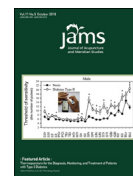


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Research Article

Combination of Exercise and Acupuncture Versus Acupuncture Alone for Treatment of Myofascial Pain Syndrome: A Randomized Clinical Trial

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Abstract

Myofascial pain syndrome (MPS) is a common musculoskeletal disorder. This study was designed to compare the effects of aerobic exercise plus acupuncture with acupuncture alone in treatment of patients with MPS. Sixty-four patients (55 female and 9 male) with MPS in their neck and shoulders participated in the study with mean age of 33.1 ± 6.4 years. Participants were randomly allocated to aerobic exercise plus acupuncture ($n = 32$) or acupuncture alone ($n = 32$) groups. Outcome measurements included visual analog scale, pressure pain threshold, neck disability index, and quality of life that was

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myofascial pain syndrome; pain; trigger points

measured with QoL-SF36 scale. Each group received 10 sessions of acupuncture in combination with aerobic exercise or acupuncture alone. The outcome measures were evaluated at baseline, at the end of the last treatment session, and at 1-month follow-up visit. While participants were waiting for their 1-month follow-up visit, the patients who received combination therapy were asked to continue their aerobic exercise by jogging 40 minutes a day. Although mean visual analog scale, pressure pain threshold, neck disability index, and QoL-SF36 were significantly improved in both groups ($p < 0.001$), there was no statistically significant difference among the measures between the two groups throughout the evaluated sessions. The interaction effect of time and groups did not show any significant difference among the outcome measures ($p > 0.29$).

1. Introduction

Myofascial pain syndrome (MPS) is a painful condition of myofascial trigger points (TrPs) among the postural skeletal muscles which frequently involves the supporting musculature of the shoulder girdle and spine [1].

MPS may also manifest as motor, sensory, and/or autonomic dysfunction. The myofascial TrPs are hyperirritable spots located in a taut band of skeletal muscle that may cause local tenderness under compression, referred pain, and twitch response during acupuncture, dry needling, or palpation across the involved muscle fibers [2,3].

Myofascial pain is one of the major causes of disability, financial disadvantage, fatigue, mood changes, reduced quality of life, and limitations in activity of daily living [3,4].

Treatments for MPS include pharmacological modalities and nonpharmacological treatment options such as acupuncture, dry needling, laser, exercise, massage, and physical therapy. There is not a gold standard approach for management of MPS [3].

Previous studies showed effectiveness of both acupuncture and exercise in managing MPS [1,3,5–16]. Theoretically, we could hypothesize that combination of these two effective treatment modalities may have additive effects in management of MPS. The aim of our study was to investigate the effects of acupuncture in combination with aerobic exercise on the symptoms of MPS around the neck and shoulders and compare those effects with the ones on patients who receive acupuncture alone. In other words, this study explores if exercise has additive effects to acupuncture in managing the symptoms of MPS around the neck and shoulders.

2. Methods

2.1. Study design and setting

This single-blind randomized clinical trial was conducted with the approval of Scientific and Ethical Review Boards of Tabriz University of Medical Sciences in 2015–2016. Patients with diagnosis of MPS who were referred to physical medicine and rehabilitation out-patient clinics were recruited. Details of the study and the research protocol were explained to all participants, and informed written consent was obtained. This research followed the tenets of the Declaration of Helsinki, and the trial was registered in Iranian Registry of Clinical Trial (registration ID: IRCT201509264641N11).

2.2. Participants

Sixty-four patients (55 female and 9 male) with MPS in upper trapezius muscles were recruited. Inclusion criteria were as following:

1. Myofascial pain in upper trapezius muscle: pain in shoulder girdle, neck area, and upper back. Pain was not confined to any particular dermatome or myotome. In physical examination, there were more than three TrP and taut bands in the trapezius muscle. Compression of these TrPs should cause the same type of pain and discomfort that the patients experienced as the result of their disease.
2. Symptoms persisted for more than 2 months.
3. Normal neurological examination including manual muscle testing, sensory exam, and deep tendon reflexes.

Exclusion criteria were as following:

1. Cervical radiculopathy (confirmed with magnetic resonance imaging, electrodiagnostic tests, and physical examination), brachial plexopathy, or nerve entrapment syndromes (confirmed with electrodiagnostic tests and physical examination).
2. Positive Spurling test, weakness in manual muscle test, reduced deep tendon reflexes or decreased in sensation.
3. Non-age-related degenerative changes in cervical imaging.
4. Knee, hip, or ankle osteoarthritis, pain or history of trauma which could restrict participation in aerobic exercise training.
5. Lumbosacral radiculopathy or degenerative changes which could restrict participation in aerobic exercise training.
6. History of cervical or shoulder girdle surgery or trauma.
7. Recent cervical pain treatments such as physical therapy within the last 8 weeks or pain medications within the last 48 hours of the study.
8. Systemic disease which interferes with aerobic exercise or acupuncture such as bleeding diathesis and rheumatologic or ischemic heart disease.
9. Sensitivity to metal (acupuncture needle).
10. Pregnancy
11. Malignancy.

2.3. Randomization and blinding

The eligible subjects who met the inclusion criteria were matched with respect to the number of their TrPs, pain severity, and duration of symptoms and then assigned into two groups by simple randomization method [12]. A randomly ordered list of the participants was generated by a computer. Participants in Group A received acupuncture and participants in Group B received aerobic exercise in addition to acupuncture treatment 3 days a week.

2.4. Intervention

2.4.1. Acupuncture

All patients in Group A received 10 sessions of acupuncture (3 sessions a week). Western medical style acupuncture was applied. Points included for acupuncture were SI11, SI12, GB20, DU14, DU20, LI10, LI11, LI14, and trigger points in trapezius, levator scapulae, rhomboids, supra and infraspinatus, and paravertebral muscles. The average number of needles inserted in each subject during each treatment session was 24 (ranged from 16 to 28). For identifying TrPs, taut bands of involved muscles were examined, and the most painful points which caused referred pain in a familiar pattern received acupuncture. Acupuncture treatment was performed by a qualified physician (specialist) with 14 years of experience in this field. Stainless steel 0.25×25 or 0.30×25 mm acupuncture needles (Dong-Bang, South Korea) in sterile manner were used. For TrPs, peppering technique was performed, and if muscle twitch was evident, the needle movement was repeated until the twitch response was disappeared [2,17]. Needles were left in place for 30 minutes while applying alternating current electrical stimulation.

2.4.2. Aerobic exercise plus acupuncture

Following acupuncture, the patients in Group B received aerobic exercise for 50 minutes in physical medicine and rehabilitation setting. Aerobic exercise included 10 minutes warm up, 30 minutes walking on treadmill and using stationary bicycle with respect to reserved heart rate based on Karvonen et al method considering 75–80% of maximal heart rate [18,19], and 10 minutes of cooling down [13]. After the 10th interventional session, the patients in this group were asked to jog 40 minutes every day until their follow-up visit 1-month later.

Participants in both groups were asked to perform stretching exercises twice a day. They were asked to stretch each involved muscle group for 20 seconds and repeat it 10 times per session. Pamphlets containing detailed explanation for stretching exercises and tables for marking after completion of each session were given to the patients to ensure compliance. Pain killer medicines were not allowed to be taken during the intervention course and the 1-month follow-up period.

2.5. Outcome measures

The primary outcome measure was the pain intensity evaluated by means on visual analog scale (VAS). Secondary outcome measures included the cervical function which

was evaluated with neck disability index (NDI), pressure pain threshold (PPT) which was measured by an algometer, and evaluating quality of life using QOL-SF36 questionnaire.

During the pretreatment visit, an examiner who was blinded to the intervention groups documented the patients' demographic findings, pain intensity, PPT at TrPs, NDI, and quality of life scales. Outcome measures were reevaluated at the last session of 10-visit treatment course and also during the 1-month follow-up visit.

VAS is a relatively reliable and valid method for evaluation of pain in MPS [2,4,12]. For PPT on TrPs, we used a Wagner standard pressure algometer (Wanger instrument, Greenwich, USA) [20]. The algometer is composed of a gauge attached to its hard rubber tip. Pressure was applied through the rubber surface with area of 1 cm^2 at a maximum rate of 4 kg/cm^2 per second. Each participant was placed in prone position, and the instrument was placed perpendicular to the skin surface of a TrP. The pressure threshold on the algometer was captured at the moment when the patient felt pain and called "stop" as instructed before examination. This method was performed for three times with 10 seconds interval between each trial, and the mean number was recorded. In the hands of a skilled investigator, this is a relatively valid tool [21]. For subjects with more than two TrPs, the two most painful TrPs were assessed [12]. We also evaluated the cervical function with NDI questionnaire which includes 10 items, and each item is scored on 5-point scales with total scores ranging between 0 and 50. Higher scores indicate greater disease severity [22].

For the assessment of quality of life, we applied the Farsi translation of short-form (SF)-36 QoL questionnaire which includes 36 items [23]. Based on the QoL SF-36 questionnaire, eight standard scales were defined with scoring from 0 to 100. A higher score indicated better vitality, general health, physical functioning, social functioning, mental health, and less bodily pain or role limitation due to physical or emotional problems [12].

2.6. Statistical analysis

Statistical analysis was performed with SPSS statistical software (version 17.0; SPSS, Chicago, IL, USA). Kolmogorov–Smirnov test showed normal distribution of data. Descriptive data are reported as mean \pm standard deviation or number (%). Differences of the posttreatment values from the baseline are reported as mean difference and 95% confidence intervals. The independent samples *t* test and Chi-square test were used where appropriate. The interaction effects of time and group on outcomes were analyzed by mixed analysis of variance and post hoc complementary tests (confidence interval = 95%). A *p* value < 0.05 was considered statistically significant.

3. Results

In this randomized clinical trial, 64 patients (55 female and 9 male) with diagnosis of MPS were recruited, and 61 patients (55 female and 6 male) completed the follow-up visits. Participants were divided into acupuncture group ($n = 32$) or acupuncture plus aerobic exercise group

($n = 32$). Thirty patients in acupuncture group (28 female and 2 male) and thirty-one patients in acupuncture plus aerobic exercise group (27 female and 4 male) completed the follow-ups. Two subjects in the first group and one in the second group refused to complete the follow-up course for different reasons, so they were excluded from the study. The flow diagram is demonstrated in Fig. 1.

Fifty-five patients were female (85.9%), and mean age of participants were 33.1 ± 6.4 years. There were no significant differences between the two groups at baseline with respect to demographic findings and outcome measures (Table 1).

3.1. Pain

Pain intensity based on VAS was evaluated at the baseline, last session of interventional course, and 1-month after the last treatment session. Although mean VAS scores were significantly reduced in both groups ($p < 0.001$), there was not statistically significant difference between the two groups in all three evaluations (Table 2, Fig. 2A).

The interaction effect of time and group was not significant on VAS: $p = 0.29$, showing no difference in the amount of improvement over time in favor of either group.

Table 1 Demographic features of the participants (mean \pm SD).

Variable	Acupuncture + aerobic exercise	Acupuncture	<i>p</i>
Number	31	30	
Age (years)	33.7 ± 5.8	23.3 ± 7.0	0.35
Gender (M/F)	4/27	2/28	0.67
Duration of disease (years)	1.3 ± 0.7	2.0 ± 1.0	0.46
VAS	8.87 ± 1.14	8.90 ± 1.02	0.91
Pain threshold	2.19 ± 0.45	2.15 ± 0.53	0.75
QOL-SF36	35.7 ± 13.6	39.7 ± 15.2	0.28
NDI	28.9 ± 9.30	26.9 ± 10.3	0.43

NDI = neck disability index; SD = standard deviation; VAS = visual analog scale.

The *p* values are for baseline differences between the two groups at significance level $\leq .05$.

3.2. Pain threshold with algometer

Mean pain threshold was significantly increased between the 1st and last treatment sessions. It was then

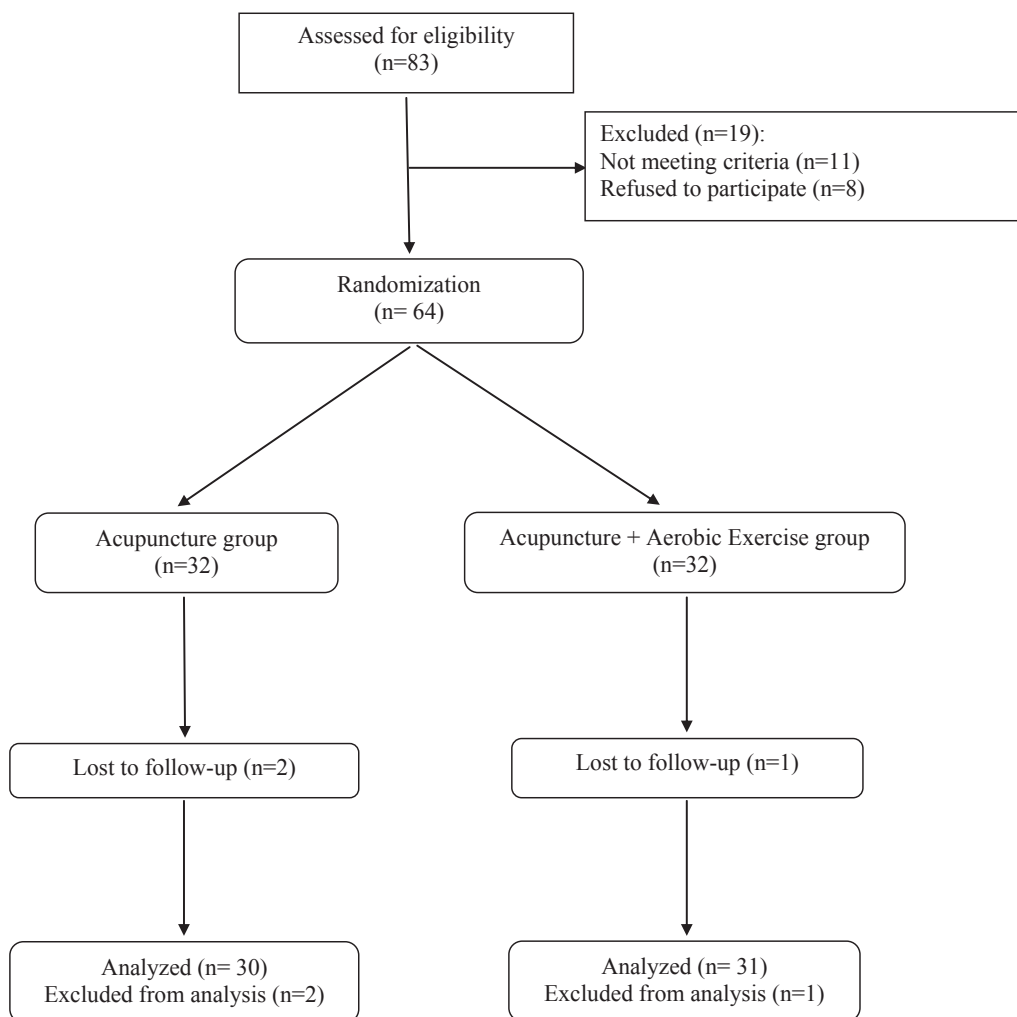


Figure 1 A flow diagram of the study protocol.

Table 2 The results of the acupuncture versus acupuncture plus aerobic exercise on the intensity of daily pain, pain threshold with algometer, neck disability index, and quality of life SF-36.

Variable	Time of intervention	Type of drugs	Mean	SD	<i>p</i>	<i>p</i>	
Pain (VAS)	First visit	Acupuncture	8.90	1.02	0.918	Group and time interaction	
		Aerobic + Acup	8.87	1.14			
	Last session	Acupuncture	2.20	2.64			0.155
		Aerobic + Acup	1.45	1.15			
	Follow-up	Acupuncture	2.76	2.38			0.393
		Aerobic + Acup	2.35	1.17			
Pain threshold with algometer	First visit	Acupuncture	2.15	0.53	0.753	Group and time interaction	
		Aerobic + Acup	2.19	0.45			
	Last session	Acupuncture	2.75	0.35			0.594
		Aerobic + Acup	2.80	0.41			
	Follow-up	Acupuncture	2.75	0.46			0.615
		Aerobic + Acup	2.69	0.50			
Neck disability index	First visit	Acupuncture	26.93	10.38	0.438	Group and time interaction	
		Aerobic + Acup	28.90	9.30			
	Last session	Acupuncture	7.13	7.65			0.749
		Aerobic + Acup	6.54	6.50			
	Follow-up	Acupuncture	11.73	7.52			0.483
		Aerobic + Acup	13.09	7.55			
Quality of life (QOL-SF36)	First visit	Acupuncture	39.71	15.23	0.283	Group and time interaction	
		Aerobic + Acup	35.70	13.68			
	Last session	Acupuncture	79.85	16.66			0.646
		Aerobic + Acup	81.60	12.77			
	Follow-up	Acupuncture	76.60	12.41			0.655
		Aerobic + Acup	77.92	10.42			

Acup = acupuncture; SD = standard deviation; VAS = visual analog scale.
Time × group interaction and intragroup *p* value significance level ≤ .05.

decreased in 1-month follow-up in both groups ($p < 0.001$). There was no statistically significant difference in pain threshold between the groups in each three sessions (Table 2, Fig. 2B).

The interaction effect of time and group was not significant on pain threshold: $p = 0.92$. It shows no difference in the amount of changes over time in favor of one group.

3.3. Neck disability index

Although mean NDI was significantly reduced in both groups ($p < 0.001$), there was no statistically significant difference between the two groups in all three evaluations (Table 2, Fig. 2C).

The interaction effect of time and group was not significant on NDI: $p = 0.62$, showing no difference in the amount of improvement over time in favor of one group.

3.4. Quality of life

Mean QoL-SF36 was significantly increased in both groups when compared to the baseline ($p < 0.001$). There was no statistically significant difference between the two groups in all three sessions (Table 2, Fig. 2D).

The interaction effect of time and group was not significant on VAS: $p = 0.92$, showing no difference in the amount of improvement over time in favor of one group.

4. Discussion

In this study, for the first time, we investigated the effectiveness of aerobic exercise plus acupuncture on patients with MPS. Although the pain, TrP pain threshold, neck disability index, and quality of life improved significantly in both treatment groups, no significant difference was noted between the two groups. We also found no significant change in the amount of improvement over time in favor of one group considering interaction effect of time and group.

To the best of our knowledge, no similar investigation has been done to compare the two methods so far.

Mechanisms of action of acupuncture are not fully understood [10]. Acupuncture may effect with different mechanisms in MPS. Acupuncture has been shown to improve tissue adhesion, relaxation, regional blood circulation, parasympathetic nervous activity, intramuscular temperature, endorphin levels, and decrease neuromuscular excitability [11].

Exercise especially short-term aerobic training benefits cardiopulmonary fitness. It also improves physical function and biopsychosocial factors while reducing pain and painful contributing factors. It is speculated that exercise provides the above benefits through the process of causing muscular microtrauma and stimulating repair and metabolic adaptation [5,6].

Sun et al evaluated the effects of six sessions of acupuncture compared with sham acupuncture among the

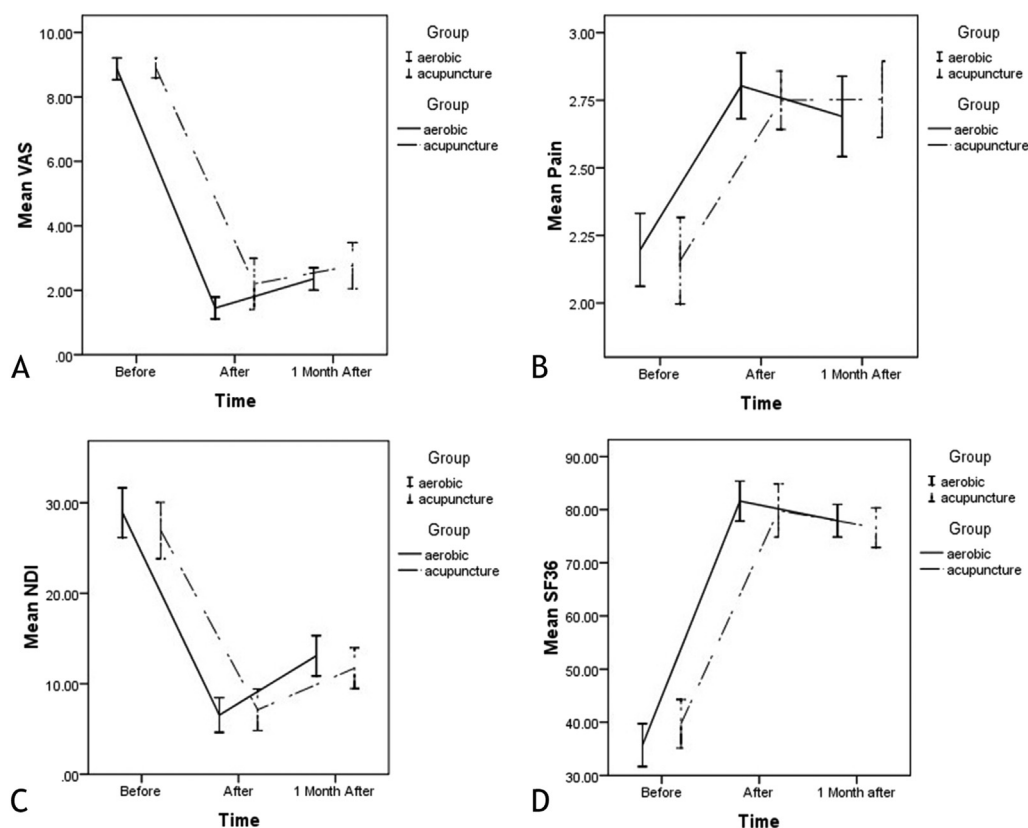


Figure 2 Comparison of study groups with respect to outcome measures: (A) Pain (VAS). (B) Mechanical pain threshold with algometer. (C) Neck disability index (NDI). (D) Quality of life (QoL-SF36). VAS = visual analog scale.

patients with chronic neck MPS. Although they noted improvement in quality of life, they did not find significant difference in the motion-related pain, range of motion, and the values in Short-Form McGill Pain Questionnaire between the two groups [3]. Wilke et al compared acupuncture with acupuncture plus stretching in very short-term follow-up (30 minutes posttreatment) among the patients with myofascial TrP pain of the neck. They did not observe meaningful difference in pain, mechanical pain threshold, and range of motion between intervention groups. However, there was significant improvement of all outcome measures in both groups in compare to placebo [15].

Wang et al in their systematic review and meta-analysis investigated randomized-controlled trials comparing manual acupuncture versus sham/placebo/no intervention in patients with MPS. They found favorable effects of manual acupuncture on pain intensity and PPT after providing acupuncture to the myofascial TrPs but not traditional acupuncture points. Acupuncture was effective in both single-session and eight-session course [14].

Langhorst et al in a systematic review and meta-analysis on the effects of acupuncture in fibromyalgia symptoms found a small analgesic effect which was not clearly distinguishable from bias. They concluded that acupuncture cannot be recommended for the treatment of fibromyalgia patients [24].

In respect to effectiveness of acupuncture for MPS—not fibromyalgia—our results are similar to previous

investigations. None of the previous studies compared acupuncture to combination of acupuncture and exercise. Previous studies compared to ours also had different number of acupuncture sessions.

Chan et al evaluated combination of home-based exercise and self-massage plus physical modalities for the treatment of MPS. They found improvement in pain, PPT, and functional status of participants in short-term follow-up [16]. Kim et al demonstrated the effects of ultrasound therapy compared to self-exercise with a therapeutic inflatable ball among patients with MPS. They found similar improvement in pain, range of motion, and PPT between the two groups [7].

We evaluated the effects of the acupuncture in combination with exercise and compared it with the effects of the acupuncture among patients with MPS in their neck. We found significant improvement in pretreatment and post-treatment evaluations in both groups.

Although the previously published articles had different combination of therapies and methods of exercise, the results showed similar effectiveness for management of MPS and TrP.

Previous investigations showed that both acupuncture and exercise were effective for MPS management. Theoretically, it seemed combination of these two could have additive effect in treatment of MPS. Present study suggests this hypothesis could be incorrect with respect to our exercise setting, follow-up period, and limitations of the study.

4.1. Limitations

The present study has some limitations. One of the limitations is lack of an exercise alone group. This study also did not have an untreated control group. We did not evaluate nonspecific effects of aerobic exercise such as fatigue among the participants. Moreover, larger numbers of subjects could result in statistically more significant differences between the two groups. Although there was no gender preference during the process of recruiting participants, most participants were women. Another issue relates to the duration of aerobic exercise training. Most of the participants were not athletes, and it might take longer time to observe the effects of aerobic exercise. We did not evaluate range of motion as outcome measure. Moreover, psychological stress in daily life could have impact on the patient's response to our interventions. We did not match groups we respect to this issue.

5. Conclusion

Both aerobic exercise combined with acupuncture and acupuncture alone are effective in management of MPS. Our study has shown that acupuncture plus aerobic exercise seem to be as effective as acupuncture alone to reduce pain, mechanical pain threshold, and improve quality of life and neck function. There was not any superiority observed between these two methods.

One of the potential fields of the studies in the future may consist of performing long-term aerobic exercise and evaluating effects of a continued treatment. Additionally, trials should include an aerobic exercise only group to delineate possible relative contributions of individual treatment components.

6. Comments

This manuscript contributes to the nonpharmacological treatment (aerobic exercise and acupuncture) for a very common disease (MPS). Recently, exercise and acupuncture are getting a lot of attention in treatment of MPS. This manuscript provides a potential interest among researchers in the field of musculoskeletal disease, rheumatology, MPS, and neck and upper limb pain.

Disclosure statement

There is no conflict of interest. No funding or grants or equipment provided for the project from any source and there are no financial benefits to the authors.

Appendix A. Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.jams.2018.04.006>.

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