Randomized Control Trial

Effect of Different Frequencies of Electroacupuncture on Chronic Low Back Pain in Older Adults: A Triple-blind, Placebo-controlled, Randomized Clinical Trial

Sarina Francescato Torres, MD[1], Ana Carolina Brandt de Macedo, PhD[2], Regina Yassue Sakai, Esp[3], Gabriele Cristina Seguro Bressan, BS[2], Matheus Bieberbach Rodrigues dos Santos, BS[2], and Amelia Pasqual Marques, PhD[1]

From: [1]Department of Physical Therapy, University of Sao Paulo, School of Medicine, Sao Paulo, Brazil; [2]Federal University of Parana, Department of Physical Therapy Prevention and Rehabilitation, Curitiba, Parana, Brazil; [3]Inspirar College, Department of Acupuncture, Curitiba, Parana, Brazil

Address Correspondence: Sarina Francescato Torres, MD Postgraduate Programme in Rehabilitation Sciences. Department of Physical Therapy, Speech Therapy, and Occupational Therapy University of São Paulo Rua das Pirararas, 101/101 Bairro Santa Branca. CEP: 37559-540 Pouso Alegre-MG. Brazil E-mail: sarinaftorres@usp.br

Disclaimer: This study was financed in part by the Coordination for the Inprovement of Higher Education Personnel - Brazil (CAPES) - Finance Code 001.

Conflict of interest: Each author certifies that he or she, or a member of his or her immediate family, has no commercial association (i.e., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted manuscript.

Manuscript received: 08-18-2022
Revised manuscript received: 11-11-2022
Accepted for publication: 11-16-2022

Free full manuscript: www.painphysicianjournal.com

Background: Acupuncture is one of the most widely used therapies to treat chronic low back pain, whose analgesic effect seems to be potentiated by the addition of electric current (electroacupuncture). However, we are not aware of any clinical trial that has evaluated the effectiveness of this technique in adults > 65 years.

Objective: To evaluate the effect of electroacupuncture in the treatment of chronic low back pain in the elderly.

Study Design: Triple-blind, controlled, and randomized clinical trial.

Setting: Faculty of Medicine, University of São Paulo (USP); Sector of Biological Sciences - Physiotherapy Course, Federal University of Paraná (UFPR).

Methods: The study included 125 elderly people with chronic nonspecific low back pain who were randomized to one of 5 study groups: 3 of electroacupuncture; one control; and one placebo, all of them treated for 5 weeks. The primary endpoint was pain intensity, and secondary endpoints included the qualitative aspect of pain, functional disability (Roland-Morris and sit and stand test), emotional functioning (depression and anxiety), and psychosocial factors. Data analysis followed the intention-to-treat principle. The confidence interval was set at 95% and the significance level at 5%.

Results: All groups achieved a reduction in pain intensity; however, a significant difference was only detected between electroacupuncture and placebo, where the latter showed greater pain reduction. Regarding secondary outcomes, all groups showed good posttreatment results for all assessments but without statistical significance. Among the groups, the placebo was the one that obtained the best results between the pre- and post-treatment for depression, qualitative aspect of pain, and functional disability, but only for the qualitative aspect of pain and for the sit-and-stand test was a significant reduction found in the intergroup comparison. The analysis of the overall effect perceived by the participants in relation to low back pain revealed that individuals from all groups felt close to full recovery.

Limitations: Absence of follow-up and a relatively small number of patients.

Conclusions: This study provides evidence that there is no one frequency of electroacupuncture that is most effective in treating chronic low back pain in the elderly and that electroacupuncture is not superior to manual acupuncture or placebo treatment.

Key words: Electroacupuncture, acupuncture, low back pain, aged, health of the elderly, rehabilitation, clinical trial, interdisciplinary research

Clinical trials registration: NCT03802045 (January 2019).

Pain Physician 2023: 26:161-173

In the last 5 decades, the number of aging populations has tripled, and it is predicted that by 2050 around 25% of the global population will be people aged 60 and over (1-3).

Among the chronic pain affecting this age group, lower back pain (LBP) is described as the most frequent (4-7). Its prevalence in these individuals ranges from 20% to 50%, increasing exponentially from 60 years of age onwards and stabilizing at around 70-80 years of age (8-10).

These figures are worrying, since data from the Global Burden of Disease Study (11) show that LBP is the main cause of years lived with disability, and is also associated with kinesiophobia, reduced mobility, limitation of daily activities, absenteeism from work, early retirement, poor quality of life and premature death, generating a great impact on the social, health and welfare systems of several countries (5,12-20).

Furthermore, this condition is also a risk factor for the abuse of analgesics in the elderly, with up to 70% of these individuals making daily use of these medications for their treatment, often without a medical prescription (5). The use of drugs in the elderly has lower efficacy and more severe adverse reactions; there is also an association between the use of these substances and the development of comorbidities and harmful outcomes, such as falls (4-6). For these reasons, the most recent guidelines recommend non-pharmacological therapies such as acupuncture (4-6) as the first option for the treatment of chronic lower back pain (CLBP) in this age group.

Acupuncture is a widely used technique for the treatment of CLBP in adults because it is safe, low cost, quick to apply, has rare side effects, and is easy to handle. And electroacupuncture (EA), which is acupuncture plus electrical current, has shown the potential to intensify and prolong the therapeutic effect of acupuncture by dosing different frequencies and intensities of electrical stimulation in the needle (21-23).

As treatments considered suitable for adults are often not suitable for older adults, given the specific physiological particularities of this population, the evaluation of safer, effective, and low-cost non-pharmacological techniques for the treatment of CLBP in older adults is a research priority (24).

Electroacupuncture shows great potential in this regard but still needs clinical trials of good methodological quality that explore the relationship between the dosage of frequency of electroacupuncture with its therapeutic efficacy since this is as important for acupuncture as it is for pharmacological agents; however, to date, there is no scientific evidence on the therapeutic effectiveness of this technique for the aging population (10,15,21,24,25). Thus, this study aimed to evaluate the effect of different frequencies of electroacupuncture in the treatment of chronic and nonspecific lower back pain in older people compared with acupuncture and placebo.

Methods

A controlled, randomized, triple-blind clinical trial was conducted in 2 Brazilian states.

The research protocol was published (26) and developed following the recommendations of the STRICTA and IMMPACT for clinical trials of treatment effectiveness for chronic pain (27-29). The research was approved by the Research Ethics Committee of the School of Medicine of the University of São Paulo, Brazil (CAAE: 89846118.7.0000.0065; Opinion: 2,903,991). All patients signed the free and informed consent form.

The sample, defined by sample calculation (26), was composed of 125 individuals of both genders, aged 60 years and older, who were recruited from the community using media such as radio, the WhatsApp application, social networks, and leafleting. The individuals should present CLBP of nonspecific origin (without identified cause), proven by medical statement (11), with or without referred pain to the lower limbs, and lasting for at least 3 months. Other inclusion criteria were: presenting pain equal to or greater than 4 (moderate pain) on the Numeric Pain Rating Scale (7,30); having independent ambulation with or without a gait aid device, and being literate. Exclusion criteria were: previous spinal surgery; diagnosis of severe spinal pathology (e.g., cancer, vertebral fracture, spinal infection, and compression of the cauda equina); fear of needles; acupuncture treatment in the last 30 days; wheelchair users.

Randomization and Grouping

The randomization of the patients was performed in blocks of 5 (31). After the numbers were generated, they were placed in sealed and serially numbered brown envelopes. Subsequently, they were delivered to the acupuncturists and opened according to their numerical sequence immediately before the first appointment. The person responsible for randomizing the research patients was not involved in any evaluation or data collection of this study (Fig. 1).

Patients were then equally distributed into 5 groups: (1) high frequency electroacupuncture (HFEA)

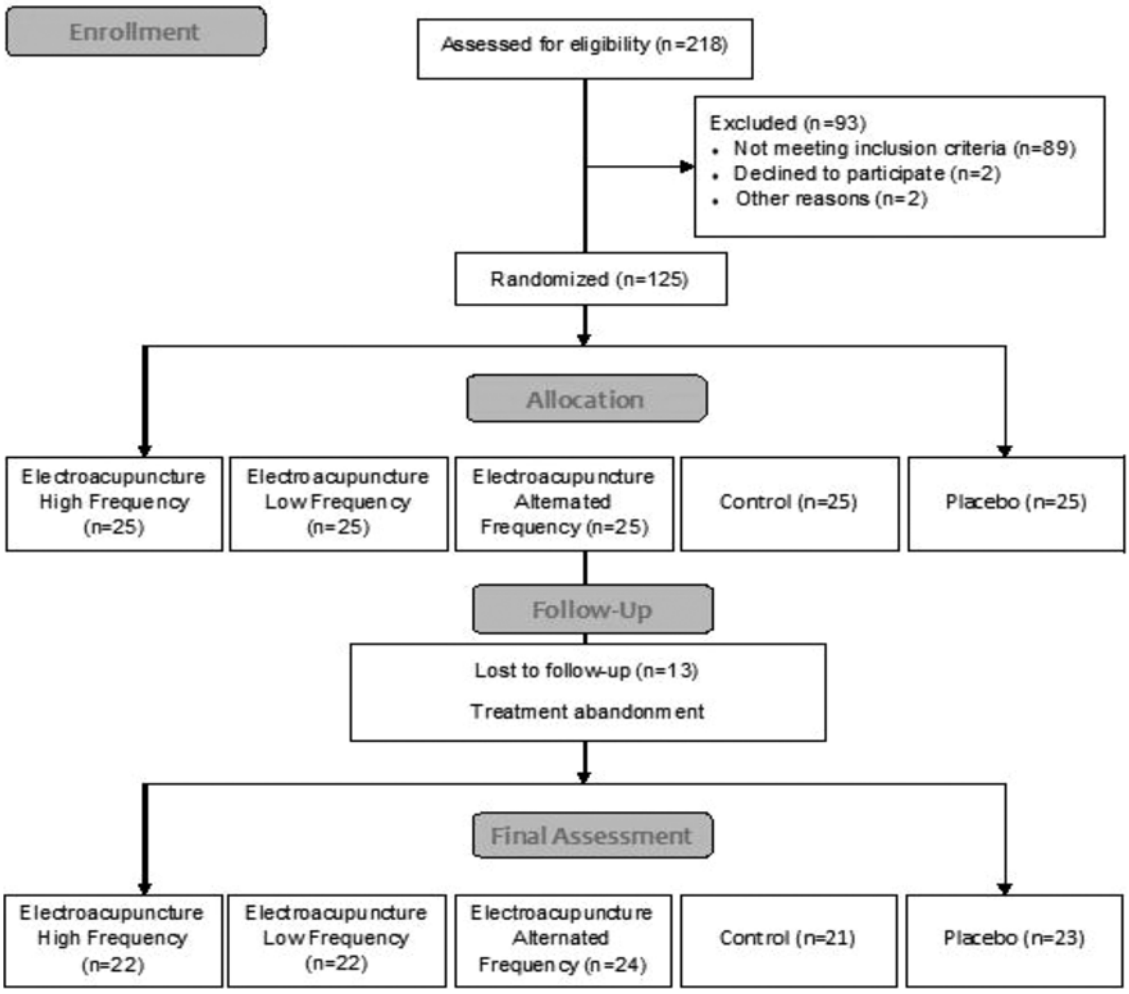

Fig. 1. *Flow diagram of study design.*

with 100 Hz; (2) low frequency electroacupuncture (LFEA) with 2 Hz; (3) alternating frequency electroacupuncture (AFEA) with 100 Hz and 2 Hz alternated for 3 seconds each; (4) control (C) no electrical stimulation; and (5) placebo (P) without electrical stimulation and that received an adhesive moxa (Dong Yang®) over each acupoint where the needle was inserted over it so that the participant only felt the needle prick, but without the skin perforation (32). In addition, as in the control group, the electrodes were connected to the needles, but no electrical current was applied (32).

The ideal placebo group should be unable to differentiate actual intervention from placebo. Thus, to ensure the effectiveness of this group, at the final evaluation, patients were asked to answer the questions, "Did you feel that the needle penetrated the skin?" and "Do you think you have undergone actual acupuncture treatment?" A significant percentage of "no" responses may suggest that the placebo effect was insufficient (33).

Blinding

The patients, researchers, and statisticians remained blind during all phases of the research. The acupuncturists, because they were responsible for the interventions, were the only ones who were not blind.

Outcomes

The primary outcome was pain intensity, assessed by the Numeric Pain Rating Scale (NPRS) (17,34,35).

The secondary outcomes included: the qualitative

aspect of pain, assessed with the McGill Pain Questionnaire validated for Brazilian Portuguese. The secondary outcomes included: the qualitative aspect of pain (36,37); the functional disability, assessed using the Roland Morris Disability Questionnaire (RMDQ) and the Five Times Sit-to-Stand Test (FTSST); the emotional functioning, assessed using the Beck Depression Inventory (BDI) (38) and the Visual Analog Scale (VAS) for global anxiety (25); and the psychosocial factors analyzed using the StarT Back Screening Tool (SBST).

At the end of the treatment, the patient's perception of improvement with the treatment was also evaluated using the Global Perceived Effect (GPE) scale (39).

Symptoms and Adverse Events

At each visit, the patients answered a questionnaire about the presence, duration, and intensity of adverse symptom(s) related to the treatment performed, which was scored using a Likert scale from 1 (no symptoms) to 5 (very severe symptoms). If there were severe or very severe adverse symptoms, this would be referred for medical evaluation, and it would be the individual's choice whether or not to continue with the treatment.

Interventions

The interventions were performed by 2 acupuncture specialists with at least 6 years of clinical experience and were in accordance with the principles of Traditional Chinese Medicine (TCM) (40).

The treatment protocol consisted of the bilateral application of electroacupuncture, using 2 previously calibrated devices, the Sikuro DS100C and the Accurate Pulse 585, with pulse width of 0.5 ms and a current intensity (amplitude) adjusted so as to avoid sensory habituation (41,42). Sterile, disposable stainless steel needles (0.25 mm x 30 mm, Dong Bang Acupuncture Inc., Seoul, Korea) were used.

Acupuncture points were located and described according to the World Health Organization (WHO) standard acupuncture locations (7). Based on the beneficial effects achieved by previous clinical studies, the acupoints selected for this study were BL23 (Shenshu), BL25 (Dachangshu), BL40 (Weizhong), SP6 (Sanyinjiao) and KI3 (Taixi) (Table 1) (43-45).

The sessions lasted 30 minutes, twice a week, for 5 weeks, totaling 10 visits (44).

Statistical Analysis

Data were analyzed using the Statistical Package for Social Sciences Version 19.0 (IBM Corporation, Armonk, NY) by a person who did not participate in any phase of the research and who received the data in coded form.

Data analysis followed the intention-to-treat principle. The normality of the distribution of numerical variables was evaluated by the Shapiro-Wilk test.

For the analysis of categorical variables, the analysis of covariance was used, considering gender, body mass index (BMI) and physical exercise practice as covariates, and the nonparametric Kruskal-Wallis test for those without normal distribution, with Bonferroni posttest to correct the test values. For the intragroup comparison analysis, the Student's t-test was performed when the distribution was normal and the Wilcoxon test when the distribution was not normal. Fisher's exact test was used to correlate categorical variables. The analysis of the association between the nominal variables was performed by the chi-square test. Numerical variables are presented as mean and standard deviation, and categorical variables as a percentage. The confidence interval was set at 95% and the significance level at 5%.

Table 1. *Electroacupuncture protocol*.

Points	Location
BL23 (Shenshu)	In the lumbar region, at the level of the inferior border of the spinous process of the second lumbar vertebra (L2), 1.5 inches lateral to the posterior midline.
BL25 (Dachangshu)	In the lumbar region, at the level of the inferior border of the spinous process of the fourth lumbar vertebra (L4), 1.5 inches lateral to the posterior midline.
BL40 (Weizhong)	In the posterior region of the knee, at the midpoint of the popliteal line.
SP6 (Sanyinjiao)	In the tibial region of the leg, posterior to the medial border of the tibia, 3 inches superior to the prominence of the medial malleolus.
KI3 (Taixi)	In the posteromedial region of the ankle, in the depression between the prominence of the medial malleolus and the calcaneus tendon.

Legend: BL, Bladder; SP, Spleen; KI, Kidney.

Results

Sample Characteristics

Of the patients, 70.4% were female, with a mean age of 67.1 [5.8] years. Based on self-report, most individuals were urban residents (96.8%), had elementary education (36.8%), and had a monthly family income of up to R$1500.00 (46.4%). In addition, 72 (57.6%) were overweight (BMI > 27 kg/m^2) (46), 67 (53.6%) were sedentary, and most reported not being a smoker (91.2%) or a drinker (98.4%) (Table 2).

The average time of living with chronic low back pain was 13 years, with 90 (72%) making daily use of one or more analgesics and 92 (73.6%) of the individuals reporting an improvement in pain after taking this medication.

There was a statistical difference for the variables gender, education, BMI, practice of physical exercise, duration of low back pain, and daily use of analgesic(s).

Primary Endpoint

In general, in the pre-treatment evaluation, patients reported moderate pain intensity with an average of 6.8 [1.8] and, at the end of treatment, mild pain intensity with an average of 1.9 [2.4].

In the comparison between the 3 electroacupuncture groups, in order to verify if there was a more effective electroacupuncture frequency for the treatment of chronic low back pain in people over 60 years old, there was no statistical difference between them pre- (P = 0.40) and posttreatment (P = 0.72) (Table 3). All groups showed significant reduction (Z = -4.21 to -3.86; P < 0.001) in pain intensity between pre- and posttreatment (Table 4).

In the comparison between the groups, a statistically significant difference was observed only between the control and placebo groups (P = 0.01) for the pretreatment and between the electroacupuncture and placebo groups (P = 0.01) for the posttreatment, where the latter significantly demonstrated the greatest reduction in pain intensity in the intra- and intergroup analysis (Table 4, Fig. 2).

Secondary Endpoints

The comparison between the 3 electroacupuncture groups in pre- and posttreatment is shown in Table 5 and the comparison between all groups in Table 6.

Pain Rating

There was a significant difference in the comparison between the electroacupuncture groups in the pre-treatment within the affective (CI = 3.14 to 3.79, P = 0.00) and miscellaneous (CI = 1.56 to 1.91, P = 0.04) components of the McGill pain questionnaire (Table 5). In the comparison between the groups, a statistical difference was found in the posttreatment for pain sensation within the sensory (CI = 2.95 to 4.41, P = 0.00), affective (CI = 0.81 to 1.40, P = 0.00) and evaluative (CI = 0.34 to 0.52, P = 0.0) McGill components, where the placebo group showed the greatest reduction in the judgment of CLBP in all components (Table 5).

Functional Disability

In the comparison between the groups, there was statistical significance in the initial evaluation (CI = 16.79 to 19.50, P = 0.00) between the control and placebo groups (P = 0.014) and between the electroacupuncture and placebo groups (P = 0.048) in the final evaluation (CI = 13.88 to 15.72, P = 0.03), the latter demonstrating the greatest reduction in the task execution time (Table 6, Fig. 3).

Emotional Functionality

A significant reduction in anxiety was found in the comparison between electroacupuncture groups after treatment (CI = 0.66 to 1.81, P = 0.00). The HFEA group differed statistically from the LFEA group (P = 0.00), demonstrating the greatest reduction of this variable (Table 5, Fig. 4).

There was no significant reduction in anxiety in the comparison between the other groups (CI = 0.51 to 1.31, P = 0.08) (Table 6).

The Placebo Effect

The results demonstrate that the placebo effect was sufficient because although 7 patients did not feel the needle penetrating the skin (HFEA = 2; P = 5), all of them believed they had undergone real treatment.

Symptoms and Adverse Events

There were no serious or very serious adverse symptoms.

Discussion

To the best of our knowledge, our study is the first to compare the efficacy of different frequencies of electroacupuncture with each other and with acupuncture and placebo in the aging population. Our results showed that in the comparison between pre- and posttreatment, all groups had a significant reduction in pain, but in the intergroup comparison, a statistically significant differ-

Table 2. *Clinical and sociodemographic characteristics of the sample.*

Characteristics	Mean [SD] or n (%)					
	HFEA (n = 25)	LFEA (n = 25)	AFEA (n = 25)	C (n = 25)	*P* (n = 25)	*P* value
Sociodemographic						
Age[a]	67.5 [7]	67.8 [7]	67.1 [5.7]	65.3 [2.9]	67.6 [5.6]	0.88
Gender[b]						
Female	22 (88)	16 (64)	20 (80)	10 (40)	20 (80)	*0.00
Male	3 (12)	9 (36)	5 (20)	15 (60)	5 (20)	
Schooling[b]						
No formal instruction	0	0	2 (8)	0	0	
Primary education	10 (40)	5 (20)	6 (24)	10 (40)	15 (60)	
Secondary education	4 (16)	10 (40)	12 (48)	8 (32)	5 (20)	
Higher or further education	11 (44)	10 (40)	5 (20)	7 (28)	5 (20)	*0.00
Resident area[b]						
Urban	23 (92)	25 (100)	24 (96)	24 (96)	25 (100)	
Rural	2 (8)	0	1 (4)	1 (4)	0	0.8
Monthly family income[b]						
Up to R$1,500.00	14 (56)	9 (36)	11 (44)	13 (52)	11 (44)	
R$1500.00-R$2500.00	2 (8)	2 (8)	3 (12)	4 (16)	5 (20)	
More than R$2500.00	9 (36)	14 (56)	11 (44)	8 (32)	9 (36)	0.44
BMI (kg/m^2)						
Underweight (< 22 kg/m^2)	3 (12)	3 (12)	1 (4)	2 (8)	0	
Eutrophy (22-27 kg/m^2)	10 (40)	14 (56)	8 (32)	3 (12)	9 (36)	
Overweight (> 27 kg/m^2)	12 (48)	8 (32)	16 (64)	20 (80)	16 (64)	*0.03
Lifestyle						
Physical exercise[b]						
Active	16 (64)	11 (44)	14 (56)	6 (24)	11 (44)	
Sedentary	9 (36)	14 (56)	11 (44)	19 (76)	14 (56)	*0.05
Smoker[b]						
Yes	23 (92)	22 (88)	23 (92)	23 (92)	23 (92)	
No	2 (8)	3 (12)	2 (8)	2 (8)	2 (8)	1.0
Alcoholism[b]						
Yes	0	0	0	2 (8)	0	
No	25 (100)	25 (100)	25 (100)	23 (92)	25 (100)	0.19
Chronic Lumbar Pain						
Duration[a]	13.7 (12.1)	12.1 (13.6)	10.5 (9.4)	20.6 (11)	8.1 (11.1)	*0.00
Improvement with medication[b]						
Yes	22 (88%)	17 (68)	20 (80)	17 (68)	16 (64)	
No	3 (12)	8 (32)	5 (20)	8 (32)	9 (36)	0.26
Daily use of analgesic(s)[b]						
Yes	22 (88)	17 (68)	21 (84)	19 (76)	11 (44)	
No	3 (12)	8 (32)	4 (16)	6 (24)	14 (56)	*0.00

Numeric variables are presented as mean [SD] and categorical variables as percentage.

[a] Analyses performed using the Kruskal-Wallis test.

[b] Analyses performed using Fischer's Exact Test.

*$P \leq 0.05$. Key: SD, standard deviation; HFEA, high frequency electroacupuncture group; LFEA, low frequency electroacupuncture group; AFEA, alternating frequency electroacupuncture group; C, control group; P, placebo group; BMI, adjusted body mass index for older adults.

Table 3. *Results of the primary outcome inter- and intragroup electroacupuncture, before and after treatment.*

	Mean [SD]				
Pain intensity	**HFEA (n = 25)**	**LFEA (n = 25)**	**AFEA (n = 25)**	**CI 95%**	***P* value**
NRS (0 to 10)*					
Pretreatment	6.8 (1.9)	6.5 (1.4)	7.3 (2.2)	6.51-7.17	0.40
Posttreatment	2.5 (2.6)	1.9 (1.8)	2.7 (3)	1.44-2.33	0.72
Intragroup Analysis* (Z-value)	-3.95*	-4.11*	-3.86*	--	*< 0.00

a Analyses performed using the Kruskal-Wallis test.
c Analysis performed using the Wilcoxon test.
*$P \leq 0.05$.
Legend: SD, standard deviation; CI, confidence interval; HFAS, high frequency electroacupuncture group; LFAS, low frequency electroacupuncture group; FAAS, alternating frequency electroacupuncture group; C, control group; P, placebo group; NPRS, numeric pain rating scale.

Table 4. *Inter- and intra-group primary outcome results at pre- and post-treatment.*

	Mean [SD]				
Pain intensity	**EA (n = 75)**	**C (n = 25)**	**P (n = 25)**	**CI 95%**	***P* value**
NPRS (0 to 10)*					
Pretreatment	6.9 (1.8)	6.1 (1.3)	7.5 (2.1)	6.51-7.17	*0.03
Posttreatment	2.4 (2.5)	1.4 (1.9)	0.9 (2.1)	1.44-2.33	*0.00
Intragroup Analysis[c] (Z-value)	-3.95*	-4.03*	-4.21*	--	*< 0.00

[a] Analyses performed using the Kruskal-Wallis test.
[c] Analysis performed using the Wilcoxon test.
*$P \leq 0.05$.
Legend: SD, standard deviation; CI, confidence interval; EA, electroacupuncture group; C, control group; P, placebo group; NPRS, numeric pain rating scale.

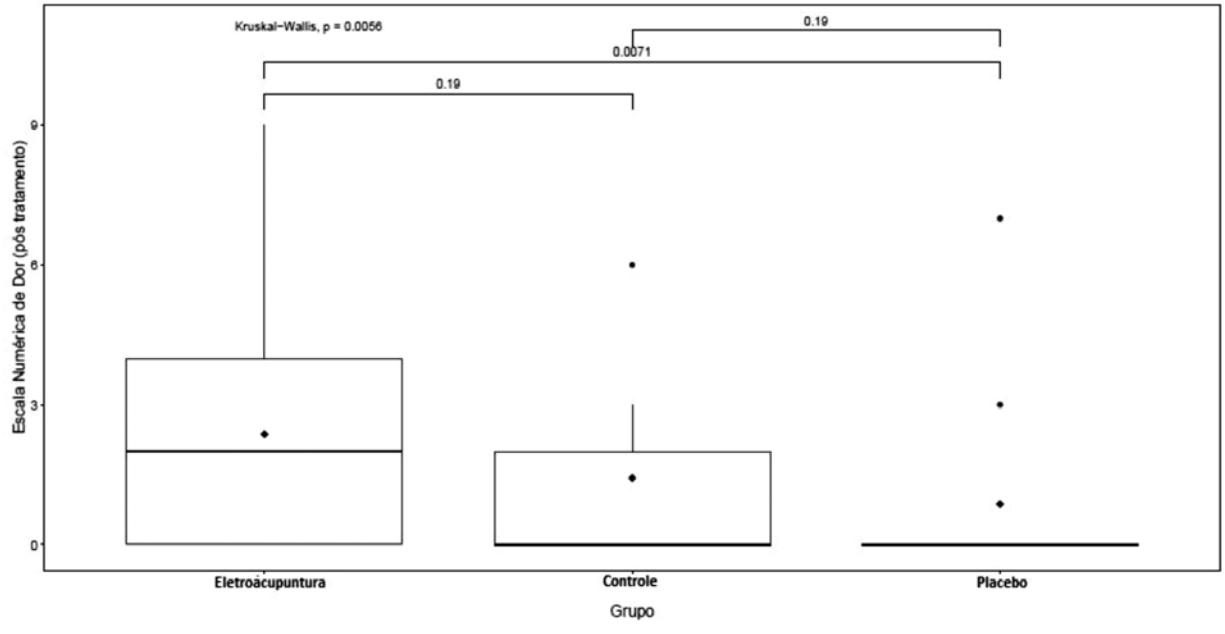

Fig. 2. *Box plot of the comparison between groups regarding intensity in posttreatment.*

Table 5. *Results of secondary outcomes in the comparison between the study electroacupuncture groups in pre- and posttreatment.*

	Mean [SD]				
Pain rating	**HFEA (n = 25)**	**LFEA (n = 25)**	**AFEA (n = 25)**	**CI 95%**	***P* value**
McGill[a]					
McGill Sensory (0 to 10)					
Pretreatment	8.7 (1.9)	7.7 (2.5)	7.8 (2.6)	7.53-8.63	0.17
Posttreatment	4.3 (3.8)	4.2 (3.8)	5.5 (3.8)	3.79-5.62	0.42
Affective McGill (0 to 5)					
Pretreatment	3.8 (1.5)	2.8 (1.2)	3.8 (1.4)	3.14-3.79	*0.00
Posttreatment	1.8 (1.8)	1 (1.4)	2 (2)	1.19-2.05	0.16
McGill evaluative (0 to 1)					
Pretreatment	0.9 (0.3)	1 (0.3)	1 (0)	0.95-1.05	0.06
Posttreatment	0.5 (0.5)	0.5 (0.5)	0.6 (0.5)	0.44-0.68	0.7
McGill miscellaneous (0 to 4)					
Pretreatment	1.6 (0.6)	1.6 (0.8)	2 (0.6)	1.56-1.91	*0.04
Posttreatment	1.1 (1.1)	0.6 (0.9)	0.9 (0.9)	0.63-1.10	0.26
Functional Disability					
Roland Morrisa (0 to 24)					
Pretreatment	11.5 (6.2)	10.7 (4.9)	12.7 (5.2)	10.40-12.91	0.4
Posttreatment	7.4 (5.6)	6.4 (5.2)	8.2 (6.5)	5.96-8.75	0.84
Sitting-Standing[a]					
Pretreatment	17.5 (9.3)	17.7 (7.4)	16.3 (4.4)	15.51-18.83	0.55
Posttreatment	15.8 (6.5)	13.9 (5.9)	14.4 (3.4)	13.37-15.96	0.30
Emotional Functionality					
IDB[a] (0 to 63)					
Pretreatment	8 (5.2)	8.6 (5.1)	9.7 (6.7)	7.45-10.07	0.53
Posttreatment	6 (4.9)	6 (4.5)	8.1 (6.2)	5.42-7.99	0.46
EVA Anxietya (0 to 10)					
Pretreatment	3.9 (3.6)	2.5 (3)	2.4 (3.1)	2.19-3.68	0.20
Posttreatment	0.5 (1.8)	2.1 (2.6)	1.1 (2.6)	0.66-1.81	*0.00
Psychosocial Factors					
SBST (0 to 2)*					
Pretreatment	0 (0.4)	0.1 (0.3)	0.3 (0.6)	0.13-0.35	0.32
Posttreatment	0 (0.2)	0 (0.2)	0.1 (0.3)	0.04-0.20	0.65
Global Perceived Effect Scale					
GPE[a] (-5 to +5)					
Posttreatment	2.9 (1.3)	3.1 (1.3)	3.2 (1.8)	2.71-3.44	0.38

[a] Analyses performed using the Kruskal-Wallis test.

*$P \leq 0.05$.

Key: SD, standard deviation; CI, confidence interval; HFEA, high-frequency electroacupuncture group; LFEA, low-frequency electroacupuncture group; AFEA, alternating frequency electroacupuncture group; BDI, Beck depression inventory; VAS, visual analog scale; SBST, start back screening tool; GPE, global perceived effect scale.

ence was only found between electroacupuncture and placebo, where the latter showed the greatest reduction in pain intensity. The placebo group also showed the best results in the secondary outcomes.

The results of this study suggest that the frequency range of electrical stimulation does not influence the analgesic response of electroacupuncture in CLBP of older adults but rather in relation to anxiety.

Table 6. *Results of secondary outcomes in the comparison between the study groups in pre- and post-treatment.*

	Mean [SD]				
Pain rating	**EA (n = 75)**	**C (n = 25)**	**P (n = 25)**	**CI 95%**	***P* value**
McGill[a]					
McGill Sensory (0 to 10)					
Pretreatment	8.1 (2.4)	8.2 (1.9)	7.9 (2.2)	7.65-8.49	0.87
Posttreatment	4.7 (3.8)	2.9 (3.8)	1.4 (3.1)	2.95-4.41	*0.00
Affective McGill (0 to 5)					
Pretreatment	3.5 (1.4)	3.2 (1.4)	3.7 (1.5)	3.21-3.73	0.42
Posttreatment	0.6 (0.5)	0.4 (0.5)	0.1 (0.3)	0.34-0.52	*0.00
McGill evaluative (0 to 1)					
Pretreatment	1 (0.2)	1 (0)	1 (0)	0.96-1.04	1
Posttreatment	0.6 (0.5)	0.4 (0.5)	0.1 (0.3)	0.34-0.52	*0.00
McGill miscellaneous (0 to 4)					
Pretreatment	1.7 (0.7)	1.7 (0.9)	1.8 (0.4)	1.60-1.88	0.98
Posttreatment	0.9 (1)	0.6 (0.9)	0.4 (0.8)	0.55-0.90	0.08
Functional Disability					
Roland Morris[a] (0 to 24)					
Pretreatment	11.7 (5.4)	10 (4.7)	13.6 (4.5)	10.76-12.67	0.06
Posttreatment	7.4 (5.8)	6.1 (4.4)	5.2 (5.1)	5.65-7.69	0.40
Emotional Functionality					
IDB[a] (0 to 63)					
Pretreatment	2.9 (3.2)	3.3 (3.1)	2.3 (3.8)	2.21-3.45	0.34
Posttreatment	1.2 (2.4)	0.7 (2.1)	0.2 (0.6)	0.51-1.31	0.08
Psychosocial Factors					
SBST (0 to 2)*					
Pretreatment	0.2 (0.05)	0.1 (0.3)	0.2 (0.4)	0.16-0.34	0.60
Posttreatment	0.12 (0.03)	0 (0)	0 (0)	0.02-0.12	0.63
Global Perceived Effect Scale					
GPE[a] (-5 to +5)					
Posttreatment	3.1 (1.5)	3.6 (1.2)	3.9 (0.8)	3.09-3.61	0.06
Adverse Events (1 to 5)					
Posttreatment	1.4 (0.5)	1.1 (0.4)	1.4 (0.5)	1.30-1.48	0.22

[a] Analyses performed using the Kruskal-Wallis test.
*$P \leq 0.05$.
Legend: SD, standard deviation; CI, confidence interval; AE, electroacupuncture; C, control group; P, placebo group; BDI, Beck depression inventory; VAS, visual analog scale; SBST, start back screening tool; GPE, global perceived effect scale.

According to Traditional Chinese Medicine, the frequency of stimulation of the needle is as important for the treatment as the choice of the acupoint; however, due to the lack of scientific studies that seek to stipulate the parameters that define the low and high frequencies, these are often chosen arbitrarily (47). This situation is aggravated by the fact that there are few clinical trials evaluating the efficacy of different frequencies of electroacupuncture on LBP, and most of them exclude the older population from their sample, besides also presenting methodologies very different from each other, which makes it difficult to know if in fact there is a frequency of electrical stimulation better than another for the treatment of LBP in older people (21,22,48-55).

In addition, the manual stimulation performed on the acupuncture needle is described as being of great importance for obtaining a good therapeutic response,

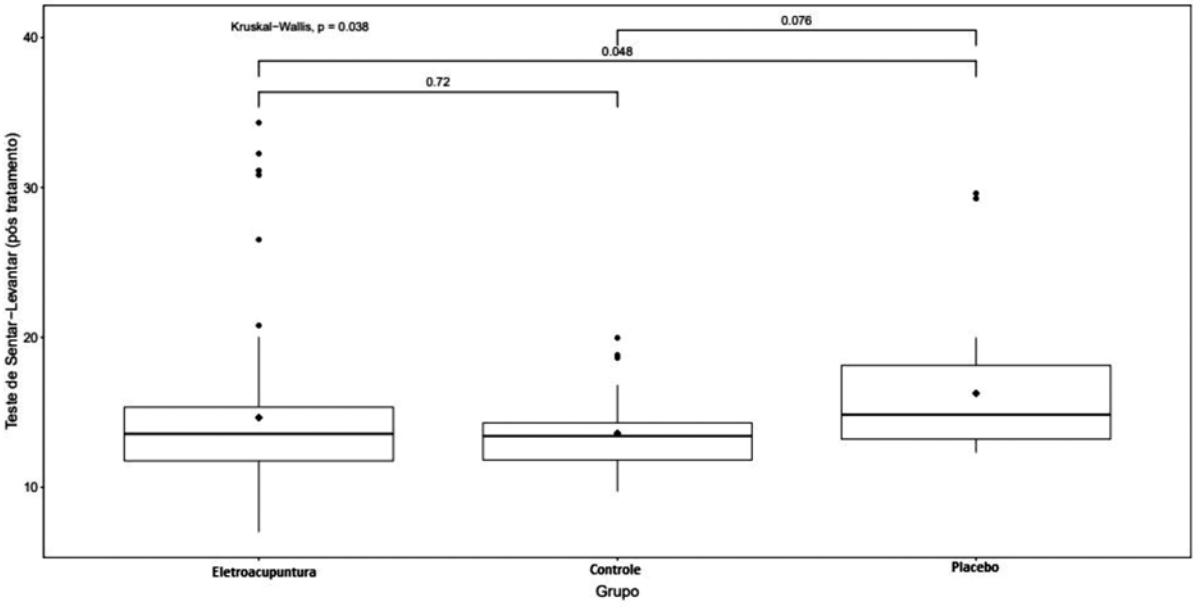

Fig. 3. *Box plot of the difference between the groups in the sitting-standing task, in posttreatment.*

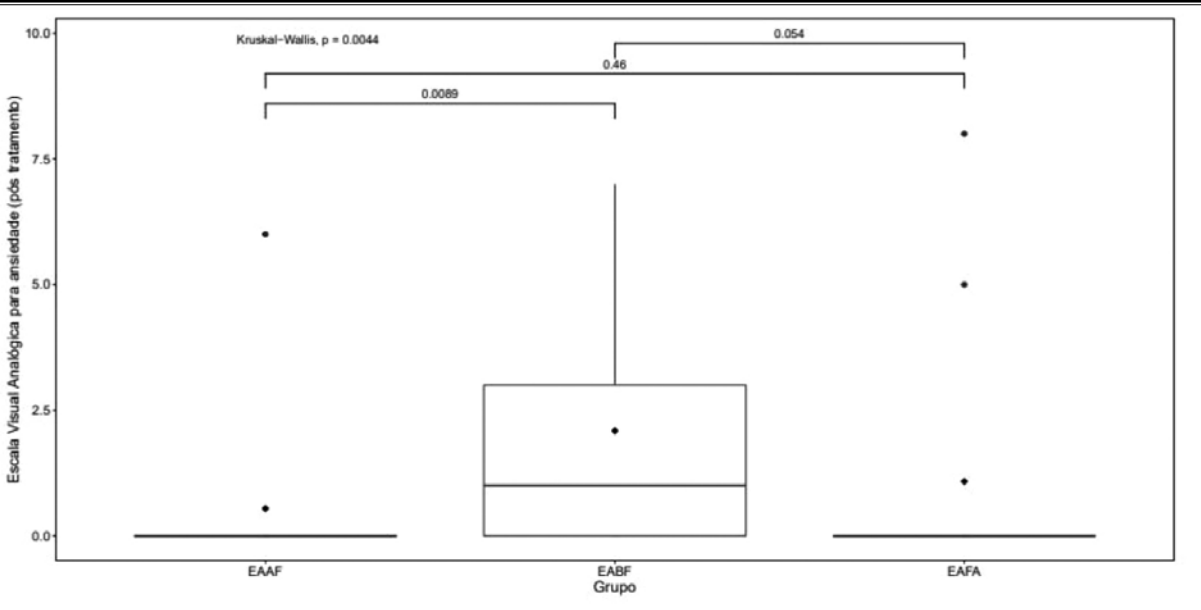

Fig. 4. *Box plot of the difference between the electroacupuncture groups in relation to anxiety, in post-treatment.*

as this stimulus prevents the sensory accommodation of the needle on the skin, making continuous the release of opioid peptides in the central nervous system, thus favoring the analgesic response (49). In this regard, the electrical stimulation in the needle, by being quantified and constant, would guarantee a greater analgesic effect and would also allow the release of different brain neuropeptides according to the range of electrical stimulation used (21,49).

In the present study, the addition of the electrical

stimulus on the needle (electroacupuncture groups) was not superior to the manual stimulus (control group).

These results show that, perhaps for older adults, the selection of acupoints is the most important factor in reducing the intensity of the LBP, and that any minimal stimulus performed on this acupoint would have the potential to increase its analgesic effect, which can be evidenced by the fact that the control group presented a very similar result to that found in the electroacupuncture groups for the reduction in pain intensity, and this group did not receive any stimulus in the needle during the treatment session, apart from the placement of the electrodes (21,52).

Furthermore, regarding the primary outcome of this study, there was a statistical difference between electroacupuncture and the placebo, which showed the greatest reduction in pain intensity. The placebo group also obtained the best results between the pre- and posttreatment in the Roland-Morris questionnaire, in the Beck Depression Inventory, in the McGill pain questionnaire, and in the sit-to-stand test, but only in the latter 2 a statistically significant reduction was found when compared to the other groups. In addition, older individuals in this group were those who significantly reported the highest satisfaction with the treatment received through MedRisk.

We believe that the placebo group presented the best therapeutic response among the 5 groups due to the fact that, besides having been submitted to the same acupoints as the other groups, this group also received 2 stimuli on top of them: the needle prick and the adhesive moxa; making this group a placebo only for the electrical stimulus (electroacupuncture) and the skin prick (manual acupuncture) (52,56,57).

Overall, the findings of this clinical trial show that the interventions of the 5 groups were effective for the secondary endpoints and also for reducing the pain intensity of older adults from moderate to mild pain. In addition, the analysis of the overall effect perceived by the patients in relation to LBP revealed that all individuals felt close to full recovery, regardless of the treatment received.

Limitations

Due to the context imposed by the COVID-19 pandemic, the follow-up of the patients in this study was not carried out, and it is not possible to know if the results obtained in this study remained in the medium and long term. Another limitation of this study was the relatively small number of patients. Finally, for budgetary reasons, it was not possible to use the pressure algometer to measure the pressure pain threshold, as stated in the initial protocol of this research.

Conclusion

The results of the present study did not confirm the initial hypothesis that there would be a more effective frequency of electroacupuncture for the treatment of nonspecific CLBP in older adults. The electroacupuncture groups also did not present superior results to manual and placebo acupuncture for both pain intensity and secondary outcomes.

References

1. Zis P, Daskalaki A, Bountouni I, Sykioti P, Varrassi G, Paladini A. Depression and chronic pain in the elderly: Links and management challenges. *Clin Interv Aging* 2017; 12:709-720.
2. Lewis R, Gómez Álvarez CB, Rayman M, Lanham-New S, Woolf A, Mobasheri A. Strategies for optimising musculoskeletal health in the 21st century. *BMC Musculoskelet Disord* 2019; 20:1-15.
3. Di Lorito C, Long A, Byrne A, et al. Exercise interventions for older adults: A systematic review of meta-analyses. *J Sport Health Sci* 2021; 10:29-47.
4. Ali A, Arif AW, Bhan C, et al. Managing chronic pain in the elderly: An overview of the recent therapeutic advancements. *Cureus* 2018; 10:e3293.
5. Domenichiello AF, Ramsden CE. The silent epidemic of chronic pain in older adults. *Prog Neuropsychopharmacol Biol Psychiatry* 2019; 93:284-290.
6. El-Tallawy SN, Nalamasu R, Salem GI, LeQuang JAK, Pergolizzi JV, Christo PJ. Management of musculoskeletal pain: An update with emphasis on chronic musculoskeletal pain. *Pain Ther* 2021; 10:181-209.
7. Treede RD, Rief W, Barke A, et al. Chronic pain as a symptom or a disease: The IASP Classification of Chronic Pain for the International Classification of Diseases (ICD-11). *J Pain* 2019; 160:19-27.
8. Chen LH, Weber K, Mehrabkhani S, Baskaran S, Abbass T, Macedo LG. The effectiveness of weight loss programs for low back pain: A systematic review. *BMC Musculoskelet Disord* 2022; 23:1-14.
9. Del Farra F, Risio RG, Vismara L, Bergna A. Effectiveness of osteopathic interventions in chronic non-specific low back pain: A systematic review and meta-analysis. *Complement Ther Med* 2021; 56:1-13.
10. Welsh TP, Yang AE, Makris UE. Musculoskeletal pain in older adults: A clinical review. *Med Clin North Am* 2020; 104:855-872.
11. Hoy D, March L, Brooks P, et al. The global burden of low back pain: Estimates from the global burden of disease 2010 study. *Ann Rheum Dis* 2014; 73:968-974.
12. Vasconcelos FH, Araújo GC. Prevalence of chronic pain in Brazil: A descriptive

study. *BrJP* 2018; 1:176-179.

13. Stewart Williams J, Ng N, Peltzer K, et al. Risk factors and disability associated with low back pain in older adults in low and middle-income countries. Results from the WHO Study on Global AGEing and Adult Health (SAGE). *PLoS One* 2015; 10:1-21.
14. Felicio DC, Pereira DS, Diz JBM, et al. Anterior trunk mobility does not predict disability in elderly women with acute low back pain - Brazilian Back Complaints in the Elders (BACE-Brazil) study results. *Spine (Phila Pa 1976)* 2017; 42:1552-1558.
15. Raja SN, Carr DB, Cohen M, et al. The revised International Association for the Study of Pain definition of pain: Concepts, challenges, and compromises. *Pain* 2020; 161:1976-1982.
16. Stubbs B, Koyanagi A, Thompson T, et al. The epidemiology of back pain and its relationship with depression, psychosis, anxiety, sleep disturbances, and stress sensitivity: Data from 43 low- and middle-income countries. *Gen Hosp Psychiatry* 2016; 43:63-70.
17. Schwan J, Sclafani J, Tawfik VL. Chronic pain management in the elderly. *Anesthesiol Clin* 2019; 37: 547-560.
18. Leonhardt C, Kuss K, Becker A, et al. Graded exposure for chronic low back pain in older adults: A pilot study. *J Geriatr Phys Ther* 2017; 40:51-59.
19. Aguiar DP, Souza CPDQ, Barbosa WJM, et al. Prevalence of chronic pain in Brazil: Systematic review. *BrJP* 2021; 4:257-267.
20. Carregaro RL, Tottoli CR, Rodrigues DDS, Bosmans JE, da Silva EN, van Tulder M. Low back pain should be considered a health and research priority in Brazil: Lost productivity and healthcare costs between 2012 to 2016. *PLoS One* 2020; 15:1-15.
21. Comachio J, Oliveira CC, Silva IFR, Magalhães MO, Marques AP. Effectiveness of manual and electrical acupuncture for chronic non-specific low back pain: A randomized controlled trial. *J Acupunct Meridian Stud* 2020; 13:87-93.
22. Kong J-T, Puetz C, Tian L, et al. Effect of electroacupuncture vs sham treatment on change in pain severity among adults with chronic low back pain: A randomized clinical trial. *JAMA Netw Open* 2020; 3:1-14.
23. George SZ, Lentz TA, Goertz CM. Back and neck pain: In support of routine delivery of non-pharmacologic treatments as a way to improve individual and population health. *Transl Res* 2021; 234:129-140.
24. Nielsen A, Ocker L, Majd I, et al. Acupuncture intervention protocol: Consensus process for a pragmatic randomized controlled trial of acupuncture for management of chronic low back pain in older adults: An NIH HEAL Initiative Funded Project. *Glob Adv Health Med* 2021; 10:1-11.
25. Clinical guidelines to address low back pain: Using the evidence to guide physical therapist practice. *J Orthop Sports Phys Ther* 2021; 51:531-550.
26. Francescato Torres S, Brandt de Macedo AC, Antunes MD, et al. Effects of electroacupuncture frequencies on chronic low back pain in older adults: Triple-blind, 12-months protocol for a randomized controlled trial. *Trials* 2019; 20:1-9.
27. Cohen M, Quintner J, van Rysewyk S. Reconsidering the International Association for the Study of Pain definition of pain. *Pain Rep* 2018; 3:e634.
28. Patel KV, Amtmann D, Jensen MP, Smith SM, Veasley C, Turk DC. Clinical outcome assessment in clinical trials of chronic pain treatments. *Pain Rep* 2021; 61:1-14.
29. Cohen SP, Vase L, Hooten WM. Chronic pain: An update on burden, best practices, and new advances. *Lancet* 2021; 397:2082-2097.
30. Boonstra AM, Stewart RE, Köke AJ, et al. Cut-Off Points for mild, moderate, and severe pain on the numeric rating scale for pain in patients with chronic musculoskeletal pain: Variability and influence of sex and catastrophizing. *Front Psychol* 2016; 7:1-9.
31. Broglio K. Randomization in clinical trials: Permuted blocks and stratification. *JAMA* 2018; 19:2223-2224.
32. Oliveira CB, Maher CG, Pinto Z, et al. Clinical practice guidelines for the management of non-specific low back pain in primary care: An updated overview. *Eur Spine J* 2018; 27:2791-2803.
33. Kreiner M, Zaffaroni A, Alvarez R, Clark G. Validation of a simplified sham acupuncture technique for its use in clinical research: A randomised, single blind, crossover study. *Acupunct Med* 2010; 28:33-36.
34. Hawker GA, Mian S, Kendzerska T, French M. Measures of adult pain: Visual Analog Scale for Pain (VAS Pain), Numeric Rating Scale for Pain (NRS Pain), McGill Pain Questionnaire (MPQ), Short-Form McGill Pain Questionnaire (SF-MPQ), Chronic Pain Grade Scale (CPGS), Short Form-36 Bodily Pain Scale (SF-36 BPS), and Measure of Intermittent and Constant Osteoarthritis Pain (ICOAP). *Arthritis Care Res* 2011; 63:S240-S252.
35. Andrade FA, Pereira LV, Sousa FA. Mensuração da dor no idoso: Uma revisão. [Pain measurement in the elderly: A review]. *Rev Lat Am Enfermagem* 2006; 14:271-276.
36. Melzack R. The McGill Pain Questionnaire: Major properties and scoring methods. *Pain* 1975; 1:277-299.
37. Varoli FK, Pedrazzi V. Adapted version of the McGill Pain Questionnaire to Brazilian Portuguese. *Braz Dent J* 2006; 17:328-335.
38. Simieli I, Padilha LAR, Tavares CFdF. Reality of population ageing in front of chronic diseases non-transmissible. *EJCH* 2019; 37:1-9.
39. Costa LO, Maher CG, Latimer J, et al. Clinimetric testing of three self-report outcome measures for low back pain patients in Brazil: Which one is the best? *Spine (Phila Pa 1976)* 2008; 33:2459-2463.
40. Fung FY, Linn YC. Developing traditional Chinese medicine in the era of evidence-based medicine: Current evidences and challenges. *Evid Based Complement Alternat Med* 2015; 2015:1-9.
41. Franco OS, Paulitsch FS, Pereira AP, et al. Effects of different frequencies of transcutaneous electrical nerve stimulation on venous vascular reactivity. *Braz J Med Biol Res* 2014; 47:411-418.
42. Zotz TG, Paula JB. Influence of transcutaneous electrical stimulation on heterotopic ossification: An experimental study in Wistar rats. *Braz J Med Biol Res* 2015; 48:1055-1062.
43. Santoro A, Bientinesi E, Monti D. Immunosenescence and inflammaging in the aging process: Age-related diseases or longevity? *Ageing Res Rev* 2021; 71:1-19.
44. Kosek E, Clauw D, Nijs J, et al. Chronic nociplastic pain affecting the musculoskeletal system: Clinical criteria and grading system. *Pain* 2021; 161:2629–2634.
45. Associação Brasileira de Medicina Física e Reabilitação. Chronic nonspecific low back pain: Rehabilitation. *Rev Assoc Med Bras* 2013; 59:536-553.
46. Pereira IF, Spyrides MH, Andrade Lde M. Nutritional status of elderly Brazilians: A multilevel approach. *Cad*

Saude Publica 2016; 32:1-12.

47. Han JS. Acupuncture analgesia: Areas of consensus and controversy. *Pain* 2011; 152:S41-S48.
48. Tsukayama H, Yamashita H, Amagai H, Tanno Y. Randomised controlled trial comparing the effectiveness of electroacupuncture and TENS for low back pain: A preliminary study for a pragmatic trial. *Acupunct Med* 2002; 20:175-180.
49. Yeung CK, Leung MC, Chow DH. The use of electro-acupuncture in conjunction with exercise for the treatment of chronic low-back pain. *J Altern Complement Med* 2003; 9:479-490.
50. Tsui ML, Cheing GL. The effectiveness of electroacupuncture versus electrical heat acupuncture in the management of chronic low-back pain. *J Altern Complement Med* 2004; 10:803-809.
51. Shankar N, Thakur M, Tandon OP, Saxena AK, Arora S, Bhattacharya N. Autonomic status and pain profile in patients of chronic low back pain and following electro-acupuncture therapy: A randomized control trial. *Indian J Physiol Pharmacol* 2011; 55:25-36.
52. Leite PMS, Mendonça ARC, Maciel LYS, et al. Does electroacupuncture treatment reduce pain and change quantitative sensory testing responses in patients with chronic nonspecific low back pain? A randomized controlled clinical trial. *Evid Based Complement Alternat Med* 2018; 2018:1-8.
53. Heo I, Shin BC, Cho JH, et al. Multicentre randomised controlled clinical trial of electroacupuncture with usual care for patients with non-acute pain after back surgery. *Br J Anaesth* 2021; 126:692-699.
54. Depaoli Lemos VJ, Selau RC, Blos C, et al. Electroacupuncture and transcutaneous electrical nerve stimulation in chronic nonspecific low back pain: A blind randomized clinical trial. *Muscles Ligaments Tendons J* 2021; 11:719-727.
55. Lin ML, Lin MH, Fen JJ, Lin WT, Lin CW, Chen PQ. A comparison between pulsed radiofrequency and electro-acupuncture for relieving pain in patients with chronic low back pain. *Acupunct Electroter Res* 2010; 35:133-146.
56. Chen ZX Li Y, Zhang XG, et al. Sham electroacupuncture methods in randomized controlled trials. *Sci Rep* 2017; 7:1-19.
57. Zhao H, Liu BY, Liu ZS, et al. Clinical practice guidelines of using acupuncture for low back pain. *World J Acupunct Moxibustion* 2016; 26:1-13.