ARTICLE ORIGINAL

The effectivity of a Pilates protocol in the treatment of chronic nonspecific low-back pain: a randomized clinical trial

A efetividade do método Pilates no tratamento da dor lombar crônica inespecífica: ensaio clínico randomizado

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ABSTRACT

Low back pain is a major health and socioeconomic problem. Exercises and patient awareness are among the possible positive strategies for treating nonspecific chronic low back pain. **Objective:** The objective of this study was to determine the effectiveness of the Pilates Method and the "Back School" program in the treatment of nonspecific chronic low back pain. **Method:** A randomized controlled trial with blinded assessors. Eighty-four individuals with chronic nonspecific low back pain. Interventions: Participants were randomly allocated into two groups: Pilates Group (n= 43) or Control Group - "Back School" (n= 41). The primary outcomes were: pain (Numeric Rating Scale), quality of life (SF-36), and disability (Roland-Morris Disability Questionnaire - RMDQ). The secondary outcomes were: Flexibility (Fingertip-to-Floor Test – FTF) and sleep quality (Pittsburgh Sleep Quality Index - PSQI). **Results:** The Pilates Group was superior to the Control Group ($p<0.05$) in outcomes of pain intensity, disability, flexibility, and in five domains of SF-36 (physical functioning, role limitations due to physical health, pain, vitality, and general health). There was no significant difference between groups for sleep quality. **Conclusion:** The Pilates protocol provided significant improvements and can be considered an option for treating nonspecific chronic low back pain. The Pilates Group was superior to the "Back School" program for pain reduction, improved functional capacity, flexibility, and five quality of life domains. Due to the considerable low adhesion to both interventions, alternatives to improve adherence should be proposed in future studies.

Keywords: Low Back Pain, Exercise Movement Techniques, Health Education, Physical Therapy Modalities, Quality of Life

RESUMO

A dor lombar crônica é um problema de saúde pública. Intervenções voltadas para seu tratamento envolvem tanto exercícios quanto a educação do indivíduo. **Objetivo:** Avaliar a efetividade de um protocolo de exercícios do método Pilates e do programa "Escola de Coluna" na redução dor e incapacidade funcional, na melhora da qualidade de vida, flexibilidade e qualidade do sono em indivíduos com dor lombar crônica inespecífica. **Método:** Ensaio controlado aleatorizado, 84 indivíduos com dor lombar crônica. Os participantes foram aleatoriamente alocados no Grupo Pilates (n= 43) ou Grupo Controle (n= 41). Os desfechos primários foram dor (Escala Visual Numérica), incapacidade funcional (Roland-Morris Disability Questionnaire - RMDQ) e qualidade de vida (SF-36). Os desfechos secundários foram flexibilidade (teste do 3º dedo ao chão) e qualidade do sono (Pittsburgh Sleep Quality Index - PSQI). **Resultados:** O Grupo Pilates foi superior ao Grupo Controle ($p < 0,05$) na intensidade da dor, incapacidade funcional, flexibilidade e em cinco domínios de qualidade de vida (capacidade funcional, aspectos físicos, dor, vitalidade e estado geral de saúde). Não houve diferença entre os grupos para a qualidade do sono. **Conclusão:** Exercícios do método Pilates podem ser considerados como uma alternativa de intervenção para indivíduos com dor lombar crônica não específica. O Grupo Pilates foi superior ao programa "Escola de Coluna" nos desfechos dor, incapacidade funcional, flexibilidade e em cinco domínios de qualidade de vida. Devido à baixa aderência às intervenções propostas, alternativas para melhorar a aderência devem ser estabelecidas em estudos futuros.

Palavras-chaves: Dor Lombar, Técnicas de Exercício e de Movimento, Educação em Saúde, Modalidades de Fisioterapia, Qualidade de Vida

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INTRODUCTION

Nonspecific low back pain is considered a public health problem and one of the leading causes of incapacity for a medical leave of absence.[1,2] Prognostic studies have shown that approximately 40% of individuals with acute low back pain will not recover within three months,[3,4] characterizing the symptom of chronic nonspecific low back pain.[5]

Due to the high prevalence of chronic low back pain, the cost of care related to this condition is considerable, rated as an economic problem.[6–9] Given the nonspecific characteristic of low back pain, several treatments have been used for its management, including physical exercises.[10,11] Physical exercise is recommended by clinical guidelines as a practical approach to chronic nonspecific low back pain.[12,13] The Pilates method is a type of physical exercise that can be performed on the floor or with the aid of devices, with potential benefits for improving range of motion, flexibility, muscle strength, coordination, balance, proprioception, functional capacity, and even quality of life.[4,14–16]

In addition to exercise, patient awareness has been recommended by the guidelines for controlling chronic low back pain.[13] The "Back School" program is a method of patient education, initially developed in 1969 to reduce the intensity of pain and prevent the recurrence of painful episodes. It is a concept that involves information about the anatomy of the spine, posture, biomechanics, and exercises.[17]

A systematic review[18] reported low to moderate evidence quality that the Pilates method is more effective than minimal interventions (usual care or waiting list) for individuals with chronic nonspecific low back pain. Specialized literature shows that educational self-care interventions can reduce disability but not pain in these patients.[13]

Considering that both exercise and patient education seem to benefit individuals with chronic nonspecific low back pain, studies should compare both treatments and establish the most viable, effective, and accessible. Once chronic nonspecific low back pain is a common health issue that bears several social problems, effective conservative treatments, which are easily accessible and inexpensive for these individuals, are a demand.

OBJECTIVE

The objective of this study is to establish the effectiveness of a Pilates exercise protocol within a "Back School" program for reducing pain and functional disability, improving quality of life, Flexibility, and sleep quality in individuals with nonspecific chronic low back pain.

METHODS

This study is a randomized clinical trial conducted according to the Consolidated Standards of Reporting Trials (CONSORT).19 This trial was approved by the Ethical Review Board of the Pontifícia Universidade Católica de Minas Gerais, with registration number 910.830 – CAAE 36579514.1.0000.5137. This study was also registered at the Brazilian Registration for Clinical Trials (Registro Brasileiro de Ensaios Clínicos – ReBEC). All participants signed the Informed Consent Form, according to Brazilian (Resolution 466/2012 – National Health Council) and international regulations. All data collection and interventions were conducted at the Clínica de Fisioterapia da Pontifícia Universidade Católica de Minas Gerais (Physiotherapy Facility of the Pontific Catholic University of Minas Gerais).

Participants were recruited from the local community by TV and internet ads and from the university's waitlist.

Individuals aged 18 to 60 years, with chronic nonspecific low back pain for at least 3 months and minimum pain intensity of 4 on a Visual Numeric Scale were included. The exclusion criteria were the presence of autoimmune rheumatologic and or inflammatory diseases, pain radiating to the lower limbs, fibromyalgia, thyroid diseases, pregnancy, neurological or cognitive diseases, morbid obesity, lower limb amputation, presence of uncontrolled diseases (hypertension, cardiac diseases, or other pathologies considered a contraindication to exercise protocol proposed by the study).

A collaborator, not directly involved in data collection or interventions, generated a random allocation sequence on www.randomization.com.The random sequence of two possible interventions, Pilate Group (PG) or Control Group (CG), was sealed in opaque envelopes. The treatment allocation was revealed after baseline evaluation and immediately before the beginning of the interventions. Due to the characteristics of the interventions, raters and patients were not blinded.

Pilate Group

Each participant in this group received 16 exercise sessions based on the Pilates Method. The program included floor and equipment-aided exercises (Barrel, Cadillac, Chair, and Reformer). Two 50-minute weekly sessions were scheduled. Twenty exercises were selected, the difficulty was progressive, and each exercise was adapted according to the abilities of each participant. The exercises involved range-of-motion work, stretching, and overall strengthening. Detailed information and description of the exercises are presented in the appendix.

Control Group

Participants had ten meetings with information and recommendations on posture and daily activities. Information about low back pain, spinal anatomy, and exercise suggestions were also given. Each participant in this group received a booklet (Back School) with a summary of the meeting content.

Primary outcomes

Pain intensity: pain was assessed with a Visual Numerical Scale, a ruler divided into 11 equal parts, successively numbered from 0 (no pain) to 10 (worst possible pain). Patients were asked to rate the mean low back pain they endured in the previous seven days.[20]

Quality of life: The SF-36 questionnaire, consisting of 36 items, grouped into eight dimensions, was the assessment of choice for quality of life. The dimensions are physical functioning, role limitation due to physical health, role limitation due to emotional problems, energy/fatigue (vitality), emotional well-being, social functioning, pain (bodily pain), and general health. The SF-36 score ranges from 0 to 100 points,

with higher scores indicating better quality of life.[21,22]

Functional disability: It was assessed with the Brazilian version of the Roland-Morris Disability Questionnaire (RMDQ), which consists of 24 yes/no questions on activities of daily living. For each answer yes, one point is added. The score is given as the sum of the points, and it ranges from 0 (no limitation) to 24 (very severe limitation).[23]

Secondary outcomes

Flexibility: It was assessed with the Fingertip-to-Floor (FTF) Test. For this test, participants should try an anterior flexion of the trunk and touch the floor with the 3rd finger without bending their knees. The vertical metric distance (centimeters) between the floor and the tip of the third finger was recorded. In this test, greater distances indicate reduced Flexibility.[24]

Sleep quality: Sleep Quality was assessed with the Brazilian version of the Pittsburgh Sleep Quality Index (PSQI) questionnaire, which assesses sleep quality for one month. This scale of 19 questions is organized into seven components subjective sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbance, sleep medication, daytime sleep dysfunction. Each component score ranges from 0 to 3, and the final score is the sum of all components, ranging from 0 to 21, with higher scores indicating poorer sleep quality. A final global score above 5 indicates that the individual has severe difficulty in at least two components, or moderate difficulty in more than three components.[25,26]

All outcomes were measured at three time points:

-T1: baseline assessment before the interventions.

-T2: immediately after the end of the interventions.

-T3: follow-up, two months after the end of the intervention.

Data analysis was conducted with SPSS 18.0 (Statistical Package for Social Sciences). Descriptive analysis was performed for all variables (mean and standard deviation). General Linear Model (GLM) with mixed design was chosen to compare the treatment effects between both groups. Pairwise comparisons independently verified the mean difference between the Pilates Group and the Control Group in all variables in each period. Intention-to-treat analysis was used, considering the Last Observation Carried Forward (LOCF) method for missing data. The significance level of 0.05 was adopted.

RESULTS

Initially, 130 individuals were screened. Forty-six individuals were excluded because they did not meet the inclusion criteria (n=31) or did not agree to participate in the study (n=15). Therefore, 84 individuals were randomly allocated into one of the groups. The final sample consisted of 63 women and 21 men, and the mean age was 47.29 ± 15.26 years.

Sample characterization is described in Table 1. There were no statistically significant differences between the groups at baseline.

Immediately after the end of the intervention (T2), the dropouts in the Pilates Group were 34.88% (n= 15) and 56.09% (n= 23) in the Control Group. For this reason, 28 participants undertook the whole treatment with the Pilates method and 18 participants all Back School visits. At follow-up (T3), three more participants (7.31%), 1 (2.43%) of the Control Group did not participate in the final evaluation.

However, following the intention-to-treat model, data from all 84 individuals were included in the statistical analysis.

Table 1. Characteristics of participants: mean (standard deviation), percentages (sex, age, and occupation), and p-values of intergroup comparisons

Variables	Pilates Group (n= 43)	Control Group (n= 41)	p-value
Sex (%)	M: 25.6% (11) F: 74.4% (32)	M: 24.4% (10) F: 75.6% (31)	0,900
Age (years)	47,51±15,26	47,07±15,69	0,897
Occupation	Housewife: 19.04% (16) Student: 10.31% (9) Housemaid: 8.33% (7) Others: 30.95% (26)		

M: male; F: female

The results for the investigated outcomes are described in Tables 2 and 3, presented with mean, standard deviation, and p-values for intra- and inter-group comparisons. Before the beginning of the intervention (T1), the groups were homogeneous ($p > 0.05$) regardless of the analyzed variables.

The findings for the outcomes of pain, functional capacity, Flexibility, and sleep quality are shown in Table 2. For these variables, the Pilates group was superior to the Control group in pain intensity measured with VNS ($p= 0.002$), Functional Capacity measured with RMDQ ($p= 0.004$), and Flexibility measured with the Fingertip-to-Floor Test ($p<0.001$). No statistically significant difference in sleep quality (PSQI) was found between both groups ($p= 0.155$).

The results for the SF-36 quality of life questionnaire are shown in Table 3. In the intergroup comparison, both at T2 and T3, the Pilates Group was superior in three domains of the SF-36 questionnaire, role limitations due to physical health ($p= 0.048$), bodily pain ($p= 0.027$), and general health ($p<0.001$). Only at T3, the Pilates Group was superior in physical functioning ($p<0.001$) and vitality ($p= 0.008$).

DISCUSSION

The present study recruited eighty-four individuals with nonspecific chronic low back pain, whose mean baseline pain intensity was 7 points on the Visual Numerical Scale. Overall, participants did not have major disability concerns and considered their general quality of health was considered good, according to the Roland Morris and SF-36 questionnaires, respectively. These aspects may contribute to the establishment of chronicity and pain duration. Patients who do not rate their quality of life as poor tend not to adhere to a continuous treatment plan effectively. The average age of participants was 47 years, confirming the notion that individuals with chronic low back pain are economically active,[6] evidencing the importance of effective interventions.

According to the outcomes, the Pilates group was superior to the Control group in pain intensity (VNS), functional disability (RMDQ), and Flexibility (Fingertip-to-Floor Test).

Table 2. Results of pain (VNS), Roland Morris and PSQI questionnaires, and flexibility test

Outcomes	Assessment	Pilates Group (n= 43)	Control Group (n= 41)	p-value Intergroup	p-value Intragroup
Pain Intensity *(Visual Numeric Scale)*	T1	7,09 ± 1,30 [a]	7,26 ± 1,88 [a]		
	T2	4,11 ± 3,00 [b]	6,17 ± 2,80 [c]	**0,002***	**< 0,001***
	T3	4,62 ± 2,92 [b]	5,87± 2,74 [c]		
Functional Disability *(Roland Morris Disability Questionnaire)*	T1	10,06 ± 5,54 [a]	10,51 ± 5,74 [a]		
	T2	6,39 ± 6,03 [b]	9,39 ± 5,64 [a]	**0,004***	**<0,001***
	T3	6,69 ± 6,07 [b]	9,46 ± 6,43 [a]		
Flexibility *(Fingertip-to-Floor Test - FTF)*	T1	11,30 ± 11,91 [a]	15,65 ± 11,94 [a]		
	T2	4,67 ±13,61 [b]	15,12 ± 12,46 [a]	**<0,001***	**<0,001***
	T3	6,62 ± 12,31 [c]	14,09 ± 13,14 [a]		
Sleep Quality *(Pittsburgh Sleep Quality Index – PSQI)*	T1	9,58 ± 4,41 [a]	9,07 ± 3,50 [a]		
	T2	8,34 ± 4,12 [b]	8,85 ± 4,00 [a,b]	0,155	**0,029***
	T3	8,48 ± 4,11 [b]	8,92 ± 3,91 [a,b]		

*Results are presented as mean and standard deviation (±), and p-values of intergroup and intragroup comparisons; T1: Immediately before the intervention; T2: at the end of the intervention; T3: two months after the last session of intervention. *Statistically significant difference (p<0.05). Caption: The superscript letters next to the values of means and standard deviations stand for the multiple comparisons (pairwise comparisons). The row within each column is group comparisons, whereas each column presents time comparisons (T1, T2, and T3). In every comparison, either between groups or between times, the values that do not share the same superscript letter are statistically different, with p < 0.05*

Table 3. Results of SF-36 questionnaire

SF-36 Domains	Assessments	Pilates Group (n= 43)	Control Group (n= 41)	p-value Intergroup	p-value Intragroup
Physical Functioning	T1	58,48 ± 20,88 [a]	57,65 ± 23,72 [a]		
	T2	69,53 ± 25,25 [b]	61,70 ± 21,14 [a,b]	**< 0,001***	**0,001***
	T3	73,02 ± 24,08 [b]	60,60 ± 23,13 [a]		
Role limitation due to physical health	T1	41,27 ± 38,53 [a]	35,97 ± 35,37 [a]		
	T2	61,04 ± 41,65 [b]	40,24 ± 37,44 [a]	**0,048***	**< 0.001***
	T3	61,62 ± 40,95 [b]	45,73 ± 35,31 [a]		
Pain	T1	43,13 ± 17,56 [a]	37,09 ± 17,37 [a]		
	T2	56,20 ± 24,91 [b]	40,14 ± 17,64 [a,c]	**0,027***	**< 0,001***
	T3	54,39 ± 24,06 [b]	43,58 ± 19,54 [c]		
Vitality	T1	43,48 ± 23,99 [a]	43,58 ± 24,15 [a]		
	T2	56,27 ± 27,43 [b]	47,48 ± 23,37 [a,b]	**0,008***	**< 0,001***
	T3	58,83 ± 27,27 [b]	47,36 ± 24,70 [a]		
Mental Health	T1	56,09 ± 24,81 [a]	60,97 ± 20,48 [a]		
	T2	64,46 ± 24,34 [b]	62,00 ± 22,52 [a,b]	0,084	**0,001***
	T3	64,65 ± 25.65 [b]	63,12 ± 22,67 [a,b]		
General Health	T1	70,62 ± 21,59 [a]	65,70 ± 25,91 [a]		
	T2	76,79 ± 21,56 [b]	62,46 ± 25,92 [a,c]	**< 0,001***	0,609
	T3	78,60 ± 20,89 [b]	59,73 ± 26,52 [c]		
Emotional Well-being	T1	50,38 ± 40,74 [a]	56,91 ± 42,97 [a]		
	T2	61,23 ± 41,74 [b]	53,66 ± 41,42 [a,b]	0,194	0,392
	T3	61,23 ± 42,99 [a,b]	56,91 ± 40,99 [a]		
Social Functioning	T1	63,08 ± 30,24 [a]	68,59 ± 26,68 [a]	0,229	0,195
	T2	66,56 ± 29,21 [a,b]	66,46 ± 26,87 [a]		
	T3	71,51 ± 27,99 [b]	68,59 ± 25,78 [a,b]		

*Results are presented as mean and standard deviation (±), and p-values of intergroup and intragroup comparisons. T1: Immediately before the intervention; T2: at the end of the intervention; T3: two months after the last intervention session. * Statistically significant differences, p<0.05 (General Linear Model – GLM). Caption: The superscript letters next to the values of means and standard deviations stand for the multiple comparisons (pairwise comparisons). The row within each column is group comparisons, whereas each column presents time comparisons (T1, T2, and T3). In every comparison, either between groups or between times, the values that do not share the same superscript letter are statistically different, with p<0.05*

For the sleep quality outcome (PSQI), there were no statistically significant differences between both groups. In the intergroup comparison, both at T2 and T3, the Pilates Group was superior in three domains of the SF-36 questionnaire: physical role limitation, pain, and general health. At T3, the Pilates Group was superior in the physical functioning and vitality domains.

The results found in this study agree with other publications[4,16,27–30] that assessed the effectiveness of the Pilates method for improving pain, functionality, quality of life, and reducing the amount of pain medication intake. A systematic review[18] concluded that, in the short term, when compared to minimal interventions, the Pilates method effectively reduces pain intensity, dysfunction, and general subjective perception of improvement. However, in intermediate follow-ups, Pilates was not shown to be superior to minimal interventions on function and general subjective perception of improvement, as effect sizes ranged from small to medium.[18] Furthermore, the Pilates method seems to have similar results to other exercise methods for treating pain and disability of individuals with low back pain.[18,31] In another review,[32] the Pilates method was not superior when compared to control groups or groups of lumbar stabilization in the outcomes of pain and functionality.

Although patient education is a recent issue, the evidence regarding the “Back School” program is controversial. Garcia et al.[33] reported improvements in pain, functional capacity, and spinal ROM in patients with nonspecific low back pain after a “Back School” intervention. The study by Nogueira & Navega[34] demonstrated the effectiveness of a "Column School" program in quality of life (SF-36), functional disability (Roland Morris), flexibility, and pain intensity (VNS) among administrative workers. Nonetheless, a literature review[35] reported very low quality of evidence that “Back School,” as they named, is no better than an exercise in improving pain intensity in the short term and no better than exercise to improve pain intensity in the medium and long term. Regarding functionality, this review found very low evidence quality that the “Back School” program was not more effective than exercises in the short, medium, or long term,[35] agreeing with the results obtained in the present study.

Some of the participants in our study had already experienced physical therapy before, and most of them reported that pain recurrence was frequently associated with emotional aspects. This characteristic was observed in some participants who reported a reduction in pain soon after the treatment. Upon returning for follow-up assessment, reported worsening, described difficulties such as family health problems, divorce, and mourning. This fact corroborates with the study by Junior et al.[36] who reported that low back pain with subtle onset is at times more associated with psychological aspects than with occupational activities.

In general, current evidence suggests that Pilates exercises seem to be effective when compared to minimal interventions. However, it does not seem to be superior to other modalities of physical exercise.[13,18] This suggests that other factors such as adherence to treatment should be strongly considered. Undoubtedly, the loss of participants was the most significant limitation of the present study. It is challenging to justify the lack of adherence to a type of treatment due to the multifactorial nature of human behavior.[37] A patient may underestimate or overestimate their adherence due to social, emotional, or even cognitive factors. In addition, concerns such as previous behavior, social support, motivation, costs, benefits of actions, and attitudes towards health professionals should be considered.[37]

Contrary to the present study, other studies showed good adherence to the Pilates method.[4,38] Individuals sought to improve their quality of life, reported relaxation at the end of sessions, pain, and stress relief. In our present study, there was a high dropout rate even with participants' reports of improvement during treatment. One factor associated with the lack of adherence may be difficulty performing the exercises proposed in Pilates Group protocol. Studies by Verbunt et al.[39] and Al-Obaidi et al.[40] reported that individuals with chronic low back pain often report intolerance to physical activity due to increased pain. Also, other factors may have influenced adherence and success in the treatment, including age, presence of kinesiophobia, the individual's ability to perform light activities, the patient's level of schooling, the understanding of the cause the presence of other sources of pain.[41]

We consider as limitations of our study the extensive number of dropouts. In addition, a follow-up of 2 months can be considered a short period.

Therefore, based on the results of the present study, the protocol with the Pilates method was superior to the "Back School" program in the variables of pain, functional disability, Flexibility, and some quality-of-life domains (physical role limitation, bodily pain, general health, physical functioning, and vitality). This means that such an approach can be indicated for the treatment of individuals with chronic low back pain. Nonetheless, the present study results should be seen with caution due to the considerable number of dropouts.

A better understanding of the clinical applicability of Pilates for low back pain may arise from future studies with an investigation on the association of both interventions, increased follow-up time, more significant the number of participants, and strategies to improve adherence.

CONCLUSÃO

In the short term, Pilates exercises can be considered an alternative to reduce pain intensity in individuals with chronic nonspecific low back pain, once an intervention consisting of exercises based on Pilates method was superior to the "Back School" program on pain, functional disability, flexibility and five quality of life domains (physical role limitation, bodily pain, general health, physical functioning, and vitality). However, due to the low adherence to the proposed interventions, the present study results must be interpreted with caution, and strategies to improve adherence must be established in future studies.

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