1-1-2017

Efficacy of Kinesio Taping as an Adjunct Intervention to Traditional Physical Therapy in the Treatment of Nonspecific Acute Low Back Pain: A Prospective Randomized Controlled Trial

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By

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A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy

Nova Southeastern University
College of Health Care Sciences
Physical Therapy Department

2017

Approval/ Signature Page

We hereby certify that this dissertation, submitted by Hossameldien Elkholy, conforms to the acceptable standard and is fully adequate in scope and quality to fulfill the dissertation requirement for the degree of Doctor of Philosophy

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Background: Acute low back pain (LBP) is a significant health problem worldwide and is one of the leading causes of disability. **Objective:** The purpose of this study was to examine the effect of Kinesio Taping (KT) on disability, fear-avoidance beliefs, and pain intensity in patients with acute, nonspecific LBP. **Research Design and Methods:** A prospective, randomized controlled study of consecutive patients referred to physical therapy with a primary complaint of LBP. Seventy-eight patients with acute, nonspecific LBP were randomized to an experimental group that received traditional physical therapy plus KT and a control group that received traditional physical therapy alone. Interventions were administered twice a week for 4 weeks. Assessment tools used were Ronald Morris Disability Questionnaire (RMDQ) for disability, Fear-Avoidance Beliefs Questionnaire (FABQ) for fear-avoidance beliefs, and Numerical Pain Rating Scale (NPRS) for pain intensity. Assessments were conducted at baseline, end of week 1, end of week 2, end of week 3, and end of week 4. **Analysis:** Repeated measures mixed model analysis of variance (ANOVA) was used to examine the effect of treatment on each variable. The group type was the between-subjects variable and the time was the within-subjects variable. A significance level of .05 was used in the analyses. **Results:** Both groups showed statistically significant lower disability, fear-avoidance beliefs, and pain levels over time compared with baseline scores ($p < .0001$). The experimental group showed statistically significant lower RMDQ scores at week 2, 3, and 4 ($p < .05$), statistically significant lower FABQ-physical activity subscale scores at the end of week 1 ($p < .01$), at the end of week 2 ($p < .01$), at the end of week 3 ($p < .01$), and at the end of week 4 ($p < .05$), statistically significant lower FABQ-work subscale scores at week 3 ($p < .05$) and week 4 ($p < .01$), and statistically significant lower NPRS scores at week 1, 2, 3, and 4 ($p < .05$). **Conclusion:** Kinesio Taping can be considered a useful adjunct intervention to reduce disability and pain and to modulate fear-avoidance beliefs in patients with acute, nonspecific LBP.

ACKNOWLEDGMENTS

I would like to thank my committee members, Drs Madeleine Hellman, Mahmoud Ibrahim, and Lance Cherry for their contributions to the successful completion of this dissertation project.

I would also like to acknowledge Dr Madeleine Hellman, who provided me with support, advice, and encouragement from the time I joined the program.

I would like to express my gratitude and thanks to Dr Mahmoud Ibrahim for mentorship and a tremendous help in the field with patients to make sure this clinical project would be fruitful and valuable.

I would like to thank Dr Lance Cherry for his support, clinical advice, and motivation from the beginning of this research study.

I would like to thank Dr Samuel Cheng for his motivation and support during my journey in the PhD program and his advice to complete this study.

I would like to thank Dr Haitham Salam, my coworker, for all his efforts and help in obtaining assessment data, helping organize files, and entering and cleaning study data. I would like to thank the management of Quick Docs Medical for their support of this research project.

I would like to thank Dr Echternach who sadly passed away. He was a great professor and person who was close to my heart and taught me a lot in research and physical therapy, and I will always be grateful to him.

I would like to thank my teachers in Egypt, Drs Mohamed Fouad, Ahmed Hassan, Ghada El-Hafz, and Salam El-Hafz, who were excellent role models since I joined the field of physical therapy.

Most importantly, I must express my profound gratitude to my parents who always believed in me and provided me with everything needed, helping me get into physical therapy and the graduate studies program.

Lastly, I would like to thank my wife and son who were patient with me during my extremely busy schedule studying and working to complete this research project and providing me with encouragement and support needed for my educational endeavors. Had it not been for the consistent love and support from my family at all levels of this project, I may not have been able to complete it.

I can go on thanking my colleagues, friends, and family for another few pages, but I'd like to stop here with thanking God for always being there for me and never allowing me to steer away from the right direction nor allowing me to give up.

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CHAPTER 1: INTRODUCTION

BACKGROUND

Low back pain (LBP) is one of the most problematical health conditions affecting the developed world.[1,2,3] It is considered to be a complex bio-psychological phenomenon that challenges clinicians for defining an optimal treatment.[4,5,6] It is one of the most costly health conditions in the developed world, and it is one of the main reasons for patients to see their primary care physician.[1,3,7-11] Low back pain affects people of all age groups and is one of the leading causes of functional limitations in the middle-aged and elderly.[12,13,14] The definition of acute low back pain varies with respect to the location of pain and duration of symptoms.[14]

As for the site of pain, the most common definition is a pain in the back between the costal margins and gluteal folds with or without leg pain.[12] Some define acute LBP as pain that occurs posteriorly in the region between the lower rib margin and the proximal thighs and that is of less than six weeks' duration.[15] The length of symptoms varies from one day to less than three months.[14] Acute low back pain has been described as pain that is of less than 4 weeks in duration while sub-acute low back pain is a pain that lasts between 4 and 12 weeks in duration.[14] An early acute phase LBP is a pain of less than two weeks in duration while a late acute phase LBP is a pain of a duration between 2 and 6 weeks.[13] On the other hand, the definition of chronic LBP is a pain in the lower back that persists for more than three months.[13]

The disability adjusted life years (DALYs) is a measure of the overall burden of a disease and represents the gap between current health condition and an ideal health situation in which the entire population lives to an advanced age, free of disease and disability.[16] Studies have shown that the prevalence and the burden of LBP globally is very high.[16,17,18] In a study of the global burden of disease (GBD), out of 291 conditions, LBP ranked as the sixth condition as a cause of disability worldwide.[6,17] The prevalence increased significantly in the old age population, which makes LBP an important cause of disability in countries with higher life expectancy.[17] Also, Hoy et al[17] indicated that older individuals in middle- and low-income countries will have more people with disability because of LBP over the coming years.

In the United States (US), the top three conditions as a cause of DALYs are ischemic heart disease, chronic obstructive pulmonary disease, and low back pain.[19] There is a considerable economic impact of LBP due to health care utilization and lost work days. In the US, the estimate of lost work days is about 149 million work days per year because of acute LBP, which causes a high economic burden.[18] In the United Kingdom, the number of lost work days due to acute episodes of LBP is around 100 million days per year.[18] On the global level, non-communicable diseases, such as LBP and other musculoskeletal conditions, are on the rise.[19]

There is a significant health care resource utilization because of low back pain. However, the statistical reports of health care utilization due to LBP lack some accuracy as visits to chiropractors, physical therapists, and others involved in the care are not counted for.[20] The reports by the National Institute of Health Statistics about LBP show more than 52 million visits to hospitals, emergency departments, outpatient clinics, and

physician offices because of low back pain.[20] These statistics demonstrate the high incidence of LBP and its effects on individuals' lives, society, and the economy. A new modality that can be added to existing interventions that may help patients feel better, return to work faster, and enjoy their leisure activities is worthy of being investigated.

Acute LBP is one of the conditions that physical therapists deal with in various clinical settings.[11,14] The condition may have a non-spine origin, and therefore, a thorough evaluation is important for proper management.[12] A percentage of those suffering from acute LBP progress to chronic LBP with a high probability of recurrent episodes.[12] People with an acute episode of LBP have a probability of 30% to 60% of recurrence.[12]

PREVALENCE AND COSTS OF ACUTE LBP

There is a high variability in the reports of prevalence of LBP.[6] Lifetime prevalence of LBP has been reported to be between 59% and 84%.[21] There is also a variability in the reports of the age range at which episodes of LBP are the most common.[12] Daily prevalence of low back pain is estimated to be between 12% and 33%.[22] In the US, yearly prevalence of LBP is between 22% and 65%.[31] Around 7.5% of US adults surveyed by phone had a minimum of one episode of acute LBP in one-year period.[22]

Studies have shown that LBP is more common in older women than in older men as one in every three older women report LBP, and one in every four men report LBP.[23] Body weight is one of the factors that influence the prevalence of LBP as one in every five normal weight adults report LBP, one in every four overweight adults report LBP, and one in every three obese adults report LBP.[23] In the elderly population, LBP is more

common in the white race.[23] People with LBP are three times as likely to report poor or fair health status, four times as likely to report inability to work, twice likely to report shortened sleeping time, and seven times as likely to report psychological distress.[23]

Low back pain is the most common type of musculoskeletal pain reported in the United States.[20] Reports about the burden of musculoskeletal diseases in the United States indicate that 29% of US adults over the age of 18 are likley to report at least one episode of LBP in the past three months.[20] The first episode of acute LBP usually occurs between the age of 20 and 40 years old.[12] Within one or two years, recurrent episodes affect around 25% to 62% of patients.[12] Recurrent episodes are mostly moderate in intensity but high enough to interfere with job-related activities, causing work absenteeism and difficulties in performing normal daily living activities.[12] In approximately 15% of patients, the recurrent episode is severe and debilitating.[12] The percentage of patients with acute low back pain who tend to exhibit recurrence and progression to chronic LBP is estimated to be around 31%.[12] Although the majority of patients may fully recover, such claim has not been supported by any evidence.[24]

Around 100 million adults are suffering from some form of pain in the US. [22] Pain is costly; it leads to disability, affects people's ability to work and function, and requires some medical treatment.[22] In 2011, according to the Committee on Advancing Pain Research, Care, and Education, the total medical cost due to pain ranged from $261 to $300 billion.[22] The total medical expenditure of musculoskeletal injuries in the US is more than $240 billion yearly.[22] It is estimated that the total cost associated with low back pain in the US exceeds $100 billion, two-thirds of which is due to lost wages and reduced productivity.[18,22,25]

ONSET AND CAUSES OF ACUTE LBP

A variety of causes can cause acute low back pain; some are more serious than others, such as trauma, arthritis, problems with intervertebral discs, and nerve root compression.[12,15,25] Other potential causes of LBP, such as osteoporosis, infection, tumor, and fractures, should be considered based on the clinical presentation, history and physical examination.[12,15,25] An acute onset low back pain that is linked to a specific pathology is referred to as specific LBP. In approximately 10% of patients suffering from acute LBP, there is some form of definite anatomic origin or pathology.[1] However, in most of the cases, which is estimated to be around 90%, a particular source of pain is unidentifiable.[1]

In the absence of red flags, most of the conditions of acute LBP are non-specific.[12,13,15] In the majority of cases, there are unclear pathoanatomic etiology of LBP.[12,13] Lack of an accurate diagnosis occurs in more than 80% of the cases.[12,26] This diagnostic issue is a source of debate about the best treatment approaches and subsequent variations in the management of acute LBP.[26] Many factors contribute to the onset of low back pain, but identifying the trigger of pain can be challenging.[15] In only one third of the cases, a specific triggering event or injury can be identified.[13] A particular mechanical factor, such as lifting, is not the cause in most of the cases.[13]

Low back pain is a multifactorial symptom.[13,15] The triggering event may be an injury or trauma, incited by a variety of factors such as de-conditioning, psychological issues, chronic illnesses, genetics, and culture.[13] These factors may prolong the course of the condition beyond the normal healing time.[13] However, some triggers of acute LBP have been identified, such as manual tasks, awkward postures, handling of objects far

from the body, handling people/animals, unstable loading (falls, trips, slips), engagement in moderate/vigorous activity, sexual activity, alcohol consumption, and fatigue.[27] Having short-term exposure to any of these triggers increases the risk of developing an acute episode of back pain.[27]

Risk factors known for increasing the risk of development of low back pain include age, fitness level, pregnancy, overweight, genetics, and occupational risk factors.[18,25] Increased age is often associated with increased risk of osteoporosis, decreased flexibility of ligaments and tendons, fluid loss from intervertebral discs, decreased muscle elasticity and tone, and increased risk of spinal stenosis.[18,25] People with low fitness level, weak abdominals, and weak back muscles are more prone to back injuries and low back pain.[18,25] Overweight increases the load on the spine and the demand on the muscles that support the back, which increases the risk of back problems and low back pain.[18,25] Some causes of low back pain have a genetic origin, such as ankylosing spondylitis.[18,25] Occupational factors also play a role as people who have jobs that require lifting or pushing are more liable for back injuries and low back pain.[18,25]

GUIDELINES FOR THE TREATMENT OF ACUTE LBP

There are several treatment approaches for acute LBP that are utilized by physical therapists, such as manipulation and exercises. One of the adjunct interventions that physical therapists are using for treatment of acute LBP is therapeutic taping. Many studies have been conducted to examine and understand the potential effects of therapeutic taping in musculoskeletal conditions. The results are usually in the gray area between an actual effect and a placebo effect without a substantial research evidence that supports the use of this tool in clinical practice.[28] The decision making is left entirely up

to the clinician who may use some clinical reasoning to justify the use of therapeutic taping for a particular purpose. Based on the clinical presentation of acute LBP and the hypothesized neurophysiological and mechanical effects of therapeutic taping, there is a high potential for an actual treatment effect in the acute phase, yet investigation of this theory is necessary.

Development of evidence-based practice guidelines for the management of acute LBP is a challenging task. The diversity of the condition remains one of the main obstacles as patients respond differently to different interventions.[29,30] The emergence of bio-psychological models as an approach to combat the problem of delayed recovery and functional limitations made it important for clinicians to consider the psychological factors in the management of acute LBP.[4,13] Sub-grouping patients with acute LBP based on their clinical features for treatment purposes is one of the most accepted approaches in research setting.[4,30] There are many classification systems for LBP, and although research has indicated the superiority of this method, their use in clinical practice is small.[30] Some of these classification schemes are mechanical diagnosis and treatment, treatment-based classification, pathoanatomic based classification, movement system impairment syndromes, and O'Suillivan classification system.[30]

Clinical classification of pain mechanisms of low back pain is another approach that research efforts are trying to shed light on to better understand the neurophysiological mechanisms of low back pain for better management and treatment outcomes.[31] Clinical features noticed and identified by the clinician during examination may provide an indication of which type of pain mechanism underlying the symptom.[31] Generally, pain mechanisms can be classified as nociceptive, neuropathic, or central

sensitization of pain based on certain clinical features.[31] This approach seems to be promising to guide further research into the best intervention strategies for superior outcomes.[31] Prognostic classification also serves as another route to classify patients for more efficient management.[13] Use of simple prognostic tools, such as the Start Back screening tool, can help classify patients based on their risk of developing chronic LBP.[13] Afterwards, treatment planning is adjusted based on the estimated risk level.[13]

A thorough assessment of patients with an acute LBP should determine the best treatment approach.[12,13] Patient evaluation usually includes subjective rating of pain; functional status; patient's history, screening for red flags; psychological indicators; assessment of prior treatment and response; employment status; and physical examination.[13] Completion of subjective reporting of pain intensity is usually performed by using scales, such as the Visual Analogue Scale and the Numerical Pain Rating Scale.[12,13] Functional evaluation can be performed using a variety of assessment questionnaires, such as the Oswestry Disability Index, the Ronald Morris Disability Questionnaire, and the Quebec Back Pain Disability Scale.[13]

Screening for red flags is a critical component of the evaluation process for patients with acute LBP.[12,13,15] Screening should include risk factors for cancer, such as age over 50, unexplained weight loss, and failure to improve after 4 to 6 weeks of conservative treatment.[12,13,15] Screening for risk factors for spinal infection should include checking for indicators, such as intravenous drug use, immunosuppressive drugs, urinary tract infections, fever above 100.4°F for more than 48 hours, and history of tuberculosis or active tuberculosis.[12,13,15] Signs and symptoms of neurological impairment should be identified early for proper treatment. New onset of urinary incontinence,

urinary retention, saddle anesthesia, and sensory and motor deficits are indicators of cauda equina syndrome, which should be checked for in the assessment.[12,13,15] A typical presentation of an acute, nonspecific LBP is absence of red flags and neurological deficits.[13] On the other hand, bio-psychological approaches for the management of LBP recommend screening for yellow flags using appropriate tools and/or questionnaires.[13]

Although there is agreement among most international guidelines about the first line of intervention for nonspecific, acute LBP, there is no explicit agreement about the second line of intervention if the first one fails.[14] Each guideline strongly recommends advice or patient education and analgesics as the most appropriate initial response.[14] Other treatment strategies used to treat acute, nonspecific LBP range from massage techniques to exercises and manipulation.[12,14] The goals in this stage are to reassure patients that the prognosis is good, to remain active, and to limit bed rest.[13,14]

The Institute for Clinical System Improvements recommends a core treatment plan for acute, nonspecific LBP in the form of patient education, use of analgesics and muscle relaxants, and exercise. [13] Bed rest, traction and cold therapy are not recommended. [13] Although there is a broad range of treatment options for LBP, the condition may persist or becomes recurrent in many patients, especially those who do not respond favorably to first lines of intervention in primary care setting. [12,13] Therefore, there is a need for other treatment options that may help improve outcomes.

STATEMENT OF THE PROBLEM

Low back pain is a significant public health problem that interferes with the individual's ability to perform various recreational and daily living activities.[12,13,24] LBP is the fifth most common reason for all physician visits and the second most symptomatic

reason.[11] It is considered to be one of the most common causes of job-related disability and impairment of activities of daily living.[2,7] LBP is the second most common neurological ailment in the US, according to the National Institute of Neurological Disorders and Stroke.[25] Acute low back pain is a problem usually encountered by most people during their lifetimes at least once.[12] It has been reported that LBP affects 70% to 85% of the population in the developed countries.[12]

Although patients with acute LBP may show improvement in the first few weeks with various types of interventions, many patients experience persistent pain and recurrence of symptoms.[12,26] LBP is assocaited with high economic burden and extensive utilization of health care resources.[1,3,7-11,20] Functional limitation in the acute stage of LBP is significant. Moreover, the common prognostic view of spontaneous recovery of acute LBP is inaccurate.[7]

In previous longitundinal studies, there was an unstable trajectory of the course of acute LBP in which pain and disability are typically ongoing in a fluctuating manner.[7] In up to 70% of patients who exhibit some sort of initial improvement, pain and disability were recurrent at an unexpected rate.[7] Therefore, efficient management of acute LBP is required to control pain, reduce disabiltity, and reduce the potential of recurrence.[7] The development of chronic LBP requires lengthy and costly treatments and is one of the leading causes of job-related disability.[7,12] Kinesio Taping (KT) is a new approach used in a variety of musculoskeletal conditions.[32] KT is a form of elastic taping that mimics the physical qualities of the skin to support injured tissues.[32] A modality that has a potential to reduce pain, improve function, reduce rehabilitation time, facilitate early return to work, and encourage patients to function with more confidence during the acute

episode of pain is worthy of being investigated. Such benefits may have a positive impact on the course of acute LBP. The effect of KT on patients with acute, nonspecific LBP has never been investigated in a randomized controlled trial. Therefore, the aims of this study are the following:

Specific Aim 1

To determine the efficacy of Kinesio Taping plus traditional physical therapy for acute, nonspecific low back pain compared with traditional physical therapy alone on disability as measured with the Ronald Morris Disability Questionnaire (RMDQ).

Specific Aim 2

To determine the efficacy of Kinesio Taping plus traditional physical therapy for acute, nonspecific LBP compared with traditional physical therapy alone on fear avoidance behavior and beliefs as measured with the Fear-Avoidance Beliefs Questionnaire (FABQ).

Specific Aim 3

To determine the efficacy of Kinesio Taping plus traditional physical therapy for acute, nonspecific LBP compared with traditional physical therapy alone on pain intensity as measured with the Numerical Pain Rating Scale (NPRS).

RELEVANCE AND SIGNIFICANCE OF THE STUDY

Low back pain is one of the most common conditions treated by physical therapists.[14] Many interventions can be used for acute low back pain, such as patient education, exercise, low impact aerobic exercises, hot packs, interferential therapy, massage, and manual therapy.[13,14,33] The patient is encouraged to resume ordinary activities gradually and forego absolute bed rest.[12,13,14,33] These interventions are used to

reduce pain and muscle spasm, improve function, reduce disability, and decrease the potential of recurrence.

Interventions utilized for the management of acute, nonspecific LBP may include pharmacological agents and nonpharmacological treatments.[34] In primary care setting, the management of acute, nonspecific LBP involves the use of oral non-steroidal anti-inflammatory (NSAID) drugs because of the evidence of their effectiveness.[12,15,26,34] Although there is conflicting evidence about the usefulness of acetaminophen, it is used as an adjunct agent clinically.[12,15] The prescription of opioids takes place when NSAIDs are not effective, but the evidence from the literature about their clinical value is weak.[12,15] Additionally, muscle relaxants are usually prescribed for patients with acute LBP.[12,15] Muscle relaxants are most effective in the first 1 to 2 weeks post onset.[15] Improvements are much better with the combination of NSAIDs and muscle relaxants.[15] Overprescribing of opioids is a common problem, despite existing clinical guidelines.[10] Opioid use is often associated with adverse reactions, such as nausea and constipation and development of other complications, such as dependency, misuse, and overdose.[10] From physical therapy perspective, interventions for acute LBP were not studied extensively.[35] In the 1990s, the use of evidence-based interventions was not a common practice.[35] Using evidence-based interventions became the standard approach across different practice settings in the last decade because they are associated with better clinical outcomes and lower health care costs.[35]

In a previous descriptive study about physical therapists' practice choices in conditions of acute LBP in the US (Florida), passive interventions, such as heat and ultrasound, were commonly used. Spinal manipulative therapy was not common in

practice by clinicians.[35] The results of the study indicated that interventions commonly used by physical therapists include home exercise programs, exercise in the clinic, back care education, joint mobilization, ice/heat, and interferential therapy.[35] The study also indicated a low rate of adherence to evidence-based guidelines.[35]

The guidelines published by the Institute for Clinical System Improvements include a core treatment plan of patient education, NSAIDs, acetaminophen, responsible use of opioids, heat, encouraging activity, addressing fear-avoidance beliefs, exercise and return to work assessment.[13] There is weak scientific evidence about the effectiveness of other interventions, such as acupuncture, use of clinical prediction rules, cold therapy, and traction.[13] On the other hand, spinal manipulaive therapy has been shown to produce modest improvement in pain and function in patients with acute LBP.[36] Exercise interventions in LBP include flexion exercises, general exercises, the McKenzie approach, and stabilization exercises.[26,33] Therapeutic taping is a relatively new modality that is becoming more popular in clinical practice and has some potential benefits.[32] From the previous discussion, there is a strong need for interventions that may help improve recovery rate, decrease rehabilitation time and cost, decrease time away from work, reduce dependence on medications, and help patients perform routine and leisure activities more comfortably.

THERAPEUTIC TAPING

Therapeutic is a term that is used to describe that which is related to therapy.[37] The definition of therapeutic is that which is good for the body and the mind that contributes to the overall sense of well-being.[37] Therapeutic taping is commonly used in rehabilitation and sports-related activities for prevention and treatment of

musculoskeletal injuries.[32,38,39] There are different types of therapeutic taping: some are elastic, and some are rigid.[39] Characteristics of the tape differ based on the purpose of taping and the desired neurophysiological and mechanical effects.[39] Rigid or non-stretch tape is widely used to provide mechanical support or to modify a mechanical alignment.[39] Rigid strapping tape, such as Leukotap, has limited flexibility as it stretches to 30% from the time of initial application, which is ideal to provide a bracing effect.[39] Most of the rigid strapping tape contain latex, restrict the range of motion, and are painful to be tolerated for prolonged periods of time.[39]

Elastic adhesive taping has greater flexibility and is utilized for other purposes, such as relieving pain and swelling reduction.[32] In the 1970s, Kinesio Taping was invented by Dr. Kenzo Kase, an American trained chiropractor.[32] The tape was developed to be used as an adjunct modality to existing interventions to maximize treatment effects.[32] KT was used initially for elderly with arthritic conditions, and later its applications extended to other conditions.[32] The use of KT become more popular in sports, rehabilitation programs, and sports medicine by clinicians and athletic trainers in the last decade.[32] The 2008 Olympics was the breakout for KT and its popularity as the KT Association donated over 50,000 rolls to be used by athletes.[32] KT is designed in such a way to simulate some of the physical properties of the human skin.[32] Its weight and thickness are closely similar to the human skin, and its wave patterns are intended to mimic the design of the mechanoreceptors in the dermis.[32] The elastic threads in the tape are used so that the tape stretches only longitudinally as the elastic threads run vertically while the cotton threads run horizontally.[32] Also, the tape is designed to be applied with specific tension levels that are hypothesized to produce different effects.[32]

Kinesio Taping can be used for many dysfunctions, such as musculoskeletal dysfunctions.[32,40,41] Since its invention, many therapeutic applications and research studies have evolved.[32] Recently, KT applications are used for neurological, vascular, and pediatric disorders.[32] This broad range of application requires more research to clarify the effectiveness of this treatment method. Although its use by physical therapists is increasing, there is a limited scientific evidence regarding its potential therapeutic benefits and the underlying mechanisms.[40,41] The use of an elastic taping to support injured tissues, to unload the nociceptors, and to create a space by lifting the skin over the inflamed tissues through KT may have a positive effect for patients with acute symptoms.[32] Although the therapeutic effects of Kinesio Taping remain to be clarified, several mechanisms have been postulated, such as improving circulation, improving lymphatic drainage, reducing swelling, enhancing positional awareness through mechanical stimulation of tissues and potentiating the afferent input to the central nervous system.[32,40,41]

The premise of KT is that it is convenient, safe, and easy to apply, and it is a method that can be a viable option for many patients who may have contraindications to other treatments, such as medications, manipulations, or exercises. The use of KT also may improve the chances of a faster recovery and may help patients cope better with their pain. Additionally, the use of KT may improve the performance of functional activities and reduce time away from work. To our knowledge, this study was the first to explore the potential effects of Kinesio Taping and its possible beneficial value for this patient population. Our study helps physical therapists understand the possible effects of Kinesio Taping in patients with acute, nonspecific low back pain and how it may influence pain,

fear-avoidance beliefs, and disability. Furthermore, the study is helpful to physical therapists as the KT technique tested can be used in conjunction with other traditional physical therapy techniques to treat acute low back pain more efficiently and reduce the potential of persistence of symptoms.

RESEARCH QUESTIONS

Research Question 1: Does the application of Kinesio Taping on the lower back in addition to traditional physical therapy improve disability significantly more than traditional physical therapy alone for the treatment of acute, nonspecific low back pain?

Research Question 2: Does the application of Kinesio Taping on the lower back in addition to traditional physical therapy reduce fear-avoidance beliefs significantly more than traditional physical therapy alone for the treatment of acute, nonspecific low back pain?

Research Question 3: Does the application of Kinesio Taping on the lower back in addition to traditional physical therapy reduce pain significantly more than traditional physical therapy alone for the treatment of acute, nonspecific low back pain?

OPERATIONAL DEFINITIONS OF TERMS

Acute Low Back Pain: A recent episode of pain in the lower back area located between the lower costal margins and the gluteal folds for less than four weeks in duration, which may or may not be associated with leg pain and was not preceded by any back pain for at least one month.

Fear Avoidance Belief: The belief that pain is harmful, leading to fear of movement or activity because of the fear of re-injury or exacerbation of injury, which causes avoidance behavior.[13]

Red Flags: Clinical features that may be observed during the clinical examination, which may indicate a serious spinal pathology and require further investigation.[12,13]

Yellow Flags: Psychosocial indicators/factors that may increase the risk of developing persistent low back pain, such as anxiety and pain-related fear.[13]

Traditional Physical Therapy: Physical therapy interventions provided for all patients involved in this study, which included patient education; manual therapy; and therapeutic exercises in the form of abdominal drawing-in maneuver, posterior pelvic tilting, alternate knee to chest, and lumbar rotation.

Manual Therapy: Spinal manipulative therapy based on Feng's spinal manipulative therapy technique.

Kinesio Taping: An elastic porous hypo-allergic adhesive tape applied to the skin on the lower back area from the sacral base to T8 on both sides of the spine.

Kinesio Taping Strip: It is a solid strip of Kinesio Tex Tape, which may be cut appropriately to fit the length and width of target tissues.[32]

Tape Anchor: It is the beginning part of the tape applied with no tension.[32]

Tape End: It is last part of the tape that is laid down and applied with no tension.[32]

Tape Base or Therapeutic Zone: The stretched portion of the tape between the anchor and the end. [32]

SUMMARY

Acute low back pain is one of the most significant health problems in the developed world.[7] Optimal management may reduce the potential for recurrence and progression to chronic LBP. Guidelines for the treatment of LBP provide a general framework for clinicians for better clinical outcomes.[33,35] Most of these guidelines are

based on moderate to strong research evidence and take into considerations the diversity of presentation of LBP.[13,14,24] Classifying patients into different sub-groups is one of the approaches that has better results in clinical practice.[30] Interventions used by physical therapists for the treatment of acute LBP include patient education, manual therapy, and exercises.[13,14] Therapeutic taping is one of the newly introduced modalities in the practice of physical therapy with a limited scientific evidence. One of the most promising types of therapeutic taping is Kinesio Taping.

Kinesio Taping is a non-invasive modality commonly used in physical therapy practice for patients with musculoskeletal conditions to relieve pain and improve function.[32] The underlying mechanisms proposed for the therapeutic effect of KT makes it a potentially useful tool in acute conditions. There is a lack of conclusive high-quality evidence of the effect of Kinesio Taping in patients with acute, nonspecific LBP. Additionally, limited information is available about the most appropriate technique. Many studies have been conducted to examine the effect of KT in patients with chronic LBP, but no randomized controlled studies have been performed to explore the effect of KT in patients with acute, nonspecific LBP. Therefore, this study was designed to examine the effect of KT on disability, fear-avoidance beliefs, and pain intensity in patients with acute, nonspecific LBP.

CHAPTER 2: REVIEW OF THE LITERATURE

INTRODUCTION

Acute low back pain is a significant health problem that presents a challenge to clinicians especially when the condition persists and affects the quality of the individual's life.[1,2,3,7] Acute low back pain is one of the most common reasons for patients to see their primary care physicians.[9,12] Nonspecific low back pain is the most common diagnosis for back pain that is not associated with a particular pathology, comprising 90% of low back pain cases.[1] Although many forms of interventions exist for the management of acute LBP, there is no definite conservative management because of the heterogeneity of the condition.[13,26] These interventions may include manipulation, massage, acupuncture, electrical stimulation, and exercises.[12,13]

Therapeutic taping is an approach that has commonly been used by clinicians to reduce pain and improve function.[32] Many types of therapeutic taping have been developed, and each has different elastic and mechanical properties and modes of action. Kinesio Taping has been uniquely designed to mimic the physical qualities of the human skin and has mechanical characteristics that may be helpful in modulating pain mechanism and improving function.[32] In this chapter, relevant studies in which low back pain has been investigated, management of low back pain, and the effect of KT in different musculoskeletal conditions are presented along with the known and unknown about KT and how this study will contribute to the field of physical therapy.

INTERVENTIONS AND CLASSIFICATION SYSTEMS

In 1994, the Agency for Healthcare Policy and Research (AHCPR) published clinical practice guidelines for the management of acute LBP.[43] These guidelines were

based on an analysis of a literature review, which included studies designed to examine the effectiveness of various interventions in patients with acute LBP.[43] The AHCPR was the first government agency to recommended manipulation as an effective treatment for patients with acute LBP.[43] Manipulation is a broad term that covers a variety of techniques and treatment approaches that introduce mechanical and manual forces into the musculoskeletal structures.[43] There has been high-quality evidence shown in the literature for the effectiveness of thrust manipulation for the treatment of acute LBP.[33,36,44-46] Additionally, published, evidence-based practice guidelines include spinal manipulative therapy as one of the most recommended interventions, followed by exercise as a part of the conservative management of acute nonspecific LBP.[14] Furthermore, the American College of Occupational and Environmental Medicine recommended the use of clinical prediction rules to identify patients who may respond better to spinal manipulative therapy.[14]

Flynn et al[47] proposed clinical prediction rules that can be useful in screening patients to identify those who may respond better to spinal manipulative therapy.[47] These criteria include: duration of current symptoms of less than 16 days, no pain extending past the knee, Fear-Avoidance Beliefs Questionnaire of work subscale score of less than 19, more than one hypomobile segment in the lumbar spine, and at least one hip with at least 35 degrees of internal rotation.[47] These criteria can be used to identify those who are most responsive to spinal manipulative therapy.[47] In a validation study by Childs et al[48], those who were positive on the rule, responded better to spinal manipulative therapy.[48]

However, Hancock et al[49] examined these criteria in a study to determine if these criteria can be generalized. The results indicated that these rules cannot be generalized for

all patients with acute LBP in primary care setting.[49] There is a broad range of variations in the practice patterns of the diagnosis and treatment of acute, nonspecific LBP. The role of physical therapy in the early onset of the condition has been the subject of debate about its effectiveness, benefits, and the specific physical therapy procedures to be performed.[50] Gellhorn et al[50] evaluated the benefits of physical therapy in the early onset of acute, nonspecific low back pain. In this retrospective cohort study, the relationship between early physical therapy, subsequent use of lumbosacral injections, lumbar surgery, and frequent physician office visits for low back pain were examined.[50] The findings indicated that early physical therapy during an acute episode of low back pain is associated with lower rate of subsequent medical services, better outcomes, and lower medical costs.[50] The study also indicated inefficient or lower rate of referral to physical therapy among generalist practitioners.[50]

Impairments in proprioception, motor output, and central processing have been shown to occur early in the acute episode of LBP.[51] Therefore, an early intervention may improve the potential of faster recovery. Fritz et al[52] conducted a randomized controlled trial to examine if early physical therapy is effective in reducing disability in patients with acute low back pain. The trial included 220 participants with acute, nonspecific LBP of less than 16 days in duration.[52] Participants were randomly selected and separated into an early physical therapy group and a usual care group.[52] The early physical therapy group included 108 patients, and the usual care group included 112 patients.[52] Both groups received the same patient education about the course of acute LBP and follow-up guidelines for primary care physician if needed.[52] The experimental group received a total of four physical therapy sessions over a course of 3 weeks.[52] Physical therapy was

provided in the form of spinal manipulative therapy and instructions for specific exercises to be performed 10 times, 3 to 4 times every day.[52] The primary outcome measure was the Oswestry Disability Index (ODI), measured at three months. The secondary outcome measures were the Numerical Pain Rating Scale, the Catastrophizing Pain Scale, the Fear-Avoidance Beliefs Questionnaire, and the Global Rating of Change (GRoC), and a measure of health status, assessed at 4 weeks, 3 months, and one year.[52] The results of this study indicated that early physical therapy led to small improvements in disability and quality of life in patients with acute, nonspecific LBP.[52]

Most of the recommended clinical guidelines for the management of acute LBP are meant to be used by primary care practitioners. Clinicians, such as physical therapists, are more concerned about the appropriateness of their procedures for the treatment of acute LBP, but studies in this area are scarce.[35] Although the first line of intervention is advice and analgesics[12,15], patients with acute LBP presenting to physical therapists expect clinicians to offer other methods. One of the proposed approaches is to provide patient education and analgesics and to monitor progress.[12] However, there is no acceptable standard for how long a clinician should wait before introducing other lines of interventions.

Hancock et al recruited 240 participants with acute LBP and examined the effect of adding diclofenac or spinal manipulative therapy (SMT) to the first line of intervention in patients with non-specific low back pain in the first two weeks post episode.[53] Patients were randomly allocated to one of four groups: a group received diclofenac 50 mg twice a day and placebo SMT, a group received SMT and a placebo drug, a group received diclofenac 50 mg twice a day and SMT, and a fourth group that received placebo drug

and a placebo SMT.[53] The results indicated that addition of SMT and/or diclofenac in the first two weeks post episode dose not reduce the number of days until recovery.[53] Around 50% of patients recovered within the first two weeks post episode with only the first-line care.[53] These findings may indicate that an appropriate plan is to provide first-line care and monitor the progress for 2 weeks and to introduce other interventions to those who do not show improvement after such time frame.[53]

The use of EBP guidelines was not common in the 1990s as it is today.[35] The use of passive interventions, such as heat, ultrasound, and electrical stimulation, was common in the 1990s and the use of manual therapies, especially spinal manipulative therapy, was not as common.[35] There are very few researchers who investigated the effect of physical therapy-specific interventions in patients with acute, nonspecific LBP in the literature.[35] Practice patterns of physical therapists in conditions of acute, nonspecific LBP was the subject of a research study by Laderia and associates.[35] The study was an electronic survey that included 327 responses from licensed physical therapists in Florida to examine treatment choices of physical therapists in acute and subacute, nonspecific LBP.[35] Therapists were categorized into outpatient musculoskeletal physical therapists (MSPT) and non-outpatient musculoskeletal physical therapists (NMSPT).[35] The investigators designed the study to demonstarte which kind of intervention was commonly used by physical therapists in patients with acute, nonspecific LBP and the rate of adherenace to evidence-based practice guidlines.[35] Ladeira et al showed that MSPTs are more adherent to EBP guidelines (30%) than NMSPTs (15%).[35] However, there was a small rate of the use of EBP guidelines overall. The most common interventions for acute and sub-acute LBP found in the study were home exercise

program, exercise in the clinic, back care education, joint mobilization, ice/heat, and interferential current.[35] Ladeira et al provided evidence about how physical therapists are approaching these patients and the commonly used interventions.

Due to lack of evidence about the effectiveness of osteopathic manipulative treatment in military individuals with acute, nonspecific LBP, Cruser and associates[44] designed a study to examine the efficacy of this treatment approach in such population. In this randomized controlled trail, 36 patients with a new episode of LBP and an age range between 18 and 35 were randomly assigned to an experimental group and a control group.[44] The experimental group received osteopathic treatment in addition to the usual care and the control group received usual care alone.[44] Osteopathic manipulative therapy in this study was in the form of soft tissue manipulation, myofascial release, strain-counter strain, muscle energy technique, manipulation of sacroiliac articulation and high-velocity low-amplitude manipulation of joints.[44] The usual care was in the form of advice, muscle relaxants (or low dose opioids), and passive modalities (such as heat or ice).[44] Treatments were provided once per week for 4 weeks.[44] Measurement tools used were the Quadruple Visual Analog Scale and the Ronald Morris Disability Questionnaire.[44] Measurements took place at baseline and after 4 weeks.[44] Clinically meaningful improvements were found in the experimental group, showing the effectiveness of osteopathic manipulative treatment in patients with acute LBP.[44] The results of this study are similar to a previous study by Sutlive et al,[45] which examined the effectiveness of two spinal manipulation techniques in military personnel with LBP and found that spinal manipulation can provide a short-term, immediate relief for LBP.

In a systematic review by Rubinstein and colleagues,[54] the effectiveness of spinal manipulative therapy in patients with acute LBP of less than six weeks in duration was investigated. The evidence provided in this report did not support the use of spinal manipulative therapy in patients with acute LBP.[54] Spinal manipulative therapy was found as effective as sham manipulative therapy and other inert interventions.[54] There was agreement between these findings and those found by Assendelft and colleagues in a previous meta-analysis.[55]

Similarly, Selhorst and Selhorst[56] compared lumbar spine manipulation and sham manipulation in patients with acute LBP. Thirty-four patients with acute LBP were included and divided into two groups. One group received lumbar manipulation plus physical therapy exercises.[56] The second group received sham manipulation plus physical therapy exercises.[56] Lumbar manipulation performed in a side-lying position, focusing on the symptomatic side.[56] The therapist used manual force through the anterior superior iliac spine while holding the thoracic spine to apply the manipulative force.[56] Physical therapy exercises included stabilization exercises, range of motion exercises, and stretching exercises tailored to individual patient's needs.[56] Measurement tools included the Numrical Pain Rating Scale, the Patient-Specific Functional Scale (PSFS), and the Global Rating of Change.[56] Measurements occurred at baseline, the first week, 4 weeks, and 6 months post intervention.[56] The findings of this study indicated no added benefits of lumbar manipulation to physical therapy exercises in patients with acute LBP.[56] However, Ruddock and associates[46] performed a systematic review in which the results were different, and the findings were shown to support the effectiveness of spinal manipulative therapy in patients with LBP.[46] Most of these analyses and research reports

are limited by the small number of studies, which makes drawing a definite conclusion troublesome.

There are many techniques that can be used to deliver spinal manipulative therapy. Feng's spinal manipulation is a technique that was developed by Dr. Feng in the 1970s.[57] The concept of Feng's spinal manipulation technique is essentially the same as traditional spinal manipulative techniques. Feng and colleagues[58] studied the effectiveness of this technique in comparison with other interventions in patients with acute lumbar disc herniations.[58] Ninety-four patients were divided into two groups. The experimental group received Feng's spinal manipulation, hot fomentation and bed rest, and the control group received hot fomentation and bed rest.[58] Outcome measures were the angle of straight leg raising, the Visual Analog Scale, and the Japanese Orthopedic Association Score of Low Back Pain before and after interventions.[58] Participants received 3 weeks of treatments.[58] The results of this study showed a significant improvement in the Feng spinal manipulative therapy group.[58] Furthermore, magnetic resonance myelography three-dimensional reconstruction imaging of the vertebral canal showed an evidence of relief of nerve root compression.[58]

The effect of spinal manipulation on the levels of circulatory pain biomarkers was evaluated by Degenhardt et al.[59] There were 20 subjects in the sample: 10 with chronic LBP and 10 without LBP.[59] Blood samples were taken for 5 consecutive days and on the fourth day.[59] Spinal manipulative therapy was introduced to all subjects one hour before blood sampling.[59] The results of analysis indicated an increase from baseline in beta-endorphin and N-Palmitoylethanolamide (PEA) levels and a decrease in anandamide (arachidonoylethanolamide [AEA]) levels immediately post intervention for both

groups.[59] Subjects with chronic LBP had significantly reduced 5-hydroxy indoleacetic acid (5-HIAA) levels at 30 minutes' post treatment (p = .05) and serotonin (5-hydroxytryptamine [5-HT]) levels at 24 hours' post treatment (p = .02) when compared with baseline concentrations.[59] The degree of alteration of pain biomarkers was more in LBP group.[59]

An inflammatory component has been thought to play a role in the development of low back pain.[60,61,62,63] Low back pain rodent models showed signs of inflammatory responses in dorsal root ganglion and an activation of satellite glia cells, infiltration of macrophages, and elevation of inflammatory cytokines.[60,61] Use of systemic non-steroidal anti-inflammatory drugs or injections of glucocorticoids is often associated with improvements.[60,61] These inflammatory changes and activation of inflammatory pathways are considered to be one of the mechanisms that contribute to the development of LBP.[60,61] The effect of a single spinal manipulative therapy on the in vitro production of inflammatory cytokines tumor necrosis factor alpha and interleukin (IL) beta in relation to the systemic in vivo levels of neurotransmitter substance P was investigated.[63] A single SMT was administered to the SMT group. Two other groups were included: a sham manipulation group and venipuncture control group.[63] Blood and serum samples were collected before, then at 20 minutes, and 2 hours after intervention.[63] The findings demonstrated gradual decline of the inflammatory cytokines in the SMT group.[63] This related down-regulation of the inflammatory responses occurred through a central but unknown mechanism.[63] The discussion presented above about the effects of manual therapy on the spine shows the benefits of spinal manipulative therapy in terms of hypoalgesia and reduction of inflammation although most of the evidence showed a

short-lived response.[63] Moreover, these chemical changes seen in previous studies occurred on the systemic level, which cannot explain the local pain relieving effect of spinal manipulation.[63] However, the theoretical basis of spinal manipulative therapy has been described to involve effects on several levels.[64] Biomechanical changes due to spinal manipulation thought to stimulate muscle spindles and Golgi tendon receptors.[64] Also, it has been suggested that spinal manipulative therapy removes sub-threshold chemical and mechanical stimuli, which in turn causes hypoalgesia and increased pain threshold.[64] These later effects can explain the effect of spinal manipulation on the segmental level.[64]

The variability of presentation of low back pain is one of the reasons for the difficulty in establishing a specific dysfunctional pattern. Treatment planning, therefore, cannot be accurately designed, which makes it difficult to create a specific consensus that can be used for all patients presenting with an episode of LBP.[30,65] To improve clinical outcomes, there have been attempts to divide patients into homogenous sub-groups so that specific interventions can be directed toward each sub-group.[30,65] Dividing or classifying patients into homogenous sub-groups is thought to improve clinical decision making and prognosis.[30,65]

Nijs and colleagues[31] described a classification scheme for LBP that is pain-driven. Pain can be neuropathic, nociceptive, or central sensitization pain as describe by Nijs et al.[31] Based on the theoretical foundation of the pain-mechanism classification system, the clinician should examine the patient for the presence of neuropathic pain initially, then differentially diagnose between nociceptive and central sensitization pain in the absence of neuropathic pain.[31]

During physical examination, one of the most important components of identifying red flags is to screen for lesions in the central or peripheral nervous system in which the pain follows a neuro-anatomically plausible distribution.[31] This type of pain, which is neuropathic, is often associated with higher pain level, lower quality of life, more disability, and higher levels of anxiety and depression than nociceptive pain.[31] Nociceptive pain is caused by injury to non-neural tissue, which results in activation of nociceptors or stimulation of peripheral receptive terminals of primary afferent neurons because of mechanical, noxious chemical, or thermal stimulus.[31] Central sensitization is defined as “an amplification of neural signaling within the central nervous system that elicits pain hypersensitivity" [31] or " an augmentation of responsiveness of central neurons to input from unimodal and polymodal receptors" [31] This classification scheme for LBP is the most relevant to our study as subjects recruited were screened for the presence of neuropathic pain.

It has been hypothesized that with this classification algorithm, some clinical criteria can be used to identify those with central sensitization pain.[31] One of the most important criterion is a pain intensity disproportionate to the nature and extent of injury.[31] Other criteria that are used to identify those with central sensitization pain mechanism are the presence of neuro-anatomically illogical pain pattern and hypersensitivity of senses unrelated to the musculoskeletal system.[31] Maladaptive psychological responses play a significant role in the central sensitization pain mechanism, which is usually referred to as emotional-cognitive sensitization.[31] Factors, such as anxiety, depression, fear/catastrophization, and illness beliefs, modulate the brain-controlled descending pain inhibition/facilitation mechanisms.[31] Because of the importance of the psychological

variables in the development of chronic LBP, previous researchers investigated the effects of interventions after subgrouping patients based on their psychological profile.[66]

THE BIO-PSYCHOLOGICAL MODEL OF LBP

Pain is a multi-dimensional experience that includes numerous sensory events, emotions, thoughts, physical, and interpersonal processes.[67] It is multifactorial in terms of being affected by biological, psychological, social, and cultural factors.[68] Altered pain perception, altered pain modulation, and psychological features are characteristics commonly seen in patients with LBP.[69] In a systemic review by Wertli and colleagues,[70] 21 studies were included for an assessment of the prognostic potential of fear-avoidance beliefs in non-specific LBP. Wertli et al provided support for the prognostic value of fear-avoidance beliefs and associated poor outcomes in patients with sub-acute LBP.[70]

Psychological factors, such as fear, anxiety, and catastrophizing, are significant in acute LBP and may affect the recovery process.[4] Catastrophizing is a phenomenon commonly observed in patients with acute LBP.[71] Catastrophizing implies an irrational belief that the condition of the individual is far worse than it is and is usually related to the current status and future consequences.[71] Anxiety often develops when the patient perceive pain as a danger signal.[72] Anxiety is induced by threat to well-being, which could be actual or potential.[72] However, a heightened anxiety that reaches a pathological level interferes with the patient's ability to cope with the pain or the threat.[72]

Pain catastrophization is a cognitive strategy broadly defined as "an exaggerated negative orientation towards an actual or anticipated pain experience".[73] Sometimes, it can be used as a strategy to attract the assistance or empathy from others.[73] It is also used as a mechanism for rumination and can cause intensification of pain.[74] Nevertheless, it

triggers noticeable physical and verbal signs that are linked to responses from others.[74] There is some evidence that catastrophization is associated with higher pain intensity and may contribute to the development of neuropathic pain.[74] Pain catastrophization has been reported to be enhanced by increased pain intensity in acute LBP.[74]

Significant predictors of disability in patients with low back pain should be identified to assist in its prevention.[75] Melton and colleagues[75] examined the relationship between some predictor variables and low back pain using a structural equation modeling. Significant predictors were identified that were based on this model included female gender, full-time employment, depression, and fear-avoidance beliefs.[75] The role played by the psychological variables in low back pain is striking and well-observed in clinical practice. The fear-avoidance beliefs model consists of multiple mental constructs, which include pain catastrophizing, fear of pain, and anxiety.[76] Socioeconomic status has been shown to interact with fear-avoidance beliefs to influence disability.[68] In individuals with low socioeconomic status, there is a high potential for a stronger association of fear-avoidance beliefs and disability. Valencia and associates[68] found this association to be significant at baseline, 4 weeks, and 6 months.

Subgrouping techniques based on psychological constructs have been commonly employed in patients with LBP.[4,66,70,77] George and associates[77] investigated the use of the Fear-Avoidance Beliefs Questionnaire to predict outcomes at 6 months in patients with low back pain. The results indicated that FABQ work subscale is a better predictor than other predictors of self-reported disability in patients with low back pain, but generalization of these results was not recommended.[77]

Subgrouping patients with LBP based on multiple fear avoidance model measures was found to be more beneficial in providing additional information about clinical outcomes than subgrouping patients based on one single measure or construct.[66] Elevated FAB are associated with poor clinical outcomes in patients with LBP of less than 6 months.[70] Including interventions to address elevated FAB may avoid delayed recovery and chronicity.[70] Wertli et al[70] showed an evidence about the importance of considering the pychological variables in the prognosis and treatment of acute LBP. Online cognitive behavioral therapy is one of the approaches that showed some promise in reducing catastrophization and improving patients' attitudes toward low back pain, but it was mainly investigated in chronic LBP.[78] Therapeutic Neuroscience Education is one of the new techniques that can be used to address fear-avoidance beliefs in patients with acute LBP, but research evidence in this area is still growing.[79]

Fear-avoidance beliefs represent cognitive and emotional processes that include concerns about the potential that physical activity may reproduce pain and cause further damage to the spine.[77,80-87] Patients with acute LBP often exhibit psychological distress in the form of pain catastrophizing, pain-related fear, anxiety, hypervigilance of pain, and avoidance behaviors.[81] Patients with elevated fear-avoidance beliefs have increased risk of not returning to work and greater use of sick days.[80-88] Early intervention may reduce the risk of delayed recovery and work-related poor outcomes.[70]

Godges and colleagues[88] investigated the effectiveness of education and counseling for pain management, physical activity, and exercise on the return-to-work status. The return-to-work status was represented by the number of days off work in the study sample.[88] Thirty-four subjects with acute, nonspecific LBP represented the

sample.[88] The investigators chose to use the Fear-Avoidance Beliefs Questionnaire score as one of the main criteria for inclusion.[88] Those with a score of 50 on the FABQ scale were selected in order to create a relatively homogenous group of patients with acute, nonspecific LBP and elevated fear-avoidance beliefs.[88] Participants were assigned to an education group or a comparison group.[88] Both groups received traditional physical therapy, but those in the education group received counseling about pain management and the importance of exercises and physical therapy.[88] Traditional physical therapy included physical agents and electrical stimulation for pain relief, stretching exercises for those who exhibit limited flexibility, strengthening exercises for those who have muscle weakness, and ergonomic training with respect to work-related tasks.[88] Participants received physical therapy two or three times per week until they were able to return to work.[88] All subjects in both groups received an educational pamphlet that described commonly used therapeutic exercises and ergonomic principles essential for acute low back pain patients.[88] Subjects in the educational group received an educational booklet titled: " Back Pain: How To Control A Nagging Backache."[88] This booklet was chosen given the importance of addressing the psychological features in acute LBP patients based on the bio-psychological model of LBP.[88] Godges et al[88] suggested that adding an explicit educational component to the traditional management of acute LBP may improve the return to work status as shown by the reduced number of days to return to work in the educational group. Godges et al[88] supported the importance of psychological variables in acute, nonspecific LBP.

Those who suffer from acute LBP with elevated fear-avoidance beliefs are most likely to show limited improvement. [81-88] It is considered to be one of the most common

used predictors for the progression to chronicity. [81-88] The fear-avoidance beliefs model is a theoretical model that includes clinical reasoning that may reflect why some individuals recover within a reasonable frame of time and return to previous level of function while others continue to exhibit pain and disability. [81-88] In this model, the individual's response to LBP lies on a spectrum that ranges between confrontation and avoidance.[83,84] Patients with acute LBP are considered with a varying degree to be either confronters or avoiders.[83]

Those with low scores on the scale of the fear-avoidance beliefs are deemed to be more confronters, and those with high scores on the scale are considered to be more avoiders.[83] An individual favorable response to return to prior level of function can be expressed as appropriate adaptive behavior, which may reduce the potential of long-term disability.[83] On the other hand, a maladaptive response to acute LBP, which is avoidance, is associated with the development of long-term disability.[83] This maladaptive response due to exaggerated pain perception, can lead to physical changes that can be seen in the clinical presentation of patients with acute LBP.[83]

Avoidance behavior may cause the patient to be reluctant to participate in essential activities, which may lead to disuse, depression, further pain, and de-conditioning.[83] This vicious cycle may be one of the mechanisms of development of chronicity and long-term disability.[83] Factors that play a critical role in the psychological condition of acute LBP include previous stressful life events, personal pain coping strategies, prior pain experiences, and personality traits.[83] Past experiences and personal reaction to pain may lead to intensification of pain and development of avoidance responses.[83] These avoidance behaviors and fear of movement or reinjury may be

affected by observational learning.[89] The progression to long-term disability and chronicity are linked to such behaviors.[81,90,91] Also, in chronic LBP, there is a strong relationship between pain severity, FABQ scores, and functional disability.[81,90,91]

Signs that may be observed during the physical exam can be consequences of such maladaptive behavior.[84] These signs may include decreased range of motion, muscle weakness, false positive tests, and weight gain. Long-term disability and continued work absenteeism were found more prominent in patients with acute LBP with exaggerated pain perception and elevated fear-avoidance beliefs even after controlling the initial episode of pain and dysfunction.[83] Interventions that take into consideration the individual's response to pain are more likely to have a positive effect on the recovery process and the development of long-term disability.[83,87] A proposed plan based on such model is to screen individuals for exaggerated pain perception and fear-avoidance beliefs and to modify the plan of care accordingly. [83,87] The modification required in the plan of care must address elevated fear-avoidance beliefs by the use of more specific interventions, such as education and graded exercises. [83,87]

The Fear-Avoidance Beliefs Questionnaire is considered to be an appropriate instrument to screen patients for elevated fear-avoidance beliefs.[87] It is suggested that a score of 15 on the physical activity subscale can be used as a cutoff point to categorize patients into the following groups: those with elevated fear-avoidance beliefs and those with low fear-avoidance beliefs for patients who are treated in primary care setting and those who receive osteopathic treatment.[87] However, there is no direct proportional increase in the probability of prolonged disability with increased scores on the scale. [83,87]

Patient education is an integral part of the first line of intervention recommended in the clinical practice guidelines for the management of acute LBP.[92] The model indicates reinforcing confrontation to modulate exaggerated pain perception through patient education about LBP.[92] Reassuring that LBP is a common condition and presence of pain does not necessarily mean that the spine is damaged is one of the messages that should be included in the educational plan.[92] Patient education can be delivered by the use of pamphlets or discussion.[92] A commonly used booklet based on the model of fear-avoidance beliefs, called the back book, contain advice to combat negative thoughts and undesirable beliefs about low back pain.[92] A traditional educational pamphlet, such as Handy Hints, does not encourage individuals to think positively about their condition.[92]

Taking into consideration the individual psychological response to pain when designing an exercise program is one of the approaches that should be adopted, particularly for those with high fear-avoidance beliefs based on the proposed theoretical model.[92] A graded exercise program that encourages tolerance to activities and return to prior level of function should be used in such condition.[92] This approach should help the patient to be more on the confrontation side of the spectrum, which reduces the limitations that could be imposed by the psychological status on the recovery and return-to-work status. Previously, even with the use of randomized controlled trials, researchers have failed to provide an appropriate recommendation for specific exercises in acute LBP. It has been argued that previous researchers did not account for individual behavioral or psychological response to pain, and programs were not based on a treatment-classification concept.[92] Considering patients' psychological response to pain and the coping strategy may be more beneficial for patients when designing an exercise

program. In addition, activity participation, socialization, and early return to work may be facilitated through introducing an adequate educational intervention as well as slow progression of exercises, which may have the potential to speed recovery and reduce the likelihood of development of disability.[88,92]

Functional performance in patients with acute LBP is often compromised.[83-88,92] The fear-avoidance beliefs model indicates to some extent why some individuals exhibit sub-maximal performance in tasks that require knee flexion-extension, trunk extension-flexion, and weight lifting.[93] In some individuals, the perception of pain is more intense, and they may react to it in a threatening or catastrophic manner.[93] Negative correlation between fear-avoidance beliefs and lumbar spine flexion range of motion (ROM) was found in patients with acute LBP.[93] Thomas and France[93] aimed to find and describe the relationship between forward-bending ROM of the lumbar spine and pain-related fear in a sample of 36 subjects with a recent episode of LBP.[93] Thomas and France demonstrated that fear-avoidance beliefs negatively affect lumbar spine motion.[93] In another cross-sectional study, Thomas et al[94] investigated the association between pain-related fear and joint motions and the role of psychological construct on motor behavior.[94] The results indicated that those with high pain-related fear exhibit lower velocities and accelerations of the lumbar spine and hip joints.[94] It has been shown that patients with elevated fear-avoidance beliefs adopt alternative movement strategies to avoid motion of the lumbar spine and hip joints during functional tasks.[95]

Pain-related fear has been shown to have a negative effect on physical activity in patients with chronic LBP.[91,96] In most clinical trials, improved outcomes were reported when fear-avoidance aspects were considered in the planning of care.[97] The Fear-

Avoidance Beliefs Questionnaire was found to be more sensitive in predicting fear-reported disability.[91] Similar findings were reported in another study in patients with acute LBP.[82] The use of Fear-Avoidance Beliefs Model/Questionnaire have been recommended to predict changes and course of the condition in patients with musculoskeletal pain.[70,82] Some researchers have demonstrated that individuals who suffer from acute work-related LBP may return to work within 4 to 8 weeks from the onset.[83] Those who do not return to work within this time frame are the ones most likely to remain with long-term disability.[83] The potential of FABQ to be used as a predictor for persistent work restrictions was examined by Fritz et al.[83] Seventy-eight patients with work-related acute LBP were included.[83] Outcome measures were the modified Oswestry Disability Index, a measure of general health status (36-item short form health survey) and psychological measures.[83] Participants were randomly assigned to two groups. One group of 37 subjects who received physical therapy based on the AHCPR clinical practice guidelines, and another group of 41 subjects who received physical therapy that was based on the classification system developed by Delitto and colleagues.[83] The conventional PT group received low stress aerobic exercises (treadmill or stationary cycling), general muscle reconditioning exercises (abdominal curls, quadruped arm and leg extensions), advice to remain active, and reassurance about return to work with no restrictions.[83]

The second group received manipulation followed by repeated end-range exercises, stabilization exercises, and traction.[83] Measurements were taken at baseline and 4 weeks after randomization and treatment.[83] The primary outcome measure was work status after 4 weeks. Return to work status is an important measure because it

affects quality of life and has an economic impact on the individual and the society.[83] In this study, the results showed that the work subscale of the FABQ can be used as a predictor of the return to work status in patients with acute LBP.[83] A strong relationship was found between high scores on the work subscale of the FABQ and prolonged work absence or returning to work with restrictions.[83]

Fritz and George[87] examined the effect of psychological variables on the recovery from acute work-related LBP. It was found that on the work subscale of the fear-avoidance beliefs questionnaire, a score of 29 or less would decrease the risk of prolonged work restrictions from 29% to 3%, and a score of more than 34 was associated with an increased risk of not returning to work in patients with acute, nonspecific LBP.[87] Therefore, it was concluded that the FABQ work subscale can be used to screen patients for prolonged work absence, work restrictions, and for the development of chronic LBP, but the interpretation of the test should be with caution considering patient's individual characteristics and incentives to return or not to return to work.[87] Similar recommendations have been proposed by George and Stryker[98] who investigated fear-avoidance beliefs across different anatomic regions in patients with musculoskeletal pain. They concluded that fear-avoidance beliefs questionnaire can be used to predict changes in patients with various musculoskeletal conditions.[98]

Researchers have investigated the predictive and the modulating effect of FABQ. In 2009, Jenson and Albertson[99] examined the association between physical work load and LBP. In the same study, the predictive effect of FABQ on the development of chronic LBP was investigated to demonstrate if FABQ has any modulating effect on the association between physical work load and LBP among health care workers with and

without previous episodes of LBP.[99] The results indicated a significant association between physical work load and LBP in individuals with a previous history of LBP, which implied that those with a previous history of LBP have a lower threshold and more sensitive to the physical strain of work-related activities.[99] Those without a previous history of LBP seem to be more tolerant and adaptive to work-related activities.[99] In turn, past experiences might have an influence on the fear-avoidance beliefs, which may affect the response of the individual.[99] However, the researchers did not find any modulating effect of the FABQ on the association between physical work-load and LBP.[99] The scores of both subscales of FAB (PA and Work) were strongly associated with high number of days with LBP (30 days or more) in those with a previous history of LBP and those without a previous history of LBP.[99] Therefore, in patients with a past history of LBP, two variables were considered significant: physical workload and fear-avoidance beliefs.[99] In patients with a new episode of LBP, only fear-avoidance beliefs have been considered significant.[99] The researchers in this study pointed out the role of fear-avoidance beliefs in patients with acute LBP and the significance of the psychological component.

Expectation of recovery is considered one of the influential factors that play a role in the recovery process in patients with acute LBP.[100] Myers et al[100] performed a secondary analysis of a randomized controlled trial that included 444 patients with acute low back pain of less than 21 days in duration to describe the association between patients' expectations and functional improvement.[100] The results of this study indicated that positive expectation of recovery is associated with better functional outcomes in patients with acute LBP.[100] In another study, George and Robinson[101] investigated

patients' expectations and preferences found that patients' preferences can affect the rate of recovery in patients with acute and sub-acute LBP. The results also demonstrated a lower pain intensity and disability scores in patients with higher expectations.[101] Influencing patients ' expectations may be used to affect the likelihood of functional recovery in patients with acute LBP. George and Robinson[101] emphasized the role of patient's education and the importance of positive expectations in the management of patients with acute LBP. In our study, patient education about LBP served as a tool to enhance positive expectation of recovery.

ECONOMIC BURDEN OF LBP AND PROGNOSTIC MODELS

The financial burden associated with LBP is high worldwide.[102] It is estimated that interventions of LBP are associated with more than $50 billion per annum in the United States and $4 billion in the United Kingdom.[102] Development of a prognostic model to screen patients for the risk of developing chronic LBP is one of the areas in which research is needed.[102] It is one of the most important steps needed to formulate prevention strategies.[102] For the model to be useful and feasible in clinical practice, it has to be predictive of the desired outcomes with an acceptable level of accuracy, and it must be easy to use in terms of time and effort.[102] A choice between a "treat-all" approach or a "treat-none" approach in acute LBP will be better estimated using accurate prognostic models.[102] Clinicians can develop appropriate treatment plans based on the predictive features of the model, therefore, avoiding overtreatment for those with excellent prognosis and undertreatment for those who have high risk for developing chronic LBP.[102] If such a group of patients is identified early, clinicians will be able to plan interventions more effectively to prevent residual pain and disability.[102] Early

intervention yields better outcomes and prognosis in many conditions, such as breast cancer and cardiovascular disease.[102] Therefore, the use of screening tools, such as FABQ, should be considered in the evaluation process of patients with acute LBP in order to target those with less favorable prognosis. Moreover, investigation of interventions, such as KT, which might modulate fear-avoidance beliefs in patients with acute LBP, is a crucial step toward the achievement of better clinical outcomes.

SELF-REPORTED MEASURES IN LBP

In research settings and clinical practice, the use of self-reported measures to assess patients' function or disability is very common. The functional decline that can be observed after an acute episode of pain can be analyzed and quantified through self-reported disability assessments.[103] There is some correlation between direct measures of functional status and self-reported disability measures.[103] Wand and Colleagues[103] investigated the influence of patients' characteristics on self-reported measures of disability and performance-based measures of disability. The relationship between self-reported measures and performance-based measures were examined.[103] In this cross-sectional study, 94 participants with acute LBP were included.[103] Outcome measures used were demographic questionnaire, measure of pain intensity (NPRS), measures of psychological characteristics, health-related quality of life assessment, self-reported measure of disability (RMDQ) and performance-based disability measures.[103] Performance-based assessment of disability included timed sit-to-stand test, timed up-and-go test, timed 5-M walk test and timed lying-to-stand test.[103] The results of this study indicated that there is a moderate correlation between RMDQ scores and two patient characteristics, which are usual pain intensity and present pain intensity (r = 0.501 and r

= 0.592).[103] There were also moderate correlations between self-reported measures and symptom distribution, medication use, physical well-being, depression, somatic distress, and anxiety.[103] Also, the researchers suggested that the battery of the tests are internally reliable. Pain intensity, symptom distribution, and physical well-being were significantly correlated with performance-based measures.[103] The researchers concluded that self-reported measures of disability are more sensitive to the psychological status of the patient and more feasible than performance-based measures in patients with acute LBP.[103] In our study, we used self-reported measures to assess patient status and monitor progress.

KINESIO TAPING

Kinesio Taping was developed by the Japanese chiropractor Kenzo Kase in the 1970s as a method to reduce pain and improve function using unrestrictive elastic taping applied in different patterns and directions.[32,38,39,41] The elasticity of Kinesio Tape is around 40% to 60% of its resting length, depending on the tape's width, which provides more stretching range than conventional tape.[32,38,39,41] Because of this flexibility, KT is adaptable to different body parts and can be applied with variable degrees of tension.[32]

KT is different from other types of therapeutic taping in many aspects.[32] KT is designed in such a way to mimic some of the physical qualities of human skin.[32] It is roughly as thin as the epidermis and can be stretched along the longitudinal axis of the tape.[32] KT is usually well tolerated because it is 100% cotton, which allows breathability.[32,38,39,41] KT is safe to be used, is tolerated more than other types of therapeutic taping, and can be worn for extended periods of time.[32,38,39,41] Also, it is considered to be safer than other forms of tape because its adhesive is a 100% medical

grade acrylic.[32] The adhesiveness of the tape is activated by rubbing the tape over the skin several times.[32] KT can be worn in the shower or pool without peeling off and applied to almost any area of the body.[32] KT is hypoallergic as it is latex free, contains no medication, and is applied to the substrate paper at 10% to 15% tension.[32] Therapeutic benefits which are hypothesized to occure as a result of KT application include (1) facilitating proper alignment of fascia, (2) stimulating the afferent input, (3) creating a space between the skin and the underlying fascia, (4) acting as a mechanical support to limit or facilitate movement, (5) assisting in improving circulation and lymphatic drainage, and (6) helping realign tissues and restore homeostasis.[32,38,39,41]

KT has been the subject of research studies in more than 25 countries.[32] It can be used in combination with other treatment approaches, such as cryotherapy, manual therapy, electrotherapy, and acupuncture.[32] KT is also hypothesized to have an immediate- and long-term effects.[32] Proper KT application should lead to mechanical changes in the skin, which could result in compressive or decompressive forces, depending on the tension of the tape.[32] Compressive forces may stimulate mechanoreceptors while decompressive forces may reduce inflammation and the load on mechanoreceptors, which may result in pain relief.[32] Furthermore, the recoil effect of the tape influences skin position and distensibility.[32]

KT application can also influence interstitial fluid dynamics through tape convolutions.[32] The fluid stasis that occurs after injuries impedes the healing process, delays recovery, and affects body function.[32] KT is thought to create a pressure gradient, which helps enhance fluid exchange between tissues.[32] This fluid dynamic effect reduces

hematoma and swelling or edema in the injured tissues, which result in relieving pain and improving function.[32]

KT also affects muscle function, depending on the direction of application and the tension induced in the tape.[32] Tape applications from distal to proximal (insertion to the origin) applied at 15% to 25% tension are hypothesized to inhibit overactive muscles, which may be helpful in acute conditions and muscle spasms.[32] Proximal to distal applications of KT (from origin to insertion) at 15% to 35% tension level may be used to facilitate muscles in chronic conditions.[32] KT can be used to assist the desired motion or inhibit certain joint movements in acute conditions.[32]

Kinesio Taping has been used for many therapeutic applications.[32] Since its invention, researchers have been investigating its effect on many conditions, including but not limited to musculoskeletal conditions.[32] According to Dr. Kase, the developer of the tape, the concept of KT stems from an idea of having some continuous therapeutic effect in between treatment sessions to augment the effect of treatment procedures and provide the patients with a safe and convenient modality to help them function more comfortably.[32] KT also has been used to improve sports performance through its application to enhance kinesthetic awareness and muscle function.[32] Therapeutic taping has been widely utilized for the prevention and treatment of sports-related injuries.[32] Other types of taping have been employed in musculoskeletal conditions but with different purposes, tension levels, and hypothesized mechanisms. The use of rigid or "non-stretch" taping in sports is mainly to provide joint or muscle support.[39] Other types of taping, such as Leukotape and CoverRoll tape, have been investigated in patients with

shoulder impingement syndrome, AC joint separation, and hemiplegic shoulders with some degree of clinical improvement.[104]

EFFECT OF KINESIO TAPING ON LYMPHATIC FLOW RATE

Shim et al[105] investigated the effect of tape on lymphatic flow rate in rabbits. This experiment was conducted on male New Zealand white rabbits with an induced peripheral lymphedema.[105] Shim et [a105l] examined the effect of elastic adhesive tape combined with passive exercises on lymphatic flow rate. By using a stereomicroscope, a cannula was inserted into the pre-popliteal lymphatic vessel in the lower leg.[105] The weight of the collected lymph fluid was measured using an electronic scale. Passive exercises were performed using an electric motor at a rate of 20 to 60 rpm for 15 minutes.[105] The findings indicated a significant increase in lymphatic flow rate in cases in which taping and passive exercises were used, and the increase was proportional to the area of the tape.[105] These results can be considered scientific evidence about the positive effect of KT on lymphatic flow rate. In another study, Białoszewski and his colleagues[106] examined the effect of kinesiology taping in patients with postoperative lymphedema treated by the Ilizarov method for limb lengthening. Two groups of 24 patients were randomized to an experimental group that received standard physical therapy plus kinesiology taping and a control group that received standard physical therapy alone.[106] In both groups, there was a significant reduction of lymphedema, but the rate of reduction was significantly faster in the kinesiology taping group.[106] The findings of these researchers support the potential benefits of KT in acute conditions and in lymphedema.[106]

EFFECT OF KINESIO TAPING IN MERALGIA PARESTHETICA

Kinesio Taping was found to be helpful in patients with meralgia paresthetica.[107] In a pilot study, Kalichman et al[107] included 10 patients with meralgia paresthetica and examined the effectiveness of KT applied on the thigh for relieving pain and paresthesia. The Visual Analogue Scale (VAS) and the VAS Global Quality of Life were used as measurement tools.[107] The findings showed that KT is an effective intervention in reducing the symptoms of meralgia paresthetica.[107] The results may indicate that KT has a sensory modulating effect on the sensory cutaneous nerves of the skin; however, they could not exclude a placebo effect as it was not controlled in the study.

EFFICACY OF KINESIO TAPING IN MUSCULOSKELETAL CONDITIONS

Thelen et al[104] investigated the clinical effectiveness of KT on shoulder pain. The study included 42 subjects diagnosed with rotator cuff tendonitis/impingement syndrome.[104] Subjects were randomly assigned to one of two groups: a therapeutic KT group and a sham KT group.[104] Therapeutic taping was applied on the shoulder in sitting position with a paper-off tension level using a Y-strip.[104] Another compression strip of 50% to 75% tension was applied downward at the area of perceived pain and tenderness.[104] Sham taping was applied using two I-strips applied with no tension.[104] The Shoulder Pain and Disability Index (SPADI) was used to measure disability, standard goniometer to measure pain-free ROM, and the Visual Analogue Scale to measure pain intensity.[104] Measurements were taken at baseline; immediately after taping for pain intensity and ROM; 3 days; and 6 days after taping for pain, ROM, and disability.[104] These findings may indicated that KT has an immediate effect on improving pain free shoulder abduction.[104] However, there was no difference between both groups at any of

the other intervals with respect to pain, disability, and ROM, suggesting that KT has been shown to have only an immediate effect and its clinical benefits afterwards are limited.[104]

Shakeri et al[108] investigated the effect of KT on pain intensity during movement, pain experienced during night (nocturnal pain), and pain-free shoulder range of motion (ROM) in patients with shoulder impingement syndrome.[108] The study included 30 subjects with shoulder impingement syndrome who were randomly assigned to an experimental group and a control group.[108] Outcome measures included pain-free active ROM during shoulder abduction, flexion, and elevation in the scapular plane and Visual Analogue Scale.[108] VAS was used to measure pain intensity during movement and to assess nocturnal pain.[108] Measurements were taken at baseline, immediately after taping, 3 days after taping, and one week after taping.[108] Shakeri et al[108] demonstrated that kinesiological taping results in an immediate improvement in pain intensity during shoulder movement and nocturnal pain in patients with shoulder impingement syndrome.[108]

In addition, Kaya et al[109] found KT to be effective in reducing shoulder pain when KT was compared with local physical therapy modalities for the treatment of shoulder impingement syndrome.[109] Fifty-five patients were assigned non-randomly to a KT group and a physical therapy modalities group.[109] The first group received KT in addition to home exercise program of isometric exercises, stretching exercises, range of motion exercises, strengthening exercises, and relaxation of trapezius twice a day.[109] The second group received hot packs, transcutaneous electrical nerve stimulation (TENS), ultrasound, and the same exercise program.[109] KT was applied on three muscles: the supraspinatus, the deltoideus, and the teres minor.[109] The base of the tape was placed 3 cm below the

greater tuberosity without tension; the patient was then instructed to adduct his shoulder and to laterally flex his neck to the opposite side.[109] The tape was then applied to the spinous process of the scapula at 15% to 25% tension.[109] The tape was then applied to the deltoid muscle using a Y-strip, starting at 3 cm below the insertion with the two tails on the anterior and the posterior fibers at 15% to 25% tension.[109] An I-strip was used to tape the teres minor by placing the tape on the lower facet of the greater tuberosity of the humerus, then after abduction, horizontal flexion and internal rotation, the tape was applied along the axillary boarder of scapula at 15% to 25% tension.[109] Pain was measured with the VAS, and disability was measured with the Disabilities Of Arm, Shoulder and Hand (DASH) scale. Pain at rest, at night, and during motion was assessed.[109] Pain measurement was taken at baseline, in the first week, and the second week.[109] Disability was measured before and after treatments only.[109] The results indicated that KT was more effective than local physical therapy modalities at the first week and was similarly effective as physical therapy modalities at the second week.[109] However, such conclusion is doubtful given the study design and lack of randomization.

Djordjevic et al[110] compared Mobilization With Movement (MWM) combined with KT to supervised exercise program in patients with shoulder pain. Twenty subjects with shoulder pain were randomly assigned to two groups: group 1 (MWM plus KT) and group 2 (supervised exercise program).[110] Patients were referred by a physician due to shoulder impingement or rotator cuff lesion.[110] The tape used in this study was a black Kinesio Tex Tape, applied at 20% to 25% tension. The tape was applied on the surpraspinatus and deltoid muscles and glenohumeral joint after passing an allergy test.[110] MWM was performed by application of a postero-lateral glide while the patient was

performing an active shoulder movement.[110] The supervised exercise program consisted of pendulum exercises, range of motion exercises, and strengthening exercises.[110] The main outcome measures were active pain-free shoulder abduction and flexion.[110] The results indicated that active pain-free shoulder range of motion improved significantly in patients who received MWM and KT.[110] However, the study design does not allow a valid conclusion of the efficacy of KT alone as KT application with combined with other interventions.[110]

Patellar taping is one of the techniques commonly used to treat anterior knee pain. KT can be used to induce a medial glide, which can be helpful in these patients.[111] Clifford and Harrington[111] studied the effects of medial glide patellar taping using KT on sagittal plane lower limb joint kinematics and knee pain during a unilateral squat in patients complaining of anterior knee pain.[111] Ten subjects with either unilateral or bilateral anterior knee pain successfully completed the study.[111] Five of these subjects had a history of unilateral knee pain and five had a history of bilateral knee pain.[111] A single leg squat, barefoot, on the painful leg with arms crossed in front of the chest was required from each subject.[111] Subjects were instructed to squat as far as they could before returning to the starting position producing a continuous movement to resemble functional activities.[111] Three squats were performed in each condition: one squat with placebo tape, one squat with patellar tape, and one squat without tape (control).[111] Kinematic data were recorded using a motion analysis system.[111] Subjective measurements of anterior knee pain at rest and following each single-legged squat under each condition were performed using the Numerical Pain Rating Scale.[111] Clifford and Harrington[111] demonstrated that patellar taping could alter knee kinematics as indicated

by deeper knee squats by the tape group and may be helpful in reducing anterior knee pain.

Campolo et al[112] investigated the effect of taping on anterior knee pain during functional activities. They compared McConnell Taping (MT) to KT. MT is a rigid, adhesive and structurally supportive tape that can be used for up to 18 hours. On the other hand, KT is elastic, porous, and more tolerable.[112] KT is usually applied with tension to the painful area, allowing full range of motion while putting muscles under functional stretch, and can be used for up to 7 days.[112] Twenty subjects were recruited, and each subject was tested in two functional positions. The first was squat lift with a weighted box. The second was stair climbing under three conditions: without tape, with MT, and with KT.[112] Tape application techniques followed the standard used for patellofemoral pain syndrome, but Campolo et al[112] did not mention the level of tension used for KT application. Pain was assessed using the Numerical Pain Rating Scale.[112] The results of this study indicated that both MT and KT were effective in reducing pain during functional activities in patients with anterior knee pain.[112]

Kuru and associates[113] investigated the effect of KT in patients with patellofemoral pain syndrome. Thirty patients were recruited and divided equally into a KT group (15 patients) that received KT and an exercise program and an electrical stimulation (ES) group (15 patients), which received ES and the same exercise program.[113] Random allocation was not employed as participants were assigned based on availability.[113] Pain, range of motion (ROM), muscle strength, function, and quality of life were measured before and after treatment.[113] Pain was measured by the VAS, ROM was measured by a standard goniometer, and muscle strength was measured by manual

muscle test.[113] Function was assessed using step test, triple-jump test, knee flexion test, and Kujala Patellofemoral Score.[113] Quality of life and overall well-being was assessed using Generic Quality of Life Questionnaire (SF-36).[113] The Step test was performed using a 25-cm step.[113] The subject was asked to step up and down until pain was triggered while the assessor counted the number of steps.[113] The triple jump test was performed by asking the subject to hop on the painful leg three times, and the overall distance was measured. Assessments were conducted before and after treatment.[113] Kuru and associates suggested that KT and ES were equally effective in reducing pain and improving function in patients with patellofemoral pain syndrome.[113]

Chen et al[114] investigated the effect of KT on the timing and recruitment ratio of the vastus medialis obliqus (VMO) and vastus laterlais (VL) in patients with patellofemoral pain syndrome (PFPS). The study included two groups: 15 female subjects with PFPS, and 10 normal subjects served as the control group.[114] KT was applied to the vastus medialis, according to the KT manual.[114] An electromyogram (EMG) system (Motion Lab System, LA) was used to record the activity of the VMO and VL.[114] Subjects were asked to perform a stepping task using two steps of 25 cm height placed on the center of a 60 cm walkway platform.[114] Each subject performed five consecutive trials while the EMG activity of the muscles were recorded in three conditions: no tape, with tape (KT), and placebo tape for all subjects.[114] The findings indicated that KT may affect the onset of VMO activity, causing an earlier onset of recruitment compared with no tape and placebo.[114] This effect would facilitate an optimal positioning of the patella into the trochlea, which would improve force/pressure distribution on the articular cartilage and also may improve the VMO/VL contraction ratio.[114]

Abnormal biomechanics of the knee is one of the most contributing factors to the development of patellofemoral pain syndrome (PFPS), which cause difficulties in weight-bearing activities.[115] KT has been used in patients with PFPS with variable degree of success. In a meta-analysis, Barton and associates[115] evaluated the clinical outcomes of patellar taping. Twenty studies about patellar taping from the MEDLINE, CINAHL, SPORTSDiscus, Web of Science, and Google Scholar databases were reviewed in January 2013.[115] The investigators showed moderate evidence that KT may cause immediate short-term pain relief with a large effect.[115] This effect is large when taping is tailored to the individual need of the patient.[115]

Several researchers have examined the effects of KT in patients with neck pain and chronic low back pain. Castro-Sánchez et al[38] examined the effect of KT on pain and disability in patients with chronic LBP.[38] In this randomized controlled trial, the effect of KT on pain, disability, and kinesiophobia was tested in 60 patients with chronic non-specific LBP.[38] The sample was randomized to an experimental group that received KT, and a control group that received placebo taping.[38] KT was applied on the lumbar spine at the point of maximum pain using four I-strips placed in a star pattern at 25% tension.[38] The placebo group received one single I-strip placed horizontally above the point of maximum pain.[38] The tape was left in place for 7 days in both groups.[38]

Measurements were taken at baseline, after one week and after 4 weeks.[38] The outcome assessment tools used in this study were the VAS, the Oswestry Disability Index, RMDQ, the Tampa Kinesiophobia Scale, trunk flexion range of motion, and the McQuade test of trunk muscle endurance.[38] Statistical analysis showed that disability improved in the KT group compared with the placebo group after the first week, but no

significant difference was found after 4 weeks.[38] The experimental group also showed statistically significant decrease in pain scores immediately after taping, and this effect was maintained until 4 weeks.[38] Trunk muscle endurance was also better in the KT group compared with the placebo group.[38] However, the reported effects were small in size to be considered clinically significant.[38]

González-Iglesias et al[41] investigated the short-term effects of cervical KT on pain and ROM in patients with acute whiplash injury. An experimental group of 21 patients received KT for one week, and a control group of 20 patients received sham taping (applied without tension) for one week.[41] The Kinesio Tex Tape (Kinesio Holding Corporation, Albuquerque, NM) was used for this study on the neck area.[41] A blue Y-2 tailed strip was applied on neck extensors from insertion to origin at paper-off tension. Another black I-strip was applied perpendicular to the Y-strips.[41] Neck pain and cervical range of motion were measured at baseline, immediately after KT application, and at 24 hours follow-up.[41] The experimental group exhibited a statistically significant improvement immediately following tape application and at 24 hours follow-up period.[41] However, the effect size was small to be translated to clinical significance, and therefore, González-Iglesias et al[41] recommended that subsequent studies should consider adding KT to other physical therapy interventions.[41]

Saavedra-Hernández and associates[40] compared the effects of KT with those of cervical thrust manipulation in patients with mechanical neck pain. Eighty patients were recruited and randomly assigned to a manipulation group and a KT group.[40] The tape used in this study was a Kinesio Tex Tape, and it was applied on the neck extensors from insertion to origin using a blue Y-stripe.[40] Another black I-strip (space-opening) was

applied horizontally at the level of T1-T2.[40] The manipulation group received high-velocity, low-amplitude manipulation on mid-cervical spine and cervico-thoracic junction.[40] Primary outcome measures were pain, disability, and cervical ROM, assessed at baseline, immediately after the intervention, and one week after the intervention.[40] Both groups exhibited similar reductions in pain and disability and similar ROM changes, which suggested that KT is as effective as cervical manipulation.[40] If KT is as good as cervical manipulation in patients with mechanical neck pain, KT should be more appropriate to use given its safety and convenience.

Bae et al[116] investigated the effect of KT on anticipatory postural control and cerebral cortex potential in patients with chronic LBP. Twenty patients with chronic LBP were recruited and randomly assigned to an experimental group, which received KT only, and a control group, which received ordinary physical therapy.[116] Ordinary physical therapy used in the study included hot packs (for 20 minutes), ultrasound (1.5 W/cm2 for 5 minutes), and transcutaneous electrical nerve stimulation applied to L1–2 and L4–5 areas for 40 minutes each time.[116] Treatments were provided three times per week, for a total of 12 weeks.[116] Four blue I-strips were placed on the area of maximum pain on the lower back.[116] Electromyography and electroencephalography were used to assess anticipatory postural control and cerebral cortex potential.[116] The Visual Analogue Scale and the Oswestry Disability Index were used to evaluate pain and disability, respectively.[116] The results of this study indicated that KT is beneficial in chronic LBP and may help reduce pain and disability.[116] Also KT was found to have a positive effect on anticipatory postural control and cerebral cortex potential.[116]

Alvarez-Álvarez et al[117] investigated the effect of KT on low back muscle fatigue. Ninety-nine subjects were recruited to the study and randomly assigned to three groups: KT group, placebo group (sham taping), and a control group.[117] For the experimental group, two I-strips were applied at 10% to 15 % tension from the sacro-iliac joint to the transverse process of T12 on both sides of the spine from a position of maximum trunk flexion.[117] For the control group, a 10 cm I-strip was placed horizontally on the lower back.[117] Low back muscle endurance was measured at baseline and immediately after the application of KT using the Biering-Sorensen test.[117] The results indicated that KT may positively influence the processes that contribute to muscle fatigue and may help improve low back muscle endurance and therefore it might be helpful in the management of LBP.[117]

In a case report by Lee and Yoo,[118] the effect of KT on pain and anterior pelvic tilt angle has been investigated in a patient with chronic LBP. This case study included a female patient who was complaining of chronic LBP, mainly at the sacroiliac joints and medial buttocks.[118] The patient had hyperlordosis, a Cobb's angle of 68º and a sacral horizontal angle of 45º.[118] The KT technique used for this patient was the posterior pelvic tilting taping technique.[118] KT was applied for 2 weeks, six times a week, for an average of 9 hours each time.[118] The results of this study showed some positive changes which may be due to KT application. The Cobb's angle was decreased from 68º to 47º, and the sacral horizontal angle was decreased from 45º to 31º.[118] Clinically, the patient experienced less pain and tenderness and better spinal mobility while performing activities of daily living.[118] Lee and Yoo recommended additional research to be

conducted using the same technique for patients with chronic LBP who have hyperlordosis.[118]

Paoloni et al[119] studied the clinical and electromyographic changes in response to KT application in patients with chronic LBP. Thirty-nine patients were randomly assigned to three groups: KT plus exercise, KT alone, and exercise alone.[119] Pain, disability, and lumbar muscle function in terms of EMG changes were measured at baseline, immediately after the application of KT, and at one-month follow-up.[119] The study included two phases. In the first phase, patients who met the study's eligibility criteria were assessed in terms of pain, disability, and lumbar muscle function.[119] KT was applied to the lower back area. Three 20 cm by 5 cm I-stripes were placed on the lower back area from T12 to L5, one strip on the midline over the spinous processes, and the other two stripes were placed 4 cm on the right and left side of the midline strip.[119] Pain intensity was evaluated by the VAS before and after KT application.[119] Lumbar muscle function was evaluated by surface electrode EMG.[137] In the second phase, patients were randomly assigned to KT only group, KT and exercises group, and exercises only group.[119] Therapeutic exercises included relaxation techniques; stretching exercises; and active exercises for the lumbar, abdominal, psoas, ischiotibial, and pelvic muscles.[119] Exercises were performed in groups; each is a maximum of 5 for 30 minutes, three times per week for four weeks.[119] The results of the first phase of the study showed that KT has an immediate positive effect on pain and lumbar muscle function.[119] There was a significant decrease in pain intensity and normalized flexion-relaxation function,[119] which indicated that KT improved sensory feedback, which improved dynamic stabilization of the lumbar spine during flexion.[119] In the second phase, which lasted 4 weeks, there was a

significant reduction in pain intensity in all groups.[119] Pain reduction observed in the KT group was almost the same as for the exercise only group.[119] Only the exercise group demonstrated significant decrease in disability.[119] Paoloni et al[119] concluded that KT may be effective in reducing pain and disability and may improve lumbar muscle function in patients with chronic LBP. They also suggested that the immediate effect of KT in chronic LBP indicated that KT can be used as an alternative treatment choice in patients with acute LBP.[119]

There has been mixed results with respect to the effect of KT in chronic non-specific LBP. Luz Júnior et al[120] recruited 60 patients with chronic LBP, and they were randomly assigned to three groups: a KT group, a placebo group (Micropore-surgical tape), and a control group. Patients with low back pain of more than 12 weeks with no prior physical therapy intervention or taping within the preceding 6 months were the subjects of this research study.[120] KT was applied at 10% to 15% (paper-off tension) on the erector spinae muscles of the lumbar spine in a stretched position.[120] The placebo group received micropore beige tape over the erector spine muscles of the lumbar spine in a stretched position.[120] No interventions were given to the control group.[120] Pain was measured with the NPRS, and disability was measured with the RMDQ.[120] Measurements were taken at baseline, 48 hours, and 7 days post intervention.[120] Statistical comparisons between groups showed no significant difference although the KT group showed some difference at 48 hours in terms of disability, but the difference was too small to be clinically significant.[120]

AlBahel et al[121] investigated the effect of KT in patients with chronic LBP. The results were more promising, yet a small sample size was noted as one of the study's

major limitations in addition to a weak research design. Twenty patients with chronic non-specific low back pain were included in this study.[121] KT was applied parallel to the vertebral column on either side of the spine over the iliocostalis lumborum from the sacrum upwards.[121] The base of the tape was applied first, then the patient assumed a position of maximum flexion in which the therapeutic zone of the tape was applied.[121] The tape was applied with slight traction; however, the applied tension of the tape was not specified.[121] Patients received physical therapy in the form of stretching exercises and strengthening exercises three times per week for 4 weeks.[121] Pain was measured with the Visual Analogue Scale, disability was measured with the RMDQ, and trunk flexion ROM was measured with modified Schober's test.[121] The study showed a significant difference between pretreatment and posttreatment measurements.[121] The conclusion drawn from this study about the effectiveness of KT as a modality for chronic LBP was weak and cannot be considered as a basis for implementation due to the limitations in the study design and sampling issues.

Ewidea and Elarian[122] examined the effect of KT in chronic LBP patients, and they found a significant effect on pain intensity and paraspinal muscles activity. This study included 50 patients with chronic LBP, who were randomly assigned to two groups: an experimental group, which received KT and a control group that received sham taping.[122] The KT technique used in this study was not explained appropriately.[122] KT was applied parallel to the spine using two I-strips.[122] Sham taping was not described in detail. The use of sham taping is questionable given the fact that any type of taping, although thought to be sham, would result in some kind of stimulation that cannot be accounted to be of no effect. The results of this study indicated a beneficial effect of KT

after two weeks of application regarding muscle activity of paraspinal muscles and pain after one month.[122] The effect of elastic therapeutic taping on low back muscle endurance was also examined by Hagen et al.[123] Although there was a positive effect of therapeutic taping on the endurance of paraspinal muscles in the study by Hagen et al[123], the effect was marginal within the measurement error.[123]

Low back muscle fatigue is considered to be one of the factors that contribute to the development of low back pain.[124] Álvarez-Álvarez et al[124] conducted a randomized controlled trial on healthy subjects, and the trial tested the effect of KT on low back muscles fatigue. Ninety-nine subjects were recruited to form three arms in the study: a taping group, a placebo group, and a control group.[124] Extensor muscles endurance was tested using with the Biering-Sorensen test.[124] The KT group received taping on the lower back area parallel to the vertebral column using two I-strips.[124] The results indicated a significant effect of KT on extensor muscle endurance which may be beneficial for patients with chronic LBP.[124]

KT was shown to have no positive effect on pain and disability in patients with chronic non-specific LBP in a study by Added et al.[125] One hundred-forty patients with chronic non-specific LBP participated in this study.[125] Subjects were randomly assigned to two groups: KT plus conventional PT group and a conventional PT group.[125] KT was applied on the lower back at 10% to 15 % tension for 48 hours a week for 5 weeks.[125] Conventional PT consisted of strengthening and stretching exercises twice a week for 5 weeks.[125] Pain intensity and disability were evaluated 5 weeks, 3 months, and 6 months after randomization.[125] No between-group differences were observed for any of the outcomes evaluated, except for disability 6 months after randomization (mean difference,

2.01 points; 95% CI: 0.03, 4.00) in favor of the control group.[125] The results of this study indicated no effect of KT on pain and disability in patients with chronic non-specific LBP.[125]

In another case report by Hwang-Bo and Lee,[126] the effect of KT in a patient with acute LBP was described. The patient was a 36-year-old male physical therapist who experienced an acute episode of low back pain while transferring a patient from a wheelchair to a mat.[126] The patient of this case report (the PT) has no history of low back pain.[122] Kinesio tape was applied to the rectus abdominis (RA), internal oblique (IO), erector spinae (ES), and latissimus dorsi (LD) muscles.[126] The tape was left in place for 3 days for 10 hours a day.[126] Pain, disability, and active trunk range of motion were measured using the VAS, the Oswestry Disability Index, and back ROM instrument at baseline and 3 days after the application of trunk KT.[126] In this case report, Hwang-Bo and Lee[126] suggested that KT may have a beneficial effect on pain, disability, and active trunk ROM in patients with acute LBP.

From the review presented above, it can be concluded that KT has some positive effect on pain and disability in patients with chronic non-specific LBP, despite conclusions by some researchers. Most researchers found some evidence of a modest positive effect of KT on pain and disability in patients with chronic LBP. Therefore, there is a strong potential for a more powerful effect in acute LBP. To the best of our knowledge, this was the first randomized controlled trial to investigate the effect of KT in patients with acute, nonspecific LBP. However, an updated literature search after the completion of this study discovered a new randomized controlled trial (RCT) in which Kelle et al[127] investigated the effect of KT in patients with acute, nonspecific LBP. In this

study, 109 patients with acute, nonspecific LBP were included and randomly assigned to two groups: KT group that received taping and information/reassurance and a control group that received information and reassurance only.[127] Patients were taking paracetamol as needed. Outcome measures included in this study were the Numerical Pain Rating Scale for pain and the Oswestry Disability Index for disability.[127] Measurements were taken at baseline, 12 days, and 4 weeks post intervention.[127] The results indicated that KT group achieved better pain control earlier.[127] The KT group had lower disability scores at 12 days, but no difference in disability at week 4.[127] Also, the KT group consumed less medications, and pain reduction was superior at 4 weeks in the KT group.[127]

Some of the limitations found in previous studies include lack of a control group, small sample size, and biased and uncontrolled designs. Although KT has been used extensively in clinical practice for patients with acute LBP, no studies have been performed to determine its effect. Therefore, this study was designed to investigate the effect of KT in patients with acute, nonspecific LBP.

SUMMARY OF WHAT IS KNOWN AND UNKNOWN ABOUT KT

Although KT has been the subject of research studies, there is very limited scientific evidence with respect to its benefits and whether it is a useful adjunct modality in the management of musculoskeletal conditions.[128] Most of the studies conducted on healthy subjects did not show any effect of KT on nerve conduction velocity or EMG activity. [129,130] Studies conducted on patients with myofascial pain syndromes and similar conditions have shown some positive clinical effects. [131,132] The effect of KT in neurological conditions was investigated in many studies. In one study by Yang and

associates[133], the results indicated that KT contributes to improvements of balance, body alignment, and neuromuscular functions. Lymphatic flow has been shown to be enhanced by KT application. [105,106] The effect of KT on shoulder pain and knee pain was positive in most studies; however, it is mostly a short-term, immediate effect. [104,110] KT has been shown to be as effective as cervical manipulation in patients with mechanical neck pain.[40] As described before, the findings of KT on LBP are mixed. Although a positive effect of KT can be seen in a few studies in chronic LBP, the effect is a small size; nevertheless, most researchers still recommend that KT can be added to existing interventions.

In a systemic review to investigate the effect of KT on different types of pain, such as nociceptive, neuropathic, or mixed type of pain, KT has been found to be a cheap and effective modality for pain control.[128] In another systemic review about the effectiveness of KT in musculoskeletal conditions, it was concluded that KT has a short-term positive effect on pain, but more research is still needed.[134] Despite conclusions made by some researchers who conducted randomized controlled trials and meta-analyses, a definite conclusion is far from being conclusive because most of the studies lack sufficient rigor to provide quality scientific evidence. The conclusions made by some researchers of systemic reviews cannot be considered definitive because they evaluated the methodological quality of the evidence irrespective of the effect size and its clinical and statistical significance. KT appears to have some merit especially in acute conditions, but the specifications of its application have not been the subject of a well-designed study. This study was the first RCT to evaluate the clinical efficacy of KT as an adjunct intervention to traditional physical therapy in the treatment of non-specific acute

LBP. In the previous studies discussed above, researchers have indicated the need for more research in this area, especially in acute conditions.

THE CONTRIBUTION OF THIS STUDY TO THE FIELD OF PHYSICAL THERAPY

Treatment procedures for patients with acute, nonspecific LBP have several aims, such as reducing pain, improving function and minimizing time away from work.[13] Physical therapists work with these patients to improve their quality of life, help them recover fast, and reduce the potential of recurrences. KT is a non-invasive modality that has been used in various musculoskeletal conditions to reduce pain, to improve healing, to improve kinesthetic awareness, and to improve function.[32,38] Based on its possible mechanism of action, KT should be more suitable for acute conditions. Surprisingly, KT has been extensively investigated in chronic conditions. Previous studies indicated that KT has some positive effect in chronic LBP and neck pain.[38,40,41,121,122]

Limitations of previous studies make it difficult to draw a definite conclusion about the effect and possible mechanisms of KT in musculoskeletal conditions. This randomized controlled trial was designed to investigate the effect of KT on patients with acute, nonspecific LBP on pain, disability, and fear-avoidance beliefs. Furthermore, this study provides clinicians with an insight into the effect of the technique used and its potential benefits. Our study contributes to the field of physical therapy by providing clinicians with a better understanding of the effects of KT in this patient population, so it can be used in a beneficial manner in the clinical settings. Our study also opens the door to test the effect of this modality in this patient population, using different techniques and parameters. The study also provides clinicians with another option for the management of

acute LBP that has fewer contraindications, less adverse reactions, and a higher safety margin. Based on this study, KT may also provide patients with an opportunity to depend less on medications and to be able to practice their daily living activities more efficiently and with more confidence. KT may also provide patients with continuous gentle stimulation between treatment visits, which may potentiate treatment effects. These potential therapeutic benefits will reduce rehabilitation time and cost and improve clinical outcomes.

SUMMARY

Low back pain is a heterogeneous disorder that presents a major challenge for health care professionals on a global level.[1,26,30] Physical therapy research in the area of acute, nonspecific LBP is very limited.[35] Many types of interventions for the treatment of low back pain have been studied in previous research, such as spinal manipulative therapy.[12,13] Spinal manipulative therapy can be used to decease pain in patients with low back pain, but the effect is a short-term effect.[36,44,45] One type of spinal manipulative therapy that was used for patients with acute lumbar disc herniation is Feng's spinal manipulative therapy (SMT).[57,58] Feng SMT has been shown to be clinically effective in patients with acute low back pain due to disc disease.[57,58] The mechanical concept of Feng SMT is the same as traditional SMT.[57]

One of the most common approaches recommended by researchers for the treatment of low back pain is to classify patients based on their clinical features.[30] Such classification serves as a basis for treatment planning.[30] According to the pain-mechanism classification system, pain can be nociceptive, neuropathic, and central sensitization based on certain signs and symptoms.[31] Clinicians can use this classification approach to

understand the behavior of patient's symptoms and their connection to pain generators,[31] which will help in designing more effective treatment procedures.[31]

Psychological variables play a key role in patient's clinical presentation, response to interventions and the potential of long-term disability.[70,74,76] Pain-related fear, anxiety, and pain catastrophization are some of the factors that can increase the likelihood of delayed recovery.[81] These factors also can increase time away from work and number of used sick days.[80-88] Previous researchers have shown that FABQ can be used as a predictor of increased potential of work restrictions or development of chronicity in patients with acute low back pain.[87] A score of 34 or more on the work subscale of the FABQ was found to be associated with increased risk of work restrictions.[87] Patient education and graded exercise programs can be used as appropriate interventions for patients with elevated fear-avoidance beliefs.[83,87] Previous researchers have indicated that self-reported measures of disability are more sensitive than direct performance measures in terms of considering the psychological aspect of the patient.[103]

Kinesio Taping is a type of therapeutic taping that can be used in different conditions to reduce pain and improve function.[32,38,39,41] There is some scientific evidence about the effect of KT on the rate of lymphatic flow, blood circulation, and sensory modulation as cited in the studies discussed earlier.[105-107] Kinesio Taping has been the subject of research studies in several conditions, such as shoulder impingement syndrome, patellofemoral syndrome, mechanical neck pain, and chronic non-specific LBP.[104,108-125] The efficacy of KT on acute LBP lacks research investigation. Moreover, its effect on fear-avoidance beliefs was not studied. Despite mixed findings noted in prior research, based on the hypothetical mechanism of action of KT, there is a strong potential

for a beneficial effect in acute LBP. Moreover, researchers have provided some evidence about the effectiveness of KT on nociceptive pain, neuropathic pain, and mixed type of pain.[128] Therefore, this study was designed to examine the effect of KT on acute, non-specific LBP because of the potential of positive clinical effects.

CHAPTER 3: METHODOLOGY

INTRODUCTION

This chapter outlines the methodology that was used to investigate the specific aims of this study, which was to examine the effect of Kinesio Taping (KT) applied with 15% to 25 % tension on disability, fear-avoidance beliefs, and pain intensity in patients with acute, nonspecific low back pain. The sampling strategy that was used is described as well as the inclusion and exclusion criteria. The randomization technique that was used is explained along with the screening and assessment plans for participants involved in this study. Moreover, detailed description of the interventions used for study participants is provided.

Assessment tools and their clinimetric properties are described in detail. The research methods that were employed as well as all relevant specific procedures are clearly explained. The methods used for data collection and data analysis are delineated. Formats for presenting results and required resources are clarified and outlined. The resource requirements and technical considerations are described. Data safety and confidentiality are discussed at the end of this chapter.

RESEARCH DESIGN AND METHODS EMPLOYED

This study followed a prospective experimental pretest-posttest control group design with repeated measures. The design of this study is a randomized controlled design, which is considered the gold standard of experimental designs due to the rigorous control of variables that increases the strength of the internal validity of the study. Two groups were included in this study: an experimental group and a control group. Randomization was used to create two groups of probabilistic pretesting equivalence. The

experimental group received traditional physical therapy and KT on the lower back. The control group received traditional physical therapy alone. Both groups were tested with respect to three main outcomes, which are disability, fear-avoidance beliefs, and pain intensity. Five points of measurements were used; at baseline, at the end of week 1, at the end of week 2, at the end of week 3, and at the end of week 4. This design was the most effective to be used to explore the effect of the proposed intervention. The study process started after institutional review board (IRB) approval, which was obtained on June 29, 2015.

RECRUITMENT PROCEDURES AND RANDOMIZATION

Consecutive patients with acute, nonspecific LBP who were referred for physical therapy services were the potential participants of this study. A flyer (see Appendix A) was given to each potential participant by the front office staff at the study location to provide an idea about the study and to serve as an invitation to participate in the study on a voluntary basis. This method was chosen in order to avoid any persuasion by the investigators involved in the study. Once a subject expressed his/her interest in participation, the front desk staff notified the principal investigator immediately. Each subject was examined by the referring physician who determined the need for physical therapy services. The principal investigator performed a thorough assessment of each participant, and he was the one who performed all treatment techniques, including KT application. After assessments, screening for red flags, and checking for eligibility criteria, participants were randomly assigned to either an experimental or a control group. During the first visit, an allergy test was performed to ensure that potential participants were not allergic to the tape. Any abnormal reaction reported by any participant was

documented, and the participant was excluded from the study. To improve the potential for an unbiased investigation of the proposed intervention, randomization and blinding were used. In this study, randomization was used to allocate participants to either an experimental group or a control group. A computer random number generator was used to determine such group allocation.[135] An independent physical therapist who was blinded to participants' group allocation performed baseline and all follow-up assessments for each participant.

DESCRIPTION OF HUMAN SUBJECTS

A total of 88 patients with a primary complaint of low back pain were enrolled and consented to participate in the study. Potential study participants were assessed for study eligibility based on the pre-defined inclusion and exclusion criteria. Subjects were pre-screened for known contraindications and precautions to thrust joint manipulation and exercises. Routine physical therapy examination, screening for red flags, and an allergy test were used to assess patients' eligibility, according to the specified inclusion/exclusion criteria. No individuals were excluded from participation in this study based on race, creed, color, gender, age, national or ethnic origin, sexual orientation, disability, or health status. Participation in this study required patients to attend two sessions per week for 4 weeks. Participants were not compensated for their travel or time as they were normally attending their physical therapy visits because of low back pain but with the change required, according to the study procedures for the study to be completed successfully. Participants also had an understanding that they were contributing to scientific research, which may help improve knowledge of one of the tools that could be useful in patients with acute, non-specific low back pain.

INCLUSION CRITERIA

The following inclusion criteria were used to determine eligibility for the study:

- Both genders with ages between 18 and 75.
- Primary complaint of pain in the lower back located between the costal margins and the gluteal folds of less than 4 weeks in duration with or without leg pain, but symptoms not distal to the knee.
- A new episode of low back pain, which is defined as an episode that was preceded by a period of at least one month without low back pain in which the participant was not consulting a health care practitioner or taking medication for his/her low back pain.
- Pain of sufficient intensity to interfere with patient's daily activities and function. A minimum pain intensity of 3 on the Numerical Pain Rating Scale to allow room for change as the minimal clinically important difference (MCID) for the NPRS is 2 points. A minimal score of 4 on the RMDQ was also required as patients with scores under 4 and over 20 may not show meaningful change over time. NPRS and RMDQ were used to determine such criteria.
- Ability to communicate in English language, which was important to complete the questionnaires successfully.
- Lumbar spine hypomobility, which was determined through palpation by applying postero-anterior pressure by the tips of the thumbs against the spinous processes of all segments of the lumbar spine. Three oscillatory postero-anterior movements were performed at each level. Through comparison of quality and range of

movements at each level, the physical therapist can determine which segments are stiff or hypomobile and the quality of the end feel.

EXCLUSION CRITERIA

- Patients with a diagnosis of severe degenerative and stenotic conditions, which make spinal manipulative therapy contraindicated.
- Known or suspected serious spinal pathology (metastatic tumors, inflammatory or infective diseases of the spine, cauda equina syndrome, spinal fracture, or dislocations/subluxations).
- Nerve root compromise as shown by at least two of the following: (1) myotomal weakness, (2) dermatomal or widespread sensory loss, or (3) hypo- or hyperreflexia of the lower limb reflexes. Examination of sensation, reflexes, and motor power were used to identify such criteria.
- Adverse skin reactions to Kinesio Taping.
- RMDQ score of less than 4 or more than 20.
- NPRS score of less than 3.
- Patients taking non-steroidal anti-inflammatory drugs (NSAIDs).
- Patients currently receiving physical therapy or any form of manual therapy.
- Previous spinal surgery.
- Patients with contraindications to manual therapy or therapeutic exercises.

INTERVENTIONS

The control group received traditional physical therapy alone while the experimental group received traditional physical therapy plus Kinesio Taping on the para-spinal area. Traditional physical therapy was in the form of patient education,

manual therapy, and therapeutic exercises. The focus of patient education was on the natural history of the condition and its favorable prognosis, positive thinking, and encouragement of activity participation. Patient education was delivered through one-on-one discussion by the principal investigator. The integration of cognitive-behavioral components in the educational discussion was aimed to reduce disability and improve function. [136,137] Patient education was provided to help patients understand their condition, facilitate coping with pain in a positive manner, reduce fear beliefs, and reduce functional limitations. [137,138]

THE CONCEPT OF FENG'S SPINAL MANIPULATIVE THERAPY

Manual therapy techniques that are commonly used in conditions of low back pain include manipulation and mobilization. [26,33,44-49] Such techniques involve the use of manual force to affect tissues and functions.[139] The spinal manipulative therapy technique used in this study was Feng's spinal manipulation technique. Feng's Spinal Manipulation (FSM) is a very popular Chinese spinal manipulation technique that was developed by Dr. Tian-you Feng in the 1970s.[57] The mechanical concept of spinal manipulative therapy is to deliver a passive force through the clinician's hand in certain positions to produce biomechanical and neurophysiological effects.[139,140] According to the American Physical Therapy Association, the definition of manual therapy techniques is "a manual therapy technique comprised of a continuum of skilled passive movements that are applied at varying speeds and amplitudes, including a small amplitude/high velocity therapeutic movement."[139] Later, the term mobilization and manipulation were used to indicate non-thrust versus thrust manual therapy techniques.[139] The parameters of the applied mechanical force, such as amplitude and velocity, determines which technique is being

used: thrust (high velocity-low amplitude) versus non-thrust (low velocity-high amplitude).[139] Feng's spinal manipulative therapy uses the same concept through graded application of torsion force in sitting position.[57] The rate of force application can be controlled by the treating therapist.[57] The involved segment can be rapidly loaded or slowly loaded.[57] The rate of this force application defines which technique is being used.[57] Manipulation refers to the use of thrust or rapid loading on the involved segment, which has the characteristics of high velocity and low amplitude, whereas mobilization refers to the slow loading of the involved segment, which has the characteristics of low velocity and variable amplitude.[139] The focus of Feng's spinal manipulative therapy is on the use of torsion force at the level of the dysfunctional segment.[57] The applied torsion force is usually gentle and delicate and is not intended to produce the signature cracking sound.[57]

APPLICATION OF FENG'S SPINAL MANIPULATIVE THERAPY

For the application of FSM, the patient was in the sitting position and the therapist was sitting next to him/her on the right side. The therapist's right hand was placed on the patient's left shoulder, and the therapist's left hand was placed on the lower back with the thumb on the spinous process of the involved segment. The position and the handling was reversed to perform spinal manipulative therapy on the other side. A torsion force applied to slowly load the affected segment by steadily rotating the patient's trunk to the end of the limitation by the therapist's right hand with the help of the therapist's thumb steadily and firmly pushing on the spinous process of the involved segment. Two rotations were performed within the range of motion of lumbar spine to the right side. With the same handling from the same position, the therapist's right hand was used to gently and

steadily rotate the trunk to the end of the limitation, and then abruptly enforcing a torsion force with the therapist's thumb, steadily pushing on the spinous process of the involved segment. Two rotations were performed to the right side. The same maneuvers were repeated on the left side (Figure 1).

Figure 1. Patient Position and Handling for Mobilization and Manipulation

EXERCISE PROGRAM

The exercise program that was delivered to each patient consisted of exercises commonly prescribed by physical therapists for patients with acute, non-specific LBP. [141,142] These exercises included abdominal drawing-in maneuver, posterior pelvic tilting, alternate knee to chest exercise, and lumbar rotation (knee rolls). [141,142] All patients were educated about the function related to the lumbar stabilizing musculature, and they were taught to perform isolated contractions of the transversus abdominis and lumbar

multifidus through an abdominal drawing-in maneuver (ADIM). [14142] The abdominal drawing-in maneuver plays a critical role in lumbar stabilization training and stimulates more effective performance of abdominal and lumbar muscles.[143] It induces simultaneous activation of muscles, which help reduce lumbar lordosis and anterior pelvic titling.[143] This maneuver is commonly prescribed by physical therapists in patients with LBP, and it is one of the exercises that has clinical evidence in the literature.[143] Abdominal drawing-in maneuver re-educates the functions of the abdominal muscles and is considered as one of the basic elements in any exercise program in patients with LBP.[143] The mechanism of producing an effective ADIM is through activation of the transverse abdominis and the internal oblique muscles with minimal contractions of the superficial muscles, such as external oblique and erector spinae muscles.[144,145] Mechanically, the patient isometrically contracts the abdominal wall toward the spine while concurrently compressing the internal organs upward into the diaphragm and downward into the pelvic floor.[144] When these muscles work together synergistically, they increase the tension in the thoracolumbar fascia and the intra-abdominal pressure transforming the abdomen into a rigid mechanical cylinder, thereby increasing lumbar stability.[144] The abdominal drawing-in maneuver was performed in hook-lying position with both knees flexed 70° to 90° and with both feet resting on the exercise mat or the bed. [142] The patient was instructed to draw the "belly button" up and in toward the spine to hollow out the abdominal region as he/she exhaled, holding for 5 seconds. Five contractions per set and three sets per session were performed.

Figure 2. Abdominal Drawing-In Maneuver

Posterior pelvic tilting is one of the mobility exercises commonly prescribed for patients with LBP. Although it is not one of lumbar stabilization exercises, it is important because it activates the rectus abdominis muscle and help the patient achieve awareness of lumbar ROM and find functional spine range.[142] Posterior pelvic tilt was performed in supine lying position with both hips and knees slightly flexed.[142] The patient was instructed to flatten the lower back and pull his/her pelvis up simultaneously, holding the contraction for 5 seconds, repeating10 times per set. Three sets were performed every session. Training was progressed to sitting then standing in the 7th and 8th sessions.

Figure 3. Posterior Pelvic Tilting
Posterior pelvic tilting from (a) supine with hips and knees flexed, (b) from sitting, (c) from standing

Alternate knee to chest exercise is a self-stretch exercise that induces a stretch in the lumbar erector spinae muscles and thoraco-lumbar fascia.[142] Alternate knee to chest holds were performed from hook-lying position.[142] The patient was instructed to hold his/her knee around the distal third of the thigh just above the knee and slowly draw his/her knee to the chest as close as possible without holding his/her breath and to keep it held for 5 seconds.[142] The same exercise was repeated on the other side. Each one was repeated 10 times per set and the patient performed three sets per session.

Figure 4. Alternate Knee to Chest Exercise

Lumbar rotation exercise is one of the general mobility exercises for thoracic and lumbar spine commonly prescribed by physical therapists for patients with acute, non-specific LBP. Side-to-side lumbar rotation (knee rolls) was performed in hook-lying position. The patient was instructed to keep his/her knees together and swing them slowly to the right side first, then return to the middle, and then swing them to the left side, and hold for 5 seconds at each side. Each one was repeated 10 times per set, and the patient performed three sets per session. The home exercise program consisted of the same exercises that were performed during treatment sessions. Patients were instructed to perform the same exercises once a day at home. Patients were given a print out of the exercises (Appendix B) and their related instructions as well as an exercise log sheet (Appendix C) to document exercise parameters with respect to timing and repetitions and any adverse reactions.

Figure 5. Knee Rolls (Lumbar Rotation)

The experimental group received the same traditional physical therapy procedures plus a standardized KT. The KT technique that was used in this study is the technique commonly used by therapists for patients with acute LBP and described in the KT manual by the Kinesio Taping Association.[32] The tape used for all subjects was a blue original Kinesio Tex FP wave pattern (Kinesio Tex Tape; Kinesio Holding Corporation, Albuquerque, NM; see Figure 6). The tape is water tolerant, porous, and adhesive with a width of 5 cm and a thickness of 0.5 mm.[32] The tape is well tolerable to be worn for extended periods of time; does not loosen or peel off with sweat, water, or exercises; and the adhesive is non-irritant and can keep the tape in place for many days.[32] The adhesive is activated by gentle rubbing on the tape after it is applied to the skin. Two I-strips of KT were used bilaterally on each side of the vertebral column over the erector spinae muscles. They were placed at a tension level between 15% and 25% parallel to the vertebral column from the sacral base at the posterior superior iliac spine (PSIS) to approximately the level of T8.

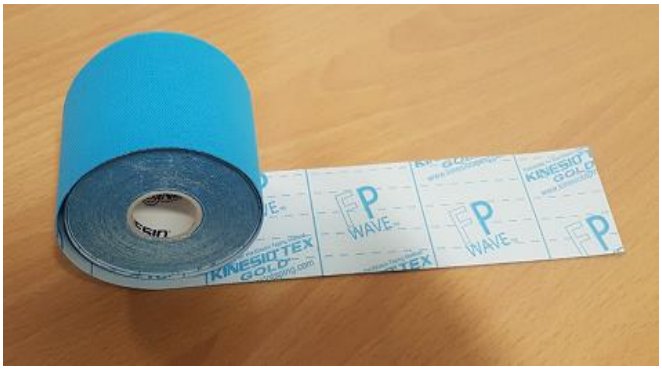


Figure 6. KT Bulk Roll

APPLICATION OF KINESIO TAPING

The principal investigator (PI) asked the patient to assume a comfortable standing position with both feet slightly apart at shoulders' width. Application usually started by estimating the required length of each I-strip. The PI unrolled a piece of the bulk roll and placed the tape on the patient's back from slightly below the sacral base to approximately the level of T8. This procedure gave the PI an idea about how long the I-strip needed to be. The tape is usually applied to the substrate paper at around 10% to 15 % tension. So, depending on the patient's height, an additional 1 to 2 inches was required to stretch the tape slightly to acquire a tension level between 15% and 25 %. The PI folded the tape to obtain twice the length required, then cut it with a scissor. The PI then cut the tape in half to obtain two I-strips of equal lengths. Then, these two I-strips were held together on the top of each other to round the edges to avoid catching with patient's garments and to allow the tape to stay in place for the required time length. Sometimes several trials were needed to obtain the correct length of the I-strip.

The tape has three zones: the anchor, the therapeutic zone (the base), and the end (Figure 7). A rule of thirds is usually used by KT practitioners to apply the tape in which

one-third of the total length of the tape is used for each zone.[32] This rule is often modified to allow for an optimal application and for a better outcome. For this study, the PI chose to decrease the length of the anchor to allow the therapeutic zone of the tape to be on the lower back area of L4-L5 and L5-S1, which are common levels of lower back pain. This modification was necessary to ensure application of the therapeutic area of the tape on the painful site.

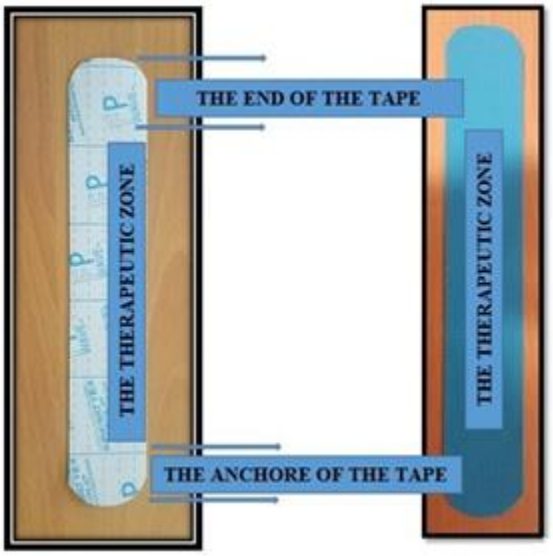


Figure 7. Zones of the Tape

The substrate paper of the tape has lines that are 5 cm apart horizontally that help the clinician to be accurate in cutting the tape to the required length. The area to be tapped was rubbed with alcohol swabs to remove any oils, debris, or body sprays that may make the tape loose or non-adherent. Then, the PI cut the substrate paper of the tape on the lower part, just around an inch from the end. Then the patient was asked to lean forward and place his/her hands on the table. The PI applied the anchor of the tape at the level of the sacral base with 0% tension by allowing the tape to recoil before it was

applied. The PI then peeled off the substrate paper to expose the therapeutic zone. The PI handled the tape by holding it by the substrate paper to stretch it slightly. The PI stretched the tape gently, allowing a tension that was between 15% and 25% to set, then asked the patient to rotate to the opposite side while leaning forward as much as possible. Next, the PI applied the tape on the para-spinal area, ending around 1 or 2 inches before approximately the level of T8. Then, the PI peeled off the substrate paper and allowed the end of the tape to recoil before it was adhered to the skin. The tape adhesive was then activated by rubbing all over the tape. The patient was then asked to return to the normal comfortable standing position. The PI repeated the same process on the other side of the spine (Figures 8, 9, and 10). The same pattern, direction, and tension level was used for all participants.

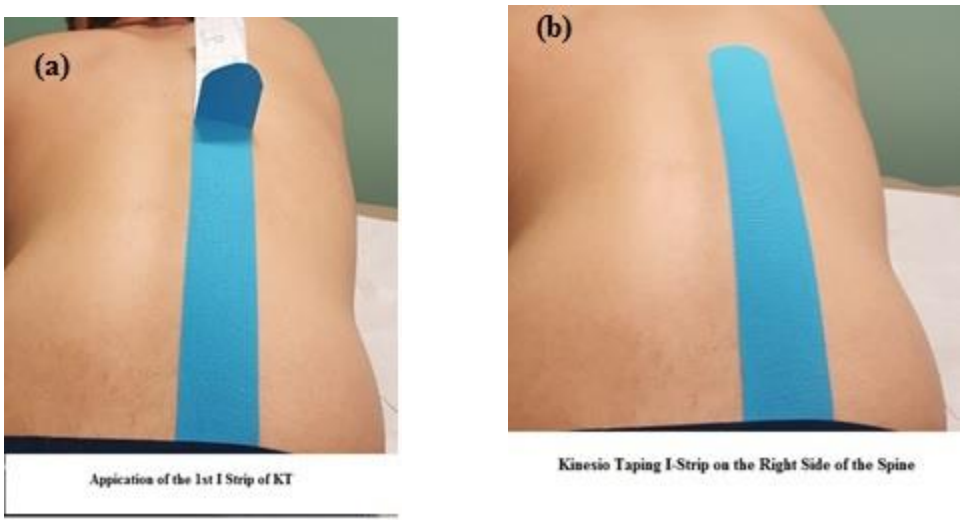


Figure 8. The First I-Strip of KT Applied on the Right Side of the Spine before Securing the End (a) and after Securing the End (b)

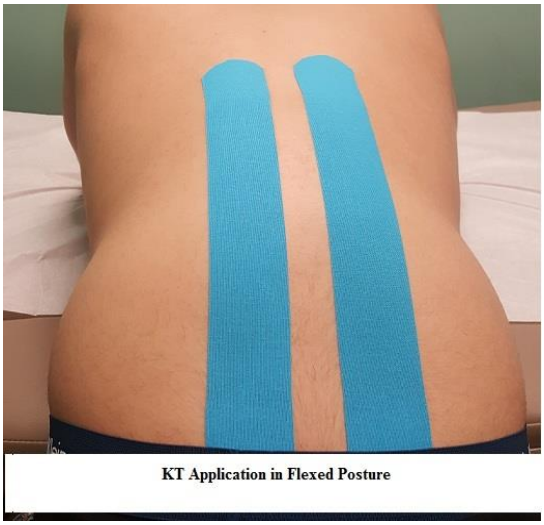


Figure 9. Completed KT Spinal Application Shown in a Flexed Spine Posture

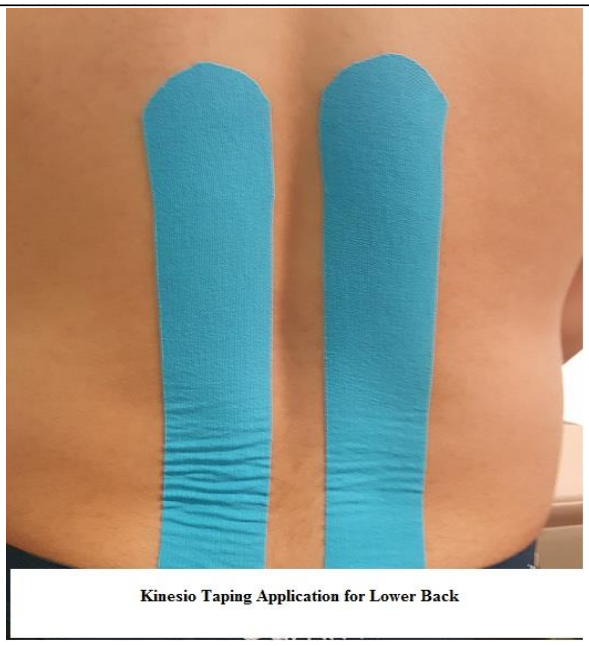


Figure 10. Completed KT Spinal Application Shown in Comfortable Standing Position

The KT was left in place for 72 hours. The main parameters that were maintained during the study were taping for 3 days every week and two sessions of PT twice a week.

Each participant was instructed to report if the tape became loose or peeled off for any reason. The KT was removed after 72 hours and then reapplied after a few days rest to allow the skin to recover and to avoid skin irritation. The patient was instructed to refrain from subjecting the tape to moisture or submersion in water for 30 to 45 minutes after application to allow for better adherence. Patients were also instructed to be careful during dressing and undressing, so the tape does not become caught with their clothes if the edges of the tape became slightly loose. No physical therapy treatment or taping was provided during the rest period except for the prescribed home exercise program. Patients in both groups received the same traditional physical therapy treatment two times a week.

SPECIFIC PROCEDURES EMPLOYED

History Taking

After obtaining the informed consent, the participant's demographic information was collected, including age, gender, ethnicity, contact information, emergency contact, employment status, and so forth. History taking also included collecting information about the patient's past medical history, family history, mechanism of injury, chief complaint, present history, number of days since onset, presence of previous episodes of low back pain, treatment of previous episodes, questions related to red flags, and review of systems and allergies. Patients were also checked for eligibility criteria. Pain characteristics were also documented, including pain intensity, location, duration, timing, character, and aggravating and alleviating factors (Appendix D). History, review of systems, and medical screening questionnaire were also used to identify red flags. Red flags are clinical features that may indicate a serious spinal pathology that warrant further investigation.[12,13,15]

Physical Examination

Each participant was examined by the PI who conducted a thorough physical exam that included observation, palpation, assessment of vertebral mobility, range of motion testing, muscle testing, neurological screening, and special tests. Neurological examination included testing of sensation for dermatomes, muscle testing for myotomes, and testing of deep tendon reflexes (knee jerk and ankle jerk). The allergy test for the Kinesio Taping was performed for all participants by the PI. An I-strip of KT was applied on either side of lumbar spine at around 25% tension and left in place for 24 hours. The patient was checked during the second visit for any signs of adverse reactions, such as rash or excessive hotness or itching in the tested area.

The PI then opened a new file for the participant that included all the information obtained from history taking, physical examination, and any other assessments. This process took between 30 minutes and 45 minutes. In the second visit, the tape was removed, and the patient was checked for any abnormal reactions. The participant was then randomly assigned to either the experimental group or the control group, using random number generator.

The PI provided the research assistant with the participant's basic information, including the case number, but the research assistant was not aware of the participant's group allocation. The research assistant then performed all baseline outcome assessments required for the study, which included disability as measured with the Ronald Morris Disability Questionnaire, fear-avoidance beliefs as measured with the Fear-Avoidance Beliefs Questionnaire, and pain intensity as measured with the Numerical Pain Rating Scale. The research assistant conducted all study-related measurements at baseline (W0),

at the end of the first week (W1), at the end of the second week (W2), at the end of the third week (W3), and at the end of the fourth week (W4) and kept all data in a separate locked file cabinet. The second visit took approximately between 45 and 60 minutes to be completed, including providing first treatment session. Assessments of study variables took 15 to 20 minutes.

Interventions which were received by the experimental group:

- Patient education
- Manual therapy two times per week for 4 weeks.
- Therapeutic exercises two times per week for 4 weeks.
- KT application 72 hours per week for 4 weeks.
- Home exercise program to be performed once a day.

Interventions which were received by the control group:

- Patient education
- Manual therapy two times per week for 4 weeks.
- Therapeutic exercises two times per week for 4 weeks.
- Home exercise program to be performed once a day.

First Treatment Session

The first treatment session started by removing the tape that was used for the allergy test, then the participant was checked for signs of abnormal skin reactions. After removing the tape, the PI educated the patient about acute, non-specific LBP and provided advice that encourage the patient to be active and not to concentrate on his/her pain or fear of activity. The mode of delivery of educational tips was discussion. The educational strategy used was based on the bio-psychological model of low back pain

that encourages positive thinking and active patient participation. The tips that were given to each patient were as the following:

- Acute LBP is not a life-threatening condition and its prognosis is good.
- In more than 80% of patients with low back pain, there is no serious spinal pathology.
- Your lower back pain does not indicate that your lower back is damaged, it just means your back is sensitized.
- Your pain may be affected by awkward postures, muscle tension, inactivity, lack of sleep, stress, anxiety, low mood, or inactivity.
- The muscles around your back and your abdominals are very important to keep your back healthy. They stabilize your back and help guard against further injury.
- Exercise, general activity, cutting down your smoking, and healthy diet can improve your back pain.
- Cope with your pain in the best feasible way and do not worry too much. Your pain can be intensified by your worry as your brain can amplify your pain.
- Minor back sprain and strains can be very painful, but the spine is a strong structure.
- The lower back area is one of the strongest area in your body, and it is unlikely that there is a permanent damage in your back.
- Overprotecting can have a negative effect. Movement and exercises within your tolerance will help you get better.
- Movements and exercises may be somewhat painful in the beginning, but you will feel less pain as you do more.

- Refrain from absolute bed rest.
- Your recovery depends on your efforts to get better.

Patients' compliance was reinforced through this educational process as the PI emphasized the importance of consistency and following instructions for better benefits. This part of education was consistent for all patients in both groups and was provided by the PI. Then the PI gave the patient a general idea about the treatment procedures and which kind of exercises he/she would be doing every time they were in treatment sessions. Also, the PI educated the patient about how to care for the tape. Manual therapy was performed next in the same manner described before. Exercises were then performed as explained previously with the same sets and repetitions.

The session was ended by application of Kinesio Taping on the lower back. Application of the Kinesio Taping on the lower back was performed as described before. Patients were then instructed to keep the area dry for 30 minutes to 45 minutes and to be careful during dressing and undressing to protect the tape from being caught into garments. Patients were then given a handout for the home exercise program and exercise log and were instructed to perform the exercises once a day and to report any adverse reactions to the PI. The first treatment session took between 35 minutes and 45 minutes to be completed. The same sequence of procedures was maintained in all sessions for all participants.

Second Treatment Session

The second treatment session started by removing the tape using mineral oil, and the duration of KT application was then documented. Any skin reaction or abnormal reaction was noted and documented. The KT log was used to document the duration of

taping (Appendix E). Patients' comments and feedback about taping was noted and documented. Taping was left in place for 72 hours between treatment sessions. The PI then reviewed the home exercise program log to confirm if the patient were compliant. Patients were instructed to perform the exercises once a day. Manual therapy was performed in the same manner described before. Exercises were then performed as shown before. For patients in the experimental group, no taping was applied on the lower back between the second and the third treatment sessions. The second treatment session took around 30 minutes to be completed.

Third Treatment Session

The third treatment session started by reviewing the home exercise program log followed by the same manual therapy techniques and exercises. The Kinesio Tape was then applied on the lower back using the same technique described before. Patients were given the same instructions about KT and exercises.

The Rest of Treatment Sessions

The fourth treatment session started by removing the tape and checking the area for any reactions. Manual therapy and exercises were performed afterwards. Patients did not receive taping or any interventions except home exercise program until the fifth treatment session. The fifth and sixth treatment sessions were the same as the third and the fourth treatment sessions, respectively. The seventh and eighth treatment sessions were also the same as the fifth and the sixth treatment sessions, respectively, except for the progression of the pelvic tilting exercise. Posterior pelvic tilting was progressed to sitting and standing in the seventh and eighth treatment sessions. Assessments were conducted at the end of week 1, at the end of week 2, at the end of week 3, and at the end

of week 4 by another independent physical therapist. Study processes can be seen in the flow chart in Figure 11.

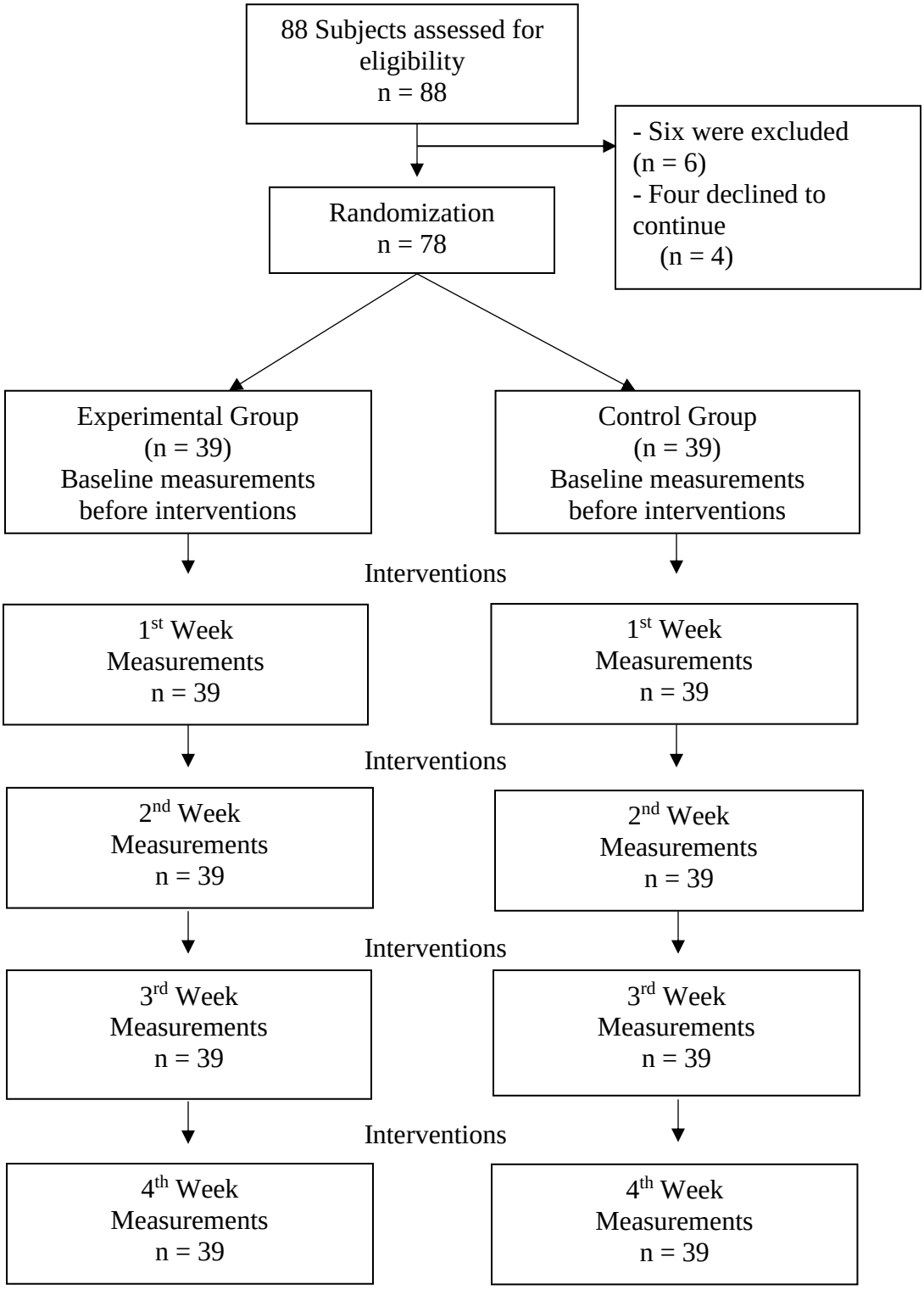


Figure 11. Study Flow Chart

SAMPLE SIZE, POWER, AND PRIORI ANALYSIS

A priori analysis was conducted with an alpha level (α) of .05, an effect size of 0.25, and a power of 80% using G*Power (Version 3.0.10). The results indicated that a total of 78 subjects would be needed for two groups. However, considering a potential 10% to 15 % dropout or loss-to-follow-up rate, around 42 to 45 participants were considered for each group.

BLINDING AND RANDOMIZATION

Blinding the physical therapist (the principal investigator) who provided interventions to both groups in the study to the type of intervention was not feasible. Blinding the principal investigator to the assessment process was possible by using another physical therapist who conducted all measurements. Blinding the assessor to participants' group assignment was done to ensure unbiased ascertainment of outcomes. Randomization also served to reduce the risk of selection bias by the principal investigator. An online random number generator available at http://www.graphpad.com/quickcalcs/randomize1/ was used to randomly assign participants to two equal groups.[135]

OUTCOME MEASURES

The outcome variables that were included in the study were disability, fear-avoidance beliefs, and pain intensity. The primary outcome was disability and the secondary outcomes were fear-avoidance beliefs and pain intensity. Disability was evaluated with the Ronald-Morris Disability Questionnaire (Appendix F). [146-148] RMDQ is a patient reported outcome measure that is composed of 24 yes/no questions to assess functional status and disability in patients with low back pain.[146-148] RMDQ scores can

range from 0, the highest functional status indicating no disability, to 24, the lowest functional status indicating maximum disability.[146-148] Patients were asked to mark the sentences that describe them at the time of evaluation.

Fear-Avoidance Beliefs Questionnaire is an assessment tool that is developed based on the fear avoidance model of exaggerated pain perception (Appendix G).[66,83,149] This model is a theoretical approach of analyzing the behavior of patients with acute conditions as some of these patients recover successfully while others develop chronic pain.[83,149] FABQ measures patient's fear of pain in terms of patients' behavior as a result of pain in relation to general physical activities and work-related functions because of their fear. [83,149] It consists of two subscales, a work subscale and a physical activity subscale; each item is scored from 0 to 6. [83,149] Greater fear and consequent avoidance behaviors are associated with higher scores. [83,149]

Assessment of pain was performed using the Numerical Pain Rating Scale (Appendix H), which is an 11-point scale from 0 to 10, 0 indicating *no pain* and 10 indicating *the worst pain*.[150] Pain assessments were conducted at baseline and at the end of each week, for 4 weeks. A verbal response was required from each participant. Three measurements were taken: the current pain level, the worst pain level over the last 24 hours, and the lowest pain level over the last 24 hours. The average of the three responses was used as the average pain level for each participant.

INFORMED CONSENT/INSTITUTIONAL REVIEW BOARD (IRB) APPROVAL

All research activities were approved by the IRB of Nova Southeastern University (NSU). IRB approval was granted on the June 29, 2015. All participants signed an

informed consent prior to participation. (See Appendix I for informed consent and Appendix J for IRB approval letter).

FORMATS FOR PRESENTING RESULTS

Descriptive statistics were conducted to describe all basic characteristics of participants of both groups. Variables, such as age, gender, presence of previous episodes, and duration of the current episode, were described. Graphical representation of the above-mentioned variables as well as the main outcome measures were obtained from statistical software. Tables and figures were used to provide an understanding of all relevant study data. Mixed model analysis of variance (ANOVA) was used to indicate main effects and interaction effects. The group type was the between-subjects variable, and the time was the within subjects variable. Bonferroni posttests were used to compare between groups at each individual point of time. SPSS Version 23.0 (SPSS, Inc., IBM Corporation, Somers, New York) and GraphPad Prism (Version 6.01 for Windows; GraphPad Software, San Diego, CA) were used for statistical analysis.

RESOURCES USED

For the study to be completed successfully, all necessary resources were checked to make sure that they were accessible and available. These resources include a facility for conducting the study, administrative support, an independent physical therapist to conduct all required assessments proposed in the study, participants to participate in the study, and an independent biostatistician to perform all statistical analyses. The study was conducted at Quick Docs Medical Center in Brooklyn, NY. This facility is the primary place of employment of the principal investigator and the research assistant. The facility has private treatment rooms in which each subject was interviewed and assessment and

intervention sessions were conducted. A letter of support from the management of Quick Docs Medical Center can be found in Appendix L. Application of KT required purchase of several KT bulk rolls (2" X 103.3'), alcohol swabs, mineral oil for ease of removal of the tape for sensitive patients, and sharp scissors for adequate cut of the tape. The study was not funded by any source. The PI was responsible for all expenses associated with this study. The study was carried out in accordance with the World Medical Association Declaration of Helsinki. Ethical approval was obtained from the IRB of NSU before starting the study.

VALIDITY AND RELIABILITY

The RMDQ has been validated in patients with acute, subacute, and chronic LBP.[144,145] The RMDQ has been found to possess an excellent test-retest reliability (same day; ICC = .91, 1 to 14 days; ICC = .93, 3 to 6 weeks; ICC = .86), an adequate test-retest reliability after 3 to 6 weeks (ICC = .86) and an excellent internal consistency (Cronbach's alpha = .83).[148] The RMDQ was found to be more responsive than other disability questionnaires in patients with acute LBP with or without leg pain but responsive as other outcome measures in patients with leg pain.[148] Researchers have shown that RMDQ is more sensitive than other disability scales in patients with mild to moderate disability and has a responsiveness rate of 0.76.[151] The responsiveness property of the scale within the individual patient has been reported to be around 5 points with a confidence in the measured score, 90%, CI = ± 3 points, and between groups, 2 to 3 points.[147] The content validity of the scale is evident but limited to the physical attributes as the scale does not count for psychological and social aspects of disability.[147] The scale was found to correlate with other measures of similar attributes, such as the physical

subscales of (Short Form Health Survey) SF-36, the physical subscales of Sickness Impact Profile, the Quebec Back Pain Disability Scale, and the Oswestry Disability Questionnaire.[152] However, some researchers have found that RMDQ is the most responsive in population with low back pain than other scales.[153]

The presence of fear-avoidance beliefs has been reported to be directly related to disability and work absenteeism, especially in acute LBP patients.[13,83,87] The belief that activity whether related to general activities or work-related activities would worsen the pain and cause more damage is very common in acute episodes of pain.[13] Patients often think that complete avoidance of physical activities and absolute bed rest is necessary for them to heal.[13] Although the FABQ has been validated in patients with chronic LBP, it has been used in populations with acute LBP to determine the risk of long-term disability.[83] It has been reported that in patients with acute LBP the internal consistency of FABQ scores range from alpha = 0.70 to 0.83 and test-retest reliability ranges from r(s) = 0.64 to 0.80 ($P < .01$).[154,155] Also, the concurrent validity of the scale has been reported to be moderate, ranging from r(s) = 0.33 to 0.59 ($P < .01$). The inter-rater reliability of FABQ has been reported to be excellent (ICC = 0.94).[155]

The Numerical Pain Rating Scale has been reported to be a valid and a reliable tool for pain assessment.[147,156,157] The NPRS has an adequate test-retest reliability when a single pair of measurements are made within 2 weeks, one each week.[157] The test-retest reliability increases with frequent measurements within the same week.[157] It has an excellent test-retest reliability when measurements are taken within 2 or more consequent days within the same week.[158] The NPRS also has been reported to have an excellent intra-rater and inter-rater reliability.[157] The minimal clinically important difference of the

NPRS has been reported to be 1.5 points at the first week of treatment and 2.2 points at 4 weeks of treatment for patients with low back pain.[158] However, the minimal detectable change for the NPRS has been reported to be 2.0 points, which is considered to be meaningfully significant and exceeds the measurement error (1.2 points).[157] In addition, patients reported their area of pain on a pain diagram.

RISKS AND BENEFITS

The risks associated with patients' participation in this study were minimal. The examination and treatment procedures, which were used in this study, are routinely used by physical therapists in patients with low back pain. All patients were screened before participation for any contraindications to the procedures that were employed. Furthermore, an allergy test was performed before administering the actual taping technique to rule out any participant with allergic reactions to taping. Kinesio Taping was applied by the principal investigator who is a certified KT practitioner. Participants were taught how to perform all exercises, and the PI supervised all exercises in every session. Slight routine discomfort was experienced by some patients during exercises, which is expected in patients with acute, nonspecific LBP. Manual therapy was provided by the principal investigator who has over 20 years of clinical experience in treating patients with musculoskeletal conditions.

DATA SAFETY AND CONFIDENTIALITY

All patients' data and records pertaining to this research study and any relevant information were stored in a locked file cabinet at the facility in which the study was conducted. A case number was used to indicate patients' identity on these records. This information was only accessible to the principal investigator, the independent physical

therapist, and other research study staff involved in conducting this research study. All assessment data were kept in a separate locked file cabinet, which was accessible only to the independent physical therapist. To ensure confidentiality, no confidential information, such as patients' name, address, phone number, or any other information that might possibly be used to link the data to the patient, was transmitted or shared. These measures were used to ensure patients' confidentiality.

DATA ENTRY, CLEANING, AND REDUCTION

All data provided by the participants via questionnaires were transferred into an electronic format of the paper-based questionnaires. Data were entered using double data entry method to improve accuracy of data records. All discrepancies encountered were resolved by authenticating the data with original questionnaire values. Once the database was created, it was transferred into SPSS Version 23.0 (SPSS, Inc., IBM Corporation, Somers, NY) and GraphPad Prism (Version 6.01 for Windows; GraphPad Software, San Diego, CA) statistical software for data cleaning and reduction.

SUMMARY

This chapter described study design, recruitment methods, and details of the human subjects included in the study. Eligibility criteria and outcome variables were described in detail. Group allocation and randomization methods were explained. The exact procedures and step-by-step process of study implementation were explained as they occurred. Potential participants were recruited using a study flyer. The sampling strategy used was the non-probability convenience sampling method. A random number generator was used for randomization.

The principal investigator explained the informed consent and study process in detail to each participant. The PI examined each participant and assessed participants' eligibility based on predetermined inclusion and exclusion criteria. The PI also conducted an allergy test to detect any abnormal responses to taping. Participants were randomly assigned to an experimental group and a control group. The experimental group received patient education, manual therapy, exercises, and Kinesio Taping. The control group received patient education, manual therapy, and exercises. All participants were required to perform home exercise program once a day. All participants received two sessions per week for 4 weeks. KT was left in place for 72 hours per week for 4 weeks. Instructions related to exercises and KT were given to each participant.

Assessment procedures for all participants were explained in detail. Assessments occurred at baseline and at the end of each week for 4 weeks. Assessments were conducted by another independent physical therapist who was blinded to participants' group allocation. Outcome measures studied were disability, fear-avoidance beliefs, and pain intensity. The Ronald Morris Disability questionnaire was used to evaluate disability, the Fear-Avoidance Beliefs Questionnaire was used to evaluate fear-avoidance beliefs, and the Numerical Pain Rating Scale was used to evaluate pain intensity. These assessment tools have been shown to be valid and reliable as described before. The data analysis plan was explained in this chapter and included the use of descriptive and inferential statistics. Resources needed for the study, such as potential participants, a facility where the study was conducted, an administrative support, and a blinded assessor, were available.

CHAPTER 4: RESULTS

INTRODUCTION

The following chapter presents the results of our research study. Descriptive statistics were used to provide a summary of the data, which are described in this chapter. The results were supported using tables and graphs. Inferential statistics are explained and how they were used in the study to test the effect of the interventions in both groups and to detect changes and differences over time in both groups. The findings are displayed based on the results of the statistical tests used.

DATA ANALYSIS

This study followed a prospective experimental pretest-posttest control group repeated measures design. Descriptive statistics, including measures of central tendency (means) and dispersion (standard deviations) for continuous variables were calculated to summarize the data. Frequency and percentages were calculated for nominal variables. The independent variables in this study are the interventions used for both groups, which are the traditional physical therapy and Kinesio Taping. The outcomes measures (the dependent variables) were disability, fear-avoidance beliefs, and pain intensity. Measurements occurred at five points of time: at baseline (W0, before interventions), at the end of the first week (W1), at the end of the second week (W2), at the end of the third week (W3), and at the end of the fourth week (W4).

During the period of July 2015 to April 2016 recruitment process of the study occurred. Eighty-eight subjects with acute, nonspecific LBP volunteered and agreed to participate in this study; 10 of them did not continue with the study. Six subjects were excluded (n = 6) and four refused to continue (n = 4). Two of those who were excluded

exhibited undesirable skin reactions (n = 2) that included significant itching and mild rash. These reactions were resolved within a few days. The other four subjects (n = 4) were excluded because of nerve root compromise. The study included 78 participants (n = 78) who completed the study to the end after randomization. None of the 78 participants (30 women and 48 men) were lost to follow-up and all of them completed the designated treatment procedures. Subjects were randomly assigned to two groups using a random number generator: an experimental group (17 women and 22 men, mean age of 37.05 years, SD = 11.97) and a control group (13 women and 26 men, mean age of 39.51 years, SD = 12.86). The mean value of the duration of symptoms in the experimental group was 12.36 days ± 3.31 days and that of the control group was 11.90 days ± 3.43 days. The number of participants who had a history of previous episodes of LBP in the experimental group was 29 (74.35%) and that of the control group was 24 (61.53%). The demographic characteristics of the sample are shown in Table 1. Graphical representations of the means of basic group characteristics are shown in Figure 12 and Figure 13 using histograms.

Table 1. Basic Characteristics of Participants in Both Groups

	Experimental Group	Control Group
Age	37.05 (11.97)	39.51 (12.86)
Gender		
Males	22 (56.41%)	26 (66.67%)
Females	17 (43.59%)	13 (33.33%)
BMI[a]	28.46 (6.84)	28.62 (4.80)
DOS[b]	12.36 (3.31)	11.90 (3.43)
PE[c]		
Yes	29 (74.35%)	24 (61.54%)
No	10 (25.64 %)	15 (38.46%)

(a) BMI: Body Mass Index. (b) DOS: Duration of symptoms in days. (c) PE: Previous episodes.
Nominal variables are expressed as Percentages.
Continuous variables are expressed as Mean (SD).

The baseline mean score for disability in the experimental group was 13.21 ± 1.78 and that of the control group was 13.05 ± 1.39. The baseline mean score of the Fear-Avoidance Beliefs Questionnaire-Physical Activity Subscale of the experimental group was 22.05 ± 2.16 and that of the control group was 22.1 ± 2.19. The baseline mean score of the Fear-Avoidance Beliefs Questionnaire-Work Subscale of the experimental group was 28.26 ± 4.01 and that of the control group was 28.95± 4.23. The baseline mean pain scores of the experimental group was 7.40 ± 1.26 and that of the control group 7.60 ± 1.06. The baseline outcome variables for all subjects can be found in Table 2.

Table 2. Mean (SD) Values of the Outcome Measures at Baseline

	Experimental Group Mean (SD)	Control Group Mean (SD)
RMDQ	13.21(1.78)	13.05 (1.39)
FABQ-PA	22.05 (2.16)	21.1 (2.19)
FABQ-W	28.26 (4.01)	28.95 (4.23)
NPRS	7.40 (1.26)	7.60 (1.06)

RMDQ: Ronald Morris Disability Questionnaire. FABQ-PA: Fear-Avoidance Beliefs Questionnaire-Physical Activity Subscale. FABQ-W: Fear-Avoidance Beliefs Questionnaire-Work subscale. NPRS: Numerical Pain Rating Scale.

Comparisons of subjects' demographic characteristics, duration of symptoms, and previous episodes of pain between both groups were performed using chi-square and Student's *t* tests as applicable. At baseline, no differences in demographic and study outcome variables were found between both groups. Statistical analysis of demographic and baseline outcome variables are shown in Table 3.

Table 3. Statistical Analysis of Basic Characteristics and Baseline Outcome Variables of Participants

Variable	Experimental Group	Control Group	Analysis
Sex Female; Male	17; 22	13; 26	Two-sided chi-square Test $X^2 = 0.8667, p = .3519$
Age (Years) Mean ± SEM[a] Range	37.05 ± 1.91 (21-65)	39.51 ± 2.06 (21-66)	Unpaired two-tailed Student's *t* test, $t = 0.8748$, $p = .3844$
BMI[b]	28.46 ± 1.096	28.62 ± 0.768	Unpaired two-tailed Student's *t* test, t = 0.1167, $p = .0314$
DOS[c] Mean ± SEM Range	12.36 ± 0.53 (9-23)	11.90 ± 0.54 (8-24)	Unpaired two-tailed Student's *t* test, t = 0.6043, $p = .8283$
Previous Episodes	Y:29, N:10	Y:24, N:15	Two-sided chi-square test, $X^2 = 1.472$, $p = .2251$
Type of Job: (Sedentary, Light, Medium-Heavy, Heavy)	1,10,27,1	2,9,28,0	Two-sided chi-square test, X2 = 1.404; $p = .7046$

(a) Standard Error of Mean.
(b) Body Mass Index.
(c) Duration of Symptoms in days.

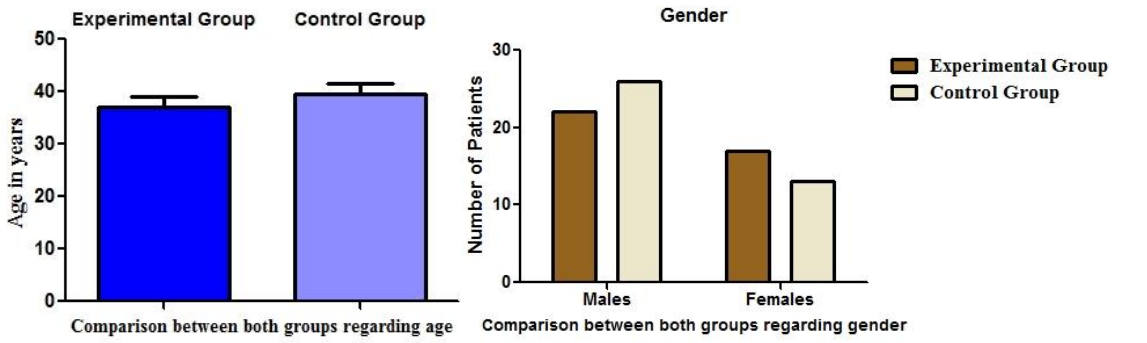


Figure 12. Comparison Between Both Groups Regarding Age and Gender

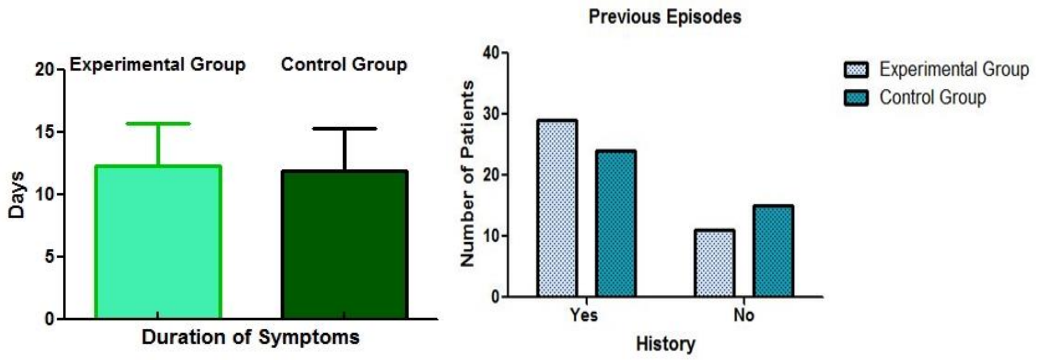


Figure 13. Comparison Between Both Groups Regarding Duration of Symptoms and Previous Episodes of LBP

FINDINGS

Data analyses were performed using GraphPad Prism (Version 6.01 for Windows; GraphPad Software, San Diego, CA) and IBM SPSS Version 23.0 (SPSS, Inc., IBM Corporation, Somers, NY). Repeated measures, mixed model analysis of variance (ANOVA) was used to examine for within subjects' differences over time, using time as a factor and between groups using the group type as a factor. The assumption of sphericity was tested using Mauchly's test. Greenhouse-Geisser correction was used to

adjust for the violation of this assumption. Data met the assumption of homogeneity as evident by Levene's test. Bonferroni posttests were used to detect differences between groups at each individual point of time. Mean and standard deviation of disability (RMDQ) scores, FABQ (physical activity and work) scores and pain (NPRS) scores were calculated at baseline before treatment and at the end of week 1, week 2, week 3, and week 4.

Specific Aim 1

To determine the efficacy of Kinesio Taping plus traditional physical therapy for acute, nonspecific LBP compared with traditional physical therapy alone on disability as measured with the Ronald Morris Disability Questionnaire.

With respect to this aim, overall, the experimental group showed statistically significant lower disability scores than the control group ($P = .002$, partial eta squared (η_p^2) = 0.116). Additionally, there was a statistically significant difference between mean disability scores within subjects over time in both groups ($P < .0001$). The group-by-time interaction for disability was statistically significant and accounts for 0.58% of the total variation (Table 4).

Table 4. Mixed-Model ANOVA for the Outcome of Disability

Source of Variation	*df*	Sum-of-squares	Mean square	*F*	*P* value	η_p^2
Interaction	4	18.91	4.727	3.271	.012	0.041
Time	4	2403	600.9	415.8	< .0001	0.845
Group Type	1	47.43	47.43	9.985	.0023	0.116
Subjects (matching)	76	361	4.75	3.287	< .0001	
Residual	304	439.3	1.445			

Comparison between both groups using Bonferroni post-tests indicated no statistically significant difference at baseline ($P > .05$). Baseline comparability showed a probabilistic pretesting equivalence of both groups, which improved the chances of presence of two homogenous groups of subjects. Moreover, the statistical comparison at week 1 between both groups did not show a statistically significant difference ($P > .05$). However, there was a statistically significant difference between both groups in week 2, 3, and 4 ($P < .05$). The experimental group showed lower disability scores in week 2, 3, and 4 compared with the control group, which was statistically significant (Table 5). These results indicate that KT may have a positive effect on disability as measured with the RMDQ, but such effect was only evident after the first two weeks of application. Graphical representation of the means of both groups over time can be seen in Figure 14.

Table 5. Posttests of Both Groups for the Outcome of Disability

	Experimental Group Mean ± SD	Control Group Mean ± SD	95% CI of diff.	*T*	*P* value
BL	13.21 ± 1.78	13.05 ± 1.39	-1.0 to 0.69	0.468	*P* > .05
Week 1	10.03 ± 1.64	10.72 ± 1.21	-0.15 to 1.54	2.107	*P* > .05
Week 2	7.53 ± 1.55	8.53 ± 1.63	0.14 to 1.85	3.043	*P* < .05
Week 3	6.82 ± 1.57	7.79 ± 1.38	0.12 to 1.82	2.965	*P* < .05
Week 4	5.67 ± 1.06	6.64 ± 1.08	0.123 to 1.82	2.965	*P* < .05

Note: BL = Baseline, CI = Confidence Interval.

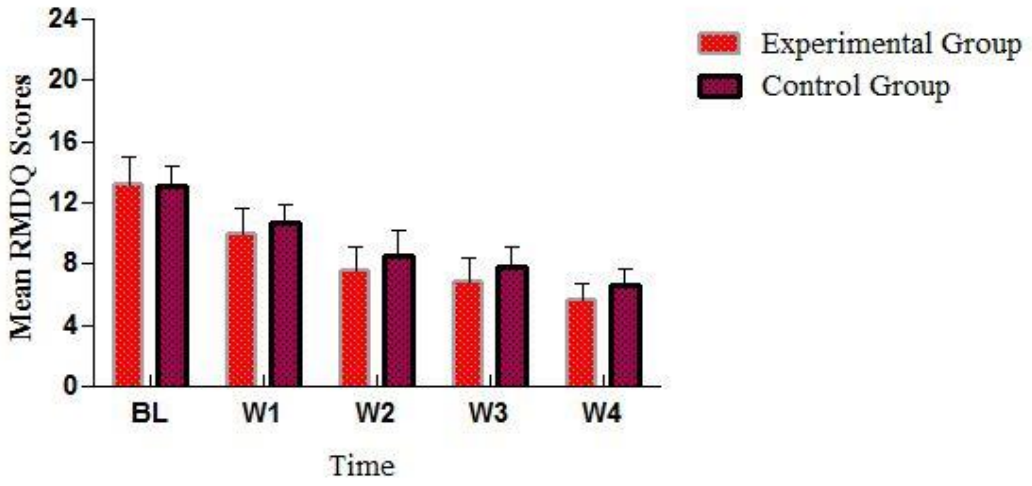


Figure 14. Mean Disability Scores of Both Groups

Specific Aim 2

To determine the efficacy of Kinesio Taping plus traditional physical therapy for acute, nonspecific LBP compared to traditional physical therapy alone on fear-avoidance beliefs as measured with the Fear-Avoidance Beliefs Questionnaire.

Two subscales of the FABQ scale were used in this study to investigate the effect of the proposed intervention on each of them. The physical activity subscale contains

items that reflect how patients' individual perception of pain affected their behavior toward physical activity. The work-subscale is also used to evaluate how pain perception affect behavior and beliefs toward work-related activities. In this study, the effect of the proposed intervention on patients' beliefs and behavior toward physical activity and work-related activities was studied. Overall, the analysis using mixed model ANOVA indicated a statistically significant lower Fear-Avoidance Beliefs-Physical Activity (FAB-PA) scores in the experimental group compared with the control group (P = .0003, partial eta squared (η_p^2) = 0.162). Also, the results of the analysis demonstrated a statistically significant decrease in fear-avoidance beliefs of both subscales within subjects over time in both groups (P < .001). The group-by-time interaction of the FAB-physical activity subscale scores was statistically significant (P < .0001) and accounted for 0.79% of the total variation, which indicated that the effect varies over time (Table 6).

Table 6. Mixed-Model ANOVA for the Outcome of FAB-PA

Source of Variation	*df*	Sum-of-squares	Mean square	*F*	*P* value	η_p^2
Interaction	4	84.5	21.12	6.373	< .0001	0.077
Time	4	7789	1947	587.5	< .0001	0.885
Group Type	1	303.4	303.4	14.69	.0003	0.162
Subjects (matching)	76	1570	20.66	6.232	< .0001	
Residual	304	1008	3.315			

FAB-PA: Fear-Avoidance Beliefs Physical Activity Subscale

Comparison between both groups using Bonferroni posttests indicated no statistically significant difference between both groups at baseline (P > .05). However, the experimental group showed statistically significant lower FABQ-PA scores at W1,

W2, W3, and W4 ($P < .001$, $P < .01$, $P < .01$, $P < .05$, respectively) compared with the control group. The difference was most significant at W1, and the difference progressively declined in W2, W3, and W4 (Table 7). These results may indicate that the addition of KT to traditional physical therapy may reduce exaggerated fear beliefs and avoidance behavior about physical activity, but the effect is most marked at the beginning of the application and decreases gradually over time. Graphical representation of the means of FABQ-PA of both groups over time can be seen in Figure 15.

Table 7. Posttests for FAB-PA for Both Groups

	Experimental Group Mean ± SD	Control Group Mean ± SD	95% CI of diff.	*t*	*P* value
BL	22.05 ± 2.16	22.10 ± 2.19	-1.47 to 1.57	0.086	$P > .05$
Week 1	14.38 ± 3.48	17.23 ± 3.63	1.319 to 4.37	4.826	$P < .001$
Week 2	11.51 ± 3.06	13.69 ± 2.94	0.65 to 3.70	3.695	$P < .01$
Week 3	9.71 ± 2.30	11.71 ± 2.16	0.47 to 3.52	3.391	$P < .01$
Week 4	8.79 ± 1.68	10.53 ± 1.43	0.21 to 3.27	2.956	$P < .05$

Note: BL = Baseline, CI = Confidence Interval.

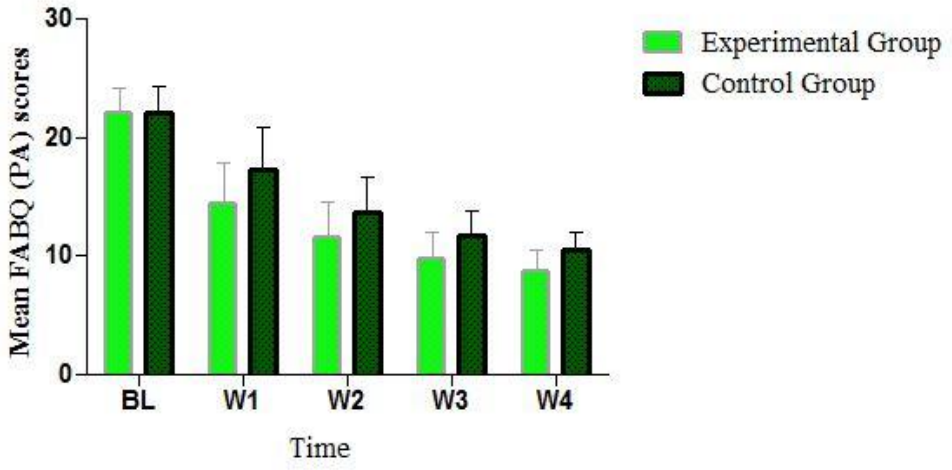


Figure 15. Mean FABQ-PA Scores of Both Groups

For the Fear-Avoidance Beliefs-Work Subscale (FAB-W), overall, the experimental group showed a statistically significant lower FAB-W scores compared with the control group (P = .006, partial eta squared (η_p^2) = 0.092). The group-by-time interaction for the FAB-work subscale was statistically significant (P < .0001) (Table 8).

Table 8. Mixed Model ANOVA for the Outcome of FAB-W

Source of Variation	*df*	Sum-of-squares	Mean square	*F*	*P* value	η_p^2
Interaction	4	65.94	16.48	2.571	.038	0.033
Time	4	13650	3414	532.4	< .0001	0.875
Group Type	1	456.6	456.6	7.732	.0068	0.092
Subjects (matching)	76	4488	59.05	9.21	< .0001	
Residual	304	1949	6.412			

FAB-W: Fear-Avoidance Beliefs-Work Subscale.

Comparison between both groups using Bonferroni posttests indicated no statistically significant difference at baseline, W1, and W2 ($P > .05$). At W3 and W4, there was a statistically significant difference between both groups ($P < .05$, $P < .01$, respectively) (Table 9). The difference was more significant at W4. The experimental group showed lower scores of FABQ-W subscale in week 3 and 4, which may indicate that the use of KT in addition to traditional physical therapy may improve fear-avoidance beliefs toward work-related activities but such effect is delayed. Graphical representation of the means of FABQ-W of both groups over time can be seen in Figure 16.

Table 9. Posttests for Both Groups for the Outcome FAB-W

	Experimental Group Mean ± SD	Control Group Mean ± SD	95% CI of diff.	*t*	*P* value
BL	28.26 ± 4.01	28.95 ± 4.23	-1.721 to 3.105	0.742	$P > .05$
Week 1	19.82 ± 5.61	21.90 ± 4.45	-0.3360 to 4.490	2.228	$P > .05$
Week 2	15.28 ± 4.11	17.46 ± 4.31	-0.2335 to 4.592	2.338	$P > .05$
Week 3	12.31 ± 3.67	15.15 ± 4.03	0.4332 to 5.259	3.054	$P < .05$
Week 4	10.64 ± 2.70	13.67 ± 3.36	0.6127 to 5.439	3.246	$P < .01$

Note: BL = Baseline, CI = Confidence Interval.
FAB-W: Fear-Avoidance Beliefs-Work Subscale.

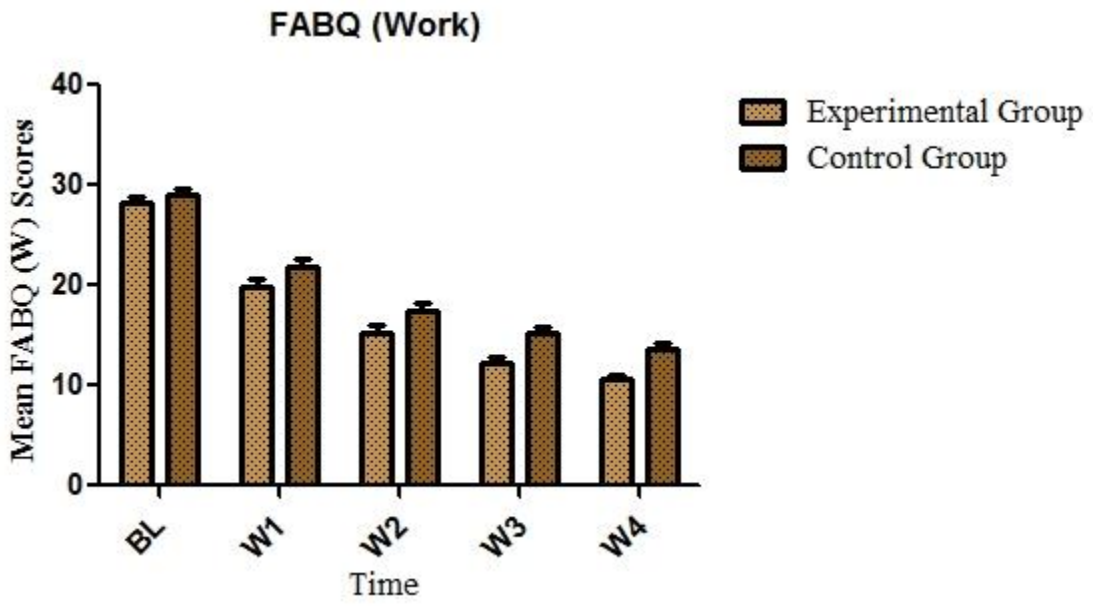


Figure 16. Mean FABQ-W Scores of Both Groups

Specific Aim 3

To determine the efficacy of Kinesio Taping plus traditional physical therapy for acute, nonspecific LBP compared with traditional physical therapy alone on pain as measured with the Numerical Pain Rating Scale.

Overall, the experimental group showed a statistically significant lower pain scores compared with the control group (P = .001, partial eta squared (η_p^2) = 0.122). The group-by-time interaction for pain scores was not statistically significant (P = .06), which indicates that the change in pain scores was independent of time. Analysis of mean pain scores within each group demonstrated a statistically significant difference over time for each group (P < .0001) (Table 10).

Table 10. Mixed Model ANOVA for the Outcome of Pain (NPRS)

Source of Variation	*df*	Sum-of-squares	Mean square	*F*	*P* value	η_p^2
Interaction	4	4.59	1.148	2.249	.0638	0.029
Time	4	976.9	244.2	478.6	< .0001	0.863
Group Type	1	37.76	37.76	10.56	.0017	0.122
Subjects (matching)	76	271.7	3.575	7.007	< .0001	
Residual	304	155.1	0.5103			

Comparison between the experimental and the control group using Bonferroni posttests with respect to NPRS scores showed no statistically significant difference at baseline ($P > .05$). The experimental group had a statistically significant decrease in mean pain scores compared with the control group at W1, W2, W3, and W4 ($P < .01$, $P < .05$, $P < .05$, $P < .05$, respectively). The difference was most significant at W1($P < .01$). These results may indicate that the use of KT on the lower back may have an additional positive effect on pain relief, but such effect is more powerful in the first week after application (Table 11). Graphical representation of the means of pain scores of both groups over time can be seen in Figure 17.

Table 11. Posttests for Both Groups for Pain Scores

	Experimental Group Mean ± SD	Control Group Mean ± SD	95% CI of diff.	*t*	*P* value
BL	7.402 ± 1.26	7.607 ± 1.06	-0.4162 to 0.8265	0.854	*P* >.05
Week 1	6.017 ± 1.11	6.855 ± 1.16	0.2163 to 1.459	3.490	*P* <.01
Week 2	4.716 ± 0.99	5.401 ± 1.10	0.06301 to 1.306	2.851	*P* <.05
Week 3	3.624 ± 0.91	4.342 ± 1.05	0.09660 to 1.339	2.991	*P* <.05
Week 4	2.820 ± 0.90	3.486 ± 0.95	0.04532 to 1.288	2.778	*P* <.05

Note: BL = Baseline, CI = Confidence Interval.

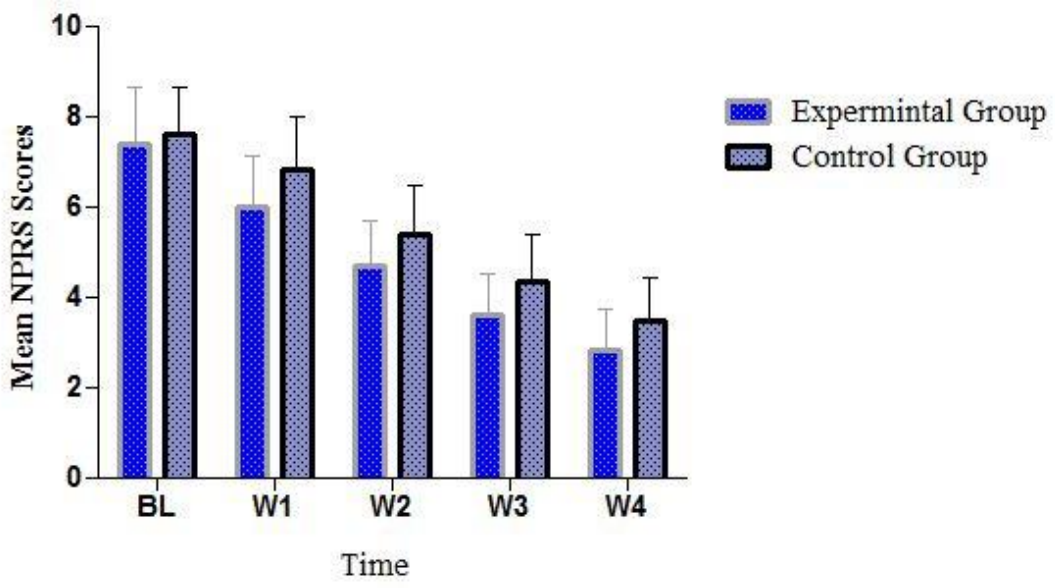


Figure 17. Mean NPRS Scores of Both Groups

It is worthy to mention that subjects in the experimental group reported many types of positive feedback about KT, such as sleeping better, much less or no more morning stiffness, and improved ability to perform functional activities.

Compliance with the Home Exercise Program

A chi-square test was used to test for the difference between both groups with respect to compliance with the home exercise program. The results indicated that there

was no statistically significant difference between both groups in week 1, 2, 3, and 4 (Table 12).

Table 12. Compliance of Both Groups with the HEP

	Experimental Group	Control Group	Two-sided Chi-Square Test
Week 1	84.46%	94.87%	X2 = 0.03457, *P* = .9983
Week 2	87.17%	89.74%	X2 = 0.1256, *P* = .7230
Week 3	76.92%	82.05%	X2 = 0.3145, *P* = .5749
Week 4	64.10%	58.97%	X2 = 0.2167, *P* = .6416

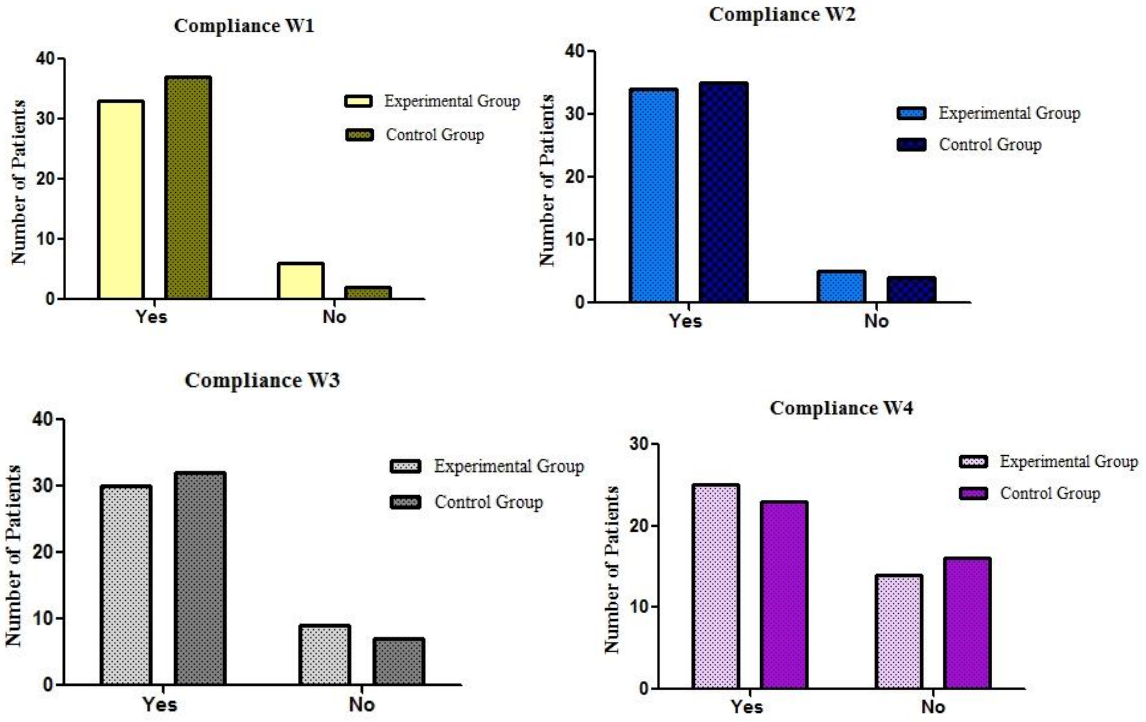


Figure 18. Comparison Between Both Groups with Respect to Compliance of HEP

SUMMARY OF RESULTS

This study included two groups of patients with acute, non-specific LBP. Subjects were randomly assigned to an experimental group, which received traditional physical

therapy plus KT on the lower back and a control group, which received traditional physical therapy alone. Three types of outcome variables used in this study: disability, fear-avoidance beliefs, and pain intensity. Measurements occurred at baseline, at the end of week 1, at the end of week 2, at the end of week 3, and at the end of week 4. Descriptive statistics were used to provide summary of the data. Graphs were used to provide a visual representation of data for an easier understanding. Mixed model analysis of variance was used to test for main effects and interaction effects using time as a within-subjects variable and group type as a between-subjects variable. Bonferroni posttests were used to compare between both groups at each individual point of time. Mixed model ANOVA assumptions were checked before analysis.

The findings of this study demonstrated a statistically significant decrease in the mean scores of all outcome variables within subjects over time in both groups. In addition, the results of the analysis showed that the experimental group had a statistically significant decrease in mean disability scores in week 2, 3, and 4 compared with the control group. The physical activity component of the FABQ showed a statistically significant lower of FABQ-PA scores in the experimental group, which peaked at week 1 compared with the control group. The work component of the FABQ showed a statistically significant decrease in the mean scores in the experimental group in week 3 and 4 compared with the control group. Mean pain scores were lower in the experimental group and showed a statistically significant decrease in week 1, 2, 3, and 4 compared with the control group and the difference was most significant after the first week of KT application.

CHAPTER 5: DISCUSSION

INTRODUCTION

This chapter is dedicated to the interpretation of the findings of the current study in the light of existing literature reflecting on current physical therapy practice. The findings are discussed in relation to the specific aims and the impact of the results on clinical practice. The limitations and delimitations of the study are explained. The chapter concludes with a discussion of recommendations for future research plans as well as a summary of the entire research project undertaken.

DISCUSSION

Low back pain is a significant health problem worldwide with many social and economic consequences.[5,8,159-161] It is one of the leading disorders that causes disability and loss of productive work hours.[2,4,8,34,160,161] Non-specific LBP is the most common type of diagnostic category in which symptoms cannot be linked to a specific pathology.[1,42] Acute, nonspecific LBP is defined in most literature as a new episode of pain of less than 4 or 6 weeks in duration.[12,13,15] Abnormal stresses imposed on lumbo-sacral and lumbo-pelvic regions of the spine may contribute to the development of low back pain through repetitive stress and micro-trauma that affect muscle tone and blood circulation.[30] It has been shown that triggers of an acute episode of LBP may include manual tasks that involve lifting, pushing or pulling, handling objects away from the body, slips, falls, and awkward postures.[27]

Clinical practice guidelines for the treatment of acute, nonspecific LBP include many forms of treatments that can be pharmacological and non-pharmacological. Physical therapy interventions, such as patient education, modalities, exercises, and

manipulation, are the most common types of treatments for acute, non-specific LBP to reduce pain and improve function.[13,14,33] Therapeutic taping is one of the interventions used in patients with musculoskeletal conditions.[32] Kinesio Taping is a type of therapeutic taping that is relatively new and has been the subject of research studies in many conditions. KT does not restrict range of motion, is tolerable, and is thought to relief pain and improve functions.[32] This study investigated the effect of this relatively new modality as an adjunct intervention to traditional physical therapy in the treatment of acute, nonspecific LBP for the outcomes of disability, fear-avoidance beliefs, and pain intensity. This study was the first randomized controlled trial that tested the effect of KT in acute, nonspecific LBP.

Specific Aim 1: To determine the efficacy of Kinesio Taping plus traditional physical therapy for acute, nonspecific low back pain compared with traditional physical therapy alone on disability as measured with the Ronald Morris Disability Questionnaire.

As mentioned previously, RMDQ is a self-report questionnaire, which was developed to assess disability in patients with acute, sub-acute, and chronic LBP. [146,147] Scoring of the scale ranges from 0, which indicates no disability, to 24, which indicates maximum disability. [146,147] The results of the study showed reduction of disability within subjects in both groups over time, which was statistically significant. Furthermore, the results of the study indicated that KT combined with traditional physical therapy may be helpful in reducing disability more than traditional physical therapy alone in patients with acute, nonspecific LBP. Such reduction was mainly observed in weeks 2, 3, and 4. First week's measurements of disability were not statistically significant between both groups, which may indicate a delayed effect of KT over time on disability.

The results of this study agree with those of Kelle et al[127] who investigated the effect of KT in patients with acute LBP and found a significant decrease in disability at 12 days post intervention. In our study, disability was lower at weeks 2, 3 and 4. Previous researchers who investigated the effect of KT on disability in patients with chronic LBP have shown mixed results. Castro-Sanchez et al[38] studied the effect of KT in patients with chronic LBP. KT has shown a positive effect on disability after 1 week of application but with a small effect size. Similarly, Al-Shareef et al[162] found reduced disability after application of KT on the lower back but with a small effect size after 2 weeks of application. These results are in agreement with the results of our study as we found some positive effect of KT on disability after 2 weeks of application. However, Poloni et al[119] investigated the effect of exercises combined with KT on pain levels and activities of daily living in patients with chronic LBP, and they found that KT did not affect disability in patients with chronic LBP.[119] In addition, Added et al[125] studied the effect of KT in chronic low back pain patients, and their findings are not in agreement with our study. Added et al[125] concluded that KT has no effect on disability in patients with chronic LBP.

The disagreement of results between our study and those in patients with chronic LBP can be explained by the difference in the clinical characteristics of our sample and the taping technique used. The participants of this study had a new episode of pain, and the response of patients with acute LBP may be different from the response of those with chronic LBP. Also, the taping technique and the parameters used in this study are different from the other techniques used in previous studies.

Specific Aim 2: To determine the efficacy of Kinesio Taping plus traditional physical therapy for acute, nonspecific LBP compared with traditional physical therapy alone on fear-avoidance beliefs as measured with the Fear-Avoidance Beliefs Questionnaire.

Fear-avoidance beliefs questionnaire was developed to assess avoidance behavior in work place and during performance of physical activity.[66,83,155] It consists of two subscales: a physical activity subscale with a score that ranges from 0 to 24 points and is used to assess beliefs toward performance of physical activity and a work subscale with a score that ranges from 0 to 42 points that is used to assess beliefs toward work-related activities. [66,83,155] Exaggerated pain perception and consequent avoidance behavior are some of the basics of the bio-psychological model of low back pain.[80] It is believed that those with elevated fear-avoidance beliefs may not fully recover and may develop chronic LBP. Therefore, an intervention that may influence such adverse behavior may have a positive effect on the course of recovery of LBP.

The findings of this study indicated decreased fear-avoidance beliefs about physical activity and work-related activities within all subjects in both groups over time. In addition, the experimental group showed a statistically significant decrease of fear-avoidance beliefs about physical activity more than the control group at weeks 1, 2, 3, and 4. Fear-avoidance beliefs scores toward work-related activities were lower in the experimental group at weeks 3 and 4 compared with the control group. Based on the results of this study, the addition of KT to traditional physical therapy interventions may reduce fear-avoidance beliefs toward physical activity, which may contribute to an overall functional improvement. Castro-Sanchez et al[38] were the only researchers to investigate the effect of KT on the fear of movement. Tampa Kinesiopobia Scale was

used as an outcome measure. Castro-Sanchez et al[38] concluded that there was no significant effect of taping on the fear of movement in chronic LBP patients. The difference in pain onset, patient population, taping technique and parameters, and the psychometric properties of the scale may explain the disagreement in the results. Fear-avoidance beliefs may cause the individual to refrain from performing basic activities of daily living, which may cause further de-conditioning and regress the course of the condition. However, the findings of our study demonstrated lower fear-avoidance beliefs scores about work-related activities (work subscale) at week 3 and 4. These findings may facilitate an early return to work, which will have a positive economic impact. The overall improvement of the fear-avoidance beliefs noted in our study may have a positive impact on the recovery from acute, nonspecific LBP.

The effect of KT in this aspect cannot be attributed merely to a neuro-physiological mechanism as a placebo factor cannot be excluded. It can be argued that patients with an acute episode of LBP are more cautious and may be reluctant to perform routine physical activities or participate in social or work-related activities. With improvements, patients may become more encouraged to return to work or perform routine physical activities, which may partially explain the obtained results in our study. The significant difference noted at weeks 3 and 4 on the FABQ-work subscale may indicate that patients started to have more positive thoughts about returning to work after some improvement.

Meier and colleagues[163] investigated the neural correlates of fear of movement in patients with chronic LBP versus healthy individuals using functional magnetic resonance imaging (MRI). The results indicated a high positive correlation between the

scores of the Tampa Scale of Kinesiophobia and harmful movements.[163] The neurological activity for this manifestation was explained by increased activity in the amygdala, and its connectivity to the anterior insula as shown on the results of functional MRI in those with fear of movements,[163] which supports the fear-avoidance beliefs model and the contribution of fear of movement to disability and functional decline. The model has also been used as a predictor for recovery and the likelihood of development of chronic symptoms and associated economic and functional burden,[163] which also emphasizes the role of patient education and the importance of the psychological aspect in the model for the management of LBP.[163] Addressing this factor is a critical component in the management process regardless of the classification system utilized by the clinician.[163]

Specific Aim 3: To determine the efficacy of Kinesio Taping plus traditional physical therapy for acute, nonspecific LBP compared with traditional physical therapy alone on pain as measured with the Numerical Pain Rating Scale.

The Numerical Pain Rating Scale is a numerical scale that ranges from 0 to 10 and is used to assess pain intensity. [147,156] The findings of our study demonstrated a statistically significant decrease in pain scores within subjects in both groups over time and between groups at weeks 1, 2, 3, and 4. The peak of the difference was found after the first week of application of KT. The decrease of pain levels observed in our study in the experimental group that received KT for 4 weeks is consistent with Kelle et al[127] who investigated the effect of KT on pain intensity in patients with acute LBP. Other researchers who investigated the effect of KT on pain levels in patients with chronic LBP yielded comparable results, such as Castro-Sanchez et al,[38] Poloni et al,[119] and Al-Shareef

el al[162] in which the application of KT in patients with low back pain resulted in decreased pain levels.

The effect of KT is hypothesized to be through stimulation of the mechanoreceptors, which provide afferent input that blocks pain perception at the spinal level.[119] This mechanism is based on the gate control theory.[119] Also, KT is thought to work by creating a space between the skin and the fascia thus promoting blood supply and lymphatic drainage, which helps in reduction of inflammation and enhancing the healing process. [105,132] The application of KT utilized in this study was from caudal to cephalic with a tension level of 15% to 25%. These parameters of clinical application are suggested by the developer of the tape to inhibit overactive muscles,[32] but there is no evidence in the literature to support such claim.

If this assumption is true, the parameters used in this study should help reduce spasms and normalize muscular performance of lower back muscles, which will influence pain, the amount of movement, and tolerance to activity. Such hypothesis may be partially supported through subjective reporting of improvement by participants of our study. Many forms of positive feedback have been expressed by the participants in the experimental group, such as better sleeping quality, increased confidence during work or daily activities, less morning stiffness, and reduced spasms and cramps. Although these subjective statements cannot be used as a valid scientific evidence, the deficiency of previous studies about the effect of the tape in acute conditions, make these comments valuable in terms of clinical practice and as a channel that may lead or guide further research efforts.

Some researchers concluded that KT may have some positive effects on pain and disability in patients with chronic, nonspecific LBP. [38,116,119,121,122] It is usually recommended that KT should be added to other interventions due to its convenience, safety, and its potential benefit. Its addition should be considered particularly for those who have low tolerance to exercises, have contra-indications to some of physical therapy interventions, and those who cannot take pain killers or muscle relaxants. This stance is observed in chronic conditions, and we believe it is actually more worthy in acute conditions. Other mechanisms proposed for the effect of KT is through stimulation of the Golgi receptors. These receptors are activated in hypertonic muscles (muscle spasms), which causes stimulation of inhibitory motor neurons.[131] KT is believed to cause activation of Golgi receptors, which may result in decreased muscle spasms.[131] Furthermore, activation of non-neural structures is one of the hypothesized mechanisms that was debated in the literature. Stimulation of keratinocytes, which act as mechanical transducers through the mechanical stimulation of KT may stimulate Ca^{2+} fluxes to evoke a response in adjacent C-fibers. [119,122]

The placebo effect refers to the positive expectation of the individual that an intervention will most likely improve his/her condition. On the other hand, a negative expectation that an intervention may worsen the individual's condition is called "nocebo."[164] Previous researchers have demonstrated how the placebo effect can cause changes in the central nervous system.[164-171] This effect is one of the confounding variables commonly found in experimental studies. [171,172] Researchers have shown that positive beliefs cause physiological changes in the endogenous opioids system.[172] A placebo-reward model was hypothesized in the literature for the effect of placebo on the

neurotransmitter dopamine.[171] Therefore, this hidden effect should not be overlooked nor underestimated in experimental studies.

A placebo effect or response as described in the literature plays a role in most experimental studies designed to examine the effects of any intervention on pain intensity or behavior. [164-171] The placebo effect in nociceptive pain is related to the expected pain levels and the individual's emotional status.[164] An assumption of additivity should be assumed in almost all clinical trials in which the effect of any agent on pain is investigated.[164] Distinguishing an effective treatment from less effective treatment is often confounded by the shadow effect of the placebo response. Researchers have shown that the placebo effect influences spontaneous pain levels and areas of hyperalgesia and leads to more positive emotions, such as reduced anxiety and better coping strategies.[164]

Bingel et al[173] used functional MRI to examine the effect of divergent expectations on the analgesic effect of a fixed dose of a potent synthetic opioid (remifentanil) in healthy subjects. Three experimental conditions were used in this study: no expectations of analgesia, positive expectations of analgesia, and negative expectations of analgesia.[173] The findings indicated that there is an enhanced analgesic effect with positive expectations and that the analgesic effect was abolished or reduced with negative expectations.[173] Functional MRI showed altered activity in the endogenous pain modulating system with positive expectations and in the hippocampus with negative expectations.[173]

The neurobiological aspect of the placebo effect is often explained by altered or enhanced activity in certain areas of the brain, which are concerned with aversion, emotions, and descending pain-inhibitory pathways.[164] Similarly, in our study, a placebo

effect or response cannot be excluded. The influence of this response may have a neurobiological component and a psychological component. The neurological component can partially explain reduced pain levels because of the effect on descending pain-inhibitory pathways, but the effect on the fear of movement component cannot be denied. The pathway described involves the amygdala, which is involved in the neurological aspect of mediation of fear of movement. Therefore, there is a possibility of neurological and psychological effects because of KT application, which could have played a critical role in participants' responses regarding fear-avoidance beliefs and pain levels. This effect is important because fear-avoidance beliefs and pain levels are closely related to disability and functional deteriorations observed in this patient population.

The development of chronic LBP, long-standing disability, work absenteeism, and decreased involvement in social activities are all consequences that can be seen in many patients with acute LBP. Battling these complications through proper evaluation and inclusion of appropriate interventions may lead to a dramatic change of the course of the disorder. These simplified proposed neurophysiologic mechanisms of KT do not provide plausible explanation of demonstrated effects on disability, pain, and avoidance beliefs observed in our study. The interaction between these effects, neurophysiologic on the spinal level, neurobiological on the brain level, and the psychological component, all play a role in the overall effects observed. In patients with mainly central sanitization pain, an amplification of the central sensory signals lead to an intensification of the pain perceived.[31] The mechanism of exaggerated pain perception described in previous studies through this type of central sensory modulation is one of the attributes clinicians observe clinically in many patients with acute LBP.[31] This illogical pain presentation may be

combated by an agent or modality that may work through a mechanism of action that may influence the same pathways or centers in a positive manner.

IMPLICATIONS

Based on the results of this study, the use of Kinesio Taping may be helpful in patients with acute, nonspecific LBP. Patients with acute, nonspecific LBP often present with pain, fear of movement or activity and functional limitations. KT should be considered as an adjunct modality for the management of acute nonspecific LBP. Based on the findings of this research study, KT provides a safe, convenient, low cost and effective modality to reduce pain and disability and improve function in patients with acute, nonspecific LBP. Clinicians should consider using the same technique with the same level of tension. An allergy test should be conducted before application to rule out those with sensitive skin who may exhibit adverse reactions. Clinicians should be aware that KT is not meant to replace existing interventions nor used as a stand-alone modality for the treatment of acute LBP rather it is a modality that can be used in conjunction with other interventions for better results. One of the advantage of this modality is that it provides some kind of therapeutic effect between treatment sessions. It should be noted that the results of the study do not imply positive effects for all types and forms of LBP. The overall presentation of the patient as well as thorough examination should be considered before application of the tape. Clinicians should also note that the effect of KT may diminish over time and peaks at the beginning of application, in terms of pain control. The effect of KT on fear of movement may enhance activity participation, socialization, and return to work status, which would reduce medical and economic burden of acute, nonspecific LBP.

RECOMMENDATIONS

This study provided a synopsis about the potential positive benefits of KT in patients with acute, nonspecific LBP. The results of the present study have shown support for the benefits of a physical therapy program combined with KT on the lower back in patients with acute, nonspecific LBP. Future research should focus on following up on participants from the early acute episode to 3 months, 6 months, or 12 months' post onset. Based on previous research, there is an association between fear-avoidance beliefs and the development of chronic LBP and long-term disability. Therefore, researchers may be able to identify which kind of modifications can be imposed by KT on such a model. Researchers should design studies to understand how KT may affect fear-avoidance beliefs in patients with LBP or other musculoskeletal conditions. In addition, other forms of KT technique and different levels of tension may be tested in the same type of patients. Use of more advanced technology such as EMG in patients with acute LBP may help better understand the mechanism of action of KT, which will open the door for more advanced applications and more for researchers to explore. More research studies are also needed in other specific LBP conditions. Future studies may also include larger samples to study more variables and employ better sampling technique and strategy. Future researchers should consider a design in which the placebo effect is controlled.

LIMITATIONS

In this study, there were some limitations that should be considered. The sampling strategy is a non-probability convenience sampling technique, which may limit generalization. The use of non-probability sampling technique was necessary for the

study to be conducted as it was the only feasible technique. Such sampling may under-represent the target population, which may weaken the external validity of the study. The sample size was restricted by the availability of subjects. Therefore, there is a limited ability to generalize the findings of this study to all individuals with acute, nonspecific LBP. Compliance to the prescribed exercise program could only be monitored through an exercise compliance log sheet that was mainly dependent upon the honesty of the participants. However, an attempt to improve compliance was made through patient education. The underlying cause of low back pain was unknown. The amount of tension used in Kinesio Taping application could not be precisely estimated during applications. The tension level used was a level that is slightly more than the paper-off tension of the tape, which was subjectively determined by the principal investigator during application. Some of the confounding variables, which were not controlled in the study are the placebo effect and the expectations of recovery. Also, the use of self-reported measures as outcome assessment tools is one the limitations because of the subjectivity of the assessment.

DELIMITATIONS

This study was conducted to investigate the clinical efficacy of KT as an adjunct modality to traditional physical therapy in patients with acute, nonspecific LBP. Patients with a recent episode of LBP of less than 4 weeks in duration were included in the study. Patients with neurological symptoms or red flags were not included in the study. Patients who had any spinal surgery, were taking NSAIDS, or receiving other physical therapy interventions or exercises were excluded. Patients who were between 18 and 75 years old and able to communicate effectively in English were included. Patients who were not

tolerant to taping were not included. Also, patients with pain intensity of sufficient level (a minimum pain score of 3 out of 10) and with a minimum score of 4 on the RMDQ were the potential participants of this study. Although, there was a high variability in the clinical presentation of LBP, randomization was used to produce two samples of probabilistic equivalence. Traditional physical therapy was standardized for all participants. The KT technique and parameters were the same for those in the experimental group. All assessments were conducted by an independent physical therapist who was blinded to the participants' allocation to avoid the assessor's bias. All treatment procedures were provided by one physical therapist who was the principal investigator. The KT application was provided by the principal investigator who is a certified KT practitioner.

SUMMARY

Low back pain is one of the most common musculoskeletal conditions that poses a significant health problem globally and is associated with medical, social, and economic consequences.[2,4,8,34,160,161] Low back pain can be specific, which constitutes around 10% of the cases, in which the pain is linked to specific pathology.[1] Non-specific low back is the most common category of diagnoses of LBP.[1] The prevalence of low back pain is on the rise in the developed and developing countries.[2] Although, many interventions exist for the management of low back pain, most have a modest effect and there is a need for other interventions to improve clinical outcomes. The variability of clinical features of low back pain requires an individualistic planning of treatment.[30,33] Evidence-based practice guidelines are clinical rules to be followed during treatment, which are associated with the best clinical outcomes at lower costs.[35] Classification

systems have been developed in order to classify patients with LBP into subgroups, each with similar common clinical features.[30,65,66] Interventions are tailored based on these clinical features, thereby improving the chances of better clinical outcomes.[30] Classification systems commonly used are the mechanical diagnosis and treatment classification system, patho-anatomic-based classification system, diagnosis-based classification system, treatment-based classification system, and pain-mechanisms-based classification system.[30] The pain-mechanism-based classification can be used to classify the type of pain mechanism into nociceptive, neuropathic, and central sanitization pain, based on certain clinical features.[31]

Understanding pain mechanisms improves clinicians' ability to understand the clinical presentation of the patient and improves the chances of developing a more effective plan of care.[31] Predictive models were also developed in order to help design preventive strategies based on tests performed early before the development of the condition or early in the course of the condition to prevent further deterioration and development of chronic syndrome.[102] The biomedical models of low back pain focused on the pathological changes that could be attributed to the development of dysfunction.[92] This model was the basic concept in understanding how to deal with patients with LBP. After the development of bio-psychological model of LBP, addressing the psychological and emotional aspects of patients' clinical symptoms became an integral part in the management process.[83,85,87] Previous researchers have shown an association between the psychological aspect of LBP and work absenteeism and disability.[83] In the literature, very few researchers investigated how acute LBP is being managed by physical therapists in outpatient settings.[35] In the 1990s, the use of hot packs, electrical stimulation, exercises,

and ultrasound was very common.[35] During such time, evidence-based practice was still developing and was not a common strategy for patient management.[35] The emergence of evidence-based practice and studies about classification systems and the effect of exercises and manipulations in patients with acute LBP improved the way clinicians manage patients with LBP.[35] Based on common evidenced-based practice guidelines, the best forms of interventions for acute LBP are patient education, manipulation, and exercises.[13,14] Flynn et al[47] developed clinical prediction rules to identify those who will most likely benefit from spinal manipulative therapy. Spinal manipulative therapy is one type of manual therapy techniques commonly used for patients with low back pain. Manual therapy techniques use manual forces applied by clinicians at different rate of force and velocity to affect tissues mechanically and neurophysiologially.[44,56,58,64,139] Mobilization refers to the use of forces at slow rate of velocity but with a variable amplitude of movement. [58,137] Manipulation refers to the use of high-velocity, low-amplitude movements to influence tissue mechanics and functions. [58,139]

This study was designed to examine the efficacy of Kinesio Taping as an adjunct intervention to traditional physical therapy in the treatment of non-specific acute low back pain. The hypotheses of this study were (1) the use of KT in addition to traditional physical therapy will reduce disability more than traditional physical therapy interventions alone in patients with acute, nonspecific LBP, (2) the use of KT in addition to traditional physical therapy will reduce fear-avoidance beliefs more than traditional physical therapy interventions alone in patients with acute, nonspecific LBP, and (3) the use of KT in addition to traditional physical therapy will reduce pain intensity more than traditional physical therapy interventions alone in patients with acute, nonspecific LBP.

Previous researchers have shown some positive effect of Kinesio taping in different conditions. Although, the effect of KT was tested in patients with chronic, non-specific LBP, no randomized controlled trials were conducted to investigate the effect of KT in acute, nonspecific LBP. Methodological limitations in previous studies, lack of randomization, weak research design, and variations in taping technique contributed to the mixed results observed.

The design of this study followed a prospective randomized controlled trial with assessor blinding. The outcome variables were disability as measured with the Ronald-Morris Disability Questionnaire, fear-avoidance beliefs as measured with the Fear-Avoidance Beliefs Questionnaire, and pain intensity as measured with the Numerical Pain Rating Scale. Recruitment of subjects occurred using non-random sampling as potential participants were offered a study flyer, and when they expressed interest to participate, they were contacted by the principal investigator. Random allocation to treatment groups was achieved using a random number generator. Participants were allocated to either an experimental group, which received traditional physical therapy plus Kinesio Taping on the lower back, or a control group, which received traditional physical therapy alone. Traditional physical therapy performed in this study was in the form of patient education, manual therapy, exercises, and home exercise program. Kinesio Taping was provided only for those in the experimental group after testing for allergy. Two I-strips of KT were placed parallel to the vertebral column from the sacral base to approximately T8 on both sides of the spine at a tension level between 15% and 25% and left in place for 3 days every week. Participants received treatments twice a week for 4 weeks.

Measurements were taken at baseline, at the end of week 1, at the end of week 2, at the end of week 3, and at the end of week 4. An independent physical therapist who was blinded to participant's group allocation performed all measurements for all participants. Mixed model analysis of variance was used to test the difference between groups and within subjects over time. Bonferroni posttests were used to compare between both groups at each individual point of time. The results of this study showed lower disability mean scores in both groups over time, and a significant reduction of disability mean scores of the experimental group compared with the control group at the second week, third week, and fourth week. These findings are mostly consistent with those observed in previous studies in terms of the effect of KT on disability. [38,119] Moreover, the experimental group showed lower fear-avoidance beliefs mean scores toward physical activities compared with the control group across all measurements. Fear-avoidance beliefs mean scores were significantly lower in both groups within subjects over time. Mean scores of fear-avoidance beliefs toward work-related activities were significantly lower in the experimental group at week 3 and 4 only. No research studies have been conducted to examine the effect of KT on fear-avoidance beliefs. Castro-Sanchez et al[38] were the only researchers to investigate the effect of KT on fear of movement, and there was no positive effect of KT on the fear of movement. Mean scores of pain intensities were lower in the experimental group compared with the control group at each point of measurement post intervention. Both groups demonstrated lower pain scores over time within subjects, which were statistically significant. In addition, the KT group showed statistically significant lower pain scores compared with the control group. These findings are in accordance with previous work by Poloni et al,[119] Castro-Sanchez et al,[38]

and Al-Shreef el al[162] that showed significant reduction of pain scores in the experimental group treated with KT. This study provides an evidence about the potential benefits of traditional physical therapy interventions combined with KT in acute, nonspecific LBP.

However, the results of our study cannot be generalized to the population of acute, non-specific LBP. The sample used in this study cannot be considered representative of population of acute, nonspecific LBP. Therefore, although it is recommended, based on the results of our study, to include KT in the treatment planning of acute, nonspecific LBP, the inclusion of such modality is mainly dependent upon the clinician's evaluation to determine the suitability and the potential benefits of such intervention. Future researchers should focus on following up with patients with acute, nonspecific LBP for longer periods of time to examine long-term effects on disability and development of chronicity. Also, further research is needed to examine the role of KT in specific LBP conditions and patients with different clinical characteristics. Also, future researchers should consider testing different taping techniques in patients with acute LBP and the inclusion of objective assessment tools. The effect of KT on fear of movement is another area that is worthy of research and may contribute to the understanding of the modifying effect of the change of fear-avoidance beliefs on the course of low back pain as result of KT application.

APPENDIX A

RESEARCH STUDY RECRUITMENT FLYER

Do you have a recent episode of low back pain?

If so, you may be eligible for participation in a study titled "The efficacy of Kinesio Taping as an Adjunct Intervention to Traditional Physical Therapy in the Treatment of Nonspecific Acute Low Back Pain: A Prospective Randomized Controlled Trial." Hossameldien Elkholy, PT, MSc, CKTP, physical therapist at Quick Docs medical center is conducting a study to examine the effect of a therapeutic taping called Kinesio Taping in patients with acute low back pain. The technique is non-invasive; the tape has been used in many studies and considered to be safe. A total of 90 males and females over the age of 18 will participate in this study. Participants will be involved in the study for 4 weeks during which they will participate in treatment sessions 2 times per week and will have Kinesio Taping for 3 days per week. Pain, disability, and fear-avoidance beliefs will be assessed at the beginning and end of the study and at the end of each week. The examination and intervention techniques used in this study are routinely used by physical therapists and do not involve any experimental approaches.

For more information, or to schedule an initial interview, please contact:
Hossameldien Elkholy, PT, M.Sc., CKTP
347-302-1604
Hossamel@nova.edu

APPENDIX B

HOME EXERCISE PROGRAM

Subject ID: _____ Date: ____/_____/_____
mm dd yy

This exercise handout contains a picture of the exercises you will be doing during physical therapy and at home during your participation in this study. You should perform these exercises within the limits of your pain every day during your participation in the study. In addition to performing these exercises, you should maintain your usual activities within the limits of your pain. You will find the number of repetitions, sets and holding time for each exercise under its perspective illustration. Continue to do all activities that do not increase your symptoms, and avoid activities that aggravate your symptoms. You have to discontinue all other forms of exercise during your participation in this study. You should not experience any significant increase in your pain while performing these exercises. Discontinue any exercise if it causes significant increase in pain level and notify your physical therapist. Exercises will be as the following:

1. Abdominal Drawing-In Maneuver

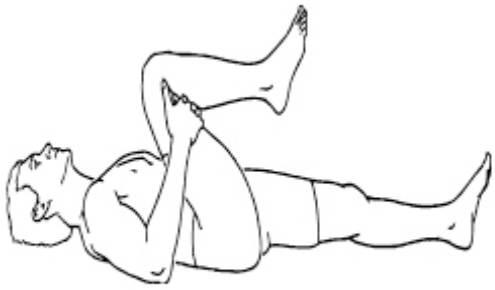
Instructions:

Draw your belly button up and in towards the spine to hollow out the abdominal region. Keep rhythmic Breathing. Hold each contraction for 5 seconds, repeat 5 times per set. Do 3 sets per session. Do one session per day.

2. Posterior Pelvic Tilting:

Instructions: Flatten your back by tightening your stomach muscles and buttocks. Hold 5 seconds. Repeat 10 times per set. Do 3 sets per session. Do one session per day.

3. Alternate Knee to Chest:



Instructions: With your hand behind your knee, pull your knee to your chest slowly until a comfortable stretch is felt in the lower back. Keep your tail bone on the table. Keep a rhythmic breathing. Hold for 5 seconds. Repeat 10 times for each leg per set. Do 3 sets per session. Do one session per day.

4. Lumbar Rotation (Knee Rolls):

Instructions: Keeping your back and feet together, swing your knees to the right side. Hold for 5 seconds. Keep rhythmic breathing. Repeat 10 times. Do 10 times per set for each side. Do 3 sets per session. Do one session per day.

APPENDIX C

HOME EXERCISE PROGRAM COMPLIANCE LOG

Subject ID: _____ Date: ____/_____/_____
mm dd yy

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Date:	Date:	Date:	Date:	Date:	Date:	Date:
Abdominal Drawing – In Maneuver.	Yes: No: Rep:	Yes: No: Rep:	Yes: No: Rep:	Yes No: Rep:	Yes No: Rep:	Yes No: Rep:
Posterior Pelvic Tilting	Yes: No: Rep:	Yes: No: Rep:	Yes: No: Rep:	Yes: No: Rep:	Yes: No: Rep:	Yes No: Rep:
Alternate Knee to Chest	Yes: No: Rep:	Yes: No: Rep:	Yes: No: Rep:	Yes: No: Rep:	Yes: No: Rep:	Yes No: Rep:
Knee Rolls	Yes: No: Rep:	Yes: No: Rep:	Yes: No: Rep:	Yes: No: Rep:	Yes: No: Rep:	Yes: No: Rep:
Notes						

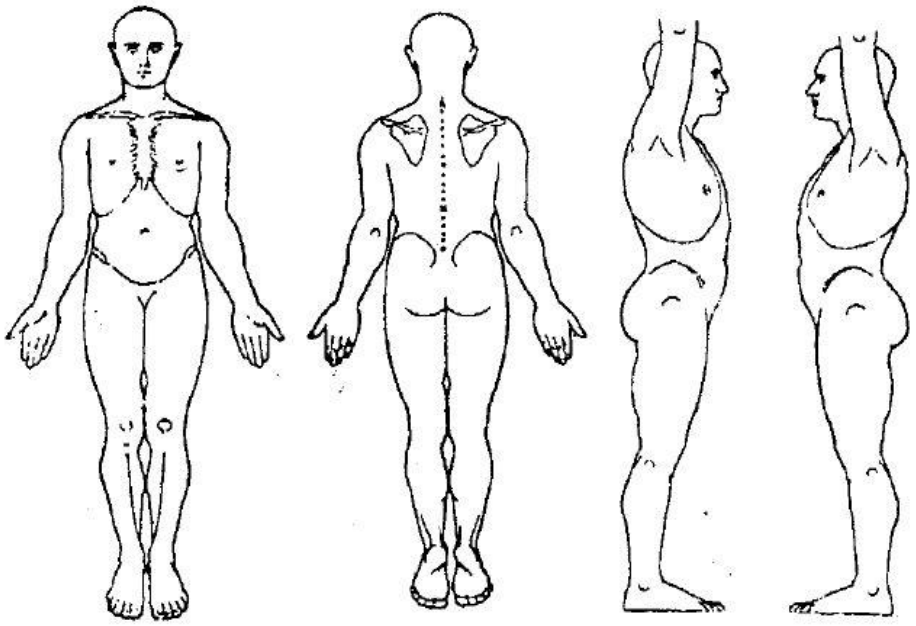
Please use the following codes to record your exercise sessions:
Y: If you completed the exercise program.
N: If you did not perform any of your exercises.
P: If you only completed part of the exercise program. Please comment in the Notes section as to the reason why.

APPENDIX D

PAIN EVALUATION

Subject ID: _____ Date: ____/_____/_____
mm dd yy

Please use the diagram below to indicate the symptoms you have experienced over the past 24 hours.
Be VERY precise when drawing the location of your pain. Use the key to indicate the type of symptoms you have experienced.
Key: Pins and Needles = 0000 Stabbing = /////////
Burning = xxxx Deep Ache = zzzz



APPENIDX E

KINESIO TAPING LOG SHEET

Subject ID: _____ Date: ____/_____/_____
mm dd yy

	KT application	KT Removal	Total Duration
Monday			
Date:	Time:	Time:	
Tuesday			
Date:	Time:	Time:	
Wednesday			
Date:	Time:	Time:	
Thursday			
Date:	Time:	Time:	
Friday			
Date:	Time:	Time:	
Comments			

APPENDIX F

THE ROLAND MORRIS DISABILITY QUESTIONNAIRE

Subject ID: _____ Date: ____/_____/_____
mm dd yy

When your back or leg hurts, you may find it difficult to do some of the things you normally do. Please mark with a cross only the sentences that describes you TODAY.

- 01. [ ] I stay at home most of the time because of my back and/or leg pain.
- 02. [ ] I walk more slowly than usual because of my back and/or leg pain.
- 03. [ ] Because of my back and/or leg pain, I am not doing any jobs that I usually do around the house.
- 04. [ ] Because of my back and/or leg pain, I use a handrail to get upstairs.
- 05. [ ] Because of my back and/or leg pain, I lie down to rest more often.
- 06. [ ] Because of my back and/or leg pain, I have to hold onto something to get out of an easy chair.
- 07. [ ] Because of my back and/or leg pain, I try to get other people to do things for me.
- 08. [ ] I get dressed more slowly than usual because of my back and/or leg pain.
- 09. [ ] I stand up only for short periods of time because of my back and/or leg pain.
- 10. [ ] Because of my back and/or leg pain, I try not to bend or kneel down.
- 11. [ ] I find it difficult to get out of a chair because of my back and/or leg pain.
- 12. [ ] My back is painful almost all of the time.
- 13. [ ] I find it difficult to turn over in bed because of my back and/or leg pain.
- 14. [ ] I have trouble putting on my socks (or stockings) because of pain in my back and/or leg pain.

- 15. [ ] I sleep less well because of my back and/or leg pain.
- 16. [ ] I avoid heavy jobs around the house because of my back and/or leg pain.
- 17. [ ] Because of back and/or leg pain, I am more irritable and bad tempered with people than usual.
- 18. [ ] Because of my back and/or leg pain, I go upstairs more slowly than usual.
- 19. [ ] I change positions frequently to try to get my back and /or leg comfortable.
- 20. [ ] My appetite is not very good because of my back and/or leg pain.
- 21. [ ] I can only walk short distances because of my back and/or leg pain.
- 22. [ ] Because of my back and/or leg pain, I get dressed with the help of someone else.
- 23. [ ] I sit down for most of the day because of my back and/or leg pain.
- 24. [ ] I stay in bed most of the time because of my back and/or leg pain.

Total Score: _____

Roland MO, Morris RW. A study of the natural history of back pain. Part 1: Development of a reliable and sensitive measure of disability in low back pain. Spine 1983; 8: 141-144\

APPENDIX G

THE FEAR-AVOIDANCE BELIEFS QUESTIONNAIRE

Subject ID: _____ Date: ____/_____/_____
mm dd yy

Fear-Avoidance Beliefs: Physical Activity Subscale

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

	Completely Disagree			Unsure			Completely Agree
My pain was caused by physical activity	0	1	2	3	4	5	6
Physical activity makes my pain worse							
Physical activity may harm my back							
I should not do physical activities which (might) make my pain worse.							
I cannot do physical activities which (might) make my pin worse.							

FABQ (PA) Score: _____

Fear-Avoidance Beliefs Questionnaire: Work Subscale

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

	Completely Disagree			Unsure			Completely Agree
My pain was caused by my work or by an accident at work.							
My work aggravated my pain.							
I have a claim for compensation for my pain.							
My work is too heavy for me							
My work makes or would make my pain worse.							
My work might harm my back.							
I should not do my regular work with my present pain.							
I cannot do my regular work with my present pain.							
I cannot do my normal work till my pain is treated							
I do not think that I will be back to my normal work within 3 months.							
I do not think that I will ever be able to go back to my normal work.							

FABQ (W) Score: _____

APPENDIX H

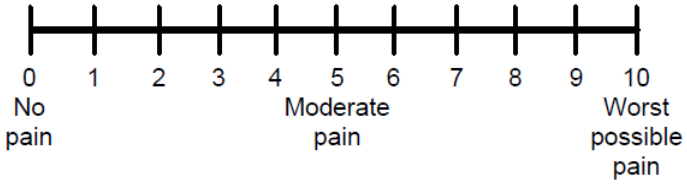
THE NUMERICAL PAIN RATING SCALE

Subject ID: _____ Date: ____/_____/_____
mm dd yy

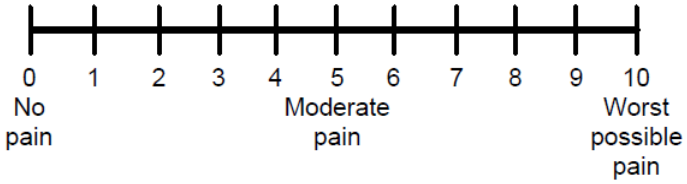
The Numerical Pain Rating Scale Instructions

On a scale from zero to ten, zero means no pain and ten means the worst pain possible, how can you describe your pain level, corresponding to current, best and worst pain experienced over the past 24 hours?

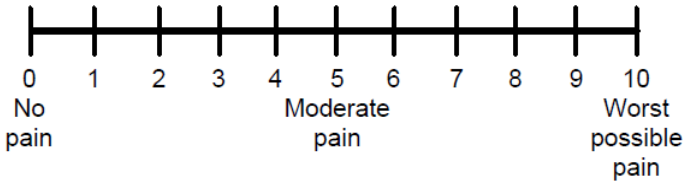
Current Pain



Best Pain



Worst Pain



APPENDIX I

INFORMED CONSENT

NSU
NOVA SOUTHEASTERN UNIVERSITY

Consent Form for Participation in the Research Study Entitled The Efficacy of Kinesio Taping as an Adjunct Intervention to Traditional Physical Therapy in the Treatment of Nonspecific Acute Low Back Pain:
A Prospective Randomized Controlled Trial

Funding Source: None
IRB protocol #: 05291519Exp

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For questions/concerns about your research rights, contact:
Human Research Oversight Board (Institutional Review Board or IRB)
Nova Southeastern University
(954) 262-5369/Toll Free: 866-499-0790
IRB@nsu.nova.edu

Site Information
Quick Docs Medical Center
255 East 98th street
Brooklyn, NY11212
718-240-2644

Initials: _____ **Date:** _____ **Page 1 of 6**

What is the study about?

We are asking you to participate in a research study. The purpose of this consent form is to give you information you will need to help you decide whether to be in the study or not. Please read the consent form very carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this consent form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent". The purpose of this study is to determine the efficacy of Kinesio Taping as an adjunct intervention to traditional physical therapy in the treatment of nonspecific acute low back pain. Participants who agree to participate in this study will be assigned a case number to protect their identity obtained from a computer random number generator. These random numbers which will be given to each participant will be used to assign each one in either an experimental group which will receive traditional physical therapy plus Kinesio taping or a control group which will receive traditional physical therapy only. You may be assigned to either one of these two groups based on that process. Such random allocation or assignment is outside the control of the researcher, you may be assigned to either one of these two groups. This process is called randomization and it will be performed to determine your group assignment.

Kinesio Taping is a form of adhesive tape that could be placed on almost any area of the body. It is made of 100% cotton and its adhesive is a medical grade acrylic so allergic reaction to this kind of taping is extremely low. However, an allergy test will be performed during your initial visit by the principal investigator to determine if you have such an allergic reaction and if so you will not be participating in the study. The tape will be placed on the lower back area and left in place for 72 hours every week for a total of four weeks. You can practice your ordinary activities including taking a shower. Manipulation of the lower back are movements of very small magnitude applied on certain parts of your lower back by the principal investigator in certain positions to reduce pain and improve function. You will be also getting therapeutic exercises which will be described to you by the principal investigator as a part of your treatment.

Why are you asking me?

The study is conducted by Hossameldien Elkholy, a licensed physical therapist with around 20 years of experience. We are asking you to volunteer to participate in this study because your physician determined that you have an acute low back pain and this study is about examining the effect of a modality called Kinesio Taping in such conditions. However, not all participants will receive Kinesio taping. This will be based on your group assignment. If you will be assigned to the experimental group, you will receive traditional physical therapy plus Kinesio taping. If you will be assigned to the control group, you will receive traditional physical therapy only.

What will I be doing if I agree to be in the study?

If you agree to participate, you will be asked to see the physical therapist at Quick Docs Medical Center, Brooklyn NY for assessment. During your first visit, the physical therapist will conduct a routine physical examination and an allergy test for Kinesio Taping. The physical therapist will then inform you about your visit schedule. You will be expected to attend two times per week for four weeks. If you are assigned to the experimental group, you will receive traditional physical therapy plus Kinesio taping on your lower back. If you are assigned to the control group, you will receive traditional physical therapy only. Participants in both groups will receive spinal manipulative therapy and therapeutic exercises as part of their traditional physical therapy, whether they are in the control or the experimental group. The taping will be placed on your lower back for 72 hours every week if you are assigned to the experimental group. All subjects will be scheduled to see the principal investigator with all treatment sessions being conducted and performed by the principal investigator. Manipulation is a term used to describe movements of the spine induced by the therapist's hands in different directions and in different positions in order to reduce pain and improve function. Therapeutic exercises are bodily movements that will be instructed to you by your physical therapists in order to reduce pain and improve function. You will be given a hand out of these exercises to practice at home. The study will take around four weeks to be completed. At that time your participation in the study will be completed. Although your time in the study will be completed you will continue to receive standard physical therapy care if you are still unable to do activities of daily living. None of the procedures used in this study is experimental in nature.

All procedures in this study are routine physical therapy procedures used by physical therapists in every day's clinical practice.

What are the dangers to me?

None of the procedures in this study is considered to be an experimental procedure. The only experimental aspect of the study is the gathering of information for the purpose of analysis. Participation in this study may be associated with risks such as skin irritation and breach of confidentiality. If you will be assigned to the experimental group, an allergy test will be conducted to determine your skin reaction to this taping. If you have any reaction to the taping and the test is positive, you will be excluded from the study. The likelihood of allergic reaction to Kinesio taping is extremely low because the tape is made of 100% cotton. Skin irritation due to prolonged taping will be minimized by using a tension level of less than 50%. Skin irritation is very unlikely to occur with such low tension level. Your confidentiality will be protected by the use of proper data storage and restricting access to only authorized personnel.

If you have any questions about the research, your research rights, or have a research-related injury, please contact Hossameldien Elkholy or Dr. Madeleine Hellman. You may also contact the IRB at the numbers indicated above with questions as to your research rights.

Are there any benefits for taking part in this research study?

There are potential benefits to you and future recipients from the information gained from this study including faster and less painful recovery. We cannot guarantee, however, that you will receive any benefits from participating in this study.

If you choose not to participate in this study, you will be receiving your prescribed physical therapy procedures.

Will I get paid for being in the study? Will it cost me anything?

You will not get paid for your participation in this study and your participation will not cost you anything beyond what you would normally have for your doctor visits and physical therapy.

How will you keep my information private?

All patients' data and records pertaining to this research study and any relevant information will be stored in a locked file cabinet at the facility in which the study will be conducted. A case number will be used to indicate patient's identity on these records.

Initials: _____ **Date:** _____ **Page 4 of 6**

This information will be only accessible to the principal investigator, the independent physical therapist, and other research study staff involved in conducting this research study. All assessment data will be kept in a separate locked file cabinet which will be accessed only by the independent physical therapist. No confidential information such as the patient's name, address, phone number, or/and other information that might possibly be used to link the data back to the patient will be transmitted or shared. All questionnaires, daily logs, and measurement data to be used in computer analysis will have number codes rather than your name. Your name will not be recorded on the information or reported in papers. A master list of code numbers will be kept confidential by the researchers and will be stored a locked file cabinet. Data that will be used for computer analyses will be kept on diskette and only researchers involved in the study and representatives of the Nova Southeastern University Institutional Review Board will have access to the records and information about the study. These measures will be used to ensure the maintenance of patient confidentiality. All information obtained in this study is strictly confidential unless disclosure is required by law. The IRB, regulatory agencies, and the dissertation chair may review research records.

What if I do not want to participate or I want to leave the study?

If you do decide to leave or you decide not to participate, you will not experience any penalty or loss of services you have a right to receive.

If you choose to withdraw, any information collected about you before the date you leave the study will be kept in the research records for 36 months from the conclusion of the study.

Other Considerations:

If significant new information relating to the study becomes available, which may relate to your willingness to continue to participate, this information will be provided to you by the investigators.

Questions about This Study: If you have any questions about this study, please ask. If you have questions later about this study, you may contact Hossameldien Elkholy at (347) 302-1604.

Voluntary Consent by Participant:

By signing below, you indicate that

- This study has been explained to you
- You have read this document or it has been read to you
- Your questions about this research study have been answered
- You have been told that you may ask the researchers any study related questions in the future or contact them in the event of a research-related injury
- You have been told that you may ask Institutional Review Board (IRB) personnel questions about your study rights
- You are entitled to a copy of this form after you have read and signed it
- You voluntarily agree to participate in the study entitled "The efficacy of Kinesio Taping as an Adjunct Intervention to Traditional Physical Therapy in the Treatment of Nonspecific Acute Low Back Pain: A Prospective Randomized Controlled Trial".

Participant's Signature: _____ **Date:** _____

Participant's Name: _____ Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

APPENDIX J

IRB APPROVAL

NOVA SOUTHEASTERN UNIVERSITY
Institutional Review Board

MEMORANDUM

To: Hossameldien Elkholy, PT, MSc, CKTP
HPD – College of Health Care Sciences

From: Matthew Seamon, Pharm.D., JD
Chair, Institutional Review Board

Date: June 29, 2015

Re: *The Efficacy of Kinesio Taping as an Adjunct Intervention to Traditional Physical Therapy in the Treatment of Nonspecific Acute Low Back Pain: A Perspective Randomized Controlled Trial* – NSU IRB No. 05291519Exp.

I have reviewed the revisions to the above-referenced research protocol by an expedited procedure. On behalf of the Institutional Review Board of Nova Southeastern University, *The Efficacy of Kinesio Taping as an Adjunct Intervention to Traditional Physical Therapy in the Treatment of Nonspecific Acute Low Back Pain: A Perspective Randomized Controlled Trial* is approved in keeping with expedited review category #4. Your study is approved on **June 26, 2015** and is approved until **June 25, 2016**. You are required to submit for continuing review by **May 25, 2016.** As principal investigator, you must adhere to the following requirements:

1) CONSENT: You must use the stamped (dated consent forms) attached when consenting subjects. The consent forms must indicate the approval and its date. The forms must be administered in such a manner that they are clearly understood by the subjects. The subjects must be given a copy of the signed consent document, and a copy must be placed with the subjects' confidential chart/file.

2) ADVERSE EVENTS/UNANTICIPATED PROBLEMS: The principal investigator is required to notify the IRB chair of any adverse reactions that may develop as a result of this study. Approval may be withdrawn if the problem is serious.

3) AMENDMENTS: Any changes in the study (e.g., procedures, consent forms, investigators, etc.) must be approved by the IRB prior to implementation.

4) CONTINUING REVIEWS: A continuing review (progress report) must be submitted by the continuing review date noted above. Please see the IRB web site for continuing review information.

5) FINAL REPORT: You are required to notify the IRB Office within 30 days of the conclusion of the research that the study has ended via the IRB Closing Report form.

The NSU IRB is in compliance with the requirements for the protection of human subjects prescribed in Part 46 of Title 45 of the Code of Federal Regulations (45 CFR 46) revised June 18, 1991.

Cc: Dr. Madeleine Hellman
Mr. William Smith
Dr. M. Samuel Cheng

3301 College Avenue • Fort Lauderdale, Florida 33314-7796
(954) 262-5369 • Fax: (954) 262-3977 • Email: *irb@nova.edu* • Web site: *www.nova.edu/irb*

APPENDIX K

LETTER OF ADMINISTRATIVE SUPPORT

Quick Docs Medical, PLLC
255 EAST 98TH Street
Brooklyn, NY 11212
Phone: 718-240-2644
Fax: 718-240-2676

Letter of Support

Quick Docs Medical PLLC
255 East 98th street, Brooklyn, NY 11212
Phone: 718-240-2644
Fax: 718-240-2676

Re: Hossameldien Elkholy Research Project.

To Whom It May Concern,

We are writing on behalf of Quick Docs medical center in Brooklyn NY to inform you that we fully support Hossameldien Elkholy to carry out his research project titled "The efficacy of Kineso Taping as an Adjunct Intervention to Traditional Physical Therapy in the Treatment of Nonspecific Acute Low Back Pain: A Prospective Randomized Controlled Trial". In support we will provide patients who are referred to our clinic with low back pain that meet the eligibility criteria likely to benefit from the study and whose participation will be fully voluntary. We will also provide the necessary means to facilitate the study such as adequate treatment environment, examination and treatment rooms.

We look forward to support your research endeavor.

Sincerely,

Quick Docs Medical Directors:

Dr. Ashraf Salem, MD

Signature: _____

Quick Docs Medical General Manager:

Mohamed Salem

Signature: _____

APPENIDX L

PARTICIANTS' DEMOGRAPHIC INFORMATION

Participant's ID: _____ Age: _____ Gender: _____

Weight: _____ Height: _____ BMI: _____

Type of Work: Sedentary ( )

Light ( )

Medium-Heavy ( )

Heavy ( )

Previous Episodes of BP: Yes ( ) No ( )

Duration of Symptoms (in days): _____

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