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ORIGINAL ARTICLE

Pilates method in low back pain: a randomized clinical trial

Método Pilates na dor lombar: um ensaio clínico randomizado

Idemar Rodrigues dos Santos Júnior, Rebecca Rickelle de Souza Mousinho, Nivaldo Antonio Parizotto, Carina Carvalho Correia Coutinho

Universidade Federal da Paraíba, João Pessoa, PB, Brasil

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Correspondence: Carina Carvalho Correia Coutinho, carina.caarvalho@gmail.com

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Abstract

Objectives: To analyze the effectiveness of the Pilates ground method in individuals with chronic non-specific low back pain (LBP) in reducing pain, improve the functionality, strength of the transverse abdomen muscle and quality of life. *Methods*: Double-blind randomized controlled trial in the University clinic. Thirty volunteers of both sexes were allocated randomly to two groups of 15 participants each: Pilates (PG) with Pilates exercises, and Control (CG). The PG held 16 sessions of 60 minutes, held twice a week for eight weeks. Participants were assessed pre-treatment and post-treatment for pain (Numerical Pain Scale - NPS and McGill Pain Questionnaire -MPQ), functional disability (Oswestry), transverse abdomen muscle strength (TrA) by the biofeedback unit test pressure (BTP) (Chattanooga Group, Australia) and quality of life by Medical Outcomes Study 36- Item Short-form Health Survey (SF-36). *Results*: There was a statistically significant increase in TrA ($p < 0.001$) and a significant reduction in pain intensity plus qualification ($p < 0.001$) and functional disability ($p < 0.001$), as well as an increase in quality of life ($p < 0.001$). A positive correlation was observed between functional disability and pain assessed by Visual Anagolic Scale (VAS) ($rho = 0.773$; $p = 0.001$), as well as a negative correlation between disability and quality of life assessed by SF-36 ($rho = -0.589$; $p = 0.021$). *Conclusion*: The present study suggests that Mat Pilates

exercises may be a choice for the treatment of patients with chronic non-specific low back pain.

Keywords: low back pain; exercise therapy; quality of life; rehabilitation.

Resumo

Objetivos: Analisar a eficácia do método Mat Pilates em indivíduos com dor lombar crônica inespecífica (DLCI) na redução da dor, e sua correlação na funcionalidade, força do músculo transverso do abdômen e qualidade de vida. *Métodos*: Ensaio Clínico controlado randomizado duplo-cego, realizado em clínica universitária. Trinta voluntários de ambos os sexos foram alocados aleatoriamente em dois grupos de 15 participantes: Grupo Pilates (GP) com exercícios de Mat Pilates; e Grupo Controle (GC) sem intervenção. O Grupo Pilates realizou 16 sessões de 60 minutos, duas vezes por semana durante oito semanas. Os participantes foram avaliados pré-tratamento e pós-tratamento para dor (Numerical Pain Scale - NPS e McGill Pain Questionnaire -MPQ), incapacidade funcional (Oswestry), força muscular transversa do abdome (TrA) pelo biofeedback unit test pressure (BTP) (Chattanooga Group, Austrália) e qualidade de vida (Medical Outcomes Study 36- Item Short-form Health Survey (SF-36). Resultados: Houve aumento estatisticamente significativo na força do transverso do abdomen ($p < 0,001$) e redução significativa na intensidade e qualidade da dor ($p < 0,001$) e incapacidade funcional ($p < 0,001$), além de aumento na qualidade de vida ($p < 0,001$) no Grupo Pilates. Observou-se correlação positiva entre incapacidade funcional e dor avaliada pela Escala Visual Analógica (EVA) ($rho = 0,773$; $p = 0,001$), assim como correlação negativa entre incapacidade e qualidade de vida ($rho = -0,589$; $p = 0,021$). *Conclusão*: O presente estudo sugere que os exercícios de Pilates podem ser uma escolha para o tratamento de pacientes com dor lombar crônica inespecífica.

Palavras-chave: lombalgia; terapia por exercício; qualidade de vida; reabilitação.

Introduction

Low back pain, according to the Global Burden of Disease (GBD), is considered the leading cause of disability in the world [1]. In Brazil, it represents the second largest complaint of pain in the population [2], and the prognosis is considered moderately favorable when presenting 41% of patients with remission in 12 weeks, however, for the others, after a period of six weeks, the clinical status improve and the intensity vary from low to medium of disability, and pain are installed persistently and present over a year (chronically) [2].

The European Guide to Clinical Practice [3] recommends supervised exercises for the treatment of non-specific LBP and several studies indicate that precise and specific exercises aimed to activating and strengthening the transverse muscle of the abdomen and other spinal stabilizers reduce the recurrence of spinal dysfunctions [4-6] One of the exercises that has gained popularity among individuals with low back pain is the Pilates method [7,8], which uses contractions of the transverse abdomen and multiple muscles combined with diaphragmatic breathing, as a basis for treating pain and promoting improvement of functional capacity in people with chronic LBP [9-11]. Some studies have observed the influence of the method in patients with chronic non-specific low back pain [12]

Wells *et al.* [13], in a systematic review, showed efficacy of the Pilates method in promoting the reduction of pain and functional disability in short term when compared to usual care and regular physical activities. Da Luz *et al.* [14] compared the effects of Pilates apparatus and Mat Pilates in patients with chronic non-specific LBP, categorized the exercises into levels and analyzed the effects of the method along with variables such as pain, disability and kinesiophobia, concluding that both forms are effective in the variables he studied in the short term.

In another systematic review it can be concluded that there is evidence of low to moderate quality that Pilates provides better results than minimal intervention, as well as there is no conclusive evidence that Pilates is superior to other forms of exercise [15]. Among the randomized controlled studies that related the Pilates method and the LBP, it was not possible to observe concise, significant and reliable results due to the difference in the methodological criteria such as: heterogeneity of the sample, brief or absence of description of the exercises performed, in addition to differences is the number and frequency of the sessions due to the lack of specific protocols for the clinical condition [16].

More, high-quality studies are needed to evaluate Pilates for LBP. Therefore, this research aims to analyze the effects of ground exercises proposed by the Pilates method compared to no intervention in individuals with chronic non-specific LBP, analyzing pain, functional disability, quality of life and activation and strength of the transverse muscle of the abdomen, observing the clinical relevance of this treatment, providing evidence to professionals and assisting in clinical decision making.

Methods

Study design

This is a randomized, double blind clinical trial. The study was approved by the Research Ethics Committee of the Health Sciences Center of the Federal University of Paraíba under protocol number 0666/15. CAAE: 51317315.2.0000.5188, in compliance with resolution 466/12 of the National Health Council. The study was registered on Clinical Trials under NCT02922322.

Participants

It was included in the study participants of both sexes, between 18 and 60 years old, with a diagnosis of chronic non-specific LBP lasting more than three months, without root symptoms for more than 12 months, and NRS [17] greater than 3 (0/10). Contraindications for physical exercise were assessed using the Physical Activity Readiness Questionnaire - PAR-Q [18] (Appendix A), suggested as a minimum pre-participation assessment standard. This instrument can identify by some positive responses the participants who need prior medical evaluation and clearance.

The exclusion criteria were: presenting degenerative or inflammatory diseases of the spine, acute crisis of pain in the shoulders, knees and spine, vertebral tumors, unconsolidated fractures or with vicious consolidation in the spine, shoulder and upper limbs, recent surgeries in the spine, shoulder and upper limbs, herniated disc, spondylolysis or spondylolisthesis; any other rheumatological disease, patients who are in labor disputes, who practice activities involving the Pilates method frequently, who are undergoing other types of physical therapy or medication treatment. Also excluded are those who do not understand the writing and speaking of the Portuguese language clearly. All volunteers signed an Informed Consent Form (ICF) and were informed of the research procedures in accordance with the World Medical Association's Declaration of Helsinki. Those who agreed to take part provided written informed consent, in line with Resolution 466/2012.

Randomization and blinding

The randomization of the research was carried out through a simple randomization scheme following the guidelines of CONSORT - CONsolidated Standards of Reporting Trials, controlled (1: 1), whose randomization list was generated through

the website www.random.org/lists/ constituted by the numbers from 1 to 30, these are randomly assigned to each research participant, after randomization 15 individuals for each group. The research randomization process was carried out by an independent researcher who was not involved with the recruitment process of the participants or with the evaluations.

Participants were divided into two groups: Pilates Group (PG) and Control Group (CG). One researcher (R1) was responsible for evaluations and reevaluations; the second researcher (R2), for the randomization process, the third (R3) for the application of the intervention protocol, and the fourth researcher (R4) for the statistical analyzes. All researchers were shielded as to the other processes developed by the other researchers.

The participants were instructed to report any complaints, whether related to the exercises or not. Moreover, they were asked not to modify their life routine and not to participate in any other treatment program.

Procedures

A total of thirty participants were included in the study and randomized into two groups: the Pilates Group (PG) and the Control Group (CG).

Pilates Group

The Pilates Group (PG) program consisted of 16 sessions, held twice a week for a period of eight weeks, each session lasting approximately 60 minutes. The exercise program was carried out and supervised by a researcher trained about the Pilates method, who was not involved in other stages of the research. Patients were instructed to report any complaints related or not to exercise during the intervention.

The intervention was based on 20 of the 34 original solo exercises proposed by the Pilates method, classified as basic, intermediate and advanced. The exercises were organized in four cycles where each cycle consisted of 5 exercises introduced according to the degree of difficulty (basic, intermediate and advanced), however, the exercises could progress or regress according to the physical fitness of each participant. Each cycle lasted four sessions, totaling 4 cycles with 20 exercises. Each exercise was performed 10 times, with two series of repetitions, respecting the limit of each patient.

Cycle I (Exercises 1-5) - Basic level;

Cycle II (Exercises 6-10) - Intermediate level;
Cycle III (Exercises 11-15) - Intermediate level.
Cycle IV (Exercises 16-20) - Advanced level.

Control group

The participants allocated to participate in the CG received instructions to remain with the usual care and not to practice any type of physical activity or physical therapy until the end of the research. After the conclusion of the study, the volunteers who made up the CG were allocated within the extension project “Prevention and care in low back pain”, consisting of prevention and physical therapy activities for individuals with LBP.

Outcome measures

The evaluations were made by the blind evaluator, in person, applied pre-treatment and after the end of the 16 treatment sessions. All the instruments adopted are validated for Brazilian Portuguese. Initially, the PAR-Q [18] instrument was applied to verify the volunteers' ability to carry out the proposed activities.

The primary outcomes of pain intensity and quality were collected using the Visual Pain Scale [19] and McGill Pain Questionnaire [20], functional disability using the Oswestry Index [21] and quality of life using the Short Form-36 validated by Ciconelli [22].

The secondary outcomes were abdomen transverse muscle strength. The activation of the transversus abdominis muscle (TrA) was evaluated using the Pressure Biofeedback Unit (PBU) / Stabilizer Pressure Biofeedback (Chattanooga Group-USA) [23] which consists of a pressure transducer with three inflatable bags, a catheter and a sphygmomanometer that varies from 0-200 mmHg graduated every 2 mmHg. Changes in body position will imply pressure changes in the bag that will be recorded by the sphygmomanometer.

The volunteers were instructed to fast for two hours before the start of the assessments (including water), in addition to having to empty their bladder immediately before the test, and not to perform abdominal exercises on the day before and on the day of the assessment. Before the test, the participants received basic educational information about anatomy, biomechanics and the function of the TrA, in addition to specific guidelines about an ideal contraction of the TrA. All evaluations were performed with the patient in prone position, where the ideal contraction of the TrA consists of the movement of the abdominal wall (infra-umbilical region) towards the spine, in a slow and

controlled manner, without movements of the trunk or pelvis, or contractions other muscles such as gluteus, quadriceps or spine extensors. During the test, the bag is positioned under the TrA with the participant in prone position. The ability to depress the abdominal wall against the lumbar spine results in a pressure reduction of 4-10 mmHg, that is, from 70 mmHg to 66-60 mmHg (optimal contraction of the TrA), which is recorded by the PBU sphygmomanometer [24].

The measurement was performed with the patient in prone position on a rigid surface below the trunk and abdomen to minimize foam deformation. The lower limbs are positioned with the feet off the stretcher and the arms at the side of the body, with the head turned to the right and the bag is positioned in the space immediately above the anterosuperior iliac spines on the umbilical scar and before start contraction, the pressure bag is inflated to a pressure of 70 mmHg with the valve closed.

Participants were instructed to perform two inspirations and exhalations using mainly the abdominal region. The bag pressure is then adjusted again to 70 mmHg. To assist in the execution of the movement, the verbal command will be given: “With the lower abdomen inward without moving the spine and pelvis and keep it”. These contractions must be maintained for at least ten seconds, measured by the timer. Participants were instructed to perform slow inhalation and exhalation, and contraction of the TrA was performed concurrently with exhalation.

Sample size

The sample size was calculated considering a statistical power of 80%, standard deviation of two data points, and 20% improvement in pain intensity [25], by G-POWER. As a result, 15 patients were required per group, with parameters of a 5% significance level and 15% sample loss.

Statistical analysis

The data were analyzed using the Statistical Package for Social Sciences v.2.0 (SPSS). Descriptive statistics were performed obtaining of absolute and relative frequency values, and measures of central tendency and variability. Initially, the Shapiro-Wilk normality test was performed to observe the distribution of values in each of the study variables, in order to choose the most suitable tests for each analysis.

Comparisons between groups with regard to the mean age, mass, height and body mass index were performed using the unpaired t test. For the paired analyzes of the two assessments made in each group, the paired t tests (normal distribution) or the

paired Wilcoxon (non-normal distribution) were used. Spearman's correlation test was also performed among all variables studied. The level of significance used in this study was 5% and the confidence interval was 95%.

Results

Thirty-five individuals with chronic low back pain were assessed at baseline, and of these, 5 were excluded for not achieving the inclusion criteria. In total, 30 individuals (24 women and 6 men) were chosen and randomly allocated to the Pilates Group (PG; n = 15) and Control (CG; n = 15) groups. A total of 240 sessions were offered with 92.91% of these being recorded, with 17 absences to the total number of participants in the Pilates group (Figure 1)

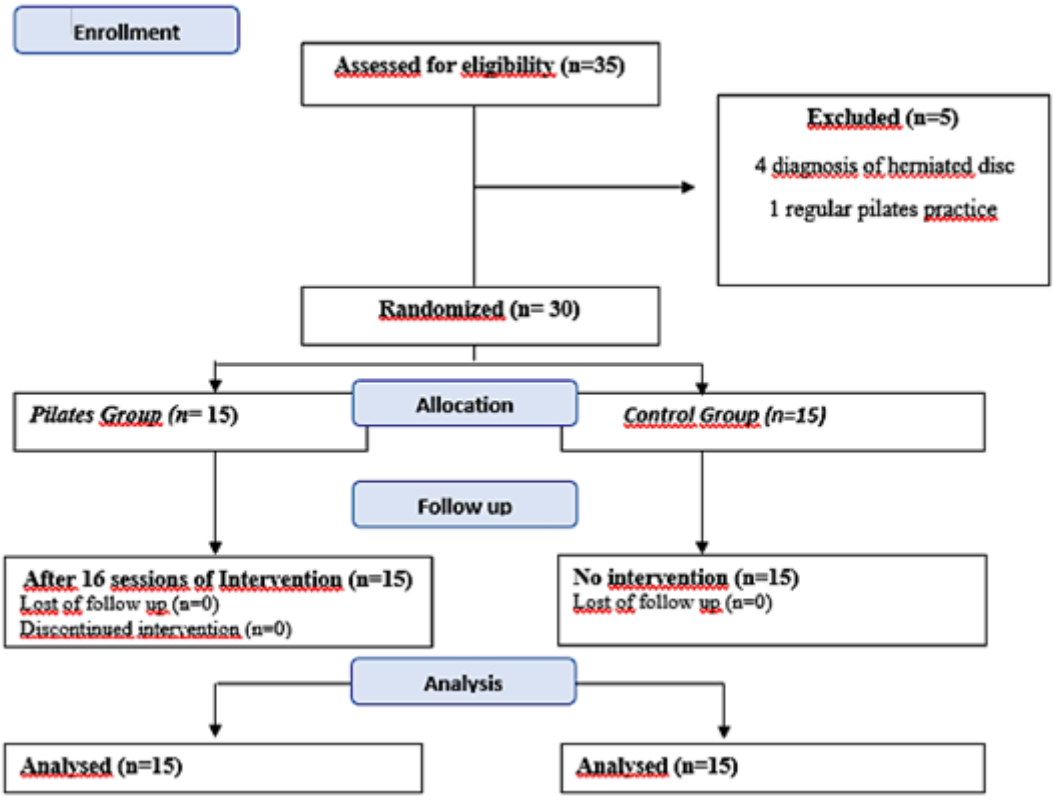

Figure 1 - *Flowchart of the randomized clinical trial*

In the table I we can see how homogeneous is the population in comparison between variables.

Table I -. *Sociodemographic characteristics of study participants*

Variables	Pilates Group		Control Group		P-value*
	Mean/n	SD/%	Mean/n	SD/%	
Age	22.47	2.95	22.67	5.75	0.905
Weight	63.55	10.28	59.47	16.04	0.414
Height	1.68	0.09	1.63	0.09	0.175
BMI	22.04	3.38	22.50	3.02	0.699
Marital status					
Single	12	80.0	15	100.0	-
Married	3	20.0	0	0.0	-
Education level					
Elementary school	0	0.0	1	6.7	-
High school	0	0.0	1	6.7	-
Incomplete higher education	11	73.3	10	66.7	-
Complete higher education	5	26.7	3	20.0	-

*Unpaired t-test

There was a significant reduction in pain ($p < 0.001$) in the mean values obtained in the VAS in the PG, which was not observed in the CG. In the same way, it was also observed in the PG a significant decrease in pain measure by the MPQ, both in the total score ($p < 0.001$) and in the sensory ($p < 0.001$) and affective ($p < 0.001$) components. This same finding was not observed in the CG (Figure 2).

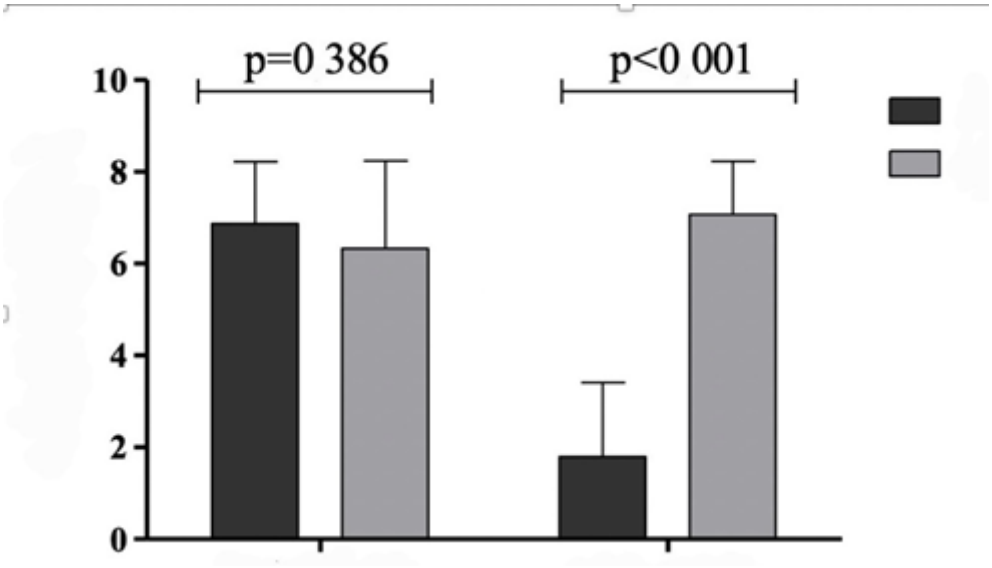

Figure 2 - *Comparison graph between the means of the Visual Analogue Scale (VAS) scores obtained in each group of the study*

There were improvements in quality of life (SF-36) after the Pilates sessions ($p = 0.001$). The assessment of disability, in the PG the scores obtained by the Oswestry Index increased significantly after the intervention as shows the present study ($p < 0.001$), in the Table II.

Table II - *Comparison between the Oswestry Index scores obtained at two time points in both groups*

Groups	2nd Assessment Mean (SD)	Mean differences (SD)	95% Confidence interval	P value*
Pilates (n = 15)	8.40 (7.64)	12.93	6.90 to 18.97	<0.001
Control (n = 15)	26.80 (10.82)	-1.20 (6.58)	-4.85 to 2.45	0.492

In the evaluation of the activation of TrA, in the PG there was a significant decrease in the pressure quantified in this test ($p < 0.001$), which was, on average, 66.53 mmHg (SD = 1.36) in the baseline and changed to 59.40 mmHg (SD = 4.10) on the final of treatment. In the CG, the values were quite similar in the two evaluations (Table III).

Table III - *Comparison between the quantified values in the assessment of the transversus abdominis muscle (TrA) at two research moments in both groups*

Grupos	TrA 1st Assessment Mean (SD)	2nd Assessment Mean (SD)	Mean differences (SD)	95% Confidence Interval	P value*
Pilates (n=15)	66.53 (1.36)	59.40 (4.10)	7.13 (4.19)	4.81 a 9.45	<0.001
Control (n=15)	66.27 (2.05)	66.53 (1.36)	-0.26 (2.19)	-1.48 a 0.94	0.644

*Unpaired t-test

A positive correlation was observed between functional disability and pain assessed by VAS (rho = 0.773; p = 0.001), as well as a negative correlation between disability and quality of life assessed by SF-36 (rho = -0.589; p = 0.021) (Table IV).

Table IV - *Correlation coefficients between pain, quality of life, functional disability (Oswestry), and transversus abdominis muscle activation after treatment in the Pilates group*

	Sensory Pain (McGill)	Affective Pain (McGill)	Pain Total Score (McGill)	SF-36	Oswestry	TrA Activation
Pain (VAS)	0.351	0.409	0.415	-0.407	**0.773***	-0.126
Sensory Pain (McGill)	-	**0.772***	**0.872***	-0.208	0.085	0.169
Affective Pain (McGill)		-	**0.939***	-0.317	0.175	0.423
Pain Total Score (McGill)			-	-0.254	0.062	0.405
SF-36				-	**-0.589***	0.211
Oswestry					-	-0.363
TrA Activation						-

VAS = Visual Analogue Scale; McGill = McGill Pain Questionnaire; SF-36 = Quality of life instrument; TrA = transverse abdominal muscle; *p < 0.05; Spearman correlation test

Discussion

This study shows that in the short-term Mat Pilates presents statistically significant results and clinically relevant effects for the primary and secondary outcomes studied in this clinical trial, when compared with no intervention.

The methodological approach used became possible to verify the expressive results in relation to the real effectiveness and impact of Mat Pilates along with factors such as quality of life, pain, disability and activation of the TrA, stabilizer of lumbar spine, in individuals with non-specific low back pain, presenting low risk of bias, since it was based on the guidelines of randomized clinical trials, following the CONSORT, thus being able to help physiotherapists in their clinical practice decision process.

In our research, the homogeneity of the subjects was maintained, verified through the comparison of demographic data. There was a predominant participation of women in the young-adult age group, and this may be explained by the physiological characteristics of less muscle and bone mass in the female sex. In this age group, there is a full productive phase, greater occupational and domestic demand, which burden the lower back, mainly due to important changes in lifestyle at home and in the work environment, such as the constant use of computers, increasing sedentary lifestyle, risk factor for the development of chronic low back pain [26].

The body mass index (BMI) in this study is within normal parameters in both groups, in contrast to some published studies that mentioned that overweight/obesity would be prevalent in individuals with low back pain [27,28]. This overweight – low back pain relationship was not observed in our research, however, some studies suggest that this is a factor to be considered, as obesity promotes an increase in the overload of articular structures of the lumbosacral spine, which may predispose to degeneration [29].

The treatment for nonspecific low back pain has the Pilates Method exercises (Mat Pilates) as a rehabilitation tool, which is composed as a set of exercises focused on stabilization, breathing and abdominal strength. In a recent systematic review, Byrnes, Wu and Whillier [30] found that Pilates is an effective rehabilitation tool in achieving the desired results, especially in reducing pain and functional incapacity in the various pathologies studied. In addition, this review indicates the need for more research to indicate the benefits of certain Pilates exercises in rehabilitating specific conditions.

In our study Mat Pilates was considered an important and effective treatment tool for patients with nonspecific low back pain when compared to no intervention. This can be explained by the fact that we promoted the adequate evolution of the exercises, and for this, 20 of the 34 original exercises developed in the field and described by Joseph Pilates in his book “Return to Life through Contrology” in 1945 [31], were selected and divided in 4 cycles according to the level of difficulty, taking into account the biomechanics and muscle actions in all phases of the exercises.

It is known that the exercises proposed by Mat Pilates, when well executed and properly evolved, improve the stability of the spine through the complex interaction of muscles, connective tissue and joint structures [32]. It is possible to observe an increase

in muscle control around the spine, which is necessary to maintain functional stability. We saw that the mean TrA strength after the intervention with Mat Pilates increased to 10.6mm Hg, a value in addition to the variation established by Hodges and Richardson [24] by electromyography, which would be between 4-10mmHg, however, this increase is confirmed in the study by Ceccato *et al.* [33] when using this sphygmomanometer to assess the TrA strength in young rowers, reaching values of 19 mmHg. According to this author, this finding can be justified due to the action of other spinal stabilizer muscles, such as the multifidus and oblique muscles, which, when activated, help to reduce intra-abdominal pressure during the test.

It is known that the lack of muscle strength, endurance or control can allow the emergence of inappropriate or excessive segmental movements, in addition to repeated trauma to tissues within or around the spine, causing activation of nociceptors and resulting in pain [32].

These results were achieved after performing 16 Mat Pilates sessions held twice a week for a period of eight weeks, each session lasting approximately 60 minutes, corroborating the systematic review by Yamato *et al.* [34], whose duration of all Pilates sessions analyzed it was approximately one hour for all included studies, and the mean number of sessions in the included studies was 15.3, ranging from six to 30 sessions.

The difference of 5.07 points ($p < 0.001$) in the VAS after the intervention with Mat Pilates compared to no intervention was a clinically important result, in addition to the statistically significant reduction in the results of the McGill Pain questionnaire, in the domain of affective and sensory. Also the data obtained through the Oswestry Index and the components of the SF-36 questionnaire, in which it was observed that the domain “functional capacity”, as opposed to disability and “pain”, obtained statistically significant responses (Table IV), respectively, according to the SF-36, indicating a direct association between the reduction of pain and disability and the overall improvement in the quality of life of individuals with low back pain intervened by Mat Pilates.

The correlations between the variables analyzed confirmed the study hypothesis: positive correlations between the domains of the SF-36 questionnaire and negative when compared to data in which higher values meant worsening of the studied variables, such as the strength of the TrA which increased while the disability decreased. The same was observed between the SF-36 and the Owestry Index, indicating that the improvement in quality of life implies an improvement in functional capacity of this patients.

The results of the present clinical trial confirmed the data compiled by the systematic review by Kamioka *et al.* [34], which showed that the vast majority of randomized clinical trials published so far obtained a positive response from Pilates to LBP in a short period of time.

Our study suggests that Mat Pilates is effective in reducing the levels of pain obtained by the VAS and the McGill Questionnaire, as well as it is possible to observe the improvement in aspects of quality of life in reducing the pain and functional disability of these individuals. The strength of the transverse muscle of the abdomen had a positive correlation with the improvement of all variables studied in this research.

In a recent systematic review [35], the authors concluded that there is no conclusive evidence that Pilates is superior to other forms of exercise due to the low to moderate quality of published studies, but there is evidence that Pilates is more effective than an intervention minimal or no intervention for pain and functional disability. Our study used a good methodology, based on the Consort, and as seen in the data found, Mat Pilates can be considered effective for reducing pain and functional disability in patients with low back pain, despite having been applied in a small sample, therefore, we suggest carrying out studies with the methodological rigors adopted here with a larger number of participants.

Conclusion

The research results show that Mat Pilates has positive responses in the quality of life, pain, disability and activation and transverse muscle strength of individuals with unspecific chronic low back pain compared to people who were not intervened by the method. However, the study needs confirmation of these implications in the medium and long term after the intervention, since other research claims positive results only for short duration.

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Conflicts of interest
The authors declare no conflicts of interest.

Authors' contribution
Conception and design of the research: Coutinho CCC, Santos IR; *Data collection*: Coutinho CCC, Santos IR; *Data analysis and interpretation*: Coutinho CCC, Santos IR, Parizotto NA; *Statistical analysis*: Coutinho CCC, Santos IR; *Manuscript writing*: Coutinho CCC, Santos IR; Mousinho RRS, Parizotto NA; *Critical review of the manuscript for important intellectual content*: Coutinho CCC, Santos IR, Parizotto NA

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