Article

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Pilates improves pain, function and quality of life in patients with chronic low back pain: a randomized controlled trial

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Abstract

Objective: To assess the effectiveness of pilates method on patients with chronic non-specific low back pain (LBP).

Method: A randomized controlled trial was carried out in sixty patients with a diagnosis of chronic non-specific LBP. Patients were randomly assigned to one of two groups: Experimental Group (EG) that maintained medication treatment with use of NSAID and underwent treatment with the pilates method and Control Group (CG) that continue medication treatment with use of NSAID and did not undergo any other intervention. A blinded assessor performed all evaluations at baseline (T0), after 45, 90, and 180 days (T45, T90 and T180) for: pain (VAS), function (Roland Morris questionnaire), quality of life (SF-36), satisfaction with treatment (Likert scale), flexibility (sit and reach test) and NSAID intake.

Results: The groups were homogeneous at baseline. Statistical differences favoring the EG were found with regard to pain ($P < 0.001$), function ($P < 0.001$) and the quality of life domains of functional capacity ($P < 0.046$), pain ($P < 0.010$) and vitality ($P < 0.029$). Statistical differences were also found between groups regarding the use of pain medication at T45, T90 and T180 ($P < 0.010$), with the EG taking fewer NSAIDs than the CG.

Conclusions: The pilates method can be used by patients with LBP to improve pain, function and aspects related to quality of life (functional capacity, pain and vitality). Moreover, this method has no harmful effects on such patients.

Keywords

Low back pain, exercise, pain rehabilitation

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Introduction

Low back pain is defined as pain located between the lower rib cage and gluteal folds. It is the most prevalent musculoskeletal condition and one of the most common causes of disability in developed nations. Low back pain results in significant levels

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of disability and restrictions on usual activity, such as the inability to work. According to epidemiological studies, 65 to 90% of all adults experience low back pain at some time in life.[1,2]

Non-specific low back pain represents 90% of all cases. Multiple factors can affect the mechanical balance of the lumbar region leading to instability that can trigger low back pain.[3] According to many guidelines for diagnosing and treating low back pain, conservative treatment including rest, pharmacological pain relief, surgery, and rehabilitation can be performed.[4,5,6]

Weak evidence regarding the effect of therapeutic exercise on chronic low back pain was found in literature prior to 1991. Since then, many therapeutic options of exercise have been evaluated through controlled studies and have gained a place in the treatment of chronic non-specific low back pain.[4,5,6] The current consensus is that therapeutic exercises are beneficial in the treatment of low back pain; however, there is no evidence, positive or negative, regarding other physical therapy interventions. [5] Hayden et al. published a review assessing the effectiveness of exercise in comparison to other treatments or no treatment at all and concluded that therapeutic exercise is effective at reducing pain and improving function in adults with chronic non-specific low back pain.[6]

Recently, pilates has been considered an option that has gained popularity. The pilates method is a unique system of stretching and strengthening exercises developed by Joseph H Pilates nearly 90 years ago that employs sets of controlled, precise movements and the use of special equipment. The exercises are performed in different positions on the ground with a mat, avoiding excessive impact or pressure on the muscles, joints and tissues.[7,8] The purpose of physical training using the pilates method is to achieve better functioning of the body based on the strengthening of the 'powerhouse', a term referring to the lower trunk that supports the body. The second major feature of the method is the six basic principles: centering, concentration, control, precision, breath and flow.[7]

Publications regarding pilates method to treat low back pain show improvement in pain and disability demonstrating that pilates could be a promising method for low back pain.[9-12] However, these studies have some limitations such as small sample,[9] small treatment duration (six or eight weeks)[10-12] or large drop-out (more than 20%).[12]

Recent systematic reviews of the literature have been published on the use of pilates for the treatment of low back pain; however, the majority of studies in these reviews had low methodological quality, heterogeneous population and outcome measures with small samples and short treatment duration. Moreover, none of the studies present the pilates protocol or its progression. Despite the benefits offered by the pilates method, the reviews are inconclusive regarding evidence of improve pain and disability in low back pain patients and concluded that further studies are needed to assess the effectiveness of this method in the medium and long term.[13-18]

The current literature demonstrated that therapeutic exercises were effective in the treatment of low back pain, but failed to demonstrate the effectiveness of pilates. Consequently, we conducted a randomized controlled trial to investigate the effect of the pilates method on chronic non-specific low back pain.

The purpose of the present study was to assess the effectiveness of the pilates method on pain, function and quality of life among patients with chronic non-specific low back pain.

Material and method

A randomized, controlled clinical trial was carried out with a blinded evaluator, the duration of the follow up period was 180 days. The study was approved by the Ethics Committee of the University.

The inclusion criteria were as follows: diagnosis of chronic low back pain (defined as pain between the lower rib cage and gluteal folds for more than 12 months); nonspecific low back pain characterized by the absence of signs of a serious underlying condition (such as cancer, infection, or cauda equina syndrome), spinal stenosis or radiculopathy, or another specific spinal cause (such as vertebral compression fracture or ankylosing spondylitis),[19] pain that becomes accentuated with physical effort

and is relieved with rest; male or female; aged 18 to 50 years; pain between four and seven on a 10-cm visual analog scale; and agreement to participate in the study.

The exclusion criteria were as follows: diagnosis of low back pain due to other causes; fibromyalgia; prior spine surgery; lawsuit; having initiated or changed regular physical activity in the previous three months; body mass index > 30; and having undergone treatment with physical therapy or acupuncture in the previous three months.

Sample

The sample size was calculated with the following parameters: 20% improvement in the pain VAS score, with 80% power at the .05 level. It was determined that a minimum of 26 patients were required per group. This number was raised to 30 patients to compensate for possible losses.

Sixty patients were selected from a physical therapy waiting list and randomly assigned to one of two groups:

- Experimental Group: patients maintained medication treatment with use of non-steroidal anti-inflammatory drug and underwent treatment with the pilates method.
- Control Group: patients continued medication treatment with use of non-steroidal anti-inflammatory drug and did not undergo any other intervention.

Randomization

Patients were randomized using an electronically generated randomization table. Sealed, opaque envelopes were used to ensure the confidentiality of the assignment. The envelopes were stored in a locked cupboard and only opened after the initial evaluation by an individual who did not participate in the study.

Intervention

The pilates sessions took place in a studio with a certified, physical educator with 10 years of experience in the method. Classes lasted 50 minutes and followed a pre-established pilates protocol. Each class consisted of three to four patients and took place twice a week for a total of 90 days (Supplementary material Chart 1).

Patients in both groups were instructed to use 50mg of sodium diclofenac at intervals no shorter than 8h when needed (VAS for pain more than 7cm). Patients were also instructed to record on a chart the number of pills taken per day throughout the study.

➢ Evaluations

An examiner blind to the assignment of the patients performed all evaluations at the following times:

- T0: immediately prior to the study randomization (baseline);
- T45: 45 days after T0;
- T90: 90 days after T0 (conclusion of the Pilates program);
- T180: 90 days after the conclusion of the exercise program.

During the baseline evaluation (T0), data were collected on demographics (gender, age), socioeconomic status (household income and level of schooling), past history of low back pain and life style (smoking habits and physical activity).

The following parameters were assessed during all evaluations:

- Primary parameter:
  - Pain – measured with the patient indicating his/her current level of pain by marking a point on a 10-cm VAS, for which 0 represents the absence of pain and 10 represents unbearable pain.
- Secondary parameters:
  - Function – the Roland-Morris questionnaire is a short, simple, sensitive, and clear measure for quantifying self-rated disability due to back pain. The questionnaire is made up of 24 items, to which the patients

chooses to what extent he/she agrees with each statement. The score ranges from 0 (absence of disability) to 24 (severe disability); [20,21]

- Quality of life – the SF-36 is a generic quality of life assessment measure that is easy to administer and understand. The SF-36 has eight domains: physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional and mental health. The scores range from 0 to 100, with higher scores denoting a better quality of life; [22,23]
- Satisfaction with treatment – a Likert scale was used to determine patient satisfaction with the treatment. Patients answered the question 'How do you feel today in comparison with your last evaluation?', to which the options were 'much better', 'a little better', 'the same', 'a little worse' and 'much worse';
- Flexibility – sit and reach test, which is the maximal distance achieved in the Wells bench. The test was performed twice, with the greater distance recorded;[24]
- Non-steroidal anti-inflammatory drug intake - sodium diclofenac intake was recorded on a chart supplied to each patient

➢ Statistical analysis

The Kolmogorov-Smirnov test was used to determine the normality of the data.

The following tests were used:

- To determine the homogeneity of the sample at the initial evaluation - $\chi 2$ (categorical variables), Student's t test (parametric variables) and Mann-Whitney (non-parametric variables).
- To determine differences in the outcomes between groups over time - repeated-measures ANOVA with Bonferroni adjustments and a to know where this difference occurs a multiple comparisons test (Post Hoc) was conducted.

Data for all patients were evaluated with intention-to-treat analysis. In cases of interrupted treatment, patients were asked to return for subsequent evaluations. For patients who refused to return, the last data collected were repeated for the subsequent evaluations.

Results

Ninety-seven patients with non-specific low back pain were screened and 60 patients who fulfilled the eligibility criteria were selected. Figure 1 displays the flowchart of the study. Three drop-outs occurred throughout the study (one in the control group and two in the experimental group). In order to conduct an intention-to-treat analysis, the data from the last evaluation of these patients were repeated in the subsequent evaluations.

Regarding the compliance ninety-six percent of patients completed all pilates sections. The other 4% missed one or two sections.

Table 1 displays social demographic data of the sample. No statistically significant differences were found between groups regarding any of the clinical or demographic variables at baseline showing the homogeneity of the sample.

The comparison between groups over time, using the ANOVA test, shows an significant difference favoring the experimental group regarding pain ($P < 0.001$), function ($P < 0.001$) and some quality of life domains (functional capacity – $P < 0.046$; pain – $P < 0.010$ and vitality – $P < 0.029$). These results are presented in Table 2. The effect size and 95%CI for the parameters that were statistically significantly different between groups with ANOVA were shown in Table 3.

Regarding satisfaction with treatment in the opinion of patient and assessor no significant differences were found between groups (Table 4).

The experimental group took fewer non-steroidal anti-inflammatory drugs than the control group and this difference was statistically significant in the comparison between groups at T45, T90 and T180 ($P < 0.010$) (Table 2).

Discussion

The purpose of the present study was to investigate the effects of the pilates method on chronic

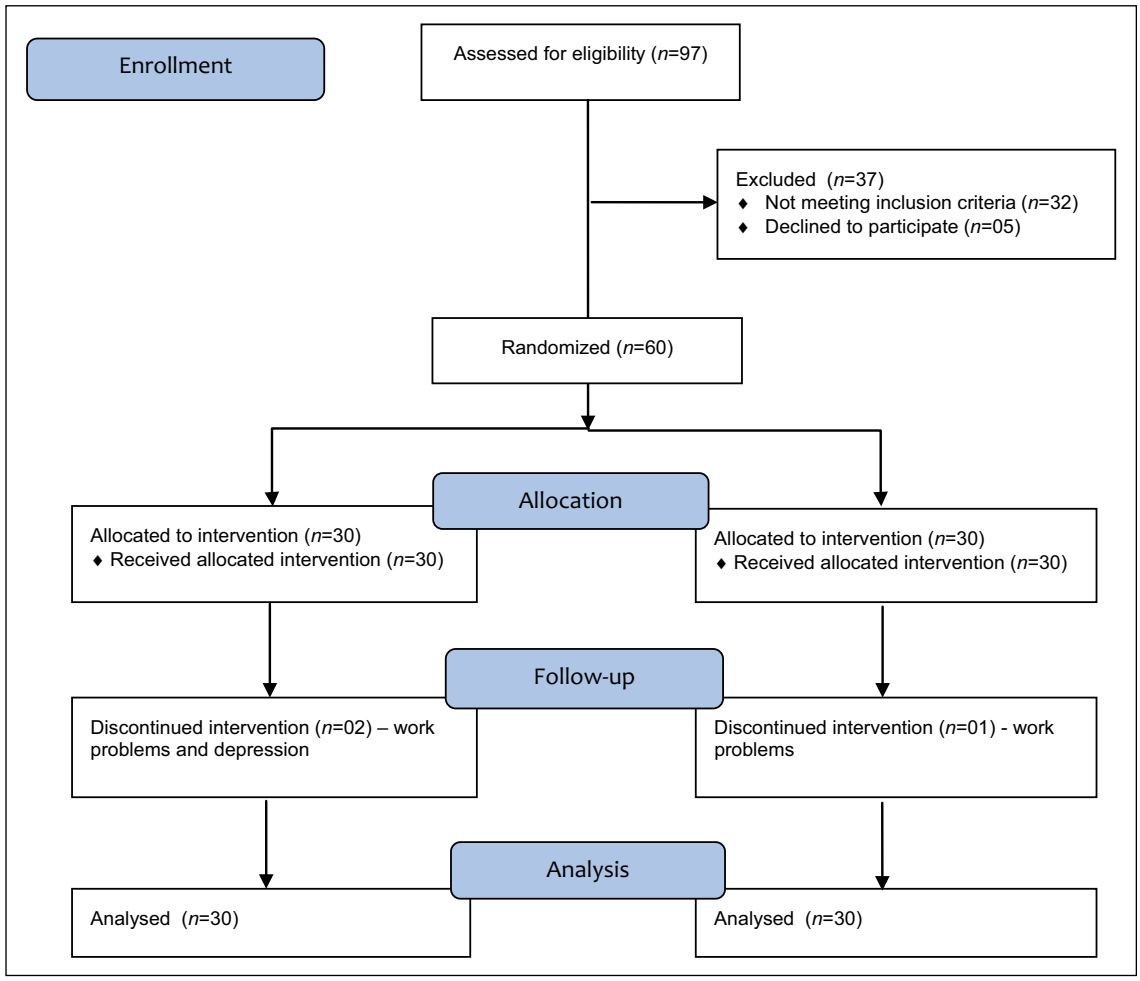

Figure 1. Flowchart of the study.

non-specific low back pain. A number of previous studies have addressed this subject,[9-12,17] but recent systematic reviews have shown that data from these studies are inconsistent.[13-15,18] The main methodological flaws found in the studies included in previous reviews were small sample sizes, short intervention periods, the use on non-validated assessment measures, and a failure to describe the intervention.[13-15] This is the first study to present a description of the pilates protocol (Supplementary material Chart 1).

Pain was chosen as the primary parameter because this is the main complaint of patients with low back pain. It is difficult to compare the baseline pain in our study with other studies: we found lower,[9,25] similar,[12,30] and higher[11,32] pain scores in the literature, showing the variability of this parameter. The improvement in pain in the experimental group was 1.59 cm on the 10-cm pain scale. We believe that this improvement achieved was because the strength of core muscles provided by the Pilates exercise training.

Improvement in pain in the experimental group in this study was greater than that reported in some studies assessing the pilates method; [25,26] however, these studies lasted only six and four weeks,

Table 1. Social demographic data of sample.

	Group		*P*
	Control	Experimental	
Gender (female/male)	23/7	24/6	0.378
Race (caucasian/non-caucasian)	18/12	16/14	0.427
Age in years (mean ± SD)	48.08±12.98	47.79±11.47	0.527
BMI in kg/m^2(mean ± SD)	24.3±4.5	23.1±4.9	0.496
Schooling (*n*)			
4 years	10	11	
8 years	8	6	
11 years	6	5	0.258
15 years	5	7	
None	1	1	
Employment (*n*)			
Unpaid work	11	9	
Paid work	18	21	0.276
None	1	0	
Smoking (*n*)			
Ex-smoker	4	3	
Current smoker	1	3	0.129
Non-smoker	25	24	
Physical activity (*n*)			
Walking	8	11	
Workout/dance	4	2	0.387
None	18	17	
Sit-and-reach test (cm)	44.83±17.40	37.54±13.80	0.355
Pain (VAS)	5.79±2.06	5.50±1.25	0.125
Function (RM)	10.58±5.12	12.12±5.24	0.895
SF-36			
Physical functioning	58.75±23.69	57.29±21.36	0.836
Role physical	42.70±40.69	34.37±38.17	0.170
Bodily pain	42.91±21.40	45.91±18.87	0.728
General health	63.66±23.37	64.37±18.81	0.414
Vitality	56.04±21.21	54.58±21.46	0.216
Social functioning	78.64±28.18	78.12±23.38	0.298
Role emotional	78.86±26.97	73.31±28.24	0.167
Mental health	67.06±21.85	60.06±23.85	0.889

BMI: body mass index, VAS: visual analog scale, RM: Roland Morris.

respectively. Two other studies addressing the pilates method report greater improvements in pain (2.5 cm on a 10-cm scale); however, these studies lasted six weeks, only some of the main pilates exercises were performed, and this study did not include a control group to compare to.[28] It should be noted that the populations in these two studies were much younger than the individuals in the present study.

Groups were homogeneous regarding all variables at initial evaluation. The mean age in the sample (48 years) clearly shows how low back pain affects an economically active portion of the population; however, mean age in the present study was

Table 2. Clinical data at all evaluation times.

	T0		T45			T90			T180			Intergroup p ANOVA
	EG	CG	EG	CG	Mean difference	EG	CG	Mean difference	EG	CG	Mean difference	
BMI	22.89±4.84	23.12±4.48	22.76±4.75	22.86±4.19	−0,10	22.45±4.52	22.97±4.53	−0,52	22.44±4.56	23.22±4.74	−0,78	0.604
Sit-and-reach test	44.83±17.40	37.54±13.80	44.58±18.52	38.95±12.25	5,63	44.97±20.23	38.20±13.08	6,77	45.37±19.22	38.83±13.36	6,54	0.239
Pain (VAS)	5.79±2.06	5.50±1.25	5.12±2.77	5.58±2.68	−0,46	4.04±2.42	5.16±2.53	−1,12	4.20±2.78	5.83±2.88	−1,63	< 0.001 *
Function (RM)	10.58±5.12	12.12±5.24	8.79±5.08	10.87±5.91	−2,08	6.79±5.34	10.59±5.88	−3,80	7.04±5.44	10.66±6.23	−3,62	< 0.001 *
SF-36												
PF	58.75±23.69	57.29±21.36	63.95±25.62	58.83±21.68	5,12	65.83±27.96	57.29±18.29	8,54	65.41±28.01	59.58±19.04	5,83	0.026 *
RP	42.70±40.69	34.37±38.17	47.37±40.68	41.95±30.40	5,42	49.00±37.27	42.66±34.57	6,34	56.37±34.77	39.95±31.27	16,42	0.086
BP	42.91±21.40	45.91±18.87	49.95±26.79	45.70±25.87	4,25	54.45±23.41	46.41±25.83	8,04	52.16±24.57	43.87±29.09	8,29	0.030 *
GH	63.66±23.37	64.37±18.81	62.79±23.75	63.54±19.64	−0,75	68.58±21.92	57.70±18.86	10,88	65.20±22.15	62.08±21.08	3,12	0.772
Vit	56.04±21.21	54.58±21.46	61.87±19.27	55.54±19.41	6,33	64.58±21.15	54.00±20.02	10,58	60.29±23.41	55.00±21.71	5,29	0.029 *
SF	78.64±28.18	78.12±23.38	83.12±25.26	80.29±19.90	2,83	83.75±24.51	79.52±25.49	4,23	86.04±22.75	80.41±23.30	5,63	0.096
RE	78.86±26.97	73.31±28.24	82.20±25.88	78.85±25.53	3,35	80.43±29.72	73.75±29.56	6,68	82.64±24.18	72.98±31.52	9,66	0.165
MH	67.06±21.85	60.06±23.85	66.53±22.97	64.26±25.12	2,27	69.30±21.14	60.63±23.23	8,67	67.90±22.05	65.33±23.07	2,57	0.243
NSAID use	–	–	7.7±12.26	13.60±18.16	−5,90	6.7±12.77	12.36±18.59	−5,66	6.6±11.46	13.73±17.11	−7,13	<0.010 *

Data expressed as mean ± standard deviation, T0: baseline, T45: 45 after baseline, T90: 90 after baseline – end of the treatment, T180: 180 after baseline – follow-up, EG: experimental group, CG: control group, BMI: body mass index, VAS: visual analog scale, RM: Roland Morris, PF: physical functioning, RP: role physical, BP: bodily pain, GH: general health, VIT: vitality, SF: social functioning, RE: role emotional, MH: mental health, NSAID: non-steroidal anti-inflammatory drug.

higher than that reported in other studies assessing the Pilates method.[25,27,28]

Mean BMI in the present sample demonstrates that the patients were within the ideal weight range. This differs from the findings of previous studies that reported an association between increased BMI and worsening low back pain.[29]

Regarding function, moderate scores were found on the Roland-Morris questionnaire at baseline. Both groups initially demonstrated an improvement, but the experimental group continued to improve while the control group remained unaltered, this improve in experimental group patients again can be explained by the strength in core muscles provided by the pilates exercises. Previous studies reported similar improvement using the same assessment measure,[25,30] while other studies reported improvement in function using different assessment measures.[26,31,32] Improvement in the present study (3.5 points) can be considered clinically significant, as a improvement of 2 points in the Rolland-Morris score for patients with only low back pain is considerate the minimum clinically importance difference.[33,34] Furthermore, improvement may have been more substantial if the treatment period had been longer.

Regarding quality of life measured using the SF-36 questionnaire, improvements were observed for functional capacity, pain, and vitality domains, which are likely related to our pain (VAS) and function (Roland-Morris) findings. The SF-36 is a generic quality of life assessment measure that should be analyzed by comparing pre-intervention and post-intervention scores for each patient individually. Findings described in previous studies on interventions for treating low back pain report a wide variety of scores making the comparison of the results difficult.

Regarding pain medication, patients in the experimental group took fewer non-steroidal anti-inflammatory drugs than the control group. Moreover, a gradual reduction in pain medication occurred throughout the study in the experimental group, which likely reflects an improvement in pain. In contrast, patients in the control group took the same amount of non-steroidal anti-inflammatory drugs through the end of the study. There have

Table 3. Effect size and 95% confident interval for the parameters that were statistically significantly different between groups with ANOVA.

	ES (95% CI)
Pain (VAS)	−0.57 (−1.08 to 0.05)
Function (RM)	−0.67 (−1.19 to 0.15)
SF-36	
PF	0.24 (−0.27 to 0.75)
BP	0.30 (−0.21 to 0.81)
Vit	0.23 (−0.28 to 0.74)
NSAID use	−0.48 (−1.00 to 0.03)

ES: effect size, CI: confidence interval, VAS: visual analogue scale, RM: Roland Morris, PF: physical functioning, BP: bodily pain, VIT: vitality, NSAID: non-steroidal anti-inflammatory drug.

Table 4. Satisfaction with treatment (Likert scale) according to patient and assessor.

		Much better	A little better	Same	A little worse	Much worse	Intergroup *P*
Patient	Group						
T45	EG	7	8	13	1	1	0.645
	CG	2	12	13	2	1	
T90	EG	7	11	9	3	0	0.387
	CG	4	11	12	2	1	
T180	EG	9	3	12	5	1	0.516
	CG	5	8	13	3	1	
Assessor							
T45	EG	6	6	16	1	1	0.775
	CG	0	10	17	2	1	
T90	EG	6	13	7	4	0	0.645
	CG	2	12	12	3	1	
T180	EG	8	4	11	6	1	0.645
	CG	3	9	14	4	0	

Data presented in *n*, T45: 45 after baseline, T90: 90 after baseline – end of the treatment, T180: 180 after baseline – follow-up, EG: experimental group, CG: control group.

been no previous studies that used non-steroidal anti-inflammatory drugs consumption as an outcome making comparisons to our data impossible.

Regarding flexibility we did not find differences between groups over time. We decided to use the sit and reach test to evaluate the flexibility of our patients, this test has a limitation because variations in arm, leg and trunk length can make comparisons between individuals misleading. This test is specific to the range of motion and muscles and joints of the lower back and hamstrings, and may not be relevant to other parts of the body. [34] We believe that pilates method works flexibility and strength and that both improves using the method, however the instrument that we choose to evaluate this was not capable to accurate it well.

One limitation for of this study is that the treatment provider and participants could not be blinded to the interventions. Other limitation is that we recruited participants who choose to volunteer for an exercise treatment, so this people already have a positive attitude toward exercise, what could influence the results. Patients in our study had moderate pain and disability so our results only could not be

applied to more severely impaired patients. We believe that our study can be easily reproduced by trainers that already work with pilates following the detailed exercise protocol, however, other studies should be done with other exercises and patients with more impairment due to low back pain

It is important to mention that the pilates protocol used in this study did not worsen pain in the experimental group demonstrating that this method had no harmful effects on the patients regarding pain.

Despite the improvements in pain and function, no significant differences were observed regarding satisfaction with treatment. A greater number of responses of 'much better' on the Likert scale in the experimental group was observed, but this difference was not statistically significant.

In conclusion, pilates method was better than no exercises for the outcomes pain, function, and aspects related to quality of life (functional capacity, pain, and vitality) for patients with chronic non-specific low back pain. Moreover, this method has no harmful effects on such patients.

Clinical messages

- The pilates method was effective in reducing pain and improving function and quality of life in patients with low back pain.
- Pilates method is safe for low back pain patients.

Conflict of interest

The authors declare that there is no conflict of interest.

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