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# The effectiveness of the McKenzie method in treating back or neck pain in adults as compared to manual therapy and education as measured by a decrease in pain

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The effectiveness of the McKenzie method in treating back or neck pain in adults as compared to manual therapy and education as measured by a decrease in pain

**Disciplines**

Physical Therapy

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## CRITICALLY APPRAISED TOPIC

**Title:** The effectiveness of the McKenzie method in treating back or neck pain in adults as compared to manual therapy and education as measured by a decrease in pain.

**Clinical Scenario:** The effectiveness of the McKenzie method was pursued due to the differing opinions of our individual clinical instructors regarding its use for the treatment of back and neck pain. The McKenzie method is a type of therapy that emphasizes mechanical diagnosis based on symptomatic and mechanical responses to differing spinal movements. Patients are encouraged to avoid painful spinal movements by stretching in the opposite direction (often extension is the preferred stretch as many people experience pain induced by flexion). While one clinical instructor was a certified practitioner and practiced the McKenzie method thoroughly, the other instructor preferred manual therapy. We saw positive results develop from the use of each of these methods and were interested to see if one approach was more beneficial to our patients or had better long term outcomes.

**Brief introduction:** Back and neck pain are common in individuals that attend outpatient orthopedic clinics where we spent our clinical internships. Individuals trained in the McKenzie method are at odds with therapists that prefer to use manual therapy and stabilization to treat back and neck pain. We are curious if the McKenzie method or manual therapy is significantly more effective and should be used with preference when treating patients with low back or cervical pain or if a combination of both treatments could be used.

**Our Clinical question:** Is the McKenzie method more effective in reducing back or neck pain than manual therapy and education?

### Clinical Question PICO:

**Population** – Individuals between the ages of 18 to 65 suffering from back or neck pain.

**Intervention** – The treatment of interest is the McKenzie method.

**Comparison** – The intervention is being compared to manipulation, mobilization, and education.

**Outcome** – The treatment outcome is measured by pain.

**Overall Clinical Bottom Line:** The general population of the studies included adults aged 18-65 years of age with low back or neck pain with or without radiation. The authors from each study compared the McKenzie method to manual therapy or education for the treatment of low back or cervical pain. Overall, the research was adequately performed to allow generalizability of the results to our patients. Based on the results found by Kjellman, G. and Oberg, B., Peterson et al, and Paatelma et al, we determined that the McKenzie method is a successful treatment to decrease pain. However, we did not find sufficient evidence to indicate that it was better than manual therapy or education. The McKenzie method is not an area we would pursue for pain management because we feel there is not adequate research to justify the cost and time required to become a certified therapist. A narrow focus of decrease in pain indicates that the McKenzie method does not provide better results. Oftentimes, patients just want to stop the pain, but as physical therapists, we may need to shift their focus away from decrease in pain to an increase in function. We would like to expand our scope in the future to look at the increase in function and the increase in self-reliance the McKenzie method appears to have for patients. Additional research is needed to determine if McKenzie has different benefits for our patients that would make the cost and education to become certified worthwhile.

**Search Terms:** McKenzie, Low Back Pain, Neck Pain, Back Pain, Education, Randomized, Control

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**Rationale for chosen articles**

Table 1. Comparison of patient population, intervention, outcome measures, and PEDro Scores

	<b>Article 1</b>	<b>Article 2</b>	<b>Article 3</b>
<b>Patient Population</b>	Similar	Similar	Similar
<b>Intervention</b>	McKenzie vs. Advice	McKenzie vs. Manual/Manipulation	McKenzie vs. Advice McKenzie vs. Manual
<b>Outcome Measures</b>	Decrease in pain using the Visual Analogue Scale	Decrease in pain using the Back and Leg Pain Questionnaire	Decrease in pain using the Visual Analogue Scale
Random Allocation	1	1	1
Allocation Concealed	1	1	1
Groups Similar at Baseline	1	1	1
Blind Subjects	0	0	0
Blind Therapists	0	0	0
Blind Assessors	0	1	1
Adequate Follow-up	1	1	0
Intention-to-Treat	0	1	1
Between Group	1	1	1
Point Estimates & Variability	1	1	1
<b>Total Score</b>	<b>6/10</b>	<b>8/10</b>	<b>7/10</b>

Article 1: Kjellman, G. and Oberg, B. A randomized clinical trial comparing general exercise, McKenzie treatment and a control group in patients with neck pain. *Journal of Rehabilitation Medicine*. 2002; 34: 183-190.

Article 2: Peterson, 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 (24): 1999-2010.

Article 3: 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* November 2008; 40(10):858-863.

We chose article one for four main reasons. First, the article matched every section of our clinical PICO. Second, the authors attempted to include a control group, which allowed us to contribute findings to the intervention. Third, the outcome measure of decrease in pain was quantified by a Visual Analogue Scale, increasing the validity of the study. Finally, this study included the neck, which is an aspect of McKenzie treatment we wanted to investigate.

We chose article two for three main reasons. This article also matched each section of our clinical PICO. We determined that this article had the highest PEDro score and an excellent attempt at blinding when applicable. Finally, this study included the back, which is another area we wanted to investigate with the McKenzie method.

Article three was chosen for four main reasons. This article's PICO matched our clinical PICO regarding the efficacy of the McKenzie method in our patient population. This article also had a good PEDro score with blinding carried out to the greatest extent reasonable, lending increased credibility to the article. This study focused on the measurement of pain using the Visual Analogue Scale, increasing the validity of the study. Finally, this article also focused on the low back, a common area for individuals to injure due to poor posture and body mechanics.

**Article 1:** Kjellman, G. and Oberg, B. A randomized clinical trial comparing general exercise, McKenzie treatment and a control group in patients with neck pain. *Journal of Rehabilitation Medicine*. 2002: 34: 183-190.

**Clinical Bottom Line:** This study indicates that the McKenzie method does significantly decrease pain. Nevertheless, it does not indicate that the McKenzie method is significantly better than a control group. The population consisted of adults 18-65 years with neck pain with or without radiation. The McKenzie treatment group followed the McKenzie protocol and received individualized exercises. The control group received common neck pain information, ultrasound at the lowest setting and a simple home exercise program. Tables 2 and 3 summarize the outcomes and statistical implications. There were no statistically significant differences between the two types of therapy, indicating that both were equally effective at reducing pain. The significant threat to validity was lack of blinding of the assessors. Additional threats included no evidence of a power analysis and no evidence of reliability of instrumentation. Overall, the treatments were comparable in cost and time for the patient and therapists. The McKenzie protocol does require additional education and expense to become proficient. This study can be generalized to our patients. Patients will benefit from the McKenzie protocol or rest, information, and a simple home exercise program. Additional research and information beyond this article is necessary for us to consider the expense of becoming a McKenzie certified therapist.

#### **Kjellman et al PICO:**

**Population:** Subjects 18-65 years of age were included in this study if a physical therapist could provoke neck pain with or without radiation in at least one of four manual pain provoking tests. Exclusion of subjects was based on six criteria: inability to understand Swedish, involvement in an accident less than 10 days before, co-morbidities, whiplash symptoms, affected nerve root symptoms, or participation in chiropractic or physical therapy treatment within the past three months.

**Intervention:** The treatment of interest is the McKenzie method.

**Comparison:** The intervention was compared to a control group and a general exercise group.

**Outcome:** The outcome measures of the study included a questionnaire on background information, pain intensity recorded using Visual Analogue Scale (VAS), pain frequency recorded on a 5-point scale, use of painkillers recorded on a 4-point scale, amount of sick leave taken, the Neck Disability Index (NDI), general health recorded on a 6-point scale and the VAS, psychosomatic and depression symptoms recorded using the Modified Somatic Perception Questionnaire, Modified Zung Depression Index, and the Distress and Risk Assessment Method, expectations of treatment recorded on a 4-point scale, treatment efficacy recorded on a 7-point scale, and satisfaction with care recorded on a 4-point scale.

**Blinding:** Throughout the study, subjects, therapists, and assessors were not blinded. It is not a significant threat that the therapists or the subjects were not blinded. The authors indicated that there was no significant difference between groups in regards to subject opinion on efficacy of treatment. The lack of assessor blinding is a major threat to validity due to the potential of rater bias in the results.

**Controls:** Although there is not a true control group, the group considered the control by the authors was given information on neck problems that is commonly available to the general public, a limited home

exercise program, and received the lowest possible setting of ultrasound bilaterally to the superior part of the trapezius muscle for 14 minutes. This control group was appropriate for this study, allowing us to assume that differences between groups can be attributed to the interventions.

**Randomization:** The assignment of subjects into three groups was randomized. The randomization was concealed by envelopes and the authors state that it successfully resulted in similar baseline data between the groups. However, there is a 9% difference in VAS score between the general exercise group and the control group at baseline, with the McKenzie group in the middle of these two values. It is important then that the statistics for this study consider change in pain rather than just a decrease in score since the control group already has a much lower average pain level.

**Study:** The authors used convenience sampling to create a prospective randomized trial with follow up at six and twelve months after treatment. Subjects 18-65 years of age were included in this study if a physical therapist could provoke neck pain with or without radiation in at least one of four manual pain provoking tests. Exclusion of subjects was based on six criteria: inability to understand Swedish, history of an accident less than 10 days before, co-morbidities, whiplash symptoms, nerve root symptoms, or a history of chiropractic or physical therapy treatment within the past three months.

The subjects were randomly divided into three groups. The control group consisted of 26 subjects, the McKenzie group consisted of 28 subjects, and the general exercise group consisted of 23 subjects. The control group was given information on neck problems that is commonly available to the general public, a limited home exercise program, and received the lowest possible setting of ultrasound bilaterally to the superior part of the trapezius muscle for 14 minutes. It had a mean and standard deviation (SD) of 8 (1) sessions with a mean treatment time of 30 (5) days.

The McKenzie group received individualized exercises based upon the McKenzie protocol. It had a mean of 7 (2) sessions and a mean treatment time of 31 (20) days. The general exercise group received individualized exercises intended to increase cervical movement, endurance, and strength. A standard home exercise program was also given to the subjects. Repetitions and resistance began at a pain-free level and increased as the treatment continued. They had a mean of 13 (3) sessions and a mean treatment time of 55 (15) days.

**Outcome Measures:** The outcome measure relevant to our Clinical PICO is reduction in pain between the control group and the McKenzie group. The authors assessed pain using a Visual Analogue Scale, measuring in millimeters, with endpoints of: 0 (no pain) and 100 (unbearable pain). Reliability and validity were not reported.

**Study Losses:** The study losses were accounted for during the treatment and were relatively equally distributed throughout the three groups. Seventy of 77 subjects completed the study; however, at the “after treatment” and the “6 month follow-up” time periods, only 68 of those 70 subjects responded. At the “12 month follow-up” time period, only 66 of the 70 subjects responded. The authors did not account for these additional study losses and did not perform an intention to treat analysis. Data was investigated with subjects in their originally assigned groups.

**Summary of Internal Validity:** The internal validity of the study is good with one major threat and three minor threats. The major threat to validity was lack of blinding of the assessors which could create rater bias. The three minor threats to validity include no evidence of a power analysis, no evidence of the reliability of instrumentation, and high study losses. The study began with 77 subjects that were eligible to participate and ended at twelve months with 65 subjects. This indicates a loss of just over 15% , but 10% of the subjects were lost during the actual treatment, while the other 5% were lost during follow up. While it is a threat to lose 15% of the individuals, it is only considered a minor threat when considering the cause for losses. The study did contain successful and concealed randomization with an appropriate control group.

**Evidence:** Using the Visual Analogue Scale (VAS) scores, the relevant outcome measures of this study are the mean differences and effect sizes between the McKenzie treatment group and the control group at each time period: before treatment, after treatment, six month follow-up, and twelve month follow-up. In addition, the mean differences and effect sizes within the McKenzie treatment group and within the control group will be analyzed to determine effectiveness of treatments.

Table 2 demonstrates that at each time period, the mean differences and effect sizes between treatments have negative confidence intervals. This indicates there is no significant difference between treatments at any time during the study. Additionally, the decrease in pain after treatment was 34 (53 before treatment – 19 after treatment) for the McKenzie group and 26 (47 before treatment – 21 after treatment) for the control group, but this difference is shown to not be statistically significant and reinforces the proportional equality between the two groups.

Table 2: Visual Analogue Scale (VAS) scores including standard deviation (SD), mean differences, and effect sizes including 95 % confidence intervals [CI] between the McKenzie treatment group and the control group at various time periods

	Before Treatment	After Treatment	Six Month Follow Up	Twelve Month Follow up
McKenzie Treatment Group: VAS Score	53 (23)	19 (18)	21 (17)	26 (23)
Control Group: VAS Score	47 (23)	21 (20)	27 (23)	25 (24)
Mean Difference	6 [-7.80 – 19.80]	2 [9.42 – 13.42]	6 [-6.13 – 18.13]	1 [-13.10 – 15.10]
Effect Size (Between)	.26 [-.30 - .82]	.11 [-.45 - .66]	.30 [-.26 - .85]	.04 [-.51 - .60]

Table 3 demonstrates that both the McKenzie Treatment Group and the Control Group significantly decreased their pain scores at the 12 month follow up. Both treatments were equal at reducing pain; however there was no significant difference in pain relief, indicating that the change elicited by the McKenzie method was not significantly greater than the pain relief felt by the control group.

Table 3: Visual Analogue Scale (VAS) scores including standard deviations (SD), mean differences, and effect sizes including 95 % confidence intervals (CI) within the McKenzie treatment group and within the control group before treatment and at the 12-month follow up

	McKenzie Treatment Group	Control Group
Before Treatment: VAS Score	53 (23)	47 (23)
12 Month Follow UP: VAS Score	26 (23)	25 (24)
Mean Difference	27 (13.20 – 40.80)	22 (7.90 – 36.10)
Effect Size (Within)	1.17 (.57 – 1.77)	.96 (.35 – 1.52)

### **Applicability of Study Results:**

**Benefits vs. Costs:** The financial costs, the therapist’s time and the patient’s time are all comparable. Both groups received similar amounts of intervention and neither group reported adverse events due to treatment.

**Feasibility of Treatment:** The authors assumed familiarity with the McKenzie protocol and provided enough information to reproduce the control group protocol. The McKenzie protocol does require additional education to become familiar with the treatment. The expense and time to become an expert in McKenzie treatment may create a barrier to performing the protocol in clinics. The number and duration of physical therapy sessions would be covered by insurance and is a feasible amount for patients. Home exercise programs were given, but adherence was not indicated. Treatment was not reported to be painful.

**Summary of External Validity:** The internal validity of this study was good allowing us to generalize the results to our patients. The subject sample contained adults, 18-65 years of age, which matches our target population. The results indicated that the McKenzie treatment group and the control group had significantly reduced pain; however, there was not a significant difference between the two treatments. This tells us that both treatments are viable options for decreasing pain.

**Article 2:** Peterson 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 (24): 1999-2010.  
Manniche C, Asmussen K, Lauritsen B, et al. Low back pain rating scale: validation of a tool for assessment of low back pain. *Pain* 1994; 57: 317-326

**Clinical Bottom Line:** The results of this study indicate that the McKenzie method was not significantly better at decreasing the level of pain experienced by subjects when compared to the use of manipulation. The study included individuals between 18 and 60 years of age with low back pain. Subjects were excluded using 16 criteria including: symptom free on the day of inclusion, positive nonorganic signs, severe nerve root involvement, fracture, cancer, osteoporosis, severe spondylolisthesis, inflammatory arthritis, visceral referred pain, pending litigation, pregnancy, application for disability, comorbidity, recent back surgery, communication problems, or abuse of drugs and alcohol. Individuals that were included in the study either received the McKenzie method for treatment of low back pain or spinal manipulation. At baseline the pain level and 95% confidence interval was 1 (-1.55 to 3.55), at two months the level of pain was 1.6 (95% CI -1.2 to 4.4) and at twelve months the pain level was 1.4 (95% CI -1.3 to 4.1). The authors used a minimal clinically important difference of 30% while analyzing their results and determined that none of these follow ups were clinically significantly different. Three scales comparing pain at different times were used to place the subject on a scale of 0 (no pain) to 60 (worst pain on all items). The number needed to treat for success with the McKenzie method over the manipulation group was eight individuals (95% CI 4 to 40) at post treatment and seven (95% CI 4 to 47) at the two month assessment. Minimal threats to internal validity, including the lack of a control group, are not considered significant when compared to the strict regimen followed to avoid bias and provide accuracy in measurements. The McKenzie method is shown to be equally as effective as manipulation in treatment of low back pain, suggesting that the costs for further education in this area are not necessary unless a therapist is prohibited by state laws from performing manipulation.

**Peterson et al PICO:**

**Population:** Subjects 18-60 years of age were included in the study if low back pain with or without leg pain persisted for more than six weeks. Subjects were required to be able to speak and understand the Danish language and show clinical signs of disc-related symptoms. Exclusion of subjects were based on 16 criteria: symptom free on the day of inclusion, positive nonorganic signs, severe nerve root involvement, fracture, cancer, osteoporosis, severe spondylolisthesis, inflammatory arthritis, visceral referred pain, pending litigation, pregnancy, application for disability, comorbidity, recent back surgery, communication problems, or abuse of drugs and alcohol.

**Intervention:** The treatment of interest is the McKenzie method.

**Comparison:** The intervention was compared to a spinal manipulation treatment group.

**Outcome:** The outcome measures of the study included patient report of success defined by a decrease of at least five points or a score below five points on the 23-item modified Roland Morris Disability Questionnaire. Secondary outcome measures included change in pain, reduction in global perceived effort, amount of work time lost, changes in mental and physical health, days of decreased activity, seeking further health care after treatment, and treatment satisfaction.

**Blinding:** Throughout the study, blinding was done when possible. The physical therapist that performed the initial assessments of subjects was blinded to treatment groups. The secretary who performed the randomization and the secretary who performed the follow-up assessments were both blinded to treatment allocation. Subjects and therapists were not blinded to treatment, but this is only a minor threat to validity.

**Controls:** A control group was not included in this study.

**Randomization:** The assignment of subjects into two groups was randomized. The randomization was concealed by envelopes and successfully resulted in similar baseline data between the groups.

**Study:** The authors used convenience sampling to create a randomized trial with follow up at two months and one year after treatment. Subjects 18-60 years of age were included in the study if low back pain with or without leg pain persisted for more than six weeks. Subjects were required to be able to speak and understand the Danish language and show clinical signs of disc-related symptoms. Exclusion of subjects were based on 16 criteria: symptom free on the day of inclusion, positive nonorganic signs, severe nerve root involvement, fracture, cancer, osteoporosis, severe spondylolisthesis, inflammatory arthritis, visceral referred pain, pending litigation, pregnancy, application for disability, co-morbidity, recent back surgery, communication problems, or abuse of drugs and alcohol.

The subjects were randomly divided into two groups. One-hundred seventy-five subjects were allotted to the McKenzie treatment group and 175 subjects were allotted to the spinal manipulation group. The McKenzie treatment group received individualized exercises based upon the McKenzie protocol. A lumbar roll could be given to the subject if indicated necessary by the physical therapist.

The spinal manipulation treatment group received all types of manual therapies including vertebral mobilization, high velocity thrusts, and myofascial trigger-point massage. Each subject could be given self-manipulation exercises, alternating lumbar flexion/extension exercises, stretches, or a wedged pillow at the discretion of the chiropractor.

Both treatment groups received advice on back care along with “The Back Book”. The maximum allowed treatment time for both groups consisted of 15 treatments for a period of 12 weeks. The therapists and chiropractors had the option to give a home exercise program for stabilization and strengthening at the completion of treatment to be continued for at least two months post treatment.

Outcome Measures: The outcome measure relevant to our clinical question is decrease in pain. Subjects’ pain was assessed at the end of treatment, after two months, and after one year of treatment. Back pain was measured with a questionnaire which included leg pain as well. The questionnaire comprised of three separate 11-box-scales that consisted of the following items: “(Low Back Pain) LBP at the moment, the worst LBP within the past 2 weeks, and the average level of LBP within the last 2 weeks.” The range of scores available was 0 points (no pain at all) to 60 points (worst possible pain on all items). Validity for the questionnaire was cited by the authors from the article “Low back pain rating scale: validation of a tool for assessment of low back pain” written by Manniche, C, Asmussen K, and Lauritsen B, et al.<sup>1</sup>

Study Losses: During the study there was a high rate of study losses. One-hundred thirty-nine out of 175 subjects completed the full McKenzie treatment program. Twenty-eight subjects withdrew due to perceived lack of effectiveness and eight subjects withdrew attributing other factors. Out of the 139 subjects who finished the study, 137 subjects could be reached for follow up at the end of treatment, 136

could be reached for follow up at two months following treatment, and 130 could be reached for follow up at twelve months following treatment. One-hundred twenty out of 175 subjects completed the full spinal manipulation treatment program. Forty-three subjects withdrew due to perceived lack of effectiveness and 12 subjects withdrew attributing to other factors. Out of the 120 subjects who finished the study, 116 could be reached for follow up at the end of treatment, 115 subjects could be reached for follow up at two months following treatment, and 115 subjects could be reached for follow up at twelve months following treatment.

The spinal manipulation group had more people withdraw due to perceived lack of effect of treatment. The large amount of study losses overall creates a threat to validity. An intention to treat analysis was performed by the authors and it seems as though all subjects were analyzed with their original groups. The intention to treat analysis provided no additional information to distinguish between the effectiveness of each treatment.

**Summary of Internal Validity:** The internal validity of this study was good, with one major threat and one minor threat. The study was made strong by effective randomization, design, validity of instrumentation, power, appropriate statistical tests, and strict protocol. The experiment did not include a control group, which makes it impossible to determine if the rates of pain decrease were due to the treatment or the natural healing process. This makes history and maturation a major threat to validity. A minor threat to validity was the extent to which blinding could be implemented. While the researchers were very thorough in blinding at all possible steps, the patients and therapists/chiropractors could not be blinded to the treatment they were receiving or providing. This was minimized by the blinding of the assessing therapist, the secretary that performed the randomization, and the secretary that performed the follow up assessments.

**Evidence:** This study gathered data comparing individuals with low back pain that received the McKenzie method of treatment as applied by a physical therapist to individuals that received various types of manipulation as applied by a chiropractor. The relevant data for the two groups at each assessment time are presented in Table 4. Subject pain levels were measured using a questionnaire with three 11 point scales. These scales compared pain at the moment, worst pain in the past 2 weeks and average pain level in the past 2 weeks. Scores ranged from 0 (no pain) to 60 (worst pain on all items). Table 4 shows that there was no significant difference in pain level between groups at any period of assessment.

Table 4. Pain measured at baseline and reduction of pain at post treatment, 2 month follow up, and 12 month follow up assessment compared between groups with a 95% confidence interval (CI) and a significance given to *P* values less than 0.05

	McKenzie Group	Manipulation Group	Between-group Difference (95% CI), <i>P</i>
Baseline	30, SD=11.2	29, SD=11.3	1 (-1.55 to 3.55)* <i>P</i> =0.746
Post Treatment	15.3 (13.4 to 17.4)	13.8 (11.8 to 15.8)	1.6 (-1.2 to 4.4) <i>P</i> =0.271
2 Months Follow Up	13.3 (12.4 to 16.4)	13.0 (11.1 to 14.9)	1.4 (-1.3 to 4.1) <i>P</i> =0.309
12 Months Follow Up	15.0 (12.9 to 17.1)	12.2 (10.1 to 14.3)	2.8 (-0.2 to 5.8) <i>P</i> =0.063

\*We ran this statistic using the data given by the authors.

SD = standard deviation

Additionally, at post treatment assessment, it was found that the number needed to treat (NNT) with the McKenzie method was eight (95% CI 4 to 40) as compared to manipulation. This means that the McKenzie method will provide one more successful outcome for every eight patients treated. At the two month assessment the NNT was seven (95% CI 4 to 47) and at twelve months there was no statistical difference observed between pain relief due to McKenzie treatment and pain relief due to manipulation.

### **Applicability of Study Results:**

Benefits vs. Costs: Both intervention methods require specialized training and specialized equipment is optional. The McKenzie method appears to rely more on patient time outside of the treatment than the manipulation intervention. Additionally, the manipulation method relies more heavily on the therapists' time. The McKenzie method requires patients to perform various exercises outside of their treatment for success, while the manipulation only requires effort on behalf of the patient if they feel uncomfortable between treatments. Both treatment groups received approximately the same amount of treatments and neither treatment elicited adverse effects. However, at the post treatment assessment and two month follow up, the NNT was eight and seven respectively. After the onetime education requirement to become trained in either of these methods, the costs and benefits are relatively equal in comparison with no significant difference in pain decrease between groups.

Feasibility of Treatment: Each intervention provided to the subjects was carried out by a therapist or chiropractor trained in the McKenzie method or manipulation. Further details on progression of treatment are vague as each patient's course of treatment would have depended on the nature of their low back pain. Both treatments are feasible within the normal capacity of a physical therapy clinic. Depending on the state in which a physical therapist is practicing, manipulation may or may not be allowed within the clinic. Insurance companies do cover both of these treatment methods and neither treatment is especially painful. Patients may be attracted to the chiropractic manipulation as it appears to be a less time demanding course of treatment than the McKenzie method. While the changes in pain level were not significant between the two groups, other outcome measures did indicate a significant improvement on other points of interest from the McKenzie group. However, for our purposes the McKenzie method did not provide compelling evidence for success in decreasing pain when compared to manipulation.

Summary of External Validity: This study has minimal threats to internal validity and the results of the study are applicable to our clinical population. The authors followed a strict regimen for ensuring that rater bias was avoided, subjects were randomized, and measurements were thorough. The research results are majorly threatened by the lack of a control group. The study showed there is no significant difference in pain levels at follow up for individuals who receive McKenzie method treatment as compared to manipulation. Based on this outcome measure alone, we do not feel the additional education in the McKenzie method would be beneficial when compared to the equally low costs and effective pain management of manipulation. In locations where a physical therapist is not permitted to perform manipulation, it may be beneficial to learn the McKenzie method in order to increase the population that they are able to serve.

**Article 3:** 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* November 2008; 40(10):858-863.

**Clinical Bottom Line:** The McKenzie method may be an effective exercise program for reducing the presence of low back pain (LBP) in individuals 18-65 years old. The control group received one session of advice for returning to regular work and activity. Additionally, they received a short booklet for support. The McKenzie group received three to seven therapy sessions that used specific McKenzie

extension or flexion exercises to reduce their low back pain. The between group averages for decrease in pain (with a 95% confidence interval) at three, six, and 12 months on the VAS in millimeters were -7 (-20 to 6), -15 (-27 to -4), and -4 (-17 to 9) respectively. Additionally, the corresponding p-values for these follow ups were 0.389, 0.009, and 0.732. These results suggest that at the six month follow-up the McKenzie method was significantly more effective in reducing LBP than advice only. When comparing the control to the manual therapy group, which received manipulation, mobilization, and stretching for three to seven visits, no significant differences appeared. The results at three, six, and 12 months for the difference at 95% CI were -1 (-14 to 12), -10 (-22 to 2), and -4 (-17 to 9) respectively. The p-values were 0.396, 0.141, and 0.714. These did not meet the 0.05 requirement for significance. The McKenzie method provides a format to decrease pain with simple exercises that are easy for patients to understand. This requires a financial investment to become a certified practitioner, but is more favorable than giving only advice to the patient. The study has incomplete blinding, insufficient power, an incomplete control, and a high percentage of subjects lost. Only the last of these threats is considered major and was accounted for using intention to treat statistics. Overall, the study is good and we feel comfortable having our patients receive McKenzie exercises. However, if we did not have the training to provide McKenzie exercises, we would not feel that our patients were being deprived by receiving manual therapy instead.

### **Paatelma *et al* PICO:**

**Population:** This study consisted of 134 patients from four Finnish occupational health care centers between the ages of 18-65 years old. Participants were included within the study if they had current non-specific low back pain (LBP), regardless of radiating pain to one, both, or neither of their legs. LBP could vary from acute to chronic and may be reported as a singular event (first time) or recurrent. Individuals were excluded from this study if they were pregnant, had low back surgery within the last two months, or “red flags” for spinal pathology as described by Bigos<sup>2</sup>.

**Intervention:** The intervention method of interest was the McKenzie method for treatment of low back pain.

**Comparison:** Individuals that did not receive the intervention of interest were given either orthopedic manual therapy or only advice to stay active.

**Outcome:** The objectives of this study were to determine the potential effects of each intervention on low back pain (and corresponding leg pain, if applicable) intensity and disability. Intensity was measured using a visual analogue scale ranging from 0 (no pain) to 100 (worst pain imaginable). Disability was measured by the 0-24 point scale Roland-Morris Disability questionnaire at the beginning of treatment and then at three months, six months, and twelve months post intervention. Outcomes were also collected at the three, six, and twelve month mark regarding the patients report of potentially influential information such as use of healthcare services for other problems and other back pain treatments used.

**Blinding:** Researchers within this study included blinding as far as is reasonably possible. Patients and therapists could not be blinded to the treatment they were receiving or giving, but blinding did occur on behalf of the research group. All measurements were made by one research assistant and then the measurements were given to another assistant who coded the results. The assistant that coded the results was blinded to the group assignment that the measurements came from. The use of single blinding is a threat to the validity of this study because it may have altered the responses that patients had to each of the different treatment strategies (based on patient preconceptions about the effectiveness of a given treatment).

**Controls:** While there was no true control group, the “advice only” group was intended to serve this purpose. Also, the orthopedic manual therapy group was used to provide an alternative treatment for comparison. The advice only group received 45-60 minutes of counseling from a physiotherapist. The counseling included education about a positive prognosis for LBP, pain tolerance, medication, and the

importance of returning to work and maintaining exercise activities as soon as allowed by their pain level. This was followed by a two page educational booklet for support. All groups were treated by a specialized therapist for that area of treatment and the same therapist treated each individual in the group.

**Randomization:** Individuals were assigned to the three intervention groups using sealed envelopes that were numbered using a random number table. This randomization process was performed with the assumption that the study would follow 180 patients for three years. The actual number of participants was 136, which caused a size imbalance between the three groups. It was determined however, that after excluding two individuals that failed to meet inclusion criteria, no significant differences existed between the groups in regards to age, gender, or clinical characteristics at the beginning of the study.

**Study:** This study was a randomized controlled trial that consisted of 134 patients from four Finnish occupational health care centers between the ages of 18-65 years old. The individuals were randomly placed in one of three intervention groups. The orthopedic manual therapy group consisted of 45 patients, the McKenzie method group had 52 patients, and the “advice only to be active” group had 37 patients.

Individuals were included within the study if they had current non-specific low back pain (LBP), regardless of radiating pain to one, both, or neither of their legs. LBP could vary from acute to chronic and reported as a singular event (first time) or recurrent. Individuals were excluded from this study if they were pregnant, had low back surgery within the last two months, or “red flags” for spinal pathology as described by Bigos.<sup>2</sup> Prior to randomization, a LBP history was taken and individuals received a structural examination by the research assistant. Participants were then randomized and confirmed eligible to participate in the study.

Patients in each group received the assigned treatment by therapists specializing in the given type of therapy (manual, McKenzie, or advice). The same therapist provided treatment to all individuals within their intervention group. Those in the advice only group were seen for one visit, while patients in the manual therapy and McKenzie group were seen for three to seven visits.

The manual therapy group received spinal manipulation, specific mobilization, and muscle stretching techniques. They also received either mobilization or high velocity-low force manipulation. Specifically, the therapists used translatoric thrust in supine or sidelying, translatoric thrust manipulation or mobilization of L1-L5 in prone or sidelying, and a sacroiliac manipulation/mobilization gliding the ileum on the sacrum in the ventral or dorsal direction while the patient was prone. Finally, each patient was taught self mobilization and stretching to be performed at home once a day.

The McKenzie method group first underwent an assessment to determine the mechanical classification of their pain. Individuals were then educated using the book *Treat Your Own Back* and taught therapeutic exercises that were to be performed 10-15 times every 1-2 hours. If progression of recovery was deemed too slow, overpressure and/or mobilization was given by the therapist during the treatment session. This group avoided the high velocity-low force techniques employed by the manual therapy group.

The advice only group received one counseling session about the positive prognosis granted to those that stay as active as possible despite their LBP and the importance of avoiding prolonged bed rest. They left the counseling session with a two page booklet for support in their efforts to recover.

Outcome measures: Relevant to the clinical PICO, data was collected using a visual analogue scale (VAS) measured in millimeters to determine the intensity of LBP. These measurements were taken at baseline, three months, six months, and twelve months post intervention. The authors of this study cite Price, McGrath, and Buchingham<sup>3</sup> as evidence of the validity provided by VAS in measuring pain levels. However, no evidence for reliability of the VAS is given.

Study losses: During the year following intervention, there was a loss of 14% of participants in the McKenzie group, 22% of participants in the manual therapy group, and 30% in the advice only group. Baseline measures and outcome measures between those that left the study and those that completed the

study only differed on the issue of leg pain. Losses were attributed to low back surgery during follow up period (necessitating exclusion), disappointment with limited treatment possibility, and inability to contact the patient upon follow up. These losses were accounted for during the analysis of the data using intention to treat post hoc ANOVA statistics and the Scheffe's adjustment, which showed that there was not a difference between the level of pain between the "drop outs" and individuals who completed full follow up.

**Summary of internal validity:** The internal validity of this study is good with potentially one major threat and three minor threats. The study is strengthened by its randomization, design, appropriate statistical tests, citation to support the validity of the use of a visual analog scale, and strict protocol. The first minor threat to validity is the lack of a true control group. While the advice only group was intended to serve as a control, these participants did receive therapeutic information for future recovery from their LBP. A second minor threat is the inability to blind the therapists and patients because patients who only receive an informational booklet may have lower expectations for improvement. The researchers did make the effort to minimize this threat by blinding those that would be coding the data, making this less of an overall threat to the experiment.

Lastly, a power analysis was not identified by the researchers, which detracts from the validity of the research as it is unknown whether the results can be applied to a larger population. It also minimized their ability to divide patients into more specific categories, such as acute and subacute. We performed our own power analysis with an effect size of 0.3 and power of 0.8, which indicated that each group within the study should have a minimum of 45 individuals. While it appears that the authors were striving for this, losses resulted in some groups having slightly fewer individuals than this requirement. The authors of this study identified that this leads to the possibility of a type II error. However, they continue by showing that the power analysis at the end of the study indicates that differences can be detected using F tests.

A potential major threat to this study is their large dropout rate. The authors of this study argue to counteract this weakness with their intention to treat statistics that demonstrated the outcome measures of the dropouts did not differ from those that did successfully complete the follow ups.

**Evidence:** This study gathered data for three separate interventions for low back pain and analyzed the effectiveness of each in decreasing pain. The relevant data for these three interventions are presented in Table 5 and Table 6. Research subjects rated their low back pain in millimeters (mm) using a visual analog scale. Table 5 shows that the advice only group had consistently higher pain levels than the McKenzie method group.

Table 5. Pain reported via visual analog scale in mm at baseline, 3 months, 6 months, and 12 months after intervention given as the median per intervention group (25<sup>th</sup> and 75<sup>th</sup> quartiles)

	Baseline LBP	LBP at 3 months	LBP at 6 months	LBP at 12 months
Orthopedic Manual Therapy	35 (20, 50)	18 (11, 28)	14 (10, 21)	11 (3, 22)
McKenzie Method	32 (20, 42)	10 (2, 22)	10 (5, 15)	8 (0, 23)
Advice Only	37 (21, 50)	17 (10, 28)	22 (15, 39)	16 (7, 33)

LBP: Low Back Pain

The information in Table 6 shows that at three and twelve months there was no significant difference in reported pain levels between the advice only group and McKenzie group. However, at the six month follow up, individuals in the McKenzie group had significantly less pain than those in the advice only group, suggesting possible long term benefits to this treatment. Values less than 0.05 are considered statistically significant. Contrasting the McKenzie group, the manual therapy group did not have significantly greater effects at any of the follow ups when compared to the control.

Table 6. A comparison of the visual analog scale results between the advice only group and McKenzie group or manual therapy at three, six, and 12 months post treatment with a 95% CI and p-values for between group differences in the analysis of variance calculated by the authors of this study

<b>McKenzie</b>	<b>LBP at 3 months</b>	<b>LBP at 6 months</b>	<b>LBP at 12 months</b>
Difference (95% CI) in mm	-7 (-20 to 6)	-15 (-27 to -4)	-4 (-17 to 9)
p-value	0.389	0.009	0.732
<b>Manual Therapy</b>	<b>LBP at 3 months</b>	<b>LBP at 6 months</b>	<b>LBP at 12 months</b>
Difference (95% CI) in mm	-1 (-14 to 12)	-10 (-22 to 2)	-4 (-17 to 9)
p-value	0.396	0.141	0.714

LBP: Low Back Pain; CI: Confidence Interval

The authors compared the McKenzie group and the manual therapy group. They determined that there was no statistically significant difference at any time point between the two groups in regards to low back pain.

### **Applicability of study results:**

Benefits vs. Costs: While the use of McKenzie does not significantly improve an individual's rate of recovery, it does provide several benefits. Within this study, the McKenzie group had the lowest percentage of drop out subjects (identified by the authors as insignificant). After a therapist has been trained in the use of the McKenzie method, this treatment allows for an approach that requires little time on behalf of the therapist. While extra equipment is not crucial, the equipment that is available is large and expensive. Also, there is a financial obligation for the therapist to become fully certified in this method of treatment. Improper use of the exercises can further exacerbate symptoms when a therapist has not received the specialized education on the theories of the McKenzie method.

In contrast, while McKenzie requires a short education from the therapist to the patient, the patient is required to be diligent in their home exercise program. The exercises may be simple, but are instructed to be completed every 1-2 hours. This may be difficult for a busy patient and result in a failure to complete the necessary exercises for recovery.

Finally, the McKenzie group required approximately the same number of visits as the orthopedic manual therapy group without significantly better results. This suggests that the McKenzie method may not be worth the cost of training and the risk of putting so much of the therapy into a reliance on the home program. However, the McKenzie method did show significant improvements as compared to the advice only group at the six month follow up. The "advice only" intervention was the least expensive, but also the least effective. This indicates that investing in specialized training for manual therapy or the McKenzie method is favorable.

Feasibility of treatment: All treatments given during this experiment required little additional equipment and can be easily reproduced if a therapist has the correct educational background. Within the study, the authors did not specifically describe the details of each exercise, manipulation, or stretch. Rather, they occasionally cited other sources from which they pulled their treatments or left a vague description (i.e. "Mackenzie exercises" instead of "repeated lying in extension performed prone using elbows for support"). Reproduction of this study could only be completed successfully by therapists specially trained in the McKenzie intervention method.

The average McKenzie patient was seen for three to seven visits, which is a feasible amount considering that this breaks down to less than two visits per week for a month. It appears that patients would be able to get their insurance company to approve this therapy, but the McKenzie method did not require significantly less visits than manual therapy and did not provide significantly better results. This

suggests that manual therapy is equally feasible and likely to be covered by insurance companies without requiring the extra certification.

The McKenzie method is not painful, but does have a home exercise program that may be difficult for patients to adhere to. The exercises are simple, but repetitive and require a lot of dedication from the patient. This treatment requires individuals to go through their exercises every 1-2 hours for many repetitions. Many patients find such a demand unrealistic when considering their busy schedules.

Summary of external validity: This study has minimal threats to internal validity and the results of the study appear applicable to my adult population with low back pain. Subjects were recruited for this study in a random manner through referrals for physical therapy treatment. The authors followed a strict regimen for ensuring that rater bias was avoided, subjects were randomized, and measurements were thorough. The study showed that McKenzie and orthopedic manual therapy both significantly reduced pain when compared to advice only. We would feel comfortable applying McKenzie to our patients if we had the certification to do so, but would not feel that we are depriving them of superior treatment by applying manual therapy.

### **Synthesis/Discussion**

Overall, all articles demonstrate that the McKenzie method is not significantly better than manual therapy or education at decreasing neck or low back pain. From the three articles, there was only one data point that showed a statistically significant decrease in pain. We consider this to be an insufficient amount of evidence to elicit McKenzie training for pain management alone.

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