

# EFFECTS OF SHIATSU IN THE MANAGEMENT OF FIBROMYALGIA SYMPTOMS: A CONTROLLED PILOT STUDY

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## ABSTRACT

**Objectives:** This pilot study aimed to evaluate the potential effects of Shiatsu massage on the symptoms of adult patients with primary fibromyalgia, propose a Shiatsu treatment protocol, verify patient acceptability, and evaluate the feasibility for a larger study.

**Methods:** Thirty-four patients aged 33 to 62 years were divided into a Shiatsu group (SG;  $n = 17$ ), who received full-body Shiatsu twice a week for 8 weeks, and a control group ( $n = 17$ ), who received an educational booklet. The patients were assessed at baseline and after 8 weeks. Pain intensity was evaluated by the visual analog scale, pressure pain threshold by dolorimetry, anxiety by the State-Trait Anxiety Inventory, sleep by the Pittsburgh Sleep Quality Index, and symptoms impact on patient's health by the Fibromyalgia Impact Questionnaire. The SG was also questioned about adverse effects and level of satisfaction.

**Results:** After treatment, the SG presented statistically significant differences ( $P < .05$ ) for the change scores of all variables, except state anxiety, compared with the control group. Relative percentage changes were considered clinically relevant for visual analog scale (40.6%), pressure pain threshold (76.4%), Pittsburgh Sleep Quality Index (34.4%), and Fibromyalgia Impact Questionnaire (22.30%). No clinically relevant effects were observed for anxiety after treatment. No adverse effects were reported during the treatment, and about 94% of the patients demonstrated satisfaction with Shiatsu.

**Conclusion:** This pilot study showed the potential of Shiatsu in the improvement of pain intensity, pressure pain threshold, sleep quality, and symptoms impact on health of patients with fibromyalgia. The proposed Shiatsu treatment protocol was feasible and well accepted by the patients. (*J Manipulative Physiol Ther* 2013;36:436-443)

**Key Indexing Terms:** *Massage; Acupressure; Fibromyalgia; Pain; Sleep; Anxiety*

Fibromyalgia is a common rheumatologic disorder characterized by chronic widespread pain and reduced pressure pain threshold (PPT), with hyperalgesia and allodynia.<sup>1,2</sup> Typically, this syndrome is associated with additional symptoms such as fatigue, morning stiffness, and nonrestorative sleep as well as comorbidities such as anxiety and depression.<sup>3,4</sup> It impairs significantly the functional capacity and quality of life.<sup>5</sup>

In the treatment of fibromyalgia, a number of pharmacologic and nonpharmacologic interventions have been used with the objective of reducing pain, improving sleep,

restoring physical function, and reestablishing emotional balance.<sup>6</sup> In the German fibromyalgia consumer reports, 8 types of medication appeared among the top 10 most harmful management strategies. In contrast, the participants attributed to nonpharmacologic therapies the highest effectiveness for relief of symptoms, highlighting its importance in the management of fibromyalgia.<sup>7</sup> Currently, complementary and alternative medicine is drawing attention for its use in considerable proportions in fibromyalgia, probably because of factors such as the dissatisfaction with allopathic medicine, the quality of patient-therapist relationship, the holistic approach of the treatment, and the contact time favoring the transfer of information and guidance.<sup>8,9</sup> However, the evidence regarding the effectiveness of such practices in fibromyalgia is inconclusive.<sup>5</sup>

Shiatsu massage therapy is a nonpharmacologic technique with a holistic approach, which consists of the combination of manipulation and stretching with the application of pressure on points and meridians of the body with the fingers, hands, elbows, knees, and feet, to restore and maintain energy balance and, consequently, health.<sup>10</sup> It was developed in Japan based on the

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fundamentals of the traditional Chinese medicine (TCM) and also influenced by the Western medicine.<sup>11</sup> According to TCM, the vital energy flows throughout the body along pathways known as meridians, maintaining health. Several factors may lead to the blockage in the flow of the vital energy. Acupuncture is one of the key components of TCM and describes a family of procedures that aims to unblock the flow of the vital energy through the stimulation of anatomical points that are connected with the meridians. The technique that involves penetrating the skin with metallic needles is the one most often studied, but acupuncture includes also other types of stimulation, such as acupressure.<sup>12</sup> Although Shiatsu is more comprehensive, one can consider that it incorporates acupressure with its principles.<sup>10</sup> The mechanisms of action are not fully known; however, studies indicate that the autonomic nervous system and the endogenous release of opioids are involved with acupressure.<sup>13–15</sup> From the Western medicine point of view, Shiatsu presents also the effects produced by massages in general: muscle tension release, increase of blood circulation facilitating the removal of toxic metabolic waste products and the oxygenation and nutrition of body cells and tissues, and release of natural analgesics such as serotonin.<sup>16</sup>

There is evidence of the efficacy of acupressure, which may be used to support claims about the efficacy of Shiatsu, in the improvement of pain and sleep, 2 main disorders frequently present in patients with fibromyalgia.<sup>10,17</sup> Few studies investigate Shiatsu for specific conditions, and no studies were found for fibromyalgia. However, some evidence suggests that it may be promising for musculoskeletal and psychological problems.<sup>10</sup> Therefore, this pilot study aimed to evaluate the potential effects of Shiatsu massage on the symptoms of adult patients with primary fibromyalgia, propose a Shiatsu treatment protocol and its feasibility for future research, and verify patient acceptability of Shiatsu.

## METHODS

### Participants

Patients aged 30 to 65 years diagnosed as having primary fibromyalgia by a rheumatologist or an orthopedist, fulfilling the 1990 American College of Rheumatology criteria, were included in the study.<sup>1,18</sup> The exclusion criteria for the sample were as follows: presence of other diseases that cause chronic pain, skin lesions and infections, pregnancy, and use of physical therapy or complementary and alternative therapies in the last 6 months. The protocol was interrupted when the patient missed 2 consecutive sessions, or a total of 4 sessions of the treatment.

The study was carried out in the Specialized Rehabilitation Service of Taboao da Serra and in the Physical

Therapy Service of Outpatient Rheumatology Clinic of the General Hospital, School of Medicine, at the University of Sao Paulo. Eligible patients seeking treatment in the former were recruited and allocated into Shiatsu group (SG), while the control group (CG) consisted of patients who sought treatment in the latter.

The study was approved by the ethics committee of the General Hospital and of the School of Medicine at the University of Sao Paulo (registration number: 1297/09), and the trial was registered at ClinicalTrials.gov (registration number: NCT01291043). All patients signed informed consent forms before participation.

### Outcome Measures

A standardized form was used to collect data to the characterization of the sample. The patients were assessed at baseline and after 8 weeks by a physical therapist, who was also responsible for the intervention.

Pain intensity was measured by the visual analog scale (VAS), a 10-cm-length straight line with no numbers. At the left end point, “no pain” was indicated, and at the right end point, “unbearable pain” was indicated. The patient marks on the line the pain intensity, which ranges from 0 to 10, with 10 being the worst pain imaginable.<sup>19</sup>

Pressure pain threshold was measured by dolorimetry. A Fischer dolorimeter (Pain Diagnostics and Thermography, Great Neck, NY) was placed perpendicular to the skin surface at the tender point (TP) sites, and pressure was applied with the rubber tip at a gradually increasing rate of 1 kg/cm<sup>2</sup> per second until the perceived sensation changed from pressure to pain. Positive TPs present pressure values below 2.6 kg/cm<sup>2</sup>.<sup>20</sup> Pressure pain threshold was calculated as the mean of the measurements of the 18 TPs.

Anxiety was assessed with the State-Trait Anxiety Inventory, which consists of a scale that measures state anxiety (how the patient feels at a certain time and under certain conditions) and another that measures trait anxiety (how the patient feels in general). Each scale is constituted of 20 items scored according to a 4-point Likert scale, resulting in a total score that ranges from 20 to 80 points. Higher scores indicate greater anxiety.<sup>21,22</sup>

Sleep was measured by the Pittsburgh Sleep Quality Index (PSQI), a 19-item questionnaire related to sleep habits during the past month, which generates 7 component scores ranging from 0 to 3: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction. The sum of these component scores yields a global score that ranges from 0 to 21. Pittsburgh Index scores greater than 5 indicate poor sleep quality and sleep disturbances.<sup>23,24</sup>

The fibromyalgia symptom impact on the health of the patients was assessed with the Fibromyalgia Impact Questionnaire (FIQ). It is composed of 10 items: physical

**Table 1.** Description of the full-body Shiatsu sequence

Position (duration)	Area of the body	Apply pressure with	Apply pressure on
Prone position (15 min)	Face	Fingertips	Points ST 3, SI 18, LI 20, ST 1, and BL 2
		Thumb pad	Point TE 23 bilaterally
	Abdomen	Palm of hand	Three longitudinal lines that cover ST, SP, KI, LR, and CY meridians
		Palm of hand	2 longitudinal lines in the medial side of the thigh, covering SP, KI, and LR meridians, with the limb semiflexed in hip and knee joints and laterally rotated in hip joint
			Thumb pad
	Lower limb	Palm of hand	ST and GB meridians in the lateral side of the thigh
		Thumb pad	ST meridian in the leg
		Fingertips	LR meridian in the leg, with the limb flexed in the knee joint
		Finger pads	A longitudinal line on the back of the foot, covering ST, GB, and LR meridians
	Foot	Fingertip	Points GB 40, BL 60, BL 62, SP 5, KI 3, and KI 6
		Thumb pad	Points ST 43, GB 42, LR 3, and KI 1; SP and KI meridians on the sole of the foot
		Thumb tip	Points ST 44, BL 66, GB 43, LR 1, and LR 2
Thumb pad		2 longitudinal lines in the lateral side of the neck, covering LI, ST, and SI meridians, with the head rotated	
Finger pads		Points LU 1, LU 2, ST 13, and ST 14 simultaneously	
Thumb tip		Point HT 1	
Neck, shoulder girdle, and upper limbs	Thumb pad	LI meridian and point HT 2 in the arm; point LI 10 and LI and TE meridians in the forearm; points LI 3 and LI 4	
	Finger pads	Points GV 16, BL 10, GB 20, GB 21; 2 longitudinal lines in the lateral side of the neck, covering LI, ST, and SI meridians; BL meridian under the medial border of scapula	
	Thumb tip	Points GB 29, GB 30, GB 34, and GB 39; ST and GB meridians in the lateral side of the thigh; with the limb semiflexed in hip and knee joints	
	Thumb pad	Spinous processes of the spine, covering GV meridian (light pressure); medial lines of BL meridian (perpendicular pressure); lateral lines of BL meridian (inferomedial pressure); point SI 13	
Side-lying position (5 min on each side)	Neck and shoulder girdle	Thumb pad	Points GV 16, BL 10, and GB 20
		Thumb pad	2 longitudinal lines in the lateral side of the neck, covering LI, ST, and SI meridians; point GB 21 and GV 21
	Lower limb	Thumb pad	3 longitudinal lines in the thigh, covering BL and KI meridians; BL and KI meridians in the leg
Supine position (10 min)	Back	Thumb pad	Point BL 57
		Thumb pad	BL and GB meridians in the head
	Head and neck	Finger pads	Points GV 16, BL 10, GB 20, HT 2, LI 3, LI 4, and LI 10
		Thumb pad	2 longitudinal lines in the lateral side of the neck, covering LI, ST, and SI meridians; point GB 21 and GV 21
Lower limbs	Palm of hand	3 longitudinal lines in the thigh, covering BL and KI meridians; BL and KI meridians in the leg	
	Thumb pad	Point BL 57	
	Thumb pad	BL and GB meridians in the head	
Sitting position (5 min)	Head, neck, and upper limbs	Fingertips	Points GV 16, BL 10, GB 20, HT 2, LI 3, LI 4, and LI 10
		Thumb tip	2 longitudinal lines in the lateral side of the neck, covering LI, ST, and SI meridians; points LI 16, SI 15, and GB 21
	Back	Thumb pad	2 longitudinal lines in the lateral side of the neck, covering LI, ST, and SI meridians; points LI 16, SI 15, and GB 21
		Palm of hand	BL meridian (friction)
		Lateral side of hand	All area of the back (percussion)

BL, bladder; CY, conception vessel; HT, heart; GB, gallbladder; GV, governor vessel; KI, kidney; LI, large intestine; LR, liver; LU, lung; SI, small intestine; SP, spleen; ST, stomach; TE, triple energizer.

impairment, well-being, loss of working days, job ability, pain, fatigue, morning tiredness, stiffness, anxiety, and depression. Each item score ranges from 0 to 10, and the sum of the items results in a total score ranging from 0 to 100. Higher scores indicate greater impact on health.<sup>25-27</sup> All

questionnaires were used in their validated Brazilian-Portuguese versions.

In each session, patients of the SG were questioned about adverse effects. In the end of treatment, they answered the question “What was your level of satisfaction

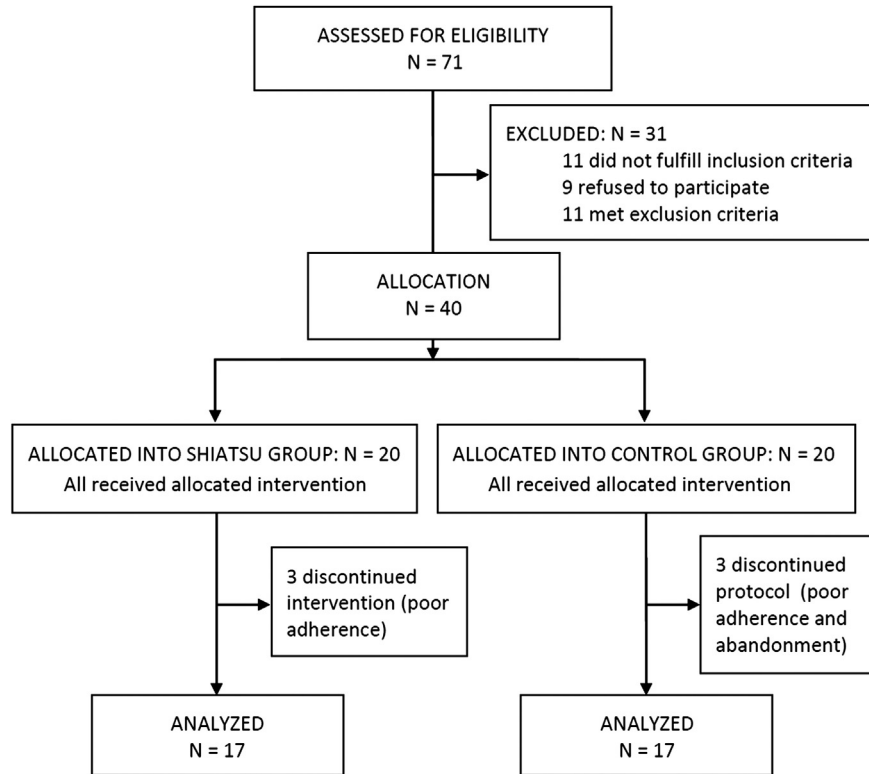


Fig 1. Study flow diagram.

with the treatment?” choosing one of these 5 options: very satisfied, satisfied, neither satisfied nor dissatisfied, dissatisfied, and very dissatisfied.

### Intervention

The CG received on the first day of assessment an educational booklet with information concerning fibromyalgia and how to manage this condition as well as a stretching exercise program. Patients remained for 8 weeks on the waiting list for usual care in the Physical Therapy Service.

The SG received a 16-session treatment with full-body Shiatsu for 8 weeks, twice a week. A physical therapist trained in Shiatsu applied pressure according to patient feedback, with the hands or fingers. The pressure intensity was as much as well tolerated and should not make the patient feel uncomfortably painful. In each session, the patients received individually a 40-minute sequence that addressed all the main meridians of the body in different positions (Table 1). Simultaneously, the meridians and acupuncture points were evaluated by touch and classified according to the level of pressure needed to evoke pain. The point is more compromised when less pressure is needed. Painful areas indicate excessive energy caused by the blockage of its flow in the meridian system. At the end of the session, a 2-minute sustained pressure treatment was applied on the 5 energetically most compromised points.<sup>28</sup>

Both groups continued with conventional pharmacotherapy during the trial.

### Data Analysis

In the statistical analysis, at baseline, groups were compared regarding sex and household income using the Fisher exact test and regarding marital status and use of medication using the  $\chi^2$  test. For age, education in years, and the outcome measures, Kolmogorov-Smirnov and Levene tests were used to verify normality and equality of variance of the data, respectively. Then, independent *t* tests were used with variables that were normally distributed, and Mann-Whitney rank sum tests were used with variables that were not normally distributed. After the 8-week study period, comparison between groups was performed through change scores, that is, the difference between the final and initial measurement of the variables. A significance level of .05 was adopted. These statistical tests were performed using software SigmaStat 3.5 (Systat Software, Inc, Erkrath, Germany).

An evaluation of clinically important differences was made, calculating the relative percentage change, according to the formula:

$$\text{Relative percentage change} = \frac{[(\text{mean absolute change in SG}) - (\text{mean absolute change in CG})]}{(\text{mean baseline scores for the variable in the sample})}.$$
<sup>29</sup>

**Table 2.** Characteristics of the sample

	SG (n = 17)	CG (n = 17)	P
Age (y), median (IQR)	52.0 (42.5-54.3)	50.0 (45.5-55.5)	1.00
Sex (female), n (%)	17 (100.0)	16 (94.1)	1.00
Education (y), mean (SD)	7.5 (4.6)	10.5 (3.4)	.042 <sup>a</sup>
Marital status, n (%)			.966
Single	4 (23.5)	5 (29.4)	
Married	7 (41.2)	5 (29.4)	
Divorced	5 (29.4)	5 (29.4)	
Widowed	1 (5.9)	2 (11.8)	
Household income, n (%)			1.00
<5 monthly minimum wage	16 (94.1)	15 (88.2)	
≥5 monthly minimum wage	1 (5.9)	2 (11.8)	
Medication, n (%)			.579
Analgesic/antiinflammatory	8 (47.1)	9 (52.9)	
Muscle relaxant	5 (29.4)	12 (70.6)	
Sedative/Anxiolytic/sleep inducer	4 (23.5)	5 (29.4)	
Antidepressant	8 (47.1)	15 (88.2)	
Others	14 (82.4)	13 (76.5)	

CG, control group; IQR, interquartile range; SG, Shiatsu group.

<sup>a</sup> Statistically significant difference.

**Table 3.** Mean, SD, and change score of the outcome measures for SG and CG

Variables	SG (n = 17)			CG (n = 17)			P
	Baseline, mean (SD)	After 8 wk, mean (SD)	Change score, median (IQR)/mean (SD)	Baseline, mean (SD)	After 8 wk, mean (SD)	Change score, median (IQR)/mean (SD)	
VAS (0-10)	7.2 (2.3)	5.1 (2.5)	-1.8 (-3.7 to -0.1)	6.4 (1.1)	7.1 (1.8)	0.4 (-0.2 to 1.6)	.004 <sup>a</sup>
PPT (kg/cm <sup>2</sup> )	0.8 (0.4)	1.2 (0.6)	0.2 (0.0 to 0.8)	0.8 (0.4)	0.6 (0.4)	-0.3 (-0.4 to -0.1)	.001 <sup>a</sup>
State-A (20-80)	53.9 (8.4)	48.0 (10.0)	-5.9 (10.0)	55.5 (11.2)	52.1 (11.3)	-3.4 (9.9)	.465
Trait-A (20-80)	57.9 (9.4)	53.1 (9.1)	-4.8 (10.8)	52.9 (11.6)	55.5 (12.0)	2.5 (9.6)	.045 <sup>a</sup>
PSQI (0-21)	12.0 (4.0)	8.1 (5.2)	-3.0 (-6.0 to -1.8)	11.9 (4.7)	12.1 (4.3)	2.0 (-1.3 to 3.0)	.004 <sup>a</sup>
FIQ (0-100)	66.7 (18.8)	48.2 (20.4)	-16.0 (-29.3 to -7.0)	65.2 (16.1)	61.4 (17.8)	-3.0 (-5.3 to 6.5)	.006 <sup>a</sup>

CG, control group; CI, confidence interval; FIQ, Fibromyalgia Impact Questionnaire; IQR, interquartile range; PPT, pressure pain threshold; PSQI, Pittsburgh Sleep Quality Index; SG, Shiatsu group; State-A, State Anxiety; Trait-A, Trait Anxiety; VAS, visual analog scale.

<sup>a</sup> Statistically significant difference between groups (change scores).

A change of 30% for VAS was considered clinically relevant, based on the study of Farrar et al,<sup>30</sup> which demonstrated the clinical importance of a change of 2 points or 30% in chronic pain intensity. For FIQ, Bennet et al<sup>31</sup> demonstrated that a 14% change in the total score could be considered the minimal clinically important difference. Because there are no specific studies of minimal clinically relevant change for the other variables, a value of 15% was adopted, according to the Philadelphia Panel guidelines on selected rehabilitation interventions for back, neck, knee, and shoulder pain.<sup>32</sup>

At baseline, the groups were similar regarding all the outcome measures ( $P > .05$ ). After the study period, statistically significant differences between groups were found for all variables, except state anxiety. These results are presented in Table 3.

The relative percentage changes obtained with Shiatsu are illustrated in Figure 2. They were considered clinically relevant for VAS (40.6%), PPT (76.4%), PSQI (34.4%), and FIQ (22.30%).

There were no reports of adverse effects with Shiatsu. At the end of treatment, 5 (29.4%) patients were very satisfied, 11 (64.7%) were satisfied, and 1 (5.9%) was neither satisfied nor dissatisfied.

## RESULTS

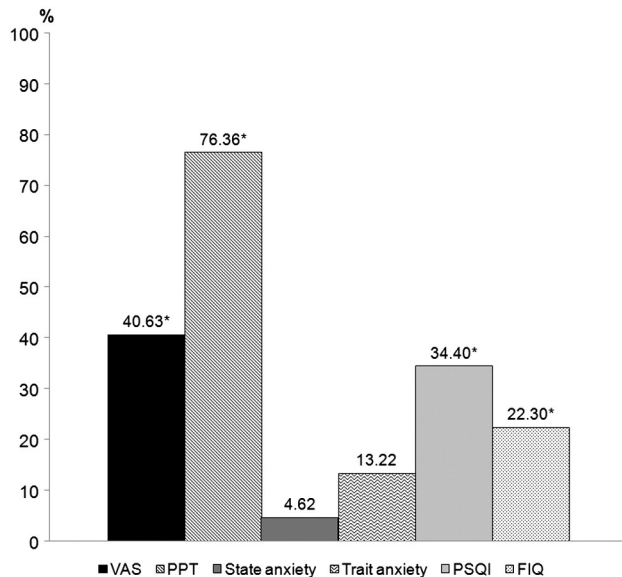
Patients were recruited, assessed, and treated between July 2010 and December 2011. A flowchart describing the clinical trial is presented in Figure 1.

The characteristics of the sample are presented in Table 2. The groups were similar in all items, except years of education, for which the SG had, on average, fewer years of education than the CG.

## DISCUSSION

The objectives of this pilot study were to evaluate the potential effects of Shiatsu on the symptoms of adult patients with primary fibromyalgia, propose a Shiatsu treatment protocol, and verify its feasibility, adequacy, and patient acceptability. The full-body Shiatsu sequence applied for 8 weeks, twice a week, presented potential





**Fig 2.** Relative percentage changes in outcome measures with Shiatsu. \*Clinically important change relative to the CG. FIQ, fibromyalgia impact questionnaire; PPT, pain pressure threshold; PSQI, Pittsburgh Sleep Quality Index; VAS, visual analog scale.

effects of reduction of pain, improvement of sleep quality, and a decrease in symptoms of fibromyalgia impact on health. No effects were observed for state anxiety after treatment, whereas for trait anxiety, a statistically significant but not clinically relevant change was observed. No adverse effects were reported during the treatment, and most patients demonstrated satisfaction with Shiatsu.

In TCM, pain is one of the signs of excess energy in areas where the flow of the vital energy is blocked along the meridian.<sup>28,33</sup> In the present study, the improvement of pain with Shiatsu may be caused by the unblocking of the flow of vital energy by pressure stimulation of the meridians and their points, contributing to restore the energy balance of the patient, according to the principles of acupuncture.<sup>12</sup> In a literature review, based on well-designed experimental studies, the authors concluded that acupressure is more effective than no-treatment or placebo control for reducing pain, namely, dysmenorrhea, lower back pain, and labor pain.<sup>10</sup>

From the Western medicine point of view, central amplification is considered the underlying process for chronic widespread pain in fibromyalgia. The ascending and descending neural pathways involved in pain processing operate abnormally. Signals in these pathways are mediated by a number of neurotransmitters and neurochemicals.<sup>34</sup> Pain reduction may be attributed to the increase in the levels of neurotransmitters, such as serotonin and dopamine, observed in several studies with massage therapy. The effects of massages in general of release of muscle tension and increase of blood circulation, facilitating the removal of toxic metabolic waste products, may also contribute to relieve pain.<sup>16</sup>

The observed improvement in PPT in TP may be caused by the analgesic effects of Shiatsu already mentioned above and also by the increase of local blood flow allowing more oxygen and nutrients to reach body tissues.<sup>16</sup> Researchers observed that a vasoconstriction occurs in the skin above TP, supporting the hypothesis that the pathogenesis of TP is related to local hypoxia.<sup>35</sup> Studies with participants with fibromyalgia showed that massage therapy decreased the number of positive TP and increased PPT.<sup>36–38</sup>

Trait anxiety refers to the individual's disposition to respond to stress with anxiety and tendency to perceive a wider range of situations as threatening, whereas the state anxiety refers to a transitory emotional state associated with subjective feelings of tension that may vary in intensity over time.<sup>39</sup> In the current study, both groups presented high levels of anxiety, which are characteristic of individuals with fibromyalgia.<sup>40</sup> Although a statistically significant difference was observed for trait anxiety, no effects on anxiety can be considered clinically relevant. These results are explained for trait anxiety because it is a more stable measure and practically unchangeable under different conditions.<sup>39</sup> For state anxiety, on the other hand, changes were not observed in this study possibly because the variable was reassessed only a few days after the last session of treatment, whereas in most studies with fibromyalgia, it is reassessed immediately after the massage. Effects of reduction of anxiety with massages in general were observed, including in fibromyalgia, in association with the decrease in stress hormone cortisol and an increase in serotonin levels.<sup>16,41</sup> In a study about acupressure, researchers observed, immediately after treatment, a decrease in preoperative anxiety, which returned to baseline values after 30 minutes.<sup>42</sup>

There are many hypotheses regarding the mechanism that causes poor sleep quality in fibromyalgia. Evidence indicates that nociceptive stimulation has an adverse effect on circadian sleep/wakefulness. Besides, studies show that serotonin deficiency causes insomnia in animals and humans, and increased levels of substance P cause sleep disturbances in animals.<sup>43</sup> In the present study, the improvement of pain achieved in the patients treated with Shiatsu may have contributed to the improvement in sleep quality. The effects of release of serotonin and decrease of substance P with massages in general may also be responsible for this sleep improvement.<sup>16,36</sup> In 2 studies about massage therapy in fibromyalgia, positive effects on sleep were observed after treatment.<sup>36,44</sup> In a literature review, authors concluded that the evidence for improving sleep quality with acupressure is consistent, based on the results of good-quality clinical trials in samples of institutionalized elderly. Most studies compared and observed that acupressure is superior to sham acupressure, providing evidence that support the hypothesis that the technique causes specific effects on sleep, from the TCM point of view.<sup>10</sup>

The statistically significant and clinically important proportion of improvement for FIQ reflects the reduction

of the symptoms of fibromyalgia impact on patients' health and confirms the benefits of Shiatsu in this syndrome. Previous studies strengthen the evidence in favor of this massage technique for also presenting improvements in FIQ total score.<sup>37,45,46</sup>

Because no prior study was found, there was a need for a pilot study of Shiatsu in fibromyalgia. The results of the present study are promising and encourage further research. It also proposes a feasible, safe, and well-accepted Shiatsu treatment protocol and provides a base for the design and implementation of future trials. Blind, randomized, placebo-controlled trials with larger samples should be conducted to confirm the preliminary evidence of the effectiveness of Shiatsu in patients with fibromyalgia observed in the present pilot study.

### Limitations of the Study

The types of medication in use by the patients were registered; however, a more detailed analysis concerning the dosages of each medication was not done. The small sample size is another limitation of the study. The assignment of patients into the groups was not randomized, and the assessment was not blinded because of logistic difficulties. The psychosocial context of the intervention of the SG was more favorable for the patients to present placebo-related effects than the CG because contextual and social stimuli may affect the patient's brain and body.<sup>47</sup> However, these types of effects were not assessed. These may be sources of bias in the current pilot study, and the results may not be generalizable to a larger population.

### CONCLUSION

The present pilot study showed the potential of Shiatsu with the observed effects of improvement of pain intensity, PPT, sleep quality, and symptoms of fibromyalgia impact on health of patients with fibromyalgia. No clinically relevant effects were observed for anxiety after treatment. The proposed Shiatsu treatment protocol was feasible and seemed to be well accepted by the patients. There is the need of future research to confirm these preliminary results, and this pilot study provides a basis for the design and implementation of larger randomized controlled trials.

#### Practical Applications

- Shiatsu showed promising improvement in pain intensity, PPT, sleep quality, and symptoms for patients with fibromyalgia in this study.
- The proposed Shiatsu treatment protocol was feasible and well accepted by the patients.

### FUNDING SOURCES AND POTENTIAL CONFLICTS OF INTEREST

No funding sources or conflicts of interest were reported for this study.

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