Paraspinal Stimulation Combined With Trigger Point Needling and Needle Rotation for the Treatment of Myofascial Pain: A Randomized Sham-controlled Clinical Trial

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Background: There are different types and parameters of dry needling (DN) that can affect its efficacy in the treatment of pain that have not been assessed properly.

Objective: To test the hypothesis that either multiple deep intramuscular stimulation therapy multiple deep intramuscular stimulation therapy (MDIMST) or TrP lidocaine injection (LTrP-I) is more effective than a placebo-sham for the treatment of myofascial pain syndrome (MPS) and that MDIMST is more effective than LTrP-I for improving pain relief, sleep quality, and the physical and mental state of the patient.

Methods: Seventy-eight females aged 20 to 40 who were limited in their ability to perform active and routine activities due to MPS in the previous 3 months were recruited. The participants were randomized into 1 of the 3 groups as follows: placebo-sham, LTrP-I, or MDIMST. The treatments were provided twice weekly over 4 weeks using standardized MDIMST and LTrP-I protocols.

Results: There was a significant interaction (time vs. group) for the main outcomes. Compared with the sham-treated group, MDIMST and LTrP-I administration improved pain scores based on a visual analog scale, the pain pressure threshold ($P < 0.001$ for all analyses), and analgesic use ($P < 0.01$ for all analyses). In addition, when comparing the active groups for these outcomes, MDIMST resulted in better improvement than LTrP-I ($P < 0.01$ for all analyses). In addition, both active treatments had a clinical effect, as assessed by a sleep diary and by the SF-12 physical and mental health scores.

Conclusions: This study highlighted the greater efficacy of MDIMST over the placebo-sham and LTrP-I and indicated that both active treatments are more effective than placebo-sham for MPS associated with limitations in active and routine activities.

Key Words: myofascial pain syndrome, intramuscular stimulation, acupuncture, sleep quality, pain threshold

(*Clin J Pain* 2014;30:214–223)

Myofascial pain syndrome (MPS) is characterized by the presence of myofascial trigger points (TrPs).[1] TrPs are defined as localized, hyperirritable nodules nested within a palpable taut band of skeletal muscle or fascia.[2] TrPs were the source of pain for 30% to 85% of patients with MPS presenting in the primary care setting and pain clinics according to some epidemiologic studies.[3–5]

TrP injections (TrP-I) with local anesthetics have been performed to alleviate musculoskeletal pain since the early 1930s. According to the results of several studies, injection continues to be the most common choice for treatment.[6–8] However, the superiority of local injection or dry needling (DN) for the inactivation of TrP is controversial; both techniques have shown similar therapeutic efficacies.[7,9] Given the evidence presented above, we sought to compare the effects of TrP injection and DN in the same context. In this way, we would be able to examine whether one treatment is beneficial compared to the other, and we could compare both treatments against a placebo because this information is relevant to future clinical decisions.

The intramuscular stimulation (IMS) technique is a type of DN that is applied in the spinal segment of the nerve roots associated with the dermatome, myotome, or sclerotome, where the trigger points were found.[10,11] Previous studies revealed that IMS may be superior to DN at TrP[12,13] and classic methods[7,12,14] for the alleviation of pain in MPS. However, these findings are counterbalanced by inconsistent results from meta-analyses[15–17] regarding the effectiveness of acupuncture and DN for myofascial TrP,[17] back and neck pain.[15–17] These gaps are corroborated by the lack of studies examining the efficacy of acupuncture and/or DN treatment for pain conditions in the same context. Parameters such as the site[18] and depth of needle penetration,[19] the combined application of TrP injection and paraspinal DN,[20] and needle rotation (NR)[21] should be taken into consideration. Thus, we designed this study to

Received for publication November 3, 2012; revised March 5, 2013; accepted March 19, 2013.

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Supported by grants from the following Brazilian agencies: The Committee for the Development of Higher Education Personnel—CAPES—PNPD/CAPES (for W.C. and I.C.C.S), the National Council for Scientific and Technological Development—CNPq (I.L.S.T. and W.C.); and the Foundation of Support of Research at Rio Grande do Sul (FAPERGS). F.F. is supported by an NIH grant (5R21DK081773-03). The authors declare no conflict of interest.

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Supplemental Digital Content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Website, www.clinicalpain.com.

assess multiple deep intramuscular stimulation therapy (MDIMST), which combines the effects of TrP deep DN (TrP-DDN) with paraspinal multiple deep intramuscular stimulation therapy and NR in the spinal segment (ie, the dermatomes, sclerotomes, or myotomes) where hyperalgesia was identified.

The present study tested the hypothesis that the effect of either MDIMST or TrP lidocaine injection (LTrP-I) would be more effective than a placebo-sham for the treatment of MPS and that MDIMST would be more effective than LTrP-I for improving pain relief, sleep quality, and the physical and mental state of the patient. Our findings provide additional evidence regarding the efficacy of MDIMST for the treatment of MPS.

METHODS

The Methods and the Results section are reported according to the CONSORT guidelines. The protocol was registered at clinical trials.gov (NCT 01708343).

Design Overview, Setting, and Participants

All patients gave their written informed consent to participate in this randomized, blind, 3-group parallel, clinical trial with blind evaluators. The study was approved by the Research Ethics Committee at the Hospital de Clínicas de Porto Alegre (Institutional Review Board IRB 0000921) and was carried out in accordance with the Declaration of Helsinki (No.: 10-0921). To increase the sample homogeneity and power of this study, we recruited women aged 19 to 50 who experienced limitations in their routine activities due to MPS several times a week during the last 3 months and who visited a primary care unit. The limitations related to the pain were assessed using yes/no–type questions for each item as follows: during the last 3 months, did the pain interfere several times a week or daily with your (1) work, (2) enjoyable activities, (3) responsibilities at home, (4) relationships, (5) personal goals, (6) thinking clearly, and problem solving, concentrating, or memory during the last 3 months? The inclusion criterion was a positive answer for 1 or more of these questions and meeting the criteria for MPS diagnosis as confirmed by an independent examiner (C.C.) with more than 10 years of experience in a pain clinic. The criteria for MPS were regional pain, normal neurologic examination, the presence of TrPs, taut bands, tender points, and pain characterized as "dull," "achy," or "deep." In addition, palpable nodules, pain that is exacerbated by stress, decreased range of motion, and ropiness in the muscle were essential to or associated with MPS diagnosis.[1,22–24] To distinguish neuropathic pain from ongoing nociception, the Neuropathic Pain Diagnostic Questionnaire (DN4) was administered to all patients. Only those with a neuropathic component (score equal or higher than 4) were included.[25]

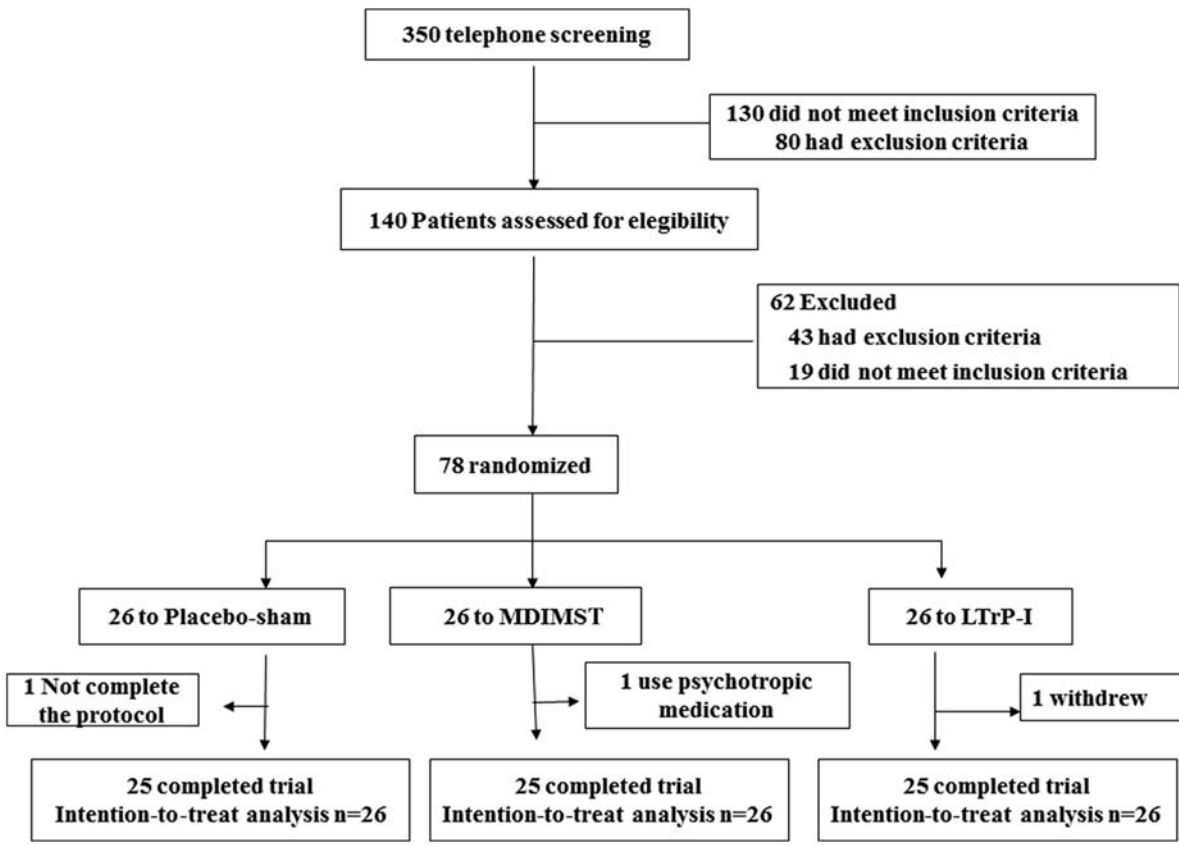

FIGURE 1. Flow chart of the study eligibility and the number of patients at each point. The 3 experimental groups were: (1) multiple deep intramuscular stimulation therapy (MDIMST); (2) TrP lidocaine injection (LTrP-I); and (3) placebo-sham.

The exclusion criteria included rheumatoid arthritis, fibromyalgia, previous surgery on the affected areas, prior experience with acupuncture, primary radiculopathy, current use of psychotropic drugs, or habitual use of anti-inflammatory steroids. Seventy-eight women were randomized into 3 groups (placebo-sham, MDIMST, and LTrP-I; see Fig. 1).

Sample Size Justification

The number of participants in each study group was determined based on previous clinical trials of myofascial pain.[26] An a priori estimate indicated that a total sample size of 69 patients, divided into 3 balanced treatment groups (n = 23), was needed to detect a reduction in pain intensity with MDIMST or LTrP-I at a minimum of 1.3 cm (average SD 1.2 cm) that would be clinically relevant and comparable to other pharmacological interventions, with a power of 0.9 and an α-level of 0.01.[27] To account for multiple outcomes and attrition, we increased the sample size to 26 patients per group.

Randomization

We used a fixed block size of 6 to ensure that equal numbers of participants were randomized into 3 groups. We stratified the randomization by neck and back pain using appropriate software to assign each participant to 1 of the 3 treatment groups: (1) MDIMST, (2) placebo-sham, and (3) LTrP-I.

Blinding

To control for possible measurement bias in the present study, the following measures were taken: all treatment sessions were administered by the same trained (C.C.) and experienced (18 y) acupuncturist physician to ensure that the treatment was homogenous among the patients. In addition, none of the patients had undergone previous treatment with acupuncture. The participants were instructed to discuss all aspects related to their treatment with the treating physician during the treatment sessions. Two independent evaluators who were blind to the group assignments were trained to apply the pain scales and conduct psychological tests. We used the method of sealed envelopes for allocation concealment. Before the recruitment phase, the envelopes containing the protocol materials were prepared. Each envelope containing the allocated treatment was sealed and numbered sequentially. After each participant agreed to participate in the trial, the envelope in the sequence was opened and the results were communicated by the investigator to the clinician administering the intervention.

Interventions

The interventions were applied during 2 sessions per week for 4 consecutive weeks, for a total of 8 sessions.

MDIMST

We used acupuncture needles with guide tubes (Suzhou Huanqiu Acupuncture Medical Appliance Co. Ltd., 218, China) that were 40 mm in length and 0.25 mm in diameter. The needling for the paraspinal MDIMST was applied to the dermatomes, myotome, or sclerotome where the trigger points were found (see the technique in the video attached—Video 1, Supplemental Digital Content 1, http://links.lww.com/CJP/A66). For TrP-DDN, the needle was inserted directly into the trigger point or the palpable taut band.[10,28] A local twitch response confirmed that the needle was placed in a taut band or TrP.[29] A maximum stimulation time of 1 minute per TrP and 3 minutes per MDIMST was permitted.

Placebo-Sham

For the placebo-controlled condition, we used an electroacupuncture device (Cosmotron, São Paulo, Brazil), which was adjusted beforehand to prevent the current from passing through the electrodes. The electrical connection between the stimulator and the patient was broken at the output jack plug of the stimulator so that no current could pass to the patient. The patients were informed that this was a high-frequency, low-intensity stimulation and that they would most likely feel no sensation from it. The paraspinal electrodes were placed over the dermatomes, myotome, or sclerotome where the TrP were found and also over the main painful TrP or tender spots at the muscle taut band, and the nerve stimulation unit was left in front of the patient for 30 minutes. This positioning ensured that the flashing diode that simulated the electrical stimulus was both visible and audible.

LTrP-I

LTrP-I was administered when a visible local twitch response was evoked during needle penetration. 0.2 to 0.5 mL of 1% lidocaine was injected each time into the trigger point using 1.25-inch-long, 25-G hypodermic needles.[30] If the TrP became inactive before the end-of-the-treatment sessions, a subcutaneous injection with 0.2 mL of 1% lidocaine was delivered over the TrP area in the taut band at each treatment session. During each treatment session, only 2 or 3 TrPs were treated.

Instruments and Assessments

All psychological tests were validated for the Brazilian population. The baseline depressive symptoms were assessed using the Beck Depression Inventory,[31] and sleep quality was assessed using the Pittsburgh Sleep Quality Index.[32] A systematic evaluation of potential technique complications, such as pneumothorax or bleeding, was also conducted.

Outcomes

The primary outcome was pain as assessed by the pain diaries (the maximum pain during the last 24 h), the amount of analgesics used throughout the treatment period and the pressure pain threshold (PPT). The secondary outcomes were the sleep quality diaries and the physical and mental health (SF-12) scores.

(1) The intensity of pain was measured by a 10 cm visual analog scale (VAS).[33] The VAS scores ranged from no pain (0) to the worst possible pain (10 cm).
(2) The PPT values were quantified using a Fisher pressure algometer (Pain Diagnostics and Thermography, Great Neck, NY). Anatomic points were evaluated by digital pressure and then registered in the patient's record. The PPT was measured at baseline and once a week during the treatment period. To assess the central sensitization, the PPT was measured contralaterally in the medial-deltoid for back pain and in the anterior-tibialis for neck pain.[34] Segmental hyperalgesia was assessed by PPT in the area with more intense pain on the baseline and at the end of treatment. All PPT values expressed in kg/cm^2 are the mean of 3 successive readings taken at intervals of 3 to 5 minutes.

(3) Pain medication diary. The patients were requested to fill out a daily registry marking any changes in as-needed medications and to confirm the use of regular medications for pain.
(4) Sleep quality was recorded daily using the 10 cm visual analog sleep quality scale (VASQS) in the sleep diary using 3 VASQSs: (1) In general, how did you feel when you woke up? (2) Assess the sleep quality of the previous night compared with your habitual sleep? (3) How well did you sleep last night? The VASQS scores ranged from the worst possible (0) to the best possible (10 cm).
(5) Health-related quality of life, assessed at baseline and the end of the treatment sessions, was measured with the SF-12 Physical and Mental Health Summary Scales.[35]

Statistical Analysis

We averaged the values collected in the pain and sleep diary (daily measurements) and generated a value for each of the 4 weeks of treatment. After first checking the assumptions of normality for the outcome measures using skewness and kurtosis tests, we conducted a group analysis by running a mixed ANOVA model in which the independent variables were time, experimental group (MDIMST, LTrP-I, and placebo-sham), the interaction term time versus experimental group, and subject identification. If appropriate, we then performed the Bonferroni adjustment for post hoc multiple comparisons to identify differences between the groups at each time point and used a paired t test to assess the effects on each experimental group. A stepwise multiple linear regression analysis was conducted with the pain scores on a VAS as the dependent variable and experimental groups (MDIMST, LTrP-I, and placebo-sham), sleep quality last night, and mental and physical health scores as independent variables.

We also calculated the adjusted mean differences defined as the relative changes compared with the placebo-sham or LTrP-I. This measurement is used to describe the treatment efficacy of the MDIMST, which is calculated as the mean active group difference (before − after) divided by the mean placebo (or the LTrP-I) group difference (before − after). This value is expressed as a percentage. We considered all the randomized patients as part of the analysis using the intention-to-treat analysis method with the last observation carried forward. Because we chose 3 main outcomes in this study, we considered them significant (for the ANOVA models) if the P-value was $< 0.05/3$ (0.017). The data were analyzed using SPSS version 18.0 (SPSS Inc., Chicago, IL).

RESULTS

Patient Characteristics

Seventy-eight patients were randomized to 1 of 3 groups, and 3 of the patients were subsequently withdrawn (Fig. 1). The baseline characteristics were similar across the groups of patients assigned to MDIMST, LTrP-I, or placebo-sham (Table 1). We did not observe pneumothorax, hematoma, or any other serious or moderate side effects.

Analysis of the Main Outcome: the Effect on Pain and Pain Threshold

There was a significant interaction between time and treatment group ($P < 0.009$) for the VAS scores. In fact, the MDIMST and LTrP-I patients had significantly lower pain VAS scores ($P < 0.001$) than those that were sham-treated (Table 2). The difference between the 2 treatment groups was significant ($P < 0.001$; Fig. 2).

Similar to the pain VAS scores, the interaction between time and group for the PPT was significant ($P < 0.001$). The PPT was significantly higher in patients treated with MDIMST ($P < 0.001$) and LTrP-I patients ($P < 0.001$) than those who were sham-treated. The efficacy of MDIMST was significantly better than that of LTrP ($P = 0.004$; Fig. 3).

The results for the use of analgesics were similar to findings for pain outcomes. There was a significant interaction between time and group ($P < 0.01$). There was a significant reduction in the analgesic doses for those receiving MDIMST and LTrP-I treatment compared with those who were sham-treated ($P < 0.01$; Table 2).

Secondary Outcomes: Sleep Quality and Health Quality of Life

The ANOVA showed that sleep quality improved with time (main effect of time, $P < 0.001$), and the interaction between time and group was also significant ($P < 0.001$). All the parameters related to sleep quality were better in patients treated with MDIMST or LTrP-I than those who were sham-treated (Table 2). Compared with LTrP-I, the MDIMST also demonstrated better scores in all sleep parameters. At the end of the study, the physical health composite score was higher for the MDIMST and LTrP-I groups than the sham-treated group ($P < 0.01$), and the mental health composite score was lower for MDIMST ($P < 0.03$; Table 2).

One important issue when assessing the secondary outcomes is whether the improvements in sleep and health quality of life are secondary to pain improvement or primary to the effects of the intervention. To address this important issue, we conducted an additional regression model in which we controlled the improvement in pain to changes in sleep and quality of life. This model revealed that the effect of group and sleep continued to be significant ($P < 0.001$ for both variables); but the mental and physical health scores became nonsignificant in this model ($P > 0.3$ for both variables), suggesting that their variability is dependent on the effects of group on the main outcome (pain; Table 3).

DISCUSSION

The results of this study demonstrated that MDIMST produces a reduction in overall pain, analgesic use, and PPT compared with both placebo-sham and LTrP-I. Although both active treatments have a clinical effect on pain, sleep quality, and physical and mental health, MDIMST led to a stronger effect overall (Tables 2 and 3).

These findings indicate that MDIMST improved the pain score and PPT when applied within the spinal segment of the nerve root associated with the dermatome, myotome, or sclerotome where the trigger points were found. This conclusion is supported by the theory that MPS is the result of disordered function in the peripheral nerve.[11] In the musculature, this is manifested as muscle shortening, pain, and the development of taut bands with MTrPs. Shortening of the paraspinal muscles leads to disk compression and narrowing of the intervertebral foramina, or direct pressure on the nerve root. Accordingly, the needling can be applied specifically on the regions of muscular contractions and in the paraspinal muscles of the same spinal segment. Hence,

TABLE 1. Characteristics of the Study Sample

Variables	Placebo-Sham (n = 26)	LTrP-I (n = 26)	MDIMST (n = 26)	*F* or χ^2	*P*
Age (y)*	33.52 ± 5.07	34.44 ± 4.68	35.84 ± 5.02	1.40	0.25
Formal education (y)*	11.52 ± 1.85	10.76 ± 1.92	10.76 ± 2.24	1.19	0.31
Work activity (yes/no)†	19/6	19/6	20/5	0.15	0.93
Married (yes/no)†	18/7	19/6	17/8	0.40	0.82
Alcohol use (yes/no)†	5/21	7/18	6/20	0.72	0.69
Smoking (yes/no)†	3/23	2/24	4/22	0.85	0.65
Chronic disease (yes/no)†	5/21	4/22	3/23	0.70	0.70
No. positive answers to the questions about the interference of pain several times a week or daily during the last 3 mo	4.45 ± 1.23	4.78 ± 1.56	4.81 ± 1.32	0.6	0.56
No. muscles identified with trigger points (mean)	4.33 ± 1.94	4.30 ± 1.97	4.34 ± 2.14	0.37	0.69
No. patients with muscles identified with trigger points†					
Upper half of the body/lower half of the body	20/6	20/6	21/5	0.73	0.69
Muscles of myofascial pain syndrome in the upper half of the body					
Splenius capitis	2	2	3		
Trapezius	11	10	13		
Supraspinatus	7	5	6		
Rhomboid	5	6	4		
Sternocleidomastoid	6	7	8		
Subscapularis	4	3	2		
Scalene	4	5	6		
Levator scapularis	3	5	4		
Infraspinatus	6	3	4		
Latissimus	2	1	3		
Thoracic paravertebral	7	5	4		
Muscles involved in myofascial pain syndrome the in lower half of the body					
Lumbar paravertebral	4	3	5		
Quadratus lumborum	5	4	5		
Piriformis	3	4	2		
Gluteus maximus	5	4	3		
Gluteus medius	3	2	5		
Gluteus minimus	1	0	0		
Daily analgesic doses (baseline 7 d)*	1.81 ± 0.84	1.93 ± 0.94	1.90 ± 0.82	3.26	0.40
Pain reported on visual analog scale*	6.66 ± 0.78	6.59 ± 1.18	6.61 ± 1.25	0.02	0.98
PPT (kg/cm^2)*	2.36 ± 0.56	2.35 ± 0.49	2.37 ± 0.61	0.10	0.90
PPT to assess segmental pressure hyperalgesia (kg/cm^2)*	0.97 ± 0.41	0.79 ± 0.20	0.84 ± 0.32	2.32	0.1
Beck Depression Inventory*	12.44 ± 10.65	13.68 ± 6.25	15.00 ± 7.81	0.58	0.56
Pittsburgh Sleep Quality*	8.88 ± 3.76	9.40 ± 3.71	9.76 ± 3.64	0.36	0.70
Physical health composite score of SF12*	43.73 ± 10.28	44.41 ± 10.28	40.12 ± 10.47	1.31	0.27
Mental health composite score of SF12*	51.78 ± 10.63	52.41 ± 8.989	50.38 ± 11.82	0.24	0.78

The values are given as the mean (SD) or frequency (n = 78).
MDIMST—TrP-DDN combined with PDIMS and NR.
*ANOVA to compare mean ± SD.
†χ^2 or the Fisher exact test to compare frequencies.
ANOVA indicates analysis of variance; MDIMST, multiple deep intramuscular stimulation therapy; LTrP-I; trigger-point lidocaine injection; NR, needle rotation; PDIMS, paraspinal deep intramuscular stimulation; PPT, pressure pain threshold; TrP-DDN, trigger point deep dry needling.

the MDIMST may alleviate pain through 3 different mechanisms: (1) by relaxing contracted muscles, (2) by decreasing C fiber ectopic impulses from the injured nerve, and (3) by inhibiting the sympatho-excitatory reflex (similar to acupuncture).[11] In addition, previous studies demonstrated that the TrPs-DN may normalize the chemical environment of active MTrPs and diminish endplate noise associated with MTrPs[29] and that the MDIMST applied within in the dermatomes corresponding to the spinal segment where the TrP were found could improve its clinical efficacy. These results suggest that these systemic effects could be mediated via segmental neuromodulatory mechanisms. Because TrP sensitivity has been linked to central sensitization,[11,36] it is plausible for the segmental effects observed in this study to be subsequent to modulation of central sensitization near the spine where the nerve root may have become irritated and supersensitive.

These findings are also in accordance with other studies that have demonstrated bilateral or mirror-image electromyographic activity associated with unilateral needle stimulation of active myofascial TrPs.[37] The changes in the PPT were observed in the spinal segment where the dermatome, myotome, or sclerotome was not associated with the TrP, implying an underlying change in the patient's pain sensitivity, including the collective influence of spinal (segmental), supraspinal, or other physiological

TABLE 2. Treatment Effect on the Comparison of the Outcome Variables Between Groups: Mean ± SD, Adjusted Mean Difference With the Confidence Interval (95% CI) and Relative Change % (CI) (n = 78)

	Placebo-Sham vs. MDIMST (n = 26)	LTrP-I vs. MDIMST (n = 26)	Placebo-Sham vs. LTrP-I (n = 26)
Primary outcomes (cumulative mean of 4 wk)			
Pain diary scores reported on VAS‡			
Adjusted mean (SD)	4.49 (1.54) vs. 2.48 (1.48)	3.48 (1.09) vs. 2.48 (1.48)	4.49 (1.54) vs. 3.48 (1.09)
Difference	2.01 (1.51-2.87)*	1 (0.26-1.73)**	1.01 (0.25-1.76)*
Relative change§	44.76 (33.63-63.91)	28.73 (7.47-49.71)	22.49 (5.56-39.19)
Mean pressure pain threshold (PPT) in kg/cm^2‡			
Adjusted mean (SD)	3.02 (0.86) vs. 4.79 (1.54)	3.90 (1.30) vs. 4.79 (1.54)	3.02 (0.86) vs. 3.90 (1.30)
Difference	−1.77 (−2.47 to −1.06)*	−0.89 (−1.71 to −0.08)**	−0.88 (−1.50 to −0.25)*
Relative change§	−58.60 (−81.78 to −35.11)	−23.07 (−43.84 to −2.05)	−29.13 (−49.66 to −8.27)
Segmental pressure hyperalgesia (PPT) in kg/cm^2‡			
Adjusted mean (SD)	2.61 (1.2) vs. 4.85 (1.56)	3.98 (1.41) vs. 4.85 (1.56)	2.61 (1.2) vs. 3.98 (1.41)
Difference	−2.24 (−2.43 to −1.81)	−0.87 (−1.06 to −0.44)	−1.37 (−1.68 to −1.06)
Relative change§	−85.82 (−93.10 to −69.34)	−21.85 (−26.63 to −11.05)	−52.49 (−64.36 to −40.61)
Analgesic doses (mean daily during 4 wk)≠			
Adjusted mean (SD)	0.92 (1.07) vs. 0.20 (0.32)	0.41 (0.36) vs. 0.20 (0.32)	0.92 (1.07) vs. 0.41 (0.36)
Difference	0.72 (0.22 to 1.17)**	0.21 (0.02 to 0.40)**	0.51 (0.06 to 0.96)**
Relative change§	78.23 (23.91 to 127.17)	51.12 (4.84 to 97.56)	55.43 (6.52 to 104.34)
Secondary outcomes (cumulative mean of 4 wk)			
Sleeping diary scores reported on VASQS‡			
VASQS—how did you feel when you woke up?			
Adjusted mean (SD)	4.87 (1.62) vs. 6.28 (1.22)	5.38 (1.34) vs. 6.28 (1.22)	4.87 (1.62) vs. 5.58 (1.34)
Difference	−1.41 (−2.22 to −0.59)*	−0.90 (−1.63 to −0.17)**	−0.51 (−1.35 to 0.33)
Relative change§	−28.95 (−45.58 to −12.11)	−16.72 (−30.29 to −3.15)	−10.47 (−27.72 to 6.78)
VASQS—sleep quality of the previous night compared with habitual sleep			
Adjusted mean (SD)	4.79 (1.48) vs. 6.27 (1.04)	5.41 (1.34) vs. 6.27 (1.04)	4.79 (1.48) vs. 5.41 (1.34)
Difference	−1.48 (−2.20 to −0.75)*	−0.86 (−1.54 to −0.17)**	−0.62 (−1.42 to 0.18)
Relative change§	−30.89 (−45.92 to −15.65)	−15.89 (−28.46 to −3.14)	−12.94 (−29.64 to 3.76)
VASQS—sleep quality in the last night			
Adjusted mean (SD)	5.21 (1.22) vs. 6.89 (1.04)	5.79 (1.23) vs. 6.89 (1.04)	5.21 (1.22) vs. 5.79 (1.23)
Difference	−1.68 (−2.32 to −1.03)*	−1.1 (−1.75 to −0.45)*	−0.58 (−1.28 to 0.11)*
Relative change§	−32.24 (−44.52 to −19.76)	−18.99 (−30.22 to −7.77)	−11.13 (−24.56 to 2.11)
Mean of physical and mental health composite score of SF12 (at end of study)†			
Physical health composite score of SF12			
Adjusted mean (SD)	45.11 (10.20) vs. 55.04 (10.99)	47.94 (8.49) vs. 55.04 (10.99)	45.11 (10.20) vs. 47.94 (8.49)
Difference	−10.29 (−16.32 to –4.25)**	−7.46 (−13.04 to −1.87)*	−2.83 (−8.30 to −2.64)
Relative change§	−22.81 (−36.17 to −9.42)	−15.56 (−27.20 to −3.90)	−6.27 (−8.16 to −2.25)
Mental health composite score of SF12			
Adjusted mean (SD)	65.96 (10.93) vs. 50.79 (12.14)	57.68 (11.77) vs. 50.79(12.14)	65.96 (10.93) vs. 57.68 (11.77)
Difference	15.17 (8.60 to 21.73)*	6.89 (0.25 to 13.52)**	8.28 (1.99 to 14.56)*
Relative change§	22.99 (13.03 to 32.94)	11.94 (0.43 to 23.43)	12.55 (3.01 to 22.07)

MDIMST—TrP-DDN combined with PDIMS and NR.
†Linear model: mean difference between groups.
‡Mixed ANOVA model: mean difference groups.
§Relative change = adjusted mean difference/adjusted placebo mean or TrP-DNI × 100%.
CI indicates confidence interval; MDIMST, multiple deep intramuscular stimulation therapy; LTrP-I, trigger-point lidocaine injection; NR, needle rotation; PDIMS, paraspinal deep intramuscular stimulation; TrP-DDN, deep trigger point dry needling; VASQS, visual analog sleep quality scale.
P values adjusted by multiple comparisons by Bonferroni post hoc test; *$P < 0.001$; **$P < 0.01$.

(ie, biochemical, electrochemical, hormonal) mechanisms.[38] A similar effect was demonstrated using DN stimulation of a single TrP, evoking short-term segmental antinociceptive effects.[11]

NR may induce neuroplastic changes as the pulling of collagen fibers and the transduction of the mechanical signal into fibroblasts can lead to a wide variety of cellular and extracellular events, including mechanoreceptor and nociceptor activation and eventually to neuropeptide liberation.[39,40] According to a previous randomized clinical trial (RCT),[39] the DDN technique resulted in better analgesia than the SDN technique or traditional acupuncture in MPS.[39] In another RCT that compared the efficacy of standard acupuncture for chronic low back pain, the DDN was more effective.[21] According to Baldry, the Aδ nerve fibers are stimulated for as long as 72 hours after needle insertion, and NR could improve the clinical effect by stimulating afferent Aδ fibers and activating enkephalinergic, serotonergic, and noradrenergic inhibitory systems.[40] Although we assessed the clinical response, our findings are supported by evidence derived from simple DN or acupuncture studies[41,42] that induced local hyperpolarization of the axon, as occurs with electrical stimulation of the Na^+/K^+ pumps.[43] Although traditional acupuncturists have maintained that acupuncture points have unique clinical effects, our findings are supported by previous

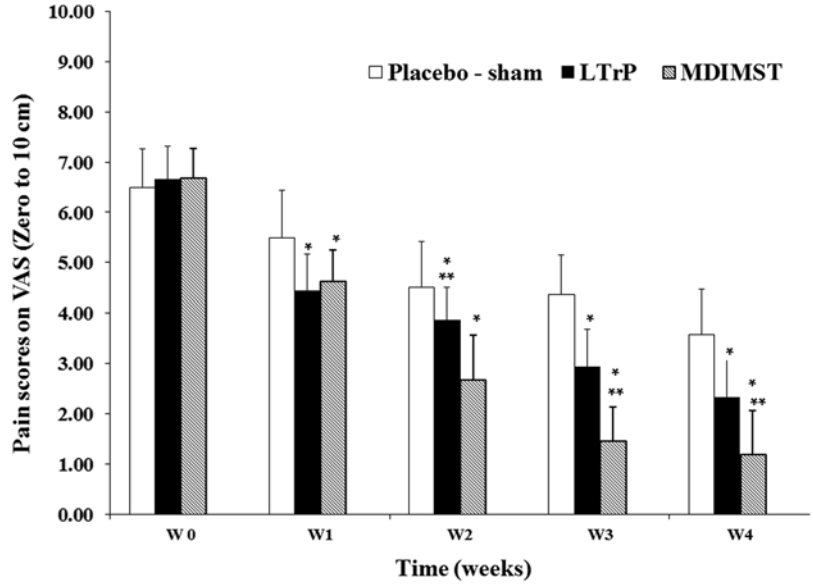

FIGURE 2. Mean pain levels (as assessed by VAS) at the baseline week (W0), W1, W2, W3, and W4 in the 3 experimental groups: (1) MDIMST ([TrP deep dry needling [TrP-DDN] combined with paraspinal deep intramuscular stimulation [PDIMS] with needle rotation [NR]); (2) TrP lidocane injection (LTrP-I); (3) placebo-sham. Error bars indicate the SEM. Asterisks positioned above the bars indicate a significant difference ($P < 0.05$) at time points. *Differences between the placebo-sham and active interventions. **Differences between LTrP-I and MDIMST. All comparisons were performed by a mixed analysis of variance (ANOVA) model, followed by the Bonferroni test for post hoc multiple comparisons.

evidence not necessarily specific to acupuncture but segmentally corresponding to the pathology and the type and intensity of the stimulus. Overall, such evidence should facilitate the increased integration of acupuncture as a technique of neuromodulation due to direct stimulation of the peripheral nervous system via DN into contemporary clinical pain management.

Accordingly, it has been suggested that the pain relieving effects are due to the insertion of a needle into the skin and subcutaneous tissues at the site of myofascial TrPs

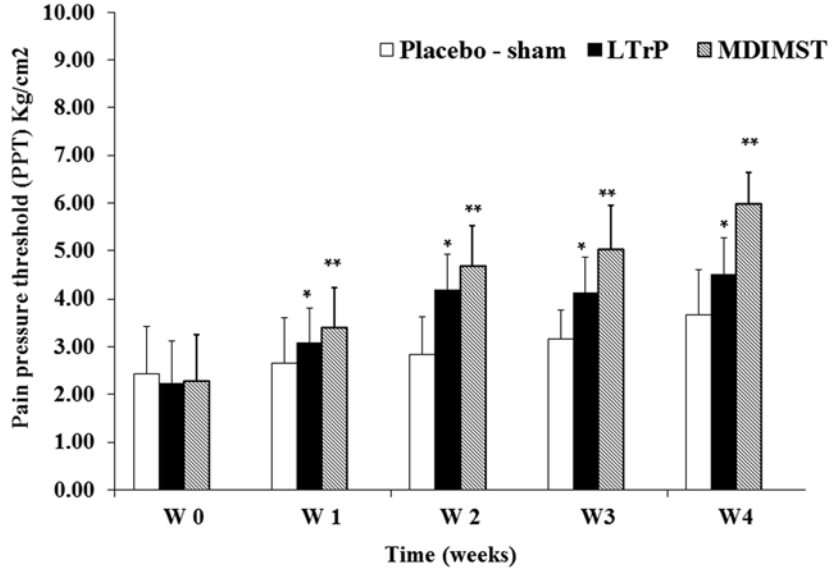

FIGURE 3. Mean pain pressure threshold (PPT) expressed in kgf/cm^2 at the baseline week (W0), W1, W2, W3, and W4 in the 3 experimental groups: (1) MDIMST ([TrP deep dry needling [TrP-DDN] combined with paraspinal deed intramuscular stimulation [PDIMS] with needle rotation [NR]); (2) TrP lidocaine injection (LTrP-I); and (3) placebo-sham. Error bars indicate SEM. Asterisks positioned above the bars indicate a significant difference ($P < 0.05$) at the time points. *Differences between the placebo-sham and active interventions. **Differences between LTrP-I and MDIMST. All comparisons were performed by a mixed analysis of variance (ANOVA) model, followed by the Bonferroni test for post hoc multiple comparisons.

TABLE 3. Multivariate Linear Regression of the Pain Reported on the VAS, Treatment Group, Sleep Quality, and Physical and Mental Health (n = 78)

Dependent Variable: Pain Diary Scores Reported on the VAS (Cumulative Mean of 4 wk)				
Parameters	**β**	***T***	***P***	**95% CI**
Group treatment				
Placebo-sham				
Lidocaine	−1.89	−10.02	0.0001	−2.08 to −1.73
MDIMST	−2.21	−11.80	0.0001	−2.51 to −2.10
VASQS—sleep quality in the last night (cumulative mean of 4 wk)	−0.29	−7.20	0.001	−0.36 to −0.20
Physical health composite score of SF12	−0.06	−0.85	0.39	−0.02 to 0.08
Mental health composite score of SF12	0.02	0.26	0.79	−0.02 to 0.03

Adjusted $R^2 = 0.34$.

MDIMST—TrP-DDN combined with PDIMS and NR.

CI indicates confidence interval; MDIMST, multiple deep intramuscular stimulation therapy; NR, needle rotation; PDIMS; paraspinal deep intramuscular stimulation; TrP-DDN, deep trigger-point dry needling; VAS, visual analog scale.

because this stimulates Aδ nerve fibers, with the subsequent release of opioid peptides from enkephalinergic inhibitory interneurons in the dorsal horn.[44] This effect would minimize the difference between LTrP-I and MDIMST. As MDIMST was better than LTrP-I for providing pain relief, this result reinforces the actual effect of MDIMST on pain. The long-term, persistent pain presented by our patients (at least 3 mo) might have led to neuroplastic changes at the level of the dorsal horn, resulting in amplification of the pain sensation (ie, central sensitization) with a tendency to spread beyond its original boundaries (ie, expansion of the receptive fields)[45] and increase the number of dermatomes, myotomes, or sclerotomes involved in the disease. The MDIMST group exhibited greater improvements with respect to general physical and mental health. These findings are supported by other trials in which pain relief from IMS was accompanied by positive effects on psychological functioning. Accordingly, experimental studies of acupuncture and electroacupuncture have shown an accelerated synthesis and release of serotonin (5-HT) and norepinephrine in the central nervous system.[46] This mechanism leads us to hypothesize that the improvement of the physical and mental state presented may be due to the physiological mechanisms behind the pain-relieving effects. It is also possible that the improvement of psychological functioning was in part due to pain relief. In fact when controlling pain for the purpose of improvement of general physical and mental health, the analysis showed that the differences among these variables were due to pain improvement, suggesting a secondary effect to pain improvement.

The greater effect of both active treatments compared with the sham intervention for improving sleep quality (Table 2) could be explained by multiple mechanisms, including the modulation of the sleep/wake cycle.[47] Interestingly, the effects on sleep seem to be independent of pain improvement; therefore, other mechanisms may explain these effects. In addition, this benefit may be explained by the effect of the needling procedure in reducing the elevation of the levels of circulating cytokines, which interrupts the melatonin surge by the pineal gland.[48] Together, these findings suggest that the multiple techniques constitute a neurophysiological approach that may be useful for the treatment of MPS, both to relieve pain and improve sleep quality.

It is important to assess the strengths and limitations of this clinical trial. We reported this trial following CONSORT guidelines and using the Delphi List, a list of criteria for quality assessment of RCTs. Our trial can be considered to have a strong quality, as all 8 items in this scale can be scored positively in our RCT.[49] However, the trial also has some limitations. Although the outcome assessor, the care provider, and the patient were blinded (as recommended in the Delphi List for the quality of clinical trials), the attending acupuncturist-physician was not because it was not possible to blind him. Although the investigator administering the intervention could not affect the outcome directly, there is a possibility of affecting it indirectly. In contrast, the objective of this trial was to compare different techniques with intrinsic characteristics making a perfect blinding impossible. However, the efficacy of the treatments needs to be established using randomized controlled trials (RCT) standardized according to guidelines such as CONSORT,[50] which will permit these techniques to be replicated in future studies and to comprise a therapeutic approach to pain management supported by strong scientific evidence. In contrast, we used a sham-treatment technique that was mostly physiologically inert type and has been used elsewhere.[51] This sham method seemed to have blinded patients in this study effectively. Although several strategies were used to maintain the blindness and to control for the placebo effect, it is possible that those undergoing more invasive procedures could have had a larger clinical response in such a way that could have biased the outcome measures. However, more invasive procedures would not necessarily be associated with a larger placebo effect. Brunoni et al[52] compared invasive sham procedures (ie, brain stimulation) versus placebo pills and found that placebo pills were associated with a larger placebo effect. In addition, the efficacy of DN was demonstrated in an RCT in which patients who were scheduled for total knee replacement surgery were randomly assigned to 1 of 2 groups: true DN or sham DN. Because the patients were unconscious at the time of the intervention (either true or sham), they were unaware of their group assignment. Postsurgery, the true DN group reported less pain, demanded significantly less analgesics and rated their VAS significantly better than the sham needling group.[53] Finally, another limitation of this study was the follow-up time, which was rather short.

CONCLUSIONS

In summary, this study highlighted the greater efficacy of MDIMST stimulation therapy over the placebo-sham and LTrP-I and demonstrated that both active treatments

are more effective than placebo-sham for MPS associated with limitation of active and routine activities. The clinical effects of MDIMST provide additional evidence to support the clinical use of this treatment. Overall, our findings provide support for a therapeutic approach with a low cost and that could benefit a large number of patients with MPS.

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