

2014

Comparing the efficacy of spinal stabilization exercises and McKenzie (i.e. repeated movement) exercises in the treatment of chronic low back pain as measured by disability scores and pain reduction

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Recommended Citation

Charbonneau, Laurel, "Comparing the efficacy of spinal stabilization exercises and McKenzie (i.e. repeated movement) exercises in the treatment of chronic low back pain as measured by disability scores and pain reduction" (2014). *PT Critically Appraised Topics*. Paper 52.

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Comparing the efficacy of spinal stabilization exercises and McKenzie (i.e. repeated movement) exercises in the treatment of chronic low back pain as measured by disability scores and pain reduction

Disciplines

Physical Therapy

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Laurel Charbonneau

CRITICALLY APPRAISED TOPIC

Title: Comparing the efficacy of spinal stabilization exercises and McKenzie (i.e. repeated movement) exercises in the treatment of chronic low back pain as measured by disability scores and pain reduction.

Clinical Scenario: A male patient in his mid-forties presents with chronic and severe low back pain for over one year. He has tried chiropractic care and massage but was not experiencing lasting relief. He had been in physical therapy for two months when I met him and was working on postural awareness, stretching, and strengthening. He continued to experience moderate to severe pain, rated a six to seven out of ten on a visual analogue scale, and was having difficulty performing activities of daily living and work duties. Being that his strengthening exercises had not provided him with much relief, I wanted to research to see if the McKenzie approach would yield greater functional improvements and reduction in pain.

Brief introduction: The two different treatments of interest utilize different approaches to alleviate low back pain and there are differing opinions and evidence on which is more effective (Miller, 2005). The McKenzie method utilizes an approach involving postural awareness and repetitive movements with the underlying idea that a reverse force can decrease pain and return function (McKenzie Institute, 2013). Whereas strengthening exercise works to rectify muscle abnormalities and restore correct function of muscles such as the multifidus and transverse abdominis to support and stabilize the spine (Garcia *et al.*, 2013 and Miller *et al.*, 2005). At my initial outpatient orthopedic internship, the physical therapist predominately utilized the McKenzie method for chronic low back pain. Currently, I am at an outpatient orthopedic clinic that uses spinal stabilization and strengthening programs for chronic low back pain. From my limited experience, patients seemed to “buy in” more to the McKenzie method than the spinal stabilization exercises. These patients seemed to notice improved function, decreased pain, and tended to be more compliant with their home exercise programs. The goal of this paper is to research which treatment is more effective at alleviating pain and decreasing disability.

My Clinical question: Which is more effective in the treatment of chronic and sub-acute low back pain for reducing pain and disability, strengthening exercises or McKenzie exercises?

Clinical Question PICO:

Population – Male and female adults, ages 18-65 with chronic non-specific low back pain.

Intervention – McKenzie exercises based on directional movement preferences, for approximately four to six weeks, and a home exercise program (HEP) that includes similar exercises

Comparison – Spinal stabilization exercises, supervised by a PT, for approximately four to six weeks, two times per week, and a HEP with similar exercises.

Outcome – Changes in patient reported pain rating and disability scores as gathered from functional outcome measures.

Overall Clinical Bottom Line: Based on the results from the articles by Miller *et al.*, and Peterson *et al.*, spinal stabilization/back strengthening exercises and McKenzie exercises appear equally effective in decreasing pain and disability for individuals with chronic low back pain. Miller *et al.* found statistically significant improvements in pain reduction, for both McKenzie ($p=0.05$) and spinal stabilization groups ($p=0.002$), but no statistically significant differences were detected between groups for pain reduction or disability scores ($p>0.05$). Poor internal validity, particularly lack of blinding and concealment of group allocation, means that results should very cautiously be applied to the clinical population. The article by Peterson *et al.* found no statistically significant benefit to using the McKenzie method compared to intensive strengthening for the treatment of patients with non-specific chronic low-back pain ($p>0.05$). The authors did not conduct a within group comparison and data provided did not allow this to be calculated independently. The study had fair internal validity and results could be cautiously applied to the clinical population. Based on the two articles and the finding that the McKenzie approach is equally as successful as low back strengthening programs for decreasing pain and disability, I could use the McKenzie approach for the patient of interest whom was not successful decreasing his pain or disability with a strengthening program.

Overall there needs to be further research on this topic using studies with stronger internal validity, increased participant population, and increased assessment points to compare initial benefits and lasting benefits of treatment. Ideas for further research include determining if one treatment is more effective at providing relief faster, such as within the first two to three weeks of treatment. Additionally, there needs to be further research conducted utilizing individualized treatment plans for both groups. Within both studies the McKenzie group received an individualized treatment plan based on directional preference, but the strengthening groups in both studies received a preformatted exercise protocol that did not allow for much specific individualization.

Search Terms: McKenzie, Low back pain, Exercise, Repeated movement, Spine stabilization, Mechanical diagnosis treatment, Randomized control trials, McKenzie Strengthening.

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Rationale for your chosen articles

The databases Medline, Cinahl, Google, Google Scholar, and PubMed were used to find articles to answer the clinical question. The search focused on articles written after 2000 to try to obtain the most current research but older articles were used if they were referenced in other articles and had high Pedro scores. Search terms that produced articles included McKenzie, low back pain and randomized control trial. After finding five articles that pertained to the topic, the article PICO was compared to the clinical PICO. Two of the articles included narrow sub-groups of participants that did not apply to my clinical question. The articles listed below closely matched the clinical PICO. Two of these three articles were selected for detailed analysis and potential application to the clinical patient population.

1. Garcia AN, Costa LC, da Silva T, Gondo TF, Cyrillo, FN. Effectiveness of back school versus McKenzie exercises in patients with chronic nonspecific low back pain: A randomized control trial. *Physical Therapy* 2013 June; 93(6):729-47.

Pedro score: 8/10.

P: 148 male and female patients from Brazil with nonspecific chronic low back pain from the ages of 18-80 years old.

I: A treatment program of back exercises to improve mobility, flexibility and strength. The treatment was comprised of four group sessions over four weeks.

C: Four weeks of McKenzie exercises based on the individual's directional preference. Treatments were one-on-one with the physical therapist (PT).

O: Pain intensity measured on a 0-10 pain intensity scale and disability rating as measured by the Roland-Morris Disability Questionnaire at one month following randomization. Secondary outcome measures include pain intensity at three and six months after randomization, quality of life as measured by the World Health Organization Quality of Life-BREF instrument, and trunk flexion range of motion.

While the article by Garcia *et al.* has a high Pedro score and represents very current research, after careful consideration I decided not to include the article in my analysis. The population, comparison, and the outcome measures all matched the clinical PICO relatively closely, but the intervention used in the article did not match the clinical PICO. The intervention was only once per week and utilized a very specific type of group strengthening that did not allow for individualization.

2. Petersen T, Kryer P, Ekdahl C, Olsen S, Soer J. The effect of McKenzie therapy as compared with that of intensive strengthening training for the treatment of

patients with subacute of chronic low back pain: A randomized control trial. *Spine* 2002 August; 27(16):1702-9.

Pedro score 7/10

P: 260 male and female patients ages 18-60 with sub-acute or chronic low back pain for more than eight weeks duration. The patients were living in Copenhagen, Denmark.

I: Eight weeks of group strength training at an outpatient clinic and then two months of self-training at home.

C: Eight weeks of McKenzie exercises based on directional overpressure, and then two months of exercises at home.

O: Manniche's Low Back Pain Rating Scale. Low back and leg pain intensity scales were measured on three separate 11 box scales. The authors also measured return to work by a questionnaire, over the counter pain medication use, and the patient's own perception of global change on a five point scale. The results were measured at the two month follow up assessment and at eight months.

Although this study included the comparison of group based therapy, there was still more individualization compared to the study performed by Garcia *et al.* The article PICO very closely matched by clinical PICO. The article was written after 2000 and the Pedro score was 7 out of 10.

3. Miller ER, Schnek RJ, Karnes JL, Rousselle JG. A comparison of the McKenzie approach to a specific spine stabilization program for chronic low back pain. *Journal of Manual and Manipulative Therapy* 2005; 12(2):103-12.

Pedro score: 5/10

P: 30 patients over the age of 18 from New York State, with non-specific chronic low back pain, as defined by having low back pain for 7 weeks or more.

I: Specific spinal stabilization exercises for 6 weeks.

C: McKenzie exercises for 6 weeks based on directional preference.

O: Functional Status Questionnaire, the short form McGill Pain Questionnaire, and straight leg raise to assess lumbar nerve root tension/irritation or low back dysfunction at baseline and after the 6 weeks of treatment.

This article has the lowest Pedro score but it includes a strength training intervention that is very similar to what I have observed clinically. This may be due to the fact that this was only study found that took place in the United States. The article PICO very closely matched my clinical PICO. The protocol was much more thorough and detailed, making the protocol easier to reproduce than the other two articles.

Table 1. Comparison of PEDro Scores; taken from pedro.org.au

	Garcia <i>et al.</i>	Petersen <i>et al.</i>	Miller <i>et al.</i>
Random	Yes	Yes	Yes
Concealed allocation	Yes	Yes	No
Baseline comparability	No	Yes	Yes
Blind Subjects	No	No	No
Blind Therapists	Yes	No	No

Blind Assessors	Yes	No	No
Adequate Follow-up	Yes	Yes	Yes
Intention-to-Treat	Yes	Yes	No
Between Group	Yes	Yes	Yes
Point Estimates & Variability	Yes	Yes	Yes
Total Score	8/10	7/10	5/10

Based on the above comparisons and reasoning, I have chosen to write this critically appraised paper on the articles by Petersen *et al.* and Miller *et al.* to determine whether strengthening exercises or McKenzie exercises are more effective in the treatment of chronic, non-specific low back pain. The two research designs contain flaws such as lack of blinding of subjects and assessors in both articles and lack of intention to treat analysis and concealed allocation in the study performed by Miller *et al.*, but the flaws of the article do not affect the ability to extrapolate the results to a similar population.

Article: Miller ER, Schnek RJ, Karnes JL, Rousselle JG. A comparison of the McKenzie approach to a specific spine stabilization program for chronic low back pain. *Journal of Manual and Manipulative Therapy* 2005; 12(2):103-12.

Clinical Bottom Line:

Based on the study performed by Miller *et al.*, stabilization exercises that focused on retraining deep or local stabilizing muscles of the spine are equally as effective as the McKenzie approach in decreasing chronic low back pain and decreasing disability. The authors compared six weeks of spinal stabilization exercises and six weeks of McKenzie intervention based on directional preference and found that both groups made statistically significant improvements from baseline but that there were no statistically significant differences between the two groups for pain or disability scores, $p > 0.05$. The study had poor internal validity with lack of blinding for PTs, subjects, and assessors, lacking statistical power and lack of concealment; results should only very cautiously be applied to a similar population. Both interventions are feasible and direct costs do not differ significantly, but the cost and time required for McKenzie certification may be a consideration. The population in the study was very similar to the clinical population, but external validity was fair due to the small population utilized which may not be representative of a larger population and the fact that the population was only from one region of New York State. The results of this study show that neither a specific spine stabilization program nor McKenzie treatment is superior for the treatment of chronic low back pain.

Article PICO:

Population — 30 male and female patients over the age of 18, with non-specific chronic low back pain defined as seven weeks or more since initial onset.

Intervention — Specific stabilization exercises for six weeks.

Comparison — McKenzie exercises for six weeks based on directional preference.

Outcomes — Functional Status Questionnaire (FSQ), the short form McGill Pain Questionnaire (SF-MPQ), which is comprised of pain descriptors, pain on a visual analog scale, and present pain index, and a straight leg raise (SLR) to assess lumbar nerve root tension/irritation or low back dysfunction, at baseline and after six weeks of treatment.

Blinding: The physical therapists, assessors, and the subjects were not blinded to treatment which poses a major threat to internal validity because the participant or the assessors may hold preconceived biases about the efficacy one treatment or another. The physical therapists also performed the assessments prior to and following treatment. Both therapists were trained in Mechanical Diagnosis and Treatment, (MDT), and had 28 years of experience between them. Being that both PTs specialized in one

type of the treatment there is the possibility for a treatment bias in favor of their specialization. Allocation was not concealed in this study.

Controls: There was no true control group in this study. It is possible that the improvements observed in each group over the six weeks could be due to the natural progression of the pathology. Low back pain is often a self-limiting condition and while a high percentage of people will experience another episode of low back pain, the improvements seen in this article may have been related to time.

Randomization: Group assignment was randomized using a random number generator to assign the participants a number. Randomization was considered successful because there were no statistically significant differences found after the authors conducted a Mann Whitney U-test, for any of the outcome measures at baseline between the treatment groups. There was no stratification which was appropriate because the authors wanted to examine the effects of the treatments on non-specific chronic low back pain.

Study: The authors utilized a randomized, pragmatic controlled trial in this study. A convenience sample of thirty subjects was obtained via physician referral to an outpatient physical therapy clinic in New York State. The ages of participants ranged from 19 to 87 years old, with a mean age of 47 years old. To be included in the study, patients needed to have had symptoms for at least seven weeks for the pain to be considered chronic; the mean duration of symptoms was 26.4 months. Patients were excluded if they were pregnant, receiving workers compensation benefits, had litigation associated with their back injury, had more than one lumbar surgery, had a diagnosis of a psychological illness, did not understand English, or had been diagnosed with a systemic inflammatory condition such as lupus or rheumatoid arthritis. The 30 patients that met the inclusion criteria were randomly assigned to either the group receiving stabilization exercises or the group receiving McKenzie treatment.

Participants were initially assessed using the SF-MPQ, the FSQ, and the SLR test by the two treating physical therapists, both of whom were MDT trained and had 28 years combined experience. The treating therapist and patient availability determined the treatment schedules, but all patients were seen for a total of six weeks including the initial examination. Patients were told they would need to perform 10-15 minutes of exercises per day at home and keep a log. The authors stated that patients in both groups were noncompliant in keeping the home exercise log so it was discontinued.

The stabilization group was instructed in use of the lumbar multifidus and transverse abdominis in various positions. For phase 1, the patients performed transverse abdominis and multifidus bracing in supine, prone, and quadruped positions with the use of a pressure gauge in prone and supine, for 10 seconds, 10 times. Once phase 1 was mastered, the patient was progressed to phase 2 which consisted of supine leg marching for 30-50 repetitions (reps), quadruped with arm lifts and then leg lifts for 10-30 reps each, and standing contraction for 10 seconds, 10 times. Once phase 2 was mastered, patients progressed to phase 3. Phase 3 consisted of alternating arms and

legs in quadruped for 30-50 reps, standing with rotation for 30-50 reps, and bridging for 10-25 reps. Pelvic floor muscles were also used to help initiate transversus abdominis contraction in the first stages of learning the exercises.

The McKenzie group participants were treated based on their history and response to the movement examination. They were classified into one of four groups depending on presentation: postural syndrome, derangement syndrome, dysfunction syndrome, and an “other” category that meant that symptoms were not deemed to be originating in the lumbar spine. After classification, patients were treated with end range movement techniques, possibly with the addition of manual techniques from the therapist, and postural education.

Outcome measures: The two groups were reassessed after the 6 weeks of treatment using two outcome measures that pertain to the clinical question, the SF-MPQ and FSQ. A passive straight leg raise was used to assess nerve root involvement but did not pertain to the clinical question. The SF-MPQ was used to assess the patient’s pain over the last two weeks. The FSQ was used to measure level of disability. The authors note that the SF-MPQ has been shown to be sensitive to changes in patient status and that the FSQ has been found to be reliable and valid for measuring perceived disability due to their low back pain. All initial examinations were performed by a single investigator; assessments following the six week treatment period were performed by one of the two providing physical therapists. The authors did not discuss the minimum clinically important difference (MCID) for either of the outcome measures, nor were the values found using an online search.

Study losses: There was only one participant lost in the study. The individual was lost after the initial evaluation but before treatment had begun and did not give a reason for leaving. Due to the low number of participants, the individual still represents a 7% loss to the McKenzie group. There was no intention-to-treat analysis performed.

Summary of internal validity: This study has poor internal validity. There was no blinding of assessors, PTs, or subjects. Additionally, physical therapists providing the interventions were also the assessors and were both McKenzie trained therapists, allowing for potential rater bias. Subjects were not blinded which may have affected the perceived efficacy of treatment and allowed for a Hawthorne or Rosenthal effect. There was small sample population, and no power analysis, so there may not have been statistical power to detect a change if there was one present. No intention to treat analysis was performed, although there was only one patient loss which occurred before the treatment began. Also, according to the authors, there may have been a ceiling effect from the outcome measures, which may have inhibited the ability to see change from the treatment if there was one.

Randomization was successful and there were no statistically significant differences between the groups at baseline. Also, the authors utilized a relatively strict protocol, and all the participants were evaluated within the groups to which they were randomized.

Evidence: There were no statistically significant differences between treatment groups for any of the outcome measures at the six week reassessment. Data points were analyzed using a Mann-Whitney test with a p -value < 0.05 (Table 1).

Table 1: P values for between group differences at six week reassessment

Outcome measures	p -values
FSQ scores	0.41
Pain descriptors	0.12
VAS	0.83
Present pain index	0.85

The data was analyzed using the Mann-Whitney test for rank data instead of a test for score data, most likely because of a skewed distribution of data. Being that the authors ran the tests using rank data, calculating the effect size and confidence interval is not appropriate.

Both groups demonstrated improvement from baseline with some values reaching statistical significance. There was a significant increase in the stabilization group for pain descriptors ($p=0.01$) and present pain index ($p=0.002$). There was a significant increase in the McKenzie group for present pain index ($p=0.05$). No MCID was reported within the study or found using an internet or database search for the FSQ or SF-MPQ. According to Haag *et al.*, an MCID for the VAS for chronic low back pain is 2 cm, which was not achieved by the stabilization group (Table 2) or the McKenzie group (Table 3).

Table 2: Within group comparison for the stabilization group

	Pre-intervention scores (SD)	Post-intervention scores (SD)	Change Score	p -value
FSQ Score	71.30 (5)	77.6 (5)	6.3	0.22
Pain Descriptors	15.33 (2)	9.6 (2)	5.73	0.01
VAS	4.1(2)	3.1 (2)	1.0	0.08
Present Pain Index	2.70 (0.7)	2.1 (0.8)	0.6	0.002

Table 3: Within group comparison for the McKenzie group

	Pre-intervention scores (SD)	Post-intervention scores (SD)	Change Score	p -value
FSQ Score	84 (21)	86 (17)	2	0.97
Pain Descriptors	9 (8)	6(6)	3	0.13
VAS	2.2 (2)	1.8 (2)	0.4	0.36
Present Pain Index	1.7 (0.8)	1.0 (0.9)	0.7	0.05

Applicability of study results:

Benefits vs. Costs: The cost of direct application for each intervention is relatively low because no expensive equipment is needed. However, there may potentially be significant time and cost involved becoming a certified McKenzie therapist whereas there is likely much less time and cost to learn the stabilization technique that demonstrated similar improvements of pain and disability scores. There was minimal risk for adverse events due to treatments.

Feasibility of treatment: The authors included a detailed description of the treatment approach for the specific spine stabilization program, making the exact treatment easily reproducible. The McKenzie treatments could be readily applied in the clinic setting if a therapist was already trained in the McKenzie approach; otherwise this intervention could not be followed as it was utilized in this study. The stabilization exercises were clearly described, did not require any addition equipment except the pressure cuff, and therapists would not need to have further training. Neither treatment interventions proposed much risk for the patient. The six week timeframe is reasonable in an outpatient orthopedic clinic setting. However, patients in this study were only seen on average once weekly for a total of five visits which is likely less than what is typically utilized.

Summary of external validity: Overall the study had fair external validity. The subjects of the study were similar to the clinical population but the poor internal validity of the study compromises the ability to generalize the results. The results cannot be extrapolated to any of the participants excluded from the study such as people who are pregnant, had more than one lumbar surgery, had been diagnosed with a systemic inflammatory condition such as lupus or rheumatoid arthritis, etc. Additionally, because all patients were referred from local physicians to one physical therapy clinic, it is difficult to know if the study population is representative of a larger population.

Article: Petersen T, Kryer P, Ekdahl C, Olsen S, Soer J. The effect of McKenzie therapy as compared with that of intensive strengthening training for the treatment of patients with subacute or chronic low back pain: A randomized control trial. *Spine* 2002 August; 27(16):1702-9.

Clinical Bottom Line:

According to the research performed by Petersen *et al.*, there is no statistically significant decrease in pain or disability using the McKenzie method compared to intensive strengthening for the treatment of patients with non-specific chronic low-back pain ($p > 0.01$). The authors compared 8 weeks of group strengthening and 8 weeks of McKenzie therapy, then two months of home exercises for both groups. There was a trend toward improvement for the McKenzie group at 2 months for decreased disability ratings but the difference did not reach statistical significance, $p = 0.04$. Based on the findings the cost of becoming McKenzie certified may not be worth the benefits. The study had fair internal validity and statistical power, and the results could be cautiously extrapolated to a similar population.

Article PICO

Population – 260 male and female patients ages 18-60 with sub-acute or chronic low back pain for more than eight weeks duration. The patients were living in Copenhagen, Denmark.

Intervention – Eight weeks of group strength training at an outpatient clinic and then two months of exercising at home.

Comparison – Eight weeks of McKenzie exercises based on directional overpressure, and then two months of exercises at home.

Outcomes – Manniche's Low Back Pain Rating Scale. Low back and leg pain intensity scales were measured separately on three 11 box scales: LBP at the moment, worst LBP within the past two weeks, and average LBP within the past two weeks. Outcomes were measured at baseline, at the end of the two month treatment, two and eight months following the end of the treatment.

Blinding: The patients and the physical therapists, who were also the assessors, were not blinded to treatment interventions. The lack of blinding could potentially allow for rater biases, Hawthorne or Rosenthal effects to impact the outcomes. All outcome measurements were self-reported so there may be less likelihood that lack of blinding impacted the assessments. Also, the authors stated that they felt they were able to minimize the threat of not blinding the therapists by selecting therapists who strongly believed in the treatments they performed.

Control: There was no true control within the study, which may constitute a threat to validity due to healing over time, although with chronic low back pain the prognosis for recovery over time decreases in comparison to acute and sub-acute pain (Miller, 2005).

Randomization: Patients were randomized into one of the two treatment groups using a computer-generated list of random numbers and concealment was achieved with sealed envelopes. Participants were not stratified. Randomization was not completely

successful because there was a difference between groups at baseline. The strengthening group (n=50) had significantly more participants with pain located below the knee than the McKenzie group (n=32). Additionally, the stabilization group participants had significantly longer duration of symptoms (n=14 months) compared to the McKenzie group (n=8 months). The authors performed a post-hoc test, and found that the two differences seen at baseline were not associated with a negative outcome for pain or disability scores.

Study: The authors utilized a randomized control design in this study. Participants were selected using a convenience sampling from a hospital clinic for rheumatology in Copenhagen, Denmark. To be considered for the study, participants must have had low back pain with or without leg pain for more than eight weeks, be between the ages of 18 and 60 years old, and have a radiograph, CT scan or MRI taken within the last two years. Patients were excluded from the study if there was clinical evidence of an affected nerve root causing decreased sensitivity, muscle strength or reflexes, or symptoms in a dermatomal distribution; severe osteoporosis; spondylolisthesis; fracture; referred pain from viscera; if the patient was in no pain; if they had undergone McKenzie treatment before; or if the patient was in social or psychological crisis. A total of 270 patients were fit to be involved in the study; 135 were randomly assigned to the McKenzie group and 135 to the strengthening group. Ten people dropped out of the study before the initial analysis, resulting in a total of 132 participants in the McKenzie group and 128 in the strengthening group.

The treatment for the McKenzie group was planned individually following the hour-long initial assessment. This treatment consisted of self-mobilizing repeated movements of sustained positions performed in certain directions, overpressure, and/or mobilization by the therapist. Each subsequent appointment was approximately 30 minutes.

Participants in the strengthening group received group care with six patients and one physical therapist. Each participant performed a 5-10 minute warm up on a stationary bike followed by low intensity warm up exercises consisting of resistance exercises for the lumbopelvic muscles in flexion, extension, and rotation for 10 minutes. The strengthening portion of the workout consisted of four exercises in extension and flexion. Initially, most participants began with 50 repetitions and were increased to 100 repetitions by the end of the eight week intervention period, but the number of repetitions was based on individual performance. The sessions concluded with 10 minutes of stretching trunk and hip musculature. Sessions were 60-90 minutes, twice per week. The details of the specific exercises were not described in this article but were referred to in a previous article written by Manniche *et al.* (1991).

Each treatment group received a maximum of 15 treatments for a period of eight weeks with the therapists. Following the eight week treatment period, participants were encouraged to continue their home exercise program independently for another eight weeks.

Outcome measures: The outcome measure used in the study that pertains to the clinical question was Manniche's Low Back Pain Rating Scale (MLBPRS), which provides self-reported data regarding disability and pain scores. The authors report that they used this questionnaire because it was the only one validated in the Danish language and the questionnaire was used in the study on which the strength training protocol was based. The questionnaire measures disability based on 15 items that impact activities of daily living and social life and gives a score ranging from 0% (no difficulties) to 100% (the most amount of difficulties). Low back and leg pain were measured separately on 11-point scales rating the amount of pain at the moment, within the past two weeks, and the average level within the last two weeks. The points were summed to total a score ranging from 0 points (no back pain or leg pain) to 60 points (worst possible back and leg pain). Assessments were completed at the beginning of treatment, at the end of the eight weeks of treatment, and two and eight months post-treatment. The authors did not include an MCID or a MDC for the MLBPRS, nor was a value found in performing an internet search. The authors did include a minimum criterion for clinical importance of 25% improvement but no description as to why this value was chosen or calculations were included.

Study Losses: Both treatment groups lost 30% of participants. The authors used an intention to treat analysis based on the reason the participant gave for leaving. If the participant left for reasons unrelated to their treatment, data was carried forward from their baseline measurements. If the patients withdrew because of negative reaction to the treatment, the worst score from the treatment group was assigned. If participant discontinued treatment because of positive results, they were assigned the median score of the group. A statistically significant amount of participants who were smokers compared to non-smokers dropped out of the study, $p=0.006$. A secondary analysis using the data for only the participants that completed was also done, which is discussed in the evidence section.

Summary of Internal validity: The study has fair internal validity. Threats to internal validity include lack of blinding the PTs, assessors, and subjects, differences between groups at baseline, and lack of a true control group. The threat of lack of blinding the PTs and assessors may have been decreased because the primary outcome measure was a subjective questionnaire, potentially decreasing assessor bias. Subjects were not blinded which may have impacted the perceived efficacy of treatment. The authors conducted a post hoc test and reported that the increased pain below the knee and duration of symptoms at baseline within the strengthening group did not negatively impact the outcomes. While there were differences between the groups at baseline, the authors report that it did not affect the ability to see improvements in pain and disability scores. Compliance with the home exercise program was important in this study, especially at the two and eight month follow-up appointments. The authors did not provide information regarding home exercise compliance, which may have also affected the outcome if one group was more compliant than the other group.

Evidence: The authors conducted a power analysis and determined that they needed 84 participants in each group to detect a 25% difference with 90% power and a 5% risk

of a type I error for a single comparison. Because multiple comparisons were being made, the authors chose to use a p -value of 0.01 rather than 0.05 to decrease the risk of a type I error of seeing a difference when there is no true difference.

The authors used Mann-Whitney U test to assess data points with an intention to treat analysis most likely because the data was not normally distributed. There were no statistical differences in pain ratings between groups following treatment, at two month follow-up, or at eight month follow-up appointments (Table 4). There was a trend toward a statistically significant difference for decreased disability ratings within the McKenzie group at two months, ($p=0.04$).

Table 4: p -values and change scores using an intention to treat analysis

	End of treatment	2 months	8 months
Disability score	0.38	0.04*	0.92
Back and Leg pain score	0.55	0.41	0.83

*Trend toward significance.

A secondary analysis was performed without using an intention to treat model, only including the 190 patients that completed the study. The groups were statistically equivalent at baseline with regard to disability and pain scores (Table 5). At two months there was a statistically significant decrease in back and leg pain in the McKenzie group compared to the strengthening group ($p=0.01$). These differences were not statistically significant at any other time points (two months $p=0.02$ and eight months $p=0.16$).

Table 5: p -values and change scores without intention to treat analysis

	End of treatment	2 months	8 months
Disability score	0.19	0.10	0.66
Back and Leg pain score	0.02*	0.01*	0.16

Change scores in self-reported pain and disability were calculated to address overall improvement from baseline (Table 6 and 7). There was no statistically significant difference between groups, and both groups showed improvement from baseline; there is, however, a visible trend toward greater improvement within the McKenzie group for pain scores (Table 6).

Table 6: Disability improvement: change scores from baseline values using the Manniche's Low Back Pain Rating Scale

	End of treatment	2 months	8 months
McKenzie	8.1	10	5.9
Strengthening Group	10.1	4.5	6

Table 7: Pain improvement: Back and leg pain change scores from baseline values using the Manniche's Low Back Pain Rating Scale

	End of treatment	2 months	8 months
McKenzie	8.5	5.5	4.5
Strengthening Group	5	2	1

Applicability of results

Benefits vs. Costs: There was no expensive equipment used in the study but there may be significant time and cost involved with becoming McKenzie certified. There was minimal risk involved for the patient or the physical therapists. The improvements in pain and function were shown to be nearly equal for both McKenzie and strengthening according to the statistical results. There may be less time involved for the PT conducting group therapy because multiple patients are being seen at once compared to individually, but there may also be lower reimbursement. According to the authors, a similar median amount of time was spent for both groups, as determined per number minutes of treatment as reported by the therapists. The McKenzie group was seen for a median of 210 minutes, and the training group was seen for a median of 225 minutes.

Feasibility of treatment: Application of both McKenzie and strengthening interventions described by the study are feasible because no additional equipment is required. However, therapists must be trained in the McKenzie approach, which may not be feasible for all therapists. The treatments were not painful but the intensive strengthening program may not be feasible for all patients, such as those in significant pain, those who may be significantly deconditioned, those with severe osteoporosis, those at high fall risk, etc. The authors did not include a thorough description of the strengthening protocol. They did reference an article with the complete protocol, but this also was not very thorough (Manniche, 1991). The participants received sixteen physical therapy visits, which may be somewhat excessive and is most likely beyond the amount allotted by insurance companies.

Summary of External Validity: Overall this study has fair external validity. The participants included in the study appear similar to the clinical population. While the study was conducted in Denmark, cultural differences would most likely not impact the ability to extend the results to populations within the United States. However, the strengthening group participated in group therapy, and the exercises selected were slightly different from the clinical population, which negatively impacts external validity. Overall, the study population appears representative of the clinical population, with the exception of utilizing group therapy. The results cannot be extended to conditions that were excluded such as spondylolisthesis and nerve root impairment causing decreased sensitivity, muscle strength or reflexes, or symptoms in a dermatomal distribution.

Synthesis/Discussion

Both of the studies appraised reached the same conclusion: there is no statistically significant difference between the McKenzie approach and a strengthening program for reducing pain and disability in the treatment of chronic low back pain. The article by Miller *et al.* had poor methodological quality and internal validity and scored 5 out of 10 on the PEDro database. Primary threats to internal validity were blinding of PTs, assessors, and participants. The study also lacked statistical power due to the small participant population. It is possible that a difference may have been detected if a larger number of participants were included. The study used a treatment technique very similar to the technique used in clinic, allowing cautious generalizability of their results.

The article by Peterson *et al.* scored 7 out of 10 on the PEDro database and had better methodological quality but still had significant threats to validity. Threats to internal validity include lack of blinding the PTs, assessors, and subjects, differences between groups at baseline, and lack of a true control group. The study utilized a group therapy technique, which was different from typical outpatient clinical practice, making the results more difficult to be extrapolated to the clinical population.

Overall, the similar results found in both studies point to the fact that one treatment technique is not clearly superior to the other. However, there was a trend toward a statistically significant difference for decreased disability ratings within the McKenzie group at two months, ($p=0.04$) within the Peterson *et al.* study. Additionally in the study conducted by Peterson *et al.* the statistical analysis without using an intention-to-treat analysis, and only used data from participants that completed the study, showed statistically significant improvements within the McKenzie group for back and leg pain initially after treatment and at the two month follow up, $p=0.02$ and $p=0.01$ respectively.

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