ABSTRACT

A COMPARISON OF THE MCKENZIE METHOD AND A FIRST-LINE EDUCATIONAL INTERVENTION FOR PATIENTS WITH ACUTE NON-SPECIFIC LOW BACK PAIN: A META-ANALYSIS OF PAIN AND FUNCTION

Context: Currently, the standard medical practice for treatment of acute non-specific low back pain (NSLBP) is through conservative education by a first-line health care professional. With physical therapists (PT) joining first-line health care through direct access and a multitude of physical therapeutic interventions currently available for acute NSLBP, it is vital to identify the most efficacious and cost effective first-line health care professional. The McKenzie Method is a physical therapy intervention specifically designed to address the issues associated with acute NSLBP, however there is no study comparing first-line health care profession with a specific proven therapeutic intervention.

Objective: The purpose of this meta-analysis is to compare the specific evaluation, treatment, and patient adherence of the repeated movement and patient education principles of the McKenzie Method and a conventional educational session by a first-line health care professional in treatment of NSLBP by comparing the outcome measures of pain and physical function.

Data Sources: Search procedures followed PRISMA guidelines using the databases PubMed, CINAHL, and PEDro. A manual search of previous systematic reviews and the McKenzie International Institute reference list was also conducted. The search was limited to randomized control trials published in peer-reviewed articles from 1984 to 2015 in the English language.

Study Selection: Four studies were included in this meta-analysis. Studies were included based on the following criteria: adults ages 18-80 years, acute too sub-acute NSLBP with or without radiating symptoms, duration of symptoms
greater than 2 days and less than 12 weeks, McKenzie Method treatment, a single education session with or without a provided booklet by a first-line health care professional, and a follow-up within 12 months of treatment. Pain was measured using the visual analog scale (VAS). The functional outcome measures used were the Short Form 36, physical function section (SF 36 PF), the Patient Specific Functional Scale (PSFS), and the Multidimensional Task Ability Profile (MTAP).

Data Extraction: Titles, abstracts, full text articles, and reference lists were screened by 1 reviewer from May 2015 to October 2015.

Results: The McKenzie Method intervention proved to be far superior statistically and clinically to a first-line educational intervention for reducing pain and improving function. The McKenzie Method outperformed first-line education for short and long-term pain improvement, moderate effect 0.48 (95% Confidence Interval (CI) = -0.68, -0.28) p = 0.43, Q = 1.66]; (95% CI) = -0.50 (-0.70, -0.30) p = 0.000048, Q = 19.86]. Results again favored McKenzie in regards to improved physical function, short-term and long-term showing strong effect 0.74, (95% CI = 0.49, 0.98) p = 0.000087, Q = 18.69], and moderate effect 0.52; (95% CI = 0.26, 0.79) p = 0.021, Q = 5.26].

Conclusion: Based on the results of this meta-analysis, patients suffering from acute NSLBP should utilize direct access and consult a physical therapist for treatment instead of consulting a first-line health care professional.

Key Words: McKenzie Method, Mechanical Diagnosis and Therapy, first-line health care, centralization, directional preference, acute low back pain, non-specific low back pain, function.

Adam Manuel Maraccini
December 2016
A COMPARISON OF THE MCKENZIE METHOD AND A FIRST-LINE EDUCATIONAL INTERVENTION FOR PATIENTS WITH ACUTE NON-SPECIFIC LOW BACK PAIN: A META-ANALYSIS OF PAIN AND FUNCTION

by

Adam Manuel Maraccini

A project
submitted in partial fulfillment of the requirements for the degree of
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in the Department of Physical Therapy
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California State University, Fresno
December 2016
APPROVED

For the Department of Physical Therapy:

We, the undersigned, certify that the project of the following student meets the required standards of scholarship, format, and style of the university and the student's graduate degree program for the awarding of the doctoral degree.

__________________________
Adam Manuel Maraccini
Project Author

__________________________
Monica Rivera (Chair)  
Physical Therapy

__________________________
Dan Barrows  
Physical Therapy

__________________________
Kevin O’Sullivan  
Physical Therapy

For the University Graduate Committee:

__________________________
Dean, Division of Graduate Studies
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BACKGROUND

Low Back Pain

Low back pain (LBP) is one of the most common medical diagnoses in the United States (U.S.) and continues to increase in prevalence each year.\textsuperscript{1} Low back pain is treated across the disciplines in the medical community and is often described with varying perspectives based on one’s professional background. From the prospective of Physical Therapy (PT), and for the purpose of this meta-analysis, LBP is operationally defined as pain or discomfort between the 12\textsuperscript{th} rib and the gluteal fold, with or without radiating lower extremity symptoms.\textsuperscript{1,2} Classification of a low back injury and the associated symptoms are based on the duration of symptoms from initial date of injury. Symptoms lasting longer than 2 days, but not exceeding 6 weeks is considered the acute phase, symptoms lasting between 6 and 12 weeks is considered subacute, and symptoms lasting longer than 12 weeks is considered chronic in nature.\textsuperscript{3} The acute phase classification will be the time frame of focus for the interventions and outcomes analyzed for this study.

Low back pain is one of the most challenging diagnoses, both financially and in medical management within the U.S. health care system. It has been estimated that up to 90% of all cases are directly related to work place injury, commonly as a result of repetitive stress or over exertion injuries.\textsuperscript{4,5} In 2005, LBP was responsible for 70\% of all worker’s compensation claims costs and was the second leading cause of disability in the U.S.\textsuperscript{4,5} A little over a decade later, the U.S. saw an exponential increase in total aggregate direct costs for persons with a spine condition. In 2011, total associated medical costs were $253 billion, a 91\% increase from the $132.4 billion in 1998.\textsuperscript{6} According to the 2016 Liberty Mutual Workplace Safety Index, over exertion low back injuries were the leading cause of
time missed from work due to injury and accounted for $15.1 billion in direct business costs due to days missed and lost wages nationwide.7

When a health concern presents itself under the current medical model, common practice dictates the patient seeks medical attention from a first-line health care professional, this includes acute non-specific low back pain (NSLBP). First contact for the patient is traditionally made with a nurse practitioner (NP), physician assistant (PA), or general practitioner (GP). The majority of first-line medical professionals practice a conservative approach consisting of radiographic imaging and a single educational session during initial contact and evaluation. This may be followed by a period of reduced activity or time off work, as seen to be most beneficial in resolving symptoms associated with acute NSLBP.3,8 Although most minor cases of acute NSLBP resolve with rest and time, a large percentage of patients who receive medical care from a first-line health care provider, do not experience symptom resolution. Therefore, these individuals often return to their first-line health care provider and then receive a referral to physical therapy, thus delaying intervention weeks after the initial injury.9

In the U.S. established first-line clinical guidelines for treatment of acute NSLBP follow the fore mentioned protocol of education regarding low back care, reducing activity, avoiding bedrest and refer to PT when symptoms persist. After a comprehensive literature review of first-line health care management of acute LBP, clinical guidelines from a dozen different countries were found to be similar.10 Commonalities among clinical guidelines included discouraging bed rest with early and progressive activity and discussing the role of psychosocial variables that increase the risk for chronicity. The primary inconsistency identified amongst the studies involved clinical guidelines and recommendations for the utilization of PT and spinal mobilization for the treatment of LBP.10 Of the 12
countries included, only 3, including the US, recommend and consistently
promoted PT and spinal mobilization as a viable treatment for LBP. A common
finding amongst all the countries was that GPs are generally unaware of PT’s
training in mobilization of the spine for treatment of acute LBP.\textsuperscript{11} Furthermore, the
standard educational session provided by GPs produces very low adherence rates,
revealing that the efforts of education was partly contributing to reductions in
lasting symptom relief or behavior modifications.\textsuperscript{12}

Due to recent legislation affording direct access in California, PTs have
been granted the right to join the list of first-line health care professionals.
Physical therapists are educated and trained on the evaluation and treatment of
acute NSLBP, with the skill to mobilize the spine through various manual
techniques. More importantly, health care consumers are unaware of the
significant benefit of obtaining early intervention utilizing manual techniques.
Moreover, the general population lacks the knowledge that manual techniques
have proven to have a greater impact on decreasing pain and improving function
compared to the traditional educational guidelines provided by a first-line health
care professional.\textsuperscript{9} The challenge moving forward is improving awareness of the
benefits of the field’s direct assess laws and utilizing physical therapists as first-
line health care professionals in the treatment of acute NSLBP.

Research indicates that without therapeutic intervention 85-90% of patients
with an acute episode of NSLBP will experience resolution of symptoms within 6
weeks, but the remaining 10-15% of this population will develop chronic LBP
(CLBP) and related disabilities.\textsuperscript{8} At first glance, this statistic appears to be
favorable as it accounts for the vast majority of the stated population. When
further analyzed, it becomes clear that the 10-15% of patients that do not receive
therapeutic interventions in the acute phase continue to suffer from pain and loss
of function. Furthermore, there is extensive research stating that once a LBP patient transitions to the chronic stage, it leads to high prevalence and associated financial burden on the health care system. However, little attention has been assigned to the 10-15% of NSLBP individuals, specifically on the transition through the initial phases of diagnosis, and the processes leading to long-term disability. The longer a patient suffers from chronic pain and related loss of function, the more difficult it is to reverse course due to physiologic, neurologic, mechanical, and psychological changes. Thus, establishing the need to address the issue of acute LBP immediately after the injury and strive for symptom resolution in the acute phase.

Besides the fore mentioned issues within the management of LBP, a significant void has been identified in the continuum of care for patients within the acute episode of NSLBP. Although the percentage appears high for symptom resolution, the reoccurrence rate remains significant for millions of patients who never experience relief as they transition to a chronic state. This void has a monumental ripple effect that creates a financial and personal burden. If an efficacious therapeutic intervention was developed to fill the void in the treatment, it would create a global benefit for the health care system impacting the consumer, provider, and payer.

As demonstrated by Grunnesjo et al., PT manual techniques have much stronger outcomes in reducing associated acute NSLBP symptoms when compared to the current model of education provided by a first-line health care professional. Although, the study used a multitude of manual techniques, it failed to identify a single superior intervention or approach for this patient population. Given the financial and medical burden to individuals and to economics, it makes sense to investigate the feasibility of a manual treatment model in comparison to the
current educational model for an efficacious and financially responsible approach for the treatment of acute NSLBP.

There is however, the McKenzie Method, a well-established educational and intervention program for the treatment of acute NSLBP. The McKenzie Method provides an established and systematic approach for the evaluation and treatment of acute LBP with patient centered interventions that has shown favorable patient outcomes. As of yet, there is no evidence directly comparing traditional first-line education to the McKenzie Method. Therefore, the purpose of this meta-analysis is to compare first-line health care education versus the McKenzie Method. The results of this meta-analysis could potentially have a significant impact on the consumer and providers in the current direct access health care environment. By producing sound evidence regarding an effective PT intervention for the treatment of acute NSLBP, potential patients will be able to make an informed decision regarding their health care. In doing so, this will speed patient recovery and greatly reduce the number of chronic spine conditions as well as overall utilization and financial burden of the U.S. health care system.

**Prevalence**

In the U.S., LBP is a serious health concern, becoming the second most commonly treated medical condition in the country behind the common cold. There has been an exponential increase of new cases of LBP over the last decade with an estimated incidence rate increase of greater then 80%. The lifetime prevalence in adults for LBP has been recorded as high as 84% with 23% advancing to CLBP. Out of the chronic population, 11 to 12% of these cases become permanently disabled due to loss of function. Health problems associated with CLBP can lead to chronic disability, involving an increased risk in
obesity, cardiovascular disease (CVD), hypertension (HTN), and type II diabetes.\textsuperscript{15} In addition, it is well established that LBP is a recurrent phenomena.\textsuperscript{16} A systematic review analyzing data from over a dozen studies found that 24-87\% of persons with an acute episode of LBP will have a recurrence of low back symptoms within 1 year.\textsuperscript{16} More concerning, are the data collected by Garcia et al.,\textsuperscript{17} which concluded approximately 60\% of patients suffering from CLBP were unable to find pain relief or symptom resolution and continued to experience moderate pain and decreased function after 12 months.

**Non-Specific Low Back Pain**

When an individual is seen by a primary care physician (PCP) for an acute episode of LBP without a direct cause and the associated symptoms are unable to be correlated with a specific pathology, the diagnostic term non-specific low back pain (NSLBP) is assigned.\textsuperscript{3,8} From a physical therapists’ standpoint, NSLBP can vary in severity of symptoms and degree of functional loss. Common impairments range from isolated LBP at the involved lumbar segment, to radiating bilateral pain with or without distal symptoms in the lower extremities, such as sharp shooting pain, gross motor impairments, numbness or burning sensations. These varying impairments are patient specific, ranging from minor loss of function and disturbed quality of life (QOL) to full disability.

The use of non-specific in LBP is a general term that is interpreted as all encompassing, therefore there is an urgent need to identify and categorize this diagnosis, in order to stream therapeutic interventions and enhance overall outcomes. Petersen et al.\textsuperscript{18} created a 12-part classification system for physical therapists (PT) that provides a methodical assessment of patients’ signs and symptoms through the history and physical exam. This method provides the
necessary information for clinicians’ to accurately assign the patient to 1 of 12 pathoanatomical syndromes, with 3 subcategories (see Appendix A). A few of the more viable physiologic and anatomical causes of NSLBP include: age related degeneration of intervertebral lumbar discs, degenerative nucleus pulposus altering the function of nerve growth factor and inflammatory and pain neurotransmitter substance p, occupation induced repetitive mechanical changes, psychosocial influences, and genetic dispositions. By classifying the patient based on their pathoanatomical presentation, this allows the PT to narrow the focus of specific interventions that can be assigned to target the identified underlying pathology. Therefore, Petersen et al.’s diagnostic classification system provides the tools for the PT to differentiate the underlying structural cause of the NSLBP at the first visit and determine a diagnosis, providing the framework for how to proceed with the functional McKenzie based evaluation for the development of a specialized plan of care (POC) utilizing repeated movements.

First-Line Health Care

For this meta-analysis, first-line health care professionals are operationally defined as the gatekeepers to the health care system. First-line health care professionals provide first contact with patients seeking medical attention for acute NSLBP, including NPs, PAs, GPs and PCPs. The standard patient educational session administered for the treatment of LBP with first-line healthcare professionals includes a one-time intervention providing general guidelines, recommendations on low back care, prevention techniques, proper lifting mechanics, avoiding bed rest, instructions to take acetaminophen as directed, an educational booklet, and continuing with non-exacerbating daily activities.
Physical Therapy

Low back pain is the most common diagnosis that PTs encounter in the outpatient clinical setting accounting for, on average, over half of the patients treated in a calendar year. The American Physical Therapy Association (APTA) has established 8 clinical practice guidelines (CPG), with recommended interventions, for the treatment of LBP based on varying levels of evidence that support PT as a strong conservative care option (Appendix B). As the field of PT has established CPGs, this raises the question as to why a void in treatment in acute LBP exists in the current era of PT. Are these recommended interventions too specific and unable to be generalized to the entire NSLBP population, or are they independently ineffective in their aim? Perhaps one method is to clearly investigate the advantages and disadvantages in the current management of acute NSLBP versus services from a PT adept in classification and intervention in LBP.

To provide evidence that Physical Therapy reduces pain and improves function in NSLBP, especially in acute episodes, 2 separate studies produced by Fritz et al. and Gellhorn et al. provide strong support for early conservative care. Each respective study demonstrated a decrease in utilization of health care services and overall associated costs when compared to a period of rest and delayed treatment. Furthermore, the impairments of pain and function were significantly reduced in the short-term, while maintaining the improvements long-term. Following an acute episode of NSLBP, these studies show strong support for early intervention with PT, but provide little to help fill the void existing between a standardized treatment protocol and intervention selection for this population.

In spite of the PT CPGs, there are no universal consensus regarding the evaluation method and the appropriate medical treatment for an acute episode of
NSLBP. A majority of what is considered common practice by today’s medical professionals in the management of LBP lacks supporting evidence towards consistent positive patient outcomes. Alternatively, the 8 recommended CPGs approved by the APTA for the treatment of LBP may provide an avenue for reducing the epidemic in LBP in the US. Therefore, a revolution in health care is required, as the statistics underline that NSLBP is becoming an increasing problem in the US.

Classification and judicious interventions are the obvious next step to alleviating the burden of NSLBP. As the field of PT has established these factors as part of their CPGs, the next steps are to compare outcomes of specific PT interventions and the traditional management of acute NSLBP. Currently, the field of PT is prepared to join front-line professionals as the gatekeepers to health care, as it is vital for society to utilize the most efficacious evidence based approach in treating LBP.

**The McKenzie Method**

One of the 8 CPGs approved by the APTA is of particular importance in regards to this meta-analysis. The CPG intervention subcategory “Centralization and Directional Preference Exercises and Procedures” describes many of the core principles of the McKenzie Method. The McKenzie Method, also known as Mechanical Diagnosis and Therapy (MDT) was developed in the late 1950s by New Zealand PT Robin McKenzie, and has since become recognized worldwide by PTs as an effective evaluation method of classifying and treating NSLBP.

The McKenzie Method is an approach-based classification system that provides a framework allowing physical therapists to assess specific spinal movement that alleviates, reduces, or centralizes the patients’ pain.
identification of “directional preference” is a key finding in the acute episode of NSLBP as it provides the main interventional objective. Once the directional preference is identified, the movement pattern is repeated to centralize the distal radiating pain back to the appropriate location at the corresponding vertebral level of the spine. Centralization of pain is the prime outcome of MDT, as the intervention changes the location of distal radiating pain to a more proximal or central location.\textsuperscript{1} The objective findings and subjective responses during the evaluation guide the development of the plan of care (POC) with the utilization of repeated or sustained movements. An essential aspect of MDT, is patient education, encouraging movements and exercises that promote centralization and avoiding those that cause peripheralization of pain and symptoms. The McKenzie Method has been implemented and reviewed for several decades as an effective method for treating NSLBP and is acknowledged and utilized by physical therapists worldwide.\textsuperscript{1,23}

For the mentioned studies, all physical therapists that provided therapeutic or educational intervention for this meta-analysis were MDT certified. The education, practical training, and evaluation to become a credentialed McKenzie clinician are exclusively controlled and regulated by the McKenzie Institute International (MII). The MII has a global influence and strong presence in the PT profession with 28 branches in 40 different countries.\textsuperscript{23} The education and training required by the MII is subdivided into 5 independent courses, parts A-E, with each focusing on a specific region of the spine.\textsuperscript{24} Each course provides the clinicians with the foundational protocol to assess and treat in accordance with MDT principles as well as live practical experience with real patients. In total, to complete the 5 separate courses requires a significant time and financial commitment.\textsuperscript{24} After completion of the 5-part education and training series the
clinician then must sit for a 2-day, 14-hour certification exam to demonstrate competency to become a credentialed MDT clinician.

McKenzie’s foundational philosophy centers on the theory that the vast majority of LBP is mechanical in origin and is the result of an external force that results in pain. In order to alleviate the pain and restore function, a reverse force must be applied. McKenzie adheres to the principle of PT education incorporating active patient involvement as one of the unique components and greatest strengths correlated with the success of MDT. The framework is based on 3 classifications, postural syndrome, dysfunction syndrome, and derangement syndrome, with the later the most common of the 3. The postural syndrome describes an impairment caused by prolonged poor posture or misalignment with gradual onset dull local pain. The dysfunction syndrome describes a more permanent adaptive shortening, scarring, or adherence of connective tissue with intermittent dull pain associated with end range movements. The derangement syndrome, most commonly identified, describes an impairment that experiences a change, either a reduction or exacerbated pain and radiating symptoms during evaluation. The underlying pathology is believed to be a misalignment of a joint component or displacement of the intervertebral disc causing nerve root compression. A typical derangement presentation is radiating numbness, paresthesia, sharp shooting pain, or burning in the low back and distally down the lower extremities. Thus, if the underlying pathology is structural in nature, the outcome is significant increase in pain with associated functional loss.

After the completion of the subjective history and a structured objective evaluation by the PT, a patient is assigned to 1 of the 3 classification categories used as the foundation for the POC. During an evaluation utilizing McKenzie principles, if centralization is achieved, the direction and movement pattern is
termed the patients directional preference, the patient is then classified under the
derangement syndrome and therapeutic interventions and the POC are developed
accordingly.1,25,26

The evaluation of a patient with NSLBP involves education regarding a
series of repeated movements and sustained static positions guided by the patients’
symptoms and subjective response. The goal of the evaluation is to identify the
directional preference and centralize the patients’ corresponding LBP and
symptoms. Conversely, if a movement promotes further peripheralization of pain
and radiating symptoms, these findings redirects the evaluation, indicating the
opposite direction may be beneficial.

Patterns of spinal movements include: repeated flexion, extension, lateral
flexion, rotation, or a combination of more than one.1 For the entire exam, the
patient is actively involved by controlling and performing the movements. This
active involvement significantly decreases fear avoidance and allows the patient to
feel and learn which movements increase pain, thus must be avoided, and which
movements reduce or abolish pain and should be repeated.1,26 For example, if the
patient has an anterior disc derangement, walking up hill and prolonged standing
will most often intensify pain and symptoms, while flexion based movements
alleviate the associated LBP. Individuals will be educated to avoid extension
based activities with the establishment of a POC based on a flexion movement
pattern. An essential aspect within the MDT philosophy arises from the timeline
of the directional preference. If identified during the evaluation and the patient
possess the ability to repeat an exercise or movement that quickly provides
symptom relief, adherence to the therapeutic POC significantly increases.27

The underlying anatomical framework behind the McKenzie Method is to
induce change by acting on the underlying spinal structures including vertebral
joints, soft tissue, and intervertebral disk material.\textsuperscript{1,26} Utilizing repeated movements in the identified directional preference acts internally by increasing the foraminal space, or repositioning a displaced nucleus pulposus protruding into the annulus fibrosus with the end result being a reduction in nerve root compression.\textsuperscript{1,26} A study done by Skytee et al.\textsuperscript{26} exemplifies these results. In a prospective comparative cohort study, 60 individuals with similar baseline characteristics suffering from sciatic pain, or possible disc herniation were enrolled and received a McKenzie evaluation utilizing repeated end range movement by a MII certified PT. In 25 individuals, a directional preference was identified with subsequent centralization, while the remaining 35 participants experienced no change in symptoms. Symptom response classified the participants into 2 groups, centralization (CG) and noncentralization (NCG). Each group received the same interventions and was followed for 1 year, reevaluating pain and disability at, 2, 3, and 12 months. At all re-evaluation intervals, the CG experienced significantly better outcomes in pain and improved function then the NCG. At the 2-month follow up improvements observed by the CG in leg pain (P = 0.007) and disability (P = <0.001), and at 12 months’ improvements in long-term disability was greatest in the CG (P = 0.029).\textsuperscript{26} More importantly the CG had less patients require surgery after experiencing centralization at the initial evaluation. The odds ratio for required surgical intervention was 6.2 for the NCG, with a total of 3 patients from the CG and 16 from the NCG.\textsuperscript{26} Patients who suffer from sciatica and possible disc herniation experienced significant improvements in pain and function after a centralization response and were 6 times less likely to need surgery to alleviate associated symptoms. Thus, these findings further support the argument that the McKenzie Method is an efficacious and cost effective conservative intervention for the treatment of acute NSLBP.
Regardless of the direction preference, if centralization is correctly identified during an evaluation, the utilization of repeated movements can dramatically reduce or abolish radiating distal shooting pain and numbness during the first visit\(^2\). For example, a patient experiences radiating lower extremity (LE) symptoms due to foraminal space degeneration causing spinal nerve root compression. The PT implements repetitive flexion movements that increases the foramina space decreasing nerve root compression, thus alleviating LE symptoms and centralizing symptoms. A skilled certified MDT clinician provides several advantages to the overall health care system. First, MDT clinicians routinely assess and identify differences between discogenic and non discogenic pain \(p<0.001\) and are competent in detecting an incompetent annulus \(p<0.042\), thus provide a superior and more cost effective diagnostic tool. This differentiation of pain syndromes presents tremendous cost saving in comparison to magnetic resonance imaging (MRI)\(^2\). Reports also suggest that patients with lumbar disc abnormalities avoid surgical intervention after achieving centralization from MDT based therapy\(^2\). To fully reveal the efficacy of MDT, 39 randomly selected patients with NSLBP underwent an MDT evaluation along with a MRI of L1-S1 to compare the clinical findings. Sensitivity of painful centralization was \([ES (95\% CI) = 0.91 (0.8-0.96)]\). The MDT intervention was effective, providing centralization in 94% of those who had discogenic MRI findings that would traditionally qualify for surgical intervention\(^2\). Based on the results researchers concluded that the centralization phenomenon is closely correlated with favorable treatment outcomes, and individuals with NSLBP should try conservative management with MDT based POC before seeking a surgical consult\(^2\).

The McKenzie Method was selected for this meta-analysis because of the overwhelming amount of efficacious literature and high rate of patient adherence
associated with this clinical intervention.\textsuperscript{1,26,30,31} Over the past decade, the McKenzie Method has been trending upward in recognition due to the significant amount of strong research produced reporting favorable patient outcomes when treating acute LBP.\textsuperscript{30} As the case when reviewing any treatment method or protocol in a research setting, it is extremely rare to find a favorable unanimous consensus. This factor remains true when reviewing the McKenzie Method because of the volume of literature that favors MDT patient outcomes far outnumbers those that negate its effect when treating LBP.\textsuperscript{30}

There is additional evidence that supports the McKenzie Method’s classification system and treatment protocols are superior to other commonly used conservative PT interventions when treating a patient with acute LBP.\textsuperscript{31} A systematic review of 6 randomized control trials (RCTs) conducted by Clare et al.\textsuperscript{31} examined the efficacy of the McKenzie Method versus commonly used interventions for the treatment of LBP using outcome measures of pain and physical function evaluated at pre-determined intervals using the VAS and SF-36 PF. The statistical analysis was conducted using the mean and standard deviation, and from these measures compiling a 95\% confidence interval (CI) for between group comparisons for each respected outcome measure and generating a grand effect size for analysis and comparison.\textsuperscript{31} Results showed the McKenzie group was superior in short-term pain reduction [ES (95\% CI) = -8.6 (-13.7, -3.5)] and improving function [ES (95\% CI) = -5.4 (-8.4, -2.4)] when compared to traditional interventions for acute NSLBP.\textsuperscript{31} Work absence due to LBP was evaluated between 3 to 12 months post injury and again the McKenzie Method was superior for reducing days missed [ES (95\% CI) = 0.81 (0.46, 1.44)].\textsuperscript{31} The study found that at the short-term follow up the success of the McKenzie group was highly correlated with the patients’ ability to self-treat their pain at home. The MDT
education and instruction provided by the PT gave the patient the tools and ability to regularly self-treat their pain, and more importantly, it created high adherence to the outlined POC ultimately leading to better outcomes.

In further comparison of techniques, PTs’ that utilized MDT techniques for LBP individuals experienced far greater patient outcomes for reducing pain and improving function when compared to those that received chiropractic manipulation and noninvasive modalities.\textsuperscript{32,33} There is strong literature support to prove the McKenzie Method is superior to a therapeutic POC based on core strengthening and stabilization exercises.\textsuperscript{34} Furthermore, comparing McKenzie to the commonly used passive therapy modalities for treating acute LBP, found that there are greater efficacy in terms of pain and function improvements.\textsuperscript{34,35} With a large array of new treatment protocols and interventions being introduced and taught yearly, clinicians are often inclined to implement the newest techniques into the treatment of LBP, even though there is minimal supporting evidence. A study by Long et al.\textsuperscript{36} documented that often when these new interventions fail to improve symptoms associated with LBP, clinicians often result back to MDT techniques to reverse course and achieve positive outcomes.

When analyzing the increasing incidence rates and financial burden placed on the health care system by LBP, it becomes clear that there is a gap in literature involving the management of new episodes of acute LBP. Are there more people experiencing LBP, are there just a greater percentage of people now seeking medical care, or are spine conditions becoming more complex and being treated with expensive ineffective outdated treatments?\textsuperscript{14} The driving force is most likely multifactorial and is heavily impacted by the aging U.S. population and societies heightened awareness, understanding of pain and increased willingness to seek medical care.\textsuperscript{14}
The results of this meta-analysis will directly relate to health care consumers and the field of physical therapy as it tries to fill the existing gap in the literature and practical treatment of acute NSLBP with the most efficacious and cost effective approach. As physical therapists transition to the group of practicing members of the first-line health care professionals, the McKenzie Method provides the clinician with the appropriate approach and skills to successfully assess and treat acute NSLBP. This meta-analysis will explore a foreground question with the following PICO question: In a patient population ages 18 to 80 years is the McKenzie Method a more effective intervention compared to a single educational session from a first-line health care professional in improving pain and function?

**Hypothesis**

The purpose of this meta-analysis is to compare a single educational session by a first-line health care professional for acute NSLBP versus seeking treatment from a PT utilizing the McKenzie Method. The null hypothesis of this meta-analysis is that there is no difference in the short-term in reducing pain and improving function between a single educational session by a first-line health care professional and a PT utilizing the McKenzie Method. The alternative hypothesis is that the McKenzie Method will show greater short-term improvements in reducing pain and increasing function when compared to a single educational session by a first-line health care professional. The expectation for this meta-analysis is that early intervention with physical therapy utilizing the McKenzie Method will statistically and clinically outperform the conventional treatment for acute NSLBP and establish a gold standard in the evaluation and treatment of this patient population.
METHODS

Search Criteria

This meta-analysis design was developed to abide with PRISMA standards and guidelines. The following databases were consulted for this meta-analysis: U.S. National Library of Medicine National Institutes of Health (PubMed), Cumulative Index of Nursing and Allied Health Literature (CINAHL) and Physiotherapy Evidence Database (PEDro). Keywords and mesh terms used in this search included “McKenzie Method [ti]”, “McKenzie method (AND) low back pain”, “McKenzie method (AND) acute low back pain”, “McKenzie method [ti] (AND) education”, “Low back pain (AND) education”, “first line care (AND) acute low back pain”, “McKenzie Method (AND) physical therapy”, “Centralization”, “Mechanical Diagnosis and Therapy” and “Extension exercises”. A manual search of previous systematic reviews and the McKenzie International Institute reference list was also conducted. The search was limited to randomized control trials published in peer-reviewed articles from 1984 to 2015 in the English language. The search was conducted within the limits of the inclusion and exclusion criteria.

Inclusion and Exclusion Criteria

Inclusion criteria for review involved adults ages 18-80 years old, participants experiencing acute to sub-acute NSLBP with or without radiating symptoms, duration of symptoms are greater than 2 days and less than 12 weeks, Mechanical Diagnosis and Therapy treatment provided by an MII credentialed therapist, single educational session with or without a provided booklet by a first-line health care professional, visual analog scale (VAS) for pain outcome measure, Short Form 36 Physical Function (SF-36 PF), Patient Specific Function Scale.
(PSFS), and Multidimensional Task Ability Profile (MTAP) for the functional outcome measures, and a follow-up within 12 months of treatment.

Studies were excluded if patients had chronic LBP, lumbar stenosis, spondylolisthesis, history of surgical interventions for LBP, pregnancy, cardiovascular or metabolic disease, osteoporosis, tumors, fibromyalgia, and presence of fractures or corticosteroid treatment within 2 weeks.

**Outcome Measures**

The visual analog scale (VAS) was utilized by all included studies to evaluate and track changes in pain levels from baseline measurement to the conclusion of the study. The VAS is the most commonly used self-reporting outcome measure for patients with acute LBP. Patients were asked to rate their pain levels on a numerical scoring based scale from 0-10, indicating no pain or worst possible pain, respectively. The VAS has excellent internal validity Cronbach’s alpha ($\alpha$) = 0.94, and good predictive validity of $r = 0.86$. The test retest reliability for the VAS for patients with LBP is excellent, and is considered reliable indicated by the interclass correlation coefficient (ICC) of 0.66 to 0.93 with a minimum clinically important difference (MCID) of 2 points.

In terms of multiple outcome measures, it has been previously demonstrated by Belogolovsky et al. that conducting a meta-analysis using statistical data from multiple outcome measures does not interfere or prevent from the accuracy of the meta-analysis as long as the mean and standard deviations are provided. The functional outcome measures used for the included studies were the Short Form 36 physical function (SF-36 PF) section, the Patient Specific Functional Scale (PSFS), and the Multidimensional Task Ability Profile (MTAP). The SF-36 PF is one of the most widely used self-reported health assessment
measure that is based on the patients’ perceived health and functional level. The data used for analysis were taken from the low back specific version of the SF-36 PF section. The assessment is a 36-item questionnaire that is subdivided into 8 separate categories, provides a cumulative score out of 100 with the lower the score indicating the greatest loss of function, while the higher the score indicates minimal loss of function. The SF-36 PF has excellent internal validity of $\alpha = 0.98$ and good predictive validity of $r = 0.81$. The test retest reliability for the SF-36 PF for patients with LBP is excellent, and is considered reliable as indicated by an ICC of 0.74 to 0.92 with a MCID of 12 points.

The PSFS is a commonly used self-reporting questionnaire utilized by PT’s due to its condensed length and ease to administer. The assessment categories are based on the most common desired daily activities. Scoring is on a ten-point scale based on patients’ current abilities, with 0 indicating that they are unable to perform and 10 indicating they are able to perform the activity at the same level prior to current episode of LBP. The PSFS has good predictive validity of $r = 0.73$, however it does not have internal validity established at this time. The test retest reliability for the PSFS for patients with LBP is excellent, and is considered reliable as indicated by an ICC of 0.86 to 0.91 with a MCID of 1 point.

The MTAP is an in depth and specific self-reporting assessment that is not commonly used because of the increased time to administer. The MTAP is a multi-section functional ability assessment that asks the patient their ability to perform 111 common physical tasks while rating using a 6-point scale, from 1 being able without limitation to 6 being unable to perform due to symptom limitation, with a cumulative score out of 200, a higher score indicating less limitation and higher functional ability. Data used for analysis were taken from the Spine section using the patients’ ratings of perceived capacity. The MTAP has excellent predictive
validity of \( r = 0.89 \), internal validity not established at this time.\(^{44}\) The test retest reliability for the MTAP for patients with LBP is excellent, and is considered reliable as indicated by an ICC of 0.87 to 0.97 with a MCID of 30 points.\(^{44}\)

**Data Collection**

All data utilized in this meta-analysis were collected from the results sections (intervention and outcomes tables) of each selected study. Data points were also extrapolated from graphs and charts as Mayer et al.\(^{45}\) visually presented results in graphs. The mean and standard deviations were used in calculating the statistical analysis portion of this meta-analysis.

**Quality Appraisal**

All studies used in the statistical analysis portion of this meta-analysis were scored using the 11-item PEDro scale. The PEDro scale was developed to evaluate the quality of physical therapy randomized control trials (RCT’s).\(^{46}\) Each satisfied item counts as 1 point to the total PEDro score except for item 1 which reflects external validity.\(^{46}\) Items 2-11 pertains to internal validity making the PEDro scale a 10-point scale (see Appendix C). The PEDro scale’s specific criterion helps identify the risk of bias in each study.\(^{46}\) A PEDro score of 8 out of 10 reflects a low risk of bias; a score of 5 to 7 reflects a moderate risk of bias, and a score of 4 or lower reflects a high risk of bias.\(^{46}\) Each study was evaluated for quality and risk of bias (see Table 1).

**Statistical Analysis**

Statistical analyses were conducted using the weighted mean difference to analyze the continuous variables. A p-value of \(<0.05\) was considered statistically significant with a 95% confidence interval (CI) for each outcome measure.
Homogeneity for each analysis was determined using the Q value in comparison with the degrees of freedom. If the Q value was smaller than the degrees of freedom, the included studies for that outcome measure were considered homogeneous. Alternatively, if the Q value was larger than the degrees of freedom the included studies were considered heterogeneous. When the Q value was deemed significant, a random effects model was used to determine the effect size for each of the outcome measures. Operational definitions for effect size have been established as small, medium, and large with respected cut-off values of 0.20, 0.50, and 0.80. Individual forest plots provide a visual representation of the effect size and the 95% confidence intervals for the within and between group comparison for each respected outcome measure, including the short and long-term follow up.
RESULTS

The initial database search for this meta-analysis produced 615 studies, of which 4 were determined appropriate for full text review. Figure 1 provides a visual overview of this study selection process. A detailed summary of characteristics for each of the 4 studies included in this meta-analysis can be referenced in Table 2. Three of the 4 studies were included for data analysis of the effects on short and long-term pain (i.e., Wand et al.35, Cherkin et al.48, and Machado et al.49), which assessed pain using the VAS. Mayer et al.45 was excluded for the pain analysis as the required data were unable to be extrapolated from its visual representation in the article. Short-term function was analyzed using data from Wand et al.35, Machado et al.49, and Mayer et al.45; Cherkin et al.48 was excluded from both short and long-term function analysis as the study did not report on function as an outcome measure. Each included study used a different outcome measure to assess function, but each provided the necessary means and standard deviations allowing the data to be synthesized and analyzed for statistical and clinical significance. Long-term function was analyzed using Wand et al.35 and Machado et al.49. Mayer et al.45 was removed as it only provided data for a 1 week follow up reevaluation.

McKenzie Method versus First-Line Care on Pain Intensity

After analysis, the within and between group comparison for pain reduction significantly favored the McKenzie Method in the short and long-term. Results of the within group comparison revealed that early intervention utilizing the McKenzie Method showed strong statistical significance for reducing short-term pain with a large grand effect size, [ES (95% CI) = -1.87 (-2.08, -1.65) p = 0.0026,
Q = 11.90] (see Figure 2). Statistical significance was confirmed by examining that the grand ES CI did not cross the zero axis on the associated forest plot. A large Q value of 11.90 with a small associated p value (p < 0.05) indicates heterogeneity, therefore the random-effects model was instituted in this analysis. Therefore, the results from the study cannot be extrapolated and generalized outside of this meta-analysis.

When the comparison was analyzed between the McKenzie Method and first-line care for reducing short-term pain, the McKenzie Method proved to be superior with a medium grand effect size, [ES (95% CI) = -0.48 (-0.68, -0.28) p = 0.43, Q = 1.66] (see Figure 3). Statistical significance was confirmed by examining that the grand ES CI did not cross the zero axis on the associated forest plot. A small Q value of 1.66 with a large associated p value (p > 0.05) indicates homogeneity throughout the compared studies in a fixed-effects model. Therefore, indicating the studies are similar and the results may be generalized to the target population.

The comparison was analyzed between the McKenzie Method and first-line care for reducing long-term pain and the McKenzie group again was superior with a medium effect size and statistical significance, [ES (95% CI) = -0.50 (-0.70, -0.30) p = 0.000048, Q = 19.86] (see Figure 4). Statistical significance was confirmed by examining that the grand ES CI did not cross the zero axis on the associated forest plot. A large Q value of 19.86 with a small associated p value (p < 0.05) indicates there is heterogeneity among the included studies in a random-effects model. Therefore, the results from the study cannot be extrapolated outside of this meta-analysis.
McKenzie Method versus First-Line Care on Function

After analysis, the between group comparison for improving function significantly favored the McKenzie Method in the short and long-term. In line with the results from the pain assessment when the comparison was analyzed between early intervention with the McKenzie Method and first-line care for improving short-term function the McKenzie Method proved to be superior with statistical significance and a medium effect size \[ ES (95\% CI) = 0.74 (0.49, 0.98) \]
\[ p = 0.000087, Q = 18.69 \] (see Figure 5). Statistical significance was confirmed by examining that the grand ES CI did not cross the zero axis on the associated forest plot. A large Q value of 18.69 with a small associated p value (p < 0.05) indicates there is heterogeneity among the included studies in a random-effects model. Therefore, the results from the study cannot be extrapolated outside of this meta-analysis.

When the comparison was analyzed between the McKenzie Method and first-line care for long-term function, the McKenzie group again was superior with statistical significance and a medium effect size, \[ ES (95\% CI) = 0.52 (0.26, 0.79) \]
\[ p = 0.021, Q = 5.26 \] (see Figure 6). Statistical significance was confirmed by examining that the grand ES CI did not cross the zero axis on the associated forest plot. A large Q value of 5.26 with a small associated p value (p < 0.05) indicates there is heterogeneity when using a random-effects model amongst the studies in this analysis. Therefore, the results from the study cannot be extrapolated outside of this meta-analysis.

Patient Safety and Associated Costs

The McKenzie Method is considered one of the safest evaluation and treatment methods available to physical therapist for treating patients with acute NSLBP. During an evaluation there is minimal hands-on contact when assessing
the patients’ symptoms as the therapists’ role is to guide the patient through a sequence of repeated movements with verbal cues and only tactile cues for proper execution of the movement pattern. This method allows the patient to control the entire movement: during the active range of motion (ROM) phase, and while the individual is generating force. This method promotes patients to listen to their body response during the entire evaluation or treatment and as an important factor to stop at any time they feel an increase in pain. The concept of patient controlled movements is unique to the McKenzie Method. Most of the commonly used assessment methods rely on therapist generated force to elicit a patient response which creates a situation of delay in the subjective response, thus the painful stimuli has already occurred. By allowing the patient complete control of the movement, it reduces fear avoidance allowing a less tense evaluation that results in more accurate objective findings.

Clinically, there are no additional fees or direct costs to the patient or PT to conduct an evaluation or treatment of a patient with acute NSLBP utilizing the McKenzie Method, as there is no specialized equipment or evaluation tools required to use MDT principles in the clinical setting. The only associated costs are those previously discussed for the education, clinical training, and credentialing exams required of the PT to become a certified MDT therapist, but these costs are absorbed by the PT and are not passed along to the patient or insurance payer. With multiple studies showing early intervention with PT for patients with acute LBP can speed recovery and reduce the overall number of therapy visits when compared to only seeking care from a GP, the McKenzie Method is not only an effective approach, it can reduce health care dependency and provide a significant cost saving for the patient and insurance payer per episode of spine care.\textsuperscript{22,50,51}
DISCUSSION

The objective of this meta-analysis was to evaluate the short and long-term effects of treating persons with acute NSLBP comparing the McKenzie Method philosophy to the conventional single educational intervention by a first-line health care professional. Results of this meta-analysis indicate that the McKenzie Method produced significantly greater outcomes in pain reduction and improved physical function in the short and long-term when compared to the conventional treatment of acute NSLBP. The results reject the null hypothesis of this meta-analysis and accept the alternative hypothesis. Based on the results it can be concluded that the McKenzie Method is most effective in improving associated LBP and function in the short-term with continued long-term benefits.

Study participants who received the MDT treatment intervention outperformed the control group in each predetermined reevaluation for outcome measures of reduced pain and improved functional ability. The McKenzie Method not only demonstrated greater improvements in pain and function, but produced these outcomes within 4 weeks of treatment with improved findings over the conventional first-line intervention. This conclusion is based on statistical analysis of 5 different comparisons with each yielding statistical significance. From the results, it can be inferred that the McKenzie Method produced greater improvement in outcome measures of pain and function in the short-term with maintained long-term benefits compared to first-line education. Additionally, the McKenzie Method contributes to an earlier return to work and individuals reach their previous level of activity compared to first line POC. The results of this meta-analysis meet the aforementioned expectation that early intervention utilizing the McKenzie Method will statistically and clinically outperform the conventional
treatment of acute NSLBP. Implementation of MDT principles and positive changes in the identified population provides support for the McKenzie Method potentially becoming a standard approach to be utilized to evaluate and treat acute NSLBP.

A closer analysis of the long-term effects further supports the benefits of early intervention utilizing the McKenzie Method compared to first-line education for an acute episode of NSLBP. With significant improvements of pain and function observed in the short-term MDT groups with associated long-term benefits focusing on maintaining progress and preventing a recurring episode of acute LBP. There were benefits to first-line education with improvements in pain and function short-term, albeit at a lesser rate than the McKenzie group. First-line education short-term improvements are attributed to rest, reduced activity, and an increased awareness of painful movements allowing the body to begin to heal. The major deficit of this approach is the absence of any long-term behavior or maintenance strategies. This typically results in patients experiencing a decrease in pain over a time period and resuming desired activates and work. This approach leads to high recurrence rate of another acute episode of LBP with the cycle leading to a likely chronic issue. As mentioned above one of the greatest strengths of the McKenzie Method is patient educational strategies of repeated movements to lessen pain and improve movement patterns. This not only provides the patient tools to continue to improve spine health independently and maintain clinical improvements, it reduces the risk of a reoccurring episode in the long-term.

**Heterogeneity of Studies**

Statistically speaking, homogeneity amongst the analyzed studies is required to confidently state that the results can be successfully generalized to the
target patient population. With homogeneity and statistical significance achieved for short-term pain, it requires further investigation as to why heterogeneity was observed for the other 4 analyses, when nearly all the same studies were included for each condition.

Heterogeneity describes the variability or differences in the effect sizes amongst the included studies. All studies met all the components of the PICO and inclusion criterion, but within each individual study variations in sample size, mean age of patients, standardized procedures for interventions, and environment were present.

The analysis clearly indicated that the Machado et al. study was a significant outlier and a probable cause for heterogeneity. In all comparisons, the results of each study favored the McKenzie group in all conditions, however, the Machado et al. study displayed far stronger positive effect compared to the others. Often in research, statistical outliers are viewed unfavorably, however, in this case, it may be cause for the support of the MDT evaluation and treatment approach. To better understand this line of thought, Machado et al. showed the highest Pedro score 8/10 (see Table 1), planned a meticulous study design, reduced threats to internal and external validity and implemented a standardization of procedural interventions across the study. For instance, PCPs involved in the study were gathered for an orientation and protocol training. The structured format of: a) the education and booklet provided and: b) the sequence of the first-line education session was established and standardized across the study. Although there was over a decade of experience reported for the included MDT certified PTs, further training was provided to ensure intervention standardization across the study. These training sessions involved a certified MII instructor who reviewed
key concepts and established a standardized approach with the PTs to complete their evaluation and follow up sessions.

A significant threat to the internal validity was the large variation in sample size and in the mean age, with Machado et al.\textsuperscript{49} and Cherkin et al.\textsuperscript{48} analyzing larger sample sizes and older patients compared to Mayer et al.\textsuperscript{45} and Wand et al.\textsuperscript{35} (see Table 2). All PTs involved in providing MDT treatments were certified by the MII, however there were possible discrepancies in the level of experience. Mayer et al.\textsuperscript{45} and Wand et al.\textsuperscript{35} did not reveal the levels of PT experience, whereas over a decade of experience was reported for Machado et al.\textsuperscript{49} and Cherkin et al.\textsuperscript{48} Experience has been noted to significantly impact the therapists’ ability to effectively and efficiently classify and treat LBP using MDT principles.\textsuperscript{52} The strongest threat to external validity was the variability of environmental settings for the evaluation and interventions and lack of standardization of the interventions. Examples are the one-time educational intervention was provided in office by a PCP in Machado et al.\textsuperscript{49} and Cherkin et al.\textsuperscript{48} and in the clinic by a PT for Mayer et al.\textsuperscript{45} and Wand et al.\textsuperscript{35} In addition, Machado et al.\textsuperscript{49} by a PCP, and Wand et al.\textsuperscript{35} by a PT provided a single first-line education session to the McKenzie group as well. All educational studies provided a one-time first-line educational session to stay active, avoid bed rest, and avoid painful movements. Each of these studies reported a single education session, albeit with varying degrees of low back care, proper lifting instruction, and each provided the patient with a different informational booklet regarding low back care. Amongst the 4 included studies Machado et al.\textsuperscript{49} was the only one who provided a training session for the involved PCPs in order to standardized the one-time education session across the study.
In an effort to maximize patient adherence, Machado et al.\textsuperscript{49} established a limit of 4 patient specific home exercises at any given time, which allowed for a significant reduction of variability within the treatment group. By inserting limitations, it strengthened the statistical outcomes that heavily favored the McKenzie group in all comparisons. A critical factor to the success of the McKenzie Method relies on patient exercise adherence. The study achieved a 75\% adherence rate, one of the most crucial and difficult aspects of any therapeutic intervention. While Cherkin et al.,\textsuperscript{48} Mayer et al.,\textsuperscript{45} and Wand et al.\textsuperscript{35} all reported high adherence rates within the McKenzie groups, none provided statistical data to support the observation. The overall results of Machado et al.\textsuperscript{49} provide an accurate representation of the effects of the McKenzie Method when treating acute NSLBP. Therefore, the stronger positive effect size results of the Machado study could be a possible source of heterogeneity identified within this meta-analysis.

While the McKenzie intervention achieved statistical significance through the process of meta-analysis, clinical significance was determined by identifying the raw scores for pain and functional outcomes and establishing if the scores were equal to or above the respective MCID scale. Minimum clinically important difference represents the minimum change in an outcome measure from the time of evaluation to the time of reevaluation; which from the patient’s perspective quantifies a clinical change in symptoms. In each study’s short-term intervention phase, pain and functional outcomes scores exceeded the MCID. Most notably was the rapid reduction of pain observed in all the short-term intervention follow up studies, in which the VAS MCID is 2 points.\textsuperscript{37,38} The average reduction of pain reported amongst the studies intervention group at the short-term follow-up using the VAS was 3.4 points, indicating a clinically important difference.\textsuperscript{35,48,49}
The same was observed when analyzing the scores for the functional assessments, even though 3 different assessments were used clinical significance was still achieved for each respected study. The MCID for the SF-36 PF is 12 points, and an average increase of 19 points was reported in the intervention groups.\textsuperscript{35,40,41} The MCID for the PSFS is 1 point, and an average increase of 2.5 points was reported.\textsuperscript{49,42,43} The MCID for the MTAP is 30 points, and an average of 40.1 points was reported.\textsuperscript{44,45} Demonstrating statistical significance is important from an evidence based approach, but more importantly, the relevant application of clinical success is determined by the use of outcome measures in comparison with the established MCID. The McKenzie Method proved to be statistically superior to a single first-line educational session, but more importantly produced greater clinical improvements in respect outcome measures of pain and function.

**Success Behind the McKenzie Method**

The level of educational and practical training of the MDT clinician is a significant factor in the success of producing favorable patient outcomes.\textsuperscript{30} A RCT by Brennan et al.\textsuperscript{53} analyzed the level of MDT training and education to ascertain if these factors had any effects on associated patient outcomes.\textsuperscript{53} The study was conducted in a large military facility with physical therapists showing varying degrees of knowledge or MDT training, but none had achieved certification from the MII. The results revealed a noticeable lack of MDT technical skill as 1,052 patients with LBP were evaluated and treated with only 123 establishing a directional preference and the associated centralization.\textsuperscript{53} Additional outcomes pointed to similar findings, as only 11\% of the included population experienced positive clinical outcomes with measures of pain and function.\textsuperscript{53} Due to
heterogeneity the results of this study were not generalizable to the patient population.

Further studies support the premise of therapist skill in the McKenzie Method as Werneke et al.\textsuperscript{54} analyzed the success rates of MII MDT certified clinicians at several outpatient facilities. Results demonstrated that extensive MDT education and training was the key to successful patient outcomes when treating acute LBP. Of the 725 patients considered, 692 (95\%) were correctly classified by their clinician, resulting in directional preference identification and subsequent centralization of symptoms.\textsuperscript{54} This further supports the notion that therapists’ MDT level of education and training directly correlates with the ability to effectively classify and treat patients with acute LBP and, as a result, achieve better patient outcomes. The inter-rater reliability of centralization amongst MDT credentialed clinicians is high, with a kappa value of 0.91-0.96.\textsuperscript{54,55} It has been shown that MII certified therapist are more easily and efficiently able to identify and properly classify each episode of LBP.\textsuperscript{52}

Pain factors in low back injury and has a cumulative effect which contributes to an immediate and forceful impact on the psychosocial level. The body’s natural response to a painful stimulus is to avoid movement or position changes that creates pain. This protective mechanism is essential immediately after an injury, however in the long-term it becomes problematic and contribute to loss of physical function due to fear avoidance behaviors. A study by Al-Obaidi et al.\textsuperscript{56} investigated the impact of the psychologic fear of pain as it pertains to recovering from an acute episode of LBP. The study examined 105 participants who received an MDT evaluation that either had partial or full centralization of pain. The patients were randomized into 2 groups and received the same MDT based intervention for 12 visits with evaluations at baseline, 5 weeks and 10
weeks. The psychologic role of pain was assessed using the Fear Avoidance Belief Questionnaire, with 1 group assessing physical activity (FABQ-PA) and the other work related tasks (FABQ-W). The aim of the FABQ is to measure the impact of the patients fear of pain with associated movements activities. Results showed that fear avoidance behaviors caused by pain, have a tremendous impact on low back injury recoveries. Both groups demonstrated significant reductions in fear scores with the greatest improvements observed between weeks 5 and 10 (FABQ-PA, p < 0.001; FABQ-W, p < 0.001). The gradual repeated movement based philosophy of the McKenzie Method used in this study allowed for patients to slowly initiate previously avoided movements in their available ROM. As a result, patients were able to regain lost ROM, significantly reduce fear avoidance behaviors with complete control of their movements, and eliminate the anticipation of pain. The improvement of these targeted aspects adds tremendous strength to the McKenzie Method and its ability to outperform first-line education for improving pain and function.

One of the greatest challenges to achieving successful outcomes is the degree by which patients adhere to an established POC and home exercise program (HEP). Though many studies within the current literature mention high levels of adherence for the McKenzie intervention group, there are no studies that specifically analyze adherence rates of MDT. Adherence, with respect to PT, is defined as the patients’ level of compliance to the detailed POC and HEP. Mirapeix et al. analyzed the elements, which demonstrate the greatest impact on patient adherence and found that level of supervision, education, and work load were highly correlated. Patients are 4 times more likely to adhere to the POC when the therapist provided direct supervision and consistent feedback of the patient when introducing a new exercise. Further, a HEP of 3 or fewer exercises had far
greater patient adherence compared to 6 or more (OR = 0.2, CI = 0.1-0.9, p < 0.05).57

In addition, Mirapeix et al.57 reported that the greatest obstacle to adherence was patients’ poor education on; 1) why they are doing the exercises and; 2) questioning if they are executing the movement properly.57 Although this study did not analyze the McKenzie Method, all of the elements identified by Mirapeix et al.57 are incorporated in the fundamental philosophy of the MDT. A prime example is the process of achieving centralization, in which the PT instructs the patient to perform 1 repeated movement in the directional preference. Assessment is performed before, during, and after the series of repeated movements with the therapist providing regular instruction and education to reassure patients and create an increased level of comfort. Optimal patient therapist interaction is a vital component of the MDT philosophy as continued education with direct verbal and tactile feedback creates a more conducive environment for patients. Immediate feedback on form correction or reassurance of proper execution of movements allows the patient to confidently explore the new movement patterns with reduced fear avoidance.

Clinical Implications

The strengths associated with the utilization of the McKenzie Method in the management of acute NSLBP have a global impact on multiple areas of patient care. With MDT principles found throughout the CPGs, the McKenzie Method provides an excellent systematic approach for treating LBP that is recommended based on strong evidence.19 The MDT assessment method allows clinicians to safely search for directional preference and centralization with patients in great pain, that may not tolerate hands on interventions, due to the passive nature of the
evaluative repeated movements controlled by the patient.\textsuperscript{31,33} The ability for the patients to learn and understand the benefits of the repeated movements in the established directional preference is one of the strongest components of the McKenzie Method. Although there is no definitive research that focuses on patient compliance, MDT is widely viewed to have strong adherence rates. McKenzie himself stated: “self-treatment is the best way to achieve a lasting improvement of back pain.”\textsuperscript{23,24} Based on this concept, McKenzie created a model that educates and provides the patient the tools to self-treat with unlimited frequency.

Costs

In 2010, 4 of 5 patients with new cases of acute NSLBP chose to visit their PCP for initial medical services. This patient ratio accounted for 78\% of all annual medial visits associated with new episodes of acute NSLBP.\textsuperscript{58} Along with the single educational intervention provided, the PCP often will require a series of costly radiographs and possible magnetic resonance imaging (MRI) before proving a diagnosis and secondary referral for specialized treatment, including PT. Further research has demonstrated that a skilled MDT certified clinician, utilizing the McKenzie assessment procedures, is as reliable as the aforementioned costly diagnostic imaging to identify structural abnormalities and determine the underlying source of the LBP symptoms.\textsuperscript{30,54} It is reported that a reduction of $2,736.23 per episode of care for new cases of acute NSLBP is possible when utilizing direct access for PT immediately after the injury occurs.\textsuperscript{58} If the entire 78\% of patients who visited their PCP in 2010 would have sought treatment by a PT through direct accesses, it would have translated to a total health care savings of $110 billion for the calendar year.\textsuperscript{58}
Limitations

Multiple variables limited the meta-analysis, the most significant limitation being the lack of RCTs available for analysis. Although research for CLBP is abundant in the literature, little has been done with respect to the acute phase. This gap in the literature was; 1) one of the motivating factors for this meta-analysis and; 2) served as a main challenge for finding quality research for analysis. Two other quality studies by Malmivaara et al.\textsuperscript{59} and Paatelma et al.\textsuperscript{60} showed favorable outcomes for the McKenzie Method. Both studies met all criteria for inclusion for MDT interventions, however they were excluded as means and standard deviations were not provided. Limitations within the included literature were a lack of consistent outcomes measures, although means and standard deviations were provided, a random effects model was required for analysis to account for the variability. The inclusion age range for most of the studies was large, ranging from 18-80 years old with the mean age of participants different for each, which can have an impact on healing rate and response to treatment. One of the largest variations between the included studies was the predetermined short-term reassessment time-frames, ranging from 1 week to 6 weeks for the first follow-up after initiating the intervention.

Implications for Future Research

Additional research is required for the McKenzie Method to be determined as the gold standard for the evaluation and treatment of patients with acute NSLBP. Consistency in future studies is crucial for comparison of results. Some examples are that researchers must consider establishing a standard protocol for evaluation and interventions across the study; consistent assessment tools for outcome measures; consistent study duration and reassessment intervals for short
and long-term comparison; subdividing populations by closer age ranges; and most importantly, providing raw data for future statistical analysis.

**Conclusion**

In conclusion, this meta-analysis identified the McKenzie Method as an effective evaluation and treatment approach for reducing pain and improving function in patients with acute NSLBP. The results from the statistical analysis favored the intervention of MDT over traditional conservative care from a first-line health care provider in all 5 comparisons. Patients who received MDT treatment experienced a more significant improvement of pain and function in the short-term and in the long-term effects when compared to a single education intervention by a PCP. The core principle and theory of the McKenzie Method are approved by the APTA CPG and are strengthened based on the evidence in the literature. The results suggest seeking treatment from an MDT certified PT through direct access yields better patient outcomes and can potentially reduce the financial burden to the patient and the U.S. health care system per episode of low back care.
REFERENCES


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<tr>
<td>Eligibility Criteria</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Random Allocation</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Concealed Allocation</td>
<td>X</td>
<td>X</td>
<td></td>
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<td>Baseline Comparability</td>
<td>X</td>
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<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Blind Subjects</td>
<td></td>
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<tr>
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<td></td>
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<tr>
<td>Blind Assessors</td>
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<td>X</td>
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<tr>
<td>Adequate Follow-up</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Intention-to-Treat Analysis</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Between-group Analysis</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Point Estimates &amp; Variability</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>TOTAL SCORE</td>
<td>8/10</td>
<td>8/10</td>
<td>6/10</td>
<td>6/10</td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>Sample Size (N)</td>
<td>Mean Age</td>
<td>Intervention Measure</td>
</tr>
<tr>
<td>---------------------</td>
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</tr>
<tr>
<td>Cherkin et al. 1998</td>
<td>Level 1 RCT</td>
<td>McK= 133 Education= 66</td>
<td>McK= 41.8 ± 11.5</td>
<td>Education¶: 1 time educational intervention from PCP</td>
</tr>
<tr>
<td>Machado et al. 2010</td>
<td>Level 1 RCT</td>
<td>McK= 73 Education= 73</td>
<td>McK= 47.5 ± 14.4</td>
<td>Education= Guidelines from PCP to stay active, avoid bed rest, reassure of favorable outcomes and instructions to take acetaminophen on a routine basis. 1 time visit with a 3-week follow up.</td>
</tr>
<tr>
<td>Mayer et al. 2005</td>
<td>Level 1 RCT</td>
<td>McK= 25 Education= 26</td>
<td>McK= 32.6 ± 10.3</td>
<td>Education¶: 1 time educational intervention from a PT</td>
</tr>
<tr>
<td>McK et al. 2004</td>
<td>Level</td>
<td>McK=</td>
<td>McK=</td>
<td>McK= At Discretion of therapist</td>
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</tr>
<tr>
<td></td>
<td>1 RCT</td>
<td>43</td>
<td>34 ± 9</td>
<td>At Discretion of therapist</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Education= 51</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Guidelines to stay active, continue normal activities from a PT</td>
</tr>
</tbody>
</table>

McK= McKenzie Group, VAS= Visual Analogue Scale, PCP= Primary Care Physician, PT= Physical Therapist

* Patients were provided educational booklet, *Back in Action: A Guide to Understanding your Low Back Pain and Learning What You Can Do About It*.

† Patients were provided educational booklet, *Acute Low Back Problems in Adults, Patient Guide: Understanding Acute Low Back Problems*. 
FIGURES
Figure 1. Search method consort of article inclusion and exclusion for statistical analysis
Figure 2. Data analysis of short-term VAS comparing within group McKenzie studies at pre and post with effect size and confidence intervals.

GES= Grand Effect Size, CI= Confidence Interval, DF= Degrees of Freedom
McKenzie vs. First-Line Between Group: Short-Term Pain

Figure 3. Data analysis of short-term VAS comparing McKenzie and First-line Care studies with effect size and confidence intervals

GES= Grand Effect Size, CI= Confidence Interval, DF= Degrees of Freedom
McKenzie vs. First-Line Between Group: Long-Term Pain

Figure 4. Data analysis of long-term VAS comparing McKenzie and First-line Care studies with effect size and confidence intervals

GES= Grand Effect Size, CI= Confidence Interval, DF= Degrees of Freedom
Figure 5. Data analysis of short-term function comparing McKenzie and First-line Care studies with effect size and confidence intervals

GES= Grand Effect Size, CI= Confidence Interval, DF= Degrees of Freedom
McKenzie vs. First-Line Between Group: Long-Term Function

Figure 6. Data analysis of long-term function comparing McKenzie and First-line Care studies with effect size and confidence intervals

GES= Grand Effect Size, CI= Confidence Interval, DF= Degrees of Freedom
APPENDIX A: CLASSIFICATION SYSTEM FOR NSLBP$^{18}$
<table>
<thead>
<tr>
<th>Syndrome</th>
<th>Definition</th>
<th>Minimal Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disc Syndrome</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A. Mechanical Reducible Disc</td>
<td>Low back and/or referred pain assumed to be caused by a displacement of the contents of an intervertebral disc that is reversible by specific mechanical loading strategies</td>
<td>At least 1 movement is painfully limited. Either there are mechanical loading strategies that centralize the symptoms from the most distal component of the pain distribution. Or isolated midline low back pain is decreased and remains better by the application of a loading strategy in 1 direction, and a loading strategy in another direction increases midline pain that remains worse and/or produces a limitation of movement.</td>
</tr>
<tr>
<td>B. Mechanical Irreducible disc</td>
<td>Low back and/or referred pain assumed to be caused by a displacement of the contents of an intervertebral disc that are not reversible by mechanical loading strategies.</td>
<td>At least 1 movement is painfully limited. There are no mechanical loading strategies that centralize, decrease and/or abolish symptoms so that they remain better as a result. Either at least 1 mechanical loading strategy peripheralize the symptoms to a more distal component or the symptoms referred into the foot are increased and remain worse by the application of a loading strategy, and a limitation of movement is produced or increased.</td>
</tr>
<tr>
<td>C. Non-Mechanical Disc</td>
<td>Low back pain with or without referred pain with dominant symptoms above</td>
<td>The criteria for reducible and irreducible mechanical disc are not satisfied. Mechanical loading strategies in any direction increase the</td>
</tr>
</tbody>
</table>
the gluteal fold in which the principal source of nociceptor receptor activity is assumed to be a chemically sensitive intervertebral disc and no evidence for a mechanical disc lesion exists.

<table>
<thead>
<tr>
<th>Adherent Nerve Root Syndrome</th>
<th>Dominant symptoms below the gluteal fold with limited nerve root mobility assumed to be caused by fibrosis or scarring involving 1 or more lumbosacral nerve roots.</th>
<th>History of acute sciatica at least 2 months ago or lumbar spine surgery. Flexion in standing is limited and produces the lower limb symptoms at the end of the available movement range that is not rapidly altered by mechanical loading strategies. Repeated flexion in standing reproduces the symptoms with each movement but they do not remain worse as a result. Extension in standing or lying, and flexion in lying do not produce the symptoms.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nerve Root Entrapment Syndrome</td>
<td>Dominant symptoms below the gluteal fold assumed to be caused by a persistent compression and movement limitation of a lumbar nerve root.</td>
<td>The criteria for reducible and irreducible mechanical disc and adherent nerve root are not satisfied. History of acute disc lesion causing nerve root symptoms for at least 2 months. Flexion in standing is limited and produces or increases the lower limb symptoms. Repeated flexion in standing</td>
</tr>
</tbody>
</table>
reproduces or increases the symptoms but they do not remain worse as a result. Repeated flexion in standing may cause an increase in movement range but this is temporary and does not remain better as a result. There are no mechanical loading strategies that centralize, decrease or abolish the lower limb symptoms so that they remain better as a result.

| Nerve Root Compression Syndrome | Dominant symptoms below the gluteal fold assumed to be caused by a compression of a nerve root that is not made worse or better by mechanical loading strategies. | The criteria for reducible and irreducible mechanical disc lesion, adherent nerve root, and nerve root entrapment are not satisfied. The straight leg raise test is positive (familiar lower limb symptoms are produced below 60 degrees of elevation) and at least 1 of the following is present in the corresponding myotome/dermatome:
• hip flexion weakness (L2/L3)
• Knee extension weakness (L3/L4)
• Ankle dorsiflexion weakness (L4–L5)
• Great toe dorsiflexion weakness (L5)
• Hip extension weakness (L4/L5–S1/S2)
• Knee flexion or great toe extension weakness (L5–S1)
• Ankle plantar flexion weakness (S1–S2)
• Patellar tendon reflex weakness (L4) |
<table>
<thead>
<tr>
<th>Section</th>
<th>Symptoms Description</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spinal Stenosis</td>
<td>Dominant symptoms below the gluteal fold that are assumed to be secondary to a narrowing of the lumbar spinal canal or a lumbar intervertebral foramen.</td>
<td>The criteria for reducible and irreducible mechanical disc, adherent nerve root, nerve root entrapment, and nerve root compression are not satisfied. History of standing or walking intolerance. Symptoms are improved when seated or there is improved walking tolerance with the spine in flexion. Best posture with regard to symptoms is sitting or worst postures with regard to symptoms are standing or walking.</td>
</tr>
</tbody>
</table>
| Zygapophysial Joint Syndrome  | Low back pain with or without referred pain with dominant symptoms above the gluteal fold in which the principal source of nociceptor receptor activity is assumed to be a zygapophysial joint. | The criteria for disc syndrome are not satisfied. Pain well-relieved by lying down and the presence of at least 4 of the following criteria:  
- Age greater than 65 years  
- Pain not increased by coughing  
- No pain with flexion in standing  
- Pain not increased by rising from flexion  
- Pain not increased by extension/rotation  
- Pain not increased by extension in standing. |
<p>| Postural Syndrome             | Low back pain with or without referred pain with dominant symptoms above             | Full range of motion in all directions. No pain with any movement. Repeated dynamic end range loading does not produce the |</p>
<table>
<thead>
<tr>
<th>Syndrome</th>
<th>Symptoms</th>
<th>Criteria</th>
</tr>
</thead>
</table>
| Sacroiliac Joint Syndrome | Low back pain with or without referred pain with dominant symptoms above the gluteal fold in which the principal source of nociceptor receptor activity is assumed to be a sacroiliac joint. | The criteria for disc syndrome, zygapophysial joint syndrome, and postural syndrome are not satisfied. Three or more of 5 sacroiliac joint pain provocation tests are positive:  
• Distraction  
• Compression  
• Thigh thrust (posterior shear)  
• Pelvic torsion (Gaenslen’s test)  
• Sacral thrust. |
| Dysfunction Syndrome | Low back pain with or without referred pain with dominant symptoms above the gluteal fold assumed to result from mechanical deformation by end range loading of innervated shortened soft tissues. | The criteria for disc syndrome, zygapophysial joint syndrome, postural syndrome, and sacroiliac joint syndrome are not satisfied. At least 1 movement is limited in range that is not rapidly altered by mechanical loading strategies. The limited movement produces familiar symptoms only at the end of the available movement range. End range loading in the painfully limited direction of motion does not progressively increase or peripheralize the symptoms and the symptoms do not remain worse. |
Repeated or sustained end range loading in the painfully limited direction does not rapidly produce limitation of movement range in any other direction.

<table>
<thead>
<tr>
<th>Myofascial Pain Syndrome</th>
<th>Low back and/or referred pain with dominant symptoms above or below the gluteal fold assumed to result from a hyperirritable point in a skeletal muscle or fascia that is painful on compression and can give rise to referred pain in a characteristic area.</th>
<th>Firm palpation of a painful point within a taut band in a specific muscle reproduces familiar symptoms.</th>
</tr>
</thead>
</table>
| Adverse Neural Tension Syndrome          | Low back and/or referred pain assumed to result from abnormal physiological and mechanical responses produced from nervous system structures when their range of movement and stretch capabilities are challenged.                                                                 | Familiar symptoms are reproduced by at least 2 stages of neural testing:  
  - Straight leg raise with cervical flexion or slump test  
  - Side lying knee bending test (femoral nerve stretch test) |
<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormal Pain Syndrome</td>
<td>Maladaptive overt illness-related behavior disproportionate to the underlying physical disease and more readily attributable to associated cognitive and affective disturbances.</td>
<td>At least 3 of 5 tests of non-organic signs are positive:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Widespread superficial or non-anatomic tenderness</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Pain provocation on axial loading or simulated rotation of the back</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Straight leg raise improved at least 30 degrees with distraction</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Regional muscle weakness or sensory disturbances in non-anatomic distribution</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Overreaction during examination.</td>
</tr>
<tr>
<td>Inconclusive</td>
<td>Non-specific low back pain patients not included in any of the above listed classes.</td>
<td>Categories 1 to 9 are mutually exclusive, however they may coexist with categories 10 to 12.</td>
</tr>
</tbody>
</table>
APPENDIX B: CLINICAL PRACTICE GUIDELINES LINKED TO THE INTERNATIONAL CLASSIFICATION OF FUNCTIONING, DISABILITY AND HEALTH FROM THE ORTHOPAEDIC SECTION OF THE AMERICAN PHYSICAL THERAPY ASSOCIATION19
<table>
<thead>
<tr>
<th>Intervention</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual therapy</td>
<td>Clinicians should consider utilizing thrust manipulative procedures to reduce pain and disability in patients with mobility deficits and acute low back and back-related buttock or thigh pain. Thrust manipulative and non-thrust mobilization procedures can also be used to improve spine and hip mobility and reduce pain and disability in patients with subacute and chronic low back and back-related lower extremity pain.</td>
</tr>
<tr>
<td>Trunk coordination, strengthening, and endurance exercises</td>
<td>Clinicians should consider utilizing trunk coordination, strengthening, and endurance exercises to reduce low back pain and disability in patients with subacute and chronic low back pain with movement coordination impairments and in patients post lumbar microdiscectomy.</td>
</tr>
<tr>
<td>Centralization and directional preference exercises and procedures</td>
<td>Clinicians should consider utilizing repeated movements, exercises, or procedures to promote centralization to reduce symptoms in patients with acute low back pain with referred lower extremity pain. Clinicians should consider using repeated exercises in a specific direction determined by treatment response to improve mobility and reduce symptoms in patients with acute, subacute, or chronic low back pain with mobility deficits.</td>
</tr>
<tr>
<td>Flexion exercises</td>
<td>Clinicians can consider flexion exercises, combined with other interventions such as manual therapy, strengthening exercises, nerve mobilization procedures, and progressive walking, for reducing pain and disability in older patients with chronic low back pain and radiating pain.</td>
</tr>
<tr>
<td>Lower-quarter nerve mobilization procedures</td>
<td>Clinicians should consider utilizing lower-quarter nerve mobilization procedures to reduce pain and disability in patients with subacute and chronic low back pain and radiating pain.</td>
</tr>
<tr>
<td>Traction</td>
<td>There is conflicting evidence for the efficacy of</td>
</tr>
</tbody>
</table>
intermittent lumbar traction for patients with low back pain. There is preliminary evidence that a subgroup of patients with signs of nerve root compression along with peripheralization of symptoms or a positive crossed straight leg raise will benefit from intermittent lumbar traction in the prone position. There is moderate evidence that clinicians should not utilize intermittent or static lumbar traction for reducing symptoms in patients with acute or subacute, nonradicular low back pain or patients with chronic low back pain.

**Patient education and counseling**

Clinicians should not utilize patient education and counseling strategies that either directly or indirectly increase the perceived threat or fear associated with low back pain, such as education and counseling strategies that (1) promote extended bed-rest or (2) provide in-depth, pathoanatomical explanations for the specific cause of the patient’s low back pain. Patient education and counseling strategies for patients with low back pain should emphasize (1) the promotion of the understanding of the anatomical/structural strength inherent in the human spine, (2) the neuroscience that explains pain perception, (3) the overall favorable prognosis of low back pain, (4) the use of active pain coping strategies that decrease fear and catastrophizing, (5) the early resumption of normal or vocational activities, even when still experiencing pain, and (6) the importance of improvement in activity levels, not just pain relief.

**Progressive endurance exercise and fitness activities**

Clinicians should consider (1) moderate-to-high intensity exercise for patients with chronic low back pain without generalized pain, and (2) incorporating progressive, low-intensity, submaximal fitness and endurance activities into the pain management and health promotion strategies for patients with chronic low back pain with generalized pain.
APPENDIX C: PEDRO SCALE
### PEDro scale

<p>| | |</p>
<table>
<thead>
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<tbody>
<tr>
<td>1.</td>
<td>eligibility criteria were specified</td>
</tr>
<tr>
<td></td>
<td>no</td>
</tr>
<tr>
<td>2.</td>
<td>subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated as order in which treatments were received)</td>
</tr>
<tr>
<td></td>
<td>no</td>
</tr>
<tr>
<td>3.</td>
<td>allocation was concealed</td>
</tr>
<tr>
<td></td>
<td>no</td>
</tr>
<tr>
<td>4.</td>
<td>the groups were similar at baseline regarding the most important prognostic indicators</td>
</tr>
<tr>
<td></td>
<td>no</td>
</tr>
<tr>
<td>5.</td>
<td>there was blinding of all subjects</td>
</tr>
<tr>
<td></td>
<td>no</td>
</tr>
<tr>
<td>6.</td>
<td>there was blinding of all therapists who administered the therapy</td>
</tr>
<tr>
<td></td>
<td>no</td>
</tr>
<tr>
<td>7.</td>
<td>there was blinding of all assessors who measured at least one key outcome</td>
</tr>
<tr>
<td></td>
<td>no</td>
</tr>
<tr>
<td>8.</td>
<td>measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups</td>
</tr>
<tr>
<td></td>
<td>no</td>
</tr>
<tr>
<td>9.</td>
<td>all subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”</td>
</tr>
<tr>
<td></td>
<td>no</td>
</tr>
<tr>
<td>10.</td>
<td>the results of between-group statistical comparisons are reported for at least one key outcome</td>
</tr>
<tr>
<td></td>
<td>no</td>
</tr>
<tr>
<td>11.</td>
<td>the study provides both point estimates and measures of variability for at least one key outcome</td>
</tr>
<tr>
<td></td>
<td>no</td>
</tr>
</tbody>
</table>

The PEDro scale is based on the Delphi list developed by Verhagen and colleagues at the Department of Epidemiology, University of Maastricht (Verhagen AP et al 1998). The Delphi list: a criteria list for assessing the quality of randomized clinical trials for conducting systematic reviews developed by Delphi consensus. Journal of Clinical Epidemiology, 51(12):1235-41. The list is based on “expert consensus” not, for the most part, on empirical data. Two additional items not on the Delphi list (PEDro scale items 8 and 10) have been included in the PEDro scale. As more empirical data comes to hand it may become possible to “weight” scale items so that the PEDro score reflects the importance of individual scale items.

The purpose of the PEDro scale is to help the users of the PEDro database rapidly identify which of the known or suspected randomised clinical trials (i.e. RCTs or CCTs) archived on the PEDro database are likely to be internally valid (criteria 2-9), and could have sufficient statistical information to make their results interpretable (criteria 10-11). An additional criterion (criterion 1) that relates to the external validity (or “generalisability” or “applicability” of the trial) has been retained so that the Delphi list is complete, but this criterion will not be used to calculate the PEDro score reported on the PEDro web site.

The PEDro scale should not be used as a measure of the “validity” of a study’s conclusions. In particular, we caution users of the PEDro scale that studies which show significant treatment effects and which score highly on the PEDro scale do not necessarily provide evidence that the treatment is clinically useful. Additional considerations include whether the treatment effect was big enough to be clinically worthwhile, whether the positive effects of the treatment outweigh its negative effects, and the cost-effectiveness of the treatment. The scale should not be used to compare the “quality” of trials performed in different areas of therapy, primarily because it is not possible to satisfy all scale items in some areas of physiotherapy practice.

Last amended June 21st, 1999
Notes on administration of the PEDro scale:

All criteria Points are only awarded when a criterion is clearly satisfied. If on a literal reading of the trial report it is possible that a criterion was not satisfied, a point should not be awarded for that criterion.

Criterion 1 This criterion is satisfied if the report describes the source of subjects and a list of criteria used to determine who was eligible to participate in the study.

Criterion 2 A study is considered to have used random allocation if the report states that allocation was random. The precise method of randomisation need not be specified. Procedures such as coin-tossing and dice-rolling should be considered random. Quasi-randomisation allocation procedures such as allocation by hospital record number or birth date, or alternation, do not satisfy this criterion.

Criterion 3 Concealed allocation means that the person who determined if a subject was eligible for inclusion in the trial was unaware of which group the subject would be allocated to. A point is awarded for this criteria, even if it is not stated that allocation was concealed, when the report states that allocation was by sealed opaque envelopes or that allocation involved contacting the holder of the allocation schedule who was “off-site”.

Criterion 4 At a minimum, in studies of therapeutic interventions, the report must describe at least one measure of the severity of the condition being treated and at least one (different) key outcome measure at baseline. The rater must be satisfied that the groups’ outcomes would not be expected to differ, on the basis of baseline differences in prognostic variables alone, by a clinically significant amount. This criterion is satisfied even if only baseline data of study completers are presented.

Criteria 4, 7-11 Key outcomes are those outcomes which provide the primary measure of the effectiveness (or lack of effectiveness) of the therapy. In most studies, more than one variable is used as an outcome measure.

Criterion 5-7 Blinding means the person in question (subject, therapist or assessor) did not know which group the subject had been allocated to. In addition, subjects and therapists are only considered to be “blind” if it could be expected that they would have been unable to distinguish between the treatments applied to different groups. In trials in which key outcomes are self-reported (eg, visual analogue scale, pain diary), the assessor is considered to be blind if the subject was blind.

Criterion 8 This criterion is only satisfied if the report explicitly states both the number of subjects initially allocated to groups and the number of subjects from whom key outcome measures were obtained. In trials in which outcomes are measured at several points in time, a key outcome must have been measured in more than 85% of subjects at one of those points in time.

Criterion 9 An intention to treat analysis means that, where subjects did not receive treatment (or the control condition) as allocated, and where measures of outcomes were available, the analysis was performed as if subjects received the treatment (or control condition) they were allocated to. This criterion is satisfied, even if there is no mention of analysis by intention to treat, if the report explicitly states that all subjects received treatment or control conditions as allocated.

Criterion 10 A between-group statistical comparison involves statistical comparison of one group with another. Depending on the design of the study, this may involve comparison of two or more treatments, or comparison of treatment with a control condition. The analysis may be a simple comparison of outcomes measured after the treatment was administered, or a comparison of the change in one group with the change in another (when a factorial analysis of variance has been used to analyse the data, the latter is often reported as a group x time interaction). The comparison may be in the form hypothesis testing (which provides a "p" value, describing the probability that the groups differed only by chance) or in the form of an estimate (for example, the mean or median difference, or a difference in proportions, or number needed to treat, or a relative risk or hazard ratio) and its confidence interval.

Criterion 11 A point measure is a measure of the size of the treatment effect. The treatment effect may be described as a difference in group outcomes, or as the outcome in (each of) all groups. Measures of variability include standard deviations, standard errors, confidence intervals, interquartile ranges (or other quantile ranges), and ranges. Point measures and/or measures of variability may be provided graphically (for example, SDs may be given as error bars in a Figure) as long as it is clear what is being graphed (for example, as long as it is clear whether error bars represent SDs or SEs). Where outcomes are categorical, this criterion is considered to have been met if the number of subjects in each category is given for each group.
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