Combined Therapy (Ultrasound and Interferential Current) in Patients with Fibromyalgia: Once or Twice in a Week?

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RESEARCH ARTICLE

Combined Therapy (Ultrasound and Interferential Current) in Patients with Fibromyalgia: Once or Twice in a Week?

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Abstract

Background and Purpose. Combined Therapy (CT) composed of ultrasound and Interferential Therapy has been reported as a cost-effective, local analgesic intervention on tender points in Fibromyalgia (FM). This study aims to investigate the difference between CT applied once a week and twice a week in patients with FM. **Methods.** Fifty patients with the diagnosis of FM were randomized into two groups (G1 = once a week treatment and G2 = twice a week treatment) with each group containing 25 patients. All eighteen tender points were assessed and treated with CT during each session, over a three-month time period. Interferential Therapy was modulated at 4,000 Hz of current carrier, 100 Hz of amplitude modulated frequency and at a bearable sensorial threshold of intensity. Pulsed ultrasound of 1 MHz at 20% of 2.5 W/cm² was used. For evaluation, the Visual Analogue Scale, Fibromyalgia Impact Questionnaire, Post Sleep Inventory and the tender point count were utilized, and the examiner was blinded to the group assignments. **Results.** G1 and G2 showed a significant improvement in Visual Analogue Scale ($p < 0.0001$ and $p < 0.0005$, respectively), Tender Points ($p < 0.005$ and $p < 0.001$, respectively), Fibromyalgia Impact Questionnaire and Post Sleep Inventory ($p < 0.005$ and $p < 0.05$, respectively). However, there was no significant difference between the two groups in all performed analyses. **Conclusion.** There is no advantage in increasing the number of sessions of combined therapy in terms of reducing generalized pain, quality of life and sleep quality for patients with FM.

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Keywords

electrotherapy; fibromyalgia; tender points; widespread pain

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Background

Fibromyalgia (FM) is a syndrome characterized by chronic widespread pain and tenderness on palpation, particularly at the tender points (TP) (Wolfe et al., 2010). Physical therapy modalities have been considered as valid approaches in reducing medication, increasing function and serving as better cost-effective strategies. It has been estimated that in Brazil, FM syndrome can be found in 0.66–4.4% of the general population and targets women 35–64 years old (Senna et al., 2004; Cavalcante et al., 2006), with lower socioeconomic status (Senna et al., 2004) and who perform physically demanding jobs (Mäckelä and Heliövaara, 1991). Studies show that high physical and psychological stress, (Mäckelä and Heliövaara, 1991; Cleare, 2004) as well as diminished socioeconomic condition, (Senna et al., 2004; Mäckelä and Heliövaara, 1991) act to sustain FM symptoms and thus worsen the quality of life. On the other hand, poor sleep has been reported in FM based on sleep recordings (Wolfe et al., 2010), particularly in those who complain of chronic musculoskeletal pain, fatigue and negative mood. Although the association of impaired sleep and the subjective experience of non-refreshing sleep is not uniformly reported in FM (Roizenblatt et al., 2001), there is a strong relationship between non-refreshing sleep and FM (Wolfe et al., 2010).

Electrotherapeutical modalities of rehabilitation are important resources in the treatment of musculoskeletal pain. Pulsed (ultrasound) US can promote tissue healing, favour microcirculation and vascular permeability, promote muscle relaxation (Srbely and Dickey, 2007), stimulate angiogenesis (Barzelai et al., 2006; Watson, 2008) and increase the metabolism and permeability of the cell membrane (Mortimer and Dyson, 1988), thereby justifying its analgesic effects. Srbely and Dickey have shown a reduction of myofascial pain with the use of pulsed US (Srbely and Dickey, 2007). There is evidence that Interferential Therapy (IFT) may inhibit the nociceptive stimulus, possibly due to the stimulation of large diameter afferent fibres that inhibit the entrance of algid stimuli into the posterior horn of the medulla through small diameter afferent fibres (Chung, 1985; Fourie and Bowerbank, 1997). Combined Therapy (CT) is defined as the combination of pulsed US and bipolar electrotherapeutical current in a modality of physical therapy (Almeida et al., 2003). The combination of both resources is widely used in cases of musculoskeletal pain. For instance, our group has obtained positive results with CT when applied to the TP of FM patients, including reduction of pain and improvement of sleep quality after twelve sessions within a four-week period (Almeida et al., 2003). However, because it is a time-consuming therapy and may raise concern over costs, we conducted this study to compare the effectiveness between once and twice-a-week sessions of CT applied to FM women.

Methods

This was a longitudinal, randomized, prospective study that had been previously approved by the Medical Ethics Committee of Pontifical Catholic University of Campinas.

Patients

The sample size estimation calculations were predicated upon detecting a six-point difference in the Visual Analogue Scale (VAS) based on a previous study that shows the minimum clinically significant difference on a four-point reduction (Almeida et al., 2003), assuming a standard deviation of two points, an alpha level of 0.05, and a power of 80%. This generated a sample size of 15 patients per group. Allowing for a conservative dropout rate and with the intent to have two groups, we recruited 68 patients to participate in the study, while providing adequate protection against type II error. These 68 female volunteers with a diagnosis of FM (Wolfe et al., 2010) were consecutively recruited from the outpatient service of the Department of Rheumatology of Pontifical Catholic University of Campinas. Inclusion criteria included an age ranging from 40 to 55 years old, current complaints of widespread pain and non-reparative sleep during the previous 6 months. Exclusion criteria were: 1) a body mass index (BMI) higher than 30 kilogrammes per square metre (BMI is defined as the patient's body weight, in kilograms, divided by the square of the patient's height, in metres,; 2) presence of neurological, endocrine, muscular, infectious diseases or other inflammatory rheumatic diseases; 3) as well as the use of medications or drugs that affect the central nervous system (such as antidepressants and analgesics). Eighteen patients were excluded because they did not match the inclusion criteria. Fifty patients were randomly allocated to groups, with the use of a computer-generated list of random numbers created and managed by a physiotherapist who was blinded to all information about the patients. Patients drawing an even number were assigned to group I (G1), and those drawing an odd number were allocated in group II (G2).

After reading and signing the informed consent form, patients were randomized into G1 that underwent CT once a week, and G2 that underwent CT twice a week within a twelve-week period. Randomization was performed by drawing with replacement. The 50 patients selected consented to the protocol before undergoing treatment with CT. However, because of lack of adherence, three patients were excluded during the study, and therefore, 47 patients (24 in G1 and 23 in G2) completed the protocol.

Study design

The treatment consisted of 12 sessions carried out on Wednesdays for G1 and of 24 sessions carried out on Mondays and Thursdays for G2. The VAS measured the pain during the assessment (VAS) and during the past 7 days (VAS7). Fibromyalgia Impact Questionnaire (FIQ) and Post Sleep Inventory (PSI) were performed before and after treatments by an experienced rheumatologist, blinded to the treatment group to which the patient belonged (Figure 1). The number of TP was also assessed by the same rheumatologist. Prior to treatment, both groups were homogeneous in all the variables (mean ± SD): VAS ($G1 = 7.6 \pm 2.6$; $G2 = 8.8 \pm 1.7$; $p = 0.240$), VAS7 ($G1 = 9.5 \pm 0.7$; $G2 = 8.8 \pm 1.9$, $p = 0.643$), FIQ ($G1 = 73.6 \pm 9.8$; $G2 = 65.1 \pm 12.2$; $p = 121$), PSI ($G1 = 99.3 \pm 15.7$; $G2 = 88.9 \pm 17.6$; $p = 0.287$), age ($G1 = 53.2 \pm 4.8$; $G2 = 52.6 \pm 4.9$; $p = 0.781$) and in the number of TP ($G1 = 15 \pm 3$; $G2 = 13.6 \pm 3.9$; $p = 0.458$). These data are described in Table 1.

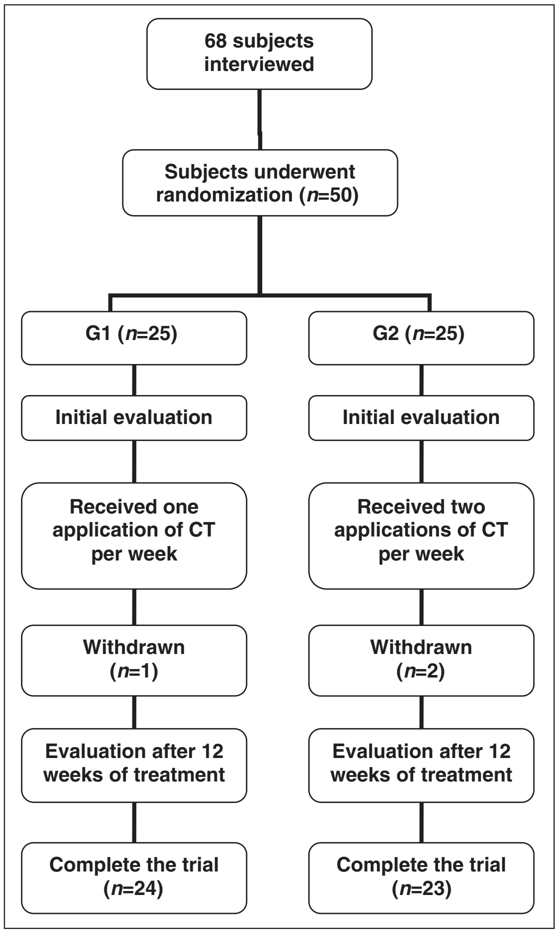

Figure 1. Participant flow through the randomized trial

Treatment

Patients in G1 (n = 25) and G2 (n = 25) underwent electrodiagnosis of painful areas by means of continuous US (ultrasound) (1 MHz; 0.5 W/cm^2) and IFT (4000 Hz; AMF-100 Hz; intensity in the tactile sensation threshold). After mapping these areas, treatment was carried out with pulsed US (1 MHz; 2.5 W/cm^2, duty cycle 20%) and IFT for 2 minutes on each of the painful TP.

The subject was comfortably seated, and dispersive electrode was positioned on the dorsal area over the T7–T8 vertebra for application over the TP on the upper part of the trunk and upper limbs. Next, the patients were positioned in prone position with the dispersive electrode positioned over L3–L4 vertebra for application over the TP of the lower part of the trunk and lower limbs. The chosen treatment dose was the same as the one suggested by Almeida et al. (Almeida et al., 2003), consisting of 1 MHz pulsed US form at 20% with a dose of 2.5 W/cm^2, an IFT at bipolar form, a current of 4,000 Hz, an AMF of 100 Hz and an intensity at a bearable sensorial threshold for the patient. In our research, the equipments used were Neurovector and Sonopulse III (Ibramed, Amparo-SP, Brazil) —the latter was custom-made for the study, with an intensity changed to 2.5 W/cm^2).

Pain evaluation

Visual Analogue Scale of Pain

The amount of pain measured with the use of VAS was used in two different forms: VAS and VAS7.

Tender Point count

Evaluation of the 18 TP by digital pressure (Wolfe et al., 2010) was performed bilaterally in sub-occipital muscle, transverse processes of C5–C7, trapezium muscle, supraspinal muscle, second chondrocostal junction, elbow lateral epicondyle, gluteus medium,

Table 1. Characteristics of the patients in the baseline and after treatment

	Before treatment			After Treatment		
	G1	G2	*p*-value	G1	G2	*p*-value
TP	15 ± 3* (16.5)	13.6 ± 3.9† (14.5)	0.458	6.9 ± 5.5* (6)	4 ± 2.8† (3.5)	0.154
VAS	7.6 ± 2.6α (8.5)	8.8 ± 1.7∞ (10)	0.240	3.1 ± 2.3α (4)	1.6 ± 2.3∞ (0)	0.162
VAS7	9.5 ± 0.7‡ (10)	8.8 ± 1.9§ (10)	0.643	3.3 ± 2.6‡ (4)	1.9 ± 1.7§ (2.5)	0.171
FIQ	73.6 ± 9.8‖ (74.5)	65.1 ± 12.2¶ (67)	0.121	48.8 ± 21‖ (55)	42.9 ± 18.7¶ (45)	0.745
PSI	99.3 ± 15.7¥ (99)	88.9 ± 17.6µ (94)	0.287	62 ± 24.7¥ (68.5)	56.3 ± 29.7µ (57)	0.688
Age in years	53.2 ± 4.8 (52.5)	52.6 ± 4.9 (52.5)	0.781			

All values are mean ± SD (median). For all scales the assessments and questionnaires, the scores decrease with relief of pain or symptoms. The main results obtained in the intra-group evaluation were as follows:

*Statistically significant improvement in the number of TP in G1 ($p < 0.0001$)

†Statistically significant improvement in the number of TP in G2 ($p < 0.0001$)

αStatistically significant improvement in VAS in G1 ($p < 0.0001$)

∞Statistically significant improvement in VAS in G2 ($p < 0.0001$)

‡Statistically significant improvement in VAS7 in G1 ($p < 0.0001$)

§Statistically significant improvement in VAS7 in G2 ($p < 0.0001$)

‖Statistically significant improvement in FIQ in G1 ($p < 0.0001$)

¶Statistically significant improvement in FIQ in G2 ($p < 0.0001$)

¥Statistically significant improvement in PSI in G1 ($p < 0.0001$)

µStatistically significant improvement in PSI in G2 ($p < 0.0001$)

femoral trochanter and knee. Assessment of TP by digital pressure has been considered as reliable as the one measured by an algometer (Tastekin et al., 2007).

Quality of life

The quality of life was measured by using the FIQ. This is a questionnaire proposed by Burckhardt et al. that aims to evaluate the quality of life of patients, specifically with FM (Marques et al., 2006).

Sleep complaints

The PSI composed of 29 items with a 13-point scale was used for this analysis. The lower the PSI score, the better quality of patient's sleep and vice-versa (Webb et al., 1976). This questionnaire was chosen because it is a valid and reliable method to be applied to patients with FM (Martinez et al., 1995).

Statistical analysis

The statistical programme GraphPad Instat III (GraphPad Software Inc., San Diego, CA, USA) was used for processing the results obtained from the two groups. Based on the results obtained from TP, VAS, VAS7, FIQ and PSI, data normalisation was carried out by using an index with the final value minus the initial evaluation divided by the initial evaluation (F-I/I). The evaluation of all the variables was carried out by the non-paired *t*-test for non-parametric samples. The values are expressed as average ± standard deviation (median) with statistical significance considered for $p < 0.05$.

Results

Fifty patients began the treatment. However, three patients didn't reach the final evaluations because of lack of regularity, and they were automatically excluded. Table 1 shows the average ± standard deviation (median) and *p*-value for these data. Figure 2 shows comparison between G1 and G2 indices (F-I/I) obtained after treatment.

Tender Points

For the evaluation after the treatment for positive TP, the results found were: G1 equals 6.9 ± 5.5 (6); G2 equals 4 ± 2.8 (3.5), showing no significant differences ($p = 0.154$) between the groups. However, G1 and G2 (Table 1) showed a significant difference between before-treatment and after-treatment evaluation ($p < 0.005$ and $p < 0.0001$, respectively). After the analysis of the index (F-I/I), the final results found were: G1 equals −0.5 ± 0.3 (−0.6); G2 equals −0.7 ± 0.2 (−0.8), showing no significant differences ($p = 0.186$) between the groups (Figure 2).

Visual Analogue Scale and Visual Analogue Scale during the past 7 days

The results found for the VAS evaluation were: G1 equals 3.1 ± 2.3 (4); G2 equals 1.6 ± 2.3 (0), showing no significant differences ($p = 0.162$) between the groups (Table 1). For the index (F-I/I) of VAS, the results were: G1 equals −0.6 ± 0.3 (−0.6); G2 equals −0.8 ± 0.2 (−1), showing no significant differences between the groups ($p = 0.122$), but there was a significant improvement in G1 and G2 ($p < 0.0001$ and $p < 0.0005$, respectively).

In the VAS7 analysis, we found: G1 equals 3.3 ± 2.6 (4); G2 equals 1.9 ± 1.7 (2.5), again no significant difference was observed ($p = 0.171$) between the groups. Both groups showed a significant improvement after treatment ($p < 0.0001$). No significant differences in the index (F-I/I) were found: G1 equals −0.7 ± 0.3 (−0.6); G2 equals −0.8 ± 0.2 (−0.7) ($p = 0.452$).

Post-Sleep Inventory

In the evaluation of PSI, the obtained values were: G1 equals 62 ± 24.7 (68.5); G2 equals 56.3 ± 29.7 (57), no significant differences were found between the groups ($p = 0.688$). In the analysis of the index (F-I/I), the results were: G1 equals −0.4 ± 0.2 (−0.3); G2 equals −0.3 ± 0.5 (−0.5), (Figure 2.) showing no significant differences between the groups ($p = 0.955$). However, G1 and G2 showed a significant improvement after treatment ($p < 0.005$ and $p < 0.05$, respectively).

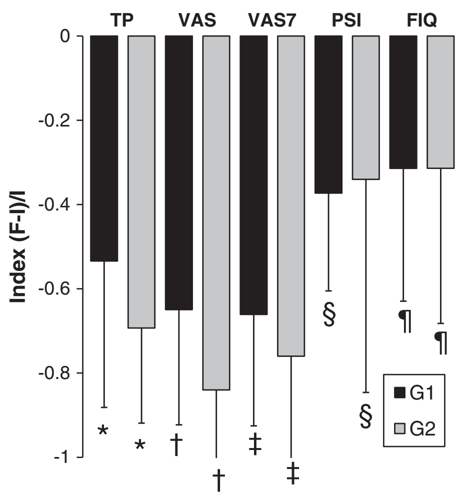

Figure 2. Comparison between the indices (F-I/I) obtained in the evaluation of the TP, VAS, VAS7, PSI and FIQ in both groups studied. Abbreviations: G1, group 1; G2, group 2. Negative numbers indicate decrease in the numbers of TP and pain, besides improvements in PSI and FIQ. * No significant difference ($p = 0.186$); † no significant difference ($p = 0.122$); ‡ difference considered not significant ($p = 0.452$); § difference considered not significant ($p = 0.955$); ¶ no significant differences ($p = 0.999$).

Fibromyalgia Impact Questionnaire

After analyzing the data of this questionnaire regarding the patient's quality of life, the results found were: G1 equals 48.8 ± 21 (55); G2 equals 42.9 ± 18.7 (45), showing no differences between the groups ($p = 0.515$). Moreover, G1 and G2 showed a significant improvement after treatment ($p < 0.005$ and $p < 0.05$, respectively). After evaluating the index (F-I/I), we found these results: G1 equals −0.3 ± 0.3 (−0.2); G2 equals −0.3 ± 0.4 (−0.4), showing no significant differences ($p = 0.999$) between the groups (Figure 2).

Discussion

The focus of the present prospective study was to compare the once-a-week and twice-a-week protocols of CT in FM women. Both protocols showed improvement in all the outcomes assessed before and after treatment, without intergroup differences. One of the most important outcomes was the improvement in the quality of life and quality of sleep, measured with the FIQ and PSI, respectively. Based on these results, we can observe that CT was effective not just in the improvement of the musculoskeletal symptoms but also helped the patients have an improved sleep quality and quality of life. The symptoms of musculoskeletal pain, as measured with VAS, VAS7 and number of TP, also had a significant improvement in both groups after treatment. In our study, once the patients have a reduction in the number of TP, the subjective feeling of pain (measured by VAS and VAS7) is diminished. Previous studies show that the VAS and algometry are highly sensitive and specific for the assessment of FM patients, showing a great discriminative power (Marques et al., 2008). This study adds evidence on the effectiveness of electrotherapeutical tools in the treatment of FM syndrome, which is a scant subject in scientific literature. Therapeutic effects have already been described in previous studies concerning electroacupuncture (Deluze et al., 1992) and TENS (Silva et al., 2008), although they appear rather contradictory. Another previous study showed the effectiveness of US in myofascial pain (Srbely and Dickey, 2007), but it was not assessed as musculoskeletal pain due to FM syndrome.

Our study is supported by the findings of further research on CT, such as Citak-Karakaya and co-workers (Citak-Karakaya et al., 2006) who obtained analgesic effects with the combination of US and high voltage-pulsed galvanic current, in patients with FM. Our study found similar results to the ones published by Almeida et al. (Almeida et al., 2003), thereby demonstrating that CT is effective in the improvement of quality of life, quality of sleep and improving pain sensation. Almeida et al. (Almeida et al., 2003) found a great reduction in the VAS score after treatment and the improvement in the quality of sleep that may be attributed to the reduction of pain. Furthermore, we suppose that improvement in quality of life, evaluated by FIQ, was limited by the persistence of some maintenance factors in the FM syndrome. Among these, we can identify high physical and psychological stress, which are features of FM (Mäckelä and Heliövaara, 1991; Cleare, 2004) that affect the cognitive and emotional factors of these patients. Therefore, other therapeutic modalities, like cognitive-behavioral therapy, antidepressants and exercise, can be used together with CT (Häuser et al., 2009).

Our findings do not exclude the effect of other therapeutic modalities in relieving FM symptoms, such as aerobic and muscle-strengthening exercises, because of tissue oxygenation and an increase in muscle endurance (Richards and Scott, 2002; Mannerkorpi et al., 2000). Mannerkorpi and co-workers (Mannerkorpi et al., 2000) randomized 69 patients for either a six-month pool exercise programme or a control group that continued with their usual activities. The final results showed significant improvement in FIQ compared with the control group. Similarly, Kayo and co-workers in a randomized clinical trial demonstrated a good improvement in VAS and FIQ in women with FM that were submitted to a muscle-strengthening or a walking programme (Kayo et al., 2011). These results indicate that exercise can be associated to other treatment modalities, such as CT, in the treatment of FM.

The mechanisms by which CT provides relief of pain are not totally known. There is evidence that IFT may inhibit the nociceptive inputs. This may be due to the stimulation of great diameter afferent fibers that inhibit the entrance of painful stimuli into the posterior horn of the medulla through the small diameter afferent fibers (Chung, 1985; Stephenson and Walker, 2003; Jorge et al., 2006). Studies show that there is a great release of substance P through the small diameter afferent fibers (type C fibers) in the posterior horn of the medulla (Zimmermann, 1991). Additionally, Zimmerman described the existence of high amounts of substance P in the cerebrospinal liquid in patients with FM (Zimmermann, 1991). This process generates an increased excitability in the posterior horn neurons that lead to an alteration over the nociceptive information that reaches the cortex (Stisi et al., 2008). Furthermore, IFT may reduce the arborization of free-nerve terminations, thus preventing synaptic plastic rearrangement of the wide dynamic range cells of the hypersensitized cells (Goats, 1990). This therapeutic process obtained with IFT can be useful in FM because there is evidence that these patients may have synaptic plastic alterations in the dorsal horn of the spinal cord and free nerve endings. Moreover, there may be insufficient pain suppression that promotes hyperalgesia and allodynia (Bennett, 1999). There is evidence that the type C fibers are hyper-stimulated in these patients, possibly because of their low excitement threshold (Staud, 2009). The IFT can promote relief of symptoms by blocking the C amyelinated afferent fibers through stimulation of the Aβ myelinated fibers (Melzack and Wall, 1965). Furthermore, Carvalho e Silva and co-workers found that IFT can also promote muscle relaxation and promote pain reduction (Carvalho e Silva et al., 2011). Bengtsson and co-workers (Bengtsson et al., 1989) showed a significant pain reduction in patients with FM after the application of local anaesthetics that prevent the transmission of painful pulses to the spinal medulla, which suggests that peripheral mechanisms are present as causes of pain in FM, and therefore a local therapeutic modality like CT can be effective.

Pulsed US can be useful in FM patients because Bazzichi and co-workers (Bazzichi et al., 2009) have shown that people who suffer with FM can demonstrate a difference in muscle fibre activation or possibly an atrophy of type II fibers, suggesting that these muscles are unable to reach muscle relaxation. Park and co-workers (Park et al., 1998) have observed metabolic changes and low blood perfusion inside the muscles of patients with FM. This can explain the focal sustained contraction and the favourable appearance of TP. Therefore, US can promote benefits in FM patients because it can promote angiogenesis (Barzelai et al., 2006), tissue healing (Jeremias Júnior et al., 2011), muscle relaxation (Srbely and Dickey, 2007) and an increase in metabolism and permeability of cell membrane (Mortimer and Dyson, 1988). Although reduction of muscular pain caused by the constant contraction of muscles can be attributed to the therapeutic effects of pulsed US, controversies still remain regarding its effect on myofascial pain (Srbely et al., 2009; Rickards, 2006). On the other hand, our results showed a good improvement in widespread pain seen in FM patients who associated pulsed US with IFT.

A limitation of the present study is the fact that researchers who applied the CT were not blinded. However, this fact probably didn't influence the final results because the patients were evaluated by a blinded assessor. The authors did not include a placebo group because Almeida et al. (Almeida et al., 2003) showed that CT is superior to a placebo group, and it would be an illegal study according to ethical considerations. Another limitation of the study was the absence of long-term follow-up, so we were not able to see if the results were maintained after the treatment.

This study helps the professional who works with FM patients to know that it is possible to obtain improvement of symptoms only with one application of CT a week, generating a smaller cost for the treatment, and thus making it more accessible. The FM treatment can be expensive because of the multiprofessional characteristic of patient care (Häuser et al., 2009). FM patients need to spend money on medication, psychologists (Cleare, 2004) and physiotherapists. In Brazil, most FM patients have lower socioeconomic status (Senna et al., 2004), and clearly, it is important to offer the most efficient treatment solution for the least amount of money.

Conclusion

Although CT can be an important tool in the treatment of woman with FM, there is no significant difference between one or two applications per week. Because one application is as effective as two applications per week, the treatment can be cheaper and more affordable.

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Conflict of interest

The authors declare no conflict of interest.

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