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Background. Back School and McKenzie methods are popular active treatment approaches that include both exercises and information for patients with chronic nonspecific low back pain.

Objective. The purpose of this study was to compare the effectiveness of Back School and McKenzie methods in patients with chronic nonspecific low back pain.

Design. The study was a prospectively registered, 2-arm randomized controlled trial with a blinded assessor.

Setting. The study was conducted in the outpatient physical therapy clinic in São Paulo, Brazil.

Patients. The study participants were 148 patients with chronic nonspecific low back pain.

Interventions. The 4-week treatment program (one session/week) was based on the Back School (delivered to the group) or McKenzie (delivered individually) principles. The participants also were instructed to perform a daily set of home exercises.

Measurements. Clinical outcomes were assessed at follow-up appointments at 1, 3, and 6 months after randomization. Primary outcome measures were pain intensity (measured by the 0–10 pain numerical rating scale) and disability (measured by the 24-item Roland-Morris Disability Questionnaire) 1 month after randomization. Secondary outcome measures were pain intensity and disability at 3 and 6 months after randomization, quality of life (measured by the World Health Organization Quality of Life–BREF instrument) at 1, 3, and 6 months after randomization, and trunk flexion range of motion measured by an inclinometer at 1 month after randomization. The data were collected by a blinded assessor.

Results. Participants allocated to the McKenzie group had greater improvements in disability at 1 month (mean effect=2.37 points, 95% confidence interval=0.76 to 3.99) but not for pain (mean effect=0.66 points, 95% confidence interval=−0.29 to 1.62). No between-group differences were observed for all secondary outcome measures.

Limitations. It was not possible to monitor the home exercise program. Therapists and participants were not blinded.

Conclusions. The McKenzie method (a more resource-intensive intervention) was slightly more effective than the Back School method for disability, but not for pain intensity immediately after treatment in participants with chronic low back pain.

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Chronic nonspecific low back pain (ie, low back pain of at least 12 weeks' duration and without a specific cause)[1,2] is one of the most common health conditions worldwide.[3] Chronic low back pain is highly associated with disability,[1] emotional changes,[2] and work absenteeism.[1] Given that chronic low back pain is very prevalent,[4] the costs associated with this condition are very high.[5] Approximately 60% of patients with chronic low back pain did not consider themselves recovered in a period of 1 year from the onset of symptoms, with moderate levels of pain and disability persisting over time.[6,7] Therefore, many of these patients become frequent users of health care services in order to find treatments to minimize the severity of their symptoms.

Supervised exercise therapy[1,8] associated with an educational component[9] has been considered one of the most effective interventions in reducing pain and disability in patients with chronic nonspecific low back pain.[1,8,9] The effects of exercise therapy tend to remain for at least 6 months after treatment[10] compared with usual care.[9] Furthermore, there is evidence that exercises also may reduce the number of recurrent episodes of low back pain.[11] The Back School method (a group-based treatment approach) and the McKenzie method (an individually based treatment approach) are good active therapy options that include both exercises and education for the treatment of patients with chronic low back pain.[12,13]

The Back School method was developed in 1969 in Sweden by Mariane Zachrisson Forssel, with the goal of managing the patient's current episode and preventing recurrent episodes of low back pain.[13] The program is composed of 4 sessions lasting approximately 45 minutes, with each session organized by theoretical components and including exercises that aim to improve mobility, flexibility, and strength.[13] The McKenzie method (which also is known as "Diagnostic and Mechanical Therapy") was proposed by Robin McKenzie in 1981.[14] This method has 3 basic components: (1) evaluation (conducted using sustained postures and repeated movements where the symptoms in the lower back and lower limbs are classified into 3 syndromes: derangement, dysfunction, and postural syndromes); (2) intervention exercises (based on the direction of preference of patients); and (3) prevention (an educational component aimed to encourage patients to use simple self-management strategies to control their symptoms).[14,15]

The evidence on the effectiveness of these methods in patients with chronic nonspecific low back pain is conflicting due to the high risk of bias among the studies.[12,13] A recent systematic review on the Back School method for patients with nonspecific low back pain[13] found a total of 19 randomized controlled trials, with only 6 trials classified as high quality. A total of 6 studies evaluated the effectiveness of this method compared with other conservative treatments for chronic low back pain, but these trials[16–21] have some methodological limitations such no concealed allocation, unblinded assessors, and absence of intention-to-treat analysis. These trials have shown a greater effectiveness of the Back School method compared with a control group,[17] a global strengthening program,[19] and when used as an additional intervention with treatments such as exercise programs,[22] medication,[23] and electrophysical agents[22] in patients with chronic low back pain for different outcomes, such as pain intensity,[17,22] disability,[19,22] quality of life,[19,22,23] and recurrent pain.[22]

Regarding the McKenzie method, most studies recruited mixed populations (ie, patients with acute, subacute, and chronic low back pain).[24–40] Among the studies that recruited only patients with chronic low back pain,[41–45] the methodological quality was moderate to low. Different active control interventions were used in these trials, such as trunk strengthening[43] and stabilization programs,[41] and no statistical between-group differences were identified. Other studies with lower methodological quality identified that the McKenzie method was better than other interventions, such as resistance exercise training,[45] the Williams method,[42] and no supervised exercise[44] for pain,[44] lumbar strength, endurance,[45] and quality of life.[45]

Therefore, high-quality randomized controlled trials are still needed for a better understanding of the effects of these 2 popular interventions. Moreover, no study has directly compared the effectiveness of these 2 methods for patients with chronic low back pain. Therefore, the objective of this randomized controlled trial was to compare the effectiveness of the Back School and McKenzie methods in patients with chronic nonspecific low back pain for the outcomes of pain intensity, disability, quality of life, and range of motion.

Method

Design Overview

This study was a prospectively registered, 2-arm randomized controlled trial with a blinded assessor. All methodological steps of this study are described in detail in the published protocol.[46]

Setting and Participants

This study was conducted in the outpatient physical therapy clinic of the Universidade Cidade de São Paulo, Brazil, between July 2010 and July 2012. To be eligible for inclusion,

Table 1.
Summarized Description of McKenzie and Back School Treatment Programs

Week	McKenzie Method	Back School Method
First week	Presentation of the method, including history and general information about the McKenzie method Completion of the exercises after initial evaluation and indication of movement direction preference: flexion, extension, or lateral shift of the spine Education component: basic information about low back pain and spinal anatomy; mechanical pain; how and why to do exercises; and types of responses that can occur in response to the exercise program Guidance on completing the exercises at home	Presentation of the method, including history and general information about the Back School method Anatomy and biomechanics of the spine Low back pain epidemiology Muscle function and its influence on the spine Pathophysiology of the main disorders that adversely affect the spine Theoretical presentation of commonly used treatment modalities No exercises were provided
Second week	Progression of the exercises defined after first session and progression in line with the responses of each patient Educational component: basic information about the most likely causes of low back pain, emphasizing posture when seated for a prolonged time; practice on finding the correct seated position and maintenance of lumbar lordosis while seated Guidance on continuing the exercises at home	Variation of the mechanical forces in different movements of the back Theoretical presentation of relaxation posture Guidance on position when seated or standing Instruction on breathing exercises, kinesthetic training, stretching of the lower back, quadriceps, and hamstring muscles Guidance on completing exercises at home once a day
Third week	Progression of the exercises defined after second session and progression toward other position in line with the responses of the patient Educational component: basic information about the most likely causes of low back pain, emphasizing work on bending positions; standing up; relaxing after vigorous activity; remaining in standing position for prolonged periods; lying down; and resting, coughing, and sneezing Guidance on continuing the exercises at home	Observation of the exercises that were performed at home Instruction on exercises for abdominal muscular strength Orientation about joint protection during daily activities Guidance on how to perform the exercises at home once a day
Fourth week	Progression of the exercises defined after third session and progression toward other positions in line with the responses of the patient Educational component, review of the most important points since the first week	Practical application of all of the exercises and learned techniques

patients seeking care had to have nonspecific low back pain of at least 3 months' duration and be between 18 and 80 years of age. Patients with any contraindication to physical exercise based on the recommendations of the guidelines of the American College of Sports Medicine,[47] serious spinal pathology (eg, tumors, fractures, inflammatory diseases), previous spinal surgery, nerve root compromise, cardiorespiratory illnesses, or pregnancy were excluded.

Randomization and Interventions

A simple randomization sequence was computer-generated using a Microsoft Excel program (Microsoft Corporation, Redmond, Washington) by one of the investigators of the study who was not directly involved with the assessments and treatment of patients. The allocation was concealed by using consecutively numbered, sealed, opaque envelopes. Eligible patients were allocated to the treatment groups (Back School or McKenzie) by a physical therapist who opened the next available numbered envelope prior to the first treatment session. Participants from both groups received 4 one-hour sessions over 4 weeks, once a week. All participants received the exercises under the supervision of the physical therapist. At the end of each treatment session, these participants were asked to perform the same exercises at home once a day (3 sets of 10 repetitions that could be performed on the same day or in different times of day depending on the patient's availability). Although participants were instructed to do the home exercises, we did not monitor the home exercise dose. The number of sessions was chosen following the recommendations from the original Back School method manual.[13] Because there is no consensus regarding the optimal number of sessions for the McKenzie method, the same treatment duration was chosen. The care provider, who treated the patients in both groups, was a fully certified McKenzie therapist (certified by the McKenzie Institute of Brazil) and had received extensive Back School training during her undergraduate training program (1 hour per week over a period of 1 year). Our outcome assessor received 2 months of McKenzie training from our McKenzie-certified therapist.

Table 1 presents a summarized description of the treatments that were provided in this study. Patients in both groups received information in order to maintain lordosis while sitting, included patients with no direction preference for extension, without exacerbating their symptoms. Patients in the McKenzie group with a direction preference for extension also were instructed to use a back roll while sitting, as recommended by the book *Treat Your Own Back*.[48]

McKenzie group. The McKenzie method is a classification-based treatment system that involves a comprehensive clinical examination of posture and range of motion of the spine, associated with the assessment of patients' symptomatic responses.[49] This method is based on exercises (sustained postures or repeated movements) and includes an educational component and postural training.[49,50]

Patients allocated to the McKenzie group received theoretical information regarding the care of the spine and performed specific exercises (Appendix 1) according to the direction of preference of movement identified by a relief of pain, centralization of the pain (pain referred in a peripheral location from the spine is progressively abolished), or abolishment of pain.[50] During the baseline assessment, the assessor identified the directional preference (for all patients) and informed the treating therapist before the randomization. Although the assessor evaluated and diagnosed each of the patients, the final decision about the patient's McKenzie diagnosis and treatment was taken by the therapist. In the case of patients with dysfunction syndrome (who did not have a directional preference), the selected movement for treatment was the one that produced consistently pain at the end range of motion, with reduction or elimination of symptoms after returning from this movement.[14] Patients with postural syndrome (who also did not have a directional preference) were treated by correcting sitting postures, because these patients had pain in a relaxed sitting posture for a long time.[14]

The directional preference could be modified during the treatment sessions if needed, and the therapist could progress the level of the exercises, tailoring the treatment to each of the patients. The progression of the exercises of McKenzie method was based on the concept of "progression of forces"[14] and the use of "alternative forces."[14] This decision of using self-overpressure or manual mobilization was based on symptomatic and mechanical responses of each of the patients. Another progression strategy used was "patient movement in a greater range of motion with extra pressure applied by the therapist." In the cases of major posterior derangement syndrome, acute lumbar kyphosis, and upper limb functional limitation, we prescribed static positions (ie, sustained extension) as their treatments. All possibilities of progression of exercises were used on an individual level following the McKenzie method principles. The progression of forces were considered only when symptoms remained unchanged after a procedure and were interrupted if the symptoms worsened.[14] In this case, we considered the use of alternative forces that aim to reduce symptoms through maintained positions or repeated movements that allowed the combination of procedures.[14]

Back School group. The Back School method is based on a program of exercises that aims to improve mobility, flexibility, and strength.[51] New exercises were prescribed and progressed in every treatment session following the sequence proposed by the program (ie, the exercise progression was not tailored to the individual). This program also has an education component based on advice that includes basic components of anatomy and biomechanics of the spine, ideal posture and rest postures, ergonomics, and most common types of treatment.[13,52] Patients allocated to this group received theoretical and practical information (Appendix 2) during the treatment sessions. The first session was conducted individually, and the 3 remaining sessions were conducted in groups. The reason for using this approach was to avoid having patients allocated to this group wait for a long period of time while composing a new treatment group. Therefore, these patients could start to receive treatment immediately after randomization. The protocol of advice and exercises of this method was developed based on the original manual[13] and by another manual specifically written for patients with chronic low back pain.[52]

Outcome Measures and Follow-up

Prior to the randomization, patients were evaluated by an assessor who was blinded to treatment allocation. During the baseline assessment, patients received information about the study and signed a consent form to participate in the study. Patients were questioned about their symptoms and received a clinical neurological examination to rule out possible nerve root compromise.[2]

The primary outcome measures were pain intensity (measured by the 0–10 pain numerical rating scale [NRS])[53] and disability (measured by the 0–24 Roland-Morris Disability Questionnaire [RMDQ])[54,55] at 1 month after randomization. The secondary outcome measures were trunk flexion range of motion (measured by an inclinometer)[56] at 1

Table 2.
Outcome Measures[a]

Measure	Construct	Description
Pain numerical rating scale (NRS)[53]	Pain intensity	Measures pain intensity on an 11-point scale ranging from 0 ("no pain") to 10 ("the worst pain possible"). Patients were asked to report their pain intensity based on the previous 7 days. This scale has good levels of reliability (ICC [2,1]=.85, 95% CI=0.77 to 0.90), responsiveness (standardized effect size=1.16), and construct validity.[53]
Roland-Morris Disability Questionnaire (RMDQ)[54,55]	Disability	Measures disability associated with low back pain using a list of 24 items (activities of daily living) that patients with back pain may have difficulty performing because of their back pain. High scores represent high levels of disability. This questionnaire has good levels of internal consistency (Cronbach alpha=0.90), reliability (ICC [2,1]=.94, 95% CI=0.91 to 0.96), responsiveness (standardized effect size=0.70), and construct validity.[53]
World Health Organization Quality of Life–BREF instrument (WHOQOL-BREF)[57]	Quality of life	This is a short version of the WHOQOL-100 questionnaire, developed by the World Health Organization to evaluate the quality of life.[58] It is composed of 26 questions, which include 4 domains: physical, psychological, social, and environmental. The total score of this instrument, ranging from 0 to 100 points, is the sum of the scores of the 4 domains. High scores represent good quality of life.[59] This questionnaire has good levels of internal consistency (Cronbach alpha=0.67–0.81) and reliability (ICC=.80).[58]
Inclinometer[56]	Trunk flexion range of motion	Measures trunk range of motion in degrees. The instrument was positioned fastened on the right-hand side of the trunk at the level of the T7–T8 vertebrae (about nipple line) (see Appendix 3 for details[56]). Patients in a standing position with their knees extended and arms crossed across the thorax were instructed to bend down as much as possible. This instrument has good levels of interrater reliability (ICC=.94) and validity (Pearson *r*=.93).[60]

[a] ICC=intraclass correlation coefficient, 95% CI=95% confidence interval.

month, pain intensity and disability at 3 and 6 months, and quality of life (measured by the World Health Organization Quality of Life–BREF instrument [WHOQOL-BREF])[57] at 1, 3, and 6 months after randomization. We measured trunk flexion range of motion only at baseline and immediately after treatment to avoid potential loss to follow-up at 3 and 6 months after randomization. Data for the remaining measures were collected at all time points. Most follow-up data were collected over the telephone. We also observed and recorded patients' adverse effects in every treatment session by asking 2 questions: (1) "Since you started receiving this treatment, did you experience any different symptom?" and (2) "Since you started receiving this treatment, did your symptoms become worse?" An outline of the outcome measures is provided in Table 2.

Blinding

The assessor was blinded to the treatment allocation. Given the nature of the interventions, it was not possible for the therapist or the patients to be blinded.

Sample Size Estimation

We designed the study to detect a between-group difference of 1 point in pain intensity measured by the pain NRS, with an estimated standard deviation of 1.84 points, and a between-group difference of 4 points for disability measured by the RMDQ, with an estimated standard deviation of 4.9 points. The specifications were: power of 80%, an alpha coefficient of .05. and a possible loss to follow-up of up to 15%. Therefore, a total of 148 patients (74 patients per group) were recruited for our study. The estimates used in our sample size calculation were lower than those suggested as the minimal clinically important difference (ie, 20% improvement for pain[61] and disability[62]) in order to increase the precision of the effects of the interventions. A higher between-group difference would dramatically reduce our sample size,[63] and this was one of the major limitations in previous trials.[64,65]

Statistical Analysis

The statistical analysis was conducted on an intention-to-treat basis (ie, the participants were analyzed in the groups to which they were allo-

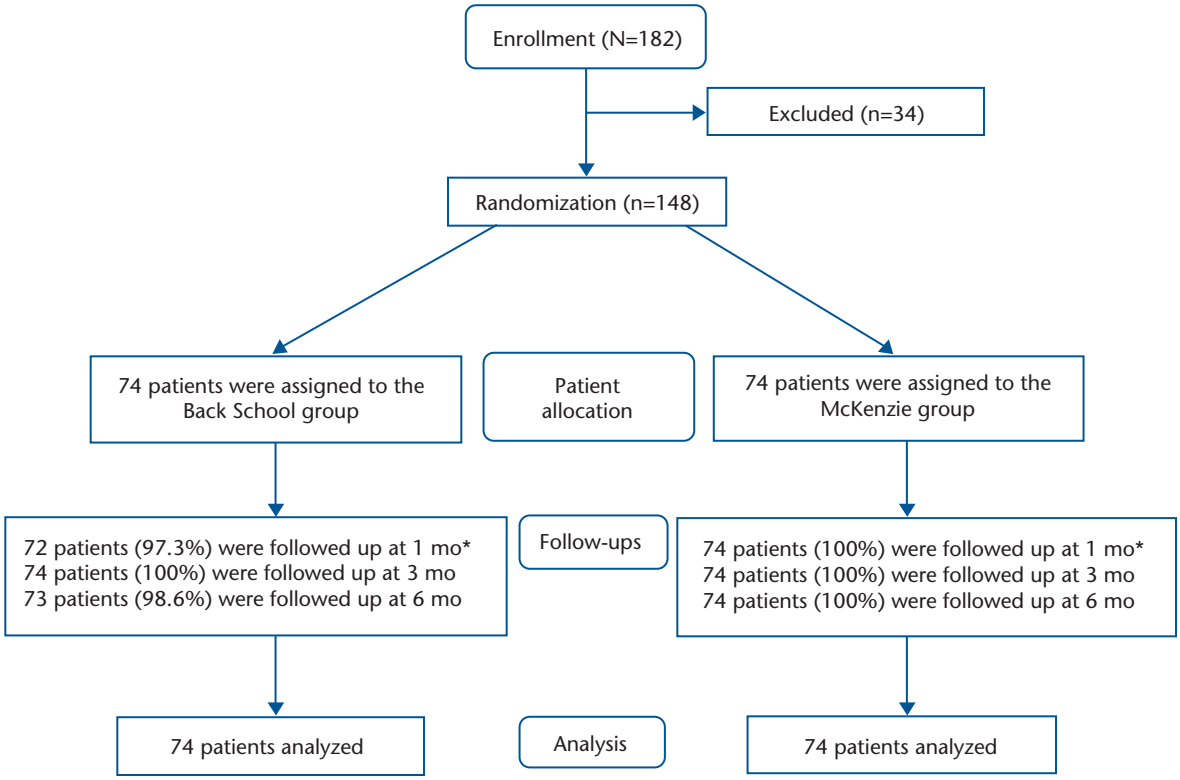

Figure.
Flow diagram of participants in the study. Asterisk indicates it was not possible to collect data for range of motion in 8 participants (10.8%) in the Back School group and for 4 participants (5.5%) in the McKenzie group at 1 month due to inability to attend the clinic.

cated). Data normality was tested through visual inspection of histograms, and all outcomes had normal distribution. The characteristics of the participants were calculated through descriptive statistical tests. The between-group differences and their respective 95% confidence intervals (95% CIs) were calculated using linear mixed models. This statistical technique deals with the dependency of baseline measures (ie, the effects of treatment were adjusted for baseline estimates only), as well as with missing data, by predicting the best-fitting line for each patient without data imputation. In this model, no additional covariant was assessed. We did not measure cointerventions in our study. We also estimated the number needed to treat for the primary outcomes by dichotomizing patients who had reached the minimal clinically important difference of 20% (ie, at least 2 points in pain intensity and 5 points in disability) compared with those who had not reached minimal clinically important difference. The differences in proportions for patients who had reached the minimal clinically important difference of 20% were calculated using chi-square tests. We used SPSS 19 for Windows (SPSS Inc, Chicago, Illinois) for all analyses.

Role of the Funding Source

This study was funded by the Fundação de Amparo à Pesquisa do Estado de São Paulo (FAPESP), Brazil.

Results

From a total of 182 patients who were seeking care for low back pain in the physical therapy clinic of the Universidade Cidade de São Paulo, 148 were considered eligible and were included in the study between July 2010 and February 2012 (Figure). The reasons for ineligibility were cardiorespiratory illnesses (n=8), age over 80 years (n=5), acute low back pain (n=4), nerve root compromise (n=4), neck pain (n=3), grade II spondylolisthesis (n=2), vertebral fracture (n=1), rib fracture (n=1), deep vein thrombosis (n=1), abdominal tumor (n=1), advanced osteoporosis (n=1), metabolic myopathy (n=1), colitis (n=1), and urinary tract infection (n=1).

All participants received the treatments as allocated. Of these participants, 146 (98.6%) completed the follow-up at 1 month for the primary outcome measures of pain and disability and for the secondary outcome measure of quality of life. However, 4 participants (5.5%) in the McKenzie group and 8 partici-

pants (10.8%) in the Back School group could not be followed up for the secondary outcome measure of trunk flexion range of motion at 1 month due to an inability to attend the clinic. All participants completed the 3-month follow-up, and only one loss to follow-up in the Back School group occurred for all outcomes at 6 months (ie, 99.3% follow-up) (Figure).

From a total of 4 sessions that could be completed, the participants allocated to the Back School group attended a mean of 3.64 sessions (SD=0.08) compared with a mean of 3.72 sessions (SD=0.06) for participants allocated to the McKenzie group. The characteristics of the participants at baseline are shown in Table 3. Most of the participants were women with a 2-year duration of symptoms, with a directional preference, and with moderate levels of pain intensity and disability. The baseline characteristics of both groups were similar.

One participant in the Back School group reported an adverse effect (temporary exacerbation of pain) in the third session, but this symptom had ceased by the fourth week. No other adverse event was observed. All participants allocated to the Back School group performed all of the exercises. However, it was necessary to make some adjustments (eg, using a lower range of motion during kinesthetic training exercise and abdominal exercises) when needed. Even with these adjustments, the participants received a similar amount of exercise. We observed a reduction in pain intensity and disability after treatment (1 month) in both groups (Tab. 4). Participants allocated to the McKenzie group had greater improvements in disability (treatment effect=2.37 points, 95% CI=0.76 to 3.99) after treatment (at 1-month follow-up). There was no statistically significant between-group difference for pain (treatment effect=0.66 points, 95% CI=−0.29 to 1.62).

For the secondary outcome measures, we observed a between-group difference only for the physical domain of quality of life after 3 months (mean=−4.67 points, 95% CI=−9.26 to −0.07) in favor of the McKenzie group. Forty-two participants allocated to the Back School group and 43 participants allocated to the McKenzie Group met the minimal clinically important difference for pain intensity (ie, improved at least 2 points on the pain NRS) (P=.25). Twenty-two participants allocated to the Back School group and 39 participants allocated to the McKenzie Group met the minimal clinically important difference for disability (ie, improved at least 5 points on the RMDQ) (P=.01). The numbers needed to treat were 72 (95% CI=−7 to 6) and 4 (95% CI=3 to 14) for pain intensity and disability, respectively, in favor of the McKenzie group.

Discussion

Statement of Principal Findings

The objective of this randomized controlled trial was to compare the effectiveness of the Back School and McKenzie methods in patients with chronic nonspecific low back pain. At 1-month follow-up, we observed a reduction in both pain intensity and disability in both groups. Most of the improvements in outcomes observed at short-term follow-up were maintained at 3 and 6 months after randomization for both primary and secondary outcomes. Participants allocated to the McKenzie group had greater improvements in disability, but not pain intensity, at 1-month follow-up compared with participants allocated to the Back School group.

Meaning of the Study: Possible Explanation and Implication for Clinicians and Policy Makers

This study provided only precise estimates of treatment effects. A minimal clinically important difference can be defined as 20% improvement for both pain (ie, 2-point improvement on the 0–10 pain NRS)[61] and disability (5-point improvement on the 0–24 RMDQ).[62] We considered that the magnitude of the difference of disability found in this study is small (ie, 2.37 points on a scale of 0–24 points)[62] and possibly of doubtful clinical importance. However, based on the analysis of the number needed to treat for disability, for every 4 people treated with the McKenzie method, 1 will improve at least 5 points in terms of disability as measured by the RMDQ, which can be considered clinically important. Finally, the number of participants who achieved the minimal clinically important difference in terms of disability was much higher in the McKenzie group (n=39) compared with the Back School group (n=22), which also can be considered clinically important. From this perspective, clinicians should inform their patients about these treatment options in order to define which method to use, taking into account the potential costs of each of the interventions, as well as patient preferences.

Strengths and Weaknesses in Relation to Other Studies

Although the dose used for the McKenzie group in our trial (ie, 4 treatment sessions) can be considered low for some McKenzie therapists, our aim was to keep the dosage of both treatments similar to avoid attention control bias. We fully reviewed all previous trials about the McKenzie method for patients with chronic low back pain. We found 2 trials that used a dosage similar to that used in our study.[44,45] These trials showed a statistically significant

Table 3.
Demographic and Clinical Characteristics of the Participants at Baseline (N=148)[a]

Variable	Back School Method	McKenzie Method
Sex		
Female	51 (68.9)	58 (78.4)
Male	23 (31.1)	16 (21.6)
Age (y)	54.16 (1.57)	53.70 (1.53)
Duration of symptoms (mo)	24 (83)	21 (28)
Weight (kg)	73.73 (1.59)	71.70 (1.59)
Height (m)	1.64 (0.01)	1.61 (0.01)
Marital status		
Single	12 (16.2)	17 (23.0)
Married	45 (60.8)	41 (55.4)
Divorced	5 (6.8)	5 (6.8)
Widowed	11 (14.9)	9 (12.2)
Other	1 (1.4)	2 (2.7)
Education status		
Elementary degree	27 (36.5)	28 (37.8)
High school	33 (44.6)	33 (44.6)
University	14 (18.9)	12 (16.2)
Illiterate	0 (0)	1 (1.4)
Use of medication	54 (74)	54 (73)
Physically active	27 (36.50)	20 (27)
Smoker	5 (7.10)	8 (11.10)
Recent episode of low back pain	47 (63.50)	46 (62.20)
Pain intensity (0–10)	6.41 (0.29)	6.77 (0.24)
Disability (0–24)	11.08 (0.68)	11.32 (0.57)
Quality of life (0–100)		
Physical domain	51.48 (1.98)	51.64 (1.68)
Psychological domain	60.11 (1.85)	62.88 (1.82)
Social domain	63.51 (2.20)	63.62 (2.12)
Environmental domain	54.74 (1.87)	55.40 (1.58)
Trunk flexion range of motion (°)	78.93 (2.63)	79.28 (2.07)
Mechanical diagnostic		
Posterior derangement syndrome	63 (85.1)	63 (85.1)
Anterior derangement syndrome	5 (6.8)	2 (2.7)
Dysfunction syndrome	2 (2.7)	6 (8.1)
Postural syndrome	2 (2.7)	2 (2.7)
Other	2 (2.7)	1 (1.4)
Directional preference	68 (91.9)	65 (87.8)
Extension	35 (51.5)	31 (47.7)
Extension/right lateral shift	15 (22.1)	15 (23.1)
Extension/left lateral shift	13 (19.1)	17 (26.2)
Flexion	4 (5.9)	1 (1.5)
Flexion/right lateral shift	1 (1.5)	0 (0)
Flexion/left lateral shift	0 (0)	1 (1.5)

[a] Categorical variables are expressed as number (%), continuous variables are expressed as mean (SD), and duration of symptoms is expressed as median (interquartile range).

Table 4.
Positive Unadjusted Mean Differences (SD) and Adjusted Mean Differences (95% CI) for Pain Intensity, Disability, Quality of Life, and Trunk Flexion Range of Motion[a]

Measure	Unadjusted Mean Difference (SD)		Back School Method vs McKenzie Method Adjusted Mean Difference (95% CI)	*P*
	Back School Method	McKenzie Method		
Pain intensity (0–10)				
Baseline	6.41 (2.54)	6.77 (2.12)		
1 mo	4.39 (2.73)	4.14 (2.87)	0.66 (−0.29 to 1.62)	.17
3 mo	5.53 (2.78)	5.18 (2.61)	0.71 (−0.23 to 1.67)	.14
6 mo	5.19 (3.08)	5.09 (2.89)	0.48 (−0.47 to 1.43)	.32
Disability (0–24)				
Baseline	11.08 (5.84)	11.32 (4.95)		
1 mo	8.15 (5.79)	6.20 (5.06)	2.37 (0.76 to 3.99)	.004
3 mo	8.39 (6.30)	7.12 (5.67)	1.51 (−0.09 to 3.11)	.06
6 mo	8.12 (6.45)	6.77 (6.02)	1.55 (−0.05 to 3.16)	.06
Quality of life (0–100)				
Physical domain				
Baseline	51.49 (17.05)	51.64 (14.49)		
1 mo	59.27 (16.88)	62.45 (16.94)	−3.65 (−8.26 to 0.96)	.12
3 mo	57.43 (17.76)	62.25 (15.37)	−4.67 (−9.26 to −0.07)	.04
6 mo	60.76 (18.87)	61.48 (16.12)	−0.44 (−5.04 to 4.16)	.85
Psychological domain				
Baseline	60.11 (15.86)	62.88 (15.86)		
1 mo	65.12 (13.98)	67.68 (15.15)	−0.18 (−4.17 to 3.80)	.92
3 mo	65.14 (14.14)	67.62 (16.07)	0.14 (−3.82 to 4.11)	.94
6 mo	66.72 (14.15)	68.00 (14.18)	1.50 (−2.48 to 5.47)	.46
Social domain				
Baseline	63.15 (18.96)	63.62 (18.27)		
1 mo	67.24 (15.96)	67.45 (18.00)	−0.47 (−5.50 to 4.56)	.85
3 mo	65.76 (16.00)	69.03 (16.11)	−3.15 (−8.16 to 1.85)	.21
6 mo	66.09 (15.00)	66.00 (18.74)	0.26 (−4.75 to 5.28)	.91
Environmental domain				
Baseline	54.74 (16.09)	55.40 (13.66)		
1 mo	57.62 (16.48)	58.57 (14.82)	−0.51 (−4.06 to 3.03)	.77
3 mo	56.16 (14.75)	58.23 (14.65)	−1.41 (−4.94 to 2.12)	.43
6 mo	57.44 (15.00)	57.84 (14.61)	0.29 (−3.24 to 3.83)	.87
Range of motion (°)				
Baseline	78.93 (22.47)	79.28 (17.88)		
1 mo	82.92 (18.86)	80.86 (17.67)	1.42 (−4.19 to 7.05)	.61

[a] Primary outcomes are highlighted in gray. Positive treatment effects favor McKenzie method for the outcomes of pain intensity and disability and negative scores for quality of life and trunk flexion range of motion. Pain intensity was measured with the pain numerical rating scale, disability was measured with the Roland-Morris Disability Questionnaire, quality of life was measured with the World Health Organization Quality of Life–BREF (WHOQOL-BREF), and trunk flexion range of motion was measured with an inclinometer. 95% CI=95% confidence interval.

difference in favor of the McKenzie exercises compared with a nonsupervised exercise program[44] and muscular resistance exercises.[45] Interestingly, trials that used a higher dosage (ie, 6 sessions[41] and 15 sessions[43]) and prescribed home exercises showed no advantage for the McKenzie group compared with stabilization exercises[41] and trunk strengthening exercises.[43] It might be a good idea for future studies to compare different doses of McKenzie exercises in this population.

For the Back School method, there is no evidence for reducing pain and disability during short-term and midterm follow-up compared with myofascial therapy and advice.[13] Other studies have shown a greater effectiveness of the Back School method compared with a nontreatment control intervention[17] and global strengthening program[19] and when used as an additional intervention with treatments such as exercise programs,[22] medication,[23] and electrophysical agents[22] in patients with chronic back pain for pain intensity,[22] disability,[22] quality of life,[19,22,23] and recurrent pain.[22]

Our study also aimed to assess the quality of life of patients, which is one of the outcomes recommended in the literature for evaluating patients with low back pain, and demonstrated that the McKenzie method was superior to the Back School method only in the physical domain of quality of life after 3 months. Although the result was statistically significant, the magnitude of the effect was very small (4.67 points, 95% CI=−9.26 to −0.07) on a scale of 0 to 100 points. Only one study[45] proposed to assess the quality of life of patients treated with the McKenzie method. The authors found positive results in favor of the McKenzie method, but this finding should be interpreted with caution due to the low quality of the study. There is evidence that patients treated with the Back School method improved in quality of life (ie, general health,[66,67] physical and mental status[68]) compared with patients who received only medical assistance or medical visits. Although the levels of pain and disability were reduced in both groups, there were no improvements in range of motion. This finding is consistent with a recent systematic review,[69] which showed weak evidence to support the relationship between the changes found in clinical outcomes of pain and disability and those found in outcomes related to mobility, muscle strength, and endurance after performing therapeutic exercises.[69]

Strengths and Weaknesses of the Study

Our study had good levels of internal and external validity and thus can guide therapists and patients considering treatment options for back pain. The trial included a number of features to minimize bias. The trial was prospectively registered and followed a published protocol.[46] We used true randomization, concealed allocation, blinded assessment, and an intention-to-treat analysis and achieved excellent follow-up. The treatments were conducted by a single therapist who was properly trained to perform the interventions, and there was an excellent treatment adherence.

Some limitations of our study were not monitoring the home exercise program and not blinding both therapist and patients to the treatment allocation. Although we believe that the therapist had similar levels of skills in delivering both interventions, this can be considered as a limitation of the study because of the risk of a possible preference bias due to heterogeneity in expertise. Therefore, one well-trained therapist for each treatment group would be ideal. We did not include a nontreatment or placebo control group in our study, which also can be considered a limitation. The rationale for not including a nontreatment group in our study is based on a recent Cochrane review that investigated the effect of exercise therapy in patients with chronic low back pain.[70] This review concluded that exercise therapy (regardless of the type of exercise) is at least 10 points (on a scale of 0–100 points) more effective than no treatment. To our knowledge, there is no randomized controlled trial of McKenzie exercise compared with a placebo intervention or no treatment for chronic low back pain. Given that our randomization was successful (ie, our baseline estimates were very similar), we can conclude that confounders such as regression to the mean, placebo effects, and natural history are very likely to occur similarly in both groups. Therefore, the difference observed in the primary outcome measure of disability, although small, is real and probably above these confounding effects. It would be interesting to compare these interventions with a placebo intervention in the future in order to provide more precise estimates of the effect of these popular physical therapy interventions. Finally, our therapist was aware of the direction of preference of all participants, which might have influenced the decision and progression of exercises for the participants who were allocated to the Back School group; this also can be considered as a limitation of the study.

Unanswered Questions and Future Research

We observed that patient outcomes improved following both treatments, which is consistent with the results reported in the literature that demonstrate the effectiveness of the combination of exercise programs and education in the treatment of patients with chronic nonspecific

low back pain.[1] Although our study did not include an economic analysis, it is likely that when treatment outcomes are similar, a group treatment such as the Back School method will be more cost-effective than an individualized intervention such as the McKenzie method. Another consideration in treatment planning would be patient preferences for each treatment, as it may be that some patients prefer individual treatment and vice versa. Given the similar treatment outcomes with both methods, we would suggest future studies evaluating the cost-effectiveness of and patient preferences for the McKenzie and Back School methods as important to help clinicians make informed treatment decisions in this area.

Another important point that should be taken into consideration while interpreting the results of our trial is that individual characteristics of patients might predict a better response to one of the interventions (ie, subgroups).[71] There are many treatment-based classifications available to better identify patients who would possibly respond better to different interventions.[72] However, these treatment-based classifications and clinical prediction rules are in the development stages, and clinicians cannot yet precisely match the "right patient" to the "right treatment."[73] Patients who experience the centralization phenomenon usually tend to respond better to the McKenzie intervention,[15,74] but our study was not powered enough to permit this type of subgroup analysis. We suggest for future studies aiming to test the McKenzie method that it would be interesting to consider the centralization phenomenon as an eligibility criterion.[39]

Conclusion

Patients allocated to the McKenzie group experienced greater improvements in disability, but not in pain intensity, after treatment compared with patients allocated to the Back School group, but the magnitude of this effect was small and possibly of doubtful clinical importance.

All authors provided concept/idea/research design. Ms Garcia, Dr Lucíola Costa, and Dr Leonardo Costa provided writing and data analysis. Ms Garcia, Ms da Silva, Ms Gondo, and Ms Renata Costa provided data collection. Ms Garcia, Dr Lucíola Costa, Ms da Silva, Ms Gondo, Ms Renata Costa, and Dr Leonardo Costa provided project management. Dr Leonardo Costa provided fund procurement. Ms Garcia, Ms da Silva, and Dr Leonardo Costa provided study participants. Ms da Silva and Dr Leonardo Costa provided facilities/equipment. Ms Garcia, Dr Lucíola Costa, Ms da Silva, Ms Gondo, and Dr Leonardo Costa provided consultation (including review of manuscript before submission).

This study was approved by the Research Ethics Committee of Universidade Cidade de São Paulo (UNICID) (no. PP 134699394).

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The study was prospectively registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12610000435088). The study protocol was published previously,[46] and there were no deviations from the registered protocol.

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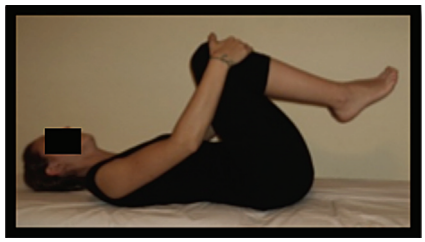
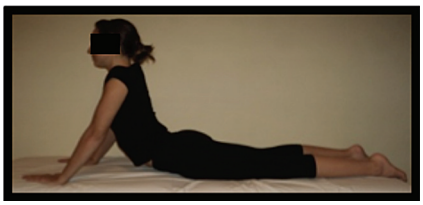
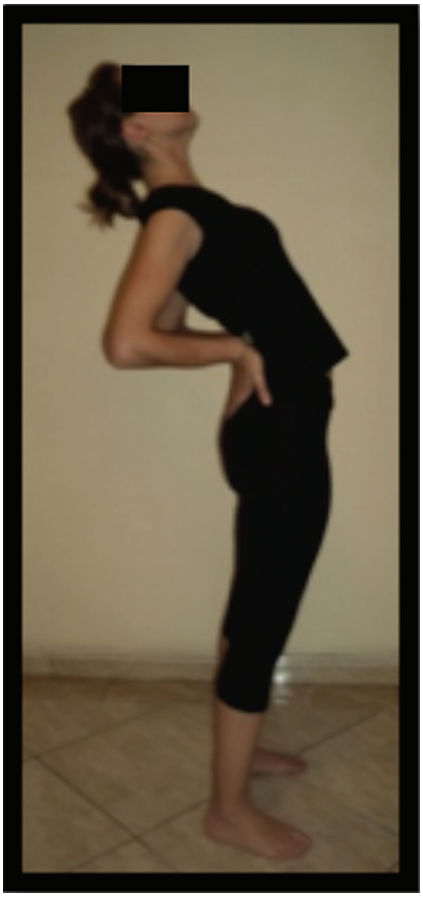
Appendix 1.

Description of McKenzie Exercises

Exercise	Position	Picture	Series
Trunk flexion	**Lying down:** From a supine position with knees and hips flexed, the patient raises the knees toward the chest, applying extra pressure using the hands.		**3 sets of 10 repetitions** Repetitions could be performed sequentially, with a small break between repetitions or split into different times of day, according to the response of the patient.
	Seated: Seated on a chair, with knees and hips flexed at 90 degrees, the patient bends forward until the head is between the knees and the hands are as close to the floor as possible. The patient can hold on to the ankles, bringing the trunk even closer to the knees.		
	Standing: With feet shoulder-width apart, the patient places his or her fingers on the front of the toes, gliding hands toward the floor and keeping the knees extended.		

(Continued)

Appendix 1.
Continued

Exercise	Position	Picture	Series
Trunk extension	**Lying down:** The patient begins in a prone position with the palms of the hands on the floor just in front of the shoulders. The patient extends the elbows, elevating the upper part of the body, while the pelvis and thighs remain relaxed.		**3 sets of 10 repetitions** Repetitions could be performed sequentially, with a small break between repetitions or split into different times of day, according to the response of the patient.
	Standing: With feet shoulder-width apart, the patient places his or her hands at the base of lower back, fingers pointed toward the floor, and extends the trunk backward as far as possible, keeping the neck relaxed.		

(Continued)

Appendix 1.
Continued

Exercise	Position	Picture	Series
Lateral shift	**Standing with upper arm support:** With feet placed shoulder-width apart and the upper arm bent at 90 degrees of elbow flexion with the hand contacting the lateral trunk. Using the hand, supported by the upper arm, the patient manually shifts the pelvis to the opposite side.		**3 sets of 10 repetitions** Repetitions could be performed sequentially, with a small break between repetitions or split into different times of the day, according to the response of the patient.

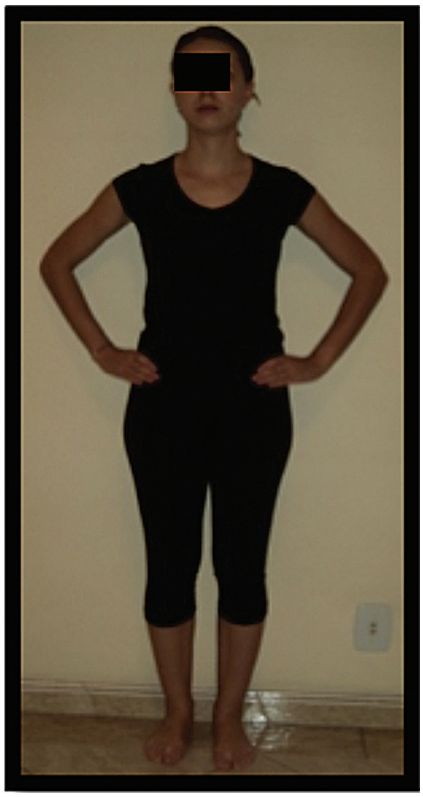
Appendix 2.

Description of Back School Exercises

Exercise	Position	Picture	Series
Diaphragmatic breathing	While seated, the patient inhales slowly and deeply through the nose, elevating the abdomen. The patient then breathes out through the mouth, raising the navel toward the spine.		1 set of 10 repetitions
Stretching of the erector spine muscles	The patient lies in a supine position with flexed knees and one foot supported on top of the opposite thigh. The patient pulls on the back of knee to manually flex the hip, one at a time, toward the chest. The patient then switch legs and does the other side.		Hold 30 seconds Repeat 10 times
Stretching of the posterior lower-limb muscles	The patient lies in a supine position with one leg bent and supported on the mattress. The other hip is flexed approximately 90 degrees with the knee extended. This position is sustained with a bed sheet looped around the extended foot.		Hold 30 seconds Repeat 10 times

(Continued)

Appendix 2.
Continued

Exercise	Position	Picture	Series
Stretching of the anterior hip muscle	The patient lies down in the lateral decubitus position. The hip should be in a neutral position with knees flexed. The patient passively extends the hips. The contralateral limb is flexed at 90 degrees, with the internal side of the knee supported by the mattress.		Hold 30 seconds Repeat 10 times
Kinesthetic training	In a standing position, the patient moves the pelvis in a front-back pelvic inclination in a comfortable range.		1 set of 10 repetitions
Strengthening of the abdominal muscles	(a) The patient lies in a supine position with knees bent and both feet supported on the mattress. Arms are placed at the sides. The patient raises the head and flexes the trunk while exhaling, maintaining alignment of the cervical spine.		(a) 1 set of 10 repetitions
	(b) The patient lies in a supine position with head supported on the mattress. The patient extends one leg at a 45-degree angle and flexes the hip, with the other leg held in triple flexion with the hands. The patient alternates legs, with leg extension performed while exhaling, maintaining contraction of the transverse abdominis, paravertebral, and pelvic-floor muscles.		(b) 1 set of 10 repetitions for each limb

Appendix 3.
Position of the Inclinometer

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Effectiveness of Back School Versus McKenzie Exercises in Patients With Chronic Nonspecific Low Back Pain: A Randomized Controlled Trial

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