td>
<td>Combined</td>
<td>Minimal to moderate</td>
<td>97.0</td>
<td>30 (90.9)</td>
<td>31 (93.9)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severe to extremely severe</td>
<td>3.0</td>
<td>3 (9.1)</td>
<td>2 (6.1)</td>
</tr>
<tr>
<td></td>
<td>Standard</td>
<td>Minimal to moderate</td>
<td>81.8</td>
<td>29 (87.9)</td>
<td>29 (87.9)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severe to extremely severe</td>
<td>18.2</td>
<td>4 (12.1)</td>
<td>4 (12.1)</td>
</tr>
<tr>
<td>Lifting</td>
<td>Combined</td>
<td>Minimal to moderate</td>
<td>51.5</td>
<td>21 (63.6)</td>
<td>21 (63.6)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severe to extremely severe</td>
<td>48.5</td>
<td>12 (36.4)</td>
<td>12 (36.4)</td>
</tr>
<tr>
<td></td>
<td>Standard</td>
<td>Minimal to moderate</td>
<td>45.5</td>
<td>16 (48.5)</td>
<td>16 (48.5)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severe to extremely severe</td>
<td>54.5</td>
<td>17 (51.5)</td>
<td>17 (51.5)</td>
</tr>
<tr>
<td>Sexual activity</td>
<td>Combined</td>
<td>Minimal to moderate</td>
<td>84.8</td>
<td>29 (87.9)</td>
<td>29 (93.9)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severe to extremely severe</td>
<td>15.2</td>
<td>4 (12.1)</td>
<td>4 (6.1)</td>
</tr>
<tr>
<td></td>
<td>Standard</td>
<td>Minimal to moderate</td>
<td>69.7</td>
<td>25 (75.8)</td>
<td>26 (78.8)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severe to extremely severe</td>
<td>30.3</td>
<td>8 (24.2)</td>
<td>7 (21.2)</td>
</tr>
<tr>
<td>Walking</td>
<td>Combined</td>
<td>Minimal to moderate</td>
<td>90.9</td>
<td>31 (93.9)</td>
<td>31 (93.9)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severe to extremely severe</td>
<td>9.1</td>
<td>2 (6.1)</td>
<td>2 (6.1)</td>
</tr>
<tr>
<td></td>
<td>Standard</td>
<td>Minimal to moderate</td>
<td>81.8</td>
<td>27 (81.8)</td>
<td>29 (87.9)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severe to extremely severe</td>
<td>18.2</td>
<td>6 (18.2)</td>
<td>4 (12.1)</td>
</tr>
<tr>
<td>Functional activity</td>
<td>Study group</td>
<td>Level of impairment</td>
<td>Baseline 1-week after treatment</td>
<td>1-month follow-up</td>
<td></td>
</tr>
<tr>
<td>---------------------</td>
<td>-------------</td>
<td>----------------------------------</td>
<td>---------------------------------</td>
<td>-------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Social life</strong></td>
<td>Combined</td>
<td>Minimal to moderate</td>
<td>75.8</td>
<td>27 (81.8)</td>
<td>26 (78.8)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severe to extremely severe</td>
<td>24.2</td>
<td>6 (18.2)</td>
<td>7 (21.2)</td>
</tr>
<tr>
<td></td>
<td>Standard</td>
<td>Minimal to moderate</td>
<td>63.6</td>
<td>24 (72.7)</td>
<td>24 (72.7)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severe to extremely severe</td>
<td>36.4</td>
<td>9 (27.3)</td>
<td>9 (27.3)</td>
</tr>
<tr>
<td><strong>Sitting</strong></td>
<td>Combined</td>
<td>Minimal to moderate</td>
<td>72.7</td>
<td>27 (81.8)</td>
<td>28 (84.8)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severe to extremely severe</td>
<td>27.3</td>
<td>6 (18.2)</td>
<td>5 (15.2)</td>
</tr>
<tr>
<td></td>
<td>Standard</td>
<td>Minimal to moderate</td>
<td>45.5</td>
<td>21 (63.6)</td>
<td>22 (66.7)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severe to extremely severe</td>
<td>54.5</td>
<td>12 (36.4)</td>
<td>11 (33.3)</td>
</tr>
<tr>
<td><strong>Traveling</strong></td>
<td>Combined</td>
<td>Minimal to moderate</td>
<td>81.8</td>
<td>29 (87.9)</td>
<td>28 (84.8)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severe to extremely severe</td>
<td>18.2</td>
<td>4 (12.1)</td>
<td>5 (15.2)</td>
</tr>
<tr>
<td></td>
<td>Standard</td>
<td>Minimal to moderate</td>
<td>81.8</td>
<td>20 (60.6)</td>
<td>23 (69.7)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severe to extremely severe</td>
<td>18.2</td>
<td>13 (39.4)</td>
<td>10 (30.3)</td>
</tr>
</tbody>
</table>
lifting impairment after 1-week of treatment, but at 1-month follow-up still more than 50% of patients reported a severe to extremely severe lifting limitation.

**Oswestry disability.** As presented on Table 4, both treatment groups had a significantly different mean OSW disability score at baseline (15.85 ± 6.05 [combined treatment group] vs. 19.82 ± 7.15 [standard treatment group], p = 0.018). After 1-week of treatment both study groups showed a reduction in OSW disability scores (Table 8). The combined treatment group reported a reduction in disability at 1-week after treatment from 18.85 ± 6.05 [baseline] to 13.06 ± 7.73 [1-week after treatment], whereas the standard treatment group reported a reduction from 19.82 ± 7.15 [baseline] to 17.15 ± 9.07 [1-week after treatment]. Even though both groups were able to reduce even further the level of disability at 1-month follow-up, the combined treatment group reported a greater reduction (from 13.06 ± 7.73 [1-week after treatment] to 12.97 ± 8.27 [1-month follow-up]).

**Roland-Morris disability.** A description of RM disability scores over time are also presented on Table 8. The combined and standard treatment groups reported a reduction in disability scores at 1-week after treatment (from 9.67 ± 4.31 [baseline] to 8.70 ± 5.03 [1-week after treatment] vs. from 10.39 ± 4.27 [baseline] to 8.67 ± 5.34 [1-week after treatment], respectively). Yet, neither of the two treatment groups reported an additional reduction at 1-month follow-up.
Table 8. *Baseline, 1-Week after Treatment and 1-Month Follow-up Disability Scores by Treatment Group*

<table>
<thead>
<tr>
<th>Disability scores</th>
<th>Combined treatment (n=33)</th>
<th>Standard treatment (n=33)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oswestry disability scores at:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline (mean ± SD)</td>
<td>15.85 ± 6.05</td>
<td>19.82 ± 7.15</td>
</tr>
<tr>
<td>1-week after treatment (mean ± SD)</td>
<td>13.06 ± 7.73</td>
<td>17.15 ± 9.07</td>
</tr>
<tr>
<td>1-month follow-up (mean ± SD)</td>
<td>12.97 ± 8.27</td>
<td>17.12 ± 9.66</td>
</tr>
<tr>
<td>Roland-Morris disability scores at:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline (mean ± SD)</td>
<td>9.67 ± 4.31</td>
<td>10.39 ± 4.27</td>
</tr>
<tr>
<td>1-week after treatment (mean ± SD)</td>
<td>8.70 ± 5.03</td>
<td>8.67 ± 5.34</td>
</tr>
<tr>
<td>1-month follow-up (mean ± SD)</td>
<td>8.55 ± 5.23</td>
<td>8.94 ± 5.85</td>
</tr>
</tbody>
</table>

*Pain intensity and frequency.* As presented on Table 6, both treatment groups had a similar mean level of pain intensity at baseline (55.5 to 58.6, \( p > 0.05 \)). After 1-week of treatment both study groups showed a reduction in pain intensity (Table 9). Yet, the combined treatment group reported a greater reduction in pain intensity at 1-week after treatment (from 58.60 ± 20.69 [baseline] to 43.94 ± 23.13 [1-week after treatment]), when compared to the standard treatment group (from 55.52 ± 15.63 [baseline] to 46.76 ± 24.13 [1-week after treatment]). Even though both groups were able to reduce even further the perceived level of pain intensity at 1-month follow-up, the combined
treatment group reported a greater reduction at follow-up (from 43.94 ± 23.13 [1-week after treatment] to 41.12 ± 27.25 [1-month follow-up]).

A description of pain frequency over time is also presented on Table 9. The combined and standard treatment groups reported a reduction in pain frequency at 1-week after treatment (from 70.64 ± 27.13 [baseline] to 47.82 ± 27.70 [1-week after treatment] vs. from 73.15 ± 22.82 [baseline] to 47.55 ± 31.93 [1-week after treatment], respectively). Yet, only the combined treatment group reported an additional reduction at 1-month follow-up (from 47.82 ± 27.70 [1-week after treatment] to 43.00 ± 30.18 [1-month follow-up]). The standard treatment group reported an intensification of pain frequency at 1-month follow-up (from 47.55 ± 31.93 [1-week after treatment] to 54.24 ± 32.17 [1-month follow-up]).
Table 9. Baseline, 1-Week after Treatment, and 1-Month Follow-up Perceived Level of Pain Intensity and Pain Frequency by Treatment Group

<table>
<thead>
<tr>
<th>Perceived pain</th>
<th>Combined treatment (n=33)</th>
<th>Standard treatment (n=33)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain intensity scores at:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline (mean ± SD)</td>
<td>58.60 ± 20.69</td>
<td>55.52 ± 15.63</td>
</tr>
<tr>
<td>1-week after treatment (mean ± SD)</td>
<td>43.94 ± 23.13</td>
<td>46.76 ± 24.13</td>
</tr>
<tr>
<td>1-month follow-up (mean ± SD)</td>
<td>41.12 ± 27.25</td>
<td>46.45 ± 27.64</td>
</tr>
<tr>
<td>Pain frequency scores at:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline (mean ± SD)</td>
<td>70.64 ± 27.13</td>
<td>73.15 ± 22.82</td>
</tr>
<tr>
<td>1-week after treatment (mean ± SD)</td>
<td>47.82 ± 27.70</td>
<td>47.55 ± 31.93</td>
</tr>
<tr>
<td>1-month follow-up (mean ± SD)</td>
<td>43.00 ± 30.18</td>
<td>54.24 ± 32.17</td>
</tr>
</tbody>
</table>
Treatment Effect on Levels of Functional Impairments, Levels of Disability and Levels of Pain Intensity and Frequency

Functional impairments. Given the fact that the level of impairment for each of the functional activities had an ordinal measurement scale, ordinal logistics modeling was originally considered to evaluate the effect of the treatment on reducing the level of functional impairment. Yet, very few participants reported severe to extremely severe levels of functional impairment at any of the time intervals. This situation caused to have many missing cells during ordinal logistic analyses. In addition, in most cases, the proportional odds assumption did not hold for the ordinal models. Consequently, functional impairment scores were dichotomized into two categories for each of the functional activities as: minimal to moderate impairment, and severe to extremely severe impairment. Thus, logistic regression models were considered to model the probability of having minimal to moderate impairment by treatment. Due to baseline significant differences between treatment groups, some models were adjusted for baseline levels of impairment. Table 10 presents each of the estimated odds ratios (ORs) for the combined treatment group in favor of minimal to moderate impairment by functional activity.
Table 10. Association between Treatment and Degree of Impairment at 1-Week after Treatment and 1-Month Follow-up

<table>
<thead>
<tr>
<th>Functional activity</th>
<th>Odds ratio (OR)</th>
<th>95% Confidence interval</th>
<th>p-valuea</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pain intensity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-week after treatment</td>
<td>1.67</td>
<td>0.62, 4.52</td>
<td>0.32</td>
</tr>
<tr>
<td>1-month follow-up</td>
<td>1.47</td>
<td>0.54, 4.01</td>
<td>0.45</td>
</tr>
<tr>
<td><strong>Standing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-week after treatment</td>
<td>0.81</td>
<td>0.17, 3.85</td>
<td>0.79</td>
</tr>
<tr>
<td>1-month follow-up</td>
<td>1.04</td>
<td>0.23, 4.61</td>
<td>0.96</td>
</tr>
<tr>
<td><strong>Personal care</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-week after treatment</td>
<td>1.79</td>
<td>0.39, 8.17</td>
<td>0.46</td>
</tr>
<tr>
<td>1-month follow-up</td>
<td>1.00</td>
<td>0.23, 4.39</td>
<td>1.0</td>
</tr>
<tr>
<td><strong>Sleeping</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-week after treatment</td>
<td>1.38</td>
<td>0.28, 6.71</td>
<td>0.69</td>
</tr>
<tr>
<td>1-month follow-up</td>
<td>2.14</td>
<td>0.36, 12.57</td>
<td>0.40</td>
</tr>
<tr>
<td><strong>Lifting</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-week after treatment</td>
<td>1.86</td>
<td>0.70, 4.98</td>
<td>0.22</td>
</tr>
<tr>
<td>1-month follow-up</td>
<td>1.86</td>
<td>0.70, 4.98</td>
<td>0.22</td>
</tr>
<tr>
<td><strong>Sexual activity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-week after treatment</td>
<td>2.32</td>
<td>0.62, 8.63</td>
<td>0.21</td>
</tr>
<tr>
<td>1-month follow-up</td>
<td>1.95</td>
<td>0.51, 7.44</td>
<td>0.33</td>
</tr>
<tr>
<td>Functional activity</td>
<td>Odds ratio (OR)</td>
<td>95% Confidence interval</td>
<td>p-value^a</td>
</tr>
<tr>
<td>---------------------</td>
<td>----------------</td>
<td>-------------------------</td>
<td>-----------</td>
</tr>
<tr>
<td><strong>Walking</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-week after treatment</td>
<td>3.44</td>
<td>0.64, 18.51</td>
<td>0.15</td>
</tr>
<tr>
<td>1-month follow-up</td>
<td>2.14</td>
<td>0.36, 12.57</td>
<td>0.40</td>
</tr>
<tr>
<td><strong>Social life</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-week after treatment</td>
<td>1.69</td>
<td>0.52, 5.44</td>
<td>0.38</td>
</tr>
<tr>
<td>1-month follow-up</td>
<td>1.39</td>
<td>0.45, 4.32</td>
<td>0.57</td>
</tr>
<tr>
<td><strong>Sitting</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-week after treatment</td>
<td>1.19</td>
<td>0.26, 5.45</td>
<td>0.83</td>
</tr>
<tr>
<td>1-month follow-up</td>
<td>1.26</td>
<td>0.25, 6.36</td>
<td>0.78</td>
</tr>
<tr>
<td><strong>Traveling</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-week after treatment</td>
<td>4.71</td>
<td>1.34, 16.57</td>
<td>0.02</td>
</tr>
<tr>
<td>1-month follow-up</td>
<td>2.44</td>
<td>0.73, 8.14</td>
<td>0.15</td>
</tr>
</tbody>
</table>

^a Odds ratios (ORs) for the combined treatment group in favor of minimal to moderate impairment.

Results illustrate that even though the combined treatment group showed a higher possibility of minimal to moderate level of impairment on most of the functional activities, at 1-week after treatment and at 1-month follow-up, results did not reach statistical significance (p > 0.05). In terms of pain intensity, the combined treatment group was 67% more likely to report a minimal to moderate level of disability, than the standard treatment group. The combined treatment
group was also 20-80% more likely than the standard group to report lower levels of impairment in activities such as sitting, sleeping, social activities, personal care and lifting at 1-week after treatment. In addition, the combined treatment group was found to be 2 times more likely to report lower impairment levels on sexual activities, and 3 times more likely to have lower impairment levels while walking at 1-week after treatment. Finally, the combined treatment group was also 5 times more likely to report lower levels of impairment on traveling activities. The standard treatment group only reported lower levels of on standing activities when compared to the combined treatment group at 1-week after treatment.

At 1-month follow-up, the combined treatment group was more likely to report lower levels of functional impairment than the standard treatment group on most of the functional activities; yet, the odds were slightly reduced, except for sleeping activities were the odds for lower levels of impairments were reduced even further for the standard group. Still, all these findings did not reach statistical significance.

*Oswestry disability.* This study’s primary analysis was directed at detecting differences in OSW disability score changes at 1-week after treatment and at 1-month follow-up between treatment groups. Two-sided two-independent samples t-test to detect differences in OSW disability score change were considered. Table 11 shows the combined treatment group had a mean change in OSW disability score of 2.79, whereas the standard treatment group had a mean change in OSW disability score of 2.67 after 1-week of treatment. This difference
in mean change in 1-week after treatment OSW disability score between groups was not statistically significant (p-value = 0.917). Results also showed that after 1-month follow-up, the mean change in OSW disability scores was greater among subjects in the combined treatment group than in subjects in the standard treatment group (-2.88 ± 4.46 vs. -2.70 ± 4.97, respectively). Yet, this difference between groups was not statistically significant (p = 0.969).

Table 11. Differences in Oswestry Disability Score Changes at 1-Week after Treatment, and at 1-Month Follow-up by Treatment Group

<table>
<thead>
<tr>
<th>Oswestry disability scores at:</th>
<th>Combined treatment (n=33)</th>
<th>Standard treatment (n=33)</th>
<th>Mean difference</th>
<th>95% CI</th>
<th>p-valuea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Changes at 1-week after treatment</td>
<td>-2.79 ± 4.46</td>
<td>-2.67 ± 4.97</td>
<td>0.12</td>
<td>(-2.20, 2.44)</td>
<td>0.917</td>
</tr>
<tr>
<td>Changes at 1-month follow-up</td>
<td>-2.88 ± 5.62</td>
<td>-2.70 ± 5.55</td>
<td>0.18</td>
<td>(-2.57, 2.93)</td>
<td>0.969</td>
</tr>
</tbody>
</table>

a Two-sided two-independent samples t-test to detect differences in mean change in Oswestry disability score between groups
Secondary analyses to detect differences in OSW disability scores between treatment groups were also carried out. In order to control for differences in OSW disability scores at baseline, a repeated measures analysis of covariance (repeated measures ANCOVA) was considered for time of evaluation (1-week after treatment and 1-month follow-up). The repeated measures ANCOVA model considered treatment as the between factor (2 levels: combined and standard treatment groups), time of evaluation as the within factor (2 levels: 1-week after treatment and 1-month follow-up) and baseline OSW score as a covariate on time of evaluation outcomes.

Given the fact that in the model proposed the within factor only had two levels, the assumption of sphericity did not apply. Therefore, there was no need to correct the degrees of freedom associated to the F statistic. Results from the ANCOVA showed that there was no interaction effect between time of evaluation and baseline OSW scores ($F_{1, 63} = 0.175, p = 0.87, \eta_p^2 < 0.001, 1 – \beta = 0.053$), or between time of evaluation and treatment ($F_{1, 63} < 0.001, p = 0.99, \eta_p^2 < 0.001, 1 – \beta = 0.050$).

The repeated measures ANCOVA showed that treatment had no effect on disability scores across time when adjusting for baseline disability scores ($F_{1, 63} = 0.005, p = 0.94, \eta_p^2 < 0.001, 1 – \beta = 0.051$). In fact, the effect noted for the covariate (baseline OSW disability score) explained approximately 70% of the variability found on the OSW disability scores across time ($F_{1, 63} = 133.717, p <$
0.001, η^2_p < 0.680, 1 – β = 1.0). Therefore, treatment had no effect on reducing levels of disability across time, when baseline scores were adjusted.

Subsequent single factor repeated measures ANOVA with time as the within factor (3 levels: baseline, 1-week after treatment and 1-month follow-up) for each of the treatment groups was carried out to determine if there was a significant reduction in OSW disability scores across time for each of the treatment groups. The repeated measures ANOVA for the combined treatment group did not meet the sphericity assumption as reported by the Mauchly’s test ($X^2_2 = 12.320$, $p = 0.002$); therefore, the Greenhouse-Geisser adjustment for the degrees of freedom for the F statistic was considered. The model showed there was a significant time effect on OSW disability scores ($F_{1.506, 48.195} = 4.466$, $p = 0.025$, $η^2_p < 0.122$, $1 – β = 0.656$).

Yet, Bonferroni adjusted post hoc test could only detect marginally significant differences in OSW disability scores from baseline to 1-week after treatment (from 14.97 ± 1.03 [baseline] to 13.06 ± 1.35 [1-week after treatment], $p = 0.069$) and from baseline to 1-month follow-up (from 14.97 ± 1.03 [baseline] to 12.97 ± 1.44 [1-month follow-up], $p = 0.102$). No significant difference in OSW disability scores was found from 1-week after treatment to 1-month follow-up (from 13.06 ± 1.35 [1-week after treatment] to 12.97 ± 1.44 [1-month follow-up], $p = 1.0$) (Table 12).
Conversely, the sphericity assumption was met for the repeated measures ANOVA for the standard treatment group (Mauchly’s test: $\chi^2_2 = 2.663, p = 0.264$); therefore, no adjustment for the degrees of freedom for the F statistic was necessary. The model showed there was a significant time effect on OSW disability scores ($F_{2,64} = 3.354, p = 0.041, \eta^2_p = 0.095$, $1 - \beta = 0.614$).

Bonferroni adjusted post hoc tests detected significant differences in OSW disability scores from baseline to 1-week after treatment (from $18.82 \pm 1.36$ [baseline] to $17.15 \pm 1.58$ [1-week after treatment], $p = 0.049$). Yet, no significant differences were noted from baseline to 1-month follow-up (from $18.82 \pm 1.36$ [baseline] to $17.12 \pm 1.68$ [1-month follow-up], $p = 0.157$), or from 1-week after treatment to 1-month follow-up (from $17.15 \pm 1.58$ [1-week after treatment] to $17.12 \pm 1.68$ [1-month follow-up], $p = 1.0$) (Table 12).

**Roland-Morris disability.** The primary analysis was directed at detecting differences in RM disability score changes at 1-week after treatment and at 1-month follow-up between treatment groups. Two-sided two-independent samples $t$-test to detect differences in RM disability score change were considered. Table 13 shows that both treatment groups showed little improvement at 1-week after treatment and at 1-month follow-up. The combined treatment group had a mean change in RM disability score of only 0.97, whereas the standard treatment group had a change in RM disability score of 1.73 after 1-week of treatment. This group difference was not statistically significant ($p = 0.371$). Changes at 1-month follow-up were also very small and not statistically significant. The standard
treatment group reported a greater mean change in RM disability scores at 1-month follow-up compared to the combined treatment group; yet, these differences were not clinically significant.
<table>
<thead>
<tr>
<th></th>
<th>Combined treatment (n=33)</th>
<th></th>
<th>Standard treatment (n=33)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Oswestry disability scores at:</strong></td>
<td><strong>p-value</strong></td>
<td></td>
<td><strong>p-value</strong></td>
<td></td>
</tr>
<tr>
<td>Baseline (mean ± SE)</td>
<td>14.97 ± 1.03</td>
<td></td>
<td>18.82 ± 1.36</td>
<td></td>
</tr>
<tr>
<td>1-week after treatment (mean ± SE)</td>
<td>13.06 ± 1.35</td>
<td>0.069</td>
<td>17.15 ± 1.58</td>
<td>0.049</td>
</tr>
<tr>
<td>Mean change from baseline (mean ± SE)</td>
<td>-1.91 ± 0.80</td>
<td></td>
<td>-1.67 ± 0.66</td>
<td></td>
</tr>
<tr>
<td>Mean percent change from baseline (%)</td>
<td>-12.76</td>
<td></td>
<td>-8.37</td>
<td></td>
</tr>
<tr>
<td>1-month follow-up (mean ± SE)</td>
<td>12.97 ± 1.44</td>
<td></td>
<td>17.12 ± 1.68</td>
<td></td>
</tr>
<tr>
<td>Mean change from baseline (mean ± SE)</td>
<td>-2.00 ± 0.90</td>
<td>0.102</td>
<td>-1.70 ± 0.84</td>
<td>0.157</td>
</tr>
<tr>
<td>Mean percent change from baseline (%)</td>
<td>-13.36</td>
<td></td>
<td>-9.03</td>
<td></td>
</tr>
<tr>
<td>Mean change from 1-week (mean ± SD)</td>
<td>-0.09 ± 0.51</td>
<td>1.000</td>
<td>-0.03 ± 0.74</td>
<td>1.000</td>
</tr>
<tr>
<td>Mean percent change from 1-week (%)</td>
<td>-0.69</td>
<td></td>
<td>-0.17</td>
<td></td>
</tr>
</tbody>
</table>

* Single factor repeated measures ANOVA for each of the treatment groups independently.
Table 13. Differences in Roland-Morris Disability Score Changes at 1-Week after Treatment, and at 1-Month Follow-up by Treatment Groups ANOVA

<table>
<thead>
<tr>
<th>Roland-Morris disability scores at:</th>
<th>Combined treatment (n=33)</th>
<th>Standard treatment (n=33)</th>
<th>Mean difference (95% CI)</th>
<th>p-value&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Changes at 1-week after treatment</td>
<td>-0.97 ± 3.58</td>
<td>-1.73 ± 3.24</td>
<td>-0.76 (-2.44, 0.92)</td>
<td>0.371</td>
</tr>
<tr>
<td>Changes at 1-month follow-up</td>
<td>-1.12 ± 4.31</td>
<td>-1.45 ± 3.67</td>
<td>-0.33 (-2.30, 1.64)</td>
<td>0.736</td>
</tr>
</tbody>
</table>

<sup>a</sup> Two-sided two-independent samples t-test to detect differences in mean change in Roland-Morris disability score between groups.

Secondary analyses to detect differences in RM disability scores between treatment groups were also carried out. The 2 x 3 repeated measures ANOVA model considering RM disability scores as the outcome, did not meet the assumption of sphericity, as reported by the Maunchly’s test ($X^2_2 = 26.920$, $p < 0.001$). Hence, the Greenhouse-Geisser adjustment on the degrees of freedom for the F statistic was considered to determine the effect of both within factors (time of evaluation, and [treatment x time of evaluation] interaction). The test for interaction between the between factor and within factor (treatment x time of evaluation) revealed that time of evaluation did not modify the effect of treatment on the RM disability score outcome ($F_{1.484, 94.975} = 0.437$, $p = 0.588$, $\eta^2_p < 0.007$, $1 – \beta = 0.110$). Consequently, main effects were analyzed and described directly.
The main effect for treatment revealed that both groups reported similar RM disability scores regardless of treatment assigned \( (F_{1, 64} = 0.100, \ p = 0.752, \ \eta^2_p = 0.002, \ 1 – \beta = 0.061) \). Yet, main effects were identified for time of evaluation on RM disability scores. Time of evaluation main effect demonstrated reduction in RM disability scores from baseline to 1-month follow-up \( (F_{1.484, 94.975} = 7.028, \ p = 0.004, \ \eta^2_p = 0.099, \ 1 – \beta = 0.855) \). Follow-up Bonferroni adjusted post-hoc tests were considered to determine differences in RM disability scores across time by treatment groups.

As previously noted, RM mean disability scores at baseline were similar between the combined therapy and the standard therapy groups \( (9.67 \pm 4.31, \ and \ 10.39 \pm 4.27, \ p = 0.493, \ respectively) \) \( (\text{Table 4}) \). After 1-week of treatment baseline RM disability scores were reduced by 10% and 17% on the combined and standard treatment groups, respectively \( (\text{Table 14}) \). The mean percent change in RM scores at 1-week showed a much larger reduction in disability scores in the standard therapy group \( (16.65 \%) \) than in the combined therapy group \( (10.03 \%) \). In fact, only the standard treatment group reported a significant reduction in RM disability scores at 1-week after treatment \( (\text{from:} \ 10.39 \pm 0.75 \ [\text{baseline}] \ to \ 8.67 \pm 0.9 \ [\text{1-week after treatment}], \ p = 0.015) \).
Table 14. Baseline, 1-Week after Treatment, 1-Month Follow-up and Percent Change in Roland-Morris Disability Scores by Treatment Group

<table>
<thead>
<tr>
<th>Roland-Morris disability</th>
<th>Combined treatment</th>
<th>p-value(^{\dagger})</th>
<th>Standard treatment</th>
<th>p-value(^{b})</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n=33)</td>
<td></td>
<td>(n=33)</td>
<td></td>
</tr>
<tr>
<td>Baseline (mean ± SE)</td>
<td>9.67 ± 0.75</td>
<td></td>
<td>10.39 ± 0.75</td>
<td></td>
</tr>
<tr>
<td>1-week after treatment (mean ± SE)</td>
<td>8.70 ± 0.90</td>
<td></td>
<td>8.67 ± 0.90</td>
<td></td>
</tr>
<tr>
<td>Mean change from baseline (mean ± SE)</td>
<td>-0.97 ± 0.60</td>
<td>0.324</td>
<td>-1.73 ± 0.60</td>
<td>0.015</td>
</tr>
<tr>
<td>Mean percent change from baseline (%)</td>
<td>-10.03</td>
<td></td>
<td>-16.65</td>
<td></td>
</tr>
<tr>
<td>1-month follow-up (mean ± SE)</td>
<td>8.55 ± 0.97</td>
<td></td>
<td>8.94 ± 0.97</td>
<td></td>
</tr>
<tr>
<td>Mean change from baseline (mean ± SE)</td>
<td>-1.12 ± 0.70</td>
<td>0.338</td>
<td>-1.46 ± 0.70</td>
<td>0.123</td>
</tr>
<tr>
<td>Mean percent change from baseline (%)</td>
<td>-11.58</td>
<td></td>
<td>-14.05</td>
<td></td>
</tr>
<tr>
<td>Mean change from 1-week (mean ± SD)</td>
<td>-0.15 ± 0.39</td>
<td>1.000</td>
<td>0.27 ± 0.39</td>
<td>1.000</td>
</tr>
<tr>
<td>Mean percent change from 1-week (%)</td>
<td>-1.72</td>
<td></td>
<td>3.11</td>
<td></td>
</tr>
</tbody>
</table>

\(^{a}\) Two-factors repeated measures ANOVA, no treatment effect, \(p > 0.05\).

\(^{b}\) Bonferroni adjusted post-hoc tests on time for each treatment groups.
At 1-month follow-up, the RM mean scores were still below the scores reported at baseline on both groups. Mean percent change in disability scores from 1-week to 1-month follow-up showed that the combined treatment group reduced the disability score by an additional 1.72% (from: 8.70 ± 0.90 [1-week after treatment] to 8.55 ± 0.97 [1-month follow-up]). On the other hand, the standard treatment group increased the disability score by a little more than 3% (from: 8.67 ± 0.90 [1-week after treatment] to 8.94 ± 0.97 [1-month follow-up]). Yet, none of these results were statistically significant (p > 0.05).

As with the OSW disability scores, it seems that the combined treatment group, but not the standard treatment group, was able to carry on the reduction of RM disability scores up to the 1-month follow-up. Yet, the overall reduction in RM mean disability scores was less than 2 points at 1-week and at 1-month follow-up on both treatment groups. Even though the RM disability measure was able to detect a larger reduction in mean disability scores in the standard treatment group at 1-week, it revealed that the standard treatment group was not able to keep the reduction in disability achieved after 1-week of treatment. In contrast, the combined treatment group was able to reduce the mean disability score by an additional 1.72% after 1-week of treatment.
**Pain intensity.** In order to determine if the combined treatment for LBP conferred an additional positive effect, in terms of reduction of pain intensity and pain frequency, two-sided two-independent sample *t*-tests were conducted. Differences in mean change in pain intensity after 1-week of treatment and at 1-month follow-up were compared between treatment groups. Table 15 shows that even though there were no statistically significant differences in mean change in pain intensity at 1-week after treatment or at 1-month follow-up between groups (*p* = 0.218 and *p* = 0.146, respectively), the combined treatment reported greater changes than the standard treatment group at 1-week after treatment (-14.67 ± 20.93 vs. -8.76 ± 17.47, respectively) and at 1-month follow-up (-17.48 ± 26.10 vs. -9.06 ± 20.04, respectively). In fact, the combined treatment group reported even lower levels of pain intensity at 1-month follow-up. The standard treatment group reported a reduction in pain intensity at 1-week after treatment; yet, change from 1-week after treatment to 1-month follow-up was not as marked.

Secondary analyses included a two-factor (2 x 3) repeated measures ANOVA. The repeated measures ANOVA considered treatment (between factor: 2 levels), and time of evaluation (within factor: 3 levels) as independent variables, and pain intensity as the dependent variable. An additional model was considered for pain frequency. Given the fact that no baseline characteristics were significantly different between treatment groups at baseline, no additional adjusting for covariates were considered for pain intensity or pain frequency outcomes.
Table 15. Differences in Changes in pain Intensity at 1-Week after Treatment, and at 1-Month Follow-up by Treatment Group

<table>
<thead>
<tr>
<th>Pain intensity at:</th>
<th>Combined treatment (n=33)</th>
<th>Standard treatment (n=33)</th>
<th>Mean difference (95% CI)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Changes at 1-week after treatment</td>
<td>-14.67 ± 20.93</td>
<td>-8.76 ± 17.47</td>
<td>5.91 (-3.57, 15.39)</td>
<td>0.218</td>
</tr>
<tr>
<td>Changes at 1-month follow-up</td>
<td>-17.48 ± 26.10</td>
<td>-9.06 ± 20.04</td>
<td>8.42 (-3.02, 19.87)</td>
<td>0.146</td>
</tr>
</tbody>
</table>

* Two-sided two-independent samples t-test to detect differences in mean change in pain intensity score between groups

During the repeated measures ANOVA analysis for pain intensity, the Mauchly’s test for sphericity revealed that the assumption was met ($X^2_2 = 4.861, p = 0.088$). Hence, no adjusting for the F statistic on subsequent analysis was necessary. In addition, the test for interaction between the between factor and within factor (treatment x time of evaluation) revealed that time of evaluation did not modify the effect of treatment on pain intensity outcome ($F_{2, 128} = 1.450, p = 0.239, \eta^2_p = 0.022, 1 – \beta = 0.306$). Consequently, main effects were analyzed and described directly.
No main effect involving treatment were noted for pain intensity ($F_{1, 64} = 0.116, p = 0.735, \eta^2_p = 0.002, 1 – \beta = 0.063$). Yet, it seems that time had a significant effect in reducing perceived level of pain intensity ($F_{2, 128} = 16.326, p < 0.001, \eta^2_p = 0.203, 1 – \beta = 1.0$). Follow-up Bonferroni adjusted post-hoc tests were considered to determine differences in pain intensity across time for each treatment group.

Table 16 shows that both groups were able to significantly reduce their perceived level of pain after 1-week of treatment. Yet, only the combined treatment group reported to have reduced pain intensity even further at 1-month follow-up. In effect, the combined treatment group showed a mean percent change in pain intensity from baseline to 1-week of -25.03%; whereas, the standard treatment group showed a mean percent change of -15.78%. When evaluating the long-term effect of treatment, the data showed that the combined treatment group was able to maintain and even amplify the reduction in pain intensity gained at 1-week after treatment (-29.84% change: from $58.61 \pm 3.19$ [baseline] to $41.12 \pm 4.76$ [1-month follow-up], $p < 0.001$). By contrast, the standard treatment group was only able to maintain the reduction in pain intensity gained at 1-week after treatment (-16.32% change: from $55.52 \pm 3.19$ [baseline] to $46.46 \pm 4.76$ [1-month follow-up], $p = 0.086$). However, changes in pain intensity from 1-week to 1-month follow-up were not statistically significant on either treatment groups ($p = 1.0$).
Table 16. *Influence of Treatment and Time of Evaluation on Perceived Level of Pain Intensity* \(^a\)

<table>
<thead>
<tr>
<th>Pain intensity scores at:</th>
<th>Combined treatment (n=33)</th>
<th>p-value(^b)</th>
<th>Standard treatment (n=33)</th>
<th>p-value(^b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (mean ± SE)</td>
<td>58.61 ± 3.19</td>
<td></td>
<td>55.52 ± 3.19</td>
<td></td>
</tr>
<tr>
<td>1-week after treatment (mean ± SE)</td>
<td>43.94 ± 4.11</td>
<td></td>
<td>46.76 ± 4.11</td>
<td></td>
</tr>
<tr>
<td>Mean change from baseline (mean ± SE)</td>
<td>-14.67 ± 3.36</td>
<td>&lt; 0.001</td>
<td>-8.76 ± 3.36</td>
<td>0.034</td>
</tr>
<tr>
<td>Mean percent change from baseline (%)</td>
<td>-25.03</td>
<td></td>
<td>-15.78</td>
<td></td>
</tr>
<tr>
<td>1-month follow-up (mean ± SE)</td>
<td>41.12 ± 4.76</td>
<td></td>
<td>46.46 ± 4.76</td>
<td></td>
</tr>
<tr>
<td>Mean change from baseline (mean ± SE)</td>
<td>-17.49 ± 4.05</td>
<td>&lt; 0.001</td>
<td>-9.06 ± 4.05</td>
<td>0.086</td>
</tr>
<tr>
<td>Mean percent change from baseline (%)</td>
<td>-29.84</td>
<td></td>
<td>-16.32</td>
<td></td>
</tr>
<tr>
<td>Mean change from 1-week (mean ± SD)</td>
<td>-2.82 ± 3.32</td>
<td></td>
<td>-0.30 ± 3.32</td>
<td></td>
</tr>
<tr>
<td>Mean percent change from 1-week (%)</td>
<td>-6.41</td>
<td>1.000</td>
<td>-0.64</td>
<td>1.000</td>
</tr>
</tbody>
</table>

\(^a\) Two-factors repeated measures ANOVA, no treatment effect, p > 0.05.

\(^b\) Bonferroni adjusted post-hoc tests on time for each treatment groups.
Pain frequency. In order to determine if the combined treatment for LBP conferred an additional positive effect, in terms of reduction of pain frequency, two-sided two-independent sample t-tests were conducted. Differences in mean change in pain frequency after 1-week of treatment and at 1-month follow-up were compared between treatment groups. Table 17 shows that both treatment groups reported a reduction in pain frequency at 1-week after treatment (-22.82 ± 23.47 [combined treatment group] vs. -25.61 ± 25.92 [standard treatment group]) and at 1-month follow-up (-27.64 ± 29.34 [combined treatment group] vs. -18.91 ± 24.50 [standard treatment group]). The standard treatment group reported a greater decrease in pain intensity than the combined treatment group. Yet, the combined treatment group reported an additional decrease in pain intensity at 1-month follow-up, whereas the standard treatment group reported an increase in pain intensity at 1-month follow-up. The differences in mean change in pain intensity between treatment groups did not reach statistical significance at either of the evaluations (p > 0.05).

Secondary analyses included a repeated measures ANOVA analysis for pain frequency. The sphericity assumption was also met for the pain frequency outcome model ($\chi^2 = 1.380, p = 0.501$); hence, no adjustment was necessary for the degrees of freedom for the F statistic. No significant treatment x time of evaluation interaction effect on pain frequency was noted ($F_{2, 128} = 1.864, p = 0.159$, $\eta^2 = 0.028, 1 - \beta = 0.382$). A main effect was identified for time of evaluation, and showed a significant reduction in pain frequency ($F_{2, 128} = 38.864,$
$p < 0.001, \eta_p^2 = 0.378, 1 – \beta = 1.0$) regardless of treatment. However, there was no difference in pain frequency between treatment groups (F$_{1, 64} = 0.539, p = 0.47, \eta_p^2 = 0.008, 1 – \beta = 0.112$). Follow-up Bonferroni adjusted post-hoc tests were considered to determine differences in pain frequency across time on each of the treatment groups.

Table 17. Differences in Mean Changes in Pain Frequency at 1-Week after Treatment, and at 1-Month Follow-up by Treatment Group Intensity

<table>
<thead>
<tr>
<th>Pain frequency at:</th>
<th>Combined treatment (n=33)</th>
<th>Standard treatment (n=33)</th>
<th>Difference</th>
<th>p-value$^a$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Changes at 1-week after treatment</td>
<td>-22.82 ± 23.47</td>
<td>-25.61 ± 25.92</td>
<td>-2.79</td>
<td>0.649</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(-14.95, 9.37)</td>
<td></td>
</tr>
<tr>
<td>Changes at 1-month follow-up</td>
<td>-27.64 ± 29.34</td>
<td>-18.91 ± 24.50</td>
<td>8.73</td>
<td>0.194</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(-4.57, 22.02)</td>
<td></td>
</tr>
</tbody>
</table>

$^a$ Two-sided two-independent samples t-test to detect differences in mean change in pain frequency score

It seems that both treatment groups were able to reduce pain frequency after just 1-week of treatment, but only the combined treatment group reported an additional reduction of pain frequency at 1-month follow-up (Table 18). The combined treatment group was able to reduce its level of pain frequency by 32%
at 1-week after treatment, and reported an additional 10% reduction in pain frequency at 1-month follow-up. Yet, this additional reduction in pain frequency from 1-week after treatment to 1-month follow-up was not statistically significant (p = 0.758). The standard therapy group was able to reduce its level of pain frequency by more than 35% after just 1-week of treatment (from 73.15 ± 4.36 [baseline] to 47.55 ± 5.20 [1-month follow-up], p < 0.001). Yet, the reduction was coupled with an increase in pain intensity between the 1-week and the 1-month follow-up (9.16% change: from 47.55 ± 5.20 [1-week after treatment] to 54.24 ± 5.43 [1-month follow-up]). This increase in pain frequency did not reach statistical significance (p = 0.340).

Clinical Improvement by Treatment Group

Treatment success was defined as a percentage of improvement ≥50%, and treatment failure as a percentage of improvement of <50%, as suggested by previous studies (Childs et al., 2004; Cleland et al., 2007; Cleland, Fritz, Childs et al., 2006; Cleland, Fritz, Whitman et al., 2006). The difference in the proportion of patients with a successful outcome between treatment groups was analyzed using the Chi square test for homogeneity of proportions. Tables 19 and 20 present the percentage and number of patients per group reaching a clinical success at 1-week after treatment, and at 1-month follow-up, respectively. Also shown, are the “odds ratios” to estimate if the odds of having a successful treatment is different in the combined treatment group when compared to the standard treatment group.
Table 18. *Influence of Treatment and Time of Evaluation on Perceived Level of Pain Frequency*<sup>a</sup>

<table>
<thead>
<tr>
<th>Pain frequency scores at:</th>
<th>Combined treatment (n=33)</th>
<th>p-value&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Standard treatment (n=33)</th>
<th>p-value&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (mean ± SE)</td>
<td>70.64 ± 4.36</td>
<td></td>
<td>73.15 ± 4.36</td>
<td></td>
</tr>
<tr>
<td>1-week after treatment (mean ± SE)</td>
<td>47.82 ± 5.20</td>
<td></td>
<td>47.55 ± 5.20</td>
<td></td>
</tr>
<tr>
<td>Mean change from baseline (mean ± SE)</td>
<td>-22.82 ± 4.31</td>
<td>&lt; 0.001</td>
<td>-25.61 ± 4.31</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Mean percent change from baseline (%)</td>
<td>-32.30</td>
<td></td>
<td>-35.01</td>
<td></td>
</tr>
<tr>
<td>1-month follow-up (mean ± SE)</td>
<td>43.00 ± 5.43</td>
<td></td>
<td>54.24 ± 5.43</td>
<td></td>
</tr>
<tr>
<td>Mean change from baseline (mean ± SE)</td>
<td>-27.64 ± 4.71</td>
<td>&lt; 0.001</td>
<td>-18.91 ± 4.71</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Mean percent change from baseline (%)</td>
<td>-39.13</td>
<td></td>
<td>-25.85</td>
<td></td>
</tr>
<tr>
<td>Mean change from 1-week (mean ± SE)</td>
<td>-4.82 ± 4.17</td>
<td>0.758</td>
<td>6.70 ± 4.17</td>
<td>0.340</td>
</tr>
<tr>
<td>Mean percent change from 1-week (%)</td>
<td>-10.08</td>
<td></td>
<td>9.16</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup> Two-factors repeated measures ANOVA, no treatment effect, p > 0.05.

<sup>b</sup> Bonferroni adjusted post-hoc tests on time for each treatment groups.
As shown on Table 19, the combined treatment group had a higher proportion of clinical successes at 1-week after treatment when compared to the standard treatment group. In fact, the odds of having a clinical success was 95% higher among those in the combined treatment group when compared to the standard treatment group (OR=1.95, 95%CI: [0.51, 7.44], p = 0.322).

Table 19. *Clinical Success by Treatment Group at 1-Week after Treatment*

<table>
<thead>
<tr>
<th>Treatment group</th>
<th>Clinical outcome</th>
<th>OR&lt;sup&gt;a&lt;/sup&gt;</th>
<th>p-value&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Success</td>
<td>Failure</td>
<td></td>
</tr>
<tr>
<td>No. (%)</td>
<td>≥ 50% improvement</td>
<td>&lt; 50% improvement</td>
<td></td>
</tr>
<tr>
<td>Combined</td>
<td>7 (21.2)</td>
<td>26 (78.8)</td>
<td>1.95</td>
</tr>
<tr>
<td>Standard</td>
<td>4 (12.1)</td>
<td>29 (87.9)</td>
<td>(0.51, 7.44)</td>
</tr>
</tbody>
</table>

<sup>a</sup> OR = odds ratio, CI = confidence interval.

<sup>b</sup> Pearson’s \( \chi^2 \).

Table 20 shows that the proportion of clinical successes at 1-month follow-up was almost the same between treatment groups (OR=1.21, 95%CI: [0.36, 4.09], p = 0.76). Yet, these results did not reach statistical significance at the 5% level.
Table 20. Clinical Success by Treatment Group at 1-Month Follow-up

<table>
<thead>
<tr>
<th>Treatment group</th>
<th>Clinical outcome</th>
<th>OR(^a)</th>
<th>p-value(^b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. (%)</td>
<td>Success</td>
<td>Failure</td>
<td>95%CI</td>
</tr>
<tr>
<td></td>
<td>≥ 50% improvement</td>
<td>&lt; 50% improvement</td>
<td></td>
</tr>
<tr>
<td>Combined</td>
<td>7 (21.2)</td>
<td>26 (78.8)</td>
<td>1.30</td>
</tr>
<tr>
<td>Standard</td>
<td>6 (18.2)</td>
<td>29 (81.8)</td>
<td>(0.39, 4.38)</td>
</tr>
</tbody>
</table>

\(^a\) OR = odds ratio, CI = confidence interval.

\(^b\) Pearson's \(\chi^2\).

Secondary analyses included dichotomization of participants randomized to combined therapy treatment with respect to the CPR’s developed by Flynn et al. (Flynn, T. et al., 2002). Participants satisfying four or more of the five criteria included in the CPR were categorized as those patients most likely to have had benefited from the manual therapy, and those with less than four of the five criteria, as less likely to have had benefited from it. Again, participants were also categorized based on clinical success (≥50% improvement) or failure (<50% improvement). Fisher’s exact test was used to determine if treatment success was dependent upon CPR’s status. Table 21 shows the proportion of participants having a clinical success by CPRs status among those in the combined treatment group. As the number of clinical outcomes (either success or failures) did not differ from 1-week after treatment, to 1-month follow-up, only the 1-week after treatment results are shown. Yet, only a small number of participants in the
combined treatment group met at least 4 of the CRP. Therefore, participants were re-categorized as those participants satisfying or not satisfying, three or more of the five criteria included in the CPRs.

Results showed that there is no significant difference in the proportion of clinical successes by CPRs status, regardless of how the criterion is defined. Participants meeting at least 4 of the CPRs were not more likely to have resulted in a clinical success ($p = 1.0$). Even a less restrictive definition for the CPRs criterion was not associated to an increase in the odds of having a successful outcome ($OR=0.59$, 95% IC [0.11, 3.29]) (Table 22).
Table 22. *Clinical Outcome by Clinical Prediction Rule Status in the Combined Therapy Group*

<table>
<thead>
<tr>
<th>CPRs status</th>
<th>Clinical outcome</th>
<th>OR(^{a})</th>
<th>95% CI</th>
<th>p-value(^{b})</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Success</td>
<td>Failure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 50% improvement</td>
<td>4 (18.2)</td>
<td>18 (81.8)</td>
<td>0.59</td>
<td></td>
</tr>
<tr>
<td>&lt; 50% improvement</td>
<td>3 (27.3)</td>
<td>8 (72.7)</td>
<td>(0.11, 3.29)</td>
<td>0.66</td>
</tr>
</tbody>
</table>

\(^{a}\) OR = odds ratio, CI = confidence interval.

\(^{b}\) Fisher’s Exact test.

In order to determine if the CPR correctly identified patients most likely to benefit from manual therapy, a Kappa analysis was conducted. The Kappa statistic determined that there was no agreement between the CPRs and the participants’ observed outcome (K = -0.11, p = 0.45). Therefore, the CPRs as described by Flynn et al., 2002, are not able to predict a successful outcome among patients with chronic LBP, who undergo manipulative therapy as part of their treatment.
CHAPTER V

DISCUSSION AND CONCLUSION

The following chapter summarizes the most important findings of this study. It provides a detailed discussion on the effect of combined manipulative therapy on non-specific low back pain (LBP), and the role the Clinical Prediction Rules (CPR) play on this particular type of patient.

Discussion

Baseline. Chronic LBP is multi-factorial in nature with socio-demographic, clinical and work-related factors playing different roles among patients (Simmonds, 1999; Lee et al., 2000; Simmonds, 2006). Socio-demographic characteristics such as annual income, employment status, and smoking have been associated to acute and chronic LBP (Manek & MacGregor, 2005; Katz 2006). Clinical characteristics such as pain chronicity, pain intensity, radiculopathy, and degenerative disk disease also contribute greatly to LBP (Manek & MacGregor, 2005; Katz, 2006; Frymoyer et al., 2008). Factors related to the type of work performed such as lifting, seating for prolonged periods of time, bending, as well as, job dissatisfaction have been found to exacerbate symptoms of LBP among workers (Manek & MacGregor, 2005; Katz, 2006; Frymoyer et al., 2008). The socio-demographic, clinical and work-related characteristics of the patients in this study were similar to other studies were injured workers have participated (Rainville et al., 1997; Lee et al., 2000; Fritz et
al., 2001; Fritz et al., 2002; Kabler Moffett et al., 2004; George et al., 2008; Godjes et al., 2008), and were similarly distributed across study groups. The lack of significant differences in socio-demographic, clinical and work-related characteristics between groups at baseline indicates that no group possessed greater risk factors for LBP at the beginning of the study.

As previously stated, the Oswestry Disability Questionnaire (ODQ) is a 10-item self-report instrument used to specifically assess functionality in patients with LBP (Fritz et al., 2001). The questionnaire asks patients to subjectively rate their pain intensity and their difficulty in performing nine different activities of daily living using a scoring system ranging from zero, or no impairment, to five, or total impairment. Patients reporting higher scores within single items reflect higher levels of impairment within those activities. Consequently, higher combined scores reflect higher levels of overall disability. In this study, patients randomized into the combined treatment reported a significantly lower mean level of Oswestry (OSW) disability when compared to patients randomized into the standard treatment. In addition, the combined treatment group also reported significantly lower levels of impairment within specific activities of daily living, such as standing and sitting. Of all activities of daily living included on the ODQ, standing and sitting represent two of the greatest risk factors associated with chronic LBP (Frymoyer et al., 1983; Manek & MacGregor, 2005).
An important remark regarding OSW disability scores is that both groups reported lower than expected levels of disability at baseline. Several investigators have recommended that patients receiving manipulative treatment have an initial disability score of at least 15 points in the ODQ (Flynn et al., 2002; Childs et al., 2003; Cleland et al., 2006). Yet, the combined treatment group reported scores close to the minimum score required to be able to detect changes after treatment (15.85 ± 6.05). The difference between treatment groups on OSW disability score at baseline was 3.97 points. However, a reduction of 6-7 points in OSW scores has been identified as a clinically significant change after treatment (Childs et al., 2006; Cleland et al., 2006). Therefore, although the difference between groups was statistically significant, these differences between groups found at baseline do not represent a clinically important difference. Yet, small baseline OSW disability scores reported by the combined treatment group at baseline could have had a negative effect on the ability to detect improvement on this particular study group.

Roland-Morris Disability Questionnaire (RMDQ) is also a self-report instrument used to specifically assess disability in patients with LBP. Yet, the RMDQ did not show a statistically significant difference in overall disability level between groups at baseline. This fact indicates that the ODQ seemed to discriminate better among injured workers with lower levels of disability than the RMDQ.
The Fear Avoidance Beliefs Questionnaire (FABQ) assesses maladaptive avoidance behaviors at the workplace and during execution of physical activity (Fritz et al., 2001; George et al., 2008). The FABQ is a self-reported questionnaire containing 2 subscales, a 7-item work subscale ranging in score from 0 to 42 points, and a 4-item physical activity scale ranging from 0 to 24 points. Higher scores on any of the respective subscale indicate greater fear avoidance beliefs leading to maladaptive musculoskeletal pain response (George et al., 2008). Maladaptive behaviors are responses to the perception that certain activities will exacerbate pain, or worsen an injury (Fritz et al., 2001; Fritz et al., 2002). Avoidance behaviors towards work-related activities and physical movement exacerbate fear and prolong disability (Fritz et al., 2002). In this study, both groups reported similar fear avoidance beliefs at baseline. However, scores indicated an elevated level of maladaptive musculoskeletal behaviors by both treatment groups.

Oswestry disability assessment. The ODQ assesses disability caused by LBP (Flynn et al. 2002). As previously described, it is a questionnaire composed by 10 question related to functional activities. These functional activities are rated with a score ranging from one to five depending on the limitation encounter by the patient in the specified activity. Higher scores indicate greater disability in functional activities. The main outcome measure on this study was disability as measured by the ODQ. The results of this study did not give evidence of greater improvements for the combined therapy group. The two-independent samples t-
test to detect differences in mean changes in OSW disability between groups at 1-week after treatment, and at 1-month follow-up did not show a significant difference between groups. In addition, the repeated measures analysis of covariance (ANCOVA) conducted in order to adjust for the difference between groups at baseline confirmed that treatment did not have an effect on OSW disability scores. The ANCOVA also showed that time had no effect in disability scores at 1-week after treatment or at 1-month follow-up after adjusting for baseline scores. Yet, single factor analysis of variance (ANOVA) with time (3 levels: baseline, 1-week & 1-month) as the within factor exhibited a statistically significant difference across time when both groups were evaluated separately. Both groups were able to significantly reduce disability scores across time, specifically at 1-week follow-up (p < 0.001). Nonetheless, Bonferroni adjusted post-hoc analyses showed only a marginally statistical difference from baseline to 1-week follow-up without further improvements towards the 1-month follow-up for both groups.

The capacity of the ODQ to discriminate better at lower levels of disability is an important measurement property. Responsiveness to self-report measures typically depends on the group of patient under study (Simmonds, 1999) and on the psychometric properties of the instrument itself (Fritz & Irrgang, 2001). Usually, self-reported measures are capable of detecting greater changes in patients with acute LBP than patients suffering from chronic LBP (Simmonds,
1999). Consequently, the changes in OSW disability scores observed in this study are not entirely surprising.

Although the results from this investigation did not give evidence of treatment efficacy to the level originally though, the small improvement observed in the combined therapy group could be of clinical importance. It has been suggested that within the rapid results expected from a spinal manipulation lie the release of endorphins altered reflexogenic responses and improved soft tissue mobility (Raney et al. 2007, Brenner et al. 2007). These immediate neurologic responses could have played an important role on the small difference registered on the combined therapy group and on helping maintain improvement until the end of the follow-up (one month).

There are several explanations related to the measurement properties of the ODQ that could explain results from this study. First, the OSW baseline scores for the intervention and standard treatment group were 32% and 40%, respectively. Several investigators have recommended that patients receiving manipulative treatment possess a score of at least 30% disability in the OSW questionnaire (Flynn et al. 2002, Childs et al. 2003, Cleland et al. 2006) in order to detect differences after treatment. This baseline percentage of disability has been suggested as a cut-point in order to prevent a floor effect, and to be able to detect a minimum of 50% change in disability score in case of successful treatment as defined by the clinical prediction rules. The experimental group in this study exhibited baseline OSW scores very close to the minimum required to
detect at least a 50% improvement in disability. Conversely, the standard
treatment group presented a 40% OSW baseline disability score, which position
them at having a better probability to exhibit clinically significant changes of 50%
in OSW scores. Clinically, OSW scores of 20% or less are indicative of greater
chronicity (Childs et al. 2003). Therefore, chronicity, by itself, might reduce the
probability of improvement with manipulative treatment (Fritz et al. 2004) and
subsequently decrease probability of changes in OSW scores. Second, it has
been estimated that the minimal detectable change while using the OSW
questionnaire is 6% change (Flynn et al. 2002, Childs et al. 2003, Cleland et al.
2006). Mean change in OSW scores between baseline and 1-week follow-up for
the combined and standard treatment groups were 2.79 and 2.67 points,
respectively. It can be hypothesized that these small changes were difficult to
detect by the ODQ, thus increasing the possibility of Type II error. Even further,
the mean score changes between 1-week to 1-month were .09 and .03 for the
combined and standard treatment group, respectively. This translates into a total
mean score change from baseline to 1-month follow-up of 2.88 for the combined
treatment group and of 2.70 for the standard treatment group. These findings are
in agreement with the premise that scores of less than 4-5 points are not
detectable by the OSW questionnaire.
Other very important factor that could explain the lack of statistically significant differences in OSW disability scores between treatment groups is the fact that study participants were patients participating in the Workers’ Compensation System. Originally, the Clinical Prediction Rules (CPRs) were developed for patients receiving physical therapy services in the United States Armed Forces. This fact decreases the generalizability of positive results previously stated by other authors (Cleland et al., 2006) when reporting about the effectiveness of manipulative treatment. It is a general understanding that military personnel participate in arduous physical activity as part of their training. Consequently, the previously reported effectiveness of manipulative therapy is being based on a healthy, physically active population, very different to the typical Worker’s Compensation Program participant recruited for this investigation. Rainville et al. (1997) assessed patients with LBP receiving compensation (n = 47) and others who were not receiving compensation (n = 38). The outcome measures used in this particular investigation were the ODQ and visual analog scales for pain (VAS) for leg and back, among others. These outcomes were collected before and after an 8-week long physical therapy program. After completion of the physical therapy treatment the group receiving compensation had greater disability and pain scores. Further analyses revealed that receiving monetary compensation had a strong influence on VAS and OSW scores. However, investigators found that patients under compensation improved on several physical function measures such as strength and flexibility, as much
as the patients without compensation. In spite of these improvements in physical function, self-reported measures did not show improvement accordingly. These results suggest that there are some inherent aspects within the compensation system that make patients underreport improvement in their condition regardless of improvements in physical functioning (Rainville et al. 1997).

As a final point, we should consider baseline scores on fear avoidance behaviors as a possible explanation for the lack of statistically significant improvements in OSW scores. It has been documented that baseline fear avoidance scores greater than 28 in the work subscale increases the likelihood of developing long term disability and not returning to work (Fritz et al. 2002). Baseline scores for the combined therapy group was 27.27 ± 8.34 which falls very close to the score in which fear avoidance beliefs jeopardize health and return to work, and over the optimum cut-off point suggested to be able to benefit from manipulative therapy (Flynn et al. 2992, Fritz et al. 2005, Cleland et al. 2006 BMC). Consequently, it can be hypothesized that not only the combined therapy group, but that both groups were initially in a state of mind and health contributing to minimal improvement with treatment.

*Roland-Morris disability assessment.* The RMDQ clinical results were similar to OSW scores. Both interventions proved to be beneficial in reducing disability scores after one week of treatment. However, only the combined therapy group exhibited additional improvements from 1-week to the 1-month follow-up. Again, it seems that the use of spinal manipulation in chronically low
back-injured workers produces a modest improvement over disability scores related to activities of daily living. Even more, the increase RMDQ scores in the standard group from 1-week to 1-month follow-up reinforces this notion. As previously mentioned, the OSW questionnaire appears to discern better the level of disability in those patients with minimal functional limitations than the RMDQ. This difference in the capability to discriminate levels of disability related to LBP between the ODQ and RMDQ could be the main reason why the discrepancy between groups in terms of disability at 1-week and 1-month follow-up.

Pain assessment. The results of this study did not show that the combined treatment group had a greater statistically significant decrease in level of pain intensity when compared to the standard treatment group. Even though there was a non-statistically significant difference between groups, both groups exhibited a reduction on their pain intensity across time. However, the combined therapy group presented with 10% greater reduction of pain intensity when compared to the standard group at one week after initiation of treatment. Typically, pain leads to movement dysfunction and significantly affects the health of those suffering from it (Simmonds, 2006). Therefore, these findings are of vast importance given that a reduction in pain may lead to initiation of physical activity at an earlier stage, and reduce its impact on the overall health of those afflicted.
Several investigators (Schonstein et al., 2003; Klaber Moffat et al., 2004; Godges et al., 2008) have reported that the ability to perform early physical activity would lead to a reduction in fear avoidance beliefs, increase return to work status and reduce sick leave. For example, Klaber Moffat et al. (2004) randomized 187 patients with chronic LBP (6 weeks to 6 months) into an exercise program, and a general practitioner group. It was reported that those patients participating in the exercise program exhibited lower fear avoidance beliefs and disability scores. Godges et al. (2008) randomized 34 patients into a group receiving physical therapy and a second group receiving physical therapy with the addition of educational sessions regarding body mechanics, ergonomics and home exercises. All patients started the program no later than five days after the episode of LBP. Investigators found that those with the combined treatment (therapy plus education) had a return to work rate of 63% in less than a month and 100% by ≤ 45 days after injury. Based on this evidence, results found in this study are of important relevance as they suggest that the longer the time of recovery from the LBP episode the lower the probability of improving with treatment and, thus, the higher the probability of developing permanent disability (Fritz et al., 2002). It is imperative to mention that only the combined treatment group was able to maintain and amplify the reduction in pain intensity at one-month follow-up when compared to baseline measures (p < 0.01). Although the follow-up in this study was only one month, the capacity of the combined treatment group to improve 30% from baseline scores translates into promising
clinical findings, since pain is one of the main symptoms most poorly managed in health care (Simmonds, 2006). Further studies should consider longer follow-up periods and assess not only pain, but also time to return to work.

Results related to pain frequency were similar to those reported for pain intensity. Essentially, no statistically significant differences were found when both groups were compared. Conversely, statistically significant changes were detected for both groups across time (p < 0.001). Yet, only the combined treatment group exhibited additional improvements in pain frequency at 1-month follow-up (42% total improvement). As previously stated, chronic pain usually leads to movement dysfunction and fear avoidance beliefs that promote disability (Fritz et al. 2001, Fritz et al. 2002, Simmonds 2006). Therefore, it can be hypothesized that higher frequency of pain could disrupt daily activities for a longer period of time. It is for this reason that not only pain intensity but pain frequency should also be reduced. These results suggest that the combined treatment continued its efficacy in decreasing pain frequency even after cessation of the manipulation intervention. This decrease in pain frequency allows for greater periods of time with less or no pain. For this reason, pain frequency might be a practical measure to assess the impact pain has on activities of daily living throughout the day. Yet, this measure of pain frequency can only portray a subjective image of how LBP is affecting daily living. Self-report measures such as these are characterized for measuring psychological, motivational and self-efficacy domains (Lee et al., 2000); however, they cannot
differentiate if functional tasks can be performed at all, or quantify the impact of pain on performance (Simmonds, 2006). Some investigators suggest that a combination of objective and self-reported measures to assess LBP (Simmonds 1999, Lee et al. 2000, Simmonds 2006) would offer a better understanding on how pain affects daily living. However, studies assessing pain frequency objectively in injured workers receiving compensation were not found.

Conclusion

Results obtained from the different outcome measures considered in this study suggest that both interventions were moderately effective in managing pain and disability in patients with chronic LBP who participate in the Worker’s Compensation Program. Even so, the addition of a spinal manipulation intervention seemed to add a supplementary minimal enhancement to standard treatment one week after treatment begins. More importantly, it seems that the addition of a spinal manipulation intervention to the standard physical therapy program propelled improvements after the first week and towards longer follow-ups. Some investigators (Raney et al. 2007, Brenner et al. 2007) have reported that utilization of rehabilitative ultrasound imaging have revealed that there are immediate muscular changes in the muscles surrounding the low back that are suggestive of improved motor function. Consequently, it can be hypothesized that the sooner motor function is restored, the earlier the exercise program can progress.
It is imperative to understand that the standardized physical therapy program at the “Centro de Medicina Deportiva del Caribe” is a very comprehensive program, covering numerous areas proven to be effective in the treatment of chronic LBP in injured workers. This intervention program integrates therapeutic exercises emphasizing muscle endurance, strength and stability combined with patient education in body mechanics, ergonomics at home and work, and includes a home exercise program. Godges et al. (2008) assessed the effectiveness of an educational program integrated into conservative physical therapy. A total of 34 patients with LBP who reported high scores (≥ 50) in the FABQ were randomized into a control and combined treatment group. The standard treatment group received physical therapy treatment 2-3 times a week until able to return to work. The combined treatment group received the same physical therapy intervention with the addition of an educational intervention. The educational intervention included a home exercise program, instruction in pain management and body mechanics. The investigators found that 100% of patients receiving the combined treatment return to work in 45 days or less while only 83.3% of the patients in the standard treatment group returned to work in 90 days or less. In addition, regression analysis revealed that scores in the FABQ and treatment group explained 15.7% and 14.8 % of the variability in days to return to work. Thus, educating patients in management of their condition and how to perform modifications throughout their activities efficiently reduced fear avoidance beliefs and consequently maladaptive behaviors that could have
created disability and impaired work performance. Other investigators (Klaber, Moffett et al., 2004) have found that the inclusion of exercise and education in workers with LBP reduces fear avoidance beliefs and subsequently decrease disability. These findings agreed with a Cochrane review of 19 trials reporting that programs that combine exercises with patient education help reduce disability and sick leave due to LBP (Schonstein et al., 2003). Consequently, is not surprising that the standard treatment group in the current study improved their health status with the intervention provided. Nonetheless, the addition of spinal manipulation to an intervention including exercise and patient education could be an asset in the management of chronic LBP among injured workers.

Even though the therapeutic intervention administered to both the standard and combined treatment group was comprehensive and effective to a certain point, deferment of the rehabilitation services was and still is, if not the most important, one of the most important factors affecting treatment effectiveness. All patients receiving treatment under the Worker’s Compensation Program typically have to wait weeks or even months before they are finally referred to the clinic to receive rehabilitation treatment. This waiting situation places patients in a position of delayed intervention. It has been estimated that patients who take longer than 4-8 weeks to resolve their current episode of LBP have greater probability of suffering from disability and not returning to work (Fritz et al. 2002). Moreover, it has been shown that the earlier the intervention is started the greater the possibility of reducing LBP with spinal manipulation and
therapeutic exercises (Fritz et al. 2005). Hence, it appears that injured workers seeking rehabilitation for LBP through the Worker’s Compensation System will experience the burden of entering the rehabilitative process too late in order to expect significant improvement, and will be at higher risk of accelerating the process of incapacitation. Therefore, not finding a significant improvement on disability scores, and stating that including a spinal manipulative intervention to the standard of care is not an effective treatment for chronic LBP in this particular population of injured workers is misleading and inadequate. Spinal manipulation might still be an appropriate intervention for chronic LBP patients regardless of their chronicity and fear avoidance beliefs.

Strengths and Limitations

One of the most important strengths of the survey questionnaire utilized for this study was that it used an index and a questionnaire that have been tested for their psychometric characteristics on LBP adult patients. Both the ODQ and the RMDQ had been designed for this purpose. Their use not only makes the outcome measures valid, but it also makes results comparable to those of other studies. An additional advantage was that the survey instrument incorporated both disability instruments in a single questionnaire, making it possible to evaluate different dimensions of treatment effectiveness. Previous studies only included one of these outcome instruments. In addition to these advantages, the survey questionnaire was designed in such a manner that it was easy to
administer it as well as answer it. A typical adult did not take more than 20 minutes to respond to the questionnaire.

However, the utilized survey also had its limitations. One of the major drawbacks of the proposed survey was that all treatment outcomes were based on self-reports of patients; thereby, increasing the probability of introducing bias due to personal perception (subjectivity). Recall bias also threatened reliability on the proposed study. Even though reliability characteristics for the ODQ and RMDQ instruments have been established, their test-retest reliability have been shown to decrease as time between measurements is increased (Roland & Fairbank, 2000). Therefore, reliability is reduced as therapy progresses across time. An additional disadvantage was that the survey instrument had been designed as a self-administered questionnaire. Consequently, there was no control over the order in which the subjects answered the questionnaire, or the way in which they interpreted and answered the questions. Furthermore, there was no control over questions not answered by the patients; thereby, increasing the likelihood of missing data. However, adequate data management and quality control measures helped reduce such deficiencies.

Other limitations relate to the number of participants in the study. Strict exclusion criteria significantly reduced the pool of potential study participants; therefore, slowing down and hampering the process of enrollment of patients into the study. As a result, only a total of 66 patients out of a total of 98 needed to achieve 80% power were invited to the study after an entire year of enrollment.
Consequently, all statistical analyses were greatly underpowered; hence, considerably increasing the probability of type II error during statistical analyses. Inability to detect statistically significant differences between study groups could have been associated with the characteristics of the population under study, but also with the small number of participants in the study.

Finally, even though all patients’ socio-demographic, clinical and work-related characteristics were appropriately distributed across study groups through the randomization process, there was a statistically significant difference in OSW disability scores between groups at baseline. In addition, this particular injured worker population reported baseline OSW scores much lower and with less variation than expected when compared to other studies. Therefore, reducing even further the power of the study, and requiring a greater sample size in order to detect a significant difference between the groups.

Recommendations

Results from this study identified and estimated different values for the mean and standard deviation of baseline OSW disability, as well as, change in OSW disability scores parameters in this particular population of injured workers with chronic LBP. It was shown that within this population of injured workers, baseline OSW mean scores and standard deviation were much lower than reported by others. In addition, the difference between groups was much smaller than expected. Therefore, a larger study should consider sample calculation based on these estimated parameters.
As previously stated self-report measures such as the ODQ, RMDQ and VAS for pain intensity and frequency are characterized for measuring psychological, motivational and self-efficacy domains (Lee et al. 2000); yet, cannot discriminate if functional tasks can be performed efficiently or at all (Simmonds, 2006). Several investigators have suggested that a combination of objective and self-reported measures to assess LBP (Simmonds 1999, Lee et al. 2000, Simmonds 2006) might offer a better understanding of how pain affects daily living. Therefore, it is highly recommended to include both types of outcome measures in order to maximize information and understand the psychologically, as well as, the physical effect LBP has on functional activities. This additional information will help determine if patients’ response to treatment is factual as measured by objective outcome measures even if no real positive change is self-reported by the patients, or if response to treatment is concordant with self-report of no improvement.

In general, chronic pain increases the risk for pain associated anxiety and depression. Delayed onset of treatment within the Worker’s Compensation Program may promote the transition of acute LBP into chronic LBP. Therefore, patients with LBP participating in the Program may show higher rates of fear avoidance beliefs and undiagnosed depression. Depression, by its self, is also a predictor of long term disability and acts as a psychological barrier during the rehabilitation process. Taking into consideration and controlling for diagnosed
and undiagnosed depression may help increase the ability to detect changes in functional impairment and disability among chronic LBP patients.

An additional important issue to take into account while trying to determine the effect of any rehabilitation program within chronic LBP patients participating in a Worker’s Compensation Program is whether or not the patient is receiving or requesting any type of disability compensation while in treatment. Patients receiving or requesting disability compensations might be inclined to magnify symptoms and underreport improvements while in rehabilitation in order to perpetuate this type of monetary remuneration. Underreporting of improvement due to monetary compensation might also diminish the ability to detect changes in functional impairment and disability among chronic LBP patients; hence, either excluding this type of participants, or controlling for such situations is warranted.

Finally, it is recommended that future research take into consideration, not only patients at various levels of disability and chronicity, but also a higher baseline disability score. Most of the subjective outcome measures available to determine improvement over time can only detect changes in impairment and disability levels when patients have moderate to severe levels of impairment and disability at baseline. Patients with moderate to severe impairment and disability will have room for improvement with treatment; yet, patients with low levels of impairment and disability will have a floor effect and will not be able improve more, or show improvement with treatment. Therefore, considering a moderate to severe level of impairment and disability at baseline is important in order to avoid
the floor effect and detect improvement with treatment. Including patients at various levels of disability and chronicity will also help determine for which level of disability and/or level of pain chronicity this type of treatment is effective.
REFERENCES


Centralization: Prevalence and Effect on Treatment Outcomes Using a
Standardized Operational Definition and Measurement Method. J Orthop
APPENDICES
APPENDIX A

Targeted Objectives and Outcome Measures
Table 1. Targeted Objectives and Outcome Measures

<table>
<thead>
<tr>
<th>Objectives</th>
<th>Outcomes Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Functional Status</td>
<td>1. Oswestry Disability Questionnaire</td>
</tr>
<tr>
<td></td>
<td>b. Score: 0-5 Higher score means higher functional impairment</td>
</tr>
<tr>
<td></td>
<td>c. Impairment Level:</td>
</tr>
<tr>
<td></td>
<td>• 0-1 Minimal impairment</td>
</tr>
<tr>
<td></td>
<td>• 2-3 Moderate Impairment</td>
</tr>
<tr>
<td></td>
<td>• 4-5 Severe Impairment</td>
</tr>
<tr>
<td>2. Disability Level</td>
<td>2. Oswestry Disability Questionnaire</td>
</tr>
<tr>
<td></td>
<td>a. Score: 0-50 Higher score means higher Disability Level</td>
</tr>
<tr>
<td></td>
<td>b. Disability Level</td>
</tr>
<tr>
<td></td>
<td>c. 0-10 Minimal Disability</td>
</tr>
<tr>
<td></td>
<td>d. 11-20 Moderate Disability</td>
</tr>
<tr>
<td></td>
<td>e. 21-30 Severe Disability</td>
</tr>
<tr>
<td></td>
<td>f. 31-40 Crippled</td>
</tr>
<tr>
<td></td>
<td>g. 41-50 Bed-bound</td>
</tr>
<tr>
<td></td>
<td>h. Change in Point Score</td>
</tr>
<tr>
<td></td>
<td>i. Percentage of Improvement</td>
</tr>
<tr>
<td></td>
<td>1. ((\text{OWS}<em>{t1} - \text{OSW}</em>{t2}))</td>
</tr>
<tr>
<td></td>
<td>j. Percentage of Improvement</td>
</tr>
<tr>
<td></td>
<td>1. ((\text{OWS}<em>{t1} - \text{OSW}</em>{t2}) / (\text{OWS}_{t1}) \times 100%)</td>
</tr>
<tr>
<td>3. Roland-Morris Disability Questionnaire</td>
<td>a. Score: 0-24 Higher score means higher Disability Level</td>
</tr>
<tr>
<td></td>
<td>b. Disability Level</td>
</tr>
<tr>
<td></td>
<td>c. 0-8 Minimal Disability</td>
</tr>
<tr>
<td></td>
<td>d. 9-16 Moderate Disability</td>
</tr>
<tr>
<td></td>
<td>e. 17-24 Severe Disability</td>
</tr>
<tr>
<td></td>
<td>f. Change in Point Score</td>
</tr>
<tr>
<td></td>
<td>i. ((\text{RMDQ}<em>{t1} - \text{RMDQ}</em>{t2}))</td>
</tr>
<tr>
<td></td>
<td>j. Percentage of Improvement</td>
</tr>
<tr>
<td></td>
<td>1. ((\text{RMDQ}<em>{t1} - \text{RMDQ}</em>{t2}) / (\text{RMDQ}_{t1}) \times 100%)</td>
</tr>
<tr>
<td>3. Perceived Level of Pain Intensity and Frequency</td>
<td>a. Score: 0-100 Higher score means higher Level of Pain</td>
</tr>
</tbody>
</table>
APPENDIX B

Timeline Scheme
Timeline

After sample determination and subject enrollment, participants were randomized into two different treatments, standard physical therapy or combined therapy. Once enrolled and randomized, participants received their treatment as prescribed.

Information on disability level, functional status and perceived level of pain were gathered at the beginning of the first, second, third and last therapy session, and at one-month follow-up after treatment termination. See Figure 1

![Figure 1. Timeline Scheme](image-url)
APPENDIX C

Institutional Review Board Approval Letter

University of Puerto Rico

Medical Sciences Campus
Date: February 16, 2007
Principal Investigator: Alexis Ortiz Rodríguez
Department / Division: CPRS – Physical Therapy
Sponsor:
Title: EFFECTIVENESS OF LOW RACK PAIN MANIPULATIVE THERAPY IN COMBINATION WITH PHYSICAL THERAPY AS COMPARED TO STANDARD PHYSICAL THERAPY

This is to certify that the above referenced research proposal/protocol received by the Human Research Subjects Protection Office was full board reviewed by the Institutional Review Board on February 15, 2007 and the research proposal was approved.

This action involves:

- New proposal/project
- Waiver of Consents
- Continuing Review of Previously Approved Protocol
- Protocol Amendment
- Revised Informed Consent Form
- Adverse Events

The following documents were reviewed under this submission:

- Informed Consent Document
- Spanish Version
- Assent Document
- Spanish Version
- Protocol
- Letter of Amendment
- Survey Instrument
- FDA #1572
- Package Insert
- Advertisement
- Investigator Brochure
- Authorization Letter
- Informative Sheet
- Clarification Memo
- Progress Report
- Letter to Participants
- Abstract
- Sponsor Notice
- Interim Safety Review
- IND Number Letter
- Patient Information Card English
- CRF
- Human Subject Certified
- HIPAA Certified
- Curriculum Vitae
- Others: Initial Evaluation, follow up questionnaire, Manipulative Techniques Pictures, Support Letter

In compliance with federal regulations the approval of this project is valid through for a period of one year or less from the time of the most recent IRB review. Approval for this study is valid through: February 14, 2008. The most recent protocol version is: N/A. The most recent consent form is: N/A.

All serious or unexpected adverse events/drug reactions should be reported to the Institutional Review Board through the Office of Research Compliance.

Sincerely,

Marlen Oliver Vázquez, EdD, MPHE
Chairperson IRB 1

PO Box 365067, San Juan, Puerto Rico 00936-5067 • Tel. / Phone 787-282-0010, 787-282-0018
Patrono con igualdad de Oportunidad en el Empleo M/M/V/I
Equal Employment Opportunity Employer M/W/W/I
APPENDIX D

Collaboration Letter
January 29, 2007

Institutional Review Board
University of Puerto Rico
Medical Sciences Center
San Juan, P.R. 00936

Dear IRB Committee,

This document is to inform the office of Institutional Review Board at the University of Puerto Rico, Medical Sciences Campus that the proposed study: “Effectiveness of Low Back Pain Manipulative Therapy in Combination with Physical Therapy as Compared to Conventional Physical Therapy”, will be carried out at the Clinica de Medicina Deportiva del Caribe, Inc. located in San Juan, Puerto Rico.

We have disposed our facility and assigned four physical therapists in our clinic to this study. In addition, I will be functioning as the physician in charge of all patients recruited for this study and will be fully responsible for their healthcare. This project will be done in collaboration with the Program of Physical Therapy within the College of Health Related Sciences of the Medical Sciences Center, University of Puerto Rico.

Our Clinic strongly supports this project and will provide all support needed.

Sincerely,

Dr. Dwight Santiago, MD
Medical Director and Proprietor
NOTE: Spanish version of Informed Consent received IRB approval from the University of Puerto Rico, Medical Sciences Campus. The University of Puerto Rico does not require an English version of the document unless the proposed research is federally funded. Nevertheless, a verbatim English version is furnished.
INFORMACIÓN PARA PARTICIPANTES DE INVESTIGACIÓN Y
CONSENTIMIENTO INFORMADO

TITULO: EFEICIVIDAD DE LA TERAPIA MANUAL COMBINADA CON TERAPIA FÍSICA EN COMPARACIÓN A
TERAPIA FÍSICA ESTÁNDAR

NÚMERO DE PROTOCOLO: A4160107

PATROCINADOR: Clínica de Medicina Deportiva del Caribe, Inc., San Juan, Puerto Rico.

INVESTIGADORES: Dr. Alexis Ortiz, PT, PhD, CSCS
               Heidi L. Venegas, BS, MS
               Dr. Dwight Santiago, MD
               Flavia Bayron, PT, MPA, ATRIC

LUGAR: Clínica de Medicina Deportiva del Caribe, Inc., San Juan, Puerto Rico.

NÚMEROS TELEFÓNICOS: 787-758-2525 ext.4201 (Terapia Física)
                        787-723-4857 (Clínica de Medicina Deportiva)

Este consentimiento informado puede contener palabras difíciles de entender. De tener alguna duda
puede preguntar a cualquier miembro del equipo de investigación para que aclare las dudas que
pueda tener. Esta forma de consentimiento informado puede ser llevada para el hogar para ser
discutido con familiares y amigos antes de tomar una decisión para participación.

PROVÓSO DEL ESTUDIO:

El propósito de la terapia física para pacientes de dolor de espalda baja es lograr que éstos
regresen a un estado físico/emocional similar al existente previo a la lesión, disminuir cualquier
impedimento causado por la lesión, y evitar, reducir o eliminar cualquier discapacidad producida
por la condición. Se ha establecido que la terapia física para lesiones a espalda baja produce
mejores resultados cuando son ofrecidos en etapas tempranas de la condición. Por tal razón, en la
actualidad, los programas de rehabilitación se enfocan en comenzar rehabilitación a etapas
tempranas.

Estudios han comprobado que la terapia manual ofrece excelentes beneficios para pacientes que
sufren dolor de espalda baja. Este tipo de terapia se compone de una manipulación de alta
velocidad y baja amplitud en el área de la espalda baja y es mejor conocida como manipulación
rápida de la articulación espinal. Sin embargo, este tipo de terapia aún no ha sido adoptada de manera definitiva en los programas de rehabilitación para pacientes que sufren dolor de espalda baja en Puerto Rico.

El propósito de este estudio es determinar si la combinación de un programa de rehabilitación que incluya terapia manual y terapia física estándar es más efectivo en mejorar o aliviar percepción de dolor, impedimento funcional y/o discapacidad en pacientes entre 21 a 65 años de edad que presentan un nuevo episodio de dolor de espalda baja.

PROCEDIMIENTOS

En este estudio se estarán comparando dos tipos de tratamientos de terapia física para el dolor de espalda baja. Los participantes se asignarán, de forma aleatoria (al azar), a uno de dos grupos – un grupo recibirá terapia física estándar de acuerdo al plan de tratamiento prescrita al paciente, el segundo grupo recibirá un tratamiento combinado que incluirá terapia manual y terapia física estándar de acuerdo al plan de tratamiento prescrito al paciente. Los pacientes asignados al grupo de terapia combinada recibirán la misma calidad de tratamiento que al grupo asignado a terapia física estándar; sin embargo, recibirán terapia manual en combinación con terapia física estándar durante las primeras dos visitas al terapeuta físico. La terapia manual incluye ejercicios y estiramientos que requieren el uso de las manos utilizando fuerza y rapidez de manera que se logren alinear segmentos de la espalda y recuperar el movimiento de la espalda baja. Luego de la segunda visita al terapeuta físico, el paciente recibirá terapia física estándar según prescrita.

Como parte del tratamiento de terapia física, el paciente será examinado por el terapeuta físico durante la evaluación inicial. Durante esta evaluación inicial el paciente completará un cuestionario dirigido a describir el dolor, impedimento funcional, y discapacidad producida por el dolor de espalda baja. Luego de la evaluación inicial, el terapeuta físico preparará un plan de tratamiento específico para el paciente de acuerdo a los resultados de la evaluación inicial. Ambos grupos de pacientes, los asignados a terapia física estándar y los asignados a terapia combinada, serán atendidos por terapeutas físicos licenciados.

Todos los pacientes que participen en este estudio completarán el cuestionario antes mencionado solo al inicio de las primeras tres visitas. Durante la última visita, los pacientes completarán un último cuestionario y serán re-evaluados por el terapeuta físico, de manera que los investigadores puedan determinar el progreso de cada paciente luego del programa de rehabilitación. Todos los cuestionarios serán completados y las evaluaciones por los terapeutas físicos realizadas en las facilidades de la Clínica de Medicina Deportiva del Caribe Inc., en San Juan, Puerto Rico, durante las visitas de tratamiento de terapia física.

RIESGOS E INCOMODIDADES
Como consecuencia de la participación en este estudio de investigación el participante podría sufrir lo siguiente:

1. Molestia física generalizada y/o dolor muscular durante las pruebas, ejercicios de estiramientos y terapias y/o hasta 48 horas luego de haber terminado estas.
2. Presión en la piel debido a la terapia manual.

Los miembros del equipo de investigación tomarán todas las precauciones necesarias para proteger a todos los participantes de posibles riesgos e incomodidades que pudieran ocurrir durante y después de la sesión de pruebas, ejercicios de estiramiento, y terapias. Las precauciones a seguir serán las siguientes:

1. Toda sesión de terapia física terminará con un periodo de enfriamiento en donde se ofrecerá hielo por un tiempo de 15 a 20 minutos si así el participante lo desea.
2. La presión en la piel será durante el proceso de la manipulación y será de la magnitud necesaria para lograr la misma. Dicha presión deberá desaparecer luego de finalizada la manipulación.

CLÁUSULA SOBRE EMBARAZO REQUERIDA POR LA INSTITUCIÓN

Si alguna de las participantes se encuentra embarazada o sospecha estar embarazada al momento de ser reclutada, quedará automáticamente excluida del estudio. De la misma manera si queda embarazada o sospecha estarlo durante el transcurso de las intervenciones o de los seguimientos a las cuatro y seis semanas quedará excluida del estudio. Las razones de exclusión están relacionadas a la falta de información científica que evidencie la seguridad de la manipulación de la espalda baja en mujeres embarazadas.

BENEFICIOS

Éste estudio es un estudio de tratamiento. Los participantes recibirán beneficio directo por su participación en este estudio. Todos los participantes de este estudio recibirán el cuidado y/o terapia física prescritos por el médico para el tratamiento de dolor de espalda baja de forma regular en la clínica sin importar a que grupo de tratamiento es asignado. El terapista físico se encargará de discutir los mismos con usted. Los pacientes asignados al tratamiento experimental recibirán en adición una sección de terapia manual para dolor de espalda baja. Esta prescripción de terapia manual será libre de costos adicionales para el participante. La información que se obtenga de esta investigación ayudará a establecer mejores técnicas de rehabilitación para personas que sufren de dolor de espalda baja.

COSTOS
No habrá ningún cargo adicional por participar en este estudio.

**PAGO POR PARTICIPACIÓN**

No habrá ninguna compensación monetaria (dinero) por participar en este estudio.

**ALTERNATIVA DE PARTICIPACION**

Este estudio es un estudio de tratamiento. Todo participante recibirá el cuidado y/o terapia física prescritos por el médico para el tratamiento de dolor de espalda baja. Sin embargo, el paciente tendrá el derecho de elegir no participar en este estudio.

**PRIVACIDAD Y CONFIDENCIALIDAD**

Si usted elige estar en este estudio, el investigador del estudio conseguirá información personal sobre usted. Esto puede que incluya la información que puede identificarle a usted. El investigador puede también conseguir información sobre la salud suya incluyendo:

- Historial médico presente y pasado.
- Historial de sus visitas a la clínica.
- Resultados de exámenes físicos.
- Resultados de cuestionarios relacionados a su tratamiento.

El investigador del estudio puede dar información sobre usted y de su salud que podrían identificarle a:

- La Administración de Drogas y Alimento de los Estados Unidos (FDA siglas en inglés)
- Agencias del Departamento de Salud y Servicios Humanos (DHHS siglas en inglés)
- Agencias Gubernamentales a las cuales ciertas enfermedades (enfermedades reportables) deben ser informadas
- El Comité de Derechos Humanos (IRB siglas en inglés) de la Universidad de Puerto Rico, Recinto de Ciencias Médicas

Información sobre usted y sobre su salud que puede identificarle a usted podría ser brindada a otros para realizar este estudio de investigación. El patrocinador analizará y evaluará los resultados del estudio. Además, personal del patrocinador y de sus consultores estarán visitando el lugar de investigación. Ellos observarán cómo se hace el estudio, y repasarán la información suya para este propósito. Los expedientes estarán guardados y custodiados según reglamentación HIPAA.

La información podría ser brindada a la Administración de Drogas y Alimentos de Estados Unidos (FDA, siglas en inglés). Podría también ser brindada a las agencias gubernamentales en otros países. Se realiza así para que el patrocinador pueda recibir la aprobación de la comercialización para los productos nuevos como resultado de esta investigación. La
información también puede ser utilizada para cumplir con los requisitos de divulgación de agencias gubernamentales.

Los resultados de esta investigación pueden ser publicados en revistas científicas o ser presentados en las reuniones médicas, pero la identidad suya no será divulgada.

La información puede ser revisada por el Comité de Derechos Humanos (IRB siglas en inglés) de la Universidad de Puerto Rico, Recinto de Ciencias Médicas. El IRB del RCM es un grupo de personas quienes realizarán la revisión independiente de la investigación según los requisitos de las regulaciones.

La información de salud suya será mantenida tan confidencial como sea posible bajo la ley. Sin embargo, esta información no podrá ser protegida por las reglas de privacidad una vez que se divulgue a nuestros asociados y pueda ser compartida con otros.

Esta autorización servirá hasta el final del estudio, a menos que usted la cancele antes. Usted puede cancelar esta autorización en cualquier momento enviando un aviso escrito al Investigador Principal en la dirección siguiente:

**Dr. Alexis Ortiz Rodriguez, PT, Ph.D, CSCS**
Programa de Terapia Física
Colegio de Profesiones Relacionadas a la Salud
UPR-Recinto de Ciencias Médicas
PO Box 365067
San Juan, PR 00936
alexisortiz@cprs.rcm.upr.edu
787-758-2525 ext. 4201

Si usted cancela esta autorización, el Investigador Principal no usará ni divulgará su información personal ni de su salud bajo la autorización para este estudio. Esta información sólo se divulgará en caso que se necesite la información personal de su salud para preservar la integridad científica del estudio. La información sometida antes de que usted cancele esta autorización puede ser utilizada por los asociados.

La autorización para el uso y el acceso de la información protegida de la salud para los propósitos de la investigación es totalmente voluntaria. Sin embargo, de no firmar este documento usted no podrá participar en este estudio. Si en el futuro usted cancela esta autorización, no podrá continuar participando en este estudio.

**COMPENSACIÓN POR LESIÓN**
En caso de lesión física o mental como resultado de participación en este estudio, el participante recibirá tratamiento médico libre de costo en la Clínica de Medicina Deportiva del Caribe, Inc., San Juan, Puerto Rico, el Hospital Universitario o algún otro hospital designado por el Rector del Recinto de Ciencias Médicas de la Universidad de Puerto Rico. La Universidad de Puerto Rico no proveerá compensación directa al participante afectado. Sin embargo, firmando este consentimiento informado no se renuncia a ningún derecho legal.

PARTICIPACIÓN VOLUNTARIA Y CANCELACIÓN

La participación en este estudio es voluntaria. Todo participante puede decidir no participar o retirarse del estudio en cualquier momento. La decisión de retirarse de cualquier participante no resultará en penalidad o pérdida de los beneficios terapéuticos para el dolor de espalda baja prescritos por su médico. La participación en este estudio puede terminar sin consentimiento del participante si el investigador principal o el patrocinador así lo requieren.

FUENTE DE FINANCIAMIENTO PARA EL ESTUDIO

Este estudio no cuenta con fondos asignados para la investigación.

PREGUNTAS

Si hubiere alguna pregunta relacionada a este estudio, a detalles sobre su participación o si en algún momento ocurre una lesión se puede contactar al investigador principal a la siguiente dirección:

Dr. Alexis Ortiz Rodriguez, PT, Ph.D, CSCS
Programa de Terapia Física
Colegio de Profesiones Relacionadas a la Salud
UPR-Recinto de Ciencias Médicas
PO Box 365057
San Juan, PR 00936
alexisortiz@cpr.rcm.upr.edu
787-758-2525 ext. 4201

Si hubiera preguntas sobre derechos de participantes en estudios de investigación puede contactar a:
Oficina de Protección de Participantes Humanos en Investigación
Teléfono (787)282-0018 o (787)-282-0010
E-mail: opphi@rcm.upr.edu
No firme este consentimiento al menos que haya tenido la oportunidad de hacer preguntas y clarificar sus dudas de manera satisfactoria.
Si decide participar en esta investigación recibirá una copia firmada con sello del Comité de Revisión como evidencia.

CONSENTIMIENTO

He leído este consentimiento en su totalidad y todas mis preguntas y dudas han sido clarificadas. De manera voluntaria doy consentimiento para participar en esta investigación.

Autorizo a que mi información privada de salud se utilice y se divulgue a las personas autorizadas de la manera antes expresadas.

Firmando este consentimiento, no he renunciado a mis derechos legales.

__________________________
Nombre del Participante (Letra de Molde)

__________________________
Firma del Participante

__________________________
Fecha

__________________________
Si Aplica

__________________________
Nombre de Padre o Madre (Letra de Molde)

__________________________
Fecha

__________________________
Firma de Padre o Madre

__________________________
Fecha

__________________________
Firma de Representante Legal Autorizado

__________________________
Fecha

__________________________
Autoridad del Representante Legal Autorizado del Participante
(Si aplica)

__________________________
Firma de la persona discutiendo el
consentimiento informado

--------------------- Use solo si aplica ---------------------

Page 7 of 8

APPROVED Consent Form Approved by the UFR-MSC IRB January 15, 2008 - January 14, 2009

136
Si este consentimiento es leído al participante (o representante legal) porque alguno; el participante o representante legal no puede leer, un testigo neutral que no sea miembro del equipo de investigación debe estar presente para otorgar consentimiento y firmar este documento.

Confirme que la información en este consentimiento informado fue explicada de manera clara y precisa. Confirme que esta información fue aparentemente entendida por el participante y/o representante legal. El participante o su representante legal aceptan de forma voluntaria participar en este estudio.

________________________________________________________________________
Firma de Testigo Neutral                         Fecha

Page 8 of 8

Consent Form Approved by the UPR-MSC IRB January 15, 2008 - January 14, 2009
INFORMATION FOR STUDY PARTICIPANTS
AND INFORMED CONSENT

TITLE: STUDY OF EFFECTIVENESS OF TREATMENT OF LOW BACK PAIN BY MANIPULATIVE THERAPY IN COMBINATION WITH CONVENTIONAL PHYSICAL THERAPY AS COMPARED TO STANDARD PHYSICAL THERAPY ALONE

PROTOCOL NUMBER: A4160107

SPONSOR: Sports Medicine Clinic of the Caribbean, Inc., San Juan, Puerto Rico
(Clínica de Medicina Deportiva del Caribe, Inc., San Juan, Puerto Rico)

INVESTIGATORS: Dr. Alexis Ortiz, PT, PhD, CSCS
Heidi L. Venegas, BS, MS
Dr. Dwight Santiago, MD
Flavia Bayron, PT, MPA, ATRIC

SITE: Sports Medicine Clinic of the Caribbean, Inc., San Juan, Puerto Rico
(Clínica de Medicina Deportiva del Caribe, Inc., San Juan, Puerto Rico)

TELEPHONE NUMBERS: 787-758-2525 ext. 4201 (Physical Therapy Department)
787-723-4857 (Sports Medicine Clinic)

This consent form may contain words that you do not understand. Please ask the study investigator or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

PURPOSE OF THE STUDY

The purpose of physical therapy for patients with low back pain is to reach a state of physical and emotional wellbeing similar to that before the injury, decrease any impairment caused by the injury, and avoid, reduce or eliminate any incapability caused by it. It has been shown that physical therapy for low back pain injuries yield better results when offered during the early
stages of the condition. For that reason, today, every rehabilitation program is aimed at starting therapy at early stages of the condition.

Studies have reported that manual therapy offers excellent benefits for patients suffering from low back pain. This type of therapy involves a high speed low amplitude thrust manipulation to the lower back area, better known as the high-speed manipulation of the spinal articulation. However, this type of therapy has not been adopted, in a definitive manner, on rehabilitation programs for low back pain patients in Puerto Rico.

The purpose of this study is to determine if manual therapy in combination with standard physical therapy is more efficient in terms of reducing perceived level of pain, functional impairments, and/or disability than standard physical therapy alone, in patients between 21 and 65 years of age who present with a new episode of low back pain.

PROCEDURES

This study will compare two different treatments for low back pain. Participants will be randomly assigned to one of the treatments – one group will receive standard physical therapy as prescribed to the patients, and the other group will receive a combined therapy including manual therapy and standard physical therapy as prescribed to the patient. Patients assigned to combined therapy will receive same quality of treatment as those assigned to standard therapy; however, they will receive manual therapy in combination with their prescribed standard physical therapy on the first two visits to the physical therapist. Manual therapy includes exercises and stretching movements requiring force and velocity in such a way as to align segments of the spine, and restore movement on the low back area. After the second visit to the physical therapist, the patient will receive standard physical therapy as prescribed.

The patient will be examined by the physical therapist during the initial evaluation as part of the physical therapy treatment. The patient will complete a questionnaire aimed to describe pain, functional impairment and disability caused by low back pain during the initial evaluation. After initial evaluation, the physical therapist will design a specific treatment plan based on the initial evaluation's results for each patient. Patients groups, those assigned to standard physical therapy and those assigned to combined therapy, will be treated by licensed physical therapists.

Every patient participating in this study will complete the questionnaire mentioned above only at the beginning of the first three visits. Participant patients will complete a final questionnaire during their last visit, and will be re-evaluated by the physical therapist, in order to let researchers determine each patient's progress after the rehabilitation program. Evaluations by physical therapists and completion of questionnaires by patients will take place during the physical treatment visits at the Sports Medicine Clinic of the Caribbean, Inc., San Juan, Puerto Rico (Clínica de Medicina Deportiva del Caribe, Inc., San Juan, Puerto Rico).
RISKS AND DISCOMFORTS

Participants might experience some of the following, as part of participating in this research study:

1. General physical discomfort and/or musculoskeletal pain during tests, stretching exercises and therapy and/or up to 48 hours after these have taken place.
2. Pressure on the skin due to manual therapy.

Members of the research team will take every necessary precaution to protect every participant from risks and discomforts that may occur during and after every stretching, exercise and therapy session. These precautions will include the following:

1. Every physical therapy session will conclude with a cool down period in which a 15 to 20 minutes ice treatment will be offered to the patient, if desired.
2. Pressure on the skin will take place during manipulation and will be equal to the magnitude needed to successfully perform the manipulation. Skin pressure will end once the manipulation has been performed.

PREGNANCY CLAUSE REQUIRED BY THE INSTITUTION

Any pregnant female participants or participants, who suspect to be pregnant at the moment of recruitment, will be automatically excluded from the study. In addition, any female participant that becomes pregnant or suspects to be pregnant at any time during the study interventions will also be excluded from the study. Reasons for exclusion are related to the lack of scientific information evidencing the safety of low back manipulation in pregnant women.

BENEFITS

This is a treatment study. Participants will not receive direct benefit for participating in the study. Every participant will receive low back pain care and/or physical therapy as prescribed to them by their physician at the clinic, regardless to what treatment group was assigned. The physical therapy will be in charge of discussing them with the participant. Participants assigned to the experimental treatment will receive, in addition, sessions of manual therapy for low back pain. This manual therapy prescription will be offered at no additional cost to participants. The information obtained from this investigation will help establish better rehabilitation techniques for people suffering from low back pain.

COSTS

There are no additional charges related to study participation.
PARTICIPANT COMPENSATION

There will not be any financial compensation for taking part in this study.

ALTERNATIVE TO PARTICIPATION

This study is a treatment study. Every participant will receive the treatment prescribed by the physician for low back pain. However, you have the right to choose not to participate in the study.

PRIVACY AND CONFIDENTIALITY

If you choose to be in this study, the investigator will get personal information about you. This may include information that might identify you. The investigator may also get information about your health including:

- Past and present medical records
- Records about your study visits
- Results from study physical exams
- Results from study questionnaires

Dr. Alexis Ortiz Rodriguez, PT, Ph.D, CSCS
Programa de Terapia Física
Colegio de Profesiones Relacionadas a la Salud
UPR-Recinto de Ciencias Médicas
PO Box 365067
San Juan, PR 00936
alexisortiz@epaps.upre.edu
787-755-2525 ext. 4201

The PI might give information about you and your health which might identify you to:

- The U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- The UPR Medical Sciences Campus Institutional Review Board (UPR MSC IRB)

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose. The records will be safeguarded as HIPAA regulations.
The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

The information may be reviewed by The UPR Medical Sciences Campus Institutional Review Board (UPR MSC IRB). UPR MSC IRB is a group of people who perform independent review of research as required by regulations.

Your personal health information will be kept as confidential as possible under the law. However, your personal health information may no longer be protected by the privacy rule once it is disclosed to our associates, and may be shared with others.

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel this authorization at any time by sending a written notice to the principal investigator at the following address:

Dr. Alexis Ortiz Rodriguez, PT, Ph.D, CSCS
Programa de Terapia Física
Colegio de Profesiones Relacionadas a la Salud
UPR-Recinto de Ciencias Médicas
PO Box 365067
San Juan, PR 00906
alexisortiz@ecpr.rcm.upr.edu
787-758-2525 ext. 4201

If you cancel this authorization, the principal investigator will no longer use or disclose your personal health information under the authorization for this study, unless he/she needs to use or disclose some of your personal health information to preserve the scientific integrity of the study. Information submitted before you cancel this authorization can still be used by the associates.

The Authorization for Use and Disclosure of Protected Health Information for research purposes is completely voluntary. However, if you do not sign this document you will not be able to participate in this study. If in the future you cancel this authorization, you will not be able to continue participating in this study.
COMPENSATION IN CASE OF INJURY

In the event of physical and/or mental injury resulting from this research study, you will receive medical treatment free of charge at the University Hospital or any other hospital designated by the Chancellor or the Medical Sciences Campus of the University of Puerto Rico. The University of Puerto Rico has no plans to provide any form of compensation directly to you. However, by signing this consent form you do not give up any legal rights.

VOLUNTARY PARTICIPATION AND STUDY WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of therapeutic benefits to which you are entitled to, and were prescribed by your doctor for your low back pain. If it is necessary your participation in this study may be stopped at any time by the investigator or the sponsor without your consent.

FUNDING RESOURCES FOR THE STUDY

No funding was assigned for this study.

QUESTIONS

If you have any questions about this study or your participation in this study, or if at any time you feel you have experienced a research-related injury or a reaction to the study medication, contact:

Dr. Alexis Ortiz Rodriguez, PT, Ph.D, CSCS
Programa de Terapia Física
Colegio de Profesiones Relacionadas a la Salud
UPR-Recinto de Ciencias Médicas
PO Box 365067
San Juan, PR 00936
alexisortiz@cpvs.rcm.upr.edu
787-758-2525 ext. 4201

If you have questions about your rights as a research subject, you may contact:

Human Research Subjects Protection Office
University of Puerto Rico
Medical Sciences Campus
Telephone: 787-282-0018 or 787-282-0010
E-mail: upphi@rcm.upr.edu
Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to be in this study, you will receive a signed and dated copy of this consent form with the stamp of IRB approval for your records.

CONSENT

I have read the information in this consent form (or it has been read to me). All my questions about the study and my participation in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

Subject Name

Signature of Subject ........................................ Date

If applicable

Name of Father of Mother ........................................ Date

Signature of Father or Mother ........................................ Date

Signature of Legally Authorized Representative ........................................ Date

Authority of Subject’s legally Authorized Representative or Relationship to Subject (When applicable)

Signature of Person Conducting Informed Consent Discussion ........................................ Date

Page 7 of 8
If this consent form (addendum) is read to the subject because the subject (or legally authorized representative) is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form (addendum) and any other written information was accurately explained to, and apparently understood by, the subject (or the subject's legally authorized representative). The subject (or the subject's legally authorized representative) freely consented to be in the research study.

Signature of Impartial Witness             Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.
APPENDIX F

Initial Evaluation and

Follow-up Evaluations Questionnaires

(SPANISH AND ENGLISH VERSIONS INCLUDED)

NOTE: Spanish version of Questionnaires received IRB approval from the University of Puerto Rico, Medical Sciences Campus. The University of Puerto Rico does not require an English version of the document unless the proposed research is federally funded. Nevertheless, a verbatim English version is furnished.
ESTUDIO SOBRE LA EFECTIVIDAD DE LA TERAPIA MANUAL COMBINADA CON TERAPIA FÍSICA EN COMPARACIÓN A TERAPIA FÍSICA ESTÁNDAR

Cuestionario para el Paciente
(Evaluación Inicial)

**Instrucciones:** Este cuestionario ha sido diseñado para ofrecer a su terapista físico información sobre cómo su dolor de espalda baja ha afectado su habilidad de manejar situaciones del día a día. Favor de contestar cada pregunta según su mejor conocimiento.

**Antes de que comience, desees que entienda que:**
- Su participación es totalmente voluntaria.
- Si usted decide participar en este estudio, usted tendrá el derecho de abandonar el mismo en cualquier momento y por cualquier razón. Su tratamiento de terapia física para dolor de espalda baja no será afectado si usted decide abandonar el estudio.

**NOTA:** Ningún tipo de información personal confidencial sobre el paciente será divulgada a investigadores o terceras personas. Sólo el personal responsable del manejo de citas tendrá acceso a la información confidencial del paciente, y sólo será utilizada para establecer las citas para tratamiento y contacto en caso de emergencia.

Estudio sobre Dolor de Espalda Baja
Evaluación Inicial
Modificado: 6 de mayo de 2007, Página 1 de 13
ESTUDIO SOBRE LA EFEICRIVEDAD DE LA TERAPIA MANUAL COMBINADA CON TERAPIA FÍSICA EN COMPARACIÓN CON TERAPIA FÍSICA ESTÁNDAR

INSTRUCCIONES: Por favor, conteste las siguientes preguntas lo más preciso posible. Esta información es confidencial y sólo será utilizada para cumplir con el propósito del estudio. Donde sea apropiado, utilice un cotejo (Z) para marcar sus respuestas.

A. INFORMACIÓN DEL PACIENTE

<table>
<thead>
<tr>
<th>Nombre y Dirección del Paciente</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Nombre: Apellidos1   Nombre2 Inicial3</td>
</tr>
<tr>
<td>2. Dirección: Calle y Número1 Urbanizaciones2</td>
</tr>
<tr>
<td>Pueblo3 Zip4</td>
</tr>
<tr>
<td>3. Teléfono: Código de Área (___) - - - - - -</td>
</tr>
<tr>
<td>4. Persona a quién contactar en caso de emergencia: Apellidos1 Nombre2 Inicial3</td>
</tr>
<tr>
<td>5. Teléfono: Código de Área (___) - - - - - -</td>
</tr>
<tr>
<td>6. Persona a quién contactar en caso de emergencia: Apellidos1 Nombre2 Inicial3</td>
</tr>
<tr>
<td>7. Teléfono: Código de Área (___) - - - - - -</td>
</tr>
</tbody>
</table>
B. INFORMACIÓN MÉDICA Y DE SALUD

1. Por favor, indíque si algún médico le ha diagnosticado alguna de las siguientes enfermedades y/o condiciones: (Por favor, MARQUE TODAS LAS OPCIONES QUE LE APLIQUEN)

<table>
<thead>
<tr>
<th></th>
<th>SI</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Osteoporosis</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>2. Osteoartritis</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>3. Lordosis</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>4. Escoliosis</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>5. Sifosis</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>6. Discos herniados</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>7. Estenosis Lumbar</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>8. Espondilitis</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>9. Espondilosis</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>10. Fractura Vertebral</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>11. Otras</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

□ Especifique: __________________________

2. ¿Se encuentra usted actualmente recibiendo tratamiento o terapia para su dolor de espalda baja?

□ Sí, me encuentro actualmente recibiendo tratamiento/terapia para mi dolor de espalda baja.

□ Actualmente NO me encuentro recibiendo tratamiento para mi dolor de espalda baja, pero he recibido tratamiento/terapia en el pasado.

□ Nunca he recibido tratamiento/terapia para mi dolor de espalda baja. → VAYA A LA PREGUNTA #6

3. ¿Se encuentra usted actualmente tomando medicamentos para su dolor de espalda baja?

□ Sí, actualmente me encuentro tomando medicamentos recetados para el dolor de espalda baja.

□ Actualmente NO me encuentro tomando medicamentos recetados para dolor de espalda baja, pero sí he tomado medicamentos en el pasado.

□ Nunca he tomado medicamentos recetados para dolor de espalda baja. → VAYA A LA PREGUNTA #5

□ Especifique: 1. __________________________ (nombre del medicamento)

□ 2. __________________________ (nombre del medicamento)

□ 3. __________________________ (nombre del medicamento)

⇒ VAYA A LA PREGUNTA #5

⇒ VAYA A LA PREGUNTA #5
4. **Instrucciones:** Conteste esta pregunta #4 **SOLO** si ha tomado medicamentos recetados en el pasado.

**Lista de medicamentos recetados utilizados en el pasado:**

Nombre de el/los medicamento(s)  __________________________  Duración del uso (meses)  ______

3. __________________________  ______

4. __________________________  ______

5. ¿Está/estuvo usted satisfecho(a) con la calidad del tratamiento/terapia que recibe/recibió para el dolor de espalda baja?

☐ Si

☐ No  Por favor, explique por qué no está/estuvo satisfecho:

6. Por favor, identifique su estatus de fumar actual:

☐ Ex-fumador  ➔ VAYA A LA PREGUNTA # 6a - 6c

☐ Fumador  ➔ VAYA A LA PREGUNTA # 6b - 6c

☐ Nunca-Fumador  ➔ VAYA A LA SECCIÓN C. EN LA PÁGINA #5

---

**Instrucciones:** Si usted es un **ex-fumador**, conteste las preguntas desde la 6a hasta la 6c. Luego vaya a la **SECCION C.** en la página #5.

Si usted es un **fumador actual**, sólo conteste las preguntas 6b y 6c. Luego vaya a la **SECCION C.** en la página #5.

6a. Si ex-fumador, ¿a qué edad dejó usted de fumar?  ______

6b. Si fumador actual o ex-fumador, ¿a qué edad comenzó a fumar?  ______

6c. Si fumador actual o ex-fumador, ¿cuántos cigarrillos fuma/fumaba al día?  ______
C. INFORMACIÓN DEMOGRÁFICA

INSTRUCCIONES: Esta sección ofrecerá información demográfica como edad, sexo, nivel de educación, ocupación, e ingreso familiar, entre otros. Esta información nos ayudará a conocer las características de los participantes de este estudio y sólo será estudiada de forma grupal. *Ninguna información sobre los participantes individuales será utilizada o disemina da en ningún momento.

1. ¿Cuál es su fecha de nacimiento?
   Ejemplo: 20/07/1974
   __________/__________/_________

   Día(dd)  Mes(mm)  Año(aaaa)

2. ¿Cuál es su sexo?
   □ 1. Hombre
   □ 2. Mujer

A. ¿Cuál es el grado de educación más alto que usted ha alcanzado?
   □ 1. Nunca fui a la escuela, o solo fui a Kindergarten
   □ 2. Asistí a la escuela, pero no se graduó de escuela superior
   □ 3. Se graduó de escuela superior, o obtuvo crédito independiente
   □ 4. Asistí a la universidad, o escuela técnica
   □ 5. Asistió a la escuela graduada

4. ¿Cuál es su estado marital actual?
   □ 1. Casado(a) legalmente
   □ 2. Conviviendo con alguien como matrimonio
   □ 3. Divorciado(a)
   □ 4. Separado(a)
   □ 5. Viudo(a)
   □ 6. Nunca casado(a)
   □ 7. Otro → Especifique: ___________________________
5. ¿Cuál es su estatus de empleo actualmente?

☐ 1. Empleado tiempo completo → VAYA A LAS PREGUNTAS # 5a-5d EN EL RECUADRO
☐ 2. Empleado tiempo parcial

☐ 3. Desempleado → VAYA A LAS PREGUNTAS #5c-5d EN EL RECUADRO

☐ 4. Ama de casa tiempo completo
☐ 5. Ama de casa tiempo parcial
☐ 6. Criando niños tiempo completo

**Instrucciones:**
Si empleado, conteste las preguntas desde la 5a hasta la 5d, luego continúe en la pregunta 6.
Si desempleado, conteste las preguntas desde la 5c hasta la 5d, luego continúe en la pregunta 6.

5a. ¿Cuál es su ocupación actual?
   (Por ejemplo: enfermera(s), maestro(a), chofer, etc.)

5b. ¿Cuánto tiempo lleva en su ocupación actual (años)? ________

5c. ¿Cuál fue su ocupación anterior?
   (Por ejemplo: enfermera(s), maestro(a), chofer, etc.)

5d. ¿Cuánto tiempo estuvo en su ocupación anterior (años)? ________

6. ¿Cuál fue su ingreso familiar total antes de las contribuciones durante el año pasado?

☐ 1. Menos de $10,000
☐ 2. Más de $10,000 pero menos de $15,000
☐ 3. Más de $15,000 pero menos a $20,000
☐ 4. Más de $20,000 pero menos $25,000
☐ 5. Más de $25,000 pero menos $35,000
☐ 6. Más de $35,000 pero menos $50,000
☐ 7. Más de $50,000 pero menos $75,000
☐ 8. Más de $75,000
☐ 9. No Aplica (desempleado durante el año pasado)
D. EVALUACIÓN DE DOLOR

INSTRUCCIONES: Por favor, conteste las siguientes.

1. Indique cuántos DIAS le comenzó el dolor de espalda baja que siente actualmente, no haga referencia a experiencias pasadas, sólo indique sobre el dolor actual (si no recuerda, por favor, provea un estimado): _________ DIAS

2. Comenzando por la izquierda de la siguiente barra, haga una línea ( | ) hacia la derecha indicando la intensidad de su DOLOR DE ESPALDA EN ESTE PRECISO MOMENTO.

   | Ningún | Moderado | Peor Dolor |
   | Dolor  |        | Imaginable |

3. Comenzando por la izquierda de la siguiente barra, haga una línea ( | ) hacia la derecha indicando la frecuencia de su DOLOR DE ESPALDA EN ESTE PRECISO MOMENTO.

   | Ocasional | Intermitente | Continuo |

4. Utilice los siguientes símbolos para describir su dolor de espalda. Marque en el dibujo exactamente donde siente el dolor y qué tipo de dolor siente en el área específica.

   MARQUE ASI:
   XXXXX = Dolor
   VVVV = Área tronca / rigida
   ===== = Sensación de ardor/quemazon
   ******* = Hormigüeo/sensación de agujas
   ↓↓↓↓↓ = Disminución en sensación
   ↑↑↑↑↑ = Aumento en sensación

Estudio sobre Dolor de Espalda Baja
Evaluación Inicial.
Modificado 6 de mayo de 2007. Página 7 de 13
E. IMPEDIMENTO FUNCIONAL Y DISCAPACIDAD

ÍNDICE DE DISCAPACIDAD DE OSWESTRY
INSTRUCCIONES: Esta sección del cuestionario ha sido diseñada para indicarle a su terapista cómo su dolor de espalda baja a afectado su habilidad de manejar actividades del diario vivir. Por favor, conteste cada pregunta utilizando una marca de cotejo (X) en el cuadro que mejor describa su condición HOY.

ENTENDEMOS QUE USTED PUEDE SENTIR QUE MÁS DE UNA RESPUESTA DESCRIBE SU CONDICIÓN, SIN EMBARGO, LE PEDIMOS QUE SÓLO MARQUE LA OPCIÓN QUE MEJOR DESCRIBA SU CONDICIÓN ACTUAL.

1. Intensidad del dolor
□ 0 Puedo soportar el dolor sin necesidad de tomar medicamentos para el dolor.
□ 1 El dolor es fuerte pero me arreglo sin tomar medicamentos para el dolor.
□ 2 Los medicamentos para el dolor me alivian completamente el dolor.
□ 3 Los medicamentos para el dolor me alivian un poco el dolor.
□ 4 Los medicamentos para el dolor apenas me alivian el dolor.
□ 5 Los medicamentos para el dolor no me alivian el dolor, por lo tanto, no los tomo.

2. Estar de pie
□ 0 Puedo estar de pie tanto tiempo como quiera sin que me aumente el dolor.
□ 1 Puedo estar de pie tanto tiempo como quiera pero me aumenta el dolor.
□ 2 El dolor me impide estar de pie más de una hora.
□ 3 El dolor me impide estar de pie más de media hora.
□ 4 El dolor me impide estar de pie más de 10 minutos.
□ 5 El dolor me impide estar de pie.

3. Cuidados personales
□ 0 Me las puedo arreglar solo sin que me aumente el dolor.
□ 1 Me las puedo arreglar solo pero esto me aumenta el dolor.
□ 2 Lavarme, vestirme, etc., me produce dolor y tengo que hacerlo despacio y con cuidado.
□ 3 Necesito alguna ayuda pero consigo hacer la mayoría de las cosas yo solo.
□ 4 Necesito ayuda para hacer la mayoría de las cosas.
□ 5 No puedo vestirme, me cuesta lavarme y suelo quedarme en la cama.

Estudio sobre Dolor de Espalda Baja
Evaluación Inicial.
Modificado 6 de mayo de 2007, Página 8 de 13
4. Dormir
- [] El dolor no me impide dormir bien
- [] Sólo puedo dormir si tomo pastillas
- [] Incluso tomando pastillas duermo menos de 6 horas
- [] Incluso tomando pastillas duermo menos de 4 horas
- [] Incluso tomando pastillas duermo menos de 2 horas
- [] El dolor me impide totalmente dormir

5. Levantar peso
- [] Puedo levantar objetos pesados sin que me aumente el dolor
- [] Puedo levantar objetos pesados pero me aumenta el dolor
- [] El dolor me impide levantar objetos pesados del suelo/piso, pero puedo hacerlo si están en un sitio cómodo (ej. en una mesa)
- [] El dolor me impide levantar objetos pesados, pero sí puedo levantar objetos ligeros o medianos si están en un sitio cómodo
- [] Sólo puedo levantar objetos muy ligeros/livianos
- [] No puedo levantar ni elevar ningún objeto

6. Actividad sexual
- [] Mi actividad sexual es normal y no me aumenta el dolor
- [] Mi actividad sexual es normal pero me aumenta el dolor
- [] Mi actividad sexual es casi normal pero me aumenta mucho el dolor
- [] Mi actividad sexual se ha visto muy limitada a causa del dolor
- [] Mi actividad sexual es casi nula a causa del dolor
- [] El dolor me impide todo tipo de actividad sexual

7. Caminar
- [] El dolor no me impide caminar
- [] El dolor me impide caminar más de una milla (1 milla = 1.6 kilómetros)
- [] El dolor me impide caminar más de ½ milla
- [] El dolor me impide caminar más de ¼ milla
- [] Sólo puedo caminar con bastón o muletas
- [] Permanezco en la cama casi todo el tiempo y tengo que ir a rastras al baño
8. Vida social

☐ Mi vida social es normal y no me aumenta el dolor
☐ Mi vida social es normal pero me aumenta el dolor
☐ El dolor no tiene un efecto importante en mi vida social, pero sí impide más actividades más energéticas como bailar, etc.
☐ El dolor ha limitado mi vida social y no salgo tan a menudo
☐ El dolor ha limitado mi vida social al hogar
☐ No tengo vida social a causa del dolor

9. Estar sentado

☐ Puedo estar sentado en cualquier tipo de silla todo el tiempo que quiera
☐ Puedo estar sentado en mi silla favorita todo el tiempo que quiera
☐ El dolor me impide estar sentado más de una hora
☐ El dolor me impide estar sentado más de media hora
☐ El dolor me impide estar sentado más de 10 minutos
☐ El dolor me impide estar sentado

10. Viajar

☐ Puedo viajar a cualquier sitio sin que me aumente el dolor
☐ Puedo viajar a cualquier sitio, pero me aumenta el dolor
☐ El dolor es fuerte pero aguanto viajes de más de 2 horas
☐ El dolor me limita a viajes de menos de una hora
☐ El dolor me limita a viajes cortos y necesarios de menos de media hora
☐ El dolor me impide viajar excepto para ir al médico o al hospital
ESCALA DE DISCAPACIDAD DE ROLAND-MORRIS
INSTRUCCIONES: Cuando su espalda le duele, puede encontrar difícil hacer algunas de las cosas que normalmente hace. Esta lista contiene muchas de las frases que las personas usan para explicar cómo se sienten cuando le duele la espalda. Lea la lista y utilice una marca de cotejo (☑) en las frases que describan cómo usted se siente HOY.

RECUERDE: MARQUE TODAS LAS FRASES QUE APLIQUEN, PERO SOLO SI DESCRIBEN COMO SE ENCUENTRA USTED HOY.

☐ 1. Me quedo en casa la mayor parte del tiempo por mi dolor de espalda.
☐ 2. Cambio de posición frecuentemente tratando de aliviar mi dolor de espalda.
☐ 3. Debido a mi espalda, camino más lento de lo normal.
☐ 4. Debido a mi espalda, no hago las tareas que usualmente hago en la casa.
☐ 5. Debido a mi dolor, uso los pasamanos cuando subo las escaleras.
☐ 6. A causa de mi espalda, tengo que acostarme más a menudo para descansar.
☐ 7. Debido a mi espalda, necesito agarrarme de algo para poder levantarme de una silla o sofá.
☐ 8. A causa de mi espalda, pido a otros que me hagan las cosas.
☐ 9. Me visto más lento de lo normal a causa de mi espalda.
☐ 10. A causa de mi espalda, me quedo de pie, por solo períodos cortos de tiempo.
☐ 11. A causa de mi espalda, evito doblarme o arrodillarme.
☐ 12. Me cuesta levantarme de una silla debido a mi espalda.
☐ 13. Me duele la espalda casi siempre.
☐ 14. Me cuesta darme vueltas en la cama por culpa de mi espalda.
☐ 15. Debido a mi dolor de espalda, no tengo mucho apetito o deseo de comer.
☐ 16. Me cuesta ponerme las medias por mi dolor de espalda.
☐ 17. Debido a mi espalda, solo camino distancias cortas.
☐ 18. Duermo peor debido a mi espalda.
☐ 19. Por mi dolor de espalda, alguien debe ayudarme a vestirme.
☐ 20. Estoy casi todo el día sentado(a) a causa de mi espalda.
☐ 21. Evito hacer trabajos pesados en casa, por culpa de mi espalda.
☐ 22. Por mi dolor de espalda, estoy más irritable y de peor humor de lo normal.
☐ 23. A causa de mi espalda, subo las escaleras más lento de lo normal.
☐ 24. Paso la mayoría del tiempo en cama por culpa de mi espalda.
F. CUESTIONARIO SOBRE CREencias Y COMPORTamiento SOBRE MIEDO Y EVASiON DE DOLOR
INSTRUCCIONES: Esta lista contiene muchas de las frases que las personas usan para explicar cómo se sienten cuando le duele la espalda.

Por favor, **para cada frase haga un círculo en un número del 0 al 6** para indicar hasta qué punto las actividades físicas tales como inclinarse/doblarse, levantar peso, caminar o conducir/guiar afectan o afectarían su dolor de espalda.

<table>
<thead>
<tr>
<th>Actividad Física</th>
<th>En total Desacuerdo</th>
<th>Ni de Acuerdo ni en Desacuerdo</th>
<th>Completamente de Acuerdo</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Mi dolor fue causado por la actividad física</td>
<td>0  1</td>
<td>2  3  4</td>
<td>5  6</td>
</tr>
<tr>
<td>2. La actividad física hace que mi dolor empeore</td>
<td>0  1</td>
<td>2  3  4</td>
<td>5  6</td>
</tr>
<tr>
<td>3. La actividad física podría dañar mi espalda</td>
<td>0  1</td>
<td>2  3  4</td>
<td>5  6</td>
</tr>
<tr>
<td>4. No debería hacer las actividades físicas que empeoran mi dolor, ni las que podrían empeorarlo</td>
<td>0  1</td>
<td>2  3  4</td>
<td>5  6</td>
</tr>
<tr>
<td>5. No puedo realizar las actividades físicas que empeoran mi dolor, ni las que podrían empeorarlo</td>
<td>0  1</td>
<td>2  3  4</td>
<td>5  6</td>
</tr>
</tbody>
</table>

La siguiente afirmación se refiere a cómo su trabajo normal afecta o afectaría su dolor de espalda.

<table>
<thead>
<tr>
<th>Actividades en su Trabajo</th>
<th>En total Desacuerdo</th>
<th>Ni de Acuerdo ni en Desacuerdo</th>
<th>Completamente de Acuerdo</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. Mi dolor se debe a mi trabajo, o a un accidente en el trabajo</td>
<td>0  1</td>
<td>2  3  4</td>
<td>5  6</td>
</tr>
<tr>
<td>7. Mi trabajo empeoró mi dolor</td>
<td>0  1</td>
<td>2  3  4</td>
<td>5  6</td>
</tr>
<tr>
<td>8. Estoy recibiendo o tramitando algún tipo de compensación por mi dolor de espalda, como una baja laboral, una pensión o una indemnización de cualquier tipo</td>
<td>0  1</td>
<td>2  3  4</td>
<td>5  6</td>
</tr>
<tr>
<td>9. Mi trabajo es demasiado pesado para mi</td>
<td>0  1</td>
<td>2  3  4</td>
<td>5  6</td>
</tr>
<tr>
<td>Actividades en su Trabajo</td>
<td>En total Desacuerdo</td>
<td>Ni de Acuerdo ni en Desacuerdo</td>
<td>Completamente de Acuerdo</td>
</tr>
<tr>
<td>---------------------------</td>
<td>---------------------</td>
<td>--------------------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>10. Mi trabajo empeora mi dolor, o podría empeorarlo</td>
<td>0 1</td>
<td>2 3 4</td>
<td>5 6</td>
</tr>
<tr>
<td>11. Mi trabajo puede dañar mi espalda</td>
<td>0 1</td>
<td>2 3 4</td>
<td>5 6</td>
</tr>
<tr>
<td>12. Con mi dolor actual, no debería hacer mi trabajo normal</td>
<td>0 1</td>
<td>2 3 4</td>
<td>5 6</td>
</tr>
<tr>
<td>13. Con mi dolor actual, no puedo hacer mi trabajo normal</td>
<td>0 1</td>
<td>2 3 4</td>
<td>5 6</td>
</tr>
<tr>
<td>14. No puedo hacer mi trabajo normal hasta que mi dolor haya sido tratado</td>
<td>0 1</td>
<td>2 3 4</td>
<td>5 6</td>
</tr>
<tr>
<td>15. No creo que pueda regresar a mi trabajo normal en los próximos 3 meses</td>
<td>0 1</td>
<td>2 3 4</td>
<td>5 6</td>
</tr>
<tr>
<td>16. No creo que sea capaz de volver nunca a mi trabajo normal</td>
<td>0 1</td>
<td>2 3 4</td>
<td>5 6</td>
</tr>
</tbody>
</table>

Estas son todas las preguntas que tenemos para usted en este momento.

Gracias por su participación.
Apreciamos el esfuerzo que ha dedicado al contestar este cuestionario.
STUDY OF EFFECTIVENESS OF TREATMENT OF LOW BACK PAIN BY MANIPULATIVE THERAPY IN COMBINATION WITH CONVENTIONAL PHYSICAL THERAPY AS COMPARED TO STANDARD PHYSICAL THERAPY ALONE

Patient Questionnaire
(Initial Evaluation)

Instructions: This questionnaire has been designed to give your therapist information as to how your back pain has affected your ability to manage in everyday life. Please answer every question to the best of your knowledge. Before you do, we want you to know that:

- Your participation is entirely voluntary.
- If you choose to join the study, you may withdraw at any time for any reason. The physical therapy treatment prescribed for your low back pain will not be affected by your decision to withdraw from the study.

NOTE: No confidential personal information about participants will be disclosed to any researcher(s) or third parties. Only the personnel responsible for scheduling patients will have access to confidential personal information, and will only be used to schedule appointments and contact you in case of an emergency.
Study of Effectiveness of Treatment of Low Back Pain by Manipulative Therapy in Combination with Conventional Physical Therapy as compared to Standard Physical Therapy Alone.

INSTRUCTIONS: Please answer the following questions as accurately as possible. This information is confidential and will only be used for study purposes. Use a check (☑) to mark your answers where appropriate.

A. PATIENT INFORMATION

<table>
<thead>
<tr>
<th>Patient name and address</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

1. Name: Last₁ First₁ M₁

2. Address: Street and number₁ Urbanization₁

City₁ Zip₁

3. Phone: Area Code (₃) ₃ ₃ ₃

4. Emergency contact person: Last₁ First₁ M₁

5. Phone: Area Code (₃) ₃ ₃ ₃

6. Emergency contact person: Last₁ First₁ M₁

7. Phone: Area Code (₃) ₃ ₃ ₃
### Health and Medical Information

1. Please mark any of the other diseases/conditions that you have been diagnosed with by a doctor:
   (Please, **CHECK [☐] ALL THAT APPLY**)

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Osteoporosis</td>
<td>□</td>
</tr>
<tr>
<td>2. Osteoarthritis</td>
<td>□</td>
</tr>
<tr>
<td>3. Lordosis</td>
<td>□</td>
</tr>
<tr>
<td>4. Scoliosis</td>
<td>□</td>
</tr>
<tr>
<td>5. Kyphosis</td>
<td>□</td>
</tr>
<tr>
<td>6. Disk Herniation</td>
<td>□</td>
</tr>
<tr>
<td>7. Spinal stenosis</td>
<td>□</td>
</tr>
<tr>
<td>8. Spondylitis</td>
<td>□</td>
</tr>
<tr>
<td>9. Spondylosis</td>
<td>□</td>
</tr>
<tr>
<td>10. Vertebral Fracture</td>
<td>□</td>
</tr>
</tbody>
</table>

11. Other → Specify: ____________________________

---

2. Are you currently receiving treatment/therapy for your Low-Back pain?

   - [ ] Yes, I am currently receiving treatment/therapy for my low-back pain.
   - [ ] I am NOT currently receiving treatment/therapy for my low-back pain, but I did in the past.
   - [ ] I have never received treatment/therapy for my low-back pain. ➔ **GO TO QUESTION 6**

---

3. Are you currently taking prescribed medications for your Low-Back pain?

   - [ ] I am currently taking:
     - Please, specify: 1. _________________ (name of drug)
     - [ ] 2. _________________ (name of drug)
     - [ ] 3. _________________ (name of drug)
     ➔ **GO TO QUESTION 5**
   - [ ] I am NOT currently taking any medications, but I did in the past.
   - [ ] I have never taken any medication for my low-back pain. ➔ **GO TO QUESTION 5**
Instructions: Answer question 4 ONLY if you have taken prescribed medications in the past.

4. List of prior medications: Name of Drug(s): ____________________ Length of time (months): ______
   ____________________________________  +  ______
   ____________________________________  +  ______

5. Are/Were you satisfied with the overall quality of treatment/therapy you currently receive/received from your health care provider?
   □  Yes
   □  No Please, explain why: ________________________________

6. Please, identify your current smoking status:
   □  Ex-smoker  ➔ GO TO QUESTIONS 6a - 6c
   □  Smoker  ➔ GO TO QUESTIONS 6b - 6c
   □  Non-smoker  ➔ GO TO SECTION D. PAIN ASSESSMENT, ON PAGE 5

Instructions: If Ex-smoker, answer questions 6a thru 6c, then go to Pain Assessment on Page 5.
If Smoker, answer questions 6b and 6c, then go to Pain Assessment on Page 5.

6a. If ex-smoker, at what age did you stop smoking? ________
6b. If smoker, or ex-smoker, at what age did you start smoking? ________
6c. If smoker, or ex-smoker, how many cigarettes did or do you smoke per day? ________
C. DEMOGRAPHICS

INSTRUCTIONS: This section will gather information about demographic characteristics, including age, gender, education, occupation, and income, among others. The information gathered in this section will enable us to understand the characteristics of the participants in this study, and will only be reported as grouped data.

*** No information on individual participants will be disclosed at any time.

1. What is your date of birth?  
   Example: 07/20/2005
   
2. What is your gender?
   
   □ 1. Male
   □ 2. Female

3. What is the highest level of school you have completed or the highest degree you have received?
   
   □ 1. Never attended school or only attended Kindergarten
   □ 2. Some grade school, No High School diploma
   □ 3. High School graduate or GED or equivalent
   □ 4. Some college or technical school
   □ 5. College graduate

4. What is your current marital status?
   
   □ 1. Married
   □ 2. Living with someone in a marriage-like relationship
   □ 3. Divorced
   □ 4. Separated
   □ 5. Widowed
   □ 6. Never married
   □ 7. Other \( \rightarrow \) Please specify: ____________________________

Low Back Pain Study Questionnaire
Initial Evaluation.
Modified on February 2, 2007, Page 5 of 13
5. What is your current employment status?

☐ 1. Employed full-time \(\rightarrow\) GOTO QUESTIONS 5a-5d
☐ 2. Employed part-time
☐ 3. Unemployed or laid-off \(\rightarrow\) GOTO QUESTIONS 5c-5d
☐ 4. Keeping house full-time
☐ 5. Keeping house part-time \(\rightarrow\) GOTO QUESTION 6
☐ 6. Raising children full-time

Instructions: If employed, answer questions 5a thru 5d, then continue to Question 6. If unemployed, answer questions 5c and 5d, then continue to Question 7.

5a. What is your current occupation?

(For example: nurse, teacher, supervisor, caterer, grinder operator)

5b. Length of Current Employment (yrs.)?

5c. What was your previous occupation?

(For example: nurse, teacher, supervisor, caterer, grinder operator)

5d. Length of Previous Employment (yrs.)?

6. What was your last year's Annual Household Income before taxes?

☐ 1. Less than $10,000
☐ 2. More than $10,000 but less than $15,000
☐ 3. More than $15,000 but less than $20,000
☐ 4. More than $20,000 but less than $25,000
☐ 5. More than $25,000 but less than $35,000
☐ 6. More than $35,000 but less than $50,000
☐ 7. More than $50,000 but less than $75,000
☐ 8. More than $75,000
☐ 9. Not Applicable (unemployed/laid-off)
D. Pain Assessment

INSTRUCTIONS:

A. Indicate how many days have gone since your low back pain started you feel today, do not refer to previous experiences, but to the pain you feel today (if you cannot recall, please, give an estimate): ________ DAYS

B. Starting from the left of the bar, place a mark towards the point that best describes the INTENSITY of the PAIN YOU ARE HAVING RIGHT NOW.

<table>
<thead>
<tr>
<th>No Pain</th>
<th>Moderate</th>
<th>Worst Pain</th>
<th>Imaginable</th>
</tr>
</thead>
</table>

C. Starting from the left of the bar, place a mark towards the point that best describes the FREQUENCY of the PAIN YOU ARE HAVING RIGHT NOW.

<table>
<thead>
<tr>
<th>Occasional</th>
<th>Intermittent</th>
<th>Continuous</th>
</tr>
</thead>
</table>

D. Use the following symbols to describe your low back pain. Mark on the drawing where exactly you feel the pain and what type of pain you feel in a particular area.

MARK USING THE FOLLOWING:

XXXXX = Pain
VVVVV = Rigid/stiff area
------ = Sting/burning sensation
******* = Tingling/needle sensation
OOOOO = Numbness/decrease sensation
++++++ = Hypersensitivity/increased sensation
E. FUNCTIONAL IMPAIRMENT AND DISABILITY

OSWESTRY DISABILITY INDEX
INSTRUCTIONS: This section of the questionnaire has been designed to give your therapist information as to how your back pain has affected your ability to manage in everyday life. Please answer every question by placing a check mark (✓) in the one box that best describes your condition today.

WE REALIZE YOU MAY FEEL THAT TWO OF THE STATEMENTS MAY DESCRIBE YOUR CONDITION, BUT PLEASE CHECK ONLY THE BOX THAT MOST CLOSELY DESCRIBES YOUR CURRENT CONDITION.

1. Pain Intensity

☐ I can tolerate the pain I have without having to use pain medication.
☐ The pain is bad, but I can manage without having to take pain medication.
☐ Pain medication provides me with complete relief from pain.
☐ Pain medication provides me with moderate relief from pain.
☐ Pain medication provides me with little relief from pain.
☐ Pain medication has no effect on my pain.

2. Standing

☐ I can stand as long as I want without increased pain.
☐ I can stand as long as I want, but it increases my pain.
☐ Pain prevents me from standing for more than 1 hour.
☐ Pain prevents me from standing for more than 1/2 hour.
☐ Pain prevents me from standing for more than 10 minutes.
☐ Pain prevents me from standing at all.

3. Personal Care (e.g., Washing, Dressing)

☐ I can take care of myself normally without causing increased pain.
☐ I can take care of myself normally, but it increases my pain.
☐ It is painful to take care of myself, and I am slow and careful.
☐ I need help, but I am able to manage most of my personal care.
☐ I need help every day in most aspects of my care.
☐ I do not get dressed, I wash with difficulty, and I stay in bed.
4. Sleeping

☐ 1. Pain does not prevent me from sleeping well.
☐ 2. I can sleep well only by using pain medication.
☐ 3. Even when I take medication, I sleep less than 6 hours.
☐ 4. Even when I take medication, I sleep less than 4 hours.
☐ 5. Even when I take medication, I sleep less than 2 hours.
☐ 6. Pain prevents me from sleeping at all.

5. Lifting

☐ 1. I can lift heavy weights without increased pain.
☐ 2. I can lift heavy weights, but it causes increased pain.
☐ 3. Pain prevents me from lifting heavy weights off the floor, but I can manage if the weights are conveniently positioned (e.g., on a table).
☐ 4. Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned.
☐ 5. I can lift only very light weights.
☐ 6. I cannot lift or carry anything at all.

6. Sexual Life

☐ 1. My sexual life is normal and does not increase my pain.
☐ 2. My sexual life is normal but it increases my pain.
☐ 3. My sexual life is almost normal but it increases my pain.
☐ 4. My sexual life is limited due to my pain.
☐ 5. My sexual life is almost nonexistent due to my pain.
☐ 6. Pain prevents me any type of sexual life.
7. Walking

☐ 1. Pain does not prevent me from walking any distance.
☐ 2. Pain prevents me from walking more than 1 mile. (1 mile = 1.6 km).
☐ 3. Pain prevents me from walking more than 1/2 mile.
☐ 4. Pain prevents me from walking more than 1/4 mile.
☐ 5. I can walk only with crutches or a cane.
☐ 6. I am in bed most of the time and have to crawl to the toilet.

8. Social Life

☐ 1. My social life is normal and does not increase my pain.
☐ 2. My social life is normal, but it increases my level of pain.
☐ 3. Pain prevents me from participating in activities that are more energetic (e.g., sports, dancing).
☐ 4. Pain prevents me from going out very often.
☐ 5. Pain has restricted my social life to my home.
☐ 6. I have hardly any social life because of my pain.

9. Sitting

☐ 1. I can sit in any chair as long as I like.
☐ 2. I can only sit in my favorite chair as long as I like.
☐ 3. Pain prevents me from sitting for more than 1 hour.
☐ 4. Pain prevents me from sitting for more than 1/2 hour.
☐ 5. Pain prevents me from sitting for more than 10 minutes.
☐ 6. Pain prevents me from sitting at all.

10. Travelling

☐ 1. I can travel anywhere without increased pain.
☐ 2. I can travel anywhere, but it increases my pain.
☐ 3. My pain restricts my travel over 2 hours.
☐ 4. My pain restricts my travel over 1 hour.
☐ 5. My pain restricts my travel to short necessary journeys under 1/2 hour.
☐ 6. My pain prevents all travel except for visits to the physician, therapist, or hospital.
ROLAND-MORRIS DISABILITY SCALE

INSTRUCTIONS: When your back hurts, you may find it difficult to do some of the things you normally do. Mark with a check (✓) only the sentences that describe you today.

PLEASE, CHECK ALL THAT APPLY:

[ ] 1. I stay at home most of the time because of my back.
[ ] 2. I change position frequently to try to get my back comfortable.
[ ] 3. I walk more slowly than usual because of my back.
[ ] 4. Because of my back, I am not doing any jobs that I usually do around the house.
[ ] 5. Because of my back, I use a handrail to get upstairs.
[ ] 6. Because of my back, I lie down to rest more often.
[ ] 7. Because of my back, I have to hold onto something to get out of an easy chair.
[ ] 8. Because of my back, I try to get other people to do things for me.
[ ] 9. I get dressed more slowly than usual because of my back.
[ ] 10. I only stand up for short periods of time because of my back.
[ ] 11. Because of my back, I try not to bend or kneel down.
[ ] 12. I find it difficult to get out of a chair because of my back.
[ ] 13. My back is painful almost all of the time.
[ ] 14. I find it difficult to turn over in bed because of my back.
[ ] 15. My appetite is not very good because of my back.
[ ] 16. I have trouble putting on my sock (or stockings) because of the pain in my back.
[ ] 17. I can only walk short distances because of my back pain.
[ ] 18. I sleep less well because of my back.
[ ] 20. I sit down for most of the day because of my back.
[ ] 21. I avoid heavy jobs around the house because of my back.
[ ] 22. Because of back pain, I am more irritable and bad tempered with people than usual.
[ ] 23. Because of my back, I go upstairs more slowly than usual.
[ ] 24. I stay in bed most of the time because of my back.


F. FEAR AVOIDANCE BELIEFS QUESTIONNAIRE (PHYSICAL ACTIVITY)

INSTRUCTIONS: Here are some of the things other patients have told us about their pain.

For each statement please mark the number from 0-6 to indicate how much physical activities such as bending, lifting, walking or driving affect or would affect your back pain.

<table>
<thead>
<tr>
<th>Physical Activity</th>
<th>Completely Disagree</th>
<th>Unsure</th>
<th>Completely Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. My pain was caused by physical activity</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>2. Physical activity makes my pain worse</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3. Physical activity might harm my back</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>4. I should not do physical activities which (might) make my pain worse</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>5. I cannot do physical activities which (might) make my pain worse</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

The following statements are about how your normal work affects or would affect your back.

<table>
<thead>
<tr>
<th>Work Activity</th>
<th>En total Desacuerdo</th>
<th>Ni de Acuerdo ni en Desacuerdo</th>
<th>Completamente de Acuerdo</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. My pain was caused by my work or by an accident at work</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>7. My work aggravated my pain</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>8. I have a claim for compensation for my pain</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>9. My work is too heavy for me</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>10. My work makes or would make my pain worse</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Work Activity</td>
<td>En total</td>
<td>Ni de Acuerdo</td>
<td>Ni en Desacuerdo</td>
</tr>
<tr>
<td>------------------------------------------------------------------------------</td>
<td>----------</td>
<td>---------------</td>
<td>------------------</td>
</tr>
<tr>
<td>11. My work might harm my back</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>12. I should not do my regular work with my present pain</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>13. I cannot do my regular work with my present pain</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>14. I cannot do my normal work until my pain is treated</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>15. I do not think that I will be back to my normal work within 3 months</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>16. I do not think that I will ever be able to go back to work</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

These are all the questions we have for you at this time.

Thank you for your participation. We appreciate your efforts in providing this information.
Effectiveness of Low Back Pain Manipulative Therapy in Combination with Physical Therapy as Compared to Standard Physical Therapy

Initial Evaluation

Data Collection Sheet

Physical Function Measures:

<table>
<thead>
<tr>
<th>Test</th>
<th>Test 1 (First visit)</th>
<th>Test 2 (Final Visit)</th>
<th>Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lumbar ROM</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flex __________</td>
<td>Flex __________</td>
<td>Flex __________</td>
<td></td>
</tr>
<tr>
<td>Ext __________</td>
<td>Ext __________</td>
<td>Ext __________</td>
<td></td>
</tr>
<tr>
<td>Internal Hip ROM</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left __________</td>
<td>Left __________</td>
<td>Left __________</td>
<td></td>
</tr>
<tr>
<td>Right __________</td>
<td>Right __________</td>
<td>Right __________</td>
<td></td>
</tr>
</tbody>
</table>
ESTUDIO SOBRE LA EFECTIVIDAD DE LA TERAPIA MANUAL COMBINADA CON TERAPIA FÍSICA EN COMPARACIÓN A TERAPIA FÍSICA ESTÁNDAR

Cuestionario para el Paciente
(Evaluación de Seguimiento)

Instrucciones: Este cuestionario ha sido diseñado para ofrecer a su terapista físico información sobre cómo su dolor de espalda baja ha afectado su habilidad de manejar situaciones del diario vivir. Por favor, conteste cada pregunta según su mejor conocimiento.

Antes de que comience, deseamos que entienda que:
- Su participación es totalmente voluntaria.
- Si usted decide participar en este estudio, usted tendrá el derecho de abandonar el mismo en cualquier momento y por cualquier razón. Su tratamiento de terapia física para dolor de espalda baja no será afectado si usted decide abandonar el estudio.

NOTA: Ningún tipo de información personal confidencial sobre el paciente será disipada a investigadores o terceras personas. Sólo el personal responsable del manejo de citas tendrá acceso a la información confidencial del paciente, y sólo será utilizada para establecer las citas para tratamiento y contacto en caso de emergencia.

Estudio sobre Dolor de Espalda Baja
Evaluación de Seguimiento.
Modificado 6 de mayo de 2007. Página 1 de 7
Estudio sobre la Efectividad de la Terapia Manual Combinada con Terapia Física en Comparación a Terapia Física Estándar

Instrucciones: Por favor, conteste las siguientes preguntas la noche anterior o la misma mañana de su próxima cita de tratamiento. Esta información es confidencial y sólo será utilizada para cumplir con el propósito del estudio.

A. Evaluación de Dolor

1. Comenzando por la izquierda de la siguiente barra, haga una línea (1) hacia la derecha indicando la intensidad de su dolor de espalda en este preciso momento.

<table>
<thead>
<tr>
<th>Ningún</th>
<th>Moderado</th>
<th>Peor Dolor</th>
<th>Imaginable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dolor</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. Comenzando por la izquierda de la siguiente barra, haga una línea (1) hacia la derecha indicando la frecuencia de su dolor de espalda en este preciso momento.

   | Ocasional | Intermitente | Continuo |

4. Utilice los siguientes símbolos para describir su dolor de espalda. Marque en el dibujo exactamente donde siente el dolor y qué tipo de dolor siente en el área específica.

   MARQUE ASÍ:

   XXXX = Dolor
   VVVV = Área trincada / rígida
   ===== = Sensación de ardor/quemazón
   ***** = Hormigueo/sensación de agujas
   ↓↓↓↓↓ = Disminución en sensación
   ↑↑↑↑↑ = Aumento en sensación
B. IMPEDIMENTO FUNCIONAL Y DISCAPACIDAD

ÍNDICE DE DISCAPACIDAD DE OWENSTRY
INSTRUCCIONES: Esta sección del cuestionario ha sido diseñada para indicarle a su terapista cómo su dolor de espalda baja a afectado su habilidad de manejar actividades del diario vivir. Por favor, conteste cada pregunta utilizando una marca de cotejo (X) en el cuadro que mejor describa su condición HOY.

ENTENDEMOS QUE USTED PUEDE SENTIR QUE MÁS DE UNA RESPUESTA DESCRIBE SU CONDICIÓN, SIN EMBARGO, LE PEDIMOS QUE SOLAMENTE MARQUE LA OPCIÓN QUE MEJOR DESCRIBA SU CONDICIÓN ACTUAL.

1. Intensidad del dolor
   ☐ 0 Puedo soportar el dolor sin necesidad de tomar medicamentos para el dolor.
   ☐ 1 El dolor es fuerte pero me arreglo sin tomar medicamentos para el dolor.
   ☐ 2 Los medicamentos para el dolor me alivian completamente el dolor.
   ☐ 3 Los medicamentos para el dolor me alivian un poco el dolor.
   ☐ 4 Los medicamentos para el dolor apenas me alivian el dolor.
   ☐ 5 Los medicamentos para el dolor no me alivian el dolor, por lo tanto, no los tomo.

2. Estar de pie
   ☐ 0 Puedo estar de pie tanto tiempo como quiera sin que me aumente el dolor.
   ☐ 1 Puedo estar de pie tanto tiempo como quiera pero me aumenta el dolor.
   ☐ 2 El dolor me impide estar de pie más de una hora.
   ☐ 3 El dolor me impide estar de pie más de media hora.
   ☐ 4 El dolor me impide estar de pie más de 10 minutos.
   ☐ 5 El dolor me impide estar de pie.

3. Cuidados personales
   ☐ 0 Me las puedo arreglar solo sin que me aumente el dolor.
   ☐ 1 Me las puedo arreglar solo pero esto me aumenta el dolor.
   ☐ 2 Lavarme, vestirme, etc., me produce dolor y tengo que hacerlo despacio y con cuidado.
   ☐ 3 Necesito alguna ayuda pero consigo hacer la mayoría de las cosas yo solo.
   ☐ 4 Necesito ayuda para hacer la mayoría de las cosas.
   ☐ 5 No puedo vestirme, me cuesta lavarme y sueño quedarme en la cama.
4. Dormir
- [ ] El dolor no me impide dormir bien
- [ ] Sólo puedo dormir si tomo pastillas
- [ ] Incluso tomando pastillas duermo menos de 6 horas
- [ ] Incluso tomando pastillas duermo menos de 4 horas
- [ ] Incluso tomando pastillas duermo menos de 2 horas
- [ ] El dolor me impide totalmente dormir

5. Levantar peso
- [ ] Puedo levantar objetos pesados sin que me aumente el dolor
- [ ] Puedo levantar objetos pesados pero me aumenta el dolor
- [ ] El dolor me impide levantar objetos pesados del suelo/piso, pero puedo hacerlo si están en un sitio cómodo (ej. en una mesa)
- [ ] El dolor me impide levantar objetos pesados, pero sí puedo levantar objetos ligeros o medianos si están en un sitio cómodo
- [ ] Sólo puedo levantar objetos muy ligeros/livianos
- [ ] No puedo levantar ni elevar ningún objeto

6. Actividad sexual
- [ ] Mi actividad sexual es normal y no me aumenta el dolor
- [ ] Mi actividad sexual es normal pero me aumenta el dolor
- [ ] Mi actividad sexual es casi normal pero me aumenta mucho el dolor
- [ ] Mi actividad sexual se ha visto muy limitada a causa del dolor
- [ ] Mi actividad sexual es casi nula a causa del dolor
- [ ] El dolor me impide todo tipo de actividad sexual

7. Caminar
- [ ] El dolor no me impide caminar
- [ ] El dolor me impide caminar más de una milla (1 milla = 1.6 kilómetros)
- [ ] El dolor me impide caminar más de ½ milla
- [ ] El dolor me impide caminar más de ¼ milla
- [ ] Sólo puedo caminar con bastón o muletas
- [ ] Permanezco en la cama casi todo el tiempo y tengo que ir a rastras al baño

Estudio sobre Dolor de Espalda Baja
 Evaluación de Seguimiento,
 Modificado 1 de febrero de 2007. Página 4 de 7
8. Vida social
☐ Mi vida social es normal y no me aumenta el dolor
☐ Mi vida social es normal pero me aumenta el dolor
☐ El dolor no tiene un efecto importante en mi vida social, pero si impide mis actividades
más enérgicas como bailar, etc.
☐ El dolor ha limitado mi vida social y no salgo tan a menudo
☐ El dolor ha limitado mi vida social al hogar
☐ No tengo vida social a causa del dolor

9. Estar sentado
☐ Puedo estar sentado en cualquier tipo de silla todo el tiempo que quiera
☐ Puedo estar sentado en mi silla favorita todo el tiempo que quiera
☐ El dolor me impide estar sentado más de una hora
☐ El dolor me impide estar sentado más de media hora
☐ El dolor me impide estar sentado más de 10 minutos
☐ El dolor me impide estar sentado

10. Viajar
☐ Puedo viajar a cualquier sitio sin que me aumente el dolor
☐ Puedo viajar a cualquier sitio, pero me aumenta el dolor
☐ El dolor es fuerte pero aguanto viajes de más de 2 horas
☐ El dolor me limita a viajes de menos de una hora
☐ El dolor me limita a viajes cortos y necesarios de menos de media hora
☐ El dolor me impide viajar excepto para ir al médico o al hospital
ESCALA DE DISCAPACIDAD DE ROLAND-MORRIS

INSTRUCCIONES: Cuando su espalda le duele, puede encontrar difícil hacer algunas de las cosas normalmente hace. Esta lista contiene muchas de las frases que las personas usan para explicar cómo se sienten cuando le duele la espalda. Lea la lista y marque una **marca de cotejo** (☑) en las frases que describan cómo se siente hoy.

**RECUERDE: MARQUE TODAS LAS FRASES QUE APLIQUEN, PERO SOLO SI DESCRIBEN COMO SE ENCUENTRA USTED HOY.**

☐ 1. Me quedo en casa la mayor parte del tiempo por mi dolor de espalda.
☐ 2. Cambio de posición frecuentemente tratando de aliviar mi dolor de espalda.
☐ 3. Debo a mi espalda, camino más lento de lo normal.
☐ 4. Debo a mi espalda, no hago las tareas que usualmente hago en la casa.
☐ 5. Debo a mi dolor, uso los pasamanos cuando subo las escaleras.
☐ 6. A causa de mi espalda, tengo que acostarme más a menudo para descansar.
☐ 7. Debo a mi espalda, necesito agarrarme de algo para poder levantarme de una silla o sofá.
☐ 8. A causa de mi espalda, pido a otros que me hagan las cosas.
☐ 9. Me visto más lento de lo normal a causa de mi espalda.
☐ 10. A causa de mi espalda, me quedo de pie, por solo periodos cortos de tiempo.
☐ 11. A causa de mi espalda, elvito doblarme o arrodillarme.
☐ 12. Me cuesta levantarme de una silla debido a mi espalda.
☐ 13. Me duele la espalda casi siempre.
☐ 14. Me cuesta darme vueltas en la cama por culpa de mi espalda.
☐ 15. Debo a mi dolor de espalda, no tengo mucho apetito/deseo de comer.
☐ 16. Me cuesta ponerme las medias por mi dolor de espalda.
☐ 17. Debo a mi espalda, solo camino distancias cortas.
☐ 18. Duermo peor debido a mi espalda.
☐ 19. Por mi dolor de espalda, alguien debe ayudarme a vestirme.
☐ 20. Estoy casi todo el día sentado(a) a causa de mi espalda.
☐ 21. Evito hacer trabajos pesados en casa, por culpa de mi espalda.
☐ 22. Por mi dolor de espalda, estoy más irritable y de peor humor de lo normal.
☐ 23. A causa de mi espalda, subo las escaleras más lento de lo normal.
☐ 24. Pasó la mayoría del tiempo en cama por culpa de mi espalda.

Estas son todas las preguntas que tendremos para usted en este momento.

*Estudio sobre Dolor de Espalda Baja*
*Evaluación de Seguimiento*
*Modificado 1 de febrero de 2007, Página 6 de 7*
Gracias por su participación.
Apreciamos el esfuerzo que ha dedicado al contestar este cuestionario.
STUDY OF EFFECTIVENESS OF TREATMENT OF LOW BACK PAIN BY MANIPULATIVE THERAPY IN COMBINATION WITH CONVENTIONAL PHYSICAL THERAPY AS COMPARED TO STANDARD PHYSICAL THERAPY ALONE

Patient Questionnaire
(Follow-Up Evaluation)

Instructions: This questionnaire has been designed to give your therapist information as to how your back pain has affected your ability to manage in everyday life. Please answer every question to the best of your knowledge. Before you do, we want you to know that:

- Your participation is entirely voluntary.
- If you choose to join the study, you may withdraw at any time for any reason. The physical therapy treatment prescribed for your low back pain will not be affected by your decision to withdraw from the study.

NOTE: No confidential personal information about participants will be disclosed to any researcher(s) or third parties. Only the personnel responsible for scheduling patients will have access to confidential personal information, and will only be used to schedule appointments and contact you in case of an emergency.
Study of Effectiveness of Treatment of Low Back Pain by Manipulative Therapy in Combination with Conventional Physical Therapy as compared to Standard Physical Therapy Alone

INSTRUCTIONS: Please answer the following questions as accurately as possible. This information is confidential and will only be used for study purposes. Use a check (✓) to mark your answers where appropriate.

A. PAIN ASSESSMENT

1. Starting from the left of the bar, place a mark towards the point that best describes the INTENSITY of the PAIN YOU ARE HAVING RIGHT NOW.

   No Pain  Moderate  Worst Pain Imaginable

2. Starting from the left of the bar, place a mark towards the point that best describes the FREQUENCY of the PAIN YOU ARE HAVING RIGHT NOW.

   Occasional  Intermittent  Continuous

3. Use the following symbols to describe your low back pain. Mark on the drawing where exactly you feel the pain and what type of pain you feel in a particular area.

MARK USING THE FOLLOWING:

XXXXX = Pain
VVVVV = Rigid/stiff area
===== = Sting/burning sensation
******* = Tingling/needle sensation
OOOO = Numbness/decrease sensation
++++++ = Hypersensitivity/increased sensation

Low Back Pain Study, Study Questionnaire Follow-up Evaluation, Modified on February 2, 2007, Page 2 of 6
B. FUNCTIONAL IMPAIRMENT AND DISABILITY

OSWESTRY DISABILITY INDEX

INSTRUCTIONS: This section of the questionnaire has been designed to give your therapist information as to how your back pain has affected your ability to manage in everyday life. Please answer every question by placing a check mark (☑) in the one box that best describes your condition today.

WE REALIZE YOU MAY FEEL THAT TWO OF THE STATEMENTS MAY DESCRIBE YOUR CONDITION, BUT PLEASE CHECK ONLY THE BOX THAT MOST CLOSELY DESCRIBES YOUR CURRENT CONDITION.

1. Pain Intensity

☐ 1. I can tolerate the pain I have without having to use pain medication.

☐ 2. The pain is bad, but I can manage without having to take pain medication.

☐ 3. Pain medication provides me with complete relief from pain.

☐ 4. Pain medication provides me with moderate relief from pain.

☐ 5. Pain medication provides me with little relief from pain.

☐ 6. Pain medication has no effect on my pain.

2. Standing

☐ 1. I can stand as long as I want without increased pain.

☐ 2. I can stand as long as I want, but it increases my pain.

☐ 3. Pain prevents me from standing for more than 1 hour.

☐ 4. Pain prevents me from standing for more than 1/2 hour.

☐ 5. Pain prevents me from standing for more than 10 minutes.

☐ 6. Pain prevents me from standing at all.

3. Personal Care (e.g., Washing, Dressing)

☐ 1. I can take care of myself normally without causing increased pain.

☐ 2. I can take care of myself normally, but it increases my pain.

☐ 3. It is painful to take care of myself, and I am slow and careful.

☐ 4. I need help, but I am able to manage most of my personal care.

☐ 5. I need help every day in most aspects of my care.

☐ 6. I do not get dressed, I wash with difficulty, and I stay in bed.
4. Sleeping

☐ Pain does not prevent me from sleeping well.
☐ I can sleep well only by using pain medication.
☐ Even when I take medication, I sleep less than 6 hours.
☐ Even when I take medication, I sleep less than 4 hours.
☐ Even when I take medication, I sleep less than 2 hours.
☐ Pain prevents me from sleeping at all.

5. Lifting

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

6. Sexual Life

☐ My sexual life is normal and does not increases my pain.
☐ My sexual life is normal but it increases my pain.
☐ My sexual life is almost normal, but it increases my pain.
☐ My sexual life is limited due to my pain.
☐ My sexual life is almost non-existent due to my pain.
☐ Pain prevents me any type of sexual life.
7. Walking

☐ 1. Pain does not prevent me from walking any distance.

☐ 2. Pain prevents me from walking more than 1 mile. (1 mile = 1.6 km).

☐ 3. Pain prevents me from walking more than 1/2 mile.

☐ 4. Pain prevents me from walking more than 1/4 mile.

☐ 5. I can walk only with crutches or a cane.

☐ 6. I am in bed most of the time and have to crawl to the toilet.

8. Social Life

☐ 1. My social life is normal and does not increase my pain.

☐ 2. My social life is normal, but it increases my level of pain.

☐ 3. Pain prevents me from participating in activities that are more energetic (e.g., sports, dancing).

☐ 4. Pain prevents me from going out very often.

☐ 5. Pain has restricted my social life to my home.

☐ 6. I have hardly any social life because of my pain.

9. Sitting

☐ 1. I can sit in any chair as long as I like.

☐ 2. I can only sit in my favorite chair as long as I like.

☐ 3. Pain prevents me from sitting for more than 1 hour.

☐ 4. Pain prevents me from sitting for more than 1/2 hour.

☐ 5. Pain prevents me from sitting for more than 10 minutes.

☐ 6. Pain prevents me from sitting at all.

10. Traveling

☐ 1. I can travel anywhere without increased pain.

☐ 2. I can travel anywhere, but it increases my pain.

☐ 3. My pain restricts my travel over 2 hours.

☐ 4. My pain restricts my travel over 1 hour.

☐ 5. My pain restricts my travel to short necessary journeys under 1/2 hour.

☐ 6. My pain prevents all travel except for visits to the physician / therapist or hospital.
ROLAND MORRIS DISABILITY SCALE

INSTRUCTIONS: When your back hurts, you may find it difficult to do some of the things you normally do. Mark with a check (✓) only the sentences that describe you today.

PLEASE, CHECK ALL THAT APPLY.

1. I stay at home most of the time because of my back.
2. I change position frequently to try to get my back comfortable.
3. I walk more slowly than usual because of my back.
4. Because of my back, I am not doing any jobs that I usually do around the house.
5. Because of my back, I use a handrail to get upstairs.
6. Because of my back, I lie down to rest more often.
7. Because of my back, I have to hold on to something to get out of an easy chair.
8. Because of my back, I try to get other people to do things for me.
9. I get dressed more slowly than usual because of my back.
10. I only stand up for short periods of time because of my back.
11. Because of my back, I try not to bend or kneel down.
12. I find it difficult to get out of a chair because of my back.
13. My back is painful almost all of the time.
14. I find it difficult to turn over in bed because of my back.
15. My appetite is not very good because of my back.
16. I have trouble putting on my sock (or stockings) because of the pain in my back.
17. I can only walk short distances because of my back pain.
18. I sleep less well because of my back.
20. I sit down for most of the day because of my back.
21. I avoid heavy jobs around the house because of my back.
22. Because of back pain, I am more irritable and bad tempered with people than usual.
23. Because of my back, I go upstairs more slowly than usual.
24. I stay in bed most of the time because of my back.

These are all the questions we have for you at this time.

Thank you for your participation. We appreciate your efforts in providing this information.
Appendix G

Manipulation Techniques
Manipulative Techniques Pictures

Sacro-iliac manipulation

Lumbo-sacral manipulation

