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Comparing the Treatment of Low Back Pain in Working Adults Using the McKenzie Method or Manual Therapy to Decrease Pain and Increase Function as Measured by Effect Size, Number Needed to Treat, the Visual Analogue Scale and a Standardized Functional Outcome Assessment Tool

Disciplines

Physical Therapy

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CRITICALLY APPRAISED TOPIC -TREATMENT-

Title: Comparing the Treatment of Low Back Pain in Working Adults Using the McKenzie Method or Manual Therapy to Decrease Pain and Increase Function as Measured by Effect Size, Number Needed to Treat, the Visual Analogue Scale and a Standardized Functional Outcome Assessment Tool

Clinical Scenario: The patient who led us to pursue this question was a 62 year old female with a medical diagnosis of piriformis syndrome and gait abnormality. The medical treatment to date included prescribed medications and physician's advice. The physical therapy diagnosis was low back pain (LBP), bilateral lower extremity (LE) pain, poor balance, and gait abnormality. The patient responded well to the McKenzie extension approach at the first visit and was instructed to perform extension-in-lying 10 times every 2-3 hours at home. At her next visit, two weeks later, she had improved slightly and responded to manual overpressure performed by the physical therapist with increased motion and decreased pain. Two weeks later, however, her symptoms had worsened and she reported that she had returned to the physician and is scheduled to have an MRI.

Brief introduction: For the purposes of our clinical question, we want to know what the research supports regarding the effect of using the McKenzie method in treating patients with LBP, as compared to using a manual therapy approach. Though we were taught the Maitland manual therapy approach to treating LBP and related symptoms, we have frequently encountered the utilization of the McKenzie method in the clinic. We would like to know which is most effective and efficient.

Our Clinical Question: Is the McKenzie method or manual therapy a more effective intervention for the treatment of working adults experiencing LBP to decrease pain and improve function at the completion of treatment and at one year follow-up as measured by the Effect Size, Number Needed to Treat (NNT), Visual Analogue Scale (VAS), and a standardized functional outcome assessment tool such as the Oswestry Disability Index (ODI), Patient Specific Functional Scale (PSFS), or the Roland-Morris Questionnaire (RMQ)?

Clinical Question PICO:

Population - Working adult patients 18-65 years of age with acute, subacute, or chronic LBP, which may or may not include pain into the LEs; systemic illness, psychosocial yellow flags, pregnancy, or previous lumbar surgeries are excluded

Intervention - McKenzie method, including a home exercise program (HEP) according to the patient's directional preference

Comparison - Manual therapy, which encompasses stretching, soft tissue mobilization, spinal mobilization, and spinal manipulation, along with a HEP

Outcome - Effect size, NNT, change in LBP as measured by the VAS, and change in functional ability as measured by a standardized functional outcome assessment tool such as the ODI, PSFS, or the RMQ to be determined at the completion of treatment and at one year follow-up

Overall Clinical Bottom Line: Based on the results of the outcomes from Paatelma *et al.*, Petersen *et al.*, and Schenk *et al.* there is weak evidence in support of treating LBP with the McKenzie method, as compared to manual therapy. Though subjects treated with either method experienced decreased pain as well as functional improvement, those in the McKenzie group had better outcomes overall. This evidence included an effect size of 0.33 favoring the McKenzie method in functional improvements, according to the Paatelma, *et al.* study. A NNT of 8.89 for the McKenzie group was found for functional improvements in the Petersen *et al.* study. Finally, the Schenk *et al.* study found a NNT of 2.33 for the McKenzie group in decreased pain. The internal validity of the studies was good, with the main uncontrolled threat being extraneous variables. One of the studies also lacked power due to having a small

sample size. We feel confident that we can generalize the results to our patient population because overall the studies included subjects similar in age to our clinical population with acute, subacute, and chronic LBP. On the other hand, convenience sampling was used for all of the studies, resulting in a less diverse patient population. Because manual therapy is such a broad category of treatment, we would be unable to replicate the progression of techniques used by the clinicians in these studies. Further research should be done comparing the McKenzie method to a specific approach of manual therapy, such as the Maitland Approach.

Search Terms: McKenzie, mechanical diagnosis and therapy, lumbar spine, low back pain, manual therapy, manipulation

Appraised By: Anne Jeffery, SPT & Ashlee Roderick, SPT
School of Physical Therapy
College of Health Professions
Pacific University
Hillsboro, OR 97123
schu0539@pacificu.edu
rode5372@pacificu.edu

Rationale for Chosen Articles: After being exposed to the McKenzie method during both the first and second clinical rotations, we formed a general clinical question regarding the effectiveness of the treatment of pain using the McKenzie method as compared to manual therapy. We approached our clinical instructors, who were each certified in Mechanical Diagnosis and Therapy (MDT), to assist us in finding research addressing our clinical question. They gave us several papers to sift through, and we added to the existing compilation by looking up applicable referenced research cited in each of the original papers we had found. In addition, we searched PubMed using the search terms noted above. We narrowed down our clinical question to address only low back pain, eliminating some of the options. We then selected articles that had a PICO closely matching our own clinical PICO. We kept internal and external validity in mind as we went through this process. After completing PEDro scores for the remaining articles, we concluded that the following three references should be used to answer our clinical question.

(1)

Paatelma M, Kilpikoski S, Simonen R., Heinonen A, Alen M, Videman T.

Orthopaedic manual therapy, McKenzie method or advice only for low back pain in working adults: a randomized controlled trial with one year follow-up. *Journal of Rehabilitation Medicine*. 2008; 40: 858-863.

P: The population included working individuals 18-65 years of age with non-specific acute or chronic LBP, which may or may not include pain into the LEs. The patient's current condition may be the first or a recurrent episode of LBP. Patients who were pregnant, had low back surgery within the last two months, or had unspecified signs indicative of serious spinal pathology were excluded.

I: The treatment of interest was the McKenzie method, including a HEP and education.

C: The comparison interventions were manual therapy and advice only, or counseling. The manual therapy included stretching, spinal mobilization, spinal manipulation, and a HEP.

O: The outcome measures included leg and LBP according to the VAS and function according to the RMQ. The outcomes were determined at three, six, and 12 months.

PEDro Score 7/10

Patient: Included patients who were similar to my patient.

Intervention: McKenzie method (including HEP and education), manual therapy (including stretching, spinal mobilization, spinal manipulation, and HEP), advice only (counseling)

Outcome measures: VAS and RMQ

(2)

Petersen T, Larsen K, Nordsteen J, Olsen S, Fournier G, Jacobsen S. The McKenzie method compared with manipulation when used adjunctive to information and advice in low back pain patients presenting with centralization or peripheralization. *Spine*. 2011; 36: 1999-2010.

P: The population included patients 18-60 years of age with LBP lasting greater than six weeks, which may or may not include pain into the LEs. They were able to speak and understand Danish. The patients presented with signs and symptoms indicative of disc pathology, as the pain either centralized or peripheralized upon evaluation. Patients who demonstrated positive nonorganic signs, had severe nerve root involvement, osteoporosis, severe spondylolisthesis, fracture, inflammatory arthritis, cancer, referred pain from the viscera, were pregnant, were receiving a disability pension, were undergoing pending litigation, had a comorbidity, had had recent back surgery, had language problems, or had other problems with communication, including abuse of drugs or alcohol, were excluded.

I: The treatment of interest was the McKenzie method, including a HEP and education.

C: The comparison intervention was manual therapy, including stretching, soft tissue mobilization, spinal mobilization, spinal manipulation, education, and a HEP.

O: The outcome measures included function according to the modified Roland Morris Disability Questionnaire (RMDQ), LBP according to the Low Back Pain Rating Scale, global perceived effect, quality of life, days with reduced activity, return-to-work, satisfaction with treatment, and use of health care after the completion of treatment. The outcomes were determined at the completion of treatment, at two months, and at 12 months.

PEDro Score: 8/10

Patient: Included patients who were similar to my patient.

Intervention: McKenzie method (including HEP and education), manual therapy (including stretching, soft tissue mobilization, spinal mobilization, spinal manipulation, education, and HEP)

Outcome measures: modified RMDQ, Low Back Pain Rating Scale, global perceived effect, quality of life, days with reduced activity, return-to-work, satisfaction with treatment, use of health care after the completion of treatment

(3)

Schenk R, Dionne C, Simon C, Johnson R. Effectiveness of mechanical diagnosis and therapy in patients with back pain who meet a clinical prediction rule for spinal manipulation. *Journal of Manual and Manipulative Therapy*. 2012; 20: 43-49.

P: The population included adults over the age of 18 with LBP, which may or may not have included pain into the LEs. The subjects met three out of five of the selection criteria in the clinical prediction rule proposed by Flynn *et al*. This criteria includes the duration of symptoms being present for less than 16 days, symptoms that are not distal to the knee, hip internal rotation that is greater than 35 degrees as measured in prone, hypomobility with lumbar P-A testing, and a Fear Avoidance Beliefs Questionnaire (FABQ) score of less than 19. Patients who had a history of spinal surgery, were diagnosed with a progressive disease process, were being treated for a psychological illness, were pregnant, had symptoms relative to cauda equina syndrome, did not understand English, were engaged in litigation related to their LBP, or were insured through workers compensation or no fault insurance were excluded.

I: The treatment of interest was the McKenzie method, including a HEP.

C: The comparison intervention was the lumbar regional spinal thrust manipulation, including a HEP.

O: The outcome measures included function according to the ODI, LBP according to the numeric pain rating scale (NPRS), and disability and work loss according to the Fear Avoidance Beliefs Questionnaire Work Subscale (FABQw). The outcomes were determined at the completion of treatment.

PEDro Score: 8/10

Patient: Included patients who were similar to my patient.
 Intervention: McKenzie method (including HEP), lumbar regional spinal thrust manipulation (including HEP)
 Outcome measures: ODI, NPRS, FABQw

Table 1. Comparison of PEDro scores.

	Paatelma <i>et al.</i>	Petersen <i>et al.</i>	Schenk <i>et al.</i>
Random	yes	yes	yes
Concealed allocation	yes	yes	***yes
Baseline comparability	yes	yes	yes
Blind Subjects	no	no	no
Blind Therapists	no	no	no
Blind Assessors	no	**yes	yes
Adequate Follow-up	yes	yes	yes
Intention-to-Treat	yes	yes	***yes
Between Group	yes	yes	yes
Point Estimates & Variability	yes	yes	yes
Total Score	7/10	8/10	8/10

*PEDro ranking was determined according to PEDro criteria and then compared with the PEDro database.

**There was one discrepancy found with regard to the Petersen *et al.* study, as indicated on the chart above. Though the PEDro database scored “blind assessors” as a “no,” the article states that “follow-up assessment was carried out by a secretary blinded to treatment allocation (2001),” indicating that the assessor was indeed blinded. Therefore, we are scoring “blind assessors” a “yes.”

***There were two discrepancies found with regard to the Schenk *et al.* study, as indicated on the chart above. Though the PEDro database scored “concealed allocation” as a “no,” the article states that “after these assessment measures were gathered...participants were randomly assigned via a computerized random number generator (45),” indicating that allocation was indeed concealed from those who performed the assessments. Therefore, we are scoring “concealed allocation” a “yes.” Secondly, the PEDro database scored “intention-to-treat” as a “no,” however the article states that “all analyses were intention to treat (46).” Therefore, we are scoring “intention-to-treat” a “yes.”

Article: Paatelma *et al.*, 2008.

Clinical Bottom Line:

The evidence from Paatelma *et al.* suggests that the McKenzie method of treatment has the potential to be more effective than manual therapy in treating subjects with LBP. The population in the study was very similar to our clinical population. The internal validity of the study was good, though a significant threat was inherent due to extraneous variables. There were also several minor threats that, when taken as whole, decrease the internal validity of the study. There is weak evidence that the McKenzie method is

better than manual therapy in improving function, due to the small-medium effect size found on the RMQ. On the other hand, there is no evidence to support the McKenzie method over manual therapy for decreasing LBP or leg pain, as measured by the VAS. The benefits of the McKenzie method outweigh any costs associated and the approach is feasible within the confines of a typical clinical setting. This is true also of manual therapy. Still, due to the lack of a strict protocol, the treatment is not perfectly reproducible. A similar study protecting against threats to internal validity, especially extraneous variables, would result in more valid data and allow for a more generalized interpretation of the results of the study.

Article PICO:

Population - Individuals 18-65 years of age with non-specific acute or chronic LBP

Intervention - McKenzie method, including a HEP and education

Comparison - Manual therapy including stretching, spinal mobilization, spinal manipulation, and a HEP; advice-only, or counseling

Outcomes - Leg and LBP according to the VAS and function according to the RMQ

Blinding:

The assessors were blinded to group allocation because the examination took place before the subjects were randomized. The therapists and patients were not blinded during the course of treatment because this would have been very difficult to do. However, the research assistant who collected post-treatment data was not blinded to group allocation.

Controls:

There was no true control group in the study. Three treatments were compared.

Randomization:

Patients were randomized into one of the three groups. The randomization was successful, as all three groups were similar at baseline.

Study:

The study design was a randomized, “controlled” clinical trial. One hundred and thirty-six patients were randomly allocated to one of two treatment groups or the control group. Two were then excluded. The population in the orthopedic manual therapy treatment group, the McKenzie method group, and the advice-only group included 45, 52, and 37 subjects, respectively. All patients were recruited from one of four occupational health care centers in Finland, for which they were admitted due to LBP. Subjects were qualified for the study if they were working individuals 18-65 years of age with non-specific acute or chronic LBP, which may or may not include pain into the LEs. The current condition could be the first or a recurrent episode of LBP. Patients who were pregnant, had low back surgery within the last two months, or had unspecified signs indicative of serious spinal pathology were excluded.

All 134 patients were evaluated at baseline. A battery of self-reported measures was taken in order to learn baseline demographics. Additionally, LBP and leg pain were taken using a VAS. Disability was measured using the RMQ. Raters were blinded to group allocation.

The manual therapy group received treatment that included stretching, spinal mobilization, spinal manipulation, and a HEP. The mobilization or manipulation techniques that were performed included a translatory thrust of the thoracolumbar junction with the patient in supine or side-lying, a translatory thrust of L1 to L5 with the patient in prone or side-lying, and a ventral or dorsal glide of the ileum on the sacrum with the patient in prone. Usually three to five individually selected home exercises were prescribed to be performed in sets of 2-3 with 15-20 repetitions each. Lumbar stabilization exercises were to be performed 10 times for 10 seconds each daily. Finally, stretching exercises were to be performed once a day for 45-60 seconds each. Subjects were seen between three and seven visits. All patients in this group were treated by a single physiotherapist with 20 years of experience in this field.

The McKenzie method group was assessed and classified into the mechanical syndromes. Patients who had a non-mechanical presentation of symptoms were transferred from conservative care for further investigation. If a syndrome was present, patients were treated according to their directional preference. The HEP included education, using the book *Treat Your Own Back*, and repeated movement exercises, with or without sustained positions, for 10-15 repetitions every 1-2 hours. Occasionally, patient-generated forces were supplemented by the therapist's over-pressure. Manipulation techniques were avoided. Subjects were seen between three and seven visits. All patients in this group were treated by an MDT physiotherapist with 10 years of experience in the McKenzie method.

The advice-only control group received one 45-60 minute educational session provided by a physiotherapist with five years of experience treating patients with LBP. Subjects were counseled to continue their activities of daily living, including exercise, as permitted by their pain. They were educated regarding the good prognosis for LBP, pain tolerance, medication, early return to work, and when to contact their physician should symptoms continue or worsen. Patients were also given a two-page educational back booklet.

The outcome measures were performed by a research assistant and coded by a second assistant who was blinded to the group assignments. At three, six, and 12 months LBP and leg pain were taken using a VAS and disability was measured using the RMQ.

Outcome Measures:

Subjects were asked to rate their leg pain and LBP on a VAS scored from 0 to 100mm and complete the RMQ on a 0-24 point scale. Both assessment tools have been proven valid and reliable. Measures were taken at baseline and following treatment after three months, six months and 12 months. The minimal clinically important difference (MCID) for the VAS is 20 points, equivalent to 2 points on a VAS using a 0-10cm scale (Childs, *et. al.*). The MCID for the RMQ is a change of 5 points (Stratford, *et. al.*).

Study Losses:

Of the 45 patients in the orthopedic manual therapy group, 10 were lost to the one year follow-up. This represents 22.2% of the patients. According to the authors, one patient underwent low back surgery, one was unwilling to participate, one moved abroad, and seven were unreachable. Of the 52 patients in the McKenzie method group, 7 were lost to the one year follow-up. This represents 13.4% of the patients. The authors reported that one patient retired, four had low back surgery, and two were unreachable. Of the 37 patients in the advice-only group, 11 were lost to the one year follow-up. This represents 29.7% of the patients. According to the authors, one patient underwent low back surgery, seven were unwilling to participate, and three were unreachable. The seven patients who were unwilling to participate dropped out due to disappointment at having only one treatment possibility. Altogether, 20.9% of the total number of subjects in the study were lost to the one year follow-up. The baseline background values and outcome measures were not statistically significant for the subjects who dropped out as compared to those who completed the study. The data was analyzed using the intention-to-treat principle. To account for drop-outs at follow-up, missing data were replaced by predicted values based on subjects' previous scores.

Summary of Internal Validity:

There were a couple of threats to internal validity that the researchers protected against. The study design was a randomized clinical trial. The randomization was successful, protecting against the threats of statistical regression, selection, and inter-subject differences. A power analysis was conducted and a sufficient number of participants were analyzed, thereby eliminating this threat as well. The instrumentation used to conduct the study, the VAS and the RMQ, has been determined to be valid and reliable. Therefore, instrumentation error is not a threat to internal validity. Appropriate statistics were performed and therefore, violation of statistical tests and statistical fishing are not threats to the study.

The study had several minor threats to internal validity. There was not a true control in this study in that the control group did receive treatment. However, there was a control group in the sense that these subjects did not receive manual therapy or the McKenzie method as interventions like the treatment

groups did. They only received education, as did all participants in the study. Therefore, history and maturation are only a minor threat to internal validity. Though the study did not have a design to eliminate testing effect, it is not likely that responses to questions about pain and function would change as a result of being better at answering the questions, so it is only a minor threat. Patients were not blinded to group allocation or study results. As a result, the Hawthorne and Rosenthal Effect may have changed the responses the subjects gave to the outcome assessment. Also, though the initial assessor was blinded to group allocation, the follow-up assessor was not. Rater bias may have changed the measures recorded by this assessor. These are only minor threats to internal validity. The authors did not report the reliability of their assessor in directing and recording results from the outcome measures, leading to unreliable data. This is a minor threat to the study because the assessor was blinded and likely conducted the analysis the same for everyone. Also, patients were by then familiar with the outcome tools used. The study did not have a strict protocol. However, patient motivation is only a small threat because it is unlikely that the interviewers could alter subjects' responses to questions through the use of motivation.

The only significant threat to internal validity was extraneous variables. The study did not have a strict protocol, allowing for the possibility that extraneous variables skewed the outcomes. The physiotherapists treating the manual therapy and McKenzie groups conducted their interventions on an individual basis. Additionally, no participants were instructed to avoid treatment, including self-management, outside of that which was provided as a result of being included in the study. As a result, some patients may have received treatment others did not receive. Therefore, differences between groups cannot necessarily be attributed to the intervention, which is a significant threat to the internal validity of the study.

The internal validity of the study is good, as the majority of the threats were controlled for by the researchers. However, a significant threat is inherent due to the lack of control for extraneous variables. There were also several minor threats that, when taken as whole, decrease the internal validity of the study.

Evidence:

Data was derived from a bar graph presented by the authors and used to create the table below.

Table 2. Visual Analogue Scale and Roland Morris Questionnaire changes with 95% confidence intervals for McKenzie group and manual therapy group from baseline to 12 month follow-up.

	Leg Pain (VAS, mm)	LBP (VAS, mm)	RMQ (0-24 scale)
McKenzie Group	-17.0 (-10.0 to -25.0)	-20.0 (-12.0 to -27.0)	-7.67 (-6.07 to -9.27)
Manual Therapy Group	-17.0 (-7.0 to -27.0)	-20.0 (-12.0 to -27.0)	-7.40 (-5.8 to -9)

The means presented show that neither group met the MCID of a 20mm change in leg pain. However, this was likely due to the low median scores at baseline, which were 20mm for the manual therapy group and 16mm for the McKenzie group. Both groups did demonstrate a clinically important decrease in low back pain, on average. The 95% CIs indicate that, if the study were repeated, subjects may or may not meet the MCID for a change on the VAS scale for either leg or low back pain. Both groups improved by more than five points on the RMQ, with 95% CIs confirming that this would be a consistent finding if the study were repeated.

To determine if there were any significant between-group differences, we calculated an effect size using the data presented in the table above.

Table 3. Effect size and 95% confidence intervals in McKenzie group and manual therapy group from baseline to 12 month follow-up.

	Leg Pain (VAS)	LBP (VAS)	RMQ
Effect Size	0 (-0.44 to 0.44)	0 (-0.44 to 0.44)	0.33 (-0.12 to 0.77)

These results indicate that the two groups had very similar results in leg pain improvement, LBP improvement, and RMQ score improvement. However, RMQ scores improved slightly more in the McKenzie group, with a small-medium effect size of 0.33. The CI of -0.12 to 0.77 indicates that, if the study were repeated, the effect size would vary in size and direction—occasionally even favoring manual therapy. This is only weak evidence in support of the McKenzie method over manual therapy.

The authors stated that they found no significant differences between the McKenzie group and the manual therapy group at any follow-up point, either on VAS scores or RMQ scores. They did not report p-values on any direct comparisons between the scores of those two groups.

Applicability of Study Results:

Benefits vs. Costs:

Based on the evidence, the McKenzie method of treatment may be more effective in improving function when compared to manual therapy. Manual therapy is entry-level knowledge for physical therapists. However, to use the McKenzie method accurately, practitioners need to complete a series of courses to receive an MDT certification. This incurs some amount of cost to the therapist, supplemental to that which therapists treating with manual therapy must pay. It has been argued that the McKenzie method requires fewer visits than manual therapy in treating LBP, limiting the time required in the clinic by both the patient and the therapist. However, there was no difference in the frequency of intervention for either group, as reported by the authors. There is no additional risk for receiving McKenzie treatment exercises over manual therapy, as no adverse events were reported by the authors. Therefore, it would seem that the benefits of McKenzie treatment for LBP outweigh the costs.

Feasibility of Treatment:

The treatment performed on the manual therapy group was progressed on an individualized basis. Though the mobilization and manipulation techniques that were used were described, the varying HEPs that consisted of stretches and strengthening exercises were not described well enough to be reproducible, apart from sets and repetitions. The treatment performed on the McKenzie method group was also progressed on an individualized basis. However, this method is much more standardized. Therefore, it can be assumed that treatment was directed according to patients’ directional preference, as was the HEP. The sets and repetitions were also specified. Though this treatment is not perfectly reproducible, therapists trained in the McKenzie method would likely take a similar approach. The counselling provided for the advice-only group was standardized topically. However, it is not reproducible because different therapists may have different advice with regards to the given topics. None of the three groups were required to track adherence to their HEP. It is likely that HEP compliance played a large role in the results of the given treatment outcomes. On the other hand, the requirements of clinical expertise, equipment, and therapist or patient time would fall within the confines of a typical clinical setting.

Summary of External Validity:

The population in this study is similar to my clinical population in that it includes working adults 18-65 years of age complaining of non-specific LBP with or without symptoms into the LEs. The interventions were applied to a broad population of patients with LBP, as there were very few exclusion criteria. However, the subjects were each recruited from the same city. A similar study sampling from a more diverse population would result in more valid data, allowing for a more generalized interpretation of the results of the study. Overall, the external validity of the Paatelma *et al.* study was good.

Article: Petersen *et al.*, 2011.

Clinical Bottom Line:

The evidence from Petersen *et al.* suggests that the McKenzie method of treatment has the potential to be more effective than spinal manipulation in treating subjects with non-specific, non-acute LBP. However, because the manipulation and other techniques were performed by chiropractors, the treatment choices and methods differed from the manual therapy that would be performed by a physical therapist. The population in the study was somewhat different from our clinical population, limiting the generalizability of the study results. For example, subjects with acute LBP were excluded, a population we would expect to see frequently as clinicians. The internal validity of the study was good, though a significant threat was inherent due to extraneous variables. There were also several minor threats that decrease the internal validity of the study. The low NNT provides only weak evidence that the McKenzie method is better than manipulation in improving function, according to the RMDQ, due to the large confidence interval. There is no evidence to support the McKenzie method over manipulation for decreasing pain, as measured by the Low Back Pain Rating Scale. The benefits of the McKenzie method outweigh any costs associated and the approach is feasible within the confines of a typical clinical setting. This is true also of manipulation. Still, due to the exclusion criteria and the lack of a strict protocol, we cannot extrapolate the results of this study to all of our patients, nor can the treatment be perfectly reproducible. A similar study sampling from a more diverse population and protecting against threats to internal validity, especially extraneous variables, would result in more valid data and allow for a broader application of the results.

Article PICO:

Population - Patients 18-60 years of age with LBP lasting greater than six weeks

Intervention - McKenzie method, including a HEP and education

Comparison - Manual therapy including stretching, soft tissue mobilization, spinal mobilization, spinal manipulation, education, and a HEP

Outcomes - Function according to the modified RMDQ, LBP according to the Low Back Pain Rating Scale, global perceived effect, quality of life, days with reduced activity, return-to-work, treatment satisfaction, and use of health care after completion of treatment

Blinding:

The examiner was blinded to group allocation because the examination took place before the subjects were randomized. The therapists and patients were not blinded during the course of treatment because this would have been very difficult to do. The secretary who collected post-treatment data was blinded to patients' allocation.

Controls:

There was not a true control group in this study. The two treatment groups were compared.

Randomization:

The subjects were randomized into two groups and the baseline characteristics were analyzed. The only significant difference between the two groups was the fact that more subjects were on sick leave in the McKenzie group than in the manual therapy group. The researchers are therefore being conservative by having the treatment group of interest start out at a lower level of function.

Study:

The study design was a randomized clinical trial. Three-hundred-and-fifty patients were randomly allocated to one of two treatment groups: the McKenzie method or manipulation. Each group included 175 subjects. All patients were recruited from September 2003 to May 2007 at a primary care specialist center in Denmark for which they were referred due to LBP. Subjects were qualified for the study if they were 18-60 years of age with LBP lasting greater than six weeks, which may or may not include pain into

the LEs. They were able to speak and understand Danish. The patients presented with signs and symptoms indicative of disc pathology, as the pain either centralized or peripheralized upon evaluation. Patients who demonstrated positive nonorganic signs, had severe nerve root involvement, osteoporosis, severe spondylolisthesis, fracture, inflammatory arthritis, cancer, referred pain from the viscera, were pregnant, were receiving a disability pension, were undergoing pending litigation, had a comorbidity, had had recent back surgery, had language problems, or had other problems with communication, including abuse of drugs or alcohol, were excluded.

All 350 patients were evaluated at baseline. A battery of self-reported measures was taken in order to learn baseline demographics and initial measures were taken of patients' disability according to the modified RMDQ and back and leg pain according to the Low Back Pain Rating Scale. The examiner was blinded to group allocation.

The McKenzie method group received treatment that was individualized according to patients' directional preference. Some patients were given an educational booklet describing self-care or the use of a lumbar roll to help correct seated posture. The three therapists providing treatment had passed a credential examination in the McKenzie method.

The manipulation group received individualized treatment that included stretching, soft tissue mobilization, spinal mobilization, spinal manipulation, and a HEP. Some patients were given an inclined wedged pillow to help correct seated posture. The treatment was provided by three chiropractors who had several years of experience in this type of treatment.

Both the McKenzie method group and the manipulation group received education regarding the course of LBP, the importance of being physically active, and self-care for LBP. In addition, all patients were given *The Back Book*. Patients were treated for a maximum of 15 sessions over a period of 12 weeks. At the end of treatment, subjects were instructed in a HEP including stretching, self-mobilization, stabilizing, and strengthening exercises according to the recommendations of the clinician. Patients were instructed to follow this program, while avoiding any other kind of treatment, for two months.

The outcome measures were taken by a secretary who was blinded to treatment allocation. The measures included the modified RMDQ, Low Back Pain Rating Scale, global perceived effect, quality of life, days with reduced activity, return-to-work, satisfaction with treatment, and use of health care after the completion of treatment.

Outcome Measures:

The Low Back Pain Rating Scale is a tool that is scored from 0-60 based on patients' assessment of their pain at that moment (0-10), worst pain in the past two weeks (0-10), and average level of pain in the past two weeks (0-10). Back and leg pain are rated separately and then combined into a total score. The tool is valid and reliable according to a study, which the authors cited (Manniche et al). The modified 23-item RMDQ has replaced five items from the original RMDQ with four different items, and includes wording that refers to leg pain as well as back pain (Patrick, *et. al.*). A reliable and validated Danish version was used (Albert, et al). Because a MCID has not been established for the modified RMDQ, we used the original MCID of a 5-point change referenced by the authors (Stratford, *et. al.*). Each of these outcome measures were assessed at baseline, post-treatment, after two months, and after 12 months.

Study Losses:

Of the 175 patients in the manipulation group, 55 were lost to the one year follow-up. This represents 31.4% of the patients. According to the author, 43 of these patients withdrew for reasons attributed to a lack of treatment effect, and the rest dropped out for unrelated reasons. Of the 175 patients in the McKenzie method group, 36 were lost to the one year follow-up. This represents 20.6% of the patients. The authors reported that 28 of these patients withdrew for reasons attributed to a lack of treatment effect, and the rest dropped out for unrelated reasons. Altogether, 26% of the total number of subjects in the study were lost to the one year follow-up, with a statistically significant larger percentage of patients dropping out from the manipulation group. This leads us to believe that there was something about the

chiropractic manual therapy that the patients did not like. An intention-to-treat analysis was performed, which the authors say included most of the drop-out subjects.

Summary of Internal Validity:

The study design was a randomized clinical trial, which protects against several threats to internal validity. The randomization was successful, protecting against the threats of statistical regression, selection, and inter-subject differences. Examiners before and after treatment were blinded to treatment allocation and therefore rater bias is not a threat to the internal validity. Instrumentation error is not a threat, because the Low Back Pain Rating Scale and the RMDQ have been determined to be valid and reliable. A power analysis was conducted and a sufficient number of participants were recruited, thereby eliminating this threat to internal validity as well. Appropriate statistics were performed; eliminating the threats of violation of statistical tests and statistical fishing.

The study had several minor threats to internal validity. There was not a true control in this study as both groups received treatment. However, both groups did receive similar education. Therefore, history and maturation are only a minor threat to internal validity. Though the study did not have a design to eliminate testing effect, it is not likely that responses to the questionnaire would change as a result of being better at answering the questions, so it is only a minor threat. Because neither the subjects nor the therapists were blinded to the intervention, the Hawthorne and Rosenthal Effect may have changed the responses the subjects gave to the outcome assessment. This is only a minor threat to internal validity. The authors did not report the reliability of their assessor in directing and recording results from the outcome measures, leading to unreliable data. This is a minor threat to the study because the assessor was blinded and likely conducted the analysis the same for everyone. Also, patients were by then familiar with the outcome tools used. Patient motivation is a small threat, due to lack of strict protocol. However, it is unlikely that the interviewers could alter subjects' responses to questions through the use of motivation.

The only significant threat to internal validity was extraneous variables that skewed the outcomes, because the study did not have a strict protocol. It was a requirement that all subjects presented with signs and symptoms indicative of disc pathology, as the pain either centralized or peripheralized upon evaluation. This may bias the McKenzie method from the start because it is in this specific population that the method had been proven most effective. However, the authors performed a Post Hoc test for interaction and concluded that centralization and/or peripheralization at initial screening had no statistical significant influence on the association between treatment group and success rate. During the treatment period, subjects in both groups received similar education, but the rest of the interventions were conducted on an individual basis. Subjects were not instructed to avoid other treatment during this time. At the conclusion of the treatment period, all participants were instructed to complete their HEPs and to avoid seeking other treatment for two months. Assuming all subjects complied, this is the only time period in the study in which differences between groups may be attributed to the intervention. Therefore, extraneous variables are a significant threat to the internal validity of the study.

The internal validity of the study is good, as the majority of the threats were controlled for by the researchers. However, a significant threat is inherent due to the lack of control for extraneous variables. There were also several minor threats that, when taken as whole, decrease the internal validity of the study.

Evidence:

Because of confusion in reading the authors' tables and determining how they accounted for drop-outs throughout the 12 months of follow-ups, we contacted the authors and obtained their raw data in order to run the statistical analyses ourselves. In generating the analysis presented below, we excluded any subjects who did not have RMDQ scores listed at baseline, post-treatment, and 12 month follow-up. This included 160 subjects in the McKenzie group and 156 in the manipulation group.

Table 4. Subjects who reported a 5 point reduction on the Roland Morris Disability Questionnaire at the conclusion of treatment.

	Subjects with 5 Point Improvement on RMDQ	Subjects without 5 Point Improvement on RMDQ
McKenzie Group	101	59
Manipulation Group	82	74

A Chi-Square analysis shows that there was not a significant difference between groups at the conclusion of treatment ($p = 0.057$).

Table 5. Subjects who reported a 5 improvement on the Roland Morris Disability Questionnaire from baseline to 12 month follow-up.

	Subjects with 5 Point Improvement on RMDQ	Subjects without 5 Point Improvement on RMDQ
McKenzie Group	98	62
Manipulation Group	78	78

A Chi-Square analysis shows that there was a significant difference between groups at 12 months after the treatment concluded ($p = 0.044$). Significantly more subjects in the McKenzie group had a clinically important (5 point) decrease on the RMDQ than in the manipulation group, indicating improved function one year after treatment.

We performed a NNT statistical analysis to determine the results presented below.

Table 6. Outcome measures with 95% confidence intervals for McKenzie group compared to manipulation group at 12 month follow-up.

Number Needed to Treat	Absolute Risk Reduction	Relative Risk Reduction	Relative Risk
8.89 (4.5 to 276.3)	0.11 (0.00 to 0.22)	0.23 (0.00 to 0.40)	0.78 (0.60 to 1.00)

The NNT is 8.89, indicating that for every nine patients treated with the McKenzie method, one will have better functional improvement than patients treated with manipulation. However, the NNT would range from 4.5 to 276.3, the 95% CI, if the study was repeated again and again. This is very weak evidence in support of the McKenzie method.

An absolute risk reduction (ARR) of 0.11 suggests that McKenzie treatment decreases a person's risk of having a decreased or similar functional level, one year after treatment, by 11%. In considering the relative risk reduction (RRR), the percentage of the general population that would have had a decrease or plateau in their functional level, the McKenzie treatment reduces the rate by 23%. Because the lower end of the CI for each of these numbers drops to zero, the numbers are meaningless. The relative risk (RR) of 78% indicates that the risk for the McKenzie group to have decreased or maintained function is 78% of that of the manipulation group, with a confidence interval of 60% to 100%. This analysis provides only weak evidence in support of the McKenzie method in comparison to manipulation for improving function.

The second outcome measure that we analyzed from the original data of the authors was the subjects' scores on the Low Back Pain Rating Scale. Because a MCID has not been established for this scale, we analyzed the data as scored data using a t-test. We ran this analysis on our calculated change in scores from baseline to post-treatment, and also from baseline to the 12 month follow-up between groups.

From baseline to post-treatment, we included the 173 subjects in the McKenzie group and 163 subjects in the manipulation group who had scores listed at baseline and at the conclusion of treatment. The two-tailed t-test result was 0.326, which implies that there was no statistical significance between groups at the end of treatment.

In analyzing the changes in score from baseline to the 12 month follow-up, we included 163 subjects from each group, those who had scores listed at baseline and at 12 month follow-up. The t-test result had a two-tailed value of 0.085, demonstrating a lack of significance between groups after 12 months. However, this number approached significance.

From the data presented by the authors, an effect size was calculated both at the conclusion of treatment and then at 12 month follow-up.

Table 8. Effect size with 95% confidence intervals for decrease in pain in McKenzie group and manipulation group at conclusion of treatment and 12 month follow-up.

	Effect Size
Post-Treatment	0.11 (-0.11 to 0.32)
12 Month Follow-up	0.19 (-.03 to 0.41)

The calculated effect sizes are very small, with 95% CIs that cross zero. This indicates that the results could favor manipulation over McKenzie if the study was repeated over and over. Although the results from the 12 month follow-up approach significance, we cannot conclude that there is any evidence to support the McKenzie method in decreasing pain more than the manipulation method of treatment.

Applicability of Study Results:

Benefits vs. Costs:

Based on the evidence, the McKenzie method of treatment may be more effective in improving function when compared to manipulation. Spinal manipulations are entry-level knowledge for physical therapists. However, to use the McKenzie method accurately, practitioners need to complete a series of courses to receive an MDT certification. This incurs some amount of cost to the therapist, supplemental to that which therapists treating with manipulation must pay. It has been argued that the McKenzie method requires fewer visits than manual therapy in treating LBP, limiting the time required in the clinic by both the patient and the therapist. However, this study did not clarify the frequency of intervention for either group, and thus it is assumed that there was no difference. There is no additional risk for receiving McKenzie treatment exercises over spinal manipulation, as no adverse events were reported by the authors. Therefore, it would seem that the benefits of McKenzie treatment for LBP outweigh the costs.

Feasibility of Treatment:

The treatment performed to the manipulation group was progressed on an individualized basis. The techniques implemented by the practitioner were determined according to his or her discretion, as was the HEP. They were not described at all and are therefore not reproducible. The treatment performed on the McKenzie method group was also progressed on an individualized basis. However, this method is much more standardized. Treatment was directed according to patients' directional preference. The HEP was not well described. Though this treatment is not perfectly reproducible, therapists trained in the McKenzie method would likely take a similar approach. Neither of the groups were required to track adherence to their HEP. It is likely that HEP compliance played a large role in the results of the given treatment outcomes. On the other hand, the requirements of clinical expertise, equipment, and therapist or patient time would fall within the confines of a typical clinical setting.

Summary of External Validity:

The population in this study is similar to my clinical population in that it includes working adults 18-60 years of age complaining of sub-acute or chronic LBP with or without symptoms into the LEs. Additionally, patients were excluded from the study for a variety of reasons. Clinically, it would be expected that patients with acute LBP, for example, would frequently require treatment. The results of this study cannot, however, be applied to this population. To narrow the application of the results further, participants were all selected from the same clinic. A similar study sampling from a more diverse population would result in more valid data, allowing for a more generalized interpretation of the results of the study. Finally, treatment for the manipulation group was provided by chiropractors rather than physical therapists. This limits our ability to extrapolate the study results to use with our patients, because the manual therapy was different than what would be provided by physical therapists. Overall, the external validity of the Petersen *et al.* study was adequate.

Article: Schenk *et al.*, 2012.

Clinical Bottom Line:

The evidence from Schenk *et al.* suggests that the McKenzie method of treatment has the potential to be more effective than spinal manipulation in treating subjects with LBP who meet the clinical prediction rule for the spinal thrust manipulation. However, manipulation is a very specific form of manual therapy, so the study only addresses a small component of the comparison treatment. The population in the study was quite different from our clinical population. Subjects were included only if they met three of five criteria for the spinal thrust manipulation clinical prediction rule, proposed by Flynn *et al.*. There were also several exclusion criteria, limiting the generalizability of the study results. The internal validity of the study was adequate, though a significant threat was inherent due to inadequate sample size. There were also several minor threats that decrease the internal validity of the study. The NNT provides only weak evidence that the McKenzie method is better than the spinal thrust manipulation in reducing LBP, according to the NPRS. However, there is no evidence to support the McKenzie method over manipulation for increasing function, as measured by the ODI. The benefits of the McKenzie method outweigh any costs associated and the approach is feasible within the confines of a typical clinical setting. This is true also of manipulation. Due to the very specific population recruited and the small sample size, we cannot extrapolate the results of this study to all of our patients. A similar study sampling from a more diverse population and protecting against threats to internal validity, especially inadequate sample size, would result in more valid data and allow for a more generalized interpretation of the results of the study.

Article PICO:

Population - Adults over the age of 18 with LBP who met three out of five of the selection criteria in the clinical prediction rule proposed by Flynn *et al.*

Intervention - McKenzie method and a HEP

Comparison - Lumbar regional spinal thrust manipulation and a HEP

Outcomes - Function according to the ODI, LBP according to the NPRS, and disability and work loss according to the FABQw

Blinding:

The assessor was blinded to group allocation because the examination took place before the subjects were randomized. The therapists and patients were not blinded during the course of treatment because this would have been very difficult to do. The researchers who collected post-treatment data were blinded to patients' allocation.

Controls:

There was not a true control group in this study. The two treatment groups were compared.

Randomization:

The subjects were randomized into two groups, but the randomization process was not well described. The authors did not report whether or not there was a significant difference between the two groups based upon baseline measures. Although the McKenzie group demographics demonstrate that the patients were generally younger, had symptoms for longer, and had higher FABQw scores than the manipulation group, the researchers are being conservative by having the treatment group of interest start out at a disadvantage.

Study:

The study design was a randomized clinical trial. Thirty-one patients were randomly allocated to one of two treatment groups. The population in the spinal thrust manipulation treatment group included 16 subjects. The population in the McKenzie method treatment group included 15 subjects. All patients were consecutively recruited from an outpatient physical therapy clinic in an unspecified regional health care center for which they were referred due to LBP. It was not specified whether the LBP was a first occurrence or a reoccurrence. Subjects were qualified for the study if they were over the age of 18 with LBP, which may or may not have included pain into the LEs. The subjects met three out of five of the selection criteria in the clinical prediction rule proposed by Flynn *et al.* This criteria includes a symptom duration of less than 16 days, symptoms that are not distal to the knee, hip internal rotation that is greater than 35 degrees, hypomobility with lumbar P-A testing, and a FABQ score of less than 19. Patients who had a history of spinal surgery, were diagnosed with a progressive disease process, were being treated for a psychological illness, were pregnant, had symptoms relative to cauda equina syndrome, did not understand English, were engaged in litigation related to their LBP, or were insured through workers compensation or no fault insurance were excluded.

All 31 patients were evaluated at baseline. A battery of self-reported measures was taken in order to learn baseline demographics. Additionally, initial measures were taken of patients' disability according to the ODI, LBP according to the NPRS, and disability and work loss according to the FABQw.

The spinal thrust manipulation group received treatment that included the lumbopelvic thrust technique at each session. In addition, these patients performed the hand-heel rock range of motion exercise both in the clinic and at home. It was performed 30 and 20 times, respectively, during the first and second sessions.

The McKenzie method group received treatment that was individualized according to patients' directional preference.

Both the spinal thrust manipulation group and the McKenzie method group were seen for four visits. Each group was expected to perform a daily HEP that included 10 repetitions of repeated lumbar movements on an hourly basis from the third treatment until discharge. The McKenzie group performed the exercises in their directional preference. The manipulation group performed 'cat and camel' lumbar flexion and extension exercises in quadruped. The participants were each instructed to maintain a daily log of HEP adherence, although the authors never reported on the difference in compliance between the two groups. After two weeks, participants were able to switch to the alternative treatment method if their condition had failed to improve, as indicated by the lack of a decrease in scores on the NPRS or peripheralization of symptoms. All patients were treated by the same physical therapists over a period of four weeks. These therapists were certified in MDT, had formal training in spinal manipulation, and had completed four hours of training in the lumbopelvic thrust technique.

The outcome measures were performed by researchers who were blinded to the group assignments. The measures included function according to the ODI, LBP according to the NPRS, and disability and work loss according to the FABQw.

Outcome Measures:

The ODI is a validated 10-item questionnaire that assesses patients' perception of their functional level. It is valid and reliable. The MCID for the ODI is a 10-point or 30% change in score (Ostelo, R., et al). This was assessed at baseline and at discharge. The NPRS is a reliable and validated 0-10 scale with an MCID of two points (Childs et al.). This was assessed at each visit.

Study Losses:

All 31 patients in the study completed the treatment. No follow-up was performed. Of the 16 patients who were randomized to the manipulation group, five (31.3%) were not included in the statistical analysis. One patient was excluded due to meeting only three of the five selection criteria. The other four patients chose to cross over from the manipulation group to the McKenzie method group, according to the clinicians' recommendations—the patients had reported no symptomatic or functional improvement with manipulation. Altogether, 16.1% of the total number of subjects in the study were not included in the statistical analysis. An intention-to-treat analysis was performed, however patients were not necessarily analyzed in the groups to which they had originally been allocated.

Summary of Internal Validity:

The researchers protected against several threats to internal validity. The study design was a randomized clinical trial. Although the authors did not report whether there was a significant difference between the groups at baseline, this does not seem to impact the validity of the study because the apparent differences at baseline are minimal and do not favor the McKenzie group. Because the randomization appeared to be successful, threats of statistical regression, selection, and inter-subject differences are not present. The examiners before treatment and the researchers following treatment were blinded to group allocation and therefore rater bias is not a threat to the internal validity. The applicable instrumentation used to conduct the study, the ODI and the NPRS, has been determined to be valid and reliable. Therefore, instrumentation error is not a threat to internal validity. Appropriate statistics were performed. Therefore, violation of statistical tests and statistical fishing are not threats to the study.

The study had several minor threats to internal validity. There was not a true control in this study, as both groups received treatment. However, both groups were prescribed lumbar exercises to be performed in the same quantity, and adherence to them was tracked. Therefore, history and maturation are only a minor threat to internal validity. Though the study did not have a design to eliminate testing effect, it is unlikely that responses to the questionnaire would change due to improvement in answering the questions, so it is only a minor threat. Neither the subjects nor the therapists were blinded to the intervention; as a result, the Hawthorne and Rosenthal Effect may have changed the responses the subjects gave to the outcome assessment. This is a minor threat to internal validity. The authors did not report the reliability of their assessors in directing and recording results from the outcome measures, leading to unreliable data. This is a minor threat to the study because the assessors were blinded and likely conducted the analysis the same for everyone. Also, patients were by then familiar with the outcome tools used. The study did not have a very strict protocol. However, patient motivation is only a small threat because it is unlikely that the interviewers could alter subjects' responses to questions through the use of motivation. On the other hand, the lack of a strict protocol allowed for the possibility that extraneous variables skewed the outcomes. No participants were instructed to avoid treatment, including self-management, outside of that which was provided as a result of being included in the study. As a result, some patients may have received treatment others did not receive. Therefore, differences between groups cannot necessarily be attributed to the intervention. Given that the study was only four weeks long, this is a small threat to the internal validity of the study.

The only significant threat to internal validity was inadequate sample size. No power analysis was conducted to determine the adequacy of the sample size and only 26 subjects were included in statistical analysis.

The internal validity of the study is good, as the majority of the threats were controlled for by the researchers. However, a significant threat is inherent due to the lack of control for inadequate sample size. There were also several minor threats that, when taken as whole, decrease the internal validity of the study.

Evidence:

There was a discrepancy between information presented in two of the authors' tables, which led us to analyze the data ourselves. We were able to obtain raw scores from one of the authors of the study

and analyzed the ODI scores as categorical data using the MCID of a 10-point change. We excluded subjects who had crossed over between groups or did not have four week follow-up scores listed. This data is presented below.

Table 9. Subjects who reported an improvement of at least 10 points on the Oswestry Disability Index from baseline to four week follow-up.

	ODI Score Improved by 10 Points	ODI Score Did Not Improve by 10 Points
McKenzie Group	9	5
Manipulation Group	4	4

A Yates-corrected Chi-Square analysis that we performed shows that there was not a significant difference between groups ($p=0.838$). This is in agreement with the authors' Mann-Whitney statistical analysis on the ODI scores, analyzing them as rank data. No significant difference was found between the McKenzie group and the manipulation group ($p=0.31$).

We performed further statistical analysis using the raw data. The table below presents our findings.

Table 10. Outcome measures with 95% confidence intervals for increased function in the McKenzie group compared to manipulation group.

Number Needed to Treat	Absolute Risk Reduction	Relative Risk Reduction	Relative Risk
7.00 (1.8 to -3.5)	0.14 (-0.28 to 0.57)	0.29 (-0.92 to 0.73)	0.71 (0.27 to 1.92)

With a confidence interval of 1.8 to -3.5, the NNT of 7.00 could vary from 1.8 to infinity if the study was repeated multiple times, rendering the number meaningless. Because the confidence intervals for ARR and RRR cross zero, these numbers cannot be used as evidence to support the McKenzie method either. If the study was repeated many times, the results would sometimes favor the McKenzie method and other times favor manipulation as the treatment of choice. The RR of 71% indicates that the risk for the McKenzie group to have maintained or decreased function is 71% of that of the manipulation group, with a confidence interval of 27% to 192%. The size of this number, as well as its large confidence interval, render this number meaningless to us as well. There is no evidence to support the McKenzie method as compared to manipulation for increasing function.

We also used the raw data provided by the authors to determine how many subjects in each group had a decrease of at least two points, the MCID, on the NPRS from baseline to their four week follow-up visit. This data is presented below.

Table 11. Subjects who reported a decrease of at least two points on Numeric Pain Rating Scale from baseline to four week follow-up.

	NPRS Decreased by 2 Points	NPRS Did Not Decrease by 2 Points
McKenzie Group	12	2
Manipulation Group	3	4

With a p-value of 0.124, the Yates-corrected Chi-Square analysis demonstrates that there is not a significant difference between groups. However, a Chi-Square analysis without a Yates-correction gave a p-value of 0.040, suggesting that there could be a significant difference found if more subjects had been analyzed. The authors analyzed the NPRS scores as rank data using a Mann-Whitney test, which showed

results that approach significance between the two groups ($p= 0.08$). If significant, the results would indicate that subjects in the McKenzie group were more likely to have decreased pain than those in the manipulation group. However, the mean NPRS scores at baseline were 5.2 and 2.6 for the McKenzie and manipulation groups, respectively. Because the manipulation group started out with a low pain level on average, there may have been a floor effect in using this outcome measure, with fewer subjects able to meet the MCID of a two point change.

We chose to run a NNT analysis. Our findings are presented below.

Table 12. Outcome measures with 95% confidence intervals for decreased pain in the McKenzie group compared to the manipulation group.

Number Needed to Treat	Absolute Risk Reduction	Relative Risk Reduction	Relative Risk
2.33 (1.2 to 53.5)	0.43 (0.02 to 0.84)	0.75 (-0.05 to 0.94)	0.25 (0.06 to 1.05)

The NNT is 2.33, implying that for every three patients treated with the McKenzie method, one will experience a decrease in pain. The confidence interval, however, is very large. If this study was repeated many times, we may see a NNT range from 1.2 to 53.5. Treating 54 patients with only one of them reporting a decrease in pain after four weeks would be a poor outcome. This is weak evidence in support of the McKenzie method.

An ARR of 0.43 suggests that McKenzie treatment decreases a person's risk of having a similar or increased pain level after four weeks by 43%. The confidence interval indicates this risk reduction could range from 2% to 84% if the study was to be repeated multiple times. In considering the RRR, the McKenzie treatment would reduce the rate of pain by 75% in the percentage of the general population that would have had an increase or plateau in their pain level. The confidence interval, however, is -5% to 94%, rendering this number insignificant. The RR of 25% indicates that the risk for the McKenzie group to have maintained or increased pain is 25% of that of the manipulation group, with a confidence interval of 6% to 105%. Because each of the confidence intervals are very large, likely as a result of the small sample size, this analysis provides only weak evidence in support of the McKenzie method in comparison to manipulation for decreasing pain.

Applicability of Study Results:

Benefits vs. Costs:

Based on the evidence, the McKenzie method of treatment may be more effective in reducing LBP, but not in improving function, when compared to the spinal thrust manipulation. The spinal thrust manipulation technique is entry-level knowledge for physical therapists. However, to use the McKenzie method accurately, practitioners need to complete a series of courses to receive an MDT certification. This incurs some amount of cost to the therapist, supplemental to that which therapists treating with manipulation must pay. It has been argued that the McKenzie method requires fewer visits than manual therapy in treating LBP, limiting the time required in the clinic by both the patient and the therapist. However, this study did not clarify the frequency of intervention for either group, and thus it is assumed that there was no difference. There is no additional risk for receiving McKenzie treatment exercises over spinal manipulation, as no adverse events were reported by the authors. Therefore, it would seem that the benefits of McKenzie treatment for LBP outweigh the costs.

Feasibility of Treatment:

The treatment performed on the manipulation group included a specified thrust technique in a dosage that has been well established in other original research, as referenced by the authors. The hand-heel rock range of motion exercise this group performed in the clinic was also well described. Therefore, the treatment these patients received is reproducible. The treatment performed on the McKenzie method group was progressed on an individualized basis. However, this method is well standardized and treatment was directed according to patients' directional preference. Though this treatment is not perfectly

reproducible, therapists trained in the McKenzie method would likely take a similar approach. The HEP each group was to perform was described well enough to be imitated as well. The requirements of clinical expertise, equipment, and therapist or patient time would fall within the confines of a typical clinical setting.

Summary of External Validity:

The population in this study is similar to my clinical population in that it includes adults over 18 years of age complaining of acute or sub-acute LBP with or without symptoms into the LEs. However, patients had to meet other very specific criteria to be in the study and were excluded for a variety of reasons. Clinically, it would be expected that patients with chronic LBP, for example, would frequently require treatment. The results of this study cannot, however, be applied to this population. To narrow the application of the results further, participants were selected from the same clinic. Additionally, there was no follow-up performed beyond the end of the treatment period, so long term outcomes are unknown. A similar study sampling from a more diverse population with a follow-up to see treatment effects over time would result in more valid data, allowing for a more generalized interpretation of the results of the study. Overall, the external validity of the Schenk *et al.* study was adequate.

Synthesis/Discussion:

Based on the results of the outcomes from Paatelma *et al.*, Petersen *et al.*, and Schenk *et al.* there is weak evidence in support of treating LBP with the McKenzie method, as compared to manual therapy. We have minor concerns regarding the generalizability of the results of the studies, which will be addressed in detail below.

We assessed the methodological quality of the studies by Paatelma *et al.*, Petersen *et al.*, and Schenk *et al.* by using the PEDro Scale. The studies scored a 7/10, 8/10, and 8/10, respectively. None of the studies blinded the therapists or the patients, as this would have been difficult, if not impossible, to accomplish. Additionally, the Paatelma *et al.* study did not blind the assessor. Still, the overall methodological quality of the studies was excellent.

The internal validity of each of the studies was good. The Paatelma *et al.* and Petersen *et al.* study each had only one major threat due to the lack of control for extraneous variables. Because there were not strict protocols, differences between groups could not necessarily be attributed to the treatments alone. The Schenk *et al.* study conducted no power analysis and thus had a major threat of inadequate sample size. Though each of the studies had several minor threats that, when taken as a whole, decrease the internal validity of the results, the majority of threats were controlled for. In general, we feel confident that we can trust the results of the studies. The external validity of the studies was adequate. The Paatelma *et al.* study population was ideal, as the inclusion criteria was identical to our own and there were few exclusions made. Though the Petersen *et al.* and Schenk *et al.* studies had narrower population criteria, between the two of them acute, subacute, and chronic LBP were addressed. The convenience sampling that each of the three studies used narrows the diversity of the population further. However, we are still confident that we can generalize the results of the studies to our treatment population.

There were several treatment differences with regards to both the McKenzie method and manual therapy—between studies, between groups, and within groups. Manual therapy is a very broad category of treatment. It might include stretching, mobilization, and manipulation. It may also be prescribed at differing intensities. As a result, the comparison intervention to the McKenzie method of treating LBP was variable. In Paatelma *et al.*, manual therapy referred to stretching, spinal mobilization, and spinal manipulation. In Petersen *et al.*, it referred to various spinal mobilization and manipulation techniques as well as myofascial trigger-point massage. And in Schenk *et al.*, it referred specifically to the spinal thrust manipulation. Taking into account the variety of HEPs between the studies and even within the manual therapy groups themselves, and also taking into account the individualized prescription of the manual therapy interventions the clinicians determined to implement, the comparison intervention was far from standardized. The treatment performed on the McKenzie method group was progressed on an individualized basis as well. However, this method is much more standardized. Treatment was directed

according to patients' directional preference. Though this treatment is not perfectly reproducible, therapists trained in the McKenzie method would likely take a similar approach. In summary, the McKenzie method of treatment is reproducible, but in the future, a more standardized manual therapy approach should be the comparison intervention.

Despite the inherent differences between each of the studies, there is weak evidence to support the McKenzie method over manual therapy in treating LBP. A summary of the outcome measures and their results are summarized in the table below.

Table 13. Summary of results from each of the three articles based on functional and pain outcome measures.

	Paatelma <i>et al.</i>	Petersen <i>et al.</i>	Schenk <i>et al.</i>
Pain outcome measures (VAS, NPRS, or LBP Rating Scale)	No difference between groups	No difference between groups	NNT of 2.33 - McKenzie method
Functional outcome measures (RMQ or ODI)	Effect size of 0.33 - McKenzie method	NNT of 8.89 - McKenzie method	No difference between groups
Summary of evidence	Weak evidence favoring McKenzie	Weak evidence favoring McKenzie	Weak evidence favoring McKenzie

According to Paatelma *et al.*, there is weak evidence that the McKenzie method is better than manual therapy in improving function, due to the small-medium effect size found on the RMQ. According to Petersen *et al.*, the low NNT provides only weak evidence that the McKenzie method is better than manipulation in improving function, according to the RMDQ, due to the large confidence interval. Finally, according to Schenk *et al.*, the low NNT provides only weak evidence that the McKenzie method is better than the spinal thrust manipulation in reducing LBP, according to the NPRS, due to the large confidence interval.

Based on the results of the outcomes from Paatelma *et al.*, Petersen *et al.*, and Schenk *et al.* there is weak evidence in support of treating LBP with the McKenzie method, as compared to manual therapy. Further research should be done comparing the McKenzie method to a specific approach of manual therapy, such as the Maitland Approach.

References:

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