TITLE: Effects of Pilates training on sleep quality, anxiety, depression and fatigue in postmenopausal women: A randomized controlled trial.

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ABSTRACT

Objectives: To analyze the effects that a Pilates-based exercise program has on sleep quality, anxiety, depression and fatigue in community-dwelling Spanish postmenopausal women of 60 and over.

Study design: A total of 110 women (69.15 ± 8.94 years) participated in this randomized controlled trial. They were randomly allocated to either a control (n = 55) or a Pilates (n = 55) group.

Main outcome measures: Sleep quality and self-perceived fatigue were assessed by the Pittsburgh Sleep Quality Index (PSQI) and the Fatigue Severity Scale, respectively. Anxiety and depression were evaluated using the Hospital Anxiety and Depression Scale (HADS).

Results: Significant improvements were observed after Pilates training in all PSQI domains as well as in the PSQI total score, with small- to medium-size effects, while significant between-group differences in post-intervention measures were only observed for sleep duration (d = 0.69) and sleep disturbances (d = 0.78). Moreover, intra- and inter-group statistical differences were observed for depression (d = 0.39 and d = 0.86, respectively) and for anxiety (d = 0.43 and d = 1.27 respectively). Finally, participants in the Pilates group experienced a decrease in self-perceived fatigue after the intervention period (d = 0.32).

Conclusions: For community-dwelling Spanish postmenopausal women aged 60 years and over, a twelve-week Pilates exercise intervention has beneficial effects on sleep quality, anxiety, depression and fatigue.

Keywords: Pilates; Sleep quality; Depression; Anxiety; Fatigue; Postmenopausal women.

1. Introduction

Postmenopausal women present with sleep difficulties with a higher frequency than younger women [1]. During the menopause transition, poor sleep and insomnia are reported by 40% to 60% of women, resulting in poor quality of life when these become severe [2]. Poor sleep quality decreases general health quality and is associated with physical and psychological problems [3,4] and a non optimal amount of sleep is significantly associated with all-cause mortality in older individuals [5]. Menopausal status is also associated with increased risk of mood disorders. In women without a history of depression or anxiety, and compared to pre-menopause, peri-and post-menopausal stages are associated with increased risk of greater symptoms of anxiety [6]. Fatigue is one of the most common complaints when seeking medical advice in primary care [7], and it significantly burdens the individual's quality of life and is one of the most common and disabling symptoms associated with menopause [8].

Faced with these conditions, physical activity is one of the most complete options due to its multiple health benefits, low cost and minimal side effects [15], and it has been associated with lower rates of cognitive and physical decline and a significant reduction in all-cause mortality in postmenopausal women [9]. The Pilates method has been shown to improve physical and psychological functioning, as well as independence in

postmenopausal women [10], and this type of exercises are suitable for all ages, body types and levels of physical ability due to the modifiable nature of their movements [11]. Taking into account all of the above, the main objective of our study was to analyze the effects that an exercise program based on the Pilates method may have on sleep quality, anxiety, depression, and fatigue in community-dwelling Spanish postmenopausal women of 60 years and over. We hypothesized that participants who performed a twelve-week Pilates exercise program would show improvements in sleep quality, as well as significant decreases in anxiety, depression, and fatigue.

2. Methods

2.1. Participants and study design

This randomized controlled clinical trial (RCT) analyzed the effects of a Pilates-based training program on sleep quality, fatigue, anxiety and depression in Spanish postmenopausal women. This study was registered at clinicaltrials.gov as NCT03201107 (https://clinicaltrials.gov/ct2/show/NCT03201107). The recruitment of participants started on July 2017 and was carried out via e-mail and telephone after contacting two associations of postmenopausal women in Jaén (Spain). The intervention took place from September 2017 through December 2017.

From a total of 113 women who were initially contacted, 110 met the eligibility criteria and accepted to be enrolled. In order to participate in the study, women were required to be 60 years old and over, not regular Pilates practitioners (two sessions/week for at least six weeks in the last year) and able to understand the instructions, programs, and protocols of this project. Exclusion criteria were conditions that contraindicated the performance of the exercise program such as psychiatric or neurological disorders, systemic diseases (i.e. diabetes mellitus, cancer or heart disease, or skeletal conditions), or being already enrolled in another training program. All participants signed an informed consent form before the beginning of the study. This study was approved by the local Human Ethics Committee of the University of Jaén according to the Declaration of Helsinki, good clinical practices, and applicable laws and regulations.

2.2 Sample size calculation

Sample size was calculated using Ene 3.0 (GlaxoSmithKline, SA, Madrid, Spain). The required sample was determined taking as a reference the data reported by Chen et al. [12] To obtain a statistically significant difference using PSQI total score as dependent variable, with a power of 0.80 and a significance level of 95%, and considering a dropout rate of 1.92%, 34 subjects per group were required.

2.3. Procedures

Participants included in the study were randomly assigned to either a Pilates group (PG), or a control group (CG) in a 1:1 ratio using a computer-generated table of numbers. Assignments were kept at a locked location in a sealed, opaque envelope, to be later opened by an independent part not involved in subject selection, evaluation of results or treatment. A total of 55 women were assigned to the PG, and 55 to the CG. Figure 1 illustrates a flow chart of the participants according to the CONSORT Statement Extension for randomized controlled trials of non pharmacological treatment [13]. Measurements were recorded at baseline before randomization (pre-intervention) and just

after the intervention period (post-intervention) by an independent assessor blinded to both allocation and intervention.

Each week for twelve weeks, participants allocated to the PG attended two one-hour sessions of Pilates exercises. Each Pilates training session was divided into three parts: warm-up (10 minutes), main Pilates training activity (35 minutes), and cool-down (15 minutes). The intervention took place every time in the same local sports center and the exercises were supervised by a well-trained instructor. During the previous week, participants were familiarized with the correct execution of the movements, the powerhouse (abdominal, paravertebral, and pelvic floor muscles) and the principles of the Pilates method. In the first four sessions, exercises were performed in a sitting position, and then, from weeks 3-6, strengthening and stretching standing exercises of progressive intensity were performed (10 repetitions per session). From weeks 7-12, several exercises with accessories (elastic bands, magic circles, and fitballs) were performed on mats to improve muscle strength, resistance and flexibility. Participants were excluded if they missed more than five sessions over the course of the twelve-week intervention. Women allocated to the CG maintained their daily habits, received a series of guidelines aimed at fostering physical activity (http://www.juntadeandalucia.es/salud/servicios/contenidos/andaluciaessalud/docs/130/Guia_Recomendaciones_AF.pdf) and were discouraged from engaging in any other exercise training program. During the intervention period they were periodically contacted (via telephone). Participants were excluded if they missed more than five sessions or more than three consecutive sessions during the twelve-week intervention

2.4. Outcomes

2.4.1. Sleep quality (primary outcome)

In order to assess sleep quality, the Pittsburgh Sleep Quality Index (PSQI) [14,15] was used. This questionnaire includes 19 self-rated questions and 5 questions to be answered by bedmates or roommates (these last questions are used only for clinical information). These items generate 7 component scores: sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, use of sleeping medication, and daytime dysfunction. Higher scores represent poorer subjective sleep quality.

2.4.2. Fatigue

The Fatigue Severity Scale (FSS), developed by Krupp et al. [16], is the most commonly used self-report questionnaire to measure fatigue [17]. It consists of 9 items scored on a Likert scale from 1–7. The mean of all scores is considered to be the final score, and a higher score denotes a higher level of fatigue.

2.4.3. Anxiety and depression

The Hospital Anxiety and Depression Scale (HADS) [18,19] was employed to evaluate anxiety and depression. This self-administered rating questionnaire consists of 14 items, 7 concerning anxiety and 7 depression.

2.5. Statistical analysis

Statistical analyses were performed using the SPSS statistical software, version 17.0 (SPSS, Inc., Chicago, IL, USA). Mean values, standard deviations, number of cases, and the percentage of total for each variable of interest were calculated. Student's *t* test for independent samples and statistical chi-squared test were used to examine the differences

between both study groups at baseline. Univariate analysis of variance (ANOVA) and Pearson's correlation coefficient were used to explore the possible association of education, marital status, occupation, age, and BMI, as well as anxiety and depression, with sleep quality. The variables which showed significant associations were then input as covariates in the analysis of covariance (ANCOVA). Independent variables were group (PG vs CG) and measurement time, while dependent variables were sleep quality, fatigue, anxiety, and depression. Separate analyses were performed for each dependent variable. Student's *t* test for *unpaired or* paired data was employed when Group x Time intervention was statistically significant. A p value below 0.05 was considered statistically significant. Intergroup effect sizes were calculated using Cohen's *d (d)* [20]. Values ≤ 0.2 represent a small-size effect, 0.2–0.5 represent a medium-size effect, and ≥ 0.8 represent a large-size effect.

3. Results

The dependent outcome measures and characteristics of the participants at baseline are presented in Table 1. Our analysis did not reveal the existence of any statistical differences between both study groups. All women took part in at least 91.6 % of the sessions and no injuries or adverse effects were observed or reported by the participants during the intervention period.

3.1. Sleep quality

Table 2 displays pre- and post-intervention values regarding sleep quality. At baseline, no associations were found between educational, occupational and marital status and sleep quality. Age was positively related with sleep duration, $r = -0.23$, $p = 0.016$, and associations were found between BMI and subjective sleep quality, $r = 0.33$, $p = 0.001$, sleep latency, $r = 0.21$, $p = 0.03$, and PSQI total score, $r = 0.23$, $p = 0.02$. Finally, there were no associations regarding depression, while the baseline anxiety score was significantly associated with sleep quality, $F(1, 103) = 13.92$, $p < .001$, for the lowest p value (Sleep latency). Beyond the effects of BMI and pre-intervention anxiety, when these were brought into the analysis as covariables Group x Time turned out to be statistically significant for all dependent measurements (Table 2).

The detailed analysis of the interactions showed improvements in sleep quality, as assessed by the PSQI total score and domains, after the Pilates training program. Moreover, higher scores were observed only in the PG regarding daytime dysfunction ($t(54) = 3.03$, $p = 0.004$, $d = 0.21$) and the use of sleeping medication ($t(54) = 3.88$, $p < .001$, $d = 0.16$). Differences between time measurements were observed in both groups in PSQI total score (PG: $t(54) = 8.19$, $p < 0.001$, $d = 0.29$; CG: $t(51) = -7.58$, $p < 0.001$, $d = 0.29$), subjective sleep quality (PG: $t(54) = 2.57$, $p = 0.001$, $d = 0.11$; CG: $t(51) = -2.33$, $p = 0.002$, $d = 0.14$), sleep latency (PG: $t(54) = 2.84$, $p = 0.006$, $d = 0.16$; CG: $t(51) = -3.96$, $p < 0.02$, $d = 0.26$), sleep efficiency (PG: $t(54) = 4.25$, $p < 0.001$, $d = 0.25$; CG: $t(51) = -3.68$, $p < 0.001$, $d = 0.25$), sleep duration (PG: $t(54) = 5.78$, $p < 0.001$, $d = 0.60$; CG: $t(51) = -5.55$, $p < 0.001$, $d = 0.41$), and sleep disturbances (PG: $t(54) = 2.81$, $p = 0.007$, $d = 0.24$; CG: $t(51) = -3.05$, $p = 0.004$, $d = 0.28$). As for these two last domains, the PG scores were significantly better than those of the CG (sleep duration: $t(105) = 3.54$, $p = 0.001$, $d = 0.69$ and sleep disturbances: $t(105) = 3.97$, $p < 0.001$, $d = 0.78$).

3.2. Anxiety and depression

The results of the present study showed that women who underwent Pilates training had lower anxiety scores than the CG (4.76 ± 3.73 vs. 9.37 ± 3.52). A main effect was found for the Group variable: $F(1, 105) = 11.74$, $p<0.01$, $\eta^2 = 0.10$ and for the Group x Time interaction: $F(1, 105) = 134.38$, $p <0.001$, $\eta^2 = 0.56$; but no effect was observed for the Time variable: $F(1, 105) = 0.57$, $p = 0.45$, $\eta2 = 0.01$. A detailed analysis of the Group x Time interaction revealed differences between the pre- and post-treatment measurements of the PG $t(54) = 8.78$, $p<0.001$, d=0.43, and CG $t(51) = -7.97$, $p < 0.001$, $d = 0.68$ as well as between both groups in the post-intervention measurement $t(105) = 6.55$, $p < 0.001$, $d = 1.27$ (Figure 2).

As for depression scores, post-treatment values turned out to be lower for the PG (3.98 ± 2.93) than the CG (6.81 ± 3.6). Results revealed a main effect in the Group variable: $F(1, 105) = 4.31$, $p > 0.04$, $\eta^2 = 0.04$ and in the Group x Time interaction: $F(1, 105) = 114.13$, $p < 0.01$, $\eta^2 = 0.52$, although no differences were found for the Time variable. $F(1, 105) = 0.61$, $p = 0.44$, $\eta^2 = 0.006$,. The analysis of the interaction revealed differences between pre- and post-treatment values in the PG ($t(54) = 6.59$, $p < 0.001$, $d = 0.39$, and in the CG $t(50) = -7.80$, $p < 0.001$, $d = 0.44$ In addition, differences appeared between both groups at the time of the post-intervention measurement $t(105) = 4.46$, $p < 0.001$, $d = 0.86$.

3.3. Fatigue

Finally, and regarding self-reported fatigue (Figure 3), participants in the PG reported lower values (19.29 ± 10.47) than those in the CG (26.98 ± 16.96), after the intervention period. We found differences in the Group x Time interaction: $F(1, 105) = 59.52$, $p < 0.001$, $\eta^2= 0.36$ but not for the Time variable, $F(105) = 0.008$, $p > 0.05$; or the group variable, $F(1.105) = 0.96$, $p > 0.05$, $\eta^2 = 0.009$. The analysis showed differences between pre- and post-treatment scores in the CG $t(50) = -7.66$, $p < 0.001$, $d = 0.32$, and the PG, $t(55) = 4.74$, $p < 0.001$, $d = 0.39$. Moreover, there were differences between both groups after the intervention period $t(105) = 2.84$, $p = 0.005$, $d = 0.55$.

4. Discussion

The aim of the present study was to assess the effects of a twelve-week Pilates intervention on sleep quality, anxiety, depression and fatigue in women aged 60 years and older. The key findings showed an improvement in sleep quality, as well as a decrease in fatigue, anxiety and depression, after Pilates exercises. These results have important clinical implications for this population, not only concerning the improvements yielded by our intervention, but also due to the well-known benefits of physical exercise on several aspects of mental and physical health. Which were reinforced by the high attendance rate of participants.

A low physical activity is a strong independent risk factor for poor sleep quality in postmenopausal women [21]. Traditional exercise training programs, such as aerobics, have been shown to have positive effects on sleep quality in postmenopausal women [22], and a systematic review and meta-analysis of RCTs concluded that programmed exercise improves sleep quality among middle-aged women [23]. Tadayon et al. [24] also found improvements in both the PSQI total score and domains among postmenopausal women after twelve weeks of pedometer-based walking. In the last years some new types of

exercise and training programs have been looked into. In a randomized controlled trial conducted by Newton et al. [25], postmenopausal women with insomnia were randomly assigned to either yoga classes, exercise at home, or their usual activity. They found that, compared to usual activity, women assigned to yoga saw improvements in their sleep quality and sleep disorders, both domains of PSQI. On the other hand, Buchanan et al. [26] could not find any beneficial effects on actigraphic sleep parameters after twelve weeks of yoga or supervised aerobic exercise, except for sleep stability (yoga) in postmenopausal women with poor self-reported sleep quality. As for Pilates exercises, randomized clinical trials that have examined their effects on the sleep quality of postmenopausal women are scarce. Curi et al. [27] reported improvements in PSQI total score, use of sleeping medication, and sleep latency after 16 weeks of intervention with Pilates exercises in women aged 60 years and over. The findings of the present RCT show improvements after twelve weeks of Pilates training in all PSQI domains as well as the PSQI total score (with small to medium size effects), considering some variables that might be linked to sleep quality such as education, occupation, marital status, age, BMI, anxiety, and depression

Exercise has been included in some clinical guidelines as a complementary method for the treatment of major depressive disorder [28], and a recent meta-analysis supports exercise as a complementary lifestyle change that improves overall health, including reduction of depressive symptoms in middle-aged and older women [29]. A recent systematic reviews support the beneficial effects of Pilates on quality of life and physical fitness [30], but there is limited evidence about its benefits on mental health. Our findings revealed the benefits brought about by a Pilates training program in depression assessed by the HADS, with significant post-intervention intergroup differences. Similar results have been previously described after Pilates exercises but in longer intervention programs (16 weeks) in elderly women [27,31]. As far as anxiety is concerned, high volumes of physical activity are associated with lower anxiety symptoms and status in adults aged ≥ 50 [32]. A recent meta-analysis concluded that programmed exercise, for at least six weeks and with low-to-moderate intensity, seems to improve mild-to-moderate anxiety symptoms in midlife and older women [33]. Regarding Pilates training program, significantly large reductions in anxiety symptoms have been reported in overweight/obese adults of both sexes (18-66 years) [34], and in chronically-ill populations such as women with type-2 diabetes or with fibromyalgia [35,36]. However, to the best of our knowledge this is the first study to evaluate the effects of a Pilates training program on anxiety in healthy postmenopausal women. Our findings showed that women who enrolled in the Pilates training program experienced an improvement in anxiety after the intervention period when compared with the control group at the time of measurement.

Finally, reports concerning the effects of physical exercise in the improvement of fatigue symptoms are controversial. There is evidence that physical exercise reduces fatigue and related symptoms [37], but other studies have failed to find a significant association between exercise and fatigue [38]. A recent systematic review with a metaanalysis suggests that Pilates is effective in improving mental health outcomes such as anxiety, depression, or feelings of fatigue in older adults, although only a small number of

controlled trials with small sample sizes were included [39]. Improvements in fatigue after Pilates exercises have been reported in different populations [40,41], but although fatigue is common in postmenopausal women [8] limited research has looked into the matter concerning this population specifically. In the current study, participants who enrolled in the Pilates training program experienced an improvement in self-perceived fatigue after the intervention period, with a large size effect.

There are some limitations to this study that must be addressed: only the short-term effects have been evaluated and sleep quality was subjectively assessed. However, in the clinical setting self-reported questionnaires are widely used to diagnose and treat sleep disorders, thus enabling patients to receive adequate advice for the improvement of their sleep, health, and well-being. Furthermore, and although blinded to study hypotheses, participants were not blinded to the intervention because of the nature of the study, and the possibility of self-reporting bias remains. Future studies describing medium- and long-term effects should probably apply objective sleep measurements techniques such as actigraphy or polysomnography.

In conclusion, the present study conducted in Spanish postmenopausal women shows that a twelve-week Pilates-based training program has beneficial effects on sleep quality evaluated with the PSQI questionnaire, anxiety and depression evaluated by the HADS scale, and fatigue measured by the FSS scale.

Trial registration number

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Contributors

Agustín Aibar-Almazán participated in the study concept and design, data acquisition, interpretation of analyses, and preparation of the manuscript. Fidel Hita-Contreras participated in the study design and concept, interpretation of analyses, writing of the manuscript and critical revision of the paper. David Cruz-Díaz participated in the study design, interpretation of analyses and critical revision of its content. Manuel de la Torre-Cruz participated in data acquisition, interpretation of analyses, and critical revision of the paper. José D. Jiménez-García participated in in data acquisition and critical revision of the paper. Antonio Martínez-Amat participated in the study concept and design, data analysis, interpretation of analyses, preparation of the manuscript and critical revision of the paper. All authors approved the final manuscript.

Conflict of Interest

The authors have no conflicts of interest to declare.

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Data statement

The data that has been used is confidential. Due to the sensitive nature of the questions asked in this study, survey respondents were assured raw data would remain confidential and would not be shared.

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Figure 1. Flow diagram of study design.

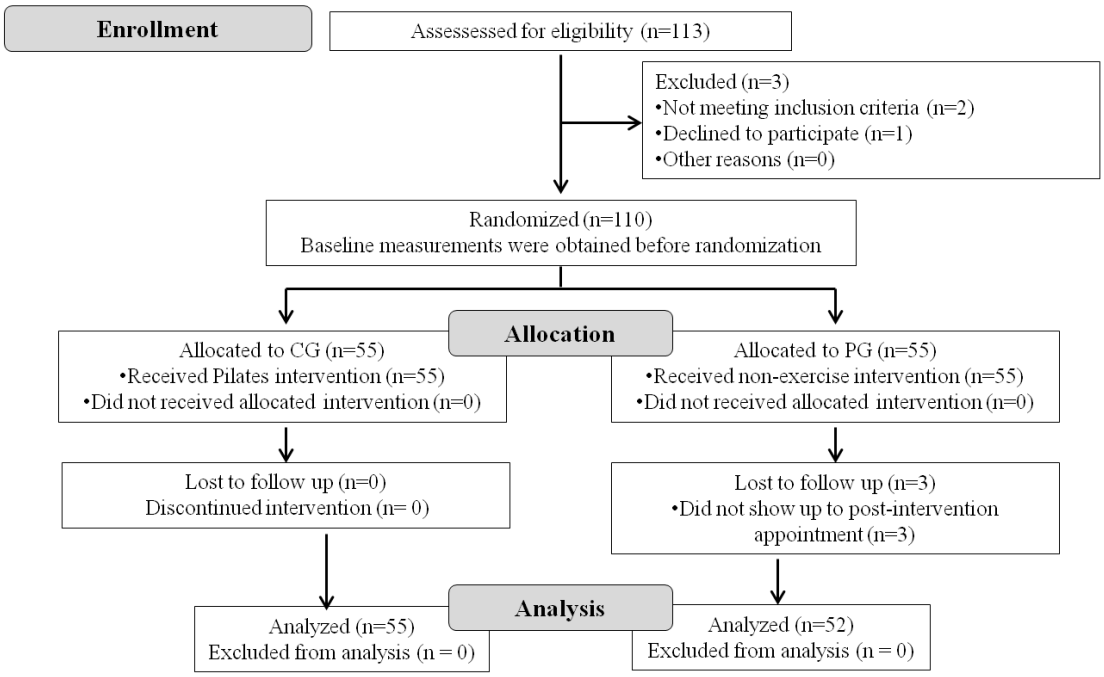

Figure 2. Between-group and within-group comparison of HADS scores. HADS: Hospital Anxiety and Depression scale. [a] $p<0.001$.

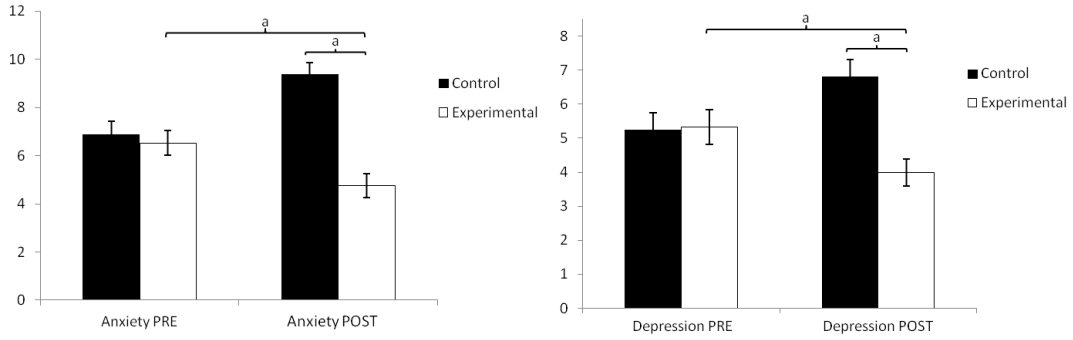

Figure 3. Between-group and within-group comparison of FSS scores. FSS: Fatigue Severity Scale. [a] $p<0.001$.

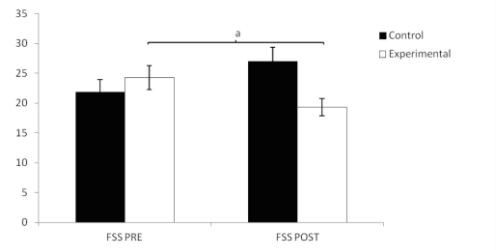

Table 1. Baseline characteristics of study participants.

		Total (n=107)	Control group (n=52)	Experimental group (n=55)	P-value
Age (years)		68.18±8.35	69.98±7.83	66.79 ±10.14	0.070
Years since menopause		20.40±9.34	20.47±7.75	17.38 ±10.43	0.084
BMI		29.40±4.54	28.62±4.44	30.17±4.55	0.074
PSQI	**Subjective sleep quality**	1.12±0.82	0.98±0.75	1.25±0.87	0.085
	Sleep latency	1.36±1.12	1.27±1.05	1.44±1.18	0.442
	Sleep duration	1.24±0.90	1.10±0.75	1.38±1.01	0.098
	Sleep efficiency	1.09±1.18	0.88±1.10	1.33±1.23	0.074
	Sleep disturbances	1.36±0.59	1.42±0.57	1.29±0.60	0.246
	Use of sleeping medication	1.05±1.33	0.85±1.27	1.24±1.37	0.131
	Daytime dysfunction	0.64±0.63	0.60±0.53	0.69±0.72	0.442
	Total score	7.85±4.75	7.10±4.42	8.56±4.98	0.110
Fatigue (FSS)		23.11±14.81	21.90±14.66	24.25±14.99	0.414
Anxiety (HADS)		6.71±4.08	6.90±3.77	6.53±4.39	0.636
Depression (HADS)		5.29±3.68	5.25±3.54	5.33±3.85	0.914

Variables are expressed as mean ± Standard Deviation.BMI: Body Mass Index. PSQI: Pittsburgh Sleep Quality Scale. FSS: Fatigue Severity Scale. HADS: Hospital Anxiety and Depression Scale.

Table 2. Effects of Pilates training on sleep quality assessed by PSQI.

	Preintervention		Postintervention		Group			Time			Group x time		
	CG	PG	CG	PG	$F(1,105)$	p	η^2	$F(1,105)$	p	η^2	$F(1,105)$	p	η^2
Sleep quality	0.98±0.75	1.25±0.87	1.08±0.71	1 .15±0.85[a]	1.28	0.26	0.012	0.048	0.828	0.00	11.99	<0.01	0.102
Sleep latency	1.27±1.05	1.44±1.18	1.54±1.06	1 .25±1.21[a]	0.075	0.79	0.001	0.88	0.35	0.008	23.39	<0.01	0.18
Sleep duration	1.10±0.75	1.38±1.01	1.54±0.73	1.00±0.84[a.b]	0.67	0.41	0.006	0.34	0.56	0.003	63.95	<0.01	0.379
Sleep efficiency	0.88±1.10	1.33±1.23	1.15±1.09	1 .04±1.23[a]	0.61	0.44	0.006	0.15	0.701	0.001	31.31	<0.01	0.23
Sleep disturbances	1.42±0.57	1.29±0.60	1.58± 0.57	1 .16±0.5[a.b]	6.98	<0.05	<0.062	0.15	0.696	0.001	17.22	<0.01	0.14
Use of sleeping medication	0.85±1.27	1.24±1.37	0.87±1.27	1 .02±1.31[a]	1.17	0.28	0.011	10.72	<0.01	0.093	15.27	<0.01	0.127
Daytime dysfunction	0.60±0.53	0.69±0.72	0.63±0.63	0 .55±0.63[a]	0.001	0.98	0.000	2.52	0.116	0.023	7.44	<0.01	0.066
Total score	7.10±4.42	8.56±4.98	8.38±4.28	7 .16±4.9[a]	0.028	0.87	0.000	0.455	0.502	0.004	123.99	<0.01	0.541

Data are expressed as mean ± standard deviation. PSQI: Pittsburgh Sleep Quality Scale. CG: Control Group. PG: Pilates Group. [a] Statistically significant intra-group difference from pre-intervention; [b] Statistically significant inter-group difference at post-intervention.