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Effect of the pilates method on people with osteoporosis: a systematic review

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ABSTRACT

Background: Aging process is a risk factor for the development of several diseases, including osteoporosis. Osteoporosis is a systemic skeletal disorder characterized by an increase in bone fragility that can result in fractures and considerably impact the lives of patients. As a means of preventing the onset of this disease or even reducing the impact of symptoms in cases where already exists, one can choose to practice physical exercises. The Pilates method was developed by Joseph Pilates with the aim of working mind, body awareness, postural control and movements through a single approach. **Objectives:** The aim of this study was to review in the available literature the effects of the Pilates method on people with osteoporosis. **Methods:** This is a systematic review of literature carried out through a comprehensive strategy in the databases PubMed, Cochrane, SciELO, Web of Science, Cinahl and Embase in August 2020. **Results:** Five studies, three clinical trials and 2 studies Observational studies, published between 2012 and 2020, were included in the review. Of a total of 210 participants, all were female and an average age of 61 years. The main factors evaluated in the studies were bone mineral density, pain, functionality and quality of life. **Conclusion:** The Pilates method was associated with pain relief, improved functionality and quality of life, and obtaining bone mineral density in women with osteoporosis.

Keywords: Osteoporosis; Exercise Movement Techniques; Exercise.

BACKGROUND

The aging process is associated with the reduction, alteration or loss of physiological processes and anatomical structures, such as changes in blood pressure, changes in gait and posture dynamics and increased risk of mortality⁽¹⁾. In addition, old age is considered a risk factor for several diseases, such as dementias, cardiovascular diseases, rheumatic diseases, and others, including osteoporosis⁽²⁾.

Osteoporosis is a systemic skeletal disorder that is characterized by increased bone fragility due to reduced bone mineral density (BMD) and deformed bone tissue microstructure, which can result in fractures, most commonly in vertebrae, femur and radius^(3,4).

This disease is a public health problem, as it can result in fractures and impact both economic and social aspects on the lives of patients, in addition to considerably affecting the performance of activities of daily living (ADL), their functionality and quality of life. (QOL)^(5,6). In order to reduce the risk of developing osteoporosis, as well as the use of drugs, one can choose to maintain an adequate lifestyle, containing, for example, the practice of physical exercise plus a diet rich in calcium, adequate intake vitamin D, sufficient exposure to the sun and smoking cessation and alcoholism⁽⁷⁾.

The Pilates method was developed by Joseph Pilates in order to improve the general flexibility of the body and health, through strength gain, improved posture and coordination of breathing through movement, that is, working mind, body awareness, postural control and movements through a single approach^(8,9), in which specialized devices may or may not be used⁽⁹⁾. This method is based on 8 principles, which are (1) control, (2) breathing, (3) fluid movement, (4) precision, (5) stability, (6) centering, (7) range of motion and (8) opposition⁽¹⁰⁾.

Initially, the Pilates method was widely used by athletes and dancers and although it is considered part of the activities developed by healthy individuals, this method has also been recommended as a therapeutic approach⁽¹¹⁾, since it has beneficial effects not only on musculoskeletal disorders, but also in the acquisition of personal autonomy, static and dynamic balance, and quality of life⁽¹²⁾. Therefore, the present study aims to review in the available literature the effects of the Pilates method in people with osteoporosis.

METHODS

Search strategy

The methodology of this review followed the items proposed by the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guideline⁽¹³⁾ and Cochrane Handbook⁽¹⁴⁾. The studies that compose it were sought through a comprehensive strategy, carried out in the PubMed databases; Cochrane; SciELO (Scientific Eletronic Library Online); Web of Science; Cinahl; and Embase, in August 2020.

Search source

The search strategy was carried out using keywords selected based on the headings of the Medical Subject (MESH) of the United States National Library of Medicine.

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For each database, a specific strategy was developed with descriptors to search for subjects in the databases.

For the PubMed database, the following strategy was used: ((Pilates[Title/Abstract] OR "Pilates method"[Title/Abstract] "Pilates OR technique"[Title/Abstract] OR "Exercise Movement Techniques/methods"[Majr] OR "Exercise Movement Techniques/therapeutic use"[Majr] OR "Exercise Movement Techniques/therapy"[Majr] OR "Pilates-Based Exercises"[Title/Abstract] OR "Pilates Based Exercises"[Title/Abstract] OR "Pilates Training"[Title/Abstract]) AND (Osteoporosis[MeSH Major Topic]).

For the Cochrane database we used: (Pilates OR "Pilates method" OR "Pilates technique" OR "Pilates-Based Exercises" OR "Pilates Based Exercises" OR "Pilates Training" OR "Exercise Movement Techniques") in Title Abstract Keyword AND "Osteoporosis" in Title Abstract Keyword - in Trials. For the Scielo database: (osteoporose) AND (técnicas de exercício e de movimento) OR (método Pilates); for the Web of Science we used: TS= (Pilates OR "Pilates method" OR "Pilates technique" OR "Pilates-Based Exercises" OR "Pilates Based Exercises" OR "Pilates Training" OR "Exercise Movement Techniques") and TS=("Osteoporosis"). For the Ebsco database: (pilates OR pilates method OR pilates exercise OR exercise movement techniques) and (osteoporosis OR bone loss).

Types of studies and participants

The inclusion criteria for the study were: randomized clinical trials; who used the Pilates training method as their primary intervention; and studies conducted with people with a clinical diagnosis of osteoporosis.

The exclusion criteria, in turn, were: studies that do not address the themes osteoporosis and Pilates; studies in which the Pilates Method has been combined with other methods in the intervention group; other systematic review studies, meta-analysis, theses or dissertations; studies not available in full; and duplicate publications.

Data extraction

The articles found were initially selected by title and abstract; those eligible were selected for full reading. The articles that fit the criteria of this study had the data extracted to a standardized and predefined Excel spreadsheet. The data extracted from the studies included, but were not limited to, variables related to the details of the publication (such as year, first author, objectives), study design, characteristics of the participants, characteristics of the exercise, among others.

Quality assessment

The risk of bias was analyzed using the Risk of Bias in Systematic Reviews (ROBIS) and the Newcastle-Ottawa scale.

ROBIS is the tool for risk assessment of bias in randomized clinical trials from the Cochrane collaboration⁽¹⁵⁾. For each study included, the following items were evaluated: (1) selection bias; (2) performance bias; (3) detection bias; (4) attrition bias; (5) reporting bias; (6) other sources of bias; and for each item a low risk, high risk or uncertain bias risk can be assigned.

For Newcastle-Ottawa⁽¹⁶⁾ graduation is done through a system where 0 to 10 stars can be assigned, distributed among the domains: selection, comparability and result, and the study is classified as high quality when methods are suitable in all three domains. Studies were not excluded based on their quality.

RESULTS

The search strategies initially resulted in 1.095 studies. After removing duplicate studies and analyzing the inclusion and exclusion criteria, 27 studies were selected for full reading and 5 studies were considered eligible to be included in this review (figure 1).



Figure 1. Study Flowchart



The studies were published between 2012 and 2020. Of the 05 eligible studies, three are randomized controlled trials and two observational studies. The samples had an average of 23 participants, all of them

female. The average age of the participants was 61 ± 6.5 years, and the duration of the studies ranged from 6 to 48 weeks (table 1).

Table 1. Characteristics o	f studies
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Year	First author	Objectives	Type of study	Sample	Age (Years)	Genre	Duration of intervention (weeks)	Results
2012	Küçükçakir.	To evaluate the effects of Pilates exercises on pain and QOL of postmenopausal patients with osteoporosis	Randomized clinical trial	67	45-65	F	48	Improvement in all evaluation parameters in the Pilates group, suggesting a beneficial effect on pain, functional capacity and QOL.
2015	Angin.	To determine the effects of Pilates on BMD, physical performance and QOL of postmenopausal women with osteoporosis, compared to the control group	Randomized clinical trial	41	40-69	F	24	Better QOL was observed in the Pilates group, while the control group showed worsening the parameters, pain daily life, housework, mobility and health in general
2017	Oksuz.	To investigate the effects of Pilates on kinesiophobia and other symptoms related to osteoporosis	Randomized clinical trial	40	50-75	F	6	Positive effects of Pilates exercises were observed on kinesiophobia, pain, functionality and QOL in patients compared to the control group.
2015	Mikalacki.	To evaluate the differences in BMD of the right and left calcaneus of a sample of adult women submitted to Pilates program	Observational	22	48,18 ± 9,59	F	24	No changes in BMD, but BUA increased in the sound velocity of the right leg decreased, which implies a better level of bone strength
2020	Gandolfi.	To evaluate the effect of the Pilates method on QOL and bone remodeling markers in a group of elderly women	Observational	40	60 anos or more	F	20	The Pilates exercise program was associated with improved QOL, with no changes in bone remodeling markers

***Note:** QOL: Quality of life; BMD: Bone mineral density; BUA: broadband ultrasonic attenuation; F: female; M: male.

Among the characteristics of the Pilates intervention, the type of exercise included Clinical Pilates; most of them had a physical therapist as an instructor. Only one study reported whether the session was conducted individually or in a group. Interventions averaged 2.4 sessions per week, with each session averaging 55 minutes in duration (table 2).





Table 2. Characteristics of Pilates exercise intervention

Year	First author	Type of Pilates Exercise	Instructor	Type of session	Number of sessions per week	Duration of session (minutes)
		Postural,				60
2012	Küçükçakir.	proprioceptive and	Physiotherapist	-	2	
		stretching exercises				
2015	Angin.	Clinical Pilates	Physiotherapist	Group	3	60
2017	Oksuz.	Clinical Pilates	-	-	3	60
2015	Mikalacki.	-	-	-	2	45
2020	Gandolfi.	Sessions of PEBPM.	Physiotherapist	-	1	50

*Note: PEBPM: pré-Pilates activity; Mat Pilates; aparelho Cadillac, Reformer, Chair, Barrel e Spine Corrector.

In the control groups, two studies did not perform any intervention, in one study the participants

performed exercise at home and one study did not report whether an intervention was performed (table 3).

Table 3. Characteristics of control group.

Year	First author	Type of Pilates Exercise	Instructor	Type of session	Protocol duration	Number of sessions per week	Duration of session (minutes)
2012	Küçükçakir.	Thoracic extension exercise	Physiotherapist	Individual	1 year	NI	30 min.
2015	Angin.	NI	NA	NA	NA	NA	NA
2017	Oksuz.	NI	NA	NA	NA	NA	NA
2015	Mikalacki.	NI	NI	NI	NI	NI	NI
2020	Gandolfi.	NI	NI	NI	NI	NI	NI

***Note:** NI: no intervention; NA: not applicable.

Two studies evaluated bone mineral density (BMD), which showed an average of 0.49 ± 0.09 in the experimental groups at the beginning of the study, and an average of 0.50 ± 0.08 at the end. Only one of these studies measured BMD in the control group, which showed 0.68 ± 0.52 at the beginning of the experiment and 0.65 ± 0.07 at the end, showing loss of BMD.

Pain measurement was performed by two authors, who showed a mean of 3.39 ± 0.85 before intervention and 0.40 ± 0.70 after intervention in the experimental group, and a mean of 3.74 ± 1.77 before intervention. and 3.24 ± 1.83 after intervention in the control group, showing improvement in pain in the experimental group. In addition, two authors performed the 6-minute walk test. The mean was 400.3 ± 79.4 meters before intervention and 471.2 ± 76.8 meters after intervention in the experimental group, in contrast to 386.2 ± 89.8 meters at the beginning of the study and 398.6 ± 89, 8 meters at the end of the study in the control group, showing improvement in functionality.

Two studies used the Quality of Life Questionnaire of the European Foundation for Osteoporosis-41 scale (table 4) to analyze the participants' quality of life, and three studies used the SF-36 scale (table 5).

The Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALFFFO-41) is specific to osteoporosis and covers five health domains: (1) pain, (2) physical function, (3) social function, (4) general health and (5) mental function, divided into subdomains such as physical activities of daily living, pain, physical function, mental function, among others. The score is calculated by adding the subdomains, which can reach a maximum of 100 points, with a score of 0 indicating excellent health status and a score of 100 indicating poor health status⁽¹⁷⁾.



	Pain	ı fu	Physi Inction live	cal - daily e	Phy funct dom acti	sical tion – estic ivity	Phy funct mol	sical tion — pility	So fund	cial ction	Ge healtl	neral n status	Ⅳ fu	lental nction	T Si	otal core
First author	х	SD	Х	SD	Х	SD	Х	SD	Х	SD	Х	SD	х	SD	X	SD
Küçükçakir.	40, 8	21	15,9	12,4	30,7	18,1	23,3	14,8	57,7	21,8	61,7	21,1	43,5	15	39, 4	12, 1
Angin.	53, 7	12, 8	78,9 4	10,0 4	58,4 2	9,44	84,4 3	8,2	29,2 9	16,6 3	29,3	12,9 9	53,9 2	10,1 9	NI	NI
Oksuz.	NI	NI	NI	NI	NI	NI	NI	NI	NI	NI	NI	NI	NI	NI	NI	NI
Final – Control																
Küçükçakir.	36 <i>,</i> 5	17	9,8	11,1	24,7	17,1	19,8	13,9	55,5	18	51,9	18,7	38,8	15,5	33, 6	11, 4
Angin.	56, 8	15, 2	81,2 4	10,8 2	60,7 9	10,8 4	85,1 1	12,8 3	30,9 4	18,4 2	32,3 8	15,3 2	54,9 4	10,5 3	NI	NI
Oksuz.	0,5	2,7 6	0,81	1,94	0	0	0	0	0	0	1,25	3,05	0,83	2,4	0,6 9	1,2 5
Initial - Experimental																
Küçükçakir.	41, 2	19	17,1	11,6	32,8	16,4	25	13,9	62,9	18,5	62,2	19,3	45,7	15,9	40, 7	11, 5
Angin.	77, 1	10, 3	89,2 8	6,83	73,1 4	11,7 2	84,4 3	8,2	62,0 1	12,2 2	52,0 5	9,24	60,2	10,1 9	NI	NI
Oksuz.	NI	NI	NI	NI	NI	NI	NI	NI	NI	NI	NI	NI	NI	NI	NI	NI
Final - Experimental																
Küçükçakir.	17, 8	14, 7	1,7	3,6	7,3	8,2	8,2	9,2	23	17,1	26,9	11,7	19,3	13,7	14, 8	9,1
Angin.	63, 2	12, 3	81,6	13,7 9	62,2 7	15,4 7	73,1 2	13,2 2	39,9 8	14,8 1	35,0 7	12,8 3	51,9 5	10,0 9	NI	NI
Oksuz.	11	14, 1	6,54	4,23	0	0	0	0	9,36	9,3	5,83	5,47	6,81	6,4	6,9	3,8 2

Table 4. Data of Quality of Life Questionnaire of the European Foundation for Osteoporosis

*Note: X: mean; SD: standard deviation; NI: not informed.





Table 5. Data of Short-Form-36

	Phy fund	Physical function		Physical limitation		Pain		Social Function		Mental health		ional ation	Vitality		General Health	
First author	х	SD	Х	SD	Х	SD	х	SD	х	SD	Х	SD	х	SD	х	SD
Küçükçakir.	60,3	22,6	61,7	44,4	45,7	16,3	63,5	17,7	59,9	17,5	68,9	41	50,2	20, 5	43, 8	17,8
Gandolfi.	57,9	22,3	36,8	49,6	50	6,7	49,3	15,3	68,2	21,2	31,6	47,8	65,3	21	68, 9	16,5
Final – Control Group																
Küçükçakir.	67,8	21,1	66,7	40,1	53	16	70,6	17,9	67,5	17,4	73,4	36,5	54,5	21, 8	51, 3	16,8
Gandolfi.	55,5	20,8 3	41,2 5	46,7 9	46,5	4,89	50	15,7 1	64,2	21,5	48,33	50,1 2	60,3	21, 4	71	11
Initial – Experimental Group																
Küçükçakir.	58,3	20,1	51,7	35,9	42,3	15,5	61,5	18,4	57,3	16,7	60	34,4	46,8	20, 7	42, 3	17,6
Gandolfi.	67,5	18,8 8	67,5	39,8 2	51	6,41	46,8 8	13,3 7	70,6	24,4	65	45,2 1	68	21, 6	75, 5	9,45
Final – Experimental Group																
Küçükçakir.	85,3	14	88,3	26	70,7	16,2	76,1	15,7	73,9	16	87,8	28,3	68,3	18, 2	69, 5	11,8
Gandolfi.	86,2 5	9,58	100	0	50,5	5,1	42,5	13,6 9	79,8	19,3	100	0	82,5	14, 3	79, 25	6,34

*Note: X: Mean; SD: Standard deviation

The Short-Form-36 questionnaire (SF-36) is a generic scale widely used to assess quality of life because it is not specific for any age, treatment group or disease. It assesses general health concepts through 36 items, which are: physical functioning (10 items), physical performance limitation (4 items), emotional limitation (3 items), pain (2 items), social participation (2 items), health mental (5 items), vitality (4 items) and general health (5 items). The score ranges from 0 (bad) to 100 (good)⁽¹⁸⁾.

Küçükçaık et al.⁽¹⁸⁾(2012) demonstrated a total score through the initial QUALEFFO-41 of 40.7 ± 11.5 and

final of 14.8 \pm 9.1, showing an improvement in the quality of life of the members of the experimental group. Angin et al.⁽¹⁹⁾ did not demonstrate the total score in their study, however it showed improvement in all domains of the questionnaire in the experimental group. Oksuz and Unal⁽²⁰⁾ did not provide in their study the initial values of the experimental and control groups for comparison.

Küçükçakir, et al.⁽¹⁸⁾ demonstrated improvement in all domains of the SF-36 questionnaire in the experimental group at the end of the study; and Gandolfi et al.⁽²¹⁾ demonstrated improvement in all domains,



except for body pain and social functioning in the experimental group.

The risk of bias by the ROBIS tool (table 6) showed a low risk of bias in four domains (performance bias, attrition, reports and other biases), a

predominantly uncertain risk in 3 domains (selection and detection bias) (figure 2). Two studies were evaluated using the Newcastle-Ottawa scale, with scores of 6 and 7 stars, showing good methodological quality since it is a scale in which the maximum score is 10 stars (table 6, 7).



Figure 2. "Bias Risk" graph: judgments by the reviewer about each bias risk item in the included studies being presented as a percentage

Table 0. Could all Collaboration Randomized Chiller Thats Dias Risk Assesment To	Table 6.	Cochrane	Collaboration	Randomized	Clinical 1	Frials Bias	Risk A	Assesment T	00
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Author	RoB 1 Random sequence generator (selection bias)	RoB 2 Allocation cancealment (selection bias)	RoB 3 Blinding patients and staff (performance bias)	RoB 4 blinding researchers (detection bias)	RoB 5 Incomplete results data (bias friction)	RoB 6 Selective reporto f results (reporting bias)	RoB 7 Other Bias
Küçükçakir.	Low risk	Uncertain risk	Low risk	Uncertain risk	Low risk	Low risk	Low risk
Angin.	Uncertain risk	Uncertain risk	Low risk	Uncertain risk	Low risk	Low risk	Low risk
Oksuz.	Uncertain risk	High risk	Low risk	Low risk	Low risk	Low risk	Low risk

Table 7. Newcaltle-Ottawa Scale

Author	Repre	sentativ	eness of	the sample		Сог	Comparability Results			ults			
	Represen Sample tativenes size s of the sample			Non- Assessment of respond exposure (risk ents factor)			Subjects in different outcomes groups are comparable, based on study design or analysis, confounding factors are controlled		Result evaluation		atistic st	-	
	ran dom sam ple	Non- rand om sam ple	Justif ied and satisf actor y	Compar ability betwee n respond ents and non- respond ents is stablish ed	Validate d measur ement tool	Measure ment too not validated, but available or described	Control for most importa nt factor	Control for any additio nal factor	Blinde d evalu ation	Link to self- repor t regist ry	Self- repo rt	Statisti cal test clearly describ ed and approp riate	
Mikalacki.		*	*		**						*	*	****
Gandolfi.		*	*	*	**		*					*	** ****





DISCUSSION

During aging, the body's physiological processes deteriorate⁽²²⁾, resulting in progressive loss of physiological integrity and reduced organ and tissue function⁽²³⁾. One of the most common causes of osteoporosis is the lack of estrogen, which makes it common for women in menopause to be diagnosed with the disease. 30% to 50% of women over 50 years of age are diagnosed with osteopenia, and 17% to 20%.

In all eligible studies, 100% of the participants were female (table 1). This is because hormonal changes that occur during menopause cause greater resorption to the detriment of bone formation, causing a reduction in BMD. When this process occurs in an intense way, there is the appearance of osteoporosis⁽²⁴⁾.

Individuals with osteoporosis are more likely to experience falls, further increasing the chance of fractures and therefore exercise modalities that improve overall muscle strength and postural stability are beneficial. The main goals in its treatment include preventing fractures by increasing BMD, preventing falls, relieving pain, increasing functionality and consequently improving quality of life⁽¹⁸⁾.

The Pilates Method is related to the improvement in BMD due to the application of mechanical force to the bones during exercise, stimulating osteoblastic activity⁽²⁵⁾, and can thus be considered a means for preventing fractures^(19, 26). In addition to the benefits for bone tissue, regular physical exercise has beneficial effects on pain, functionality, balance and quality of life⁽²⁷⁾. Angin et al.⁽¹⁹⁾ in their study evaluated the effects of Pilates exercises in patients with osteoporosis. All participants underwent a 6-minute walk test to assess physical performance; a significant increase in the distance covered by the Pilates group was observed at the end of the experiment while there were no changes in the control group, indicating an improvement in the physical performance of the members of the Pilates group. In addition, pain was assessed using the Visual Analogue Scale (VAS) and a significant reduction in pain scores was observed in the Pilates group.

Mikalacki et al. ⁽²⁸⁾ observed a better level of bone resistance in the experimental group after intervention with Pilates method exercises, indicating that it has a beneficial effect on bone tissue, and therefore can be recommended as a means to prevent bone loss in aging.

Oskuz et al.⁽²⁰⁾ reported a significant reduction in pain in the Pilates group compared to the control group. According to them, the participants' pain resulted in a decline in the performance of the ADLs and after the Pilates exercise program, the participants had their pain controlled and developed body awareness, thus reducing their disability. In addition, positive effects of the Pilates Method have been demonstrated in individuals with osteoporosis on kinesiophobia, balance, strength, flexibility, levels of anxiety and depression.

Low physical performance, as well as chronic pain, can lead to limitations in carrying out activities of daily living and reduced functionality, thus generating psychological problems and a consequent reduction in quality of life⁽²⁰⁾.

Küçükçaık et al.⁽¹⁸⁾ suggested that a Pilates Method exercise program has beneficial effects on pain, functionality and quality of life in postmenopausal women with osteoporosis.

The study by Angin et al.⁽¹⁹⁾ reported positive effects on the quality of life of participants in the Pilates group observed by the QUALEFFO-41 questionnaire. It was reported that, in addition to the physical benefits that provide QoL gain, group exercises increase the motivation of practitioners and enable interactivity, thus providing mental well-being. Oskuz et al.⁽²⁰⁾. evaluated the effects on quality of life in the same way as Angin et al.⁽¹⁹⁾ and showed improvement in all scores on the QUALEFFO-41 scale in 6 weeks of experiment.

Factors such as pain, loss of functionality, social isolation and emotional disturbances can negatively and significantly affect quality of life and mental health, leading the patient to have feelings such as lack of self-confidence, worthlessness and depression^(18,29).

Gandolfi et al.⁽²¹⁾ showed that a Pilates exercise program, applied to a group of elderly women, was associated with an improvement in quality of life, functionality and emotional component, reinforcing the idea that the Pilates method improves quality of life of elderly women.

The practice of physical exercise has been associated with maintenance and even the acquisition of independence by the elderly⁽³⁰⁾. In addition, drug and surgical treatments for osteoporosis can generate a significant increase in patients' expenses⁽³¹⁾. Therefore, simpler alternative treatment strategies with minimal or even nonexistent side effects are gaining popularity⁽¹⁸⁾.

The Pilates Method can be a means of preventing or mitigating physiological changes resulting from aging, such as loss of bone mass, balance, muscle strength and flexibility, as it is associated with injury prevention, improvement of balance, posture and psychological status in individuals Older ⁽³²⁾.

CONCLUSION

Pilates exercises have been associated with pain relief, increased functionality, improved quality of life



and bone mineral density in postmenopausal women with osteoporosis.

Authors' contribution: RSBR and MLS contributed to the elaboration of the design of the study; RSBR, VSR, LBR, MLS development of the study and data acquisition. RSBR, VSR, LBR, MLS contributed to article design and data tabulation. RSBR, VSR, LBR, MLS contributed to the critical review, correction and approval of the final version.

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