Efficacy of the Addition of Modified Pilates Exercises to a Minimal Intervention in Patients With Chronic Low Back Pain: A Randomized Controlled Trial

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Background. The Pilates method has been used to improve function and reduce pain in patients with chronic nonspecific low back pain, although there is little scientific evidence that describes its efficacy.

Objective. The purpose of this study was to investigate the effectiveness of the addition of modified Pilates exercises to minimal intervention in patients with chronic low back pain.

Design. A randomized controlled trial was conducted.

Setting. The study was done in an outpatient physical therapy department in Brazil.

Patients. Eighty-six patients with chronic nonspecific low back pain participated in the study.

Intervention. All participants received an education booklet containing information about low back pain and were randomly allocated to receive 12 sessions, over 6 weeks, of exercises based upon Pilates principles (n=43) or of education alone (n=43).

Measurements. Primary outcomes were pain intensity and disability measured at 6 weeks and 6 months. Secondary outcomes were patient-specific functional disability, global impression of recovery, and kinesiophobia measured at 6 weeks and 6 months. All outcomes were measured by a blinded assessor in all time points.

Results. There was no loss to follow-up at any of the time points. Improvements were observed in pain (mean difference=2.2 points, 95% confidence interval [CI]=1.1 to 3.2), disability (mean difference=2.7 points, 95% CI=1.0 to 4.4), and global impression of recovery (mean difference=−1.5 points, 95% CI=−2.6 to −0.4) in favor of the Pilates group after intervention, but these differences were no longer statistically significant at 6 months.

Limitations. Treatment provider and participants could not be blinded to the interventions.

Conclusions. The addition of modified Pilates exercises to an educational booklet provides small benefits compared with education alone in patients with chronic nonspecific low back pain; however, these effects were not sustained over time.

Chronic low back pain (CLBP) is defined as pain or discomfort between the costal margins and the inferior gluteal folds, with or without referred pain in the lower limbs, with a duration of at least 12 weeks.[1] Low back pain is strongly associated with disability, absence from work, and mood changes such as depression and anxiety.[1–4] In the United Kingdom, approximately £12 billion was spent in 1998, with direct costs related to medical and nonmedical expenses and indirect costs related to productivity and absenteeism.[5] A recent inception cohort study demonstrated that 40% of patients with acute low back pain seen in primary care settings developed CLBP.[6]

Exercise therapy has been recommended by clinical practice guidelines as an effective intervention for the treatment of people with nonspecific CLBP.[2,7] The most updated systematic review from the Cochrane Collaboration on exercise for CLBP concluded that any type of exercise therapy is equally effective as another and that exercise therapy is at least as efficacious as other types of conservative interventions for this condition.[7] Finally, the European guidelines[2] recommend that specific exercise interventions that are commonly used but poorly investigated should be further tested in high-quality randomized controlled trials.

A very popular type of exercise used for the treatment of patients with low back pain is the Pilates method. The Pilates method has 6 basic principles: centering, concentration, control, precision, flow, and breathing.[8] These exercises can be performed using specific equipment (equipment-based Pilates) or without specific equipment (also known as mat Pilates). These exercises aim to improve static and dynamic stability, as well as posture and movements in general.[8] The traditional Pilates method was modified to adapt the exercises to specific health conditions such as low back pain by gradually increasing the difficulty of performing these exercises, and it has been used in studies of the Pilates method in the treatment of people with CLBP.[8–12] In 2011, 2 systematic reviews that retrieved 7[13] and 5[14] clinical trials were published on the effectiveness of a modified Pilates method in the treatment of people with CLBP. One systematic review[13] showed a greater reduction in pain intensity with Pilates method exercises compared with minimal intervention (usual care or waiting list group). The other systematic review[14] suggested that Pilates-based exercises for CLBP are as efficient as no treatment or motor control exercises for pain and disability outcomes. Previously published studies on the effectiveness of Pilates exercises in patients with CLBP[9,10,12,15–17] included small samples ranging from 17[16] to 40[9] participants. None of the studies assessed medium-term effects (assessment after 6 months), and only 1 study had a low risk of bias.[12]

Current literature shows moderate evidence that brief educative interventions based on self-care reduce disability, but not pain, in patients with CLBP.[2] To our knowledge, no study has investigated the efficacy of the addition of exercises based on a modified Pilates method in the treatment of patients with CLBP who received a brief education intervention as their baseline care. Therefore, the objective of this study was to investigate the efficacy of the addition of the Pilates method to a minimal intervention (an educational booklet about anatomy and biomechanics of the spine, posture, and movement) in the treatment of patients with chronic nonspecific low back pain for the following outcomes: pain intensity, general and specific disability, global perceived effect, and kinesiophobia.

Method

Design Overview

This clinical trial was prospectively registered in the Australian and New Zealand Clinical Trials Registry (ACTRN12610000523000) in June 2010, prior to data collection (August 2010). The protocol for this study has been published previously,[18] and additional methodological details are included in that report.

Setting and Participants

This randomized controlled trial was carried out at the outpatient physical therapy department of (Universidade Cidade de São Paulo, São Paulo, Brazil). The study included patients with chronic nonspecific low back pain with a duration of at least 3 months and aged between 18 to 60 years who responded to an advertisement placed in a regional newspaper and on the university website. Exclusion criteria were: any contraindication for physical exercise (assessed with the Physical Activity Readiness Questionnaire),[19] previous regular Pilates method training, pregnancy, serious spinal pathologies, previous or scheduled spine surgery, low back pain due to nerve root compromise, physical therapy treatment for CLBP in the previous 6 months, and inability to write or speak in Portuguese.[1] The exclusion criteria reported here are slightly different from those described in the registry (pregnancy, contraindications to exercise, nerve root compromise, and serious spinal pathology); however, this deviation from the original protocol was decided prior to the enrollment of the first participant. Written informed consent was obtained from all participants.

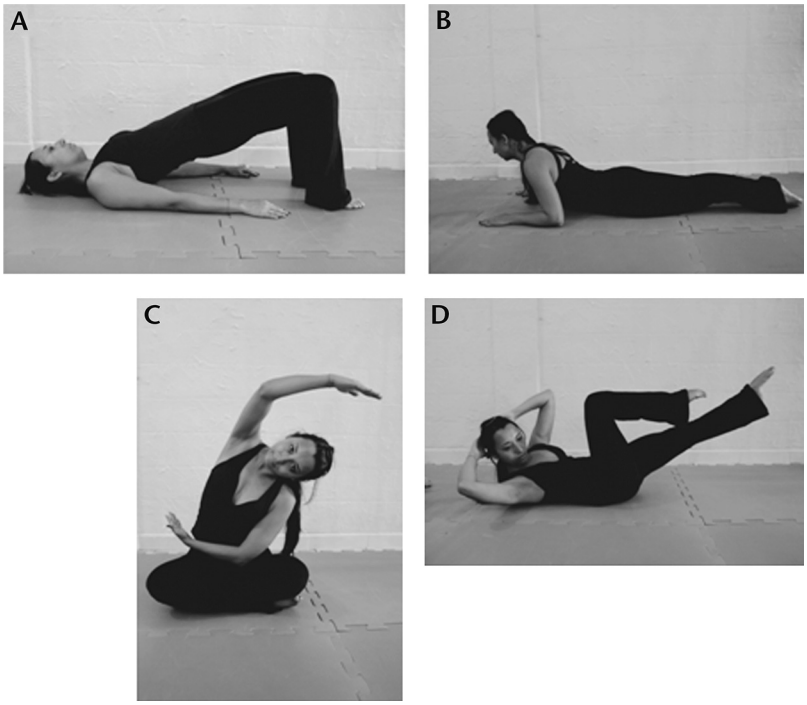

Figure 1.
Examples of modified Pilates method exercises performed in the Pilates group intervention: (A) shoulder bridge preparation, (B) breast stroke preparation, (C) mermaid, (D) obliques.

Randomization—Sequence Generation

Simple randomization was conducted using Microsoft Excel for Windows software (Microsoft Corporation, Redmond, Washington) by a researcher who was not involved in participant recruitment.

Allocation Concealment

The allocation sequence was generated by one of the authors who was not involved with participant recruitment and treatment. Allocation was concealed by using consecutively numbered, sealed, opaque envelopes. After the baseline assessment, the eligible participants were referred to the physical therapist overseeing the treatment, who conducted the randomized allocation to 2 treatment groups: a booklet group (education only) and a Pilates group (modified Pilates exercises + education).

Interventions

In the first session, the participants allocated to the booklet group received an educational booklet containing information about the anatomy of the spine and pelvis and the low back pain and recommendations regarding posture and movements involved in activities of daily living.[3] The participants in this group did not receive additional exercise, and they were instructed not to undergo treatment elsewhere during the period of the study. However, they had direct access to the physical therapist overseeing the intervention and, over the next 6 weeks, they received twice-weekly telephone calls for clarifications regarding the booklet instructions. After the 6-month follow-up, the intervention using the modified Pilates method also was offered to this group.

The participants allocated to the Pilates group received the same educational booklet in the first session of treatment. In addition to the educational booklet, they received an individual, supervised treatment using the modified Pilates method. The Pilates group received a 1-hour session, twice a week, over 6 weeks. These exercises followed the traditional Pilates principles of centering (contracting deep trunk muscles known as "power house muscles"), concentration, control, precision, flow, and breathing. All exercises aimed at improving breathing, core stability, motor control, posture, flexibility, and mobility with the spine in neutral position.[8,20–22] In the beginning of all treatment sessions, 5 warm-up exercises were performed. These exercises were aimed at improving spine and pelvis mobility. Then participants received the modified Pilates protocol that was based on 8 exercises aimed at improving breathing associated with core stability, posture, strengthening of specific muscles (such as abdominal wall muscles, multifidus, gluteal muscles, and hip flexors, extensors, adductors and abductors), and flexibility of the lower limbs and spinal muscles in all planes of movement. The number of repetitions for each exercise was individualized for each patient and ranged from 5 to 10 repetitions. These exercises were tailored individually and progressed in difficulty in 3 levels (basic, intermediate, and advanced).[10,11,15]

Figure 1 shows some common exercises used in the program for patients with CLBP. The participants were allowed to make up for missed sessions as long as the intervention period, including the replacement sessions, did not exceed 8 weeks. The physical therapist who provided the intervention is a certified Pilates instructor with 3 years of clinical experience. In order to enhance the pragmatism of this trial, participants

were allowed to keep taking their medication normally as prescribed by their medical doctor.

Outcome Measures and Follow-up

Initially, a previously trained, blinded assessor conducted an evaluation to gather information to confirm the eligibility criteria, demographic and anthropometric data, and details concerning the use of medication, physical therapy treatment, and other types of treatment for CLBP. This initial evaluation occurred before the allocation of the participants to treatment groups. Due to the nature of the interventions, it was not possible to blind the participants and the therapist involved in the study.

Measurements of primary and secondary outcomes were obtained at baseline and at 6 weeks and 6 months after randomization by the same blinded assessor who collected baseline data. Both 6-week and 6-month follow-up data were collected over the telephone. Primary outcomes were pain intensity (0–10 Pain Numeric Rating Scale)[23] and disability (0–24 Roland-Morris Disability Questionnaire) measured at 6 weeks and 6 months after randomization.[23–25] The secondary outcomes were: specific disability (0–10 Patient-Specific Functional Scale),[24] global perceived effect (−5 to +5 Global Perceived Effect Scale),[23] and kinesiophobia (17–68 Tampa Scale for Kinesiophobia) measured at 6 weeks and 6 months after randomization.[26,27] The participants were instructed not to provide information about the treatments to the assessor. All outcome measures were previously adapted cross-culturally into Brazilian-Portuguese, and the measurement properties of these measures are equivalent to those of the original versions in English.[23,24,26]

Each participant's expectation for improvement after treatment (measured with the 0–10 Expectancy for Improvement Scale) was obtained only at baseline. The Treatment Credibility Scale was used only after the first treatment session in both groups.[28,29] Both credibility and expectancy were not considered as primary or secondary outcomes for this study. Table 1 presents the description of each of these outcome measures.

Data Analysis

A sample of 86 participants was determined by a sample size calculation designed to detect a difference of 1 point in the Pain Numerical Rating Scale[23] (estimate for standard deviation=1.4 points), 4 points in the Roland-Morris Disability Questionnaire[23–25] (estimate for standard deviation=4.9 points), 1 point in the Patient-Specific Functional Scale[23] (estimate for standard deviation=1.4 points), and 1 point in the Global Perceived Effect Scale[23] (estimate for standard deviation=1.3 points). The following specifications were considered: α=.05, statistical power of 80%, and follow-up loss of 15%.

The estimates used in our sample size calculation were lower than those suggested as minimal important change in order to increase the precision of the effects of the interventions. A higher difference to be detected would have dramatically reduced our sample size, and this has been one of the major limitations in trials that used Pilates as an intervention.

All data were double entered prior to the analysis. The statistician received coded data and was blinded to the participants' allocation groups. The mean effects of the interventions and the group differences for all outcomes were calculated using linear mixed models[30] that incorporated terms for the treatment groups, time (follow-ups), and interaction terms "treatment groups" and "time." The term "time" was coded as a categorical variable (ie, 3 variables were created for the categories: baseline, 6-week follow-up, and 6-month follow-up). The coefficients of treatment versus time interactions were equivalent to the estimates for the group differences. We calculated number needed to treat (NNT) and absolute risk reduction (ARR) using the Global Perceived Effect Scale score at discharge, with +4 as the cutoff for improvement. We used the Global Perceived Effect Scale for the NNT and ARR calculations because this scale is directly related to recovery of patients, making the interpretation of these estimates easier to understand. The analyses followed the intention-to-treat principles.

Nonparametric tests were used for between-group comparisons for the variables "treatment credibility" and "treatment expectation," as the distribution of the data for these variables was skewed. For all statistical analyses, the level of significance was set at 5%, and IBM SPSS Statistics Version 19 for Windows software (IBM Corporation, Armonk, New York) was used.

Results

In total, 214 patients registered in the study's selection process between August 2010 and April 2011 (Fig. 2). Of these, 128 were excluded: 40 for declining to participate and 88 for not meeting the eligibility criteria (10 had undergone spinal surgery, 24 were older than 60 years, 12 had serious spine disorders, 20 had a contraindication for exercise, 1 was already a Pilates method practitioner, 15 exercised regularly, and 6 were already undergoing physical therapy treatment).

The study included 86 participants with nonspecific CLBP divided into the booklet group (34 women, 9

Table 1.
Description of the Outcome Measures

Measure	Construct	Description
Pain Numerical Rating Scale[32]	Pain intensity	11-point scale (0–10), with 0 being "no pain" and 10 being "pain as bad as could be." The participants were asked to classify their average pain in the previous 7 days.[a]
Roland-Morris Disability Questionnaire[32–34]	Disability	24-item questionnaire related to normal activities of daily living. Participants were asked to tick the items that they perceived as difficult to perform due to low back pain. Each answer is scaled either "no" (no difficulty=0 points) or "yes" (difficulty=1 point), thus leaving a range of scores from 0 to 24, with a higher score indicating higher levels of disability.[a]
Patient-Specific Functional Scale[32]	Specific disability	Participants identified 3 important activities that they had difficulty performing or were unable to perform due to low back pain at the time of the evaluation. They also indicated on an 11-point scale (0–10) how capable they felt of performing specific activities, with 0 representing "unable to perform the activity" and 10 representing "able to perform the activity at preinjury level." The average of the scores for the 3 activities was calculated. The higher the score, the greater the functional ability.[a]
Global Perceived Effect Scale[32]	Global impression of recovery	Assesses global perceived effect comparing the onset of symptoms with the last few days. It is an 11-point numerical scale (−5 to +5), with −5 being "vastly worse," 0 being "no change," and +5 being "completely recovered." Higher scores mean greater recovery from the condition.[a]
Tampa Scale for Kinesiophobia[35,36]	Kinesiophobia	Scale consists of a self-applied questionnaire with 17 questions about pain and intensity of symptoms. The scores range from 1 to 4 points, where 1 represents "strongly disagree," 2 represents "partially disagree," 3 represents "partially agree," and 4 represents "strongly agree." For the overall final score, the scores for questions 4, 8, 12, and 16 must be inverted. The final score ranges from 17 to 68 points, with higher scores indicating a higher degree of kinesiophobia.[a]
Expectancy for Improvement Scale[c]	Expectation for improvement	An 11-point scale (0–10), with 0 being "no expectancy for improvement" and 10 being "expectancy for the greatest possible improvement."[b]
Treatment Credibility Scale[37,38,c]	Degree of confidence with respect to treatment	This modified version comprises 4 questions that assessed the participants' degree of confidence that symptoms will improve and confidence in the proposed treatment. The score varies from 0 ("not at all confident") to 6 ("very confident").[d]

[a] Scale or questionnaire has been translated and adapted to Brazilian Portuguese, and its measurement properties have been assessed.
[b] Scale's measurement properties have not been tested.
[c] Scale was not considered a measure of treatment outcomes.
[d] Scale has not been validated or translated into Brazilian Portuguese; however, the measurement properties of the original version have been tested.

men; mean age=38.3 years, SD=11.4) and the Pilates group (36 women, 7 men; mean age=40.7 years, SD=11.8). The participants' demographic characteristics are shown in Table 2. Among the participants who had undergone previous physical therapy, the main treatments were exercise therapy in the booklet group (n=12 [27.9%]) and electrophysical agents in the Pilates group (n=10 [23.3%]). Additionally, among the participants who used medication to control symptoms, the main drugs were analgesics in the booklet group (n=9 [20.9%]) and analgesics and anti-inflammatories in the Pilates group (n=14 [32.6%]). Table 2 also shows the means and standard deviations for the characteristics measured at baseline. The baseline data from both groups were similar for most of the characteristics. Participants allocated to the Pilates group had a greater duration of symptoms and have higher previous experience with physical therapy

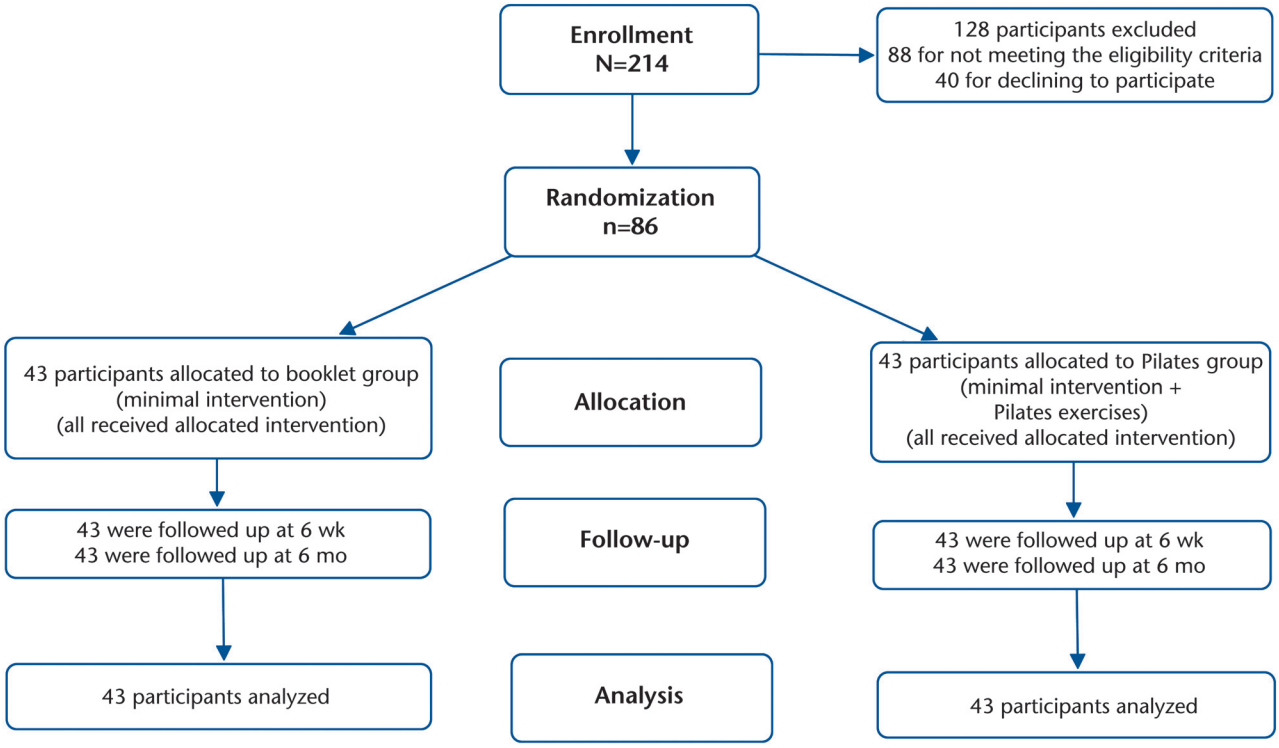

Figure 2.
Flow diagram of participants through the study.

treatment compared with the participants allocated in the booklet group.

No adverse effects were observed. Regarding attendance at the sessions in the Pilates group, of the 516 sessions, there were 50 absences (mean attended sessions per participant=10.8, SD=3.0), which represents 90.3% attendance at the sessions offered. Furthermore, there was no loss of follow-ups. Two participants in the Pilates group did not complete the Treatment Credibility Scale.

Table 3 shows the medians and interquartile ranges for the Treatment Credibility Scale and the Expectancy for Improvement Scale. At baseline, the participants showed greater expectancy for improvement for the modified Pilates method than for the educational booklet ($P<.001$). However, after the first intervention session, both groups presented high credibility scores.

We observed improvements in pain intensity (mean difference=2.2 points, 95% CI=1.1 to 3.2 points), disability (mean difference=2.7 points, 95% CI=1.0 to 4.4 points), and global impression of recovery (mean difference=−1.5 points; 95% CI=−2.6 to −0.4 points) in favor of the Pilates group at 6 weeks after intervention. However, no significant difference was observed for specific disability and kinesiophobia after intervention. We did not observe between-group differences at the 6-month follow-up for any of the outcomes (Tab. 4). The NNT was 4 (95% CI=2 to 32), and the ARR was 0.23 (95% CI=0.03 to 0.41).

Discussion

This randomized controlled trial showed small to moderate short-term improvements in pain intensity, disability, and global impression of recovery in participants who received modified Pilates exercises in addition to a minimum education intervention (Pilates group) compared with participants who received education alone (booklet group). However, these improvements were not sustained after 6 months. Additionally, no short-term or medium-term improvement was found in patient-specific disability and kinesiophobia. These results demonstrate that the exercises based on the modified Pilates method can be useful in the treatment of patients with CLBP in the short term; however, this difference is not maintained over time. This trial was performed in a public outpatient physical therapy department of a university, and the results from this study are generalizable for patients with similar characteristics (ie, patients recruited from the community with a long duration of symp-

Table 2.
Baseline Characteristics of the Participants

Variable[a]	Booklet Group (n=43)	Pilates Group (n=43)
Sex		
Female	34 (79.1)	36 (83.7)
Male	9 (20.9)	7 (16.3)
Age (y)	38.3 (11.4)	40.7 (11.8)
Duration of low back pain (mo)	56.7 (53.5)	73.3 (79.6)
Weight (kg)	68.6 (12.0)	68.5 (14.3)
Height (m)	1.7 (0.1)	1.6 (0.1)
Body mass index (kg/m^2)	24.6 (4.0)	25.5 (4.9)
Marital status		
Single	17 (39.5)	13 (30.2)
Married	22 (51.2)	22 (51.2)
Divorced	4 (9.3)	8 (18.6)
Academic level		
Primary education	5 (11.6)	1 (2.3)
Secondary education	14 (32.6)	18 (41.9)
Incomplete tertiary education	12 (27.9)	12 (27.9)
Complete tertiary education	12 (27.9)	12 (27.9)
Income (in minimum wages)	3.6 (2.8)	3.8 (2.8)
Physical therapy treatment		
Yes	1 (2.3)	18 (41.9)
No	42 (97.7)	25 (58.1)
Other type of treatment		
Yes	3 (7)	4 (9.3)
No	40 (93)	39 (90.7)
Use of medication		
Yes	18 (41.9)	17 (39.5)
No	25 (58.1)	26 (60.5)
Pain intensity (0–10)	6.5 (1.7)	6.6 (1.5)
Disability (0–24)	10.5 (5.4)	9.7 (4.5)
Patient-specific disability (0–10)	4.3 (1.8)	4.9 (1.8)
Global impression of recovery (−5 to +5)	−1.0 (2.5)	−1.0 (2.3)
Kinesiophobia (17–68)	39.5 (7.1)	39.4 (6.1)

[a] The categorical variables are expressed as n (%), and the continuous variables are expressed as mean (SD).

toms and with moderate levels of pain and disability).

Our interpretation of the results of the present study with regard to the clinical importance of the group mean differences (based on parameters from previous studies[31,32]) is that the addition of exercises based on the modified Pilates method produced a clinically important improvement in pain intensity and a moderate improvement in disability, although the between-group difference observed for disability was not large enough to be considered clinically significant, in the 6-week follow-up for this population with nonspecific CLBP compared with patients who received minimal intervention only. Nevertheless, there is still no clear definition of what represents a clinically important reduction in low back pain.[33] Although the patient's perception of improvement due to treatment (global impression of recovery) and the patient's specific disability are important tools to assess perception of pain in this population, we found no studies on the Pilates method that assessed these outcomes.

One possible explanation for the larger effect found in the participants allocated to the Pilates group may be the much larger difference in dosage in that group compared with the participants allocated to the booklet group. We tried to counterbalance this difference in treatment dosage by calling all participants in the booklet group twice a week to respond to any questions, as well as to provide enough attention to these patients. Nevertheless, it is clear that the dosage of treatment in the booklet group was lower. As motor control deficits are common in patients with CLBP, we believe that the addition of specific exercises might have contributed to better outcomes in terms of pain and disability in the Pilates group compared with the group that received education only.[34–36] Furthermore, although the use of educational strategies based upon anatomy and posture are recommended by some clinical practice guidelines,[2] there is evidence that psychosocial interventions are more efficacious than education on anatomy and posture for reducing fear of pain and disability.[37]

A study on the effectiveness of motor control exercises in patients with nonspecific CLBP showed improvement in global perceived effect, disability, and patient-specific disability

Table 3.
Expectancy for Improvement and Treatment Credibility[a]

Characteristic			
Expectancy for improvement	**Booklet Group (n=86)**	**Pilates Group (n=86)**	***P***
	7 (4)	10 (2)	<.001
Treatment credibility	**Booklet Group (n=43)**	**Pilates Group (n=41)**	***P***
How confident do you feel that this treatment can help to relieve your pain?[b]	5 (3)	5 (1)	.06
How confident do you feel that this treatment will help you manage your pain?[b]	5 (2)	5 (1)	.44
How confident would you be in recommending this treatment to a friend who has similar complaints?[b]	6 (2)	6 (1)	.03
How logical does this therapy seem to you?[c]	6 (1)	6 (1)	.23

[a] Data are expressed as median and interquartile range.
[b] The score ranges from 0 ("not at all confident") to 6 ("very confident").
[c] The score ranges from 0 ("not at all logical") to 6 ("very logical").

Table 4.
Between-Group Differences at 6-Week and 6-Month Follow-ups[a]

Outcome	Unadjusted Mean (SD)		Booklet Group vs Pilates Group	
	Booklet Group	**Pilates Group**	**Adjusted Mean Difference (95% CI)**	***P***
Pain intensity (0–10)				
6-week follow-up	5.2 (2.3)	3.1 (2.3)	2.2 (1.1 to 3.2)	<.01[b]
6-month follow-up	5.3 (2.3)	4.5 (2.2)	0.9 (−0.1 to 1.9)	.08
Disability (0–24)				
6-week follow-up	7.1 (5.7)	3.6 (3.4)	2.7 (1.0 to 4.4)	<.01[b]
6-month follow-up	6.7 (5.6)	4.5 (4.5)	1.4 (−0.03 to 3.1)	.10
Patient-specific disability (0–10)				
6-week follow-up	6.4 (2.0)	7.5 (2.1)	−0.4 (−1.3 to 0.4)	.35
6-month follow-up	6.1 (2.0)	6.9 (1.8)	−0.2 (−1.1 to 0.6)	.62
Global impression of recovery (−5 to +5)				
6-week follow-up	1.7 (2.2)	3.2 (1.5)	−1.5 (−2.6 to −0.4)	<.01[b]
6-month follow-up	1.7 (2.1)	2.4 (1.7)	−0.7 (−1.8 to 0.4)	.22
Kinesiophobia (17–68)				
6-week follow-up	38.1 (8.3)	36.3 (7.4)	1.6 (−0.9 to 4.1)	.20
6-month follow-up	38.9 (7.3)	38.1 (7.2)	0.6 (−1.8 to 3.1)	.61

[a] The shaded rows refer to primary outcomes, and the remaining rows refer to secondary outcomes. 95% CI=95% confidence interval.
[b] Significant difference between groups in the 6-week follow-up ($P<.01$).

in the short term, which was maintained in the medium term. For pain intensity, however, there was only a significant reduction in the long term.[38,39] Previous evidence demonstrates moderate effects of exercises versus minimal intervention in the reduction of pain and disability in patients with CLBP.[7] Moreover, there is no convincing evidence that specific exercises are better than general exercises for this condition.[2]

The results described above are similar to those of the present study except for pain intensity and patient-specific disability. The distinction between these outcomes can be justified by the difference between the treatment programs with regard to duration and intensity of exercise (eg, 12 sessions, each lasting 90 minutes, for 8 weeks), which may have provided better pain management over time to these patients. No studies were found on the Pilates method in the treatment of CLBP that analyzed kinesiophobia. One study that aimed to compare the efficacy of an educational intervention and exercise training in patients with CLBP demonstrated that the educational intervention group had greater improvement in the degree of kinesiophobia in the short term and the medium term.[40] Although we hypothesized that participants allocated to the Pilates group would show improvement in kinesiophobia, as this form of exercise includes graded exposure components,[41] we observed no improvements in kinesiophobia in either group. In the assessment of expectancy for improvement, the patients had greater expectation for improvement if allocated to the Pilates group. A study on the importance of beliefs and expectations for satisfactory recovery from back pain showed that high expectations and preferences contribute to a better response to treatment because they increase adherence, motivation, and satisfaction with the treatment.[42] Thus, we expected that the improvement in the Pilates group after 6 weeks would be maintained, which was not the case. In the assessment of treatment credibility, the results of both groups show that the participants were confident and satisfied with the treatment they received initially. These results are similar to those of a study that assessed treatment credibility after motor control exercises and a placebo treatment.[38]

A systematic review with meta-analysis of the efficacy of the Pilates method in the treatment of nonspecific CLBP showed that this method reduces pain compared with minimal intervention (usual care); however, no improvements in disability were observed. In a comparison between the Pilates method and other types of exercise, Lim et al[13] found no significant reduction in pain or improvement in disability. Nevertheless, their conclusions must be interpreted with caution because most of the studies (n=7 trials) analyzed had serious methodological limitations. During the development of the present study, we avoided the methodological problems observed in previous studies, such as in the process of randomization, concealed allocation, blinding of assessors, intention-to-treat analysis, and loss to follow-up. Finally, the Pilates method sessions were conducted by an experienced, certified Pilates instructor to ensure the quality of treatment, and training was provided on how to follow the protocol during the telephone calls to the booklet group. To our knowledge, our sample was the largest to date among studies of the effects of the Pilates method on the treatment of people with nonspecific CLBP.

More studies with high methodological quality and larger samples are needed to assess the effects of the Pilates method on the treatment of people with nonspecific CLBP in the short term, medium term, and long term, taking into consideration the method's exercise protocol, as well as the best intensity, duration, and frequency for the exercises. Studies also are needed to assess the use of an educational booklet in the treatment of people with nonspecific CLBP to identify the positive effects of this method on pain and disability. In general, the results of this randomized controlled trial show that the addition of a modified Pilates method to a minimal intervention is more efficacious for patients with nonspecific CLBP than minimal intervention alone. Nevertheless, these effects were not maintained over time, and the interventions proposed in this study did not affect kinesiophobia in these participants.

The main limitation of the present study was the inability to blind the participants and the therapist with regard to treatment allocation. However, to minimize therapist preference and interference, the professional who conducted the sessions had no access to the information relative to the assessments until the completion of the 6-month follow-up. Another possible limitation was the difficulty in controlling participant adherence to the instructions in the educational booklet. The participants of the booklet group may have adhered more strictly because it was the only treatment offered initially, whereas the participants of the Pilates group may not have adhered completely because an exercise treatment was added, making them believe that it would be sufficient to improve their symptoms.

Although we observed a short-term advantage of the addition of using modified Pilates interventions in patients with CLBP over an educational booklet in our study, the recommendation for the use of Pilates exercises must be discussed with

patients, as this type of treatment is much more expensive than a simple, brief education intervention.

Ms Miyamoto, Dr Costa, and Dr Cabral provided concept/idea/research design and writing. Ms Galvanin provided data collection. Dr Costa and Dr Cabral provided project management. Ms Miyamoto provided study participants. Dr Cabral provided facilities/equipment. Dr Costa provided consultation (including review of manuscript before submission).

This was approved by the Research Ethics Committee of Universidade Cidade de São Paulo.

This clinical trial was prospectively registered in the Australian and New Zealand Clinical Trials Registry (ACTRN12610000523000).

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