Acta Scientific Dental Sciences
Volume 2 Issue 6 June 2018
Research Article

Acupuncture for the Treatment of Masticatory Musculature Myofascial Pain Syndrome: Study Protocol for a Randomized, Assessor-Blinded, Sham-Controlled Trial

Gui-Youn Cho-Lee[1]*, Hoon Cho-Jung[2], Francisco Abad-Santos[3], Sergio Castrejón-Castrejón[4], Mario-Fernando Muñoz-Guerra[5], Francisco-José Rodríguez-Campo[5] and Luis Naval-Gías[5]

[1]*Department of Oral and Maxillofacial Surgery, Torrejón University Hospital, Madrid, Spain*
[2]*Golden Clover Foundation for Natural Medicine, Madrid, Spain*
[3]*Department of Pharmacology, La Princesa University Hospital, Autónoma University, Madrid, Spain*
[4]*Department of Cardiology, La Paz University Hospital, Autónoma University, Madrid, Spain*
[5]*Department of Oral and Maxillofacial Surgery, La Princesa University Hospital, Autónoma University, Madrid, Spain*

***Corresponding Author:** Gui-Youn Cho-Lee, Department of Oral and Maxillofacial Surgery, Torrejón University Hospital, Madrid, Spain.

Received: May 04, 2018; **Published:** May 15, 2018

Abstract

Background: Myofascial Pain Syndrome (MPS) of the Masticatory Muscles (MM) is one of the most prevalent diseases included in the Temporomandibular Joint Dysfunction Syndrome. Regarding its treatment, there are not standardized protocols. There is some evidence that acupuncture is effective in MPS of the MM treatment. The objective of the present study was to analyze the efficacy of acupuncture for the treatment of MPS of the MM, in terms of pain intensity reduction and duration of the pain reduction along time.

Methods/Design: This study was a randomized, assessor blinded, sham-controlled clinical trial with three parallel arms. Ninety patients between 18 and 65 years of age with masticatory muscles myofascial pain, without temporomandibular joint pain, lasting for at least the previous six months were included in the study. Participants were randomly allocated into the three groups of treatment (30 patients/group): splint therapy, real acupuncture and sham acupuncture. Assessor were blinded to group allocation. The outcome measurements of the study included: 1) Percentage of patients that achieved a relevant clinical response (pain reduction of at least 50% from the initial value, in a visual analogue scale; or a visual analogue scale pain value less than 30 millimeters). 2) Pain reduction after treatment, measured in millimeters in a visual analogue scale (VAS). 3) Maximal mouth opening measured in millimeters. 4) Stability of the pain reduction. The outcome measurements were evaluated before treatment and 3, 6, 9 and 12 months after.

Discussion: The results from this study will provide clinical evidence on the efficacy and safety of acupuncture in patients with Myofascial Pain Syndrome (MPS) of the Masticatory Muscles (MM).

Keywords: Acupuncture; Sham Acupuncture; Myofascial Pain Syndrome; Masticatory Muscles; Randomized Clinical Trial

Abbreviations

MPS: Myofascial Pain Syndrome; MM: Masticatory Muscles; TMJ: Temporomandibular Joint; cm: Centimeters; Mm: Millimeters; VAS: Visual Analogue Scale; TMD: Temporomandibular Dysfunction; CAM: Complementary and Alternative Medicine; RA: Real Acupuncture; SA: Sham Acupuncture; CRC: Clinical Research Coordinator S: Stomach; TW: Triple Warmer; LI: Large Intestine; L: Liver; GB: Gallbladder; CRF: Case Report Form

Introduction

Masticatory musculature (MM) myofascial pain syndrome (MPS) is the main cause of Temporomandibular Disorders (TMD). The prevalence of TMD is between 40% and 75%. TMD is common in adults aged 20 - 50 years, and it is more prevalent amongst women than men. Its aetiology regards as multifactorial, structure-related, and controversial [1-4].

Current medical interventions for the management of MPS of the MM consist of jaw-appliance therapy (splint therapy), medications, physiotherapy, home self-care and botulinum toxin injections [1-4]. A survey showed that 74% of TMD patients used complementary and alternative medicine (CAM) therapies. Most of the respondents reported being most satisfied with the ''hands on'' CAM therapies such as acupuncture [5]. Acupuncture has been claimed to be effective in TMD treatments in the mechanism of pain reduction, antiinflammation, and neurohormonal effects [6,7]. It is reported that MPS of the MM patients tend to concurrently use both conventional treatment and CAM in the hopes of more positive effects and safety profile [8]. The use of CAM therapeutic modalities including acupuncture has been increased [9-12].

Although combined treatments between conventional and acupuncture treatments have been frequently utilized, the effectiveness and safety has not been fully investigated in rigorously designed clinical trials. This study may be a preliminary evaluation of the non-inferiority of acupuncture against splint therapy. The results from this pilot study will provide clinical evidence to evaluate the feasibility for full-scale randomized controlled trial (RCT) on acupuncture treatment for MPS of the MM.

Methods/Design

Trial design

This is a controlled, randomized, parallel, assessor-blinded and sham-controlled clinical trial with three parallel arms (1:1:1 ratio) conducted at the Department of Oral and Maxillofacial Surgery at La Princesa University Hospital (Madrid, Spain). We compared the effects of splint therapy and pharmacological treatment, real acupuncture (RA) and sham acupuncture (SA) in patients with MPS of the MM. Outcome assessment and statistical analyses were be performed by independent researchers who were blinded to the patient assignment (Figure 1).

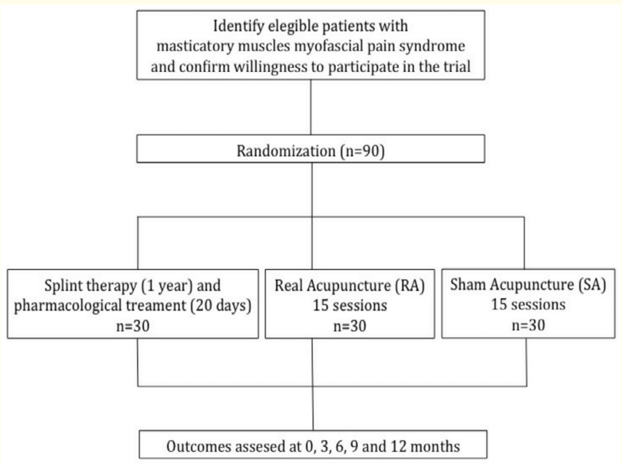

Figure 1: Study flowchart.

Participants

Ninety participants with MPS of the MM were recruited to the study from the medical consultations at the Department of Oral and Maxillofacial Surgery at La Princesa University Hospital (Madrid, Spain). All participants were scheduled for a screening visit by the clinical research coordinator (CRC). After completing the screening questions and clinical examination, participants were guided through the informed consent process. Participants were informed that they might be randomly allocated into any of the three treatment groups (Splint therapy and pharmacological treatment, RA and SA); and that they might withdraw their voluntary participation at any stage. Patients were provided enough time to deliberate their participation with the written information and the informed consent form. After random allocation, the CRC scheduled treatment sessions.

Eligibility criteria

Patients between 18 and 65 years of age who could read and write in Spanish, who agreed to participate after providing written informed consent, and who have been experiencing myofascial pain in the MM for at least six months preceding the time of the screening visit and had not received previous treatment were selected as study volunteers.

Patients were excluded from the study if they had: 1) TMJ pain; 2) TMJ clicking; 3) lateral deviation while opening the mouth; 4) previous TMJ surgery; 5) previous orthognathic surgery; 6) radiological alterations such as TMJ osteoarthrosis, tumours, condylar resorption, previous condylar fractures; 7) allergy to ibuprofen, tetrazepam, paracetamol or metamizole; 8) pregnancy or lactation; 9) current use of corticosteroids, narcotics, muscle relaxants or herbal medicines to treat pain or any medication considered inappropriate by the investigator; and 10) a severe psychiatric or psychological disorder.

Interventions

Patients allocated in the splint therapy and pharmacological treatment group were prescribed lbuprofen 600 mg/ 8 hours; Tetrazepam 50 mg/ 24 hours and Omeprazole 20 mg/ 24 hours, within 20 days. Simultaneously, they had to use occlusal splints for 7 hours per night. The occlusal splints were full coverage hard acrylic resin appliances, constructed to fit in the maxillary arch. The splint surface was adjusted to provide a maximum occlusion after habitual closure and after passively recorded terminal hinge movement. The splint was constructed so that the anterior and canine guidance was stablished. After one week, the splints were checked and adjusted. The splints were used at night, at least for 7 hours, until the end of the follow up period. All splints were made and checked by the same prosthetic technician.

The RA and SA groups were treated with a protocol of 15 sessions over 4 - 6 weeks. After sterile skin preparation, participants were administered a perpendicular, subcutaneous injection at a depth of 0.5 to 1 cm (SA) and 3 to 4 cm (RA) with the patient lying in the prone position. Each session lasted 30 minutes. The acupuncturist treated participants under a predefined acupuncture protocol at predefined acupoints. The predefined points (S2, TW17, S36, S41, LI4, LI11, L3, GB34, GB39) had been carefully selected by the acupuncturist based on his experience in the treatment of myofascial pain. All RA and SA group patients were treated by the same acupuncturist.

Allowance of concurrent treatment of patients

During the follow up period, patients were allowed to use analgesics if they considered it necessary based on their pain intensity. The allowed analgesics were Paracetamol 1gr/ 8 hours and Metamizole 575 mg/ 8 hours. The use of these analgesics was recorded at every visit. Regular medications not intended to affect myofascial pain related dysfunction were allowed.

Outcomes

Assessment of MM myofascial pain dysfunction, pain and quality of life were collected before treatment and 3, 6, 9 and 12 months follow up sessions. Medical history and sociodemographic characteristics, including age and gender were taken from the screening visit. Any unpredicted, adverse events were recorded at each visit (Table 1).

Day	0	90	180	270	360
Informed consent	X				
Eligibility/Exclusion criteria	X				
Pain intensity (VAS)	X	X	X	X	X
Patient functional perspective (VAS)	X	X	X	X	X
Maximal mouth opening (MAO)	X	X	X	X	X
Clinical relevant response		X	X	X	X
Adverse effects		X	X	X	X
Consumption of rescue medication		X	X	X	X

Table 1: Schedule for data collection: outcome measures per visits.

Primary outcome measurement

The primary outcome measurement was the percentage of patients that achieved a relevant clinical response which was defined as a pain reduction of at least 50% from the initial value, in a visual analogue scale (VAS), or a VAS pain value less than 30 millimeters (0 to 100).

Secondary outcome measurements

1) Pain reduction after treatment, measured in millimeters (mm) in a visual analogue scale (VAS).
2) Maximal mouth opening (MMO) measured in mm.
3) Patient functional perspective. About 100 mm VAS functional scale was used. A reading of 0 mm was equal no functional impairment, e.g. in eating, talking or sleeping. A reading of 100 mm meant maximal functional impairment, severely limiting the subject in all such functions.
4) Stability of the pain reduction.
5) Necessity of rescue medication use during the follow up period and type of analgesic.
6) Adverse events of the treatments.

Randomization and allocation concealment

A total of 90 participants were randomly assigned following simple randomization procedures, with a 1:1:1 allocation ratio. The randomization sequence was generated by an independent researcher using a table of random numbers table (groups of six) and a balanced random allocation. Opaque envelopes labeled by study patient number were conveyed to the CRC. The CRC opened the sealed envelopes and allocate participants into the predefined treatment arms. The random allocation assignment was performed only after a participant was confirmed to be eligible and written informed consent had been obtained. Detailed information, including the treatment arm and randomization number from an individual participant was recorded in the case report form (CRF) and randomization table.

Blinding

As assessor-blind RCT, the researcher performing the outcome measure assessment was blinded to each patient`s treatment allocation and was prohibited from taking part in any conversation about the treatment procedures. For patients allocated in RA and SA groups, the study was double blind, because those patients ignored if they were receiving RA or SA treatments. It was not possible to conceal RA and SA acupuncturist to patient allocations. The acupuncturist was prohibited from any conversations other than those regarding acupuncture treatment. Statistical analysis was performed by an independent statistician who was blinded to patient allocation.

Withdrawal and dropout

Participation in the study would end at any stage if the patient refused to continue, withdrew consent or violated inclusion or exclusion criteria or the trial protocol. The trial would stop if the principle investigator believed that there were unacceptable risks of serious adverse events.

Planned statistical analysis

The analysis was focused on exploring the feasibility and acceptability of protocol implementation and refining the protocol of future RCT. The results from hypothesis testing was treated as preliminary and interpreted with caution. The results of this study may provide a preliminary evaluation of the non-inferiority of acupuncture to splint therapy and pharmacological treatment. All statistical analyses were carried out using the Statistical Package for the Social Sciences (SPSS) for Windows version 15.0 and were expressed by median and interquartile range or mean and standard deviation. The level of significance was set at $P < 0.05$. Trends over time and time-by-treatment interactions were explored using a repeated-measures analysis of variance (ANOVA). A Chi-square test or a Fisher's exact test were performed to determine differences between groups and adverse effects, which were recorded and described as a frequency and percentage.

Ethical approval and monitoring

This study has been approved by the Ethical Committee for Clinical Investigation and Investigation Commission of La Princesa University Hospital (Madrid, Spain). Study procedures and documents were monitored by a qualified clinical researcher from the Clinical Trials Unit of La Princesa University Hospital (Madrid, Spain).

Data handling

Data obtained during the study were confidentially treated according to the standard operation protocol of the Clinical Trials Unit of La Princesa University Hospital (Madrid, Spain), and were stored in lockable cabinets. All data were processed using the participants numbers which were unrelated to participants' personal information. Data were compiled into CRFs and data integration was thoroughly verified by independent researchers. Non-obvious errors or omissions were put into data query forms, which were used for the researchers' workshop. Data were gathered and summarized with respect to demographic baseline characteristics, effectiveness and safety observations.

Discussion

During the last decades, some clinical trials have been performed in order to prove the efficacy of acupuncture in the treatment of TMD [13-28]. Three systematic reviews [29-31] summarized the results of those clinical trials. The trial data available suggest that acupuncture is a useful symptomatic treatment of MPS of the MM. But these clinical trials have limitations. Their main limitations were:

- Clinical trials that compared acupuncture and splint therapy [13-20] showed the overall message that acupuncture is effective as a symptomatic treatment of TMD. However, these results should be interpreted with caution. None of the trials was performed with blinded evaluators, details of randomization or adverse events were not given, and therefore all studies were subject to important bias. Inclusion criteria were heterogeneouos. Except *List and cols.* studies [17,18], sample size was very small and follow up period less than six months. More important, none of the studies was designed in a way that a placebo effect of acupuncture could be excluded as the underlying mechanism of action. It is notable that all studies came from Scandinavia. To increase the reliability, one would therefore wish to see further confirmatory studies from other areas [29].
- Clinical trials that compared RA and SA [22-28] did not include a splint therapy group, and only evaluated immediate effects of both treatments, without any follow up period [30,31].

Based on all these clinical trials, it would seem the evidence is limited in amount and quality. A lot more rigorous and detailed research is needed to confirm the efficacy of acupuncture for the treatment of MPS of MM; as to which points and or combination of points to use and duration of efficacy of acupuncture.

This study compares for the first time three treatment groups (Splint therapy and pharmacological treatment, RA and SA) that had not been compared simultaneously in previous trials. The sample size was of 30 patients per group, which is the largest one in this type of studies; and was assessor-blinded.

Trial status

This study began in January 2010. Trial completion was achieved in December 2013.

Conclusion

This trial provided enlightening results regarding acupuncture efficacy for the treatment of MPS of the MM due to its rigorous methodology.

Conflict of Interest

There are not any financial interest nor conflict of interest.

Bibliography

1. Monje-Gil F. "Diagnóstico y tratamiento de la patología de la articulación temporomandibular". 1st edition. Madrid: Ripano (2009): 846.
2. Leeuw R. "American academy of orofacial pain: guidelines for assessment, diagnosis and management". 4th edition. Chicago: *Quintessence Publishing* (2008): 129-175.
3. Martín-Granizo R., *et al*. "Manual de Cirugía Oral y Maxilofacial". 2nd edition. Madrid (2004).
4. McNeill C. "Craniomandibular Disorders: Guideline for Evaluation, Diagnosis, and Management". Chicago: Quintessence (1990): 54.
5. List T., *et al*. "TMD in children and adolescents: prevalence of pain, gender differences, and perceived treatment need". *Journal of Orofacial Pain* 13.1 (1999): 9-20.
6. Lin JG., *et al*. "Acupuncture analgesia: a review of its mechanisms of actions". *The American Journal of Chinese Medicine* 36.4 (2008): 635-645.
7. Zhao ZQ. "Neural mechanism underlying acupuncture analgesia". *Progress in Neurobiology* 85.4 (2008): 355-375.
8. Choi MK., *et al*. "The recognition and attitude of users using the combined western-oriental medical institutions". *Journal of Health Informatics and Statistics* 30.1 (2005): 35-44.
9. Eisenberg DM., *et al*. "Trends in alternative medicine use in the United States, 1990-1997: results of a follow-up national survey". *Journal of the American Medical Association* 280.18 (1998): 1569-1575.
10. Furlan AD., *et al*. "Complementary and alternative therapies for back pain II". *Evidence Report Technology Assessment* 194 (2010): 1-764.
11. Grazio S and Balen D. "Complementary and alternative treatment of musculoskeletal pain". *Acta Clinica Croatica* 50.4 (2011): 513-530.
12. Plastaras CT., *et al*. "Complementary and alternative treatment for neck pain: chiropractic, acupuncture, TENS, massage, yoga, Tai Chi, and Feldenkrais". *Physical Medicine and Rehabilitation Clinics of North America* 22.3 (2011): 521-537.
13. Raustia AM., *et al*. "Acupuncture compared with stomatognathic treatment for TMJ dysfunction. Part I: A randomised study". *Journal of Prosthetic Dentistry* 54.4 (1985): 581-585.
14. Raustia AM., *et al*. "Acupuncture compared with stomatognathic treatment for TMJ dysfunction. Part II: components of the dysfunction index". *Journal of Prosthetic Dentistry* 54 (1986): 372-376.
15. Raustia AM., *et al*. "Acupuncture compared with stomatognathic treatment for TMJ dysfunction. Part III: Effects of treatment on mobility". *Journal of Prosthetic Dentistry* 56.5 (1986): 616-623.
16. Johansson A., *et al*. "Acupuncture in treatment of facial muscular pain". *Acta Odontologica Scandinavica* 49.3 (1991): 153-158.
17. List T., *et al*. "Acupuncture and occlusal splint therapy in the treatment of craniomandibular disorders Part I. A comparative study". *Swedish Dental Journal* 16.4 (1992): 125-141.

18. List T., *et al*. "Acupuncture and occlusal splint therapy in the treatment of craniomandibular disorders Part II. A 1-year follow up study". *Acta Odontologica Scandinavica* 50.6 (1992): 375-385.

19. List T., *et al*. "Pressure pain thresholds in patients with craniomandibular disorders before and after treatment with acupuncture and occlusal splint therapy: a controlled clinical study". *Journal of Orofacial Pain* 7.3 (1993): 275-282.

20. Vicente-Barrero M., *et al*. "The efficacy of acupuncture and decompression splints in the treatment of temporomandibular joint pain-dysfunction syndrome". *Medicina Oral, Patologia Oral Y Cirugia Bucal* 17.6 (2012): e1028-e1033.

21. Smith P., *et al*. "The efficacy of acupuncture in the treatment of temporomandibular joint myofascial pain: A randomised controlled trial". *Journal of Dentistry* 35.3 (2007): 259-267.

22. Goddard G., *et al*. "Acupuncture and sham acupuncture reduce muscle pain in myofascial patients". *Journal of Orofacial Pain* 16.1 (2002): 71-76.

23. Goddard G., *et al*. "A controlled trial of placebo versus real acupuncture". *Journal of Pain* 6.4 (2005): 237-242.

24. Schmid-Schwap M., *et al*. "Oral acupuncture in the therapy of craniomandibular dysfunction syndrome - a randomized controlled trial (RTC)". *Wiener Klinische Wochenschrift* 118.1-2 (2006): 36-42.

25. Shen YF., *et al*. "Randomized clinical trial of acupuncture for myofascial pain of jaw muscles". *Journal of Orofacial Pain* 23.4 (2009): 353-359.

26. Simma I., *et al*. "Immediate effects of microsystem acupuncture in patients with oromyofascial pain and craniomandibular disorders (CMD): a double-blind, placebo-controlled trial". *British Dental Journal* 207.12 (2009): E26.

27. Katsoulis J., *et al*. "Laser acupuncture for myofascial pain of the masticatory muscles. A controlled pilot study". *Research and Science* 120 (2010): 213-19.

28. Itoh K., *et al*. "Effects of trigger point acupuncture treatment on temporomandibular dirorders: a preliminary randomized clinical trial". *Journal of Acupuncture and Meridian Studies* 5.2 (2012): 57-62.

29. Ernst E and White AR. "Acupuncture as a treatment for temporomandibular joint dysfunction. A systematic review of randomized trials". *Archives of Otolaryngology - Head and Neck Surgery* 125.3 (1999): 269-272.

30. La Touche R., *et al*. "Effectiveness of acupuncture in the treatment of temporomandibular disorders of muscular origin: a systematic review of the last decade". *Journal of Alternative and Complementary Medicine* 16.1 (2010): 107-112.

Volume 2 Issue 6 June 2018