










Effects of 12-week Pilates training program on cardiac autonomic modulation: a randomized controlled clinical trial

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Aim: To evaluate the effects of 12-week Pilates training program on cardiac autonomic modulation.

Materials & methods: A randomized controlled trial of a 12-week Pilates training program was conducted. A total of 54 men were randomly allocated to either a control or a Pilates group. Initially, the RR intervals were captured for 20 min for later analysis of heart rate variability (HRV). The training protocol was then initiated, in which the Pilates group performed 36 sessions of the Pilates method for approximately 60 min each session, three-times a week, totaling 12 weeks. The control group was instructed to maintain their normal activities during this period. One week after the end of the training, the final evaluations were performed with the capture of RR intervals in both the groups. Linear indices in the time (SDNN and rMSSD) and frequency (low frequency [LF] and high frequency [HF]) domains, and the Poincaré plot (SD1 and SD2) were used. Nonlinear indices were also analyzed (approximate entropy and detrended fluctuation analysis). Descriptive statistics and generalized mixed models were performed. **Results:** There was a group effect for LF (ms^2) and a time effect for SD2. There was a training effect observed by the time*group interactions in which an increase in global HRV indices was found for the Pilates group after 12 weeks (SDNN: mean difference [MD] = 9.82; standard deviation [SD] = 18.52; ES = -0.514; LF [ms^2]: MD = 334.23; SD = 669.43; ES = -0.547; SD2: MD = 14.58; SD = 24.28; ES = -0.693). **Conclusion:** A 12-week Pilates training program promotes significant improvement in global modulation of HRV in the Pilates group considering the significant increase in SDNN, LF (ms^2) and SD2 indices.

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Heart rate (HR) in healthy humans can be influenced by stimuli from both the internal environment, stress and emotions, and the external environment, such as physical exercise [1]. High resting HR can be a risk factor for heart disease [2], and heart rate variability (HRV) is a noninvasive and easy tool to analyze autonomic nervous system (ANS) function, defined as the oscillations in intervals between consecutive heart beats (RR intervals) [3].

HRV reflects a dynamic stability resulting from the activation and/or inhibition of the sympathetic and parasympathetic ANS [4]. Furthermore, nonlinear analysis methods founded on chaos theory are more sensitive for the detection of complexity of biological systems, since cardiovascular regulation mechanisms interact in a nonlinear fashion [5].

HRV oscillations provide early and sensitive indicators of ANS-related phenomena in healthy individuals, athletes and sick [5–8]. Therefore, HRV can be considered the most sensitive and easily accessible indicator of the autonomic regulation of the humans [6]. High HRV demonstrates good adaptation of the body, since its reduction has been

pointed out as a strong indicator of risk related to adverse events in normal individuals and in patients who present a cardiopathy [6,7].

As already well informed in the literature, the practice of physical exercise results in health benefits, and can be used as a way to promote well-being, and prevent chronic noncommunicable diseases, musculoskeletal disorders and psychological disorders [9]. Physical exercise when well adapted may improve tolerance to different stimuli and thereby reduce the risk of cardiovascular disease [9]. One type of exercise program that has gained prominence in recent decades is the Pilates method [10–12]. This method was created in the early 20th century by a German named Joseph Pilates and expanded in the USA in the 1960s where the method gained worldwide visibility [13].

Currently, the Pilates method is widely used in health clinics where professionals apply this method to provide their practitioners with voluntary body control and improved posture, stabilizing the *core* muscles during dynamic movements, promoting physical and mental vitality [14,15]. However, the applicability of this method in the individuals who practice it is still unclear, since the method is already used by many different populations, including healthy young individuals, who are looking for models of less strenuous exercise [16].

The scarcity of studies that evaluate the Pilates method on cardiac autonomic modulation in a standardized way and with methodologies applicable limits its clinical applicability. In addition, monitoring of the ANS modulation of these individuals may provide greater safety to the population that practices it, allowing better understanding of its effects on autonomic behavior. Therefore, a study that evaluates the effect of the Pilates method on the HRV is pertinent, enabling future studies to safely investigate possible treatments in specific populations.

Thus, the objective of the present study was to evaluate the effects of 12-week Pilates training program on the cardiac autonomic modulation. It was hypothesized that Pilates training would provide positive adaptations in the ANS, leading to HRV improvement.

Materials & methods

Participants

The study population consisted of 54 men (height: 1.77 ± 0.06 m, weight: 78.72 ± 16.13 kg, BMI: 25.02 ± 4.78 kg·m⁻²) randomized into two groups: control or Pilates. The CONSORT (CONsolidated Standards of Reporting Trials) guideline was used to improve the reporting this randomized controlled trial. The trial was registered at ClinicalTrials.gov (NCT03232866) and approved by the Research Ethics Committee (number 061942/2017). Participants received oral and written instructions and signed the consent form agreeing to participate in the study.

The sample calculation was performed based on the study of Barbosa *et al.* in which the variable SDNN was selected [17]. The difference to be detected was 25.13 ms, a 24.00 ms standard deviation, 5% significance level, 80% test power and two-tailed hypothesis test. The value obtained from the sample calculation was 14 volunteers and more participants were added to the total sample to statistically supply the analyses in case of dropouts during the collection dynamics.

Individuals who had not practiced Pilates prior to the study were included. The following individuals were not included: smokers, individuals who used drugs that influence the autonomic modulation of the heart, alcoholics, people with known metabolic and/or endocrine disorders, and those with physical limitations such as musculoskeletal or neurological diseases that prevent the performance of Pilates. Volunteers were recruited through pamphlets distributed at a college and through social networking sites.

As exclusion criteria, the following were applied: individuals who had an episode of musculoskeletal injury during training, adherence to training of less than 85% of the sessions and capture errors in the RR intervals.

During assessment of the eligibility criteria, four volunteers were excluded from the study, three of whom did not meet the inclusion criteria and one volunteer who gave up participating for logistical reasons. In the final evaluations, there was lost to follow-up to errors in the capture of RR intervals and withdrew. Missing data were handled. The flowchart of participants is shown in Figure 1.

Randomization & masking

The baseline data of participants were collected prior to the randomization process. To ensure concealed allocation, group randomization (Pilates group or control group) was performed by a researcher not involved in the recruitment, using a computer-generated randomization schedule. A randomization sequence was created using software, and a randomly generated computer list was used for allocation. Participants were allocated to two groups: a control group (did not participate in the Pilates method sessions and were instructed to maintain their normal activities) and a

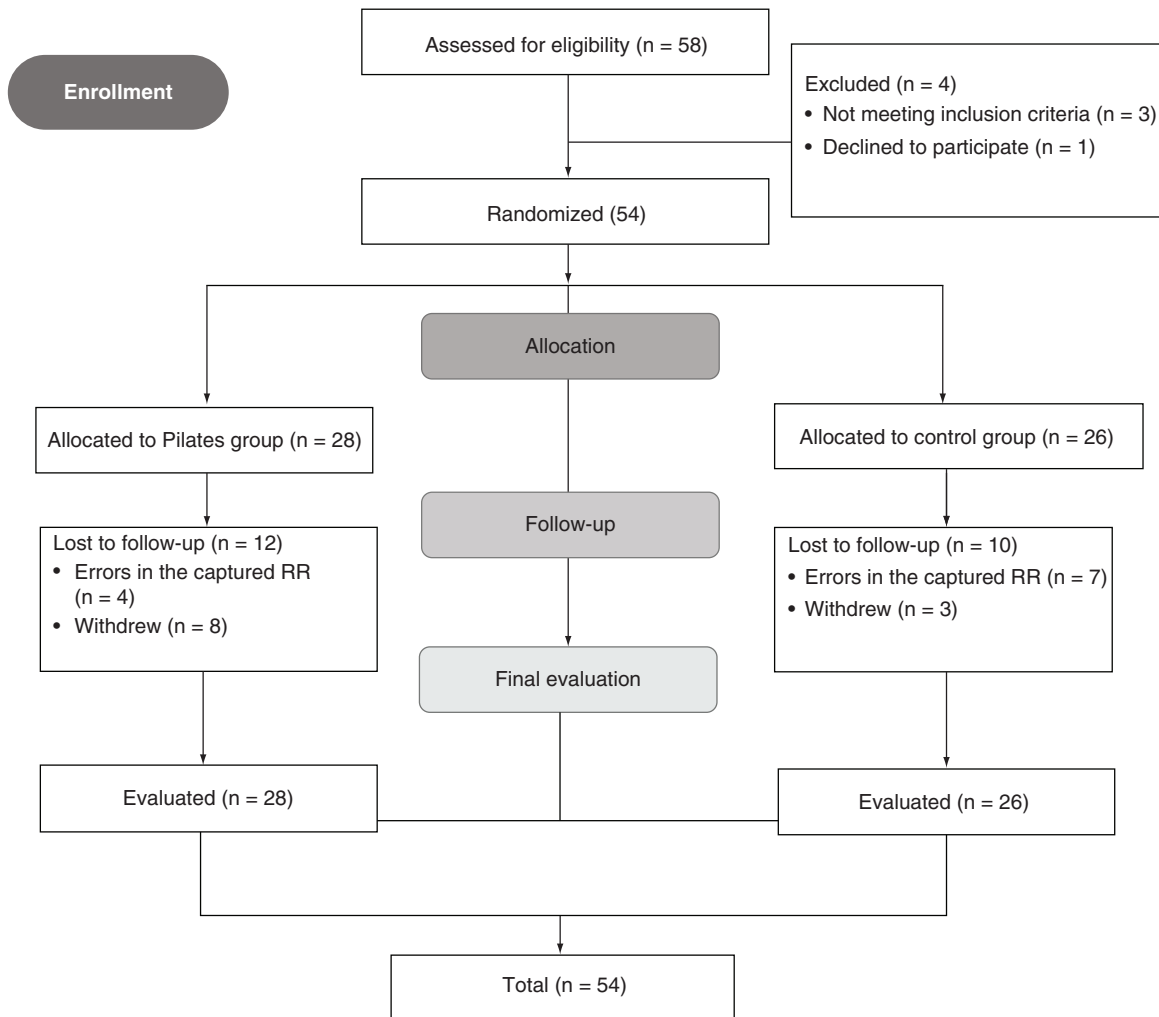


Figure 1. Study flowchart.

Pilates group (36 sessions of the Pilates method, three-times a week, 60-min sessions, totaling 12 weeks). Researchers involved in the outcome assessment and data analysis were blinded to the type of intervention. However, it was not possible to totally blind participants because of the control condition. Pilates training program was offered to the control group after the end of the study.

Study design

A controlled randomized clinical trial was conducted at the Center for Studies and Assistance in Physical Therapy and Rehabilitation of the Universidade Estadual Paulista (FCT/UNESP), Presidente Prudente, SP, Brazil. All procedures were performed under standard conditions (temperature: 21–23°C, relative humidity: 40–60%) from March to August 2018. Participants were instructed to maintain their daily dietary routine and refrain from taking anti-inflammatory medications and analgesics, as well as not performing any other type of exercise during the collection period. This information was reinforced during the training period and monitored by self-report.

Initially, the anthropometric parameters of each participant were collected. Weight was measured using a digital scale (Tanita BC554, Iron Man/Inner Scanner) and stature using a stadiometer (Sanny, American Medical do Brasil, São Paulo, Brazil), from which the BMI was calculated.

After these collections, the participants were directed to a quiet room where the HR monitor (Polar Electro Oy, Kempele, Finland – model V800) was located. The participants remained at rest in the supine position with spontaneous breathing for 20 min to record the HR beat by beat for subsequent analysis of baseline HRV.

After these initial procedures, the Pilates method familiarization sessions were held on 3 days of the week for participants to understand the principles of the method. Pilates training was started the following week. There were 36 sessions, over 12 weeks, each session lasting approximately 60 min, performed three-times a week. During the 12 weeks, the participants went through three levels of training: basic, intermediate and advanced. In the week following the last Pilates training session, the final evaluation of the HRV was performed, similar to the baseline evaluation.

Pilates training program

The Pilates training program was proposed by Cavina *et al.* [18]. The exercises were performed by a professional with 5 years experience in the Pilates method. At each level, the necessary period of adaptation was considered for progression of the exercises. The basic level lasted 7 weeks and 15 repetitions of each exercise were performed, while the moderate and advanced level lasted 14 and 15 weeks, with 12 and 10 repetitions of each exercise, respectively.

The following exercises were performed: the hundred, roll up, one leg circle, single leg stretch, double leg stretch, scissors, crisscross, spine stretch forward, jack knife, corck crew, swan dive, sidekicks series, teaser, leg pull-up, leg pull front, swimming, showder bridge, neck pull, obliques roll back, push-up, side bend, saw, rocking, boomerang, side leg lift/lateral flexion.

It is worth noting that the exercises and their respective progressions were based on the degree of difficulty of each exercise, range of motion and angulations of the exercises and on the progression of intensity between the different levels of the Pilates method, being confirmed by the training impulse (TRIMP). TRIMP considers the intensity (calculated by the effort perception) and the duration of exercise (measured in minutes) [19].

HR variability

HRV analysis was performed from the series of RR intervals captured by the HR monitor Polar Electro Oy – model V800. Nonlinear methods and linear methods analyzed in the time and frequency domains and the Poincaré plot were used for analysis. All HRV indices were obtained using Kubios HRV software, version 3.1 [20].

For the analysis, the times series of RR intervals was initially subjected to moderate digital filtering by the software Kubios HRV – version 3.1, supplemented by manual filtering to eliminate premature ectopic beats and artifacts, and only series with more than 95% of sinus beats were included in the study [6]. Through the visual analysis of the times series, we observed the absence of ectopic artifacts or beats that could interfere in the HRV analysis. The RR interval series was analyzed in the times before and after the 12 weeks of training with 256 RR intervals in each analysis. The section with the greatest stability was observed in order to avoid biases of analysis and interpretation of the data [21]. The HRV indices in the time domain (SDNN and rMSSD), frequency domain (low frequency [LF] and high frequency [HF]) and the Poincaré plot (SD1 and SD2) [21–25] were evaluated. In addition, nonlinear indices were also analyzed (approximate entropy and detrended fluctuation analysis [DFA]) [26–29].

In the time domain, the rMSSD index represents the parasympathetic modulation and corresponds to the root mean square of the successive differences between the RR intervals in the record, divided by the number of RR intervals in a given time minus one RR interval [21]. The SDNN is an index that evaluates the standard deviation of all normal RR intervals, corresponding to the total power of the frequency spectrum, that is, the global variability, thus reflecting the participation of all the rhythmic components responsible for the variability [21].

In the frequency domain, spectral components of LF and HF were used in ms^2 . The frequency bands used for each component were: LF = 0.04–0.15 Hz and HF = 0.15–0.40 Hz. The LF component indicates sympathetic and parasympathetic oscillations of cardiac autonomic regulation [22,23], while the HF component represents the parasympathetic component [22,23]. The spectral analysis was calculated using the Fast Fourier Transform algorithm.

The Poincaré plot is a 2D graphical representation of the correlation between consecutive RR intervals, in which each interval is plotted against the next interval [23]. The analysis was performed quantitatively by adjusting the ellipse of the figure formed by the attractor, from which the following indices were obtained: SD1 and SD2 [23]. SD1 represents the dispersion of points perpendicular to the line of identity and appears to be an index of instantaneous record of beat-to-beat variability, reflecting parasympathetic modulation [24]. SD2 represents the dispersion of points along the identity line and represents HRV as a measure of long- and short-term combined variability, reflecting overall variability [23].

The DFA quantifies the presence or absence of fractal correlation property of the RR intervals and has been validated for time series data. This measurement is partially related to changes in the spectral characteristic of the HR behavior [26]. In each segment, the short-term (4–11 beats, α_1) and the long-term scaling exponents (>11

Table 1. Anthropometric characteristics of the groups studied.

Variables	Control (n = 26)	Pilates (n = 28)	p-value
Age (years)	26.00 ± 4.63	27.11 ± 3.78	0.34
Height (m)	1.77 ± 0.06	1.76 ± 0.07	0.64
Weight (kg)	76.59 ± 15.13	80.46 ± 17.22	0.39
BMI (kg·m ⁻²)	24.28 ± 4.21	25.80 ± 5.33	0.25

Values are presented as mean ± standard deviation.

beats, $\alpha 2$) are assessed by the DFA [27]. Approximate entropy describes the predictability or randomness of physical systems that change with time: the higher the entropy value, the more complex is the process [28,29].

Statistical analysis

The statistical analysis was conducted using the software SPSS (version 22; SPSS Inc., IL, USA). To describe the population profile data, the results are presented as mean values, standard deviations, median, 95% CI, minimum and maximum values. Overall, data were normally distributed as tested by the Shapiro-Wilk test and visually confirmed by Q-QPlots. Goodness-of-fit was tested by Akaike's Information Criterion and all indexes were then analyzed by generalized mixed models with gamma distribution and unstructured covariance matrix. The models included group and time as fixed factors and participant ID as random factor and used Bonferroni for post-hoc testing when main effects were found. Missing data were handled using linear mixed models [30] (i.e., imputation methods were not needed). Effect size was calculated using partial eta-squared and interpreted as small (≥ 0.01), medium (≥ 0.06) or large (≥ 0.14) [31]. All analysis were performed assuming a significance level of $p < 0.05$. Between and within-group differences are expressed as mean difference (MD), standard deviation (SD) and 95% CI. The statistical process was blinded.

Results

The anthropometric characteristics of the groups studied are shown in Table 1. There were no statistically significant differences in relation to age, height, weight and BMI, demonstrating homogeneity the between groups. There was an increase in the internal training load calculated through the TRIMP in arbitrary units (a.u.) between the basic, intermediate and advanced levels of the Pilates method (basic: 75.15 ± 69.91 a.u.; intermediate: 85.15 ± 78.07 a.u.; advanced: 104.12 ± 81.79 a.u.). In addition, there was a statistically significant difference between the advanced level and the basic and intermediate levels ($p = 0.0032$).

Table 2 shows the results for linear indices of HRV in the time and frequency domain and the Poincaré plot. There was a group effect for LF (ms^2) ($F_{(1,75)} = 5.430$; $p = 0.022$; MD = 352.06; SD = 1154.8; 95% CI = 38.99–665.14; ES = 0.587) and a time effect for SD2 ($F_{(1,75)} = 4.03$; $p = 0.048$; MD = 6.99; SD = 831.56; 95% CI = 0.145–13.84; ES = -0.693). There was a training effect observed by the time*group interactions in which an increase in global HRV indices was found for the Pilates group after 12 weeks (SDNN: MD = 9.82; SD = 18.52; IC = 2.849, 16.79; ES = -0,514; LF [ms^2]: MD = 334.23; SD = 669.43; IC = 82.20, 586.25; ES = -0,547; SD2: MD = 14.58; SD = 24.28; IC = 5.43, 23.72; ES = -0,693). Although there was no significant interaction we found within group differences for Pilates on indices LF (n.u.) and HF (n.u.), which showed an increase in sympathetic modulation and a decrease in parasympathetic modulation.

Table 3 shows the results for nonlinear indices of HRV. There were no significant time*group interactions or group effect and time effect for the nonlinear indices.

Discussion

The present study investigated the effects of 12-week Pilates training program on cardiac autonomic modulation in healthy young men. The findings suggest that a 12-week Pilates training program promote significant improvement in global modulation of HRV in the Pilates group considering the significant increase in SDNN, LF (ms^2) and SD2 indices.

According to Carter *et al.* [32], physical exercise produces physiological alterations that significantly influence the ANS modulation. In addition, it has been shown in the literature that resistance training tends to significantly increase HRV and parasympathetic modulation, and to decrease resting sympathetic modulation [33].

Table 2. Mean (standard deviation) of groups, and between-group difference (95% CI) for linear indices in the time and frequency domain and Poincaré plot.

Linear indices in the time domain	Within-group differences (mean ± SD)		Between-group differences (mean ± SD) Control vs Pilates (n = 54)	Effect size (Cohen's d)
	Control (n = 26)	Pilates (n = 28)		
SDNN (ms):				
• Baseline	51.33 ± 19.98	40.86 ± 16.13	5.07 ± 14.20 (-2.78, 12.93)	-0.582
• 12 weeks	49.84 ± 20.29	50.68 ± 16.98		
• Change baseline → 12 weeks	-1.48 ± 20.29; (0.71, -9.42)	9.82 ± 18.52*; (2.84, 16.79)		
rMSSD (ms):				
• Baseline	44.29 ± 20.29	35.16 ± 16.35	5.83 ± 21.85; (-2.40, 14.08)	0.360
• 12 weeks	41.44 ± 17.23	38.94 ± 16.77		
• Change baseline → 12 weeks	-2.85 ± 19.52 (-10.48, 4.77)	3.78 ± 17.19; (-2.69, 10.26)		
Linear indices in the frequency domain				
LF (n.u.):				
• Baseline	57.32 ± 24.42	48.59 ± 21.00	3.51 ± 34.83 (-5.92, 12.96)	-0.545
• 12 weeks	54.40 ± 16.57	56.36 ± 17.72		
• Change baseline → 12 weeks	-2.92 ± 21.51; (-5.50, 11.34)	7.77 ± 19.68*; (0.35, 15.19)		
HF (n.u.):				
• Baseline	39.85 ± 19.27	44.53 ± 21.90	-0.15 ± 31.74 (-8.78, 8.46)	0.453
• 12 weeks	39.41 ± 16.87	35.56 ± 15.71		
• Change baseline → 12 weeks	-0.44 ± 18.10; (-7.51, 6.63)	-8.97 ± 19.57*; (-16.35, -1.59)		
LF (ms²):				
• Baseline	1120.24 ± 1073.2	550.62 ± 506.66	352.06 ± 1154.8* (38.99, 665.14)	-0.587
• 12 weeks	927.26 ± 629.17	854.85 ± 600.9		
• Change baseline → 12 weeks	-192.98 ± 1078.8; (-614.45, 228.48)	334.23 ± 669.43; (82.20, 586.25)*		
HF (ms²):				
• Baseline	669.71 ± 620.55	447.64 ± 421.36	178.70 ± 898.35 (-64.83, 422.25)	-0.173
• 12 weeks	628.91 ± 543.86	494.07 ± 440.84		
• Change baseline → 12 weeks	-40.80 ± 571.7; (-264.16, 182.55)	46.43 ± 424.27; (-113.30, 206.17)		
Poincaré plot				
SD1 (ms):				
• Baseline	31.37 ± 14.32	24.94 ± 11.58	4.10 ± 21.53 (-1.73, 9.94)	-0.366
• 12 weeks	29.33 ± 12.23	27.59 ± 13.17		
• Change baseline → 12 weeks	-2.03 ± 13.81; (-7.44, 3.36)	2.65 ± 12.17; (-1.93, 7.25)		
SD2 (ms):				
• Baseline	65.07 ± 25.49	51.10 ± 20.37	6.42 ± 36.22; (-3.40, 16.24)	-0.627
• 12 weeks	63.65 ± 20.34	65.68 ± 21.69		
• Change baseline → 12 weeks	-1.41 ± 26.66; (-11.83, 9.00)	14.58 ± 24.28; (5.43, 23.72)*		

HF: High frequency; LF: Low frequency; n.u.: Normalized unit; rMSSD: Root mean square of the successive differences between the RR intervals; SD: Standard deviation; SD1: Standard deviation of instantaneous variability; SD2: Standard deviation of the long-term interval between consecutive heart beats; SDNN: Standard deviation of RR intervals.

It is noteworthy that the current literature only addresses the acute effects of Pilates training; therefore, there is a lack of evidence demonstrating the chronic behavior of this type of training on cardiac autonomic modulation. In this sense, the importance of the current study is highlighted, characterized as the first study to verify the impact of a 12-week Pilates training protocol on cardiac autonomic modulation in a healthy adult population.

Table 3. Mean (standard deviation) of groups, and between-group difference (95% CI) for nonlinear heart rate variability indices.

	Within-group differences (mean ± SD)		Between-group differences (mean ± SD) Control vs Pilates (n = 54)	Effect size (Cohen's d)
	Control (n = 26)	Pilates (n = 28)		
ApEn-:				
• Baseline	857.50 ± 656.14	729.25 ± 566.88	33.00 ± 497.79; (-101.831, 167.84)	-0.456
• 12 weeks	708.103 ± 594.14	810.93 ± 699.06		
• Change baseline → 12 weeks	-149.40 ± 495.22; (-342.73, 43.92)	81.68 ± 518.67; (-113.42, 276.78)		
DFA α1:				
• Baseline	844.32 ± 448.25	851.15 ± 459.04	-135.16 ± 619.11; (-302.85, 32.53)	-0.142
• 12 weeks	936.46 ± 426.48	1031.62 ± 487.51		
• Change baseline → 12 weeks	92.14 ± 595.11; (-140.16, 324.44)	180.46 ± 644.61; (-62.01, 422.95)		
DFA α2:				
• Baseline	684.00 ± 282.49	760.81 ± 319.18	68.17 ± 509.98; (-69.97, 206.31)	0.222
• 12 weeks	691.90 ± 436.99	616.68 ± 404.16		
• Change baseline → 12 weeks	7.90 ± 513.78; (-208.46, 192.65)	-98.72 ± 443.00; (-335.30, 47.04)		

ApEn-: Approximate entropy; α1: Short-term component; α2: Long-term component; DFA: Detrended fluctuation analysis; SD: Standard deviation.

High HRV represents good adaptability of the heart, just as low HRV suggests abnormal adaptability of the ANS [34,35]. In the present study, significant improvements in SDNN and SD2 indices were observed in the Pilates group, suggesting that the training performed promoted increases in global variability of the ANS. The mechanisms involved in the increase in HRV in individuals submitted to exercise are speculative.

Studies indicate that the fact could be related to a reduction in levels of angiotensin II, a substance that inhibits vagal activity [36]. In addition, the increase in nitric oxide could be related to an activation of vagal modulation, however, further investigations related to this aspect are still necessary [37].

In addition to the indices described above, a significant increase in LF (ms^2) was observed in our study. Studies demonstrate that this index is related to the global modulation of ANS with sympathetic predominance [21]. Furthermore, the LF was related to baroreflex gain, suggesting that it represents the ability to modulate the ANS influence on the heart through the baroreflex action [38].

In addition, Leite *et al.* [39] conducted a study to determine HRV characterization parameters in several populations, including healthy individuals, and found that the average RR intervals presented higher values, as well as greater variability. Thus, the results of the present study can be justified, at least in part, by the population studied.

Rocha *et al.* [40] investigated blood pressure and HRV responses to a single Pilates session in middle-aged adults with hypertension and found a reduction of approximately 5–8 mmHg during the first 60 min of postexercise recovery. In addition, the acute reduction in blood pressure was concomitant with lower cardiac parasympathetic activity. Thus, it is emphasized that, in a hypertensive population, the Pilates method may be a promising alternative to physical exercise for improving cardiac autonomic modulation.

Another possible interpretation for the findings of the present study is the training time. Marinda *et al.* [41] found that 8 weeks of Pilates training with a frequency of three-times per week and increasing intensity were not sufficient to promote improvements in cardiometabolic variables such as resting HR, fasting glucose, cholesterol and triglycerides when compared with the control group. Jago *et al.* [42] also did not find changes in HR in 11-year-old girls after a 4-week Pilates program, and the authors believe that as the method is not considered an aerobic activity, cardiorespiratory gain is limited. In the present study, 12-week interventions were performed, a fact that may have contributed to the improvement of global modulation.

The increase in autonomic modulation of the individuals who performed the Pilates training program suggests a better adaptation capacity to external stimuli and less heart vulnerability to the risk of cardiovascular events [43,44], acting as an important protector mechanism.

It is noteworthy that the exercises included in this protocol are easy to apply and do not require high-cost equipment, therefore, they can be applied in clinical practice for both prevention and rehabilitation. Study limitations include the lack of individual control of the training intensity of the Pilates method, which could have led to different workloads among participants.

Future studies should evaluate the effects of Pilates training on cardiac autonomic modulation with different populations. In addition, further studies on the Pilates method with intensity control should be performed.

Conclusion

It was concluded that a 12-week Pilates training program promotes significant improvement in global modulation of HRV in the Pilates group considering the significant increase in SDNN, LF (ms^2) and SD2 indices.

Summary points

- The practice of physical exercise can be used as a way to promote well-being and prevent cardiovascular disease.
- This paper reports the effects of 12-week Pilates training program which demonstrate on autonomic heart rate modulation in healthy individuals.
- The results may contribute to future studies that intend to evaluate this modality as a rehabilitation technique for cardiac patients or even in the prevention of these diseases.

Author contributions

APS Cavina and FM Vanderlei are responsible for the study design. APS Cavina, NM Silva, LCM Vanderlei, CM Pastre and FM Vanderlei commented on the various versions of this study. APS Cavina, NM Silva, TM Biral, LK Lemos and E Pizzo were involved in recruiting and collecting data. All the authors approved the final manuscript.

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No writing assistance was utilized in the production of this manuscript.

Ethical conduct of research

The authors state that they have obtained appropriate institutional review board approval or have followed the principles outlined in the Declaration of Helsinki for all human or animal experimental investigations. In addition, for investigations involving human subjects, informed consent has been obtained from the participants involved.

Data sharing statement

Trial registration number: ClinicalTrials.gov (NCT03232866). The spreadsheets containing the raw numeric data will be stored on two external hard drives and two 'clouds.' After analyzing the data, scientific articles related to the study will be made, and after publication, the data will remain preserved and will also be shared and made available in its entirety for a period of 5 years. The datasets analyzed during the current study are available from the corresponding author on reasonable request.

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